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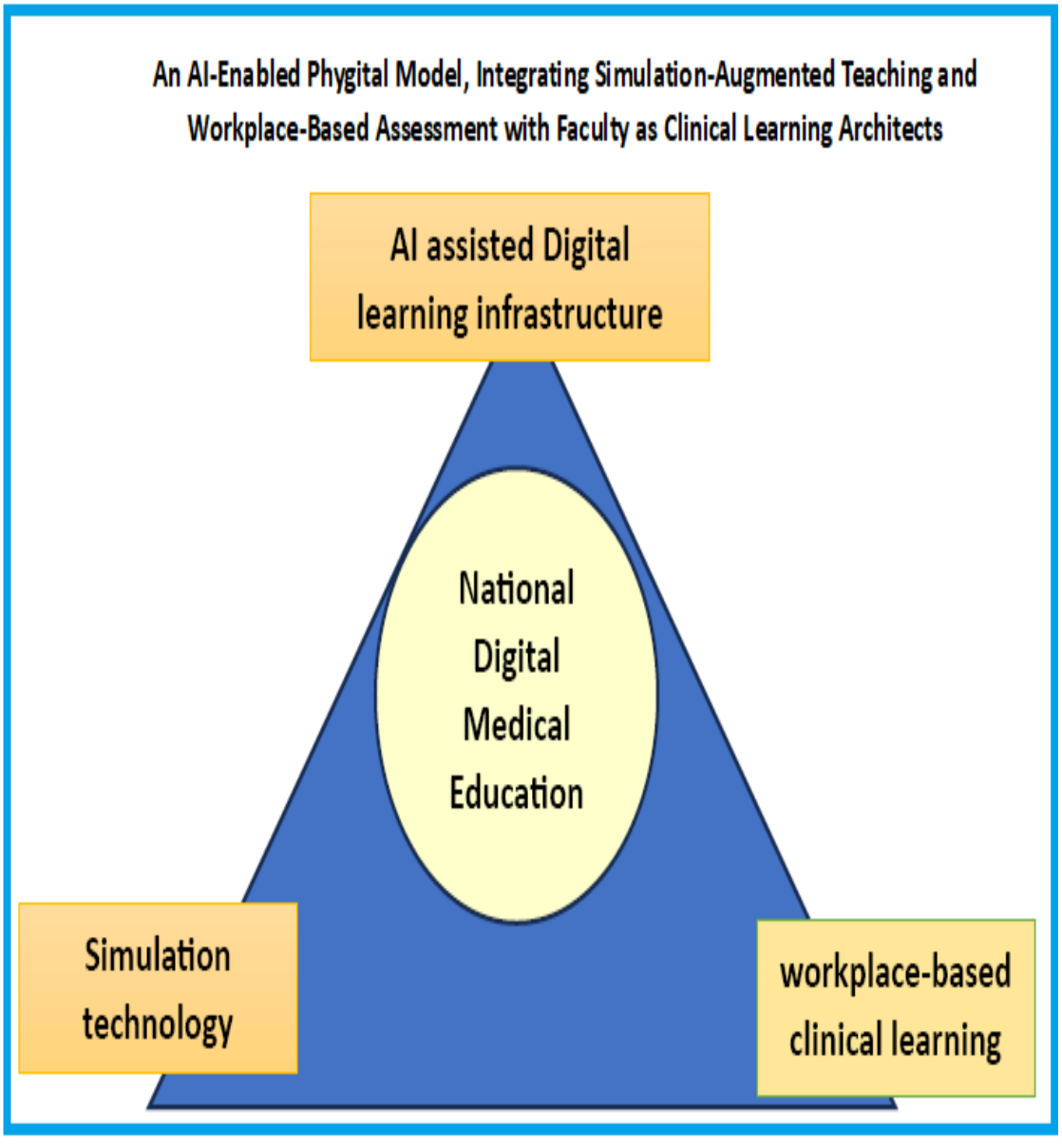

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EDITORIAL

National Digital Medical Education Grid (NDMEG): Integrating Community Health Centres in Clinical Training

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The **National Digital Medical Education Grid (NDMEG)** is a comprehensive national framework designed to modernise medical education by uniting artificial intelligence, digital learning systems, simulation-based training, and workplace-based clinical assessment into a single coordinated ecosystem. Its central mission is to create a **scalable, competency-driven educational architecture** that can produce future-ready physicians who are **clinically skilled, technologically fluent, and capable of delivering high-quality care in an increasingly digital healthcare environment**.

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NDMEG connects medical colleges, teaching hospitals, district health facilities, simulation centers, and national digital health platforms, forming **a "phygital"**—physical plus digital—network. This integrated structure allows academic learning, clinical training, and technological innovation to continuously inform and reinforce one another.

The model is built on three major pillars:

1. **FIRST PILLAR:** The first is a national digital learning backbone powered by AI. This includes adaptive learning tools, virtual patient cases, intelligent tutoring systems, and standardised content libraries that ensure consistent, high-quality education across institutions while still allowing personalisation based on learner needs.
2. **SECOND PILLAR:** The second pillar is simulation-augmented training. High-fidelity simulators, VR platforms,

and structured skills labs offer a safe, controlled environment where learners can practice difficult or high-risk procedures, receive targeted feedback, and demonstrate competence before treating real patients.

3. **THIRD PILLAR:** The third is workplace-based learning integrated directly into clinical service. Students build real-world competence through supervised patient care activities across hospitals and community health centres. These experiences are evaluated using structured assessment tools such as Mini-CEX, DOPS, and case-based discussions, all documented digitally in evolving learner portfolios (Figure 1).

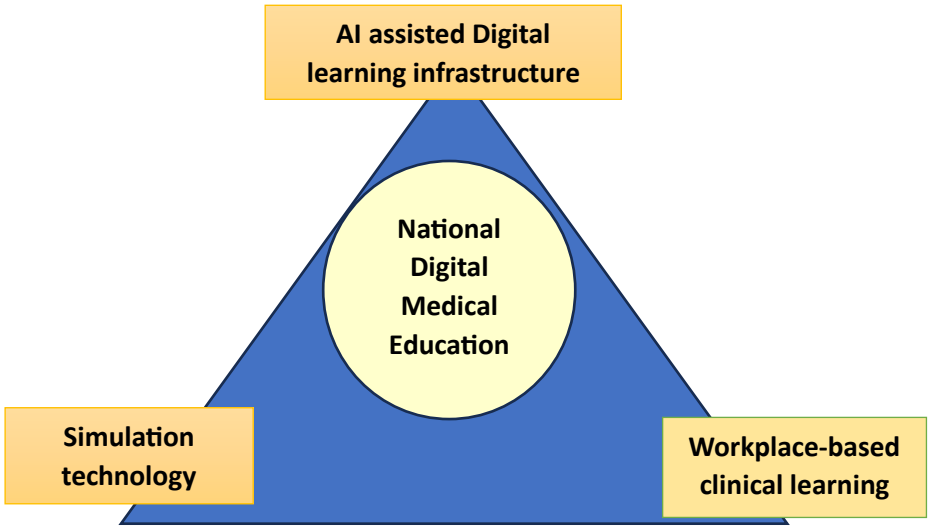

Figure 1. An AI-Enabled Phygital Model, Integrating Simulation-Augmented Teaching and Workplace-Based Assessment with Faculty as Clinical Learning Architects

AI acts as the unifying engine that synthesizes data from digital platforms, simulation sessions, and workplace assessments. It generates individualized competency dashboards, identifies learning gaps, and recommends targeted interventions. Faculty review these analytics to guide mentorship, determine supervision levels, and make evidence-based entrustment decisions, shifting away from reliance on single high-stakes exams.

Integrated Clinical Training Network

Training extends beyond the teaching hospital to a **distributed clinical ecosystem**.

Network nodes include:

- district hospitals
- community health centres
- specialty referral hospitals
- telemedicine-linked rural facilities

This model exposes students to **diverse clinical environments**.

NDMEG also creates a national academic network where institutions share resources, collaborate on research, and benchmark performance. By linking medical education to national digital health systems—EHRs, telemedicine, and real-world clinical registries—the framework ensures that students learn in environments aligned with the digital transformation of healthcare.

At a system level, NDMEG offers several strategic advantages: standardization of competency-based education nationwide, expanded access to advanced simulation tools, integration of district hospitals into the training ecosystem, better governance through data-driven decision-making, and enhanced patient safety through improved clinical preparedness.

Faculty as Clinical Learning Architects: A core transformation lies in redefining the faculty's role. Instead of primarily delivering lectures, **faculty become Clinical Learning Architects** who design integrated learning experiences across digital, simulated, and clinical settings. They guide learners through complex cases, interpret AI-generated insights, and help shape clinical reasoning and professional judgment. Sustained national faculty development programs are essential to prepare educators for these expanded responsibilities.

Ultimately, NDMEG envisions medical education as a connected, intelligent, national learning ecosystem—where AI, digital technologies, simulation, and real-world clinical practice converge under skilled faculty leadership to produce competent, confident, and digitally empowered physicians for the healthcare systems of the twenty-first century.

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ORIGINAL ARTICLE

Clinical Profile, Treatment Combinations, and Glycemic Outcomes in Indian Patients with Type 2 Diabetes: An Observational Study

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Abstract

Background: Indian Type 2 diabetes mellitus (T2DM) is characterised by premature onset, high prevalence of insulin resistance, and concomitant comorbidities. Timely control of glycemia often calls for multiple drug combinations, but real-world data on treatment, outcomes, and adherence are scarce. **Objective:** To compare clinical profiles, treatment strategies, glycemic control, drug adherence, and safety outcomes in T2DM patients during a six-month follow-up in the real-world Indian clinical practice. **Methods:** This was an observational study of 57 adults with T2DM attending an medicine OPD. Patients received one of six fixed-dose triple drug formulations: dapagliflozin–glimepiride–metformin (1A, 1B), sitagliptin–glimepiride–metformin (2A, 2B), or pioglitazone–glimepiride–metformin (3A, 3B). Data on demographics, anthropometry, laboratory values (HbA1c, FBG, PPBG), comorbidities, treatment combinations, adherence, and adverse effects were extracted from medical records across two follow-up visits. **Results:** The patients' mean age was 58.95 ± 8.24 years, and 57.9% were female. All patients had baseline HbA1c >7.1%, which were highly improved over time; 35.3% had HbA1c ≤7.1% by visit 2 ($P < 0.0001$). The most frequent regimen was 1A + 2A combination with 2 mg Glimepiride. Mean BMI was 23.5 kg/m². The most frequent comorbidity was hypertension (56.1%). Adherence was modestly improved, and adverse events were rare, with hypoglycaemia reduced from 8.8% to 5.3%. **Conclusion** T2DM patients in this real-world population had significant glycemic control improvements on combination therapy. Enhanced adherence and a low rate of adverse events underscore the practicability of early treatment intensification in Indian clinical practice.

Keywords: Type 2 diabetes mellitus, combination therapy, glycemic control, India, real-world study, adherence

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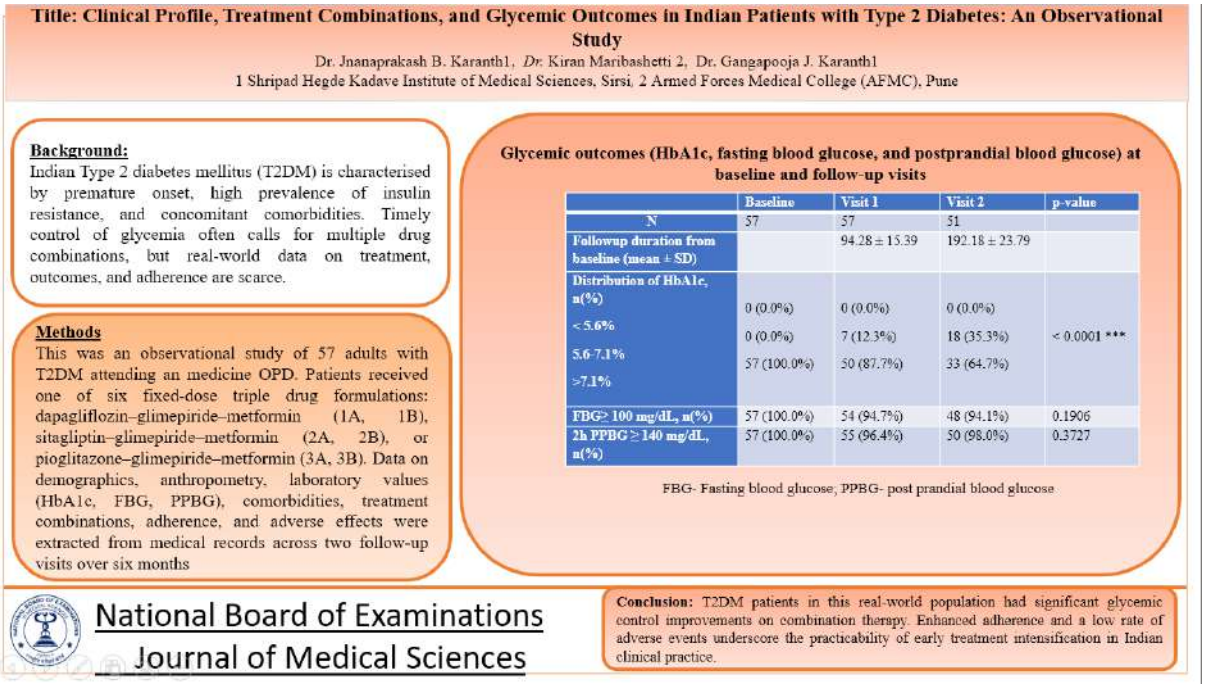
Graphical Abstract



Introduction

Type 2 diabetes mellitus (T2DM) is an evolving public health issue in India, and it bears one of the largest diabetes burdens worldwide [1]. The pathophysiology of T2DM among Indians is often dominated by the onset of disease at a young age, a modest body mass index (BMI), and extensive central obesity, insulin resistance, and cardiometabolic comorbidities [2]. These specific characteristics account for a faster disease course and increased risk of complications, requiring early and tailored interventions [3].

Even with improvement in pharmacologic choices, glycemic control is suboptimal in a large percentage of patients [4]. Contributing to poor control are clinical inertia, variable medication adherence, and patient-level barriers like cost, lack of understanding, and lack of formal diabetes education [5]. Early combination therapy is frequently required in the management of T2DM to attain and maintain glycemic goals, particularly in low-resource settings where postponement of treatment intensification is prevalent. Yet, evidence for treatment patterns, efficacy, and tolerability of combination regimens in actual Indian clinical practice is limited [6].

This research was conducted to assess the clinical and demographic features, treatment regimens, glycemic response, patterns of adherence, and safety events in patients with T2DM at one center. The aim was to provide real-world evidence regarding the efficacy and tolerability of different treatment strategies in early- to mid-stage T2DM in the Indian setting.

Materials and Methods

This was an observational study in an Indian specialised Medicine OPD. The aim was to assess the clinical and biochemical profiles, patterns of antidiabetic treatment, glycemic control, and safety outcomes in type 2 diabetes mellitus (T2DM) patients within a six-month follow-up. The data were gathered from the medical records of the patients

who had a minimum of two follow-up appointments following the first consultation. The research period ranged from June 2024 to April 2025.

Adult patients aged 18 years or older with a confirmed T2DM diagnosis with baseline HBA1C > 7.1. They were included and followed up for two visits. Patients were excluded if they had missing records, known chronic kidney disease (stage ≥2), type 1 diabetes mellitus, secondary diabetes, or were pregnant or lactating during data collection. Complete clinical and biochemical data on at least two visits were available for fifty-seven patients and were included in the final analysis.

Demographic information such as age and gender, and anthropometric measures such as height, weight, BMI, waist circumference, and waist–hip ratio were obtained from patient records. Clinical information consisted of the duration of diabetes and presence or documentation of comorbidities like hypertension, dyslipidemia, cardiovascular disease, thyroid disease, or chronic kidney disease. Laboratory investigations recorded at baseline and subsequent visits included glycated haemoglobin (HbA1c), fasting blood glucose (FBG), and two-hour postprandial blood glucose (PPBG). Antidiabetic treatment regimens were documented for each visit, including changes in combination therapies. Medication adherence was assessed based on patient-reported frequency of missed doses during each follow-up. Adverse events, including episodes of hypoglycaemia and urinary tract infections, were also documented.

Patients were treated with numerous oral antidiabetic drug combinations. These were generally divided into three classes on the basis of pharmacologic class and action mechanism: insulin sensitisers, insulin secretagogues or incretin-based agents, and SGLT2 inhibitors or other newer drugs. Combinations of these classes were denoted as 1A, 2A, 3A, etc., for the analysis (Table 1). Discontinuation of any medication was not observed during the follow-up.

Table 1. Fixed-dose triple combination formulations of oral antidiabetic agents

Class Combination	Formulation Code	Composition
SGLT2 inhibitor + Sulfonylurea + Biguanide	1A	Dapagliflozin 10 mg + Glimepiride 2 mg + Metformin 1000 mg
	1B	Dapagliflozin 10 mg + Glimepiride 1 mg + Metformin 1000 mg
DPP-4 inhibitor + Sulfonylurea + Biguanide	2A	Sitagliptin 50 mg + Glimepiride 2 mg + Metformin 1000 mg
	2B	Sitagliptin 50 mg + Glimepiride 1 mg + Metformin 1000 mg
Thiazolidinedione + Sulfonylurea + Biguanide	3A	Pioglitazone 15 mg + Glimepiride 2 mg + Metformin 1000 mg
	3B	Pioglitazone 15 mg + Glimepiride 1 mg + Metformin 500 mg

The major outcome was glycemic control change, measured by HbA1c levels between visits. Secondary outcomes were changes in FBG and PPBG, trends in adherence, and rates of adverse events. The average interval between the baseline and each follow-up visit was computed to measure the time-dependent change in the parameters.

Descriptive statistics were employed to present baseline demographic, clinical, and laboratory data. Continuous measures were represented as mean ± standard deviation (SD), and categorical variables were presented as absolute counts and percentages. Repeated measures analysis was used to compare the glycemic parameters between visits. A p-value of less than 0.05 was regarded as statistically significant. IBM SPSS Statistics software (version, IBM Corp., Armonk, NY, USA) was used for statistical analysis.

The research was done in accordance with ethical standards of the Declaration of Helsinki. Individual patient consent was not required as this was a retrospective analysis of anonymised clinical data. Institutional Ethics Committee approval was sought before data retrieval and analysis**.** We also deny using AI in analysing the data and interpreting results or conclusions,

Results

Patient Demographics and Baseline Characteristics

A total of 57 patients were enrolled in the study. The mean age was 58.95 ± 8.24 years, and 24 (42.1%) were men and 33 (57.9%) were women. The mean height and weight were 163.65 ± 7.32 cm and 62.92 ± 10.19 kg, respectively. Body mass index profile revealed that five patients (8.8%) were with BMI <19 kg/m², 23 (40.4%) were with BMI 19–22.9 kg/m², and 29 (50.9%) were with BMI >23 kg/m². Waist circumference greater than the risk threshold (≥90 cm in men and ≥80 cm in women) was found in six female patients (10.5%) while none of the male patients crossed the cut-off. The mean waist-to-hip ratio was 0.91 ± 0.03 in men and 0.81 ± 0.05 in women, giving a combined mean of 0.86 ± 0.07. The mean length of diabetes was 3.71 ± 2.05 years. These features are presented in Table 2.

Comorbid Conditions

The most common comorbidity was hypertension, with 32 patients (56.1%), followed by cardiovascular disease (7 patients, 12.3%), dyslipidemia (6 patients, 10.5%), and thyroid disease (5 patients, 8.8%). CKD was not observed (Table 2).

Treatment Regimens and Adaptations

At visit 1, most patients (n = 52, 91.2%) were taking the 1A + 2A combination regimen, and five patients (8.8%) were taking 3A + 2A. By visit 2, treatment allocation had become more varied, with 42 patients (82.2%) on 1A + 2A, 5 (9.8%) on 3A + 2A, 2 (4.0%) on 1B + 2B, and one patient each on 3A + 2B and 3B + 2B (2.0% each). There were no discontinuations of medications throughout the study (Table 2).

Table 2. Baseline demographic, anthropometric, comorbidity profile, and treatment regimens of the study population

	N= 57
Age, in years (mean ± SD)	58.95 ± 8.24
Gender	
Male	24 (42.1%)
Female	33 (57.9%)
Height (mean ± SD)	163.65 ± 7.32
Weight (mean ± SD)	62.92 ± 10.19
BMI (kg.m^2)	
<19	5 (8.8%)
19-22.9	23 (40.4%)
>23	29 (50.9%)
Waist circumference	
Male ≥ 90 cm	0 (0.0%)
Female ≥ 80 cm	6 (10.5%)
Waist:hip ratio (mean ± SD)	0.86 ± 0.07
Male	0.91 ± 0.03
Female	0.81 ± 0.05
Duration of diabetes (mean ± SD)	3.71 ± 2.05
Comorbidities	
Hypertension	32 (56.1%)
Dyslipidemia	6 (10.5%)
CKD	0 (0.0%)
CVD	7 (12.3%)
Thyroid disease	5 (8.8%)
Combination therapies*	
Visit 1 **(N = 57)**	
1A and 2A	52 (91.2%)
3A and 2A	5 (8.8%)
Visit 2 **(N = 51)**	
1A and 2A	42 (82.2%)
1B and 2B	2 (4.0%)
3A and 2A	5 (9.8%)
3A and 2B	1 (2.0%)
3B and 2B	1 (2.0%)
Medication discontinuation	Nil

*Formulation codes:

1A: Dapagliflozin 10 mg + Glimepiride 2 mg + Metformin 1000 mg; 1B: Dapagliflozin 10 mg + Glimepiride 1 mg + Metformin 1000 mg; 2A: Sitagliptin 50 mg + Glimepiride 2 mg + Metformin 1000 mg; 2B: Sitagliptin 50 mg + Glimepiride 1 mg + Metformin 1000 mg; 3A: Pioglitazone 15 mg + Glimepiride 2 mg + Metformin 1000 mg; 3B: Pioglitazone 15 mg + Glimepiride 1 mg + Metformin 500 mg.

Glycemic Control

The average follow-up period was 94.28 ± 15.39 days for visit 1 and 192.18 ± 23.79 days for visit 2. At baseline, 100.0% of patients had HbA1c >7.1%. At visit 1, 7 (12.3%) patients achieved 5.6–7.1%, and 50 (87.7%) continued to be >7.1%. At visit 2, the improvement in HbA1c was more significant, with 18 (35.3%) patients achieving 5.6–7.1% and 33 (64.7%) continuing to be >7.1%. Decrease of HbA1c with time was significant ($p < 0.0001$) (Table 3, Figure 1).

By contrast, FBG ≥100 mg/dL was found in all patients at baseline (100.0%), 54 (94.7%) at visit 1, and 48 (94.1%) at visit 2 (P = 0.1906). Likewise, two-hour postprandial blood glucose (PPBG) ≥140 mg/dL was found in all patients at baseline (100.0%), 55 patients (96.4%) at visit 1, and 50 (98.0%) at visit 2 (P = 0.3727). These were not statistically significant (Table 3).

Table 3. Glycemic outcomes (HbA1c, fasting blood glucose, and postprandial blood glucose) at baseline and follow-up visits.

	Baseline	Visit 1	Visit 2	p-value
N	57	57	51	
Followup duration from baseline (mean ± SD)		94.28 ± 15.39	192.18 ± 23.79	
Distribution of HbA1c, n(%) < 5.6% 5.6-7.1% >7.1%	 0 (0.0%) 0 (0.0%) 57 (100.0%)	 0 (0.0%) 7 (12.3%) 50 (87.7%)	 0 (0.0%) 18 (35.3%) 33 (64.7%)	 < 0.0001 ***
FBG≥ 100 mg/dL, n(%)	57 (100.0%)	54 (94.7%)	48 (94.1%)	0.1906
2h PPBG ≥ 140 mg/dL, n(%)	57 (100.0%)	55 (96.4%)	50 (98.0%)	0.3727

FBG- Fasting blood glucose; PPBG- post prandial blood glucose

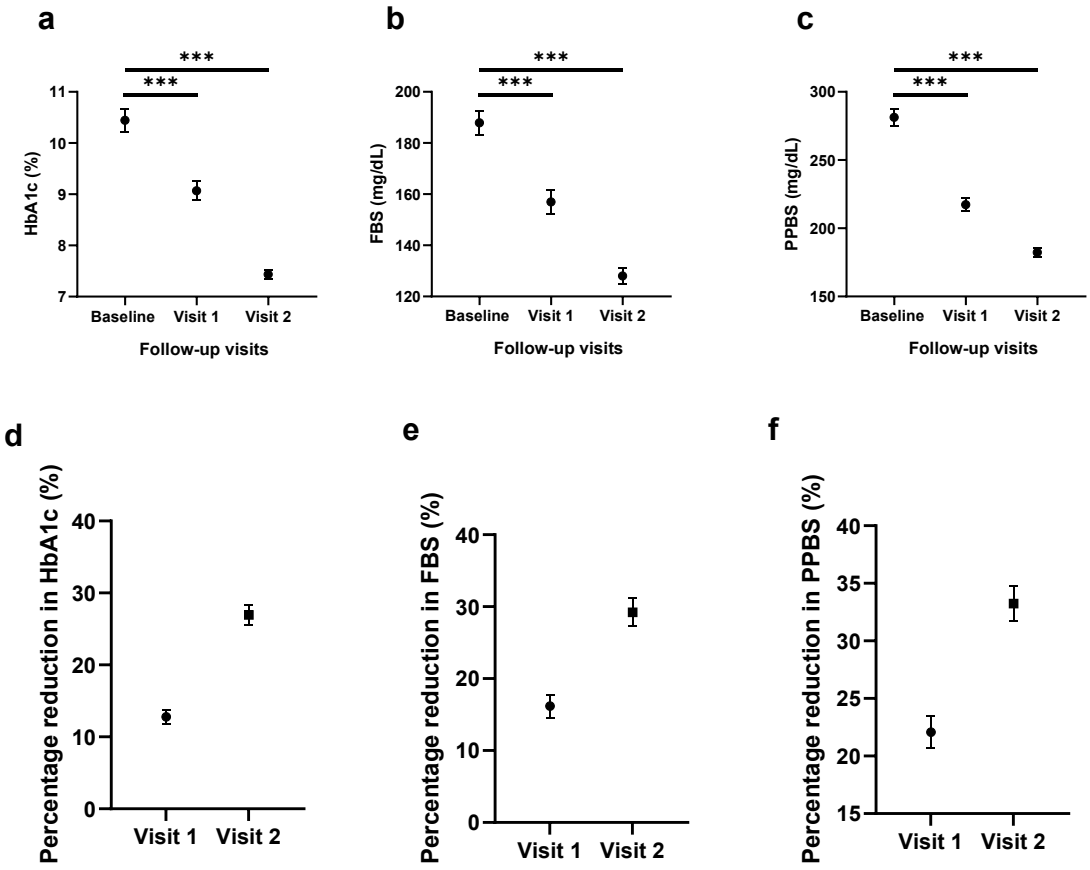


Figure 1. Changes in glycaemic indices over two follow-up visits and percentage reduction from baseline.

(a) HbA1c (%), (b) fasting blood glucose (FBG; mg/dL), and (c) postprandial blood glucose (PPBG; mg/dL) at baseline, Visit 1 (~3 months), and Visit 2 (~6 months). (d–f) Percentage reduction from baseline in HbA1c, FBG, and PPBG at Visit 1 and Visit 2. Data are mean ± SEM (baseline/Visit 1, n=57; Visit 2, n=51). Statistics by repeated-measures analysis with post-hoc paired comparisons; significance shown as * p<0.05, ** p<0.01, *** p<0.001. Abbreviations: FBG, fasting blood glucose; PPBG, postprandial blood glucose; SEM, standard error of the mean.

Medication Adherence

At visit 1, 6 patients (10.5%) had not missed any doses, but this increased to 12 (21.1%) at visit 2. The number of patients missing doses once a week decreased from 24.6% to 8.8%, and once every three weeks, from 61.4% to 47.4%. On the other hand, the number of patients missing once every two weeks rose from 0.1% to 12.3% (Table 4).

Safety Outcomes

There were a few adverse events. Hypoglycaemia was noted in five patients (8.8%) at visit 1 and 3 patients (5.3%) at visit 2. 5 patients (8.8%) developed urinary tract infection (UTI) at visit 1, but none at visit 2 (Table 4).

Table 4. Medication adherence patterns and adverse events reported across study visits.

	Visit 1	Visit 2
N	57	57
Frequency of missing a dose		
None	6 (10.5%)	12 (21.1%)
Once a week	14 (24.6%)	5 (8.8%)
Once every 2 weeks	2 (3.5%)	7 (12.3%)
Once every 3 weeks	35 (61.4%)	27 (47.4%)
Adverse events		
Hypoglycaemia	5 (8.8%)	3 (5.3%)
Urinary tract infections	5 (8.8%)	0 (0.0%)

Discussion

This observational study sought to compare clinical features, treatment regimens, and their effects on glycemic control in Indian patients with type 2 diabetes. The results indicated that in real-world settings, earlier consideration of combination therapies was effective in achieving good glycemic response in terms of HbA1c reduction, along with a reasonable tolerance.

The study population included a heterogeneous set of individuals at relatively earlier stages of diabetes and presenting with multiple comorbidities, thus reflecting the real-world clinical setting. The mean age of the cohort in the study of 58.9 years was dominated by females (57.9%). Over half of the patients (50.9%) had BMI >23 kg/m² (Table 2), consistent with Asian-specific cut-offs for overweight [7]. These findings are in line with previous Indian studies in that overweight and obesity are common among type 2 diabetic patients [8]. Interestingly, central adiposity was more prevalent in female patients (Table 2), which is a reflection of earlier South Asian observations indicating gender-differentiated fat distribution and cardiometabolic risk [9]. The relatively shorter mean duration of diabetes (3.7 years) (Table 2) suggests that the majority of patients were in the early disease phase, at earlier time points, either immediately following diagnosis or say, less than five years of disease duration, intensive glycemic interventions are considered to be most effective in maintaining β-cell function and retarding the onset of complications [10]. The highest comorbidity rate was of hypertension in 56.1% of the patients, followed by cardiovascular disease (12.3%) and dyslipidemia (10.5%) (Table 2). These results are similar to earlier Indian and South Asian literature, where hypertension has been reported between 50–70% in diabetics [11]. Lack of chronic kidney disease in our cohort may be due to the early stage of the disease. However, longitudinal studies indicate that CKD prevalence increases sharply with duration of diabetes [12].

Worldwide recommendations like the ADA/EASD consensus also support

early combination therapy treatment in patients not likely to reach targets with monotherapy [13]. The practice setting in India usually considers metformin along with sulfonylureas or incretin agents as the pillar of therapy based on cost-effectiveness and availability [14]. Accordingly, in the study cohort, most of the patients had received the 1A + 2A regimen, which was the most commonly employed combination. There was notable improvement in HbA1c with 35.3% of patients attaining levels of 5.6–7.1% by Visit 2 versus none at baseline (Table 3, Figure 1). The result follows the increasing evidence for the benefits of early combination therapy in diabetes treatment. The VERIFY trial showed similar results, in which vildagliptin and metformin early dual therapy offered more sustained glycemic control than stepwise escalation [15].

During follow-up with combinations, the postprandial glucose and fasting levels did not vary significantly. This can be attributed to the relatively short study period, inter-individual dietary variability, and non-adherence, similar to other Indian studies [16]. However, HbA1c is still the strongest marker of long-term glycemic control, and its substantial decrease supports the efficacy of the therapeutic approach used. Compliance was modestly better, with patients reporting zero missed doses increasing from 10.5% at Visit 1 to 21.1% at Visit 2. Absence of medication discontinuations supports the tolerability and acceptability of these regimens for clinical practice. The treatment regimens were tolerated well, with hypoglycaemia incidence decreased from 8.8% to 5.3% and urinary tract infection being zero at Visit 2. These are reassuring data, and according to reports, contemporary double or triple regimens, particularly those with incretin-based or SGLT2 inhibitors, have a lower risk of adverse events than previous regimens [6,18]. A decrease in hypoglycaemia could also be because of improved dose adjustment and closer follow-up. Despite this, patterns of non-adherence continued, which is consistent with well-documented issues including pill burden, expense, and absence of organised diabetes education for the population [17]. Past research indicates that fixed-dose combinations, simplified regimens [14] and electronic adherence support [17] have the potential to greatly enhance compliance, and therefore, the incorporation of such measures into day-to-day practice is imperative.

Limitations

Limitations to the study include its small sample size, brief follow-up (~6 months), and lack of control group or randomisation, which restrict causal inference.

Conclusion

This study proved early initiation of combination therapies in type 2 diabetic Indian patients with a remarkable reduction in HbA1c, modest increase in adherence, and a good safety profile. The prevalence of comorbid conditions like hypertension and obesity highlights the necessity for comprehensive cardiometabolic management. Higher cohorts, longer follow-up, and randomised trials are needed in the future to confirm the durability of glycemic effects and study intensive interventions for enhancing adherence.

Statements and Declarations

Funding

The authors did not receive support from any organization for the submitted work.

Competing interests

The authors have no competing interests to declare that are relevant to the content of this article.

Ethics Statement

This observational study used anonymized data collected in routine clinical practice. In accordance with institutional and national regulations, formal ethics committee approval was not required.

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ORIGINAL ARTICLE

Unilateral Hemilaminotomy for Intradural Extramedullary Spinal Tumors: Safety, Efficacy, and Neurological Outcomes

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Abstract

Introduction and Objectives: Intradural extramedullary (IDEM) spinal tumors constitute the most common group of intraspinal tumors and frequently present with progressive neurological deficits due to spinal cord or nerve root compression. Conventional laminectomy, though widely used, is associated with significant postoperative morbidity and spinal instability. With advancements in minimally invasive spine surgery, unilateral hemilaminotomy has emerged as an alternative approach aimed at preserving spinal stability while achieving adequate tumor excision. **Materials and Methods:** This hospital-based longitudinal observational study was conducted in a tertiary care neurosurgical center between January 2014 and December 2018. A total of 30 patients with IDEM tumors who underwent surgical excision using unilateral hemilaminotomy were included. Ethical approval was obtained, and written informed consent was secured from all participants. Preoperative evaluation included detailed neurological assessment using Nurick's grading and magnetic resonance imaging for tumor localization. **Results:** The study population had a mean age of 51 years with equal gender distribution. Thoracic spine was the most commonly involved region. Gross total tumor excision was achieved in all cases without conversion to conventional laminectomy. There was a statistically significant improvement in neurological status, with mean Nurick grade improving from 2.63 preoperatively to 0.30 postoperatively ($p < 0.0001$). Schwannomas were the most common histopathological diagnosis, followed by meningiomas. **Conclusion:** Minimally invasive unilateral hemilaminotomy is a safe and effective surgical approach for IDEM tumors, providing excellent neurological outcomes with minimal morbidity while preserving spinal stability. This technique represents a reliable and durable alternative to conventional laminectomy.

Key words: Intradural extramedullary tumor, Hemilaminotomy, Spinal tumors, Minimally invasive spine surgery, Neurological outcome

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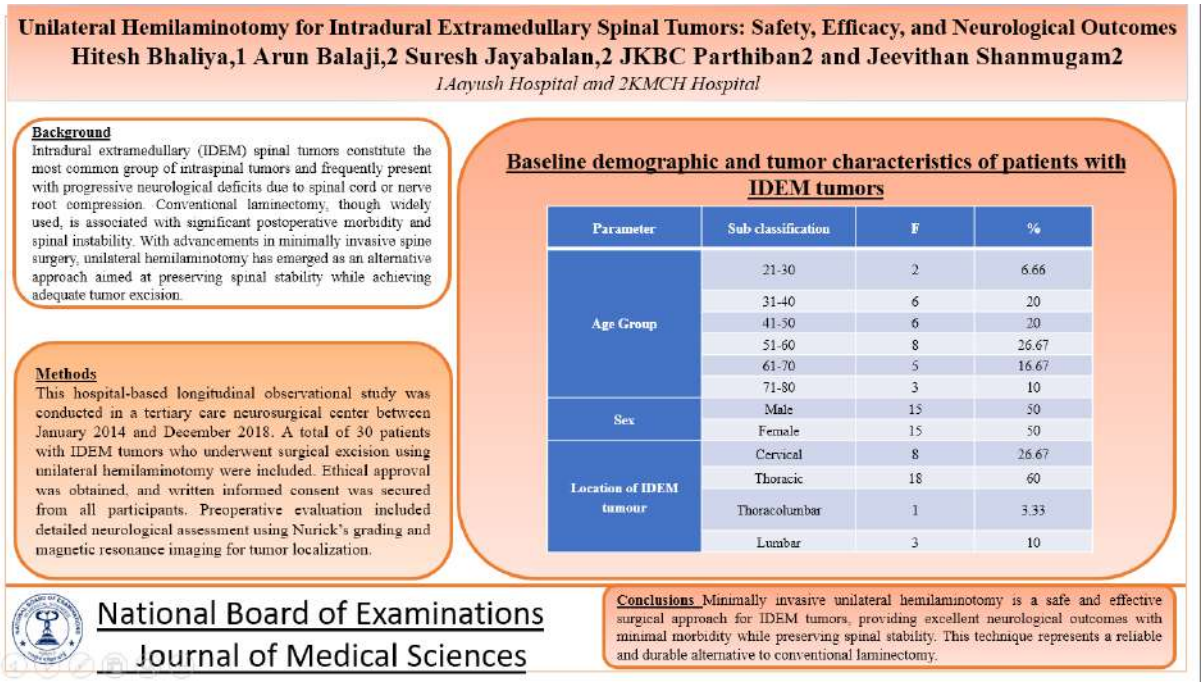
Graphical Abstract



Introduction

Spinal tumors constitute approximately 15% of all central nervous system tumors and are classified anatomically as extradural or intradural lesions. Intradural tumors are further subdivided into intramedullary and extramedullary tumors based on their relationship to the spinal cord. Among these, intradural extramedullary (IDEM) tumors represent the most common type of intraspinal tumors [1].

Nerve sheath tumors and meningiomas account for the majority of IDEM tumors. Among nerve sheath tumors, schwannomas are more frequently encountered than neurofibromas and typically arise from the dorsal nerve roots, whereas neurofibromas are more often associated with ventral roots and may present with a dumbbell configuration [2,3]. IDEM tumors are generally slow-growing lesions and often present with progressive spinal cord compression, leading to neurological deficits that may worsen over time if left untreated.

Surgical excision remains the treatment of choice for IDEM tumors, with the primary objectives being complete tumor removal, adequate decompression of the spinal cord and nerve roots, and histopathological diagnosis [4]. Traditionally, laminectomy has been the standard surgical approach for the excision of IDEM tumors because it provides wide exposure and is familiar to most surgeons. However, conventional laminectomy is associated with several drawbacks, including extensive muscle dissection, increased blood loss, prolonged hospital stay, epidural scarring, postoperative axial pain, and a significant risk of postoperative spinal instability and kyphotic deformity, which may ultimately result in progressive myelopathy [5-10,35-37,43,46,47].

To overcome these limitations, alternative surgical techniques such as laminotomy and laminoplasty have been developed. Although laminoplasty aims to

preserve posterior spinal elements, studies have shown that it does not completely eliminate the risk of postoperative spinal instability and may be technically demanding, time-consuming, and associated with a higher risk of dural injury, particularly in elderly patients [9-14,38-40]. These approaches also require bilateral stripping of posterior musculoligamentous structures, which play a crucial role in maintaining spinal stability.

With advances in microsurgical techniques and a growing emphasis on minimally invasive spine surgery, unilateral hemilaminotomy has gained attention as an effective alternative for the management of IDEM tumors. Biomechanical studies have demonstrated that hemilaminotomy preserves the structural integrity of the spine by maintaining posterior stabilizing elements [12,15-22,32-34]. Clinical studies have further shown that this approach is associated with shorter operative time, reduced intraoperative blood loss, fewer postoperative complications, shorter hospital stay, and better preservation of spinal stability when compared with conventional laminectomy.

In this study, we analyze the clinical and neurological outcomes of patients with spinal IDEM tumors treated using a minimally invasive unilateral hemilaminotomy approach and evaluate the efficacy and safety of this technique in achieving adequate tumor excision while preserving spinal stability.

Materials and Methods

This hospital-based longitudinal observational study was conducted in the Department of Neurosurgery at a tertiary care referral centre in South India. Prior to initiation of the study, approval was obtained from the Institutional Ethics Committee and the concerned university authorities. All procedures were carried out in accordance with the ethical principles outlined in the Declaration of Helsinki. Eligible patients and their immediate relatives were approached during the preoperative period, and the nature of the study, surgical procedure, potential benefits, possible risks, and follow-up requirements were explained in detail in their vernacular language. Written informed consent was obtained from both the patient and a responsible attendant before inclusion in the study. Participation was entirely voluntary, and confidentiality of patient data was strictly maintained throughout the study.

Patients diagnosed with intradural extramedullary (IDEM) spinal tumors who underwent surgical excision by unilateral hemilaminotomy were included in the study. Patients who were medically unfit for surgery, unwilling to undergo surgical intervention, had a history of previous spinal surgery, or were operated for recurrent tumors were excluded. A total of 30 patients fulfilling the inclusion criteria were enrolled. Demographic details, clinical presentation, neurological status, comorbid conditions, imaging findings, intraoperative observations, histopathological diagnosis, postoperative complications, and follow-up details were recorded using a structured proforma.

All patients underwent detailed preoperative clinical and neurological evaluation. Neurological status was assessed using Nurick's grading system at admission and during follow-up. Magnetic resonance imaging of the spine was performed in all cases to determine the level, size, side, and extent of the tumor. Histopathological classification of tumors was carried out according to World Health

Organization criteria. Preoperative preparation included routine laboratory investigations, anesthetic evaluation, and administration of prophylactic antibiotics. Intraoperative electrophysiological monitoring, including somatosensory evoked potentials, motor evoked potentials, and free-run electromyography, was employed in all cases to enhance surgical safety and preserve functional neural structures.

All patients were operated in the prone position under general anesthesia. After appropriate positioning and padding of pressure points, a midline skin incision was made over the involved spinal level. Unilateral subperiosteal dissection of paraspinal muscles was performed on the side of the tumor. A unilateral hemilaminotomy was carried out using a high-speed drill and Kerrison rongeurs, preserving the contralateral lamina, spinous process, and posterior ligamentous structures. Partial facetectomy, undercutting of the spinous process base, or limited contralateral laminar undercutting was performed when necessary to improve exposure, without compromising spinal stability. After achieving meticulous hemostasis, the dura was opened paramedially and dural hitch sutures were applied. The arachnoid membrane was carefully opened, and the tumor was internally decompressed using ultrasonic aspirators or tumor biopsy forceps, followed by piecemeal excision. In cases of schwannoma, the involved nerve root was coagulated and divided when found to be nonfunctional, while in meningiomas, the dural attachment was excised as far as possible or coagulated when complete excision was not feasible. After complete tumor removal, watertight dural closure was performed using continuous prolene sutures. An epidural suction drain was placed, and the wound was closed in layers. Patients were mobilized on the first or second postoperative day.

Postoperatively, patients were monitored for neurological status and surgical complications such as cerebrospinal fluid leak, wound infection, pseudomeningocele formation, or new neurological deficits. Follow-up evaluations were performed at regular intervals, with a minimum follow-up period of six months. At follow-up, neurological status was reassessed using Nurick's grading system, and radiological evaluation including computed tomography, dynamic X-rays, and magnetic resonance imaging was performed to assess spinal stability, alignment, and presence of residual or recurrent tumor.

Statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) version 16.0 for Windows. Descriptive statistics were used to summarize demographic and clinical variables, expressed as frequencies, percentages, means, and standard deviations. Preoperative and postoperative neurological outcomes were compared using paired t-test. A p-value of less than 0.05 was considered statistically significant.

Results

The study population comprised 30 patients with intradural extramedullary (IDEM) tumors, with an equal gender distribution (50% males and 50% females). The mean age of the patients was 51 years, with the majority of cases observed in the fifth and sixth decades of life, particularly in the 51–60 year age group (26.67%). Thoracic spine was the most common location of IDEM tumors, accounting for

60% of cases, followed by cervical (26.67%), lumbar (10%), and thoracolumbar (3.33%) regions, indicating a clear predominance of thoracic involvement in the study cohort (Table 1).

Table 1. Baseline demographic and tumor characteristics of patients with IDEM tumors

Parameter	Sub classification	F	%
Age Group	21-30	2	6.66
	31-40	6	20
	41-50	6	20
	51-60	8	26.67
	61-70	5	16.67
	71-80	3	10
Sex	Male	15	50
	Female	15	50
Location of IDEM tumour	Cervical	8	26.67
	Thoracic	18	60
	Thoracolumbar	1	3.33
	Lumbar	3	10

Preoperatively, the majority of patients presented with moderate to severe neurological impairment, with 46.66% of patients classified as Nurick grade 3 or 4, reflecting significant functional limitation. Postoperatively, there was a marked improvement in neurological status, with all patients improving to either Nurick grade 0 (70%) or grade 1 (30%) at six months follow-up, and none having higher grades. Clinically, motor weakness (66.68%) and sensory disturbances (63.33%) were the most common presenting symptoms, followed by local pain (60%), sphincter dysfunction (26.68%), and radicular pain (20%), highlighting the varied but predominantly motor-sensory presentation of IDEM tumors (Table 2).

Table 2. Clinical presentation and neurological status of study participants

Parameter	Sub classification	F	%
Preoperative Nurick grading.	0	5	16.68
	1	4	13.33
	2	3	10
	3	7	23.33
	4	7	23.33
	5	4	13.33
Postoperative Nurick grading	0	21	70
	1	9	30
Clinical features	Radicular pain	6	20
	Local pain	18	60
	Motor weakness	20	66.68
	Sensory disturbance	19	63.33
	Sphincter dysfunction	8	26.68

There was a statistically significant improvement in neurological status following unilateral hemilaminotomy, as reflected by a substantial reduction in the mean Nurick grade from 2.63 ± 1.69 preoperatively to 0.30 ± 0.46 postoperatively. This improvement was highly significant ($p < 0.0001$), demonstrating the effectiveness of the surgical approach in achieving meaningful functional recovery among patients with IDEM tumors (Table 3).

Table 3. Comparison of Mean Pre and post operative Nurick grade

Nurick grade	Mean	SD	P-value
Preoperative	2.63	1.69	<0.0001
Postoperative	0.3	0.46	

*Paired t test

Histopathological analysis revealed schwannomas as the most common IDEM tumor, constituting 56.67% of cases, followed by meningiomas in 40% of patients, while neurofibromas were rare (3.33%). This distribution underscores the predominance of nerve sheath tumors among IDEM lesions and is consistent with the commonly reported pathological profile of intradural extramedullary spinal tumors (Table 4).

Table 4. Histopathological distribution of IDEM tumors

Histopathology of tumors	Number of patients	Percentage
Schwannomas	17	56.67
Meningiomas	12	40
Neurofibromas	1	03.33

Discussion

Conventional laminectomy has long been the standard surgical approach for the excision of intradural extramedullary (IDEM) spinal tumors because it provides wide exposure and is familiar to most neurosurgeons. However, long-term follow-up studies have demonstrated that extensive removal of posterior spinal elements during laminectomy is associated with several complications, including postoperative spinal instability, kyphotic deformity, epidural fibrosis, persistent axial pain, and progressive neurological deterioration [5,9,36,37,43,46,47]. These drawbacks have prompted the development of alternative surgical techniques aimed at minimizing tissue trauma while maintaining adequate exposure for complete tumor excision.

In the present study, unilateral hemilaminotomy provided sufficient exposure for complete excision of IDEM tumors in all patients without the need for conversion to conventional laminectomy. This approach preserved the contralateral musculoligamentous structures and posterior bony elements, thereby maintaining spinal stability. Biomechanical and clinical studies have previously demonstrated that unilateral approaches reduce disruption of posterior tension bands

and significantly lower the risk of postoperative instability when compared to bilateral laminectomy [12,21]. The absence of spinal deformity or instability in our patients during follow-up further supports these findings.

The demographic profile of patients in this study showed a mean age of 51 years, with most patients presenting in the fifth and sixth decades of life, which is comparable with several published series [4,16,27,29,30]. Thoracic spine was the most commonly involved region, followed by cervical and lumbar regions, consistent with earlier reports indicating thoracic predominance of IDEM tumors, particularly meningiomas and nerve sheath tumors [4,12,16,29,31]. The equal gender distribution observed in our study aligns with reports showing variable sex predilection depending on tumor type and study population [12,26,29].

Clinically, most patients presented with motor weakness, sensory disturbances, and pain, reflecting progressive spinal cord compression due to the slow-growing nature of IDEM tumors [45,46]. Preoperatively, a significant proportion of patients had moderate to severe neurological impairment as assessed by Nurick grading, indicating delayed presentation. Following surgery, all patients demonstrated significant neurological improvement, with a marked reduction in mean Nurick grade, which was statistically significant. Similar favorable neurological outcomes following hemilaminotomy have been reported by several authors, who observed substantial improvement in functional status with minimal morbidity [12,21].

Gross total resection was achieved in all cases in this study. Schwannomas constituted the most common histopathological diagnosis, followed by meningiomas, with neurofibromas being rare, a distribution consistent with previously reported large series of IDEM tumors [4,12,16,25,29,31]. In meningioma cases, Simpson grade II excision was achieved, and no recurrence was observed during follow-up, supporting earlier observations that coagulation of the dural attachment provides satisfactory tumor control [47].

The mean operative time in our study was comparable with other published series using hemilaminotomy and minimally invasive approaches [4,29]. The incidence of postoperative complications was low, with only one patient developing cerebrospinal fluid leak, which resolved spontaneously. No patient developed wound infection, pseudomeningocele, new neurological deficit, spinal instability, or deformity. These findings are in agreement with earlier studies reporting lower complication rates, reduced blood loss, and faster recovery with unilateral hemilaminotomy compared to conventional laminectomy [12,26,25,27,29-31].

During a mean follow-up period of 35 months, none of the patients demonstrated radiological evidence of spinal instability, deformity, residual tumor, or recurrence. Similar long-term outcomes have been reported by multiple authors, further reinforcing the durability and safety of the hemilaminotomy approach for IDEM tumors [26,29-31]. The preservation of posterior spinal elements appears to play a crucial role in maintaining sagittal alignment and preventing late complications.

Despite these favorable outcomes, the present study has certain limitations, including a relatively small sample size and the absence of a control group undergoing

conventional laminectomy. Additionally, comorbidities were not included in outcome assessment. Nevertheless, the consistent neurological improvement, low complication rate, and preservation of spinal stability observed in this study support the growing body of evidence favoring unilateral hemilaminotomy as a safe and effective minimally invasive approach for the management of IDEM tumors.

Conclusion

Minimally invasive unilateral hemilaminotomy is a safe and effective surgical technique for the management of intradural extramedullary spinal tumors. This approach allows complete tumor excision with significant neurological improvement while preserving posterior spinal elements and maintaining spinal stability. The procedure is associated with minimal surgical morbidity, low complication rates, and early postoperative mobilization. Adequate exposure can be achieved without the need for extensive bone removal or conversion to conventional laminectomy. The absence of postoperative spinal deformity or tumor recurrence during follow-up further supports the durability of this technique. Unilateral hemilaminotomy should be considered a preferred minimally invasive option for IDEM tumors across different spinal levels.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Impact of Mobile Display Technology and Settings on Reaction Time in Young Adults: A Cross Sectional Observational Study

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Abstract

Background: The continuous and increased exposure to mobile screen increases the concern about its effects on cognitive functions, particularly reaction time which serves as a sensitive indicator of sensorimotor integration and processing speed. Recent researches report the increased screen reduces the reaction time. However, the relationship between mobile display technology and screen settings remains unclear. **Aims & Objectives:** To assess difference in reaction time (Visual and Auditory) with various mobile display and display settings and to determine the association between gender and reaction time among the study participants. **Methods:** A cross sectional observational study was conducted among young healthy adults aged 18-30 years in a tertiary care teaching hospital in Puducherry district. 387 participants were recruited through convenience sampling method. Each participant mobile phone type screen type and settings of blue filter and duration phone usage were recorded. After completion of baseline assessments participants visual and auditory reaction time were measured. The data were analysed using SPSS 22 version. Reaction times across display types and blue-light filter categories were compared using One-way ANOVA, while Mann–Whitney U and paired t tests examined gender differences. **Results:** Out of 387 part, 156 (54.4%) were females out of which, 180 (62.7%) were between 20 to 30 years of age. Most of the participants reported more than 6 hours of daily mobile use. Reaction times did not differ significantly across display types or refresh rates ($p > 0.05$). In contrast, visual reaction times varied with blue-light filter status, discriminatory visual RT reports significant difference among groups ($p = 0.020$), and simple visual RT was borderline significant ($p = 0.050$), while auditory measures were unaffected. A small but significant gender difference was observed for simple visual RT, and mean heart rate increased post-testing ($p = 0.022$). **Conclusions:** In young adults with high mobile use, display types does not significantly affect the reaction time, whereas the blue light filter settings significantly change the reaction time. Standardising screen settings may be important when using smartphones for reaction time assessment.

Keywords: Reaction time, Mobile screen types, Blue light filters, screen time

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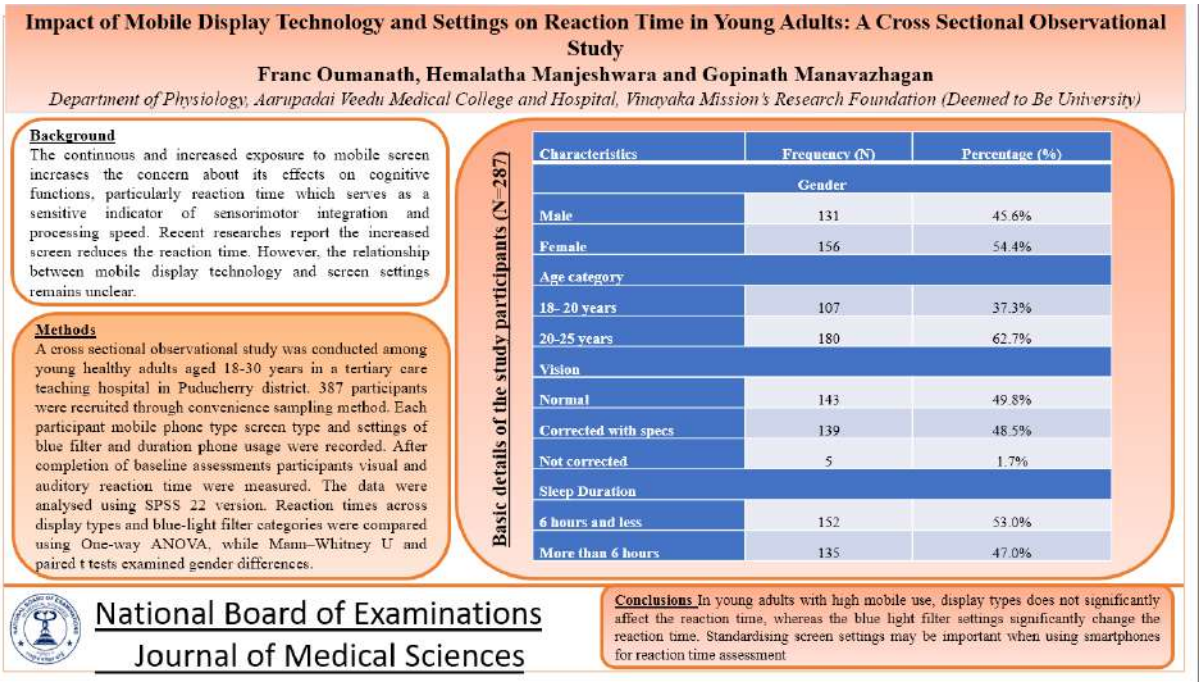
Graphical Abstract



Introduction

Mobile phones have been become essential part of everyone's life particularly in young adults with average daily screen time more than seven hours for various activities ranging from education to entertainment [1]. This continuous use increases the concern about its effects on cognitive functions, particularly reaction time which serves as a sensitive indicator of sensorimotor integration and processing speed. Reaction time represents the interval between stimulus onset and motor response encompassing sensory detection, neural processing and effector activation [2].

Visual reaction time typically exceeds the auditory reaction time due to additional retinal to cortical processing demands. The normal visual reactive time value in young adults aged 18 to 25 years at optimal condition ranges from 250-350 minutes. These values vary with stimulus complexity and individual factors like age, gender and fatigue [3].

Many researches have reported that increase in daily screen time and prolongs the reaction time. Most of the investigations focus on the usage duration and overlooking device specific factors [4]. With the surge in mobile phone use for academic, recreational, and clinical tasks, concerns have risen about how digital screen exposure influences cognitive-motor performance. Modern mobile displays differ markedly in refresh rates, panel type, brightness levels and modulation technique. Display types and display setting also tend to influence the reaction time. There was a dearth of research related to the reaction time with display type and display screen. Hence, this study was planned to assess the differences in the various screen type and to find relationship between screen type with reaction time.

Objectives:

1. To assess difference in reaction time (Visual and Auditory) with various mobile display and display settings
2. To determine the association between gender and reaction time among the study participants.

Methodology

Study design and setting

This cross-sectional observational study was carried out among young healthy adults between the age group 18 to 30 years. The present study was conducted in the Department of Physiology of a a tertiary care teaching hospital in the district of Puducherry over a period of three months from October 2025 to December 2025.

Study participants, sampling technique, and sample size

As per the study conducted by Asuthosh Padhya et al., the expected mean reaction time was 314±50.8 with precision of 6 and level of significance of 5% in the formula [5] $n = [\frac{Z_{(1-a/2)}}{d}]^2$, the minimum required sample size was calculated as 276 participants. The healthy adults aged 18 years to 25 years convenience sampling method. Individuals with Musculoskeletal disorders or recent with normal vision or corrected vision was included in the study. Participants were recruited through convenience sampling method. Participants currently on psychoactive medication, and those who had physical activity within 2 hours were excluded from the study.

Data collection tool and technique

A proforma was developed for collecting participants information and basic health details. At baseline participants anthropometric measurements such as height and weight were measure to assess the Body Mass Index (BMI). Baseline vitals such as heart rate were measured. Each participant mobile phone type screen type and settings of blue filter and duration phone usage were recorded. After completion of baseline assessments participants visual ad auditory reaction time were measured. After completion of the procedure, heart rate was assessed.

Reaction time apparatus

Reaction time apparatus gives a simple discriminatory and choice reactions for auditory and visual stimuli with built in chronoscope.

Data analysis

All the data were collected and was entered in MS Excel 2019. Analysis was done by using SPSS version 22. The qualitative variables were presented in the form of numbers and percentages. Mean, standard deviation/median, and interquartile range were used for quantitative variables. Suitable statistical tests (according to the nature and distribution of data, e.g., chi-square test) were applied to assess the significance of study findings. One-way ANOVA was used to assess the association between screen type and screen settings. p-value < 0.05 were considered as statistical significance.

Ethical considerations

Written informed consent was obtained from all the participants who were enrolled in the current study. Research and ethical committee approval were obtained from the Institute Research Committee and the Institute Human Ethics Committee (AV/IHEC/september2025/02) respectively. Data safety and confidentiality were maintained at every step of the study.

Results

A total of 287 young adults participated in the study, aged 18 years to 30 years. The results were described under the following headings:

- Sociodemographic and basic details
- Mobile use and display characteristics
- Comparison of reaction time with display type and blue light filter
- Gender differences in reaction time
- Changes in heart rate before and after reaction time testing

Sociodemographic and basic details

Among the study participants nearly half of them were females which accounts for about 54.4%. Majority of the study participants (62.7%) were aged between 20 years to 30 years.

With respect to visual status almost half of the participants had a normal vision without any visual aids (49.8%) and 48.5% were having vision with corrective specs and only 1.7% of the participants were having vision without corrected refractive error. Similarly, around half of the study participants. More than half of the study participants were reported sleep duration of 6 hours or less than 6 hours of sleep at night (Table 1).

Table 1: Basic details of the study participants (N=287)

Characteristics	Frequency (N)	Percentage (%)
Gender		
Male	131	45.6%
Female	156	54.4%
Age category		
18- 20 years	107	37.3%
20-25 years	180	62.7%
Vision		
Normal	143	49.8%
Corrected with specs	139	48.5%
Not corrected	5	1.7%
Sleep Duration		
6 hours and less	152	53.0%
More than 6 hours	135	47.0%

Mobile use and display characteristics

Table 2 summarizes mobile phone usage patterns and display-related settings among the study participants. Nearly two-thirds of the participants (63.4%) reported using their mobile phone for more than 6 hours per day, whereas only 36.6% used it for 6 hours or less. This shows that consistent high digital among the study participants in similar age groups. Regarding blue-light filter usage, 65.5% of participants was not using the blue light filter, 30.7% were using the mobile phone with blue light filter all the time and only 3.8% reported partial use (turning on during night time only). With respect to display technology, AMOLED 120 Hz was the most common configuration (37.3%), followed by OLED 60 Hz (23.3%), while other combinations such as AMOLED 90 Hz, LCD 60/90/120 Hz, and OLED 120 Hz were represented in smaller proportions which ranges from 3% to 13%.

Table 2. Details related to mobile phone usage pattern and display settings

Characteristics	Frequency (N)	Percentage (%)
Average mobile usage		
6 hours and less	105	36.6%
More than 6 hours	182	63.4%
Use of Blue Light filter		
On	88	30.7%
Off	188	65.5%
Partially on	11	3.8%
Mobile Display type		
AMOLED 120 Hz	107	37.3%
AMOLED 60 Hz	11	3.8%
AMOLED 90 Hz	21	7.3%
LCD 120 Hz	16	5.6%
LCD 60 Hz	17	5.9%
LCD 90 Hz	10	3.5%
OLED 120 Hz	38	13.2%
OLED 60 Hz	67	23.3%

Comparison of reaction time with display type and blue light filter

Comparative analysis of reaction time with display type and blue light filter is shown in Table 3. The reaction times such as Discriminatory Auditory Reaction Time (DART), Discriminatory Visual Reaction Time (DVRT), Simple Auditory Reaction Time (SART) and Simple Visual Reaction Time (SVRT) were compared with various display types of the mobile phone. It was found that there was no statistically significant difference between the display types.

Similarly, the reaction time on comparison with blue light filter status shows significant changes in visual reaction times. The Discriminatory Visual Reaction Time (DVRT) and the Simple Visual Reaction Time (SVRT) were statistically significant with p value of 0.020* and 0.050* respectively.

Table 3. Comparison of reaction time with display type and screen display settings

		Sum of Squares	df	Mean Square	F	Sig.
Reaction time with different display types						
DART	Between Groups	.001	7	.000	.810	.580
	Within Groups	.034	279	.000		
	Total	.035	286			

DVRT	Between Groups	.001	7	.000	.609	.749
	Within Groups	.036	279	.000		
	Total	.037	286			
SART	Between Groups	.001	7	.000	.750	.630
	Within Groups	.073	279	.000		
	Total	.074	286			
SVRT	Between Groups	.001	7	.000	.443	.874
	Within Groups	.052	279	.000		
	Total	.053	286			
Reaction time with blue light filter status						
DART	Between Groups	.001	2	.000	2.184	.114
	Within Groups	.035	284	.000		
	Total	.035	286			
DVRT	Between Groups	.001	2	.000	3.982	.020*
	Within Groups	.036	284	.000		
	Total	.037	286			
SART	Between Groups	.001	2	.000	1.529	.219
	Within Groups	.074	284	.000		
	Total	.074	286			
SVRT	Between Groups	.001	2	.000	2.548	.050*
	Within Groups	.052	284	.000		
	Total	.053	286			

*One-way ANOVA was applied *p value<0.005 was statistically significant*

Gender differences in reaction time

The mean score of SVRT in male was 0.144±0.11 and female was 0.145±0.010. This difference was statistically significant with p value of 0.012*. The mean score of DVRT in males were 0.127±0.13 and in females were 0.129±0.014 respectively. The mean score of SART and DART in males were 0.146±0.10 and 0.137±0.16 and in females were 0.147±0.011 and 0.139±0.015 respectively however there was no statistically significant changes between both genders.

Table 4. Comparison of Gender with Reaction time

Variable	Gender		P value
	Male	Female	
SVRT	0.144±0.11	0.145±0.010	0.012*
SART	0.146±0.10	0.147±0.011	0.065
DVRT	0.127±0.13	0.129±0.014	0.342
DART	0.137±0.16	0.139±0.015	0.677

*Mann Whitney U test was applied, *p value<0.005 was statistically significant*

Changes in heart rate before and after reaction time testing

Heart rate has increased significantly from baseline following reaction time setting among the study participants. The mean heart rate at baseline was 89.52± 12.62 beats per min and has been increased to 95.40±44.178 beats per min post reaction time testing which was statistically significant. (t = -2.300 , p =0.022) (Figure 1).

Among the study participants 1.70% of participants reported eye strain and 0.30% reported headache (Figure 2).

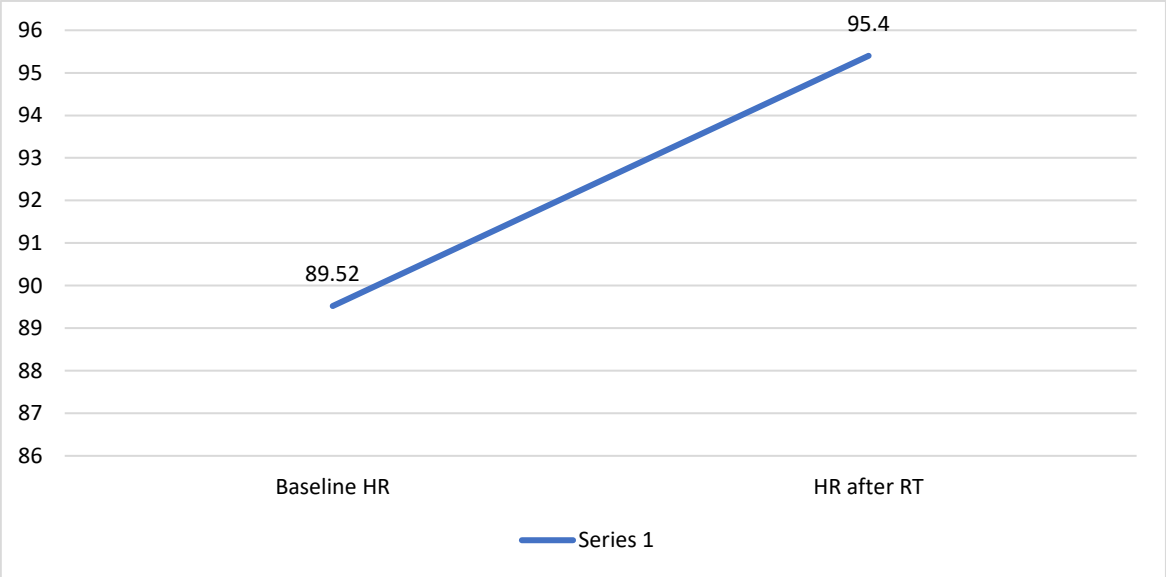


Figure 1. Comparison of change in vital statistics pre and post reaction time:

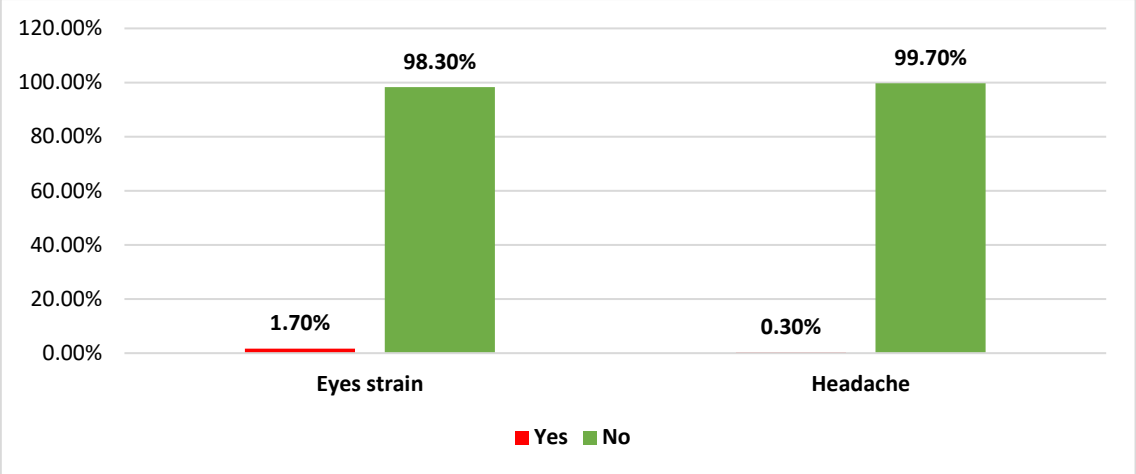


Figure 2. Proportion of participants reported headache and eye strain

Discussion

The present observational cross-sectional study was conducted among the young healthy adults aged 18 years to 30 years for a period of three months in the Department of Physiology of tertiary care teaching hospital in Puducherry district. The study was aimed to assess the difference in reaction time (Visual and Auditory) with various mobile display and display settings and to determine the association between gender and reaction time among the study participants.

In the current study, nearly half of them were females which accounts for about 54.4%. Majority of the study participants (62.7%) were aged between 20 years to 30 years. Similar findings were reported by Pandey et al., that most of the participants were aged 18 to 23 years with female predominance [2].

With respect to visual status almost half of the participants had a normal vision without any visual aids (49.8%) and 48.5% were having vision with corrective specs and only 1.7% of the participants were having vision without corrected refractive error.

The mean score of SVRT in male was 0.144±0.11 and female was 0.145±0.010. This difference was statistically significant with p value of 0.012*. The mean score of DVRT in males were 0.127±0.13 and in females were 0.129±0.014 respectively. The mean score of SART and DART in males were 0.146±0.10 and 0.137±0.16 and in females were 0.147±0.011 and 0.139±0.015 respectively however there was no statistically significant changes between both genders. Concurrent findings were reported by the study conducted by shat et al that the reaction time in male and females does not show any statistical significant [6]. In contrast the study conducted by Panday et al., stated that there was significant difference in reaction time between men and women [7].

The reaction times such as Discriminatory Auditory Reaction Time (DART), Discriminatory Visual Reaction Time (DVRT), Simple Auditory Reaction Time (SART) and Simple Visual Reaction Time (SVRT) were compared with various display types of the mobile phone. It was found that there was no statistically significant difference between the display types.

Similarly, the reaction time on comparison with blue light filter status

shows significant changes in visual reaction times. The Discriminatory Visual Reaction Time (DVRT) and the Simple Visual Reaction Time (SVRT) were statistically significant with p value of 0.020* and 0.050* respectively. The study conducted by Usgaonkar et al., stated that blue light filter improves task performance, however participants reported visual fatigue while using the filter [8]. Sirayder et al., in their study assessed the effect of blue and red light on cognitive function it was reported that Blue light exposure led to a significant and large improvement in SRT ($\Delta = -53.33$ ms; $p < 0.001$, $\eta 2p = 0.270$) and enhanced dynamic balance [9].

Strengths and Limitations

This was the first study which compares the real-world mobile configurations including multiple display technologies and use of blue light filter among the participants. This study has few limitations, as it was conducted in a single institute, which may limit the generalisability. And the self-reported screen time and use of blue light filters may leads to recall bias.

Conclusion

The present study shows that, in healthy young adults with high daily mobile phone use, variation in smartphone display hardware (LCD vs OLED/AMOLED and different refresh rates) does not produce significant differences in simple or discriminatory visual and auditory reaction time. In contrast, visual reaction times varied with blue-light filter status and showed small gender-related differences, while auditory reaction times remained largely unaffected.

Conflicts of interest

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

Funding

No funding was received for conducting this study.

Ethical Approval

Ethical approval receive from the institute (AV/IHEC/september2025/02).

Acknowledgement

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ORIGINAL ARTICLE

A Prospective Observational Study on Chronic Anal Fissure in a Tertiary Care Centre

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Abstract

Background: Chronic anal fissure is a common and painful anorectal condition that may become resistant to conventional medical treatment in a significant proportion of patients. Chronic resistant anal fissure poses a therapeutic challenge, and early diagnosis and timely escalation of therapy remain essential to improve patient outcomes. **Objectives:** To describe the clinical profile of chronic anal fissure in patients attending a tertiary care center and to analyze its association with age, sex, mode of disease onset, clinical symptoms, and outcomes over a six-month follow-up period. **Methods:** This prospective observational study was conducted on 30 patients with chronic anal fissure admitted to the Department of General Surgery, GMKMCH, Salem, between July 2022 and June 2024. Patients with typical chronic anal fissure were included, while pregnant women, patients with pacemakers, and those on anticoagulant therapy were excluded. Data on demographic characteristics, socioeconomic status, clinical presentation, duration of symptoms, and disease onset were collected using a structured proforma. **Results:** The proportion of chronic resistant anal fissure was 36.7%. Most patients were aged 40 years or above, with a slight male predominance. Pain was the predominant symptom, often associated with bleeding and itching. Chronic resistance was significantly associated with age ≥40 years ($p = 0.05$) and symptom duration of one year or more ($p = 0.05$). No significant association was found with sex, socioeconomic status, or mode of disease onset. At six months, only 30.0% of patients showed complete improvement, while the remainder had partial or no improvement. **Conclusion:** Chronic resistant anal fissure was observed in more than one-third of patients, particularly among older individuals and those with longer symptom duration. These findings underscore the need for early diagnosis and timely escalation of treatment in high-risk groups. Future studies with larger sample sizes and standardized outcome measures are warranted.

Keywords: Chronic anal fissure; Chronic resistant anal fissure; Anal pain; Conservative management; Lateral internal sphincterotomy; Treatment outcomes

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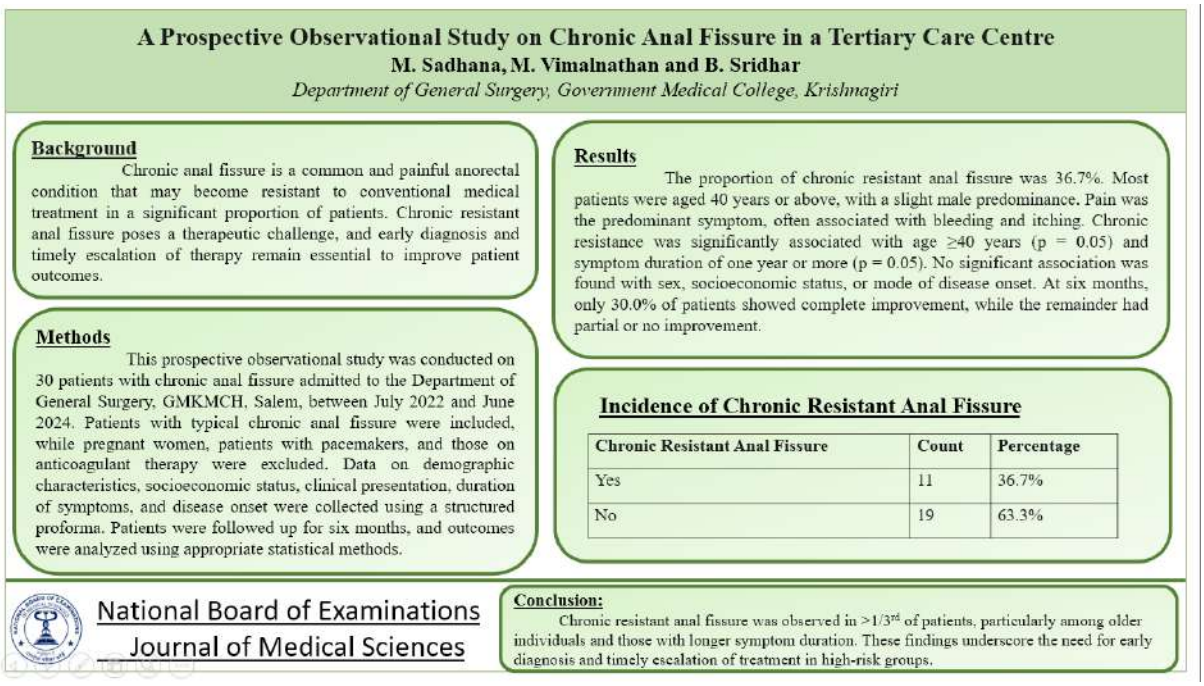
Graphical Abstract



Introduction

Chronic anal fissure is a common and difficult condition in colorectal practice, affecting about 1 in 350 adults and causing significant discomfort due to persistent pain, bleeding, and difficulty during defecation [1]. Acute anal fissures usually heal within 6 weeks with conservative treatment. However, nearly 40% progress to chronic anal fissure, defined as symptoms lasting more than 8 weeks, and the presence of features such as sentinel pile or exposed internal sphincter fibers, making management more challenging [2].

The underlying pathophysiology involves a continuous cycle of internal anal sphincter hypertonia, reduced blood flow to the anoderm, and delayed healing. This cycle perpetuates pain and prevents fissure resolution, thereby highlighting the importance of therapeutic strategies aimed at reducing sphincter spasm and improving local perfusion [3].

Treatment options for chronic anal fissure range from conservative measures to surgical intervention. Medical management with topical agents such as glyceryl trinitrate (GTN) and calcium channel blockers achieves healing in approximately 40–60% of patients, though their use is often limited by side effects and high recurrence rates [4,5]. Lateral internal sphincterotomy remains the most effective surgical treatment, with healing rates above 90%, but carries a risk of fecal incontinence in a subset of patients [6].

Resistant anal fissure refers to fissures that fail to heal despite appropriate medical treatment for 8–12 weeks [7]. This subgroup poses a clinical dilemma, as patients often have to choose between ongoing symptoms and surgical intervention with potential complications.

A subset of patients with chronic anal fissure fails to respond adequately to both medical and surgical management, constituting a clinically challenging group often referred to as chronic resistant anal

fissure. This subgroup is poorly characterized in the literature, particularly in tertiary care settings in resource-limited environments [8]. Factors such as older age, prolonged symptom duration, comorbidities affecting wound healing, and delayed health-seeking behavior may contribute to treatment resistance [9].

Early identification of patients at risk of developing treatment resistance is crucial for optimizing therapeutic strategies and preventing prolonged morbidity. Understanding the demographic and clinical factors associated with chronic resistance may help clinicians tailor treatment plans and determine the appropriate timing for escalation of therapy [10,11,12].

Aim & Objectives

To describe the clinical profile of chronic anal fissure in patients attending a tertiary care center and to analyze its association with age, sex, mode of disease onset, clinical symptoms, and outcomes over a six-month follow-up period.

Study Methodology

This prospective observational study was conducted on 30 patients with a clinical diagnosis of chronic anal fissure admitted to the general surgical and trauma wards of the Department of General Surgery, GMKMCH, Salem, between July 2022 and June 2024. All patients admitted with chronic typical anal fissure were included, while pregnant women, patients with pacemakers, and those receiving low molecular weight heparin or warfarin therapy were excluded.

After obtaining written informed consent, eligible patients were enrolled in the study. Data were collected using a structured proforma, which included demographic details, socio-economic status, and a detailed clinical history focusing on presenting complaints and duration of symptoms. Past medical history such as diabetes mellitus, systemic hypertension, tuberculosis, asthma, epilepsy, jaundice, and previous surgeries, along with personal habits including smoking, alcohol consumption, and drug addiction, were recorded. A thorough general examination, vital assessment, systemic examination, per rectal examination, and oral cavity examination were performed.

Routine laboratory investigations and relevant imaging were carried out as part of the evaluation. Patients who did not respond to conservative management were referred for further surgical evaluation, and details of subsequent treatment decisions were documented. Patients were followed up during hospital stay and at regular intervals thereafter. All collected data were systematically compiled and analyzed using appropriate statistical software.

Results

A total of 30 patients were included in the study. The age of patients ranged from 20 to 69 years, with the highest proportion belonging to the 60–69 year age group (26.7%), followed by 50–59 years (23.3%). Younger age groups were less represented, with 13.3% in the 20–29 year group. Males constituted 56.7% of the study population, while females accounted for 43.3%. Most patients belonged to the middle socioeconomic status (56.7%), followed by high (23.3%) and low socioeconomic groups (20.0%).

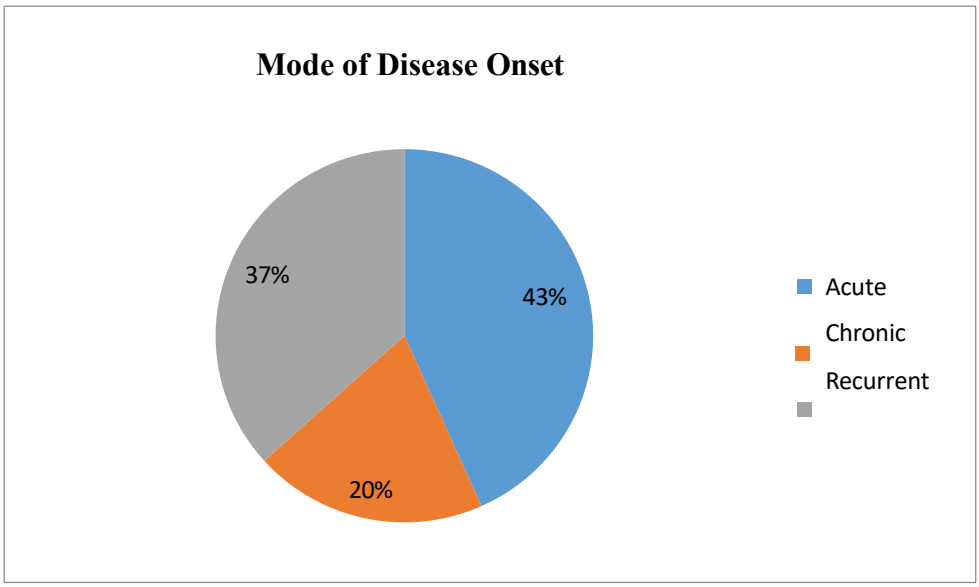


Figure 1. Mode of disease onset.

Table 1. Incidence of Chronic Resistant Anal Fissure [n=30]

Chronic Resistant Anal Fissure	Count	Percentage
Yes	11	36.7%
No	19	63.3%

Table 2. Association of Patient Characteristics with Chronic Resistant Anal Fissure[n=30]

Factor	Category	Number of Patients (n)	Chronic Resistant Anal Fissure (Yes)	Chronic Resistant Anal Fissure (No)	p-value
Age	< 40 years	12	3	9	**<0.05***
	≥ 40 years	18	7	11	
Sex	Male	15	5	10	0.20
	Female	15	5	10	

Socioeconomic Status	Low	7	2	5	0.45
	Middle	15	6	9	
	High	8	2	6	
Mode of Disease Onset	Acute	16	5	11	0.30
	Chronic/ Recurrent	14	5	9	
Duration of Symptoms	< 1 year	12	3	9	**<0.05***
	≥ 1 year	18	7	11	

* Indicates statistical significance

Regarding disease characteristics, 43.3% of patients presented with acute onset of symptoms, 36.7% had recurrent symptoms, and 20.0% had a chronic onset (Figure 1). The most common clinical symptom patterns included combinations of pain, bleeding, itching, soreness, and swelling, with pain being a predominant complaint across all patients. Sharp pain associated with itching and soreness was the most frequently reported complaint (36.7%), followed by severe pain with occasional bleeding (26.7%). The duration of symptoms varied widely, with 33.3% of patients reporting symptoms for 7–12 months and another 33.3% for 19–24 months, indicating prolonged symptom duration in a substantial proportion of cases.

At six months of follow-up, improvement without recurrence was observed in 30.0% of patients, while 33.3% had partial improvement with persistent symptoms, and 36.7% showed no improvement. Chronic resistant anal fissure was identified in 36.7% of patients (Table 1) indicating that more than one-third of cases were difficult to treat. Chronic resistant cases were distributed across all age groups, sexes, socioeconomic statuses, symptom patterns, and modes of disease onset without a clear predominance in any single category.

Analysis of associations showed that age and duration of symptoms were significantly related to the incidence of chronic resistant anal fissure (Table 2). Patients younger than 40 years had a lower incidence of resistance (25.0%) compared to those aged 40 years and above (38.9%), with a p value of 0.05. Similarly, patients with symptom duration of less than one year had a lower incidence of chronic resistance (25.0%) compared to those with symptoms lasting one year or more (38.9%), also with a p value of 0.05. No statistically significant association was found with sex ($p = 0.20$), socioeconomic status ($p = 0.45$), or mode of disease onset ($p = 0.30$). Overall, the findings suggest that older age and longer duration of symptoms are important factors associated with chronic resistant anal fissure, while other demographic and clinical variables did not show a significant influence.

Discussion

In this prospective observational study of 30 patients, a higher proportion of cases was observed in older age groups. This pattern differs from population-based studies, where anal fissures are more commonly reported in younger and middle-aged adults [1]. Most patients belonged to the middle socioeconomic status, which may reflect healthcare access and health-seeking behavior influencing hospital-based attendance [13].

The clinical presentation was typical, with pain and bleeding being the most common symptoms. Pain-predominant symptoms are the main reason for seeking medical care [14]. Prolonged symptom duration is clinically important, as it is associated with poor response to therapy [7]. These findings are consistent with recent evidence showing variable healing rates and need for second-line therapy [7,15].

Chronic resistant anal fissure was identified in 36.7% of patients. Age ≥40 years and symptom duration ≥1 year were significantly associated with resistance. Other factors like sex and socioeconomic status were not significant, suggesting that time-related factors play a larger role [16]. These findings are clinically relevant, especially when considering surgical management. While lateral internal sphincterotomy is effective, it carries risks, highlighting the need for early identification of high-risk patients [17,18].

Improving patient awareness and reducing diagnostic delays may help prevent chronic resistance [19]. However, due to small sample size and hospital-based design, findings require validation in larger studies [20].

Conclusion

This study describes the demographic profile, clinical features, and outcomes of patients with chronic resistant anal fissure. Most patients were older adults, with a slight male predominance, and predominantly belonged to the middle socioeconomic group. Pain, bleeding, itching, and swelling were the common presenting symptoms, often persisting for more than one year, underscoring the chronic and debilitating nature of the disease.

Treatment outcomes showed that many patients failed to achieve complete symptom relief with conventional therapy, particularly those with longer symptom duration and older age, indicating poorer prognosis in these groups. Sex and socioeconomic status were not significantly associated with treatment resistance.

Overall, the findings highlight the need for early diagnosis and individualized management. Prompt escalation of treatment in patients with longer symptom duration and older age may improve outcomes and reduce the burden of chronic resistant disease. Future multicenter studies with larger sample sizes, standardized outcome measures, and longer follow-up are needed to validate these findings and establish evidence-based management protocols for this challenging patient group.

Limitations

Relatively small sample size may limit the generalizability of the results. As a single-center study, the findings may not be representative of broader populations or different healthcare settings. Observational design precludes establishing causal relationships between variables. Additionally, potential confounding factors were not fully controlled for, which may

have influenced the observed associations. Future multicenter studies with larger sample sizes and robust analytical designs are warranted to validate these findings.

Statements and Declarations

Author Contributions

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

Data availability statement

The datasets generated and analysed in this study are available from the corresponding author on reasonable request. They are not publicly shared because they contain sensitive information that could indirectly identify participants.

Ethical approval

This study has been approved by the Institution Ethics Committee Ref. No. 6103/ME-G/2023 held on 13/05/2022 at Government Mohan Kumaramangalam Medical College & Hospital, Salem

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

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ORIGINAL ARTICLE

A Comparative Study on Treatment Outcome Among Tuberculosis Patients with and without Co-morbidities in DOTS Centres Covered under Urban Health Centres (UHCs)

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Abstract
Background: Tuberculosis remains a major public health challenge in India, accounting for two-fifths of incident global cases. Despite being preventable, comorbidities can negatively impact treatment outcomes. This study assesses the impact of co-morbidities on treatment outcomes among tuberculosis patients in a tertiary care setting. **Methods:** A community-based longitudinal study was conducted among 272 drug-sensitive tuberculosis patients registered at directly observed treatment short-course centres under urban health centres of the Kurnool tuberculosis unit between January 2021 and October 2022. Data on socio-demographic factors, personal habits, co-morbidities, and treatment outcomes were collected and analysed using chi-square tests and logistic regression. **Results:** Among the 272 patients, 28.7% had comorbidities—most commonly diabetes (56.4%), hypertension (30.8%), and human immunodeficiency virus (12.8%). The overall favourable treatment outcome was 85.3%. Significant associations were found between unfavourable outcomes and male sex, smoking, alcohol use, and absence of family screening. Comorbidities, especially diabetes, chronic respiratory disease, and cardiovascular disease, were associated with significantly lower cure rates. **Conclusion:** Co-morbidities and behavioural risk factors significantly affect treatment outcomes in tuberculosis patients. Strengthening integrated care for tuberculosis and non-communicable diseases, along with family contact screening and behavioural counselling, is crucial for improving outcomes and achieving national tuberculosis elimination goals.

Keywords: Co-morbidities, Risk factors, Tuberculosis, Treatment outcomes

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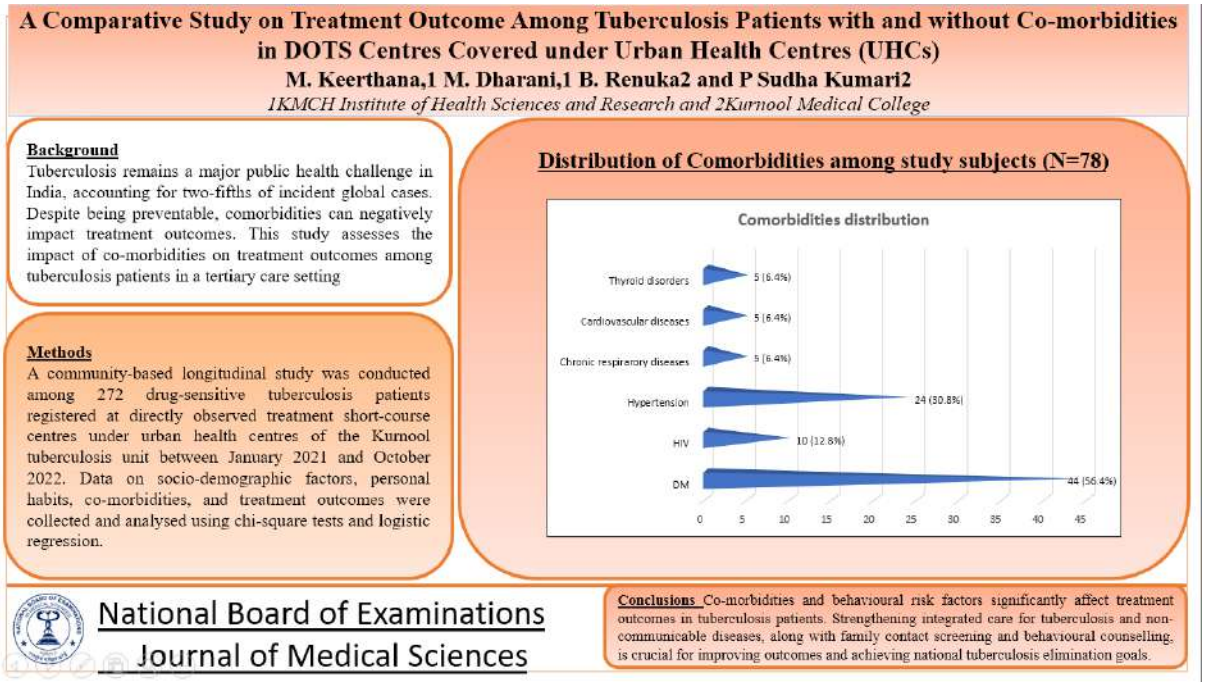
Graphical Abstract



Introduction

Tuberculosis (TB) is a contagious disease caused by *Mycobacterium tuberculosis* (MTB), a bacillus first identified by Robert Koch in 1882. While TB primarily affects the lungs, it can also involve lymph nodes, intestines, meninges, bones and joints, skin, and other tissues [1]. Around 10 million new cases occur each year, with India contributing nearly two-fifths of the global TB incidence in 2021 [2]. Treatment success is a key indicator of the effectiveness of the National TB Elimination Program (NTEP). The treatment success rate for drug-susceptible TB (DS-TB) patients in India was reported at 87.6% [3]. One of the health targets under the Sustainable Development Goals (SDGs) is to end the TB epidemic by 2030. India has set an even earlier goal—to eliminate TB by 2025 [4].

TB often becomes active when the immune system is compromised. Managing TB along with other health conditions is very important, as co-morbidities can make TB harder to diagnose and treat, increase the risk of complications, delay recovery, cause drug interactions, and lead to poor outcomes or even death. A shred of growing evidence highlights the association between TB and various co-morbidities such as diabetes, HIV, malnutrition, chronic respiratory diseases, cancer, smoking, alcoholism, and cardiovascular conditions. These co-morbidities can negatively influence TB treatment outcomes, especially in developing countries like India, where a "double burden of disease" persists [5]. Previous studies have shown that TB is associated with several factors, including prior TB treatment, poor adherence to therapy, lung cavities, contact with active TB cases, HIV, diabetes or impaired glucose tolerance, alcohol use, malnutrition, and smoking. In addition, social and demographic factors such as income, place of residence, and family size influence the occurrence of TB [6,7].

The WHO's End TB strategy has closely studied the factors affecting TB cases and deaths, especially focusing on managing other chronic illnesses alongside TB [8]. Although diabetes and HIV affect TB treatment outcomes, there remains limited evidence regarding the impact of other co-morbid conditions. Understanding the effects of these comorbidities on TB treatment outcomes is essential for improving patient care. Hence, this study aimed to assess the prevalence of co-morbidities among registered TB cases and their impact on treatment outcomes in a tertiary care setting.

Methodology

A community-based longitudinal study was conducted at DOTS (Directly observed treatment short-course) centres under Urban Health Centres (UHCs) of the Kurnool TB Unit from January 2021 to October 2022. Ethical clearance was obtained from the Institutional Ethical Committee. The study included all drug-sensitive (DS-TB) patients—both newly diagnosed and previously treated—of any age or sex, who were registered in the first and second quarters of 2021, and all received the same TB treatment regimen. Drug-resistant TB (DR-TB) cases were excluded. Considering the prevalence of successful treatment outcomes as 80.5% from a study by Ramya MS et al[9] and a 5% margin of error, the required sample size was 241, which was adjusted to 265 after accounting for a 10% non-response rate.

The study purpose was explained to all the participants in their language, and written consent was obtained. Data were collected using a pre-tested semi-structured questionnaire covering socio-demographic details, personal habits, co-morbidities, adverse events, clinical progress, and treatment outcomes. Follow-ups included assessment of sputum status and adverse events. At the end of treatment, patients are classified into one of six outcomes [10]: cured, treatment completed, died, treatment failed, lost to follow-up, or transferred out with unknown outcome. Cases marked as cured or treatment completed are grouped as favourable outcomes, while all others are considered unfavourable.

Data were analysed using SPSS 26, with results expressed as means and percentages. The link between comorbidities and treatment outcomes was assessed using chi-square tests, cure rates, risk ratios (RR), attributable risk (AR), and attributable fraction (AF). Variables that showed statistical significance in the chi-square test were included in the Multivariate logistic regression to identify adjusted odds ratios (aOR) of unfavourable treatment outcomes, while adjusting for confounders.

Results

Almost half of the participants (43.8%) were between 19 and 39 years old. There were equal numbers of men and women. Most of them were Hindus (70.6%) and married (66.2%). Many lived in nuclear families (74.6%). About one-fourth (23.9%) had no formal education. More than half (53.7%) were not working, and most (52.9%) belonged to the lower middle-income group. Most patients were newly diagnosed TB cases (89%), while the rest (11%) were retreatment cases (Table 1).

Table 1. Socio-demographic profile of TB patients in relation to their treatment outcomes

Variables	Sub-types	Favourable outcome n (%)	Unfavourable outcome n (%)	Total N=272	P-value
Age (in years)	<19	35 (92.1)	3 (7.9)	38	
	19-39	101 (84.9)	18 (15.1)	119	
	40-59	69 (85.2)	12 (14.8)	81	0.501
	>60	27(79.4)	7 (20.6)	34	
Sex	Female	121 (90.3)	13 (9.7)	134	**0.022***
	Male	111 (80.4)	27 (19.6)	138	
Religion	Christians	10 (100)	0	10	
	Muslims	60 (85.7)	10 (14.3)	70	0.511
	Hindus	162 (84.4)	30 (15.6)	192	
Socio-economic status	upper middle (ii)	31 (96.9)	1 (3.1)	32	
	Lower middle (iii)	123 (85.4)	21 (14.6)	144	0.081
	Upper lower (iv)	71 (82.6)	15 (17.4)	86	
	Lower (v)	7 (70.0)	3 (30.0)	10	
Marital status	Death of spouse	12 (70.6)	5 (29.4)	17	
	Married	155 (86.1)	25 (13.9)	180	0.208
	Unmarried	65 (86.7)	10 (13.3)	75	
Type of family	Three generation	21 (27)	6 (22.2)	27	
	Joint	29 (87.9)	4 (12.1)	33	0.486
	Living alone	7 (77.8)	2 (22.2)	9	
	Nuclear	175 (86.2)	28 (13.8)	203	
Overcrowding	Present	61 (89.7)	7 (10.3)	68	
	Absent	171 (83.8)	33 (16.2)	204	0.236
Smoking	Yes	40 (70.2)	17 (29.8)	57	**0.001***
	No	192 (89.3)	23 (10.7)	215	
Type of smoking (n=57)	Smoke	33 (67.3)	16 (32.7)	49	
	Smokeless	7 (87.5)	1 (12.5)	8	0.413
Smoking tobacco (n=49)	Current	14 (53.8)	12 (46.2)	26	
	Former	19 (82.6)	4 (17.4)	23	**0.032***
Alcohol consumption	Yes	18 (62.1)	11 (37.9)	29	**0.001***
	No	214 (88.1)	29 (11.9)	243	

*P<0.05 Statistically significant

Relative risk was calculated for significant variables

Sex: RR: 2.3, 95% CI: 1.1–4.6

Smoking: RR: 3.5, 95% CI: 1.7–7.2

Alcohol consumption: RR: 4.5, 95% CI: 1.9–10.5

Co-morbidities

In this study, 28.7% of the participants had co-morbidities (Figure 1). Among them, diabetes mellitus (56.4%) was the most common.

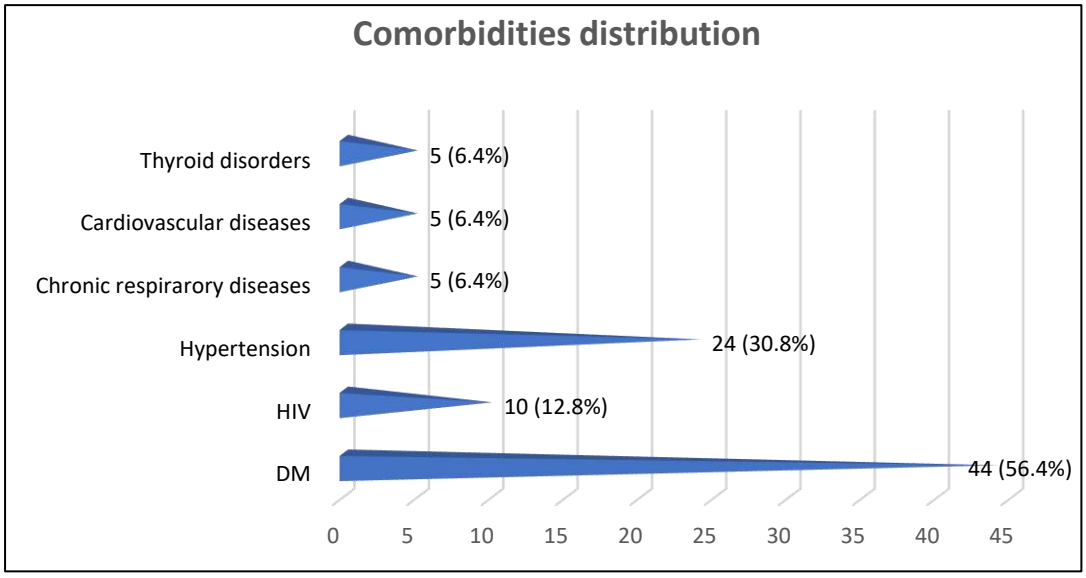


Figure 1. Distribution of Comorbidities among study subjects (N=78).

Treatment outcome

The favourable treatment outcome (85.3%) includes treatment completed and cured. The unfavourable outcome (14.7%) includes death, loss to follow-up, and treatment failure (Figure 2).

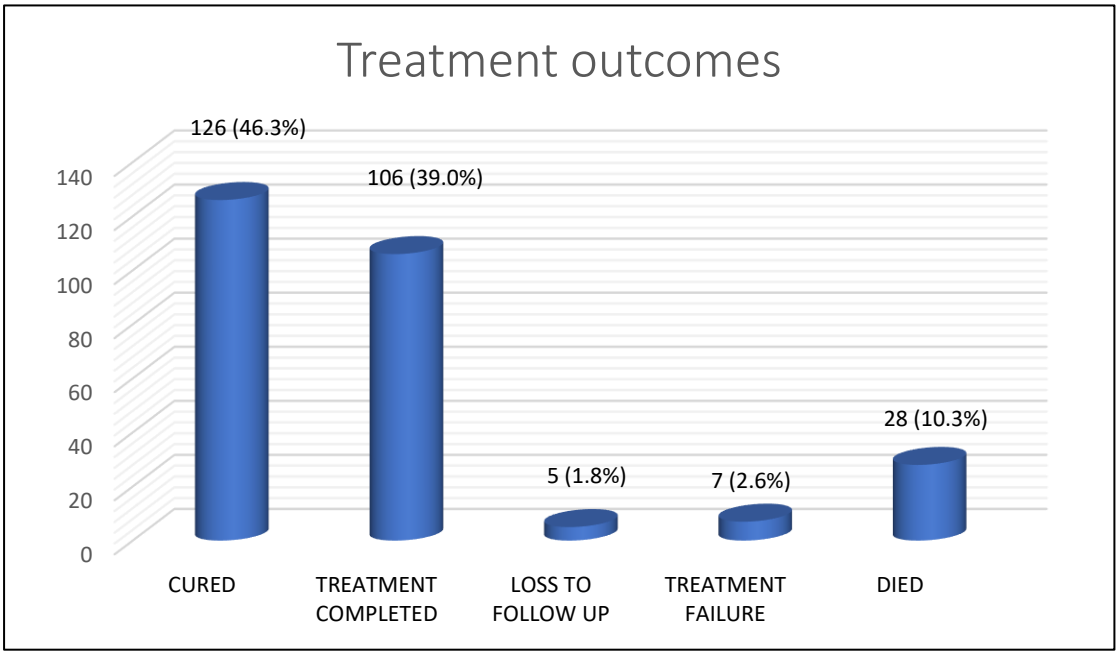


Figure 2. Distribution of the study subjects based on TB treatment outcomes

Factors influencing treatment outcome

A significant association was found between sex and treatment outcomes, with females having better outcomes than males (RR: 2.3, 95% CI: 1.1–4.6). Lifestyle factors such as smoking and alcohol use

significantly affected outcomes. Non-smokers had better treatment outcomes compared to smokers (RR: 3.5, 95% CI: 1.7–7.2), although current smokers were not at increased risk (RR: 0.2, 95% CI: 0.1–0.9). Alcohol users (RR: 4.5, 95% CI: 1.9–10.5) had significantly worse outcomes than non-users (Table 1).

Screening family members for TB was also linked to better outcomes, with families who underwent screening showing a lower risk of poor outcomes (RR: 0.2, 95% CI: 0.1–0.6). In addition, newly treated TB cases (RR: 2.9, 95% CI: 1.2–6.9) had better outcomes than previously treated patients (Table 2).

Table 2. Clinical characteristics of TB patients in relation to their treatment outcomes

Variables	Sub-types	Favourable outcome n (%)	Unfavourable outcome n (%)	Total N=272	P-value
Screening status among the family	Yes	84 (95.5)	4 (4.5)	88	**0.001***
	No	148 (80.4)	36 (19.6)	184	
Family history of TB	Yes	22 (84.6)	4 (15.4)	26	1.000
	No	210 (85.4)	36 (14.6)	246	
Contact history of TB	Yes	29 (87.9)	4 (12.1)	33	0.445
	No	203 (84.9)	36 (15.1)	239	
Category of TB patients	New	211 (87.2)	31 (12.8)	242	**0.012***
	Retreatment	21 (70.0)	9 (30.0)	30	
Site of involvement	Pulmonary	162 (84.4)	30 (15.6)	192	0.474
	Extrapulmonary	70 (87.5)	10 (12.5)	80	
Treating Facility	Public	187 (83.5)	37 (16.5)	224	0.047
	Private	45 (93.8)	3 (6.2)	48	
Duration of complaints	<3 weeks	215 (85.3%)	37 (14.7%)	252	1.000
	>3 weeks	17 (85.0%)	3 (15.0%)	20	
Delay in the initiation of treatment	<1 week	137 (85.1)	24 (14.9)	161	0.918
	>1 week	10 (90.9)	1 (9.1)	11	
	No delay	85 (85.0)	15 (15.0)	100	
Adverse effects on treatment	Yes	57 (87.7)	8 (12.3)	65	0.531
	No	175 (84.5)	32 (15.5)	207	

*P<0.05 Statistically significant
Relative risk was calculated for significant variables
Screening status among the family: RR: 0.2, 95% CI: 0.1–0.6
Category of TB patients: RR: 2.9, 95% CI: 1.2–6.9

Patients with co-morbid conditions had a lower cure rate (74.4%, *P* 0.001) with an attributable fraction of 17.09%. Diabetics had a lower cure rate (75%, *P* 0.035), with an attributable fraction of 14.07%. Patients with chronic respiratory diseases had a lower cure rate (40%, *P* 0.024) with an attributable fraction of 53.57%. Patients with cardiovascular disease (CVD) had a lower cure rate (40%, *P* 0.024) with an attributable fraction of 53.57%. Hypertension, HIV, and thyroid disorders do not influence the observed cure rates (Table 3).

Table 3. Impact of comorbidities on treatment outcomes in TB patients

Study variables	Favorable outcomes	Unfavorable outcomes	Cure Rate (%)	Risk Ratio Ie/Io	Attributable Risk Ie-Io	Attributable fraction in exposed Ie-Io/ Io *100 (%)
Chronic illness						
Yes	58	20	74.4	0.83	15.33	17.09
No	174	20	89.7			
Diabetes mellitus						
Yes	33	11	75.0	0.86	12.28	14.07
No	199	29	87.3			
Hypertension						
Yes	21	3	87.5	1.03	2.42	2.84
No	211	37	85.1			
HIV						
Reactive	7	3	70.0	0.82	15.88	18.49
Non-reactive	225	37	85.9			
Chronic respiratory illness (COPD, Asthma)						
Yes	2	3	40.0	0.46	46.14	53.57
No	230	37	86.1			
Cardiovascular diseases (coronary artery disease)						
Yes	2	3	40.0	0.46	46.14	53.57
No	230	37	86.1			
Thyroid disorders (Hypothyroidism)						
Yes	5	0	100	1.18	14.98	17.62
No	227	40	85.0			

Logistic regression

Multivariate logistic regression was conducted to identify the predictors of unfavourable TB treatment outcomes (Table 4). The full model containing all predictors was statistically significant, $\chi^2(9) = 37.794$, $P < 0.001$ (Omnibus Test), indicating that the model was able to distinguish between patients with favorable and unfavourable outcomes. The model explained 22.9% of the variance in TB treatment outcomes (Nagelkerke $R^2 = 0.229$) with a *P*-value <0.05.

Table 4. Independent factors influencing TB treatment outcomes

Independent Variables	**Standard Error**	**Significance**	**Exp(B)**	**95% C.I. for EXP(B)**	
				Upper	**Lower**
Sex	0.430	0.489	1.347	0.580	3.130
Screening status of family members	0.594	**0.003**	6.001	1.875	19.207
Smoking status	0.575	0.465	1.522	0.493	4.697
Alcohol Intake	0.642	0.328	1.872	0.532	6.585
Category of TB patients	0.516	0.050	2.748	0.999	7.556
Chronic illness	0.642	0.720	1.258	0.358	4.425
DM	0.684	0.784	1.207	0.316	4.615
Respiratory disease	1.237	0.148	5.992	0.531	67.626
Cardiovascular disease	1.116	0.165	4.707	0.528	41.965
Constant	0.642	0.000	.020	-	-

<0.05 Statistically significant
Degrees of freedom (dof):1
Exp(B): Exponential of the regression coefficient (B)
CI: Confidence Interval

Patients whose family members were not screened for TB had significantly higher odds of experiencing unfavourable outcomes (adjusted OR = 6.001; 95% CI: 1.875–19.207; $P = 0.003$). Retreatment cases also showed higher odds of unfavourable outcomes compared to new TB cases (adjusted OR = 2.748; 95% CI: 0.999–7.556; $P = 0.050$), but there is no statistical significance. Other variables, including smoking (aOR = 1.522; $P = 0.465$), alcohol use (aOR = 1.872; $P = 0.328$), chronic illness (OR = 1.258; $P = 0.720$) and sex (aOR = 1.347; $P = 0.489$), were not statistically significant. Comorbidities such as diabetes mellitus (aOR = 1.207; p = 0.784), respiratory illness (aOR = 5.992; $P = 0.148$), and CVD (aOR = 4.707; $P = 0.165$) had higher odds ratios, but no statistical significance.

Discussion

In this study, overcrowding was observed in 25% of participants, which is lower (11.7%) than that of Tagaram et al[11] but much higher (79.8%) in Pooja S

et al[12]. Most of the participants (87.9%) had no prior TB contact, which is comparable to the 89.1% reported by Mathavaswami V et al[13]. Tobacco use was noted in 21% of subjects, aligning with the findings of previous studies[13,14]. Alcohol consumption was reported by 10.7%, which is lower than in studies by Ramya et al. [9] (36.9%) and Rupali et al. [14] (30.3%). Clinically, 55.9% of participants had positive sputum smear results. Pulmonary TB was more common (70.6%) than extrapulmonary TB (29.4%), with lymph nodes being the most frequently affected extrapulmonary site. These findings are in line with reports by Avinash et al. [15] and Mohandas et al. [16]. Adverse drug effects were reported in 23.9% of participants, which is lower than the 36.7% reported by Rupali et al. [14].

Comorbidities were observed in 28.7% of TB patients, with diabetes mellitus being the most common (56.4%), followed by hypertension (30.8%), HIV (12.8%), chronic respiratory diseases (6.4%), CVD (6.4%), and thyroid disorders (6.4%). The high prevalence of diabetes among TB patients in this study is notably higher compared to previous studies. For instance, Viswanathan et al. [17] reported diabetes in 23% of TB cases, Balakrishnan et al. [12] in 44%, and Murali et al. [18] in 31.4% of TB cases. Similarly, Kunoor et al. [19] reported diabetes in 28% of TB patients, which was the most common comorbidity in their study. In contrast, Anwith HS et al[20] found that with Chronic obstructive pulmonary disease (COPD) being the most prevalent (22.5%), followed by diabetes (16.3%), HIV (7.5%), and hypertension (5.0%). Likewise, Ramya MS et al[9] reported COPD in 25% of TB patients, followed by diabetes (16.1%), hypertension (12.1%), and HIV (10.7%).

Treatment success (cured or treatment completed) was observed in 85.3% of cases. Similarly, the treatment success rate among notified drug-sensitive TB (DS-TB) cases was 87% in India (2023) [3]. The success rate is consistent with studies like Ramya et al[9] (80.5%), Kumar et al. [21] (84.4%), and Mohandas B et al[16] (89%), suggesting similar program performance across various regions. Slightly higher rates in studies like Sengul et al. [22] (92.6%) and Srinivas et al. [23] (91.2%) may reflect variations in healthcare services or patient compliance.

In this study, favourable outcomes were seen in patients aged <19 years (92.1%) and among Christians (100%), but without statistical significance. Similar findings were reported by previous studies [14,24,25], while Rupali [14] found significance for younger age (p=0.027) and Ramya MS[9] for religion (*P*=0.015). Females had significantly better outcomes than males (*P*=0.022; RR: 2.3, 95% CI: 1.1–4.6), supported by Pooja and Karanjekar et al. [25,26]. Non-smokers (89.3%) and non-alcoholics (88.1%) had better outcomes, and statistically significant (p<0.05). Ramya et al. [9] reported similar results for smoking (*P*=0.008) and alcohol (p=0.001). In contrast, Srinivas and Rupali found no significant association in their studies [14,23]. Newly treated patients had better outcomes (87.2%), which was statistically significant (RR=2.9, 95% CI: 1.2–6.9, *P*=0.012). Sengul and Mohandas reported similar findings [16,22].

Patients with **co-morbid** conditions had a significantly lower cure rate (74.4%, AF: 17.09%, *P*=0.001). Similar findings were reported by Yusupova [27] (RR=0.83, *P*=0.001), Sengul A[22] (RR=1.19; 95% CI: 0.35–4.07; *P*<0.001), and Kunoor et al. [19] (p=0.000019). Lall [28] had higher

cure rates among TB patients without comorbidities (79.6%, *P*=0.024). However, a study by Anwith et al. [20] did not find a significant association between the presence of co-morbidities and treatment outcomes.

Non-diabetic TB patients had a significantly better cure rate (87.3%, AF: 14.1%, $P = 0.035$) compared to **diabetics**. Rupali et al. [14] reported comparable findings, where non-diabetics had a better outcome (84.2%, $P < 0.05$). Yusupova et al. also found significant associations with diabetes ($P < 0.01$). Although Ramya et al. and Kunoor et al. reported higher cure rates among non-diabetics (81.6% and 83.3% respectively), the association was not statistically significant. Patients with **chronic respiratory diseases** and CVD had a much lower cure rate (40%, AF: 53.6%, $P = 0.024$). Similarly, Lal et al. had lower cure rates (60%) in COPD patients. Yusupova et al. [27] also found a significant association with COPD ($P = 0.02$). However, contrasting results were observed by Kunoor et al. [19], where 83.3% of patients with chronic respiratory diseases achieved successful treatment outcomes. **HIV patients** showed a lower cure rate (70%, AF:18.49, $P = 0.169$). Lall et al. [28] reported much lower cure rates (42.9%). In contrast, previous studies found a significant association with HIV ($P < 0.001$) [9,27]. Higher cure rates are observed in **Hypertensives** (87.5, $P = 1.000$). Lall [28] reported a lower cure rate (60%). Sengul et al. [22] observed a significant association with hypertension ($P = 0.002$). **CVD** significantly reduced the TB cure rate to 40% (AF: 53.6%, $P = 0.024$). Similarly, Kim et al. [29] reported CVD in 32.5% of TB patients, where delayed treatment was significantly associated with increased all-cause mortality. Diana et al. [30] observed CVD in 8.2% of cases, with comorbidities increasing the risk of poor treatment outcomes (OR = 2.56; 95% CI: 2.22–3.03).

Lack of TB screening among family members has been shown to significantly increase the odds of unfavourable treatment outcomes. The reason may be that untreated family members can continue to spread the infection or cause reinfection, particularly in crowded households. However, Lall et al[28] found a significant association with age (OR = 1.05), diabetes (OR = 1.82), and HIV (OR = 2.23) for disease progression.

Conclusion

The overall treatment success rate was 85.3%, consistent with national data. However, poorer outcomes were linked to male gender, alcohol and tobacco use, retreatment cases, and the absence of family screening. Comorbidities, especially diabetes, chronic respiratory diseases, and CVD, were also associated with lower cure rates. These findings emphasise the importance of addressing coexisting illnesses and ensuring household contact screening.

Recommendation

Integrating TB and non-communicable disease (NCD) services at the primary care level will support coordinated screening, treatment, and counselling. Additionally, collaboration between the National TB Elimination Programme (NTEP), other national health programs, and the private sector is crucial for reducing TB transmission, improving outcomes, and lowering the financial burden on patients.

Statements and Declarations

Ethical Approval

The ethical committee approved this longitudinal study (IEC-KMC-GGH 27/01/2021).

Authors' contribution

All authors have contributed equally.

Conflicts of interest

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

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ORIGINAL ARTICLE

Mindful Yoga Intervention for Management of Systemic Hypertension

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Abstract

Background: Hypertension is one of the leading causes of premature mortality worldwide, affecting over 1.28 billion adults, with a disproportionately higher burden in low- and middle-income countries. In India, the prevalence of hypertension is increasing in both rural and urban populations, with low levels of awareness, treatment, and control. Lifestyle factors such as physical inactivity, unhealthy diet, stress, obesity, alcohol use, and smoking significantly contribute to its development. **Objective:** To evaluate the effectiveness of mindful yoga intervention as an adjunct to standard treatment in reducing blood pressure and perceived stress among individuals with prehypertension and stage I hypertension. **Methods:** A randomized controlled trial was conducted among 60 hypertensive patients aged ≥40 years attending the NCD clinic at Urban Health Centre (UHC), Thirumazhisai. Participants with systolic blood pressure less than 160 mmHg and diastolic blood pressure less than 100 mmHg were considered eligible. Participants were randomly divided into two groups namely intervention (n=30) and control (n=30) groups. Control group and experimental group received standard treatment, including antihypertensive medication, dietary advice (low sodium <5 g/day, low fat, high fiber diet). **Results:** After the two month intervention period, it was found that intervention group had significant reduction in blood pressure levels when compared with the control group. A notable reduction in perceived stress scores was seen in intervention group. The findings suggest that mindful yoga, when practiced regularly alongside standard treatment, contributes to improved blood pressure control and stress reduction. **Conclusion:** Mindful yoga intervention is an effective, low-cost, and culturally acceptable adjunct therapy for the management of systemic hypertension. Incorporating yoga into routine hypertension management programs may enhance blood pressure control and support national strategies aimed at reducing the burden of noncommunicable diseases.

Keywords: Hypertension, Yoga, Mindfulness, Blood Pressure, Lifestyle Modification, Stress Management, Noncommunicable Diseases

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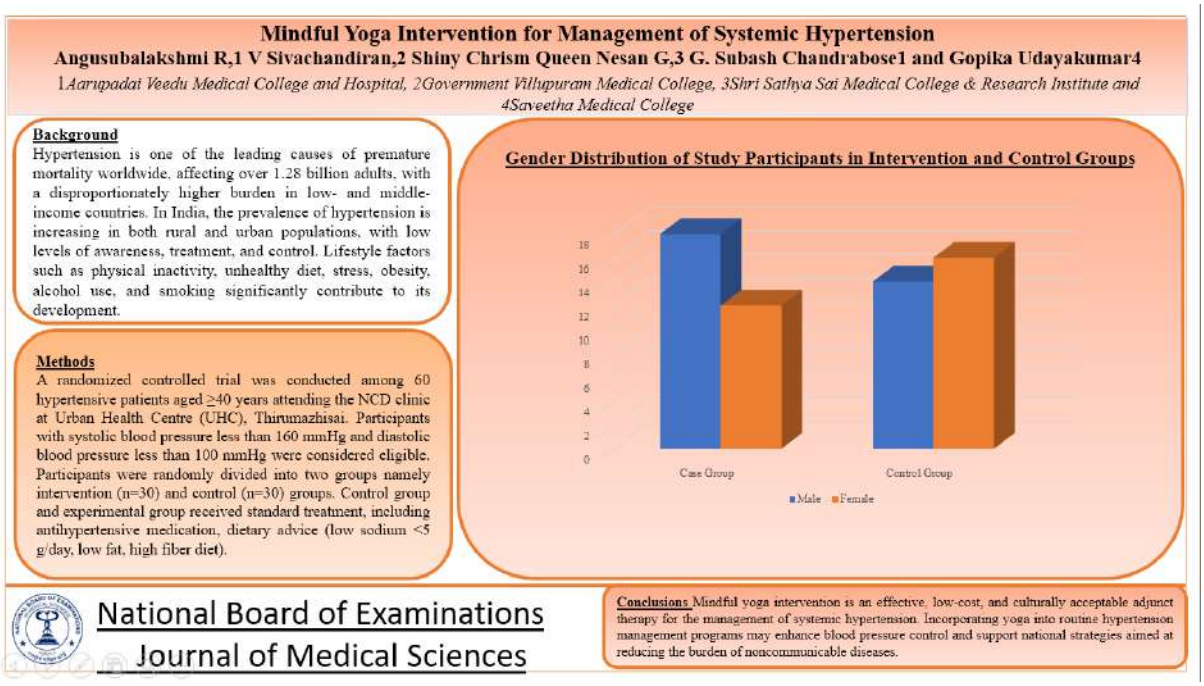
Graphical Abstract



Introduction

In the global context, hypertension affects 1.28 billion adults in the age group of 30–79 years, with nearly two-thirds of the affected individuals living in Low- and Middle-Income Countries. A substantial proportion of individuals remain undiagnosed, as 46% of people with hypertension are unaware of their condition. Among those affected, less than half receive appropriate treatment, and only about one-fifth achieve adequate blood pressure control. These figures highlight the significant global burden of hypertension and the gaps that continue to exist in awareness, treatment, and control. [1]. Hypertension is one of the leading causes of premature death worldwide [2]. One of the global objectives for noncommunicable illnesses is to reduce the prevalence of hypertension by 33% between 2010 and 2030 [3].

Hypertension affects about 25% of Indians who live in rural regions and 33% of those who live in cities [4,5]. Of these, 42% in cities and 25% in rural regions know they have high blood pressure. In rural areas, just 25% of Indians receive treatment for hypertension, compared to 38% in metropolitan areas. One-fifth of Indians with hypertension live in cities, whereas 10% of those with controlled blood pressure live in rural regions [6].

Hypertension has become a lifestyle disorder as a result of the population's aging and increased exposure to lifestyle risk factors, such as obesity, an unhealthy diet high in salt and saturated fat and low in fruits, vegetables, and dairy products, physical inactivity, stress, hazardous alcohol use, and smoking [7]. The prevalence of hypertension is increasing globally, making it imperative to address these lifestyle factors. However, there are regional differences in the prevalence of hypertension.

Over the past two decades, prevalence of hypertension has decreased

in High-Income Countries (HICs) whereas it has increased in many Low- and Middle-Income Countries (LMICs). This highlights the difference in global trends. These variations in the prevalence of hypertension suggest that health systems in low- and middle-income countries are facing a growing burden in non-communicable diseases while still managing load of communicable diseases [2].

Yoga is a long-standing Indian practice that is likely to lower blood pressure and assist in reducing stress [8]. In the age of evidence-based medicine, producing data to back up this assertion is crucial. In order to determine the efficacy of yoga intervention in prehypertensive and hypertensive individuals, an experiment was carried out. The trial's main goal was to evaluate scheduled yoga intervention with regular treatment in addition to the conventional intervention, which is the usual treatment guideline. Reductions in blood pressure readings and perceived stress scores were the outcome variables. Studying the sociodemographic profile and risk variables, particularly with regard to stress, were the secondary goals.

Methodology

The NCD clinic at UHC Thirumazhisai's outpatient department (OPD) for hypertension patients was the source of the target group. The standard deviation of hypertension patients' systolic blood pressure (SBP) was used to generate the sample size, which had an 80% power of study and a 5% significance level. Following the intervention, a 5 mm Hg drop in SBP was anticipated. There were sixty people in the sample. The experiment recruited individuals who were 40 years of age or older, male or female, and had blood pressure that was less than 160 systolic and less than 100 diastolic, regardless of treatment status. Blood pressure measurements were recorded by trained nursing staff at the NCD clinic following standard measurement protocols. Blood pressure was measured using a validated automated digital sphygmomanometer, with participants in a seated position after at least five minutes of rest. Patients with severe complications, stage-II and malignant hypertension, and pregnant women were not included.

Participants were randomly allocated into two groups, with 30 participants each in the intervention and control groups. Both groups received standard care, including advice on regular brisk walking with mild stretching for 30 minutes per day, dietary counselling emphasizing low sodium intake (<5 g/day) and a high-protein, high-fiber diet, routine antihypertensive medication, and counselling for smoking and alcohol cessation [9]. Intervention group had similar advice with additional weekly 5 days for 20 mins yoga sessions conducted by a certified yoga instructor over a period of 2 months. The intervention included pharmaceutical therapy: Both groups of study participants were taking antihypertensive medication as directed by a licensed doctor.

Dietary advice was given to both groups. It included suggestions for a healthy diet, such as eating three to four small meals a day, sticking to a diet low in fat and sugar, and reducing salt intake to less than 5 g (one teaspoon) per day. Other food items to be avoided included fried foods, pickles, sauces, papad, packaged foods, and sprouts. We took into account the participants' eating habits, food items' availability, feasibility, and cultural acceptability. Another recommendation

was to cut back on alcohol intake and quit smoking.

Physical exercise advice: The study participants were told to take a brisk walk (i.e., walk at a rate that permits them to cover 100 steps in a minute) in the nearby garden for thirty minutes every day at any convenient time. They should ideally do this in the morning or at night. People who can't walk for more than thirty minutes should start out slowly and increase their level of activity gradually. Participants were advised to walk at least five days a week. The yoga intervention package consisted of a set of asanas, pranayama and meditation. Intervention module was designed as per the guidelines of Ministry of AYUSH, Government of India.

The 25-year-experienced yoga trainer who designed the yoga programme was also involved in the process. Experts in the department with training as yoga teachers validated the final yoga plan. Asanas (Ardha-halasana, Ardha-pavanmuktasana, Bhujangasana, Makarasana, Paschimattanasana, Vakrasana, Parvatasana, Chakrasana) were performed at the beginning of the yoga session. Each yoga session lasted approximately 20 minutes and consisted of a structured sequence of yoga asanas (10–12 minutes), followed by pranayama (3–4 minutes), shavasana (2–3 minutes), and meditation (2–3 minutes). The sessions were conducted five days per week for a duration of two months under the guidance of a certified yoga instructor.

Participants were deemed compliant with the intervention if they practiced yoga at home, followed dietary recommendations, and engaged in physical activity for at least five days per week or more than twenty days per month. Every participant had a monthly follow-up. Reminder calls were made repeatedly to stay in contact with the participants and to support their continued follow-up. All participants completed the two-month follow-up period and no dropouts were recorded during the intervention period, largely due to regular reminder calls and continuous engagement with participants.

Data were entered into Microsoft Excel and then analyzed using IBM SPSS software version 22. A Chi-square test for categorical categories was used to compare the baseline characteristics of participants between two groups. Variables between the intervention and control groups were examined using the Mann-Whitney U test and the independent sample t-test. The Wilcoxon signed-rank test and the paired t-test were used to compare variables within each group (Figure 1 and Tables 1 and 2).

Results

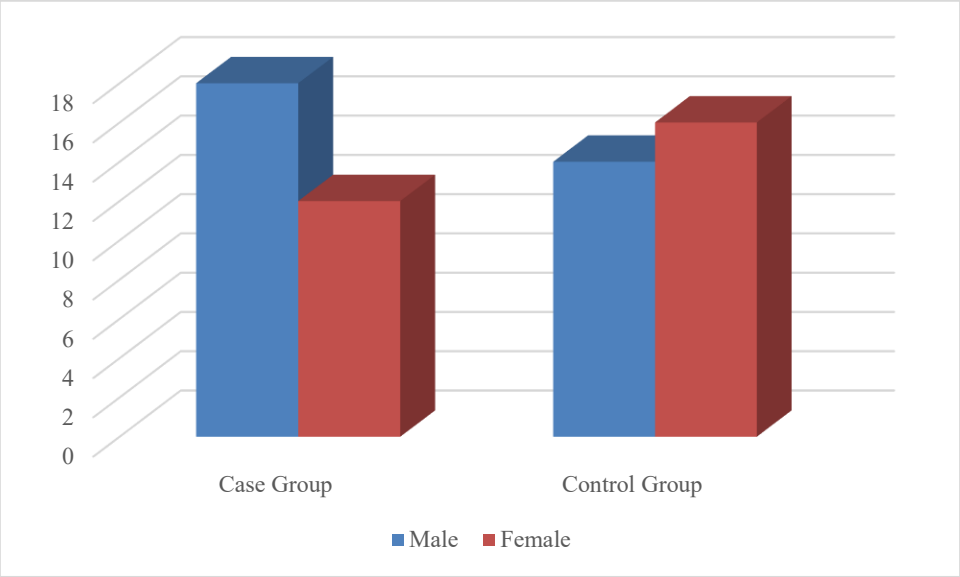


Figure 1. Gender Distribution of Study Participants in Intervention and Control Groups

Table 1. Outcome Variables Before and After Intervention

Outcome Variable	Before Intervention Case Group	Before Intervention Control Group	After Intervention Case Group	After Intervention Control Group
Mean Weight (kg)	66.9 ± 11.9	66.7 ± 10.7	64.4 ± 11.4	65.7 ± 10.4
Mean BMI (kg/m²)	26.7 ± 4.2	27.2 ± 4.0	25.7 ± 4.1	26.7 ± 3.9
Mean SBP (mm Hg)	132.3 ± 6.6	133.5 ± 5.9	125.3 ± 6.1	129.7 ± 4.9
Mean DBP (mm Hg)	86.1 ± 5.2	85.6 ± 5.3	80.8 ± 3.5	83.1 ± 3.9

Table 2. Statistical Analysis of Outcome Variables

Outcome Variable	Intervention Group Mean Difference	Control Group Mean Difference	Between Group Difference	P Value
Weight (kg)	2.5	1.0	1.5	<0.001
BMI (kg/m²)	1.0	0.5	0.5	<0.001

SBP (mmHg)	7.0	3.8	3.2	<0.001
DBP (mmHg)	5.3	2.4	2.9	<0.001

Participants' sociodemographic characteristics and hypertension risk factors were similar in both the groups. Because the intervention sessions were conducted on weekdays, it was easier for women to attend than men who were engaged in work, resulting in a higher participation of women. Of the participants, 82.8% followed a varied diet, while 17.2% were vegetarians. Every participant consumed legumes and cereal grains as part of their daily diet. While it was shown that fewer people consumed unhealthy food, such as fast food, deep-fried food, and food with added salt, just 14% of people reported eating more fruits and vegetables. Using paired t-tests and Wilcoxon signed-rank tests, significant reductions were observed in mean weight, BMI, systolic blood pressure, and diastolic blood pressure within both the intervention and control groups ($P < 0.001$).

In the intervention arm, mean diastolic blood pressure (DBP) decreased by 5.3 mmHg and mean systolic blood pressure (SBP) decreased by 7 mmHg. In the control arm, there was a 3.8 mmHg drop in mean SBP and a 2.4 mmHg drop in mean DBP. Blood pressure has decreased statistically significantly as a result of both modalities. The greater reduction observed in the intervention arm may be attributed to the yoga intervention. Despite the fact that both groups' mean weight and BMI decreased during the intervention, there was no statistically significant difference between the intervention and control groups.

Discussion

In order to effectively manage hypertension and control blood pressure, lifestyle changes must be made in addition to medical intervention. The incidence of cardiovascular problems could be significantly decreased with a simple 2 or 3 mmHg drop in the population's average blood pressure. A 5 mmHg drop in SBP in the population is predicted to lead to a 14% overall decrease in stroke mortality and a 9% decrease in coronary heart disease mortality. Therefore, any population-based technique that decreases blood pressure in the general population, even marginally, can reduce morbidity and death or delay the onset of hypertension. According to a review, practicing the three fundamental components of yoga—postures, meditation, and breathing—may have a slight but noteworthy impact on lowering blood pressure [10].

However, it is challenging to suggest a particular style of yoga due to the diversity of yoga practice and the lack of data regarding its long-term effects. Current hypertension management guidelines emphasize the importance of lifestyle modification along with pharmacological therapy for effective blood pressure control [11,12]. Earlier studies evaluating yoga and relaxation techniques have also reported reductions in blood pressure among hypertensive individuals [13–16].

This study demonstrated the beneficial effects of yoga on lowering hypertensive people's blood pressure. Following yoga practice, there was a

significant decrease in systolic blood pressure (SBP), diastolic blood pressure (DBP), and BMI. Cardiovascular diseases remain a leading cause of morbidity and mortality in India and lifestyle interventions play an important role in their prevention and management [17].

Integrating yoga-based interventions into routine hypertension management programs in public health settings may face several challenges, including limited availability of trained instructors, time constraints in busy NCD clinics, patient adherence issues, and infrastructural limitations. However, these challenges can be addressed through training healthcare workers in basic yoga guidance, conducting group-based sessions, and integrating such lifestyle interventions within existing national programs such as the NPCDCS [18].

As expressed by some participants, "Isn't it easier to take a pill rather than engage in physical activities such as yoga?", indicating a lack of motivation toward behavioral change. Mind–body interventions including yoga have also been reported to improve metabolic and psychosocial health outcomes in different populations [19]. Therefore, in order for society to embrace a healthy lifestyle that includes physical activities like yoga as a cultural practice, a high degree of motivation and a significant behavioural shift in communication are necessary. Systematic reviews have further supported the role of yoga as an adjunct therapy in the management of hypertension [20].

The present study had certain limitations. The relatively small sample size and short duration of follow-up may limit the generalizability of the findings to the wider hypertensive population. Future studies with larger sample sizes, multicentric settings, and longer follow-up periods are required to establish the long-term effectiveness and scalability of yoga-based interventions in hypertension management.

Conclusion

Patients with hypertension were able to receive a systematic intervention because of this trial. Basic techniques like yoga ought to be freely accessible to the whole public. Yoga is increasingly being incorporated into integrative healthcare settings. More health care providers offering counseling sessions could enhance adherence. Even if this will increase the cost of healthcare, the resources needed to make yoga a way of life for people are worthwhile. Yoga ought to become ingrained in society for the purpose of influencing and encouraging young people to lead healthy lifestyles from an early age. Integrated lifestyle interventions will play an important role in the future management of non-communicable diseases. A holistic health unit is required to manage non-communicable diseases (NCDs) such as obesity, hypertension, and diabetes mellitus using an integrated approach. Larger-scale trials are needed to confirm the effectiveness of non-pharmacological therapies in the management of hypertension.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Association of CTLA4 (Cytotoxic T-Lymphocyte Associated Antigen-4) Gene Single Nucleotide Polymorphism with Vasculitis

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Abstract

Background: Vasculitis is a autoimmune disorders represented in heterogenous groups and it is characterized by inflammation and destruction of blood vessels. This leads to multi-organ involvement and substantial morbidity. Genetic susceptibility plays a very important key role in the pathogenesis of vasculitis disorders. Cytotoxic T-lymphocyte associated antigen-4 (CTLA4) has emerged as a critical immune checkpoint molecule regulating T-cell activation and maintaining peripheral immune tolerance. **Aim**: To evaluate the association between CTLA4 gene single nucleotide polymorphism (SNP) rs3087243 (CT60 G>A) and susceptibility to vasculitis in a South Indian population. **Materials and Methods:** This case-control study was conducted among patients who were diagnosed with systemic vasculitis and healthy controls. Peripheral blood samples were collected and genomic DNA was isolated. Genotyping of CTLA4 polymorphism rs3087243 was performed using polymerase chain reaction–based techniques. Allelic and genotypic frequencies were compared between cases and controls using appropriate statistical tests. **Results**: The distribution of CTLA4 polymorphism differed between vasculitis patients and healthy individuals, suggesting a possible association between CTLA4 genetic variation and susceptibility to vasculitic disorders. **Conclusion**: The CTLA4 rs3087243 polymorphism may contribute to genetic predisposition to vasculitis in the studied population. Further studies with larger sample sizes and multi-center cohorts are necessary to confirm these findings and clarify the role of CTLA4 in the immunopathogenesis of vasculitis.

Keywords: Vasculitis, CTLA4 polymorphism, Autoimmune disease, Gene polymorphism, Immune checkpoint

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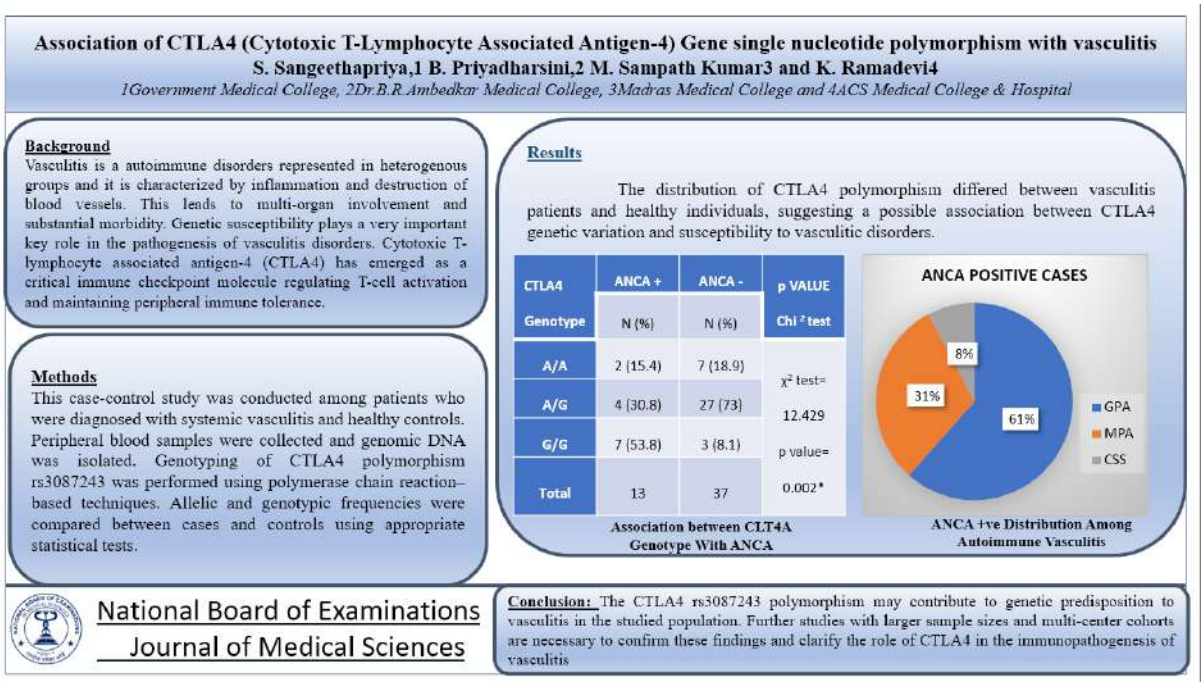
Graphical Abstract



Introduction

Vasculitis is an autoimmune disorder that is caused due to inflammation and destruction of blood vessels, which results from leukocyte infiltration of the vascular wall. Inflammatory process can affect the arteries, veins, or capillaries of varying sizes and it may involve one or multiple organ systems simultaneously. In clinical aspect vasculitis represents a multisystem autoimmune disease which may lead to significant morbidity due to ischemia and tissue damage resulting from vascular injury [1].

Large-vessel vasculitis includes disorders such as giant cell arteritis and Takayasu arteritis. Medium-vessel vasculitis can be due to diseases such as Kawasaki disease and polyarteritis nodosa, whereas small-vessel vasculitis commonly includes antineutrophil cytoplasmic antibody (ANCA) associated vasculitis such as microscopic polyangiitis, granulomatosis with polyangiitis, and eosinophilic granulomatosis with polyangiitis [2,3].

Primary systemic vasculitis (PSV) is an uncommon disorder, with a global estimated incidence of approximately 15–20 cases per million population annually. Epidemiological studies reported in Europe between 1989 and 2003 mentioned an annual incidence of PSV of 19.6 cases per million population, with granulomatosis with polyangiitis accounting for approximately 10.2 cases per million, microscopic polyangiitis for 5.8 cases per million, and Churg–Strauss syndrome for about 4.2 cases per million [4]. The prevalence of vasculitis fiffers based on geographic location and it is higher rates among European populations when compared with non-European populations which may be due to genetic susceptibility [5].

From an adult cohort study in the United States the 5-year survival rate for vasculitis ranges from 45% to 75% in microscopic polyangiitis and

approximately 75–80% in polyarteritis nodosa and Churg–Strauss syndrome. Takayasu arteritis reported with a 10-year survival rate of nearly 87% [6]. Granulomatosis with polyangiitis is associated with significant morbidity, with approximately 11% of patients requiring mechanical ventilation or dialysis during the course of the disease, and a 5-year survival rate of around 75%. Kawasaki disease, although primarily affecting children, may lead to coronary artery complications with an acute mortality rate of approximately 0.12% and coronary artery involvement reported in 2–4% of cases [7].

Vasculitis pathogenesis is multifactorial and it involves a complex interaction between environmental triggers, immune dysregulation, and genetic predisposition. It was also reported that genetic variations affecting immune regulatory pathways contribute significantly to susceptibility to autoimmune diseases, including ANCA-associated vasculitis. Genome-wide association studies (GWAS) and candidate gene approaches have identified several genetic loci involved in immune regulation which includes polymorphisms in human leukocyte antigen (HLA) genes and non-HLA immune regulatory genes [8].

The cytotoxic T-lymphocyte associated antigen-4 (CTLA4) gene has got an considerable attention and it is an inhibitory immune checkpoint molecule expressed on activated T lymphocytes that plays a crucial role in maintaining peripheral immune tolerance. T-cell activation normally occurs through the interaction between the T-cell receptor (TCR) and antigen presented by the major histocompatibility complex (MHC), along with co-stimulatory signaling mediated by CD28 and its ligands CD80 and CD86. CTLA4, a homolog of CD28, competes for binding to these ligands and transmits inhibitory signals that down-regulate T-cell activation [1]. Genetic variants in CTLA4 have been associated with several autoimmune conditions, including rheumatoid arthritis, systemic lupus erythematosus, and autoimmune thyroid disease [9].

It is important to understand the role of CTLA4 polymorphisms in vasculitis may provide important insights into the genetic mechanisms underlying disease susceptibility and pathogenesis. Thus, in the present study we intend to investigate the association between CTLA4 gene polymorphism rs3087243 (CT60 G>A) and vasculitis in South Indian population.

Aim and Objectives

Primary Objective

To determine the association between CTLA4 gene polymorphism rs3087243 (CT60 G>A) and vasculitis in a South Indian population.

Secondary Objectives

1. To determine the genotype distribution of CTLA4 polymorphism among patients with vasculitis.
2. To compare allele frequencies between vasculitis patients and healthy controls.
3. To evaluate the possible role of CTLA4 polymorphism in susceptibility to autoimmune vasculitic disorders.

Materials and Methods

Study Design and Study Setting

This study was a hospital-based case–control study that was carried out at the Institute of Biochemistry, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai.

The study involved departments of Biochemistry, Rheumatology, and Vascular Surgery to facilitate patient recruitment and sample collection. Ethical approval for the study was obtained from the Institutional Ethics Committee prior to initiation of the research work.

Study Population

Patients got diagnosed with vasculitis and healthy control individuals from the outpatient and inpatient services of the departments of Rheumatology and Vascular Surgery at Rajiv Gandhi Government General Hospital, Chennai were included in our study. Diagnosis of vasculitis was made by clinicians based on clinical presentation, laboratory investigations, and established diagnostic criteria. Control participants were healthy individuals selected from volunteers without any known history of autoimmune diseases or chronic inflammatory disorders, matched for age and gender.

Inclusion Criteria

Patients diagnosed with systemic vasculitis based on established clinical criteria were included in the study. Individuals aged above 18 years who were willing to participate and provide written informed consent were considered eligible for inclusion. Controls included healthy individuals with no personal or family history of vasculitis or other autoimmune diseases.

Exclusion Criteria

Individuals with secondary vasculitis due to infections, malignancies, drug-induced causes, or other systemic autoimmune diseases were excluded from the study. Patients with severe comorbid conditions that could interfere with interpretation of results were also excluded.

Sample Size and Sampling Method

A total of 100 participants, comprising 50 patients diagnosed with vasculitis as cases and 50 healthy individuals were included as controls. Participants were selected using a convenient sampling technique from the eligible population presenting to the hospital.

Collection of Clinical Data

Detailed clinical information of each participant was recorded using a structured proforma. Demographic variables such as age and sex were documented. Clinical details including type of vasculitis, presenting symptoms, organ involvement, laboratory findings, and relevant medical history were obtained from patient records and clinical examination.

Sample Collection

After obtaining informed consent, approximately 5 mL of peripheral venous blood was collected from each participant under aseptic conditions. Blood samples were drawn into ethylenediaminetetraacetic acid (EDTA) anticoagulant tubes to prevent clotting. The samples were labeled appropriately and transported immediately to the Molecular Biology Laboratory of the Institute of Biochemistry for further processing and genetic analysis.

DNA Extraction

Genomic DNA was extracted from peripheral blood leukocytes using standard laboratory protocols. The collected blood samples were first subjected to cell lysis to release cellular components. Leukocytes

were separated and treated with lysis buffer containing detergents and proteinase enzymes to break down cellular membranes and proteins. The DNA was then precipitated, washed, and dissolved in appropriate buffer solution. The purity and concentration of the extracted DNA were assessed using spectrophotometric methods and agarose gel electrophoresis to ensure suitability for downstream molecular analysis.

Genotyping of CTLA4 Gene Polymorphism

The CTLA4 gene polymorphism analyzed in this study was the single nucleotide polymorphism rs3087243 (CT60 G>A), located in the CTLA4 gene on chromosome 2q33. This polymorphism has been previously reported to influence immune regulatory mechanisms and susceptibility to autoimmune diseases. Genotyping was performed using polymerase chain reaction (PCR)–based molecular techniques.

Specific primers targeting the CTLA4 gene region containing the rs3087243 polymorphism were used for amplification of the DNA segment. The PCR reaction mixture consisted of genomic DNA template, forward and reverse primers, deoxynucleotide triphosphates (dNTPs), magnesium chloride, buffer solution, and Taq DNA polymerase. The amplification process was carried out in a thermal cycler using standard cycling conditions including initial denaturation, repeated cycles of denaturation, annealing, and extension, followed by a final extension step.

The amplified PCR products were then analyzed to determine the genotype of each participant. The resulting band patterns allowed identification of different genotypes corresponding to the CTLA4 polymorphic variants. To ensure accuracy and reliability of the molecular analysis, strict laboratory quality control measures were implemented. All reagents were prepared using sterile techniques, and negative controls were included in PCR reactions to detect contamination. DNA samples were handled carefully to prevent degradation. Selected samples were reanalyzed to confirm reproducibility of genotyping results.

Statistical Analysis

Statistical analysis of the data was performed using appropriate statistical software. Descriptive statistics were used to summarize demographic and clinical characteristics of the study population. Comparisons between cases and controls were performed using the chi-square test to determine whether there were significant differences in genotype and allele distributions. Odds ratios (OR) and 95% confidence intervals (CI) were calculated to estimate the strength of association between CTLA4 polymorphism and vasculitis susceptibility. A p-value of less than 0.05 was considered statistically significant.

Results

The present study included a total of 100 participants, comprising 50 clinically and radiologically confirmed cases of vasculitis and 50 healthy controls. The cases were diagnosed after excluding secondary causes such as rheumatoid arthritis, systemic lupus erythematosus, and peripheral vascular disease.

The mean age of vasculitis patients in our study was 33.46 ± 16.6 years, and in the control group it was 33.36 ± 9 years. The mean serum urea level was significantly higher in cases with 34.6 ±

13.8 mg/dL compared to controls with 27.1 ± 8.1 mg/dL. The mean serum creatinine level was higher among vasculitis patients was 1.1 ± 0.61 mg/dL than controls with 0.89 ± 0.3 mg/dL with a statistically significant difference. The erythrocyte sedimentation rate (ESR) was markedly elevated in cases 37.1 ± 21.1 mm/hr compared with controls it is 5.70 ± 2.7 mm/hr. The white blood cell count was also significantly higher in cases with 13.1 ± 15.9 $\times 10^3/\mu L$ compared to controls (7.6 ± 1.09 $\times 10^3/\mu L$) (p = 0.01). In contrast, the mean hemoglobin level was significantly lower among vasculitis patients 12.2 ± 2.0 g/dL compared with healthy controls it is 14.7 ± 1.65 g/dL as shown in Table 1.

Table 1. Mean comparison of variables

Variable	CASES n=50	CONTROLS (NORMAL) n=50	p value
	Mean± S.D	Mean± S.D	
AGE (years)	33.46 ± 16.6	33.36 ± 9	0.970
UREA (mg/dL)	34.6 ± 13.8	27.1 ± 8.1	0.00**
CREATININE (mg/dL)	1.1 ± 0.61	0.89 ± 0.3	0.01 **
ESR (mm/hr)	37.1 ± 21.1	5.70 ± 2.7	0.001**
WBC (*10^3 /µL)	13.1 ± 15.9	7.6 ± 1.09	0.01**
HB (gm%)	12.2 ± 2.0	14.7 ± 1.65	0.001**

*p<0.05- Statistically significant

The distribution of vasculitis subtypes among the cases showed that Takayasu arteritis was the most common form seen in 15 cases followed by non-specific vasculitis among 12 cases, Kawasaki disease in 10 cases, granulomatosis with polyangiitis in 8 cases, microscopic polyangiitis among 4 cases, and Churg–Strauss syndrome was observed in 1 case. A higher occurrence of vasculitis was observed among female patients, particularly in Takayasu arteritis, Kawasaki disease, and non-specific vasculitis as shown in Figure 1.

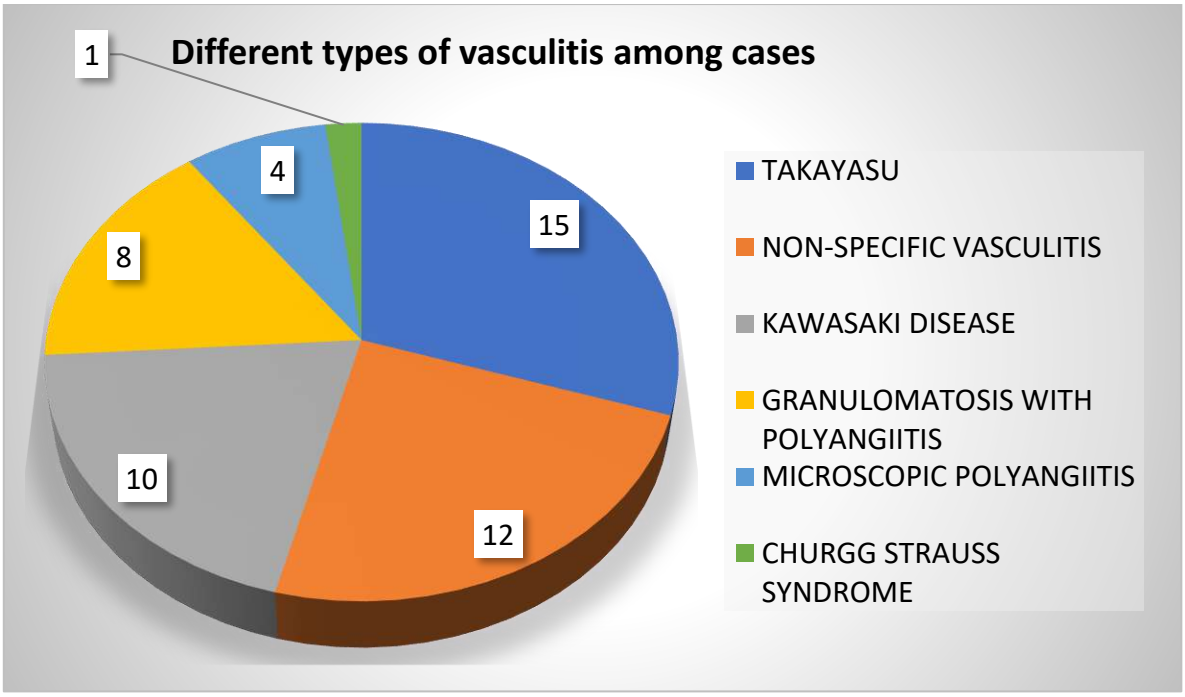


Figure 1. Different Type of Vasculitis Among Cases

Evaluation of antineutrophil cytoplasmic antibody (ANCA) status revealed that 13 patients (26%) were ANCA positive, of which 8 patients had granulomatosis with polyangiitis, 4 had microscopic polyangiitis, and 1 had Churg–Strauss syndrome, indicating that ANCA positivity was predominantly associated with small-vessel vasculitis in the study population as shown in Table 2 and Figure 2.

Table 2. ANCA Distribution of Vasculitis Among Cases

ANCA	**Cases n (%)**
ANCA +	13 (26%)
ANCA -	37 (74%)
Total	50

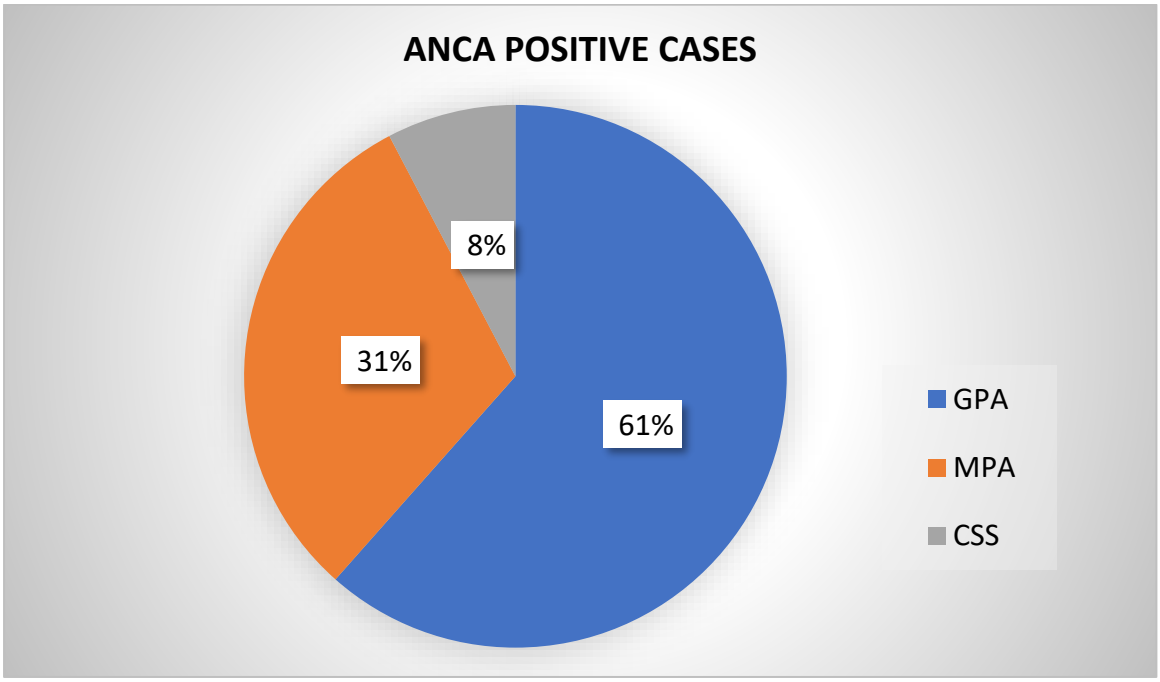


Figure 2. ANCA Positive Distribution Among Autoimmune Vasculitis

The genotype frequencies of the CTLA4 rs3087243 (CT60) polymorphism were analyzed among cases and controls. The distribution of genotypes among vasculitis patients was AA – 18%, AG – 62%, and GG – 20%, whereas in the control group the frequencies were AA – 14%, AG – 78%, and GG – 8%, with no significant difference in genotype distribution between cases and controls (p = 0.154) as shown in Table 3.

Table 3. Distribution of CTLA4 genotype

CTLA4	**CASES**	**CONTROLS (NORMAL)**	**p VALUE Chi ^{2} test**
	n (%)	**n (%)**	
A/A	9 (18)	7 (14)	
A/G	31 (62)	39 (78)	0.154 – NS
G/G	10 (20)	4 (8)	
Total	50	50	

Allele frequency analysis in our study reported that there is no statistically significant difference between the vasculitis group and controls. The G allele frequency was 82% among cases and 86% among controls, whereas the A allele frequency was 18% among cases and 14% among controls, with a p value of 0.584, indicating that CTLA4 rs3087243 polymorphism was not significantly associated with overall vasculitis susceptibility in the study population as shown in Table 4.

Table 4. Allele Distribution Among Cases and Controls

CTLA4	**CASES**	**CONTROLS (NORMAL)**	**p VALUE Chi ^{2} test**
	n (%)	**n (%)**	
G+	41 (82)	43 (86)	
G -	9 (18)	7 (14)	0.584
Total	50	50	

The subgroup analysis showed that among ANCA-positive patients, the genotype distribution was AA – 15.4%, AG – 30.8%, and GG – 53.8%, indicating a significantly higher frequency of the GG genotype compared with ANCA-negative patients (8.1%), with p VALUE <0.05 as shown in Table 5.

Table 5. Association between CTLA4 Genotype With ANCA

CTLA4 Genotype	**ANCA +**	**ANCA -**	**p VALUE Chi ^{2} test**
	n (%)	**n (%)**	
A/A	2 (15.4)	7 (18.9)	χ^2 test=
A/G	4 (30.8)	27 (73)	12.429
G/G	7 (53.8)	3 (8.1)	p value=
Total	13	37	0.002*

*p<0.05- Statistically significant

Our present study findings reports that the CTLA4 rs3087243 polymorphism does not show a significant association with general vasculitis susceptibility, the G allele may contribute to genetic susceptibility in ANCA-associated vasculitis, highlighting the possible role of immune regulatory gene polymorphisms in specific vasculitis subtypes.

Discussion

The present study evaluated the association between CTLA4 gene polymorphism and vasculitis in a cohort consisting of 50 patients with vasculitis and 50 healthy controls. Among the vasculitis cases, Takayasu arteritis was the most common subtype seen in 30% followed by non-specific vasculitis among 24%, Kawasaki disease among 20%, granulomatosis with polyangiitis in 16%, microscopic polyangiitis and Churg–Strauss syndrome in 10% of the study participants. This pattern reflects the epidemiological trend observed in Asian populations, where large-vessel vasculitis such as Takayasu arteritis is relatively more common compared with Western populations. Hospital-based epidemiological studies in India have also demonstrated a similar distribution of vasculitis subtypes, highlighting the relatively higher prevalence of Takayasu arteritis and other large-vessel vasculitides in the Indian subcontinent compared with European cohorts [2].

Evaluation of antineutrophil cytoplasmic antibody (ANCA) status in our study revealed that 13 of the 50 vasculitis patients (26%) were ANCA positive, including 8 patients with granulomatosis with polyangiitis, 4 with microscopic polyangiitis, and 1 with Churg–Strauss syndrome. This observation is consistent with the established role of ANCA in the pathogenesis of small-vessel vasculitis. ANCA antibodies, directed primarily against proteinase-3 (PR3) and myeloperoxidase (MPO), are known to activate neutrophils and trigger inflammatory cascades that lead to vascular injury. Previous studies have demonstrated that ANCA-mediated neutrophil activation and the formation of neutrophil extracellular traps (NETs) play a crucial role in endothelial damage and the development of ANCA-associated vasculitis [7-14].

The primary objective of the present study was to determine whether CTLA4 gene polymorphism rs3087243 (CT60 G>A) is associated with susceptibility to vasculitis. Analysis of genotype distribution showed that among vasculitis patients the frequencies were AA – 18%, AG – 62%, and GG – 20%, whereas among healthy controls the frequencies were AA – 14%, AG – 78%, and GG – 8%. Statistical comparison demonstrated no significant difference in genotype distribution between cases and controls ($p = 0.154$). These findings suggest that CTLA4 rs3087243 polymorphism may not be directly associated with overall susceptibility to vasculitis in the studied population. However, CTLA4 plays a well-recognized role in immune regulation by inhibiting T-cell activation through interaction with CD80 and CD86 ligands, thereby maintaining immune tolerance and preventing excessive immune responses [15-17].

Allele frequency analysis further demonstrated that the G allele frequency was 82% among vasculitis cases and 86% among controls, whereas the A allele frequency was 18% among cases and 14% among controls, and this difference was not

statistically significant (p = 0.584). These findings indicate that the presence of the G allele alone may not confer increased risk of vasculitis in the overall population studied. Similar variations in allele frequencies have been reported across different ethnic groups, and studies have shown that the G allele frequency may vary significantly among populations. Previous genetic studies have also highlighted population-specific differences in CTLA4 polymorphism frequencies, particularly in South Asian populations [18-21].

The subgroup analysis based on ANCA status revealed a significant association between CTLA4 genotype and ANCA-positive vasculitis. Among ANCA-positive patients, the genotype distribution was AA – 15.4%, AG – 30.8%, and GG – 53.8%, whereas among ANCA-negative patients the GG genotype was observed in only 8.1% of cases, with a statistically significant p value of 0.002. This suggests that the GG genotype and G allele of CTLA4 rs3087243 may be associated with susceptibility to ANCA-associated vasculitis. Previous studies investigating CTLA4 polymorphisms in autoimmune diseases have reported similar findings. For instance, Bonatti et al. demonstrated that the G allele of CTLA4 CT60 polymorphism was associated with increased susceptibility to autoimmune disorders including vasculitis [1]. Kamesh et al. reported a significant association between CTLA4 polymorphism and ANCA-associated vasculitis in a large cohort of British patients, suggesting that genetic variation in CTLA4 may influence immune dysregulation and susceptibility to small-vessel vasculitis [22].

The findings of our study indicate that while CTLA4 rs3087243 polymorphism does not appear to influence the overall risk of vasculitis, it may play a role in ANCA-associated vasculitis, particularly through the increased prevalence of the GG genotype among ANCA-positive patients. This observation supports the hypothesis that genetic variations in immune regulatory genes such as CTLA4 may contribute to the pathogenesis of specific vasculitis subtypes rather than vasculitis as a single disease entity.

Conclusion

The present study included 50 cases of clinically and radiologically proven vasculitis patients and 50 healthy controls.

We evaluated the association of CTLA4 rs3087243 single nucleotide polymorphism with vasculitis and found that 26% of cases were ANCA positive and 37% of cases were ANCA negative. There is no significant difference in frequency of genotype among vasculitis group and controls. There is an increased frequency of patients homozygous for CTLA4 CT60 (rs3087243) single nucleotide polymorphism in ANCA associated vasculitis (53.8%). The G allele of CT60 indicated a positive role in susceptibility to autoimmune vasculitis. Present results need to be confirmed by investigation of large cohorts to show differences between the subgroups.

Limitations of Study

The present study has certain limitations that should be considered while interpreting the findings. The relatively modest sample size may have limited the statistical power to detect subtle associations between CTLA4 polymorphism and vasculitis susceptibility. In addition, the subgroup analysis of ANCA-positive vasculitis included a small

number of cases (n = 13), and therefore the observed association between the GG genotype and ANCA positivity should be interpreted cautiously due to the potential risk of type I error. The functional implications of this polymorphism, particularly the relationship with soluble CTLA4 isoform levels, were not evaluated in this study. Furthermore, as one of the few studies conducted in a Southern Indian population, the findings should be considered preliminary and warrant validation through larger multicentric studies with detailed subgroup analyses of vasculitis.

Statements and Declarations

Conflicts of interest

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

Funding

No funding was received for conducting this study.

Ethical approval

This study has been approved by the Institution Ethics Committee of Madras Medical College carrying certificate number 27082018 dt:07.08.2018 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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Use of AI: The authors declare the usage of AI tool (ClaudeAI) for language moderation. After using this tool, the authors reviewed and edited the content and took full responsibility for the contents of this article.

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.

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Prevalence and Associated Factors of Low Back Pain Among Elderly Persons in an Urban Resettlement Colony of Delhi

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Abstract

Background: Low back pain (LBP) is a prevalent musculoskeletal problem globally and a leading cause of disability-adjusted life years (DALY) among all age groups. Elderly persons aged 60 years and over are particularly vulnerable, and the proportion of the ageing population is increasing in India. Prevalence of LBP among elderly persons in urban areas of India range from 17.5 to 20.7%. **Methods:** This is a cross-sectional study conducted in an urban resettlement colony of Delhi to determine the one-year prevalence of LBP among elderly persons. Simple random sampling was applied to select participants. LBP was defined as pain lasting more than a day in the area between the lower costal margin and the gluteal folds. LBP due to injuries or organic causes were excluded. The study also assessed association of LBP with various socio-demographic, behavioural and clinical characteristics of the participants. Statistical analysis was performed with multiple logistic regression. A p-value <0.05 was considered statistically significant. **Results:** The study included 526 participants. The one-year prevalence of LBP was 21.5% with men and women being 27.4% and 12.2%, respectively. It was found that poverty, depression, bad self-reported health, occurrence of two or more self-reported chronic conditions, and being overweight were independently associated with LBP in the multivariable logistic regression. **Conclusion:** Health system should integrate screening, management of LBP and rehabilitation in routine elderly care. Addressing poverty, chronic diseases, and mental health is also essential to reduce the burden of LBP.

Key words: Low back pain, prevalence, cross-sectional study, associated-factors

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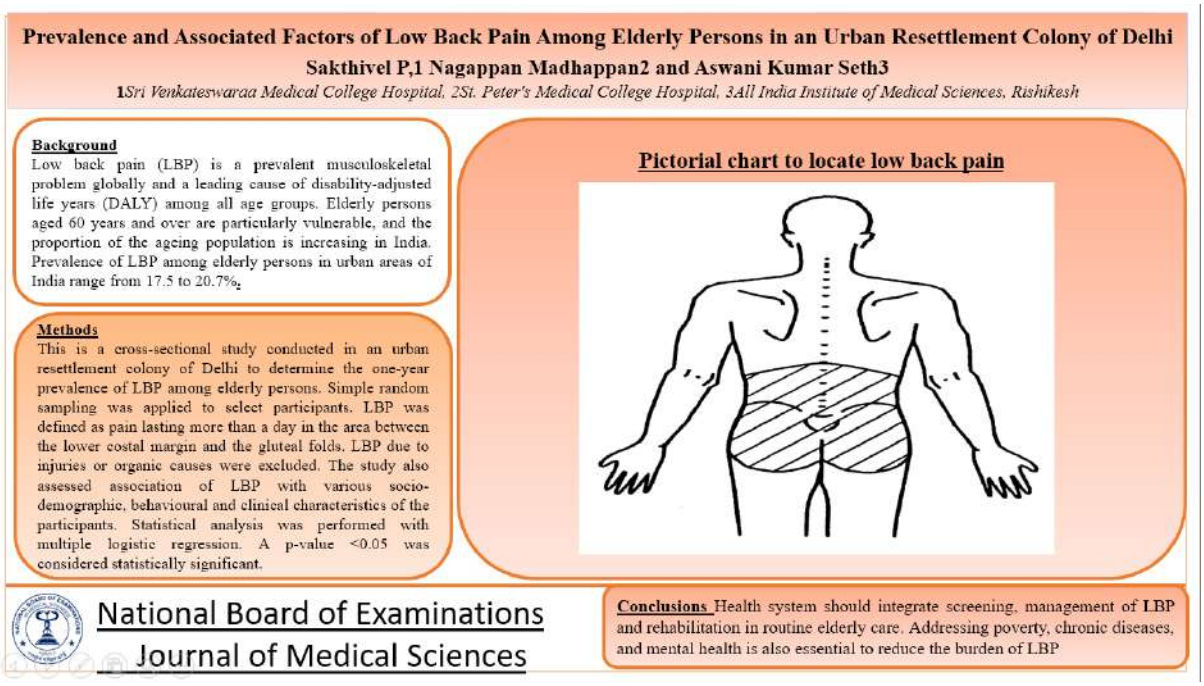
Graphical Abstract



Introduction

Low back pain is defined as pain lasting more than a day in an area between the lower costal margin and the gluteal folds with or without radiation into leg [1]. Low back pain (LBP) was the most common musculoskeletal problem globally [2]. It was the leading cause of activity limitation and absenteeism from work [3]. The number of LBP patients increased from 377.5 million in 1990 to 577 million in 2017. Global YLD (years lost due to disability) due to LBP increased by 52.7% from 1990 to 2017 [4]. It resulted in a huge medical burden and economic cost, globally [5]. LBP remained in the top 10 causes of disability-adjusted life years (DALY) among all age-groups for the last three decades (1990-2019). In the 50-74 years age-group, LBP was the eighth leading cause of DALY in 1990; it became the sixth cause in 2019 [6].

As per Global Burden of Disease, in 2017, the global prevalence of LBP increased with age, and peaked around the age of 80 to 89 years [4]. In 60-64 years, the prevalence of LBP in men was around 13% and in women it was around 17%. In 80-89 years, the prevalence of LBP in men was around 18% and in women it was around 23%.

Elderly persons were the persons who were aged 60 years or more [7,8]. The proportion of ageing population was increasing in India. According to census 2001, the population share of elderly persons was 7.4% [7]. In census 2011, this increased to 8.4% [9]. Based on Sample Registration System (SRS)-2018, elderly persons comprised 6.5% of the total population of urban Delhi. This proportion among men and women was 6.2% and 6.8%, respectively [10].

Prevalence of LBP among elderly persons in an urban area of Coimbatore, Tamilnadu was 17.5% and an urban area of Hisar, Haryana was 20.7% [1,11]. Several studies investigated the risk factors associated with LBP. LBP was found to be associated with smoking, obesity,

overweight, low physical activity, long sitting time, increasing age, comorbidities, and depression [5,12–15]. Individuals with LBP who were smokers were less likely to seek treatment [16].

Depression was associated with higher risk (frequency) and more severity of LBP [17,18]. People experiencing depression were approximately 60% more likely to develop back pain in their lifetime versus non-depressed people [18].

LBP was a common musculoskeletal disorder in elderly population. LBP was responsible for a large percentage of functional limitations resulting in difficulty in performing daily life activities, which deteriorated the quality of life [19]. Moreover, pain threatened the safety, autonomy and independence of elderly persons [20]. Globally, many studies have been conducted to estimate the prevalence of LBP and its associated factors among elderly persons. In India, it has been studied among groups like young adults, students, housewives, handloom workers, menopausal women, etc. However, there is scant published literature on factors associated with LBP among elderly persons in India. There is limited evidence on the prevalence of LBP among elderly persons in urban communities of northern India.

Estimation of prevalence and associated factors of LBP will help in designing appropriate intervention in the target population. Hence, our aim was to estimate the prevalence and associated factors of LBP, among elderly persons (aged 60 years and above) in an urban resettlement colony of Delhi.

Materials and Methods

This community-based cross-sectional study was conducted in the Urban Field Practice Area (UFPA) of Centre for Community Medicine, All India Institute of Medical Sciences (AIIMS), New Delhi. It is a resettlement colony with about 5,600 houses with a population of about 38,000.

Elderly persons residing in this area for at least six months were included. LBP due to injuries or organic causes (with history and/or documentary proof) and elderly persons who were unable to comprehend were excluded.

Sample size was calculated using the formula ($n=Z^2pq/d^2$). The anticipated prevalence of LBP was based on an earlier study by Kulandaivelan et al., because of similar study setting [1]. This study had reported prevalence of LBP among elderly as 20.7%. The absolute precision was assumed to be 3.5%. The calculated sample size was 536. Further, assuming an overall non-response rate of 10% and death and migration of 25%, a total of 738 elderly persons were required to estimate the prevalence of LBP with a level of significance of 5%. Hence, 800 elderly persons were recruited in this study, after rounding off.

A list of elderly persons (≥ 60 years) was generated from the Health Management and Information System (HMIS), of the UFPA. The list was the sampling-frame for this study. Using this sampling frame, a simple random sample of 800 elderly persons was drawn. Data collection was done from June 2021 to August 2021.

LBP was defined as pain lasting more than a day in an area between the lower costal margin and the gluteal folds with or without radiation into leg during past one-year [1]. A pictorial chart (Figure 1) was shown to the participant and they were asked to locate their pain. If they located their pain within the shaded area, it

was considered as LBP. LBP due to injury and organic causes were excluded. Severity of LBP was classified as mild, moderate and severe as claimed by the participants.

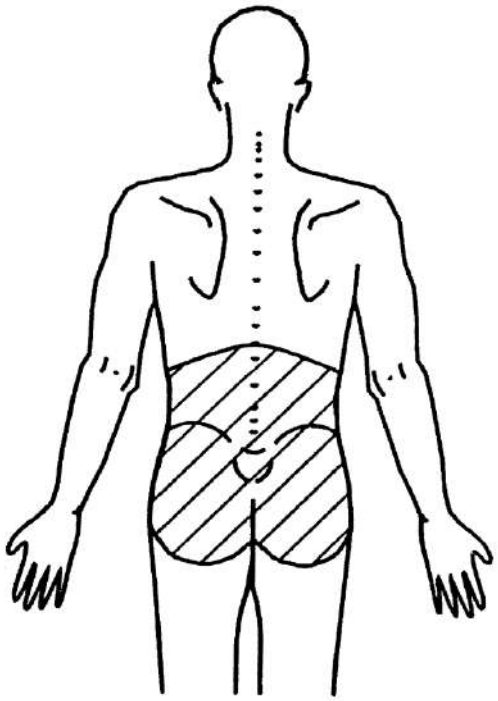


Figure 1. Pictorial chart to locate low back pain

Elderly persons were persons who were aged 60 years or above [7,8]. Poverty was assessed by the possession of Below Poverty Line (BPL) card provided by the Government of India. Others were categorised as Above Poverty Line (APL).

Physical activity was assessed by Global Physical Activity Questionnaire (GPAQ) in Hindi [21]. MET-minutes of 600 or more was considered to be physically active. Sitting time was the total number of hours a participant had been sitting per week. Total bed time was the total number of hours a participant had been spending lying down on bed per week. Participants were classified based on smoking habits into former smokers, current smokers and never smoker. Participants were classified based on alcohol use into former alcohol user, current alcohol user and never used alcohol.

Self-reported health was obtained by asking the participants to rate their perceived health from very good to very bad. Depression was assessed by Patient Health Questionnaire (PHQ-9) in Hindi [22]. Total score of five or more was considered as presence of depression. Self-reported chronic condition was defined as having documentary proof or taking medicines for any of the chronic conditions (e.g. diabetes, hypertension, asthma, chronic obstructive pulmonary disease, etc).

Digital weighing machine (Rossmax, model: WB100) was used to record the weights of the participants in kilograms. Non-elastic measuring tape was used to measure the arm span of the participants in centimetre. Arm-span was used instead of height. In elderly persons, because of change in curvature of spine,

height may vary [23]. Body Mass Index (BMI) was classified based on WHO Asia-Pacific criteria [24].

Statistical Analysis

Data entry was done in Microsoft Excel and analysis was carried out using Stata version 16.0 (StataCorp LLC, Texas, USA). Prevalence of LBP with 95% Confidence Interval (CI) was calculated. Chi-square test / Fisher's exact test was done to determine the relation between two categorical variables. Bivariable logistic regression analysis was done to find crude odds ratio for LBP with associated factors. Those variables with a p-value <0.2 in the bivariable model were included in the multivariable model. A p-value less than 0.05 was considered statistically significant.

Results

Based on the HMIS (with 2018 census data), UFPA of Centre for Community Medicine, AIIMS, New Delhi had a population of 38000 including 2176 elderly persons. A simple random sample of 800 elderly persons was drawn from HMIS. During the survey, it was found that 100 participants had died, and 109 had migrated. Ten participants were ineligible. Out of the 10 participants, four were less than 60 years of age, three had LBP due to injury, and three had organic causes of LBP, namely, tuberculosis of the spine, spondylolisthesis and scoliosis. Out of the remaining 580 participants, 526 participated in the study with a response rate of 90.7% (Table 1).

Table 1. Response rate of participants

	Number of participants approached	**Number of participants responded**	**Response rate %**
Total	580	526	90.7
Men	238	205	86.1
Women	342	321	93.9

Women constituted about 61% of the participants. Out of the 526 participants 30%, 30.6%, and 39.4% were in the age-group 60-64, 65-69, and ≥ 70 years, respectively. Of all participants, 63.3% were illiterate, and 90.7% were currently not working. Based on the previous occupation, 34% were homemakers with almost all of them being women, 37.1% were skilled and semiskilled workers and 16.2% being unskilled workers. Remaining participants (categorised as others for the analysis) were service class workers, professionals and unemployed. Among the 526 participants 57.8% were currently married, 41.6% were widow or widower, one participant was unmarried and two were separated. Out of the total participants 52.7% were living with spouse and children and 41.1% were living with their children only. About 83.8% were above poverty line (Table 2).

Table 2. Distribution of participants by sociodemographic variables

Variables	Men n = 205 (%)	Women n = 321 (%)	Total n = 526 (%)
Age-group (years)			
60-64	46 (22.4)	112 (34.9)	158 (30.0)
65-69	67 (32.7)	94 (29.3)	161 (30.6)
70 and above	92 (44.9)	115 (35.8)	207 (39.4)
Education			
Literate	131 (63.9)	62 (19.3)	193 (36.7)
Illiterate	74 (36.1)	259 (80.7)	333 (63.3)
Previous occupation			
Homemakers	2 (1.0)	177 (55.1)	179 (34.0)
Skilled workers	95 (46.3)	100 (31.2)	195 (37.1)
Unskilled workers	53 (25.9)	32 (10.0)	85 (16.2)
Others	55 (26.8)	12 (3.7)	67 (12.7)
Previous occupation that needed weight lifting			
No	118 (57.8)	273 (74.4)	391 (74.5)
Yes	86 (42.2)	48 (15.0)	134 (25.5)
Previous occupation that needed long sitting time			
No	130 (63.7)	300 (93.5)	430 (81.9)
Yes	74 (36.3)	21 (6.5)	95 (18.1)
Current occupation			
Working	20 (9.8)	29 (9.0)	49 (9.3)
Not working	185 (90.2)	292 (91.0)	477 (90.7)
Current occupation that needs weight lifting			
No	15 (75.0)	28 (96.6)	43 (87.8)
Yes	5 (25.0)	1 (3.45)	6 (12.2)
Current occupation that needs long sitting time			
No	10 (50.0)	24 (82.8)	34 (69.4)
Yes	10 (50.0)	5 (17.2)	15 (30.6)
Marital status			
Unmarried	0 (0)	1 (0.3)	1 (0.2)
Married	159 (77.6)	145 (45.2)	304 (57.8)
Widow/widower	45 (22.0)	174 (54.2)	219 (41.6)
Divorced/separated	1 (0.5)	1 (0.3)	2 (0.4)
Living condition			
Living alone	4 (2.0)	10 (3.1)	14 (2.7)
Living with spouse only	8 (3.9)	7 (2.2)	15 (2.9)
Living with spouse and children	144 (70.2)	133 (41.4)	277 (52.7)
Living with children only	49 (23.9)	167 (52.0)	216 (41.1)
Living with other family members	0 (0)	4 (1.3)	4 (0.8)
Poverty			
Above Poverty Line (APL)	168 (82.0)	273 (85.1)	441 (83.8)
Below Poverty Line (BPL)	37 (18.1)	48 (15.0)	85 (16.2)

Out of the 526 participants, 73% of the participants never smoked beedi or cigarettes in their lifetime, 15.8% were former smokers and 11.2% were current smokers. Out of the former and current smokers, female constituted only 0.6% (2 participants) each. Similarly, 75.7% never consumed alcohol in their lifetime, 14.1% were former alcohol users with all of them being men and 10.3% were current alcohol users among which only two were female participants. Each 1/3 of the participants had sitting time upto 14 hours, >14 to 28 hours and > 28 hours per week. Around 2/3 of the participants had 56 to <70 hours of total bed time per week, 11.4% had <56 hours and 22.2% had ≥70 hours of total bed time per week. Totally, 59.1% were physically active (Table 3).

Table 3. Distribution of participants by behavioural variables

Variables	Men n = 205 (%)	Women n = 321 (%)	Total n = 526 (%)
Smoking			
Never smoker	67 (32.7)	317 (98.8)	384 (73.0)
Former smoker	81 (39.5)	2 (0.6)	83 (15.8)
Current smoker	57 (27.8)	2 (0.6)	59 (11.2)
Alcohol consumption			
Never used alcohol	79 (38.5)	319 (99.4)	398 (75.7)
Former alcohol user	74 (36.1)	0 (0.0)	74 (14.1)
Current alcohol user	52 (25.4)	2 (0.6)	54 (10.3)
Sitting time per week (hours)			
Upto 14 hours	54 (26.3)	106 (33.0)	160 (30.4)
More than 14 to 28 hours	82 (40.0)	109 (34.0)	191 (36.3)
More than 28 hours	69 (33.7)	106 (33.0)	175 (33.3)
Total bed-time per week (hours)			
Less than 56 hours	30 (14.6)	30 (9.35)	60 (11.4)
56 to less than 70 hours	126 (61.5)	223 (69.5)	349 (66.4)
70 hours and above	49 (23.9)	68 (21.2)	117 (22.2)
Physically active			
Yes (>=600 METS per week)	115 (56.1)	196 (61.1)	311 (59.1)
No	90 (43.9)	125 (38.9)	215 (40.9)

Out of the total participants, 58.6%, 14.6% and 15% reported very good, good and fair health respectively and 9.1% and 2.7% reported bad and very bad health, respectively. Around 1/3 of the participants (i.e., 35.4%) did not report any chronic conditions, 1/3 reported only one chronic condition and around 1/3 (31.4%) reported two or more chronic conditions. About 15.2% had depression. Out of the 515 participants, 20.6 % were underweight, 15% were overweight and 26% were obese (Table 4). Arm-span and/or weight could not be measured in 11 participants due to stooped posture (seven), injured lower limb (two), deformed lower limb (one), cerebrovascular accident (CVA) (one).

Table 4. Distribution of participants by clinical variables

Variables	Men n = 205 (%)	Women n = 321 (%)	Total n = 526 (%)
Self-reported health			
Very good	136 (66.3)	172 (53.6)	308 (58.6)
Good	26 (12.7)	51 (15.9)	77 (14.6)
Fair	31 (15.1)	48 (15.0)	79 (15.0)
Bad	10 (4.9)	38 (11.8)	48 (9.1)
Very Bad	2 (1)	12 (3.7)	14 (2.7)
Self-reported diabetes			
Absent	147 (71.7)	211 (65.7)	358 (68.1)
Present	58 (28.3)	110 (34.3)	168 (31.9)
Self-reported hypertension			
Absent	128 (62.4)	145 (45.2)	273 (51.9)
Present	77 (37.6)	176 (54.8)	253 (48.1)
Self-reported asthma			
Absent	197 (96.1)	307 (95.6)	504 (95.8)
Present	8 (3.9)	14 (4.36)	22 (4.2)
Self-reported 'other' chronic condition			
Absent	169 (82.4)	261 (81.3)	430 (81.8)
Present	36 (17.6)	60 (18.7)	96 (18.3)
Self-reported chronic condition (Count)			
Nil	84 (41.0)	102 (31.8)	186 (35.4)
1	70 (34.2)	105 (32.7)	175 (33.3)
2 or more	51 (24.9)	114 (35.5)	165 (31.4)
Depression			
Absent	184 (89.8)	262 (81.6)	446 (84.8)
Present (PHQ-9 score >= 5)	21 (10.2)	59 (18.4)	80 (15.2)
Body mass index (Kg/m^2) (Asian categories) (n = 515)*			
Normal (BMI 18.5 to less than 23.0)	81 (40.1)	117 (37.4)	198 (38.5)
Underweight (BMI < 18.5)	53 (26.2)	53 (16.9)	106 (20.6)
Overweight (BMI 23.0 to less than 25.0)	27 (13.4)	50 (16.0)	77 (15.0)
Obese (BMI >= 25.0)	41 (20.3)	93 (29.7)	134 (26.0)

*Weight and/or arm-span could not be measured in 11 participants.

The one-year prevalence of LBP (95% CI) was 21.5% (18.5, 25.2). Prevalence of LBP among men and women were 27.4% and 12.2%, respectively. Prevalence of LBP among the age-groups 60-64, 65-69 and ≥70 years were 18.4%, 23.6% and 22.2%, respectively. After adjusting for age and sex, the prevalence of LBP was 21.4% (Table 5).

Table 5. Prevalence of LBP among participants

Variables	Number of participants n = 526	LBP present n = 113	Prevalence % (95% CI)
Total	526	113	21.5 (18.0-25.2)
Gender			
Men	205	25	12.2 (8.0-17.5)
Women	321	88	27.4 (22.6-32.6)
Age-group (years)			
60-64	158	29	18.4 (12.7-25.3)
65-69	161	38	23.6 (17.3-30.9)
70 and above	207	46	22.2 (16.8-28.5)

About 24% of the illiterate participants and 17.1% literates had LBP. Around 28.5% of the homemakers, 20.5% of skilled workers, 20% of the unskilled workers had LBP. A total of 16.5% of those who were married, and 28.8% of widow/widower suffered LBP. A total of 15.9% of those living with spouse and children, and 25.9% of those living children only had LBP. Prevalence of LBP among those below and above poverty line was 32.9% and 19.3%, respectively.

About 24.5% of the never smokers, 12% of the former smokers and 15.3% of the current smokers had LBP. 23.9% of those who never used alcohol, 14.9% of former alcohol users 13% of current alcohol users had LBP. Prevalence of LBP among those who had sitting time per week upto 14 hours, >14 to 28 hours and >28 hours were 18.1%, 23.6% and 22.3%, respectively. Prevalence of LBP among those who had total bed time per week <56 hours, 56 to <70 hours and ≥70 hours were 13.3%, 19.5% and 31.6%, respectively. A total of 18.3% of those who were physically active, and 26% of those with low physical activity had LBP.

Around 11% of those who reported very good health and 64.3% of those who reported very bad health had LBP. The prevalence of LBP was 27% among those who reported one or more chronic condition(s) and 11.3% among those who did not report any chronic condition. About 57.5% of those with depression and 12.6% of those without depression had LBP. A total of 16.2% of those with normal BMI, 24.5% of those who were underweight, 27.3% of those who were overweight, 21.6% of those who were obese suffered LBP.

Out of the 113 participants who had LBP in the past one year, 89.4% were suffering LBP currently (at the time data collection). Apart from those suffering from LBP currently, 9.7% out of the 113 participants, had their last episode of LBP in the last three months, 0.9% had their last episode more than three months ago. About 1/4th of the participants with LBP were suffering from LBP since last one year or less, around 1/4th were suffering from LBP since past two years, around 1/4th were suffering from LBP since past three years, and around 1/4th were suffering from LBP since more than three years. Most of the participants (87.6%) suffered LBP daily, around 10.7% suffered once in a week, around 2% suffered more than once in a

week and around 1% suffered one to three times in a month. About 30% reported mild pain, 45% reported moderate pain and 25% reported severe LBP (Table 6).

Table 6. Distribution of participants having LBP by characteristics of LBP (n = 113)

Variables	Number of participants with LBP n = 113	(%)
Suffering from LBP now?		
No	12	10.6
Yes	101	89.4
Duration of LBP		
Up to 12 months	29	25.7
13 to 24 months	33	29.2
25 to 36 months	24	21.2
More than 36 months	27	23.9
How many days ago was your last episode of LBP?		
Not applicable	101	89.4
During last three months	11	9.7
More than three months ago	1	0.9
Number of episodes of LBP		
1-3 per month	1	0.9
Once a week	2	1.8
More than once a week	11	9.7
Daily	99	87.6
Severity of LBP		
Mild	34	30.1
Moderate	51	45.1
Severe	28	24.8

Sixteen variables were entered in the bivariable logistic regression analysis to find out any association with LBP. In the analysis sociodemographic variables, namely, gender, age-group, education, previous occupation, marital status, living arrangement and poverty were included. Behavioral variables included for the analysis were smoking, alcohol consumption, sitting time per week, total bed time per week and physical activity. Clinical variables, namely, self-reported health, number of self-reported chronic conditions, depression and body mass index were included for the analysis.

According to current occupation status, only 49 elderly persons were working, out of which only six had LBP. So, it was not included in any of the further analysis. The variables 'previous occupation that needed weight lifting' and 'previous occupation that needed long sitting time' were not included in the analysis, as there were only a few participants in each of the sub-categories.

In the following variables, few sub-categories were merged together, as there were only a few participants in each of the sub-categories. In the marital status, sub-categories like unmarried, widow/widower and separated were merged together. Similarly, in living arrangement, those 'living with spouse and children' and those 'living with other family members' were merged together; likewise, those 'living with spouse only, and those 'living alone' were merged together.

Out of the 16 variables entered in bivariable logistic regression analysis, p-value was < 0.2 for 14 variables which were entered in multivariable logistic regression analysis, except age-group and sitting time per week.

In the multivariable logistic regression analysis, it was found that poverty, depression, bad self-reported health, occurrence of two or more self-reported chronic conditions, and being overweight were independently associated with LBP. The statistical significance of the variables are as follows; above poverty line (aOR 0.40, 95% CI: 0.21-0.76, p-value 0.005), bad and very bad self-reported health (aOR 3.83, 95% CI: 1.80-8.16, p-value 0.001), one self-reported chronic condition (aOR 2.10, 95% CI: 1.07-4.14, p-value 0.032), two or more self-reported chronic conditions (aOR 2.89, 95% CI: 1.46-5.71, p-value 0.002), depression (aOR 4.35, 95% CI: 2.23-8.48, p-value <0.001) and overweight (aOR 2.29, 95% CI: 1.11-4.70, p-value 0.024) (Table 7).

Table 7. Association of LBP with socio-demographic, behavioural and clinical variable

Variables	Number of participants n	LBP present n (%)	Unadjusted odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Gender						
Men	205	25 (12.2)	1.0		1.0	
Women	321	88 (27.4)	2.72 (1.67-4.42)	<0.001	2.58 (0.85-7.85)	0.094
Age-group (years)						
60-64	158	29 (18.4)	1.0			
65-69	161	38 (23.6)	1.37 (0.80-2.36)	0.251		
70 and above	207	46 (22.2)	1.27 (0.76-2.14)	0.365		
Education						
Literate	193	33 (17.1)	1.0		1.0	
Illiterate	333	80 (24.0)	1.53 (0.98-2.41)	0.063	1.03 (0.55-1.93)	0.927
Previous occupation						
Homemaker	179	51 (28.5)	1.0		1.0	
Skilled workers	195	40 (20.5)	0.65 (0.40-1.04)	0.073	1.07 (0.57-2.04)	0.827
Unskilled workers	85	17 (20.0)	0.63 (0.34-1.17)	0.142	1.10 (0.47-2.60)	0.821
Others	67	5 (7.5)	0.20 (0.08-0.53)	0.001	0.50 (0.15-1.59)	0.240

Marital status						
Married	222	63 (28.4)	1.0		1.0	
Widow/widower /separated/ unmarried	304	50 (16.4)	0.50 (0.33-0.76)	0.001	0.54 (0.14-2.10)	0.371
Living condition						
With Spouse and children or living with other family members	281	45 (16.0)	1.0		1.0	
With Children only	216	56 (25.9)	1.84 (1.18-2.85)	0.007	0.73 (0.18-2.95)	0.664
With Spouse only or living alone	29	12 (41.4)	3.70 (1.66-8.28)	0.001	2.59 (0.78-8.61)	0.120
Poverty						
BPL	85	28 (32.9)	1.0		1.0	
APL	441	85 (19.3)	0.49 (0.29-0.81)	0.006	**0.40** (0.21-0.76)	**0.005**
Smoking						
Never smoker	384	94 (24.5)	1.0		1.0	
Former smoker	83	10 (12.0)	0.42 (0.21-0.85)	0.016	0.83 (0.23-3.01)	0.776
Current smoker	59	9 (15.3)	0.56 (0.26-0.41)	0.123	0.83 (0.20-3.47)	0.793
Alcohol consumption						
Never used alcohol	398	95 (23.9)	1.0		1.0	
Former alcohol user	74	11 (14.9)	0.56 (0.28-1.10)	0.092	1.62 (0.43-6.06)	0.476
Current alcohol user	54	7 (13.0)	0.48 (0.21-1.09)	0.078	1.50 (0.34-6.49)	0.590
Sitting time per week (hours)						
Upto 14 hours	160	29 (18.1)	1.0			
More than 14 to 28 hours	191	45 (23.6)	1.39 (0.83-2.35)	0.215		
More than 28 hours	175	39 (22.3)	1.30 (0.76-2.22)	0.345		
Total bed-time per week (hours)						
Less than 56 hours	60	8 (13.3)	1.0		1.0	
56 to less than 70 hours	349	68 (19.5)	1.57 (0.71-3.47)	0.261	2.01 (0.73-5.55)	0.178
70 hours and above	117	37 (31.6)	3.00 (1.30-6.96)	0.010	2.53 (0.81-7.86)	0.110
Self-reported health						

Very good & Good	385	56 (14.5)	1.0		1.0	
Fair	79	19 (24.1)	1.86 (1.03-3.35)	0.039	1.02 (0.50-2.08)	0.967
Bad and very bad	62	38 (61.3)	9.3 (5.19-16.69)	<0.001	**3.83** (1.80-8.16)	**0.001**
Self-reported chronic condition (Count)						
Nil	186	21 (11.3)	1.0		1.0	
1	175	43 (24.6)	2.56 (1.45-4.52)	0.001	**2.10** (1.07-4.14)	**0.032**
2 or more	165	49 (29.7)	3.32 (1.89-5.83)	<0.001	**2.89** (1.46-5.71)	**0.002**
Physically active						
Yes (>=600 METS per week)	311	57 (18.3)	1.0		1.0	
No	215	56 (26.0)	1.57 (1.03-0.17)	0.035	1.14 (0.65-2.0)	0.656
Depression						
Absent	446	67 (12.6)	1.0		1.0	
Present (PHQ-9 score >= 5)	80	46 (57.5)	7.65 (4.58-12.80)	<0.001	**4.35** (2.23-8.48)	**<0.001**
Body mass index (Asian categories) (n = 515)*						
Normal	198	32 (16.2)	1.0		1.0	
Underweight	106	26 (24.5)	1.69 (0.94-3.02)	0.079	1.98 (0.95-4.11)	0.067
Overweight	77	21 (27.3)	1.95 (1.04-3.65)	0.038	**2.29** (1.11-4.70)	**0.024**
Obese	134	29 (21.6)	1.43 (0.82-2.51)	0.207	1.11 (0.57-2.19)	0.756

* Weight and/or arm-span could not be measured in 11 participants.

Discussion

In our study, we found that the prevalence of LBP was 21.5% among the elderly persons aged ≥ 60 years and 22.8% among those aged ≥ 65 years.

Similar findings were reported by Kulandaivelan et al. (2018) [1] in Hisar, Haryana, where LBP prevalence among the elderly was 20.7%. Mathew et al. (2013) [11] in Coimbatore, Tamil Nadu, found a prevalence of 17.5%. Both studies used the same definition of LBP as ours.

Studies from other countries reported LBP prevalence between 9.3% and 68.3%. Four studies showed results similar to ours. Ludwig et al. (2017) [25] in Switzerland found 29.2% prevalence among people ≥65 years, and Lavsky-Shulan et al. (2004) [26] in the USA reported 21.7% in the same age group. Both are close to our findings. Dijken et al. (2008) [27] in Sweden found 17.4% among those ≥55 years, while Gilgil et al. (2005) [12] in Turkey reported 30.6% among those ≥56 years. Differences may be due to age group (55–59 years) and sociodemographic factors. None of these studies defined LBP.

However, the studies from other countries reported higher or lower prevalence of LBP compared to ours. Gonzalez et al. (2021) [28] in Brazil found 44.4% among those ≥60 years, using a similar definition to ours. Ikeda et al. (2019) [29] in Spain reported 65.1% among ≥65

years, but did not define LBP. Exarchou et al. (2013) [30] in Sweden found 44.3% among men aged 69–81 years, which may be higher due to male-only participants. Bikbov et al. (2009) [31] in Russia reported 57.3% among ≥65 years, while Woo et al. (2009) [32] in Hong Kong found 43% without defining episode duration. Omokhodian et al. (2004) [33] in Nigeria reported 46% among ≥60 years, possibly influenced by small sample size and unclear definition.

In the present study, poverty, depression, bad self-reported health, one or more self-reported chronic condition(s), overweight were the independent factors significantly associated with LBP.

In the following studies, results were consistent with our study. Ikeda et al. (2019) [29] in Spain found poverty associated with LBP in those ≥65 years. Figueiredo et al. (2013) [34] in Brazil and Meyer et al. (2007) [35] in the USA both showed depression as a significant factor. Altinel et al. (2008) [36] in Turkey identified depression and obesity, while Machado et al. (2018) [13] in Brazil reported overweight, low physical activity, and depression as associated with LBP among the elderly. Quintino et al. (2017) [37] in Brazil found self-reported morbidity and weight lifting associated with LBP in those ≥60 years. Palacios Cena et al. (2014) [38] in Spain reported associations with illiteracy, poor health, obesity, depression, and anxiety in those ≥51 years. Bikbov et al. (2009) [31] in Russia found female gender, obesity, poverty, low physical activity, comorbidity, and depression associated with LBP in those ≥65 years. Differences may be due to variation in LBP definitions and measurement methods such as self-reported height and weight for BMI and CES-D for depression.

However, the following three studies showed different results. Palma et al. (2014) in Brazil reported age, sedentary lifestyle, and sitting time as risk factors. Dijken et al. (2008) [27] in Sweden reported low physical activity associated with LBP in those ≥55 years. Gilgil et al. (2005) [12] in Turkey found female gender and smoking associated with LBP in those ≥56 years. These differences may be due to variations in LBP definition, sociodemographic factors, and inclusion of age group 55–59 years. Physical activity was also measured differently across studies such as IPAQ and other activity categories as compared to GPAQ in our study.

Strength of the study

This is a community-based study among the elderly persons. We used simple random sampling and the response rate was high, making the sample representative. We used a pictorial chart that helped participants identify LBP clearly. Standard tools such as PHQ-9 for depression, GPAQ for physical activity with their validated Hindi versions were used, ensuring better understanding by the participants and comparability with other studies.

Limitations of the study

Due to cross-sectional nature of study, temporality of the associated factors could not be established. Stigmatized behaviours such as smoking and alcohol consumption are likely to be under-reported. Long time-frame (i.e. one year) for recalling LBP could be influenced by recall bias. Severity of LBP was self-reported and was subjective.

Conclusion

In our study, the prevalence of LBP among the elderly persons residing in the urban resettlement colony was 21.5%. The age-adjusted and sex-adjusted prevalence of LBP was 21.4%. The association of LBP with poverty, depression, bad self-reported health, one or more self-reported chronic condition(s) and overweight was statistically significant. Based on these findings, it is recommended that policymakers integrate systematic screening and management of LBP into routine elderly care, with emphasis on physiotherapy and rehabilitation services. Additionally, interventions addressing poverty reduction, chronic disease control, and mental health support should be prioritized to reduce the burden of LBP.

Ethical Approval

Ethical approval was obtained from the Institute Ethics Committee with reference number – IECPG-742/23.12.2020.

Informed Consent

Informed written consent was obtained from all participants. Participants were explained that their identity would remain confidential.

Conflicts of interest

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

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ORIGINAL ARTICLE

Age-Related Changes in Refractive, Corneal, and Ocular Residual Astigmatism: A Power Vector Analysis

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Abstract

Introduction: Astigmatism results from the combined contribution of corneal and internal ocular components. Understanding the relationship between refractive astigmatism (RA), corneal astigmatism (CA), and ocular residual astigmatism (ORA) across different age groups is essential for optimizing outcomes in refractive surgery, toric intraocular lens implantation, and contact lens correction. **Materials and Methods:** This prospective cross-sectional study was conducted at a tertiary care hospital in South India from July 2023 to March 2024. A total of 150 eyes from 86 patients aged 10–59 years were included and categorized into five age groups. RA and CA were measured using automated refractometry and keratometry. ORA was calculated using power vector analysis as described by Thibos. Statistical analysis included descriptive statistics and Pearson correlation. **Results:** Refractive astigmatism was predominantly with-the-rule (WTR) in younger age groups (81% in 10–19 years) and shifted progressively to against-the-rule (ATR) in older age groups (76.9% in 50–59 years). Corneal astigmatism showed a similar age-related trend, with decreasing WTR and increasing ATR patterns. In contrast, ORA remained predominantly ATR (66%) across all age groups without significant age-related variation. ORA was found to compensate for corneal astigmatism in younger individuals and accentuate it in older individuals. **Conclusion:** Refractive astigmatism shows a significant age-related shift influenced primarily by corneal changes and modulated by ocular residual astigmatism. Accurate assessment of ORA is crucial for individualized refractive correction and improving surgical outcomes.

Keywords: Refractive astigmatism, Corneal astigmatism, Ocular residual astigmatism, Power vector analysis, Age-related changes, Toric intraocular lens

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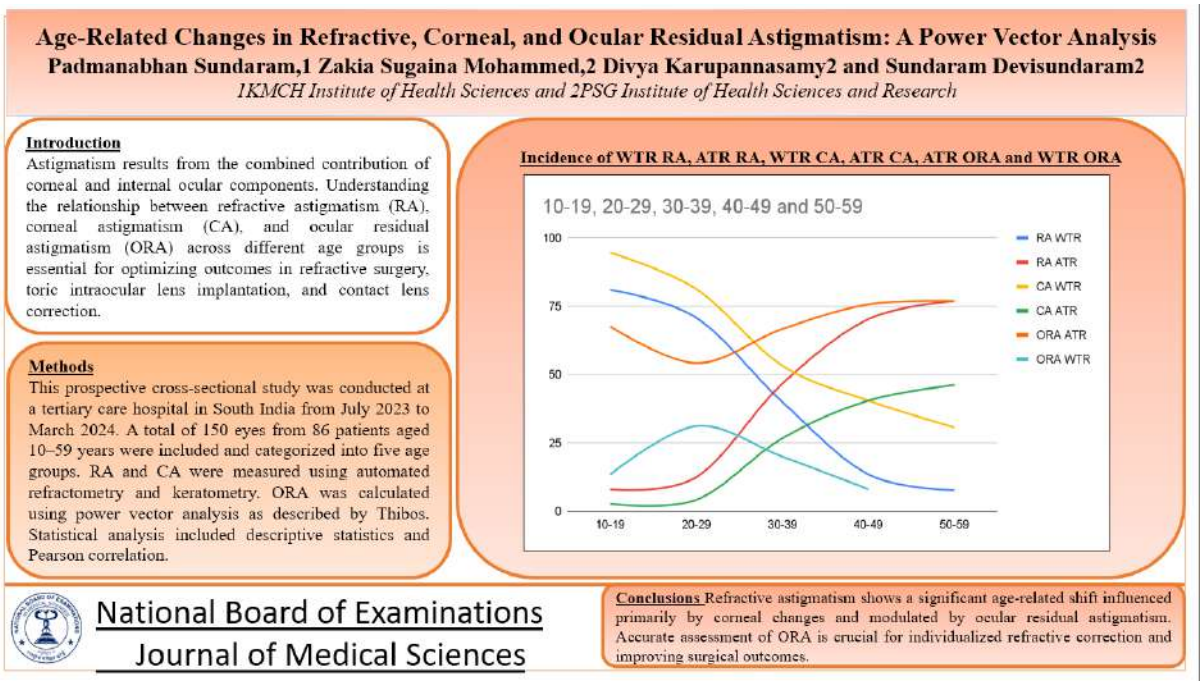
Graphical Abstract



Introduction

Astigmatism is one of the most common refractive errors globally, affecting both children and adults [1]. It arises due to meridional asymmetry of the cornea or lens, lens tilt or decentration, variations in refractive index within the crystalline lens [2], or posterior segment asymmetry [3], leading to unequal refraction of light along different meridians.

Astigmatism is classified based on axis orientation into regular (with-the-rule [WTR], against-the-rule [ATR], and oblique) and irregular types. Regular astigmatism occurs when principal meridians are perpendicular, while irregular astigmatism involves multiple meridians. Based on contributing components, refractive astigmatism (RA) represents total ocular astigmatism and is the sum of corneal astigmatism (CA) and ocular residual astigmatism (ORA). ORA, a term introduced by Alpins [4], accounts for internal ocular contributions including posterior corneal astigmatism, lenticular, and retinal factors. While RA and CA can be directly measured, ORA is derived mathematically using power vector analysis as described by Thibos [5].

Although internal astigmatism was recognized early [6], detailed evaluation of its relationship with RA and CA has expanded after the introduction of power vector analysis. ORA has been shown to significantly influence outcomes in refractive procedures such as LASIK [7,8], LASEK [9], SMILE [10], orthokeratology [11], and RGP lens fitting [12]. It also plays a compensatory role in early life, particularly in offsetting WTR astigmatism [11,13,14], while studies in elderly populations highlight age-related changes in astigmatism patterns [15].

Several studies have explored age-related variations in astigmatism components. Attebo et al. [16] reported increasing ATR astigmatism with age, while Remon et al. [17], Leung et al. [18], Harvey et al. [19], Schuster et al. [20],

Naeser et al. [21], and Rozema et al. [22] demonstrated shifts in astigmatism patterns across different age groups. However, Indian studies utilizing power vector analysis remain limited. Senthil et al. [23] demonstrated its application in evaluating surgically induced astigmatism.

Given the limited Indian data and the clinical importance of understanding astigmatism components, this study was undertaken to analyze RA, CA, and ORA using power vector analysis across different age groups (10–59 years). Patients above 60 years were excluded due to potential confounding effects of cataract-induced astigmatism [24,15].

Materials and Methods

A prospective cross-sectional study was conducted among patients attending the Ophthalmology outpatient department of a multidisciplinary tertiary care hospital in South India between July 2023 and March 2024. The study protocol was approved by the Institutional Ethics Committee (Approval No: PSG/IHEC/2023Appr/Exp/101), and the study adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants, and assent with parental/guardian consent was obtained for minors.

The sample size was calculated based on a reported prevalence of astigmatism of 13% as stated by Schuster et al. [20], using the formula $n = 4pq/d^2$, with an absolute precision (d) of 6% and an anticipated non-response rate of 25%, yielding a required sample size of 150 eyes.

A total of 150 eyes from 86 patients aged 10–59 years, irrespective of gender, with a minimum refractive astigmatism of 0.5 diopters were included in the study. Participants were recruited using consecutive sampling. Patients with ocular surface disorders, squint, intraocular diseases such as uveitis, cataract, or glaucoma, history of contact lens use, or prior extraocular or intraocular surgery were excluded.

Participants were categorized into five age groups: 10–19, 20–29, 30–39, 40–49, and 50–59 years. All subjects underwent a comprehensive ophthalmic evaluation including visual acuity assessment, retinoscopy, automated refractometry and keratometry, subjective refraction, non-contact tonometry, and slit-lamp examination. Refractive astigmatism (RA) and corneal astigmatism (CA) were measured using an automated refractometer and keratometer (TOPCON KR-800). All measurements were performed by the same examiner to minimize inter-observer variability.

Ocular residual astigmatism (ORA) was calculated using power vector analysis as described by Thibos et al. [5]. Refractive and corneal cylinder values were converted into their vector components J0 and J45 using the following equations:

$$J0 = -C/2 \times \cos(2\beta)$$
$$J45 = -C/2 \times \sin(2\beta)$$

where C represents cylinder power and β represents the positive cylinder axis. J0 corresponds to the Jackson cross-cylinder power at 0° and 90°, and J45 corresponds to the Jackson cross-cylinder power at 45° and 135°. Both RA and CA were converted to positive cylinder format prior to analysis.

ORA was determined as the vectorial difference between refractive and corneal astigmatism:

$$J0\ (ORA) = J0\ (RA) - J0\ (ACA)$$
$$J45\ (ORA) = J45\ (RA) - J45\ (ACA)$$

The magnitude and axis of ORA were calculated as:

$$\text{ORA magnitude} = 2\sqrt{(J0^2 + J45^2)}$$
$$\text{Axis of ORA} = \tfrac{1}{2} \tan^{-1} [J45 / J0] + 90°$$

Descriptive statistics were expressed as frequencies and percentages. Pearson correlation coefficient was used to assess the strength and direction of association between continuous variables. A p-value of <0.05 was considered statistically significant. All data were entered in Microsoft Excel and analyzed using SPSS software (version 28).

Results

The overall distribution of astigmatism showed that refractive astigmatism (RA) was predominantly with-the-rule (WTR) (50.7%), followed by against-the-rule (ATR) (34.7%) and oblique astigmatism (14.6%). Corneal astigmatism (CA) demonstrated a stronger predominance of WTR (67.3%), with lower proportions of ATR (18.7%) and oblique (13.3%). In contrast, ocular residual astigmatism (ORA) exhibited a markedly different pattern, being predominantly ATR (66%), while WTR (17.3%) and oblique (16.7%) were comparatively less frequent. This indicates that although corneal astigmatism largely determines the WTR nature of refractive astigmatism, the predominantly ATR nature of ORA plays a significant modifying role in the overall refractive outcome (Table 1).

Analysis across different age groups revealed a clear age-related shift in the pattern of astigmatism. In younger individuals (10–19 years), both refractive and corneal astigmatism were predominantly WTR (81% and 94.6%, respectively), while ORA was mainly ATR (67.6%), suggesting a compensatory role. With increasing age, the proportion of WTR astigmatism progressively decreased, while ATR astigmatism increased in both RA and CA, becoming predominant in older age groups (76.9% in 50–59 years). ORA consistently remained predominantly ATR across all age groups (ranging from 52.1% to 76.9%) without a significant age-dependent trend. These findings indicate that ORA compensates for corneal WTR astigmatism in younger individuals and accentuates ATR astigmatism in older individuals, thereby influencing the overall refractive astigmatism pattern with age (Table 2).

Table 1. Overall astigmatism (n=150)

Type of astigmatism	WTR	ATR	OBLIQUE
RA	76(50.7%)	52(34.7%)	22(14.6%)
CA	101(67.3%)	28(18.7%)	20(13.3%)
ORA	26 (17.3%)	99(66%)	25(16.7%)

Table 2. Proportion of WTR, ATR and oblique astigmatism in RA, CA and ORA in different age groups (in numbers and by percentage)

Age group (number of eyes)	**Type of astigmatism**	**Component of astigmatism**		
		CA n (%)	**ORA n (%)**	**RA n (%)**
10-19(n=37)	WTR	35(94.6)	5(13.5)	30(81)
	ATR	1(2.7)	25(67.6)	3(8)
	OBLIQUE	1(2.7)	7(18.9)	4(11)
20-29(n=48)	WTR	39(81.3)	15(31.2)	34(70.8)
	ATR	2(4.2)	26(54.2)	6(12.5)
	OBLIQUE	6(12.5)	7(14.6)	8(16.7)
30-39(n=15)	WTR	8(53.3)	3(20)	6(40)
	ATR	4(26.7)	10(66.7)	7(46.7)
	OBLIQUE	3(20)	2(12.3)	2(13.3)
40-49(n=37)	WTR	15(40.5)	3(8.1)	5(13.5)
	ATR	15(40.5)	28(75.7)	26(70.3)
	OBLIQUE	7(18.9)	6(16.2)	6(16.2)
50-59(n=13)	WTR	4(30.7)	0	1(7.7)
	ATR	6(46.2)	10(76.9)	10(76.9)
	OBLIQUE	3(23.1)	3(23.1)	

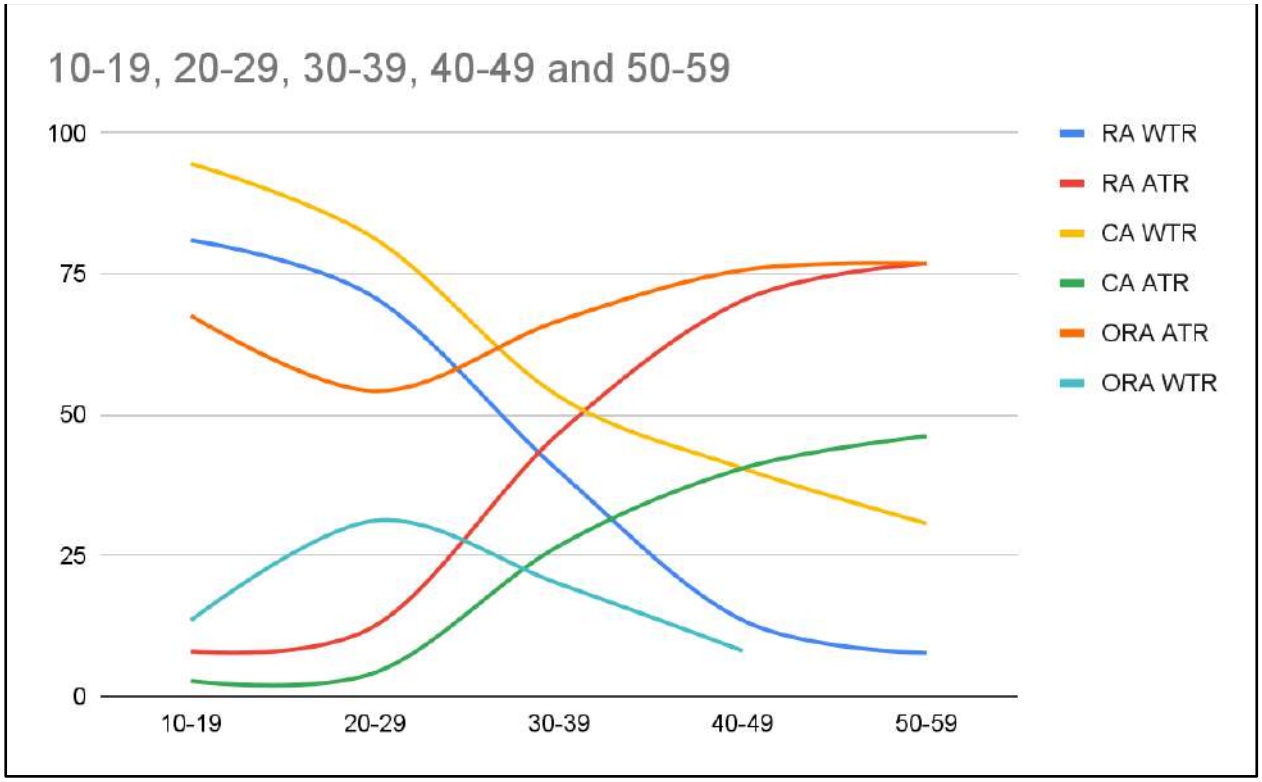


Figure 1. Showing course of incidence of WTR RA, ATR RA, WTR CA, ATR CA, ATR ORA and WTR ORA (in percentage) with increasing age

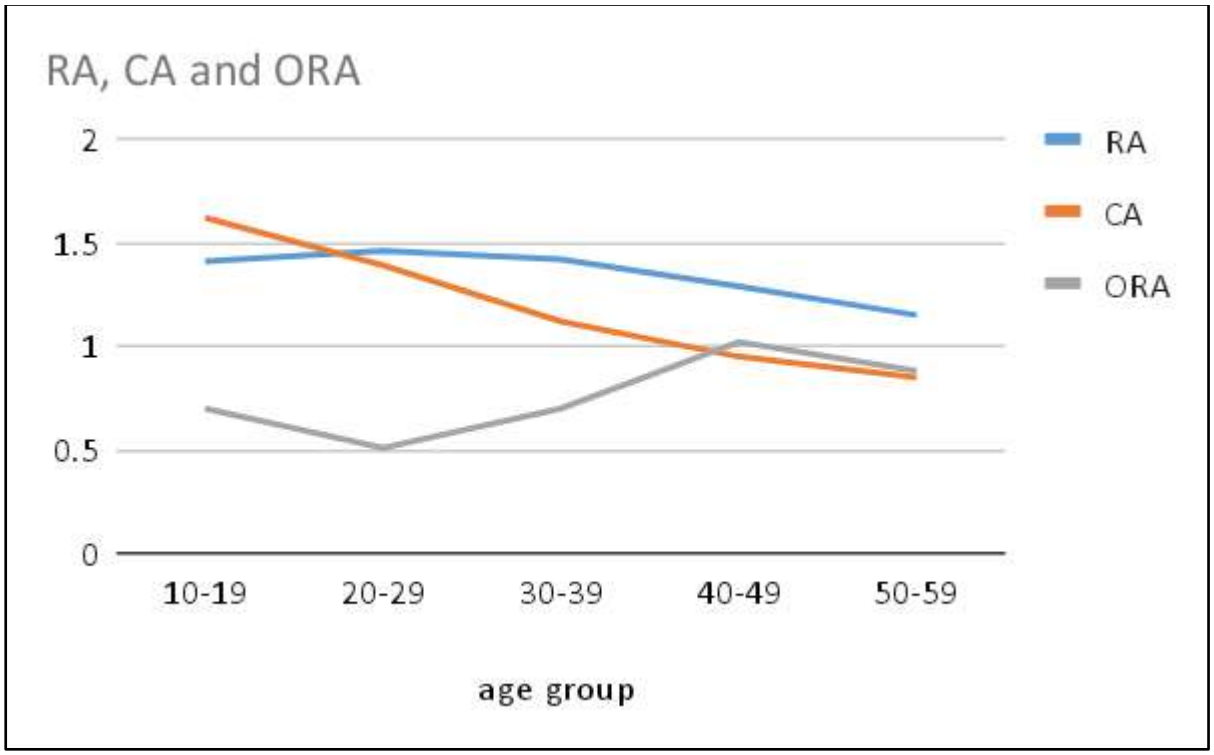


Figure 2. Showing course of magnitude of RA, CA and ORA with increasing age.

Vertical axis: Magnitude of astigmatism in diopters, horizontal axis shows increasing age groups

Discussion

A total of 150 eyes from 86 subjects were included in this study, distributed across five age groups (10–19, 20–29, 30–39, 40–49, and 50–59 years). The magnitude of refractive astigmatism ranged from 0.5 to 5.75 D with a mean of 1.375 ± 1.03 D. Unlike many previous studies that predominantly focused on myopic astigmatism [9,11,25], the present study included a broader spectrum of refractive errors such as compound hypermetropic astigmatism [15], simple myopic astigmatism [10], mixed astigmatism [19], and compound myopic astigmatism [18], thereby providing a more comprehensive representation. Refractive astigmatism was predominantly with-the-rule (WTR) (54.7%), followed by against-the-rule (ATR) (34.7%) and oblique astigmatism (14.6%), while corneal astigmatism was mainly WTR (67.3%) and ocular residual astigmatism (ORA) was predominantly ATR (66%).

The pattern of corneal astigmatism demonstrated a clear age-related transition. The mean corneal astigmatism was 1.26 ± 0.94 D, ranging from 0 to 5 D. In younger individuals (10–19 years), corneal astigmatism was almost entirely WTR (94.6%) with minimal ATR (2.7%). With increasing age, the proportion of WTR progressively declined to 30.7% in the 50–59 age group, while ATR increased to 46.2%. Notably, in the 40–49 age group, WTR and ATR were equal (40.5% each), indicating a transitional phase. This shift from WTR to ATR with advancing age is consistent with earlier observations by Baldwin and Mills [26] and Leung et al. [18]. The underlying mechanism is attributed to age-related biomechanical changes in the cornea, including reduction in eyelid pressure effects and progressive flattening of the vertical meridian, resulting in relative steepening of the horizontal meridian. Additionally, the proportion of oblique astigmatism increased with age, from 2.7% in the youngest group to 23.1% in the oldest group, consistent with findings by Ho et al. [27].

Refractive astigmatism followed a pattern closely paralleling corneal astigmatism. It was predominantly WTR in younger individuals (81% in 10–19 years) and shifted progressively towards ATR dominance with age (76.9% in 50–59 years). This observation is in agreement with the meta-analysis by Zhang et al. [28], which reported WTR predominance in individuals below 40 years and increasing ATR and oblique astigmatism with age. Similar trends have also been reported by Ho et al. [27] and Leung et al. [18]. Furthermore, Naeser et al. [21] observed a gradual increase in ATR astigmatism after 50 years of age. The strong positive correlation observed between refractive astigmatism and corneal astigmatism (WTR and ATR) suggests that corneal astigmatism is the primary determinant of refractive astigmatism patterns.

However, the role of ORA is crucial in modulating this relationship. In younger age groups, the proportion of WTR refractive astigmatism was lower than corneal astigmatism, while in older age groups, ATR refractive astigmatism exceeded corneal astigmatism. This is explained by the predominantly ATR nature of ORA across all age groups, which compensates for WTR corneal astigmatism in younger individuals and accentuates ATR corneal astigmatism in older individuals. Similar compensatory and augmenting effects of ORA have been reported by Rozema et al. [22] and Liu et al. [25], particularly in younger populations.

Correlation analysis further supported this relationship, showing strong positive correlations between refractive and corneal astigmatism, and contrasting associations with ORA, highlighting its modifying influence on overall refractive astigmatism.

The magnitude of refractive astigmatism also demonstrated a strong positive correlation with corneal astigmatism and a negative correlation with ORA, suggesting that while corneal factors contribute directly to the magnitude of astigmatism, ORA plays a modulatory role. Similar findings have been reported in earlier studies [18], emphasizing the interplay between corneal and internal components in determining refractive astigmatism.

Ocular residual astigmatism in this study had a mean value of 0.73 ± 0.59 D, ranging from 0.01 to 4.46 D, which is comparable to findings reported by Lin et al. [13], Tang et al. [29], and Mohammedpour et al. [30]. ORA was predominantly ATR (66%), with WTR and oblique components contributing 17.3% and 16.7%, respectively. This predominance of ATR ORA is consistent with previous studies, including those by Remon et al. [17] and Lin et al. [13]. Importantly, the proportion of ATR ORA remained relatively stable across all age groups (52.1%–76.9%), indicating that ORA does not exhibit significant age-dependent variation, unlike corneal and refractive astigmatism.

The consistent ATR nature of ORA explains its dual role: compensating for WTR corneal astigmatism in younger individuals and amplifying ATR corneal astigmatism in older individuals. In cases where ORA is WTR, it may further enhance WTR refractive astigmatism, particularly in younger age groups. These findings highlight the importance of individualized assessment of ORA, especially in refractive surgical planning. High ORA has been associated with suboptimal outcomes in LASIK [7], LASEK [9], and SMILE procedures [10], as well as in orthokeratology [11]. Additionally, accurate consideration of ORA is essential in toric intraocular lens calculations, where posterior corneal astigmatism also plays a significant role [31,32].

ORA includes contributions from posterior corneal astigmatism (PCA), which is typically ATR in nature, and lenticular astigmatism. Although keratometry accounts for total corneal power, it does not measure posterior corneal astigmatism directly, thereby including it within ORA. Advances in imaging techniques such as Scheimpflug imaging have enabled direct measurement of PCA, which has been reported to be approximately 0.25–0.3 D and predominantly ATR [21,32]. The remaining component of ORA is likely lenticular, which may vary in orientation and magnitude, explaining the presence of WTR and oblique ORA in some individuals. Further studies are required to isolate and quantify these components more precisely.

Unlike many previous studies that focused exclusively on myopic populations, the present study included all types of refractive errors, enhancing its generalizability. However, Hashemi et al. [33] reported that emmetropic individuals tend to have WTR ORA, a group that was not included in the present study. Additionally, oblique astigmatism was observed across all components (RA, CA, ORA) with proportions ranging from 2.7% to 23.1%, indicating its variable but significant presence.

The study has certain limitations. The sample size was relatively small and based on an OPD-based convenience sampling method, resulting in unequal distribution across age groups. Older age groups had fewer participants due to exclusion of individuals with cataract and other intraocular conditions. This uneven distribution may affect the precision of age-specific estimates. Nevertheless, the observed trends are consistent with findings from previous studies. Larger population-based studies in the Indian context, incorporating advanced imaging modalities for posterior corneal astigmatism and modern astigmatism calculators, are recommended to further enhance understanding of astigmatism components.

Conclusion

Refractive astigmatism demonstrates a clear age-related shift from predominantly with-the-rule in younger individuals to against-the-rule in older age groups, largely reflecting corresponding changes in corneal astigmatism. Ocular residual astigmatism, which remains predominantly against-the-rule across all age groups, plays a crucial modulatory role by compensating for corneal astigmatism in younger individuals and accentuating it in older individuals. This dynamic interaction between corneal and internal ocular components significantly influences the overall refractive astigmatism pattern. Therefore, accurate estimation of ocular residual astigmatism is essential for individualized planning in refractive surgery and toric intraocular lens implantation, as it contributes to variability in surgical outcomes and refractive correction.

Statements and Declarations

Conflicts of interest

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

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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.

Ethics approval

The study protocol was approved by the Institutional Ethics Committee (Approval No: PSG/IHEC/2023Appr/Exp/101),

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ORIGINAL ARTICLE

Study of Serum Vitamin D Levels, Atherogenic Index of Plasma, and Cardiovascular Risk in Type 2 Diabetes Mellitus

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Abstract

Background: Patients with type 2 diabetes mellitus (T2DM) have an increased risk of cardiovascular disease, largely driven by atherogenic dyslipidaemia. Vitamin D deficiency is highly prevalent in this population and has been implicated in adverse cardiometabolic profiles. The relationship between serum vitamin D levels and composite lipid risk markers such as the atherogenic index of plasma (AIP) remains insufficiently explored, particularly in Indian clinical settings. **Objectives:** To assess serum vitamin D levels and lipid profile parameters in patients with T2DM and to evaluate the association between vitamin D status and the atherogenic index of plasma. **Methods:** This prospective observational study was conducted in the Department of General Medicine, ACS Medical College and Hospital, Chennai, from December 2018 to March 2019. A total of 120 patients with T2DM were enrolled using consecutive sampling. Fasting blood samples were analyzed for lipid profile using enzymatic methods on a semi-autoanalyzer, and serum vitamin D levels were estimated by ELISA. The atherogenic index of plasma was calculated as $\log_{10}$(triglycerides/HDL cholesterol). Associations were assessed using Pearson correlation analysis. **Results:** The mean serum vitamin D level was 20.0 ± 7.8 ng/mL. Serum vitamin D showed significant inverse correlations with triglycerides ($r = -0.246$, $p = 0.007$), VLDL cholesterol ($r = -0.244$, $p = 0.007$), and the atherogenic index ($r = -0.278$, $p = 0.002$). No significant correlations were observed between vitamin D levels and total cholesterol, HDL cholesterol, LDL cholesterol, fasting blood glucose, or post-prandial blood glucose. **Conclusion:** Lower serum vitamin D levels were associated with higher atherogenic index values in patients with T2DM, suggesting a link between vitamin D status and lipid-related cardiovascular risk. Evaluation of serum vitamin D alongside composite lipid indices may aid cardiovascular risk stratification in this population.

Keywords: Type 2 diabetes mellitus, Vitamin D deficiency, Atherogenic index of plasma, Dyslipidaemia, Cardiovascular risk

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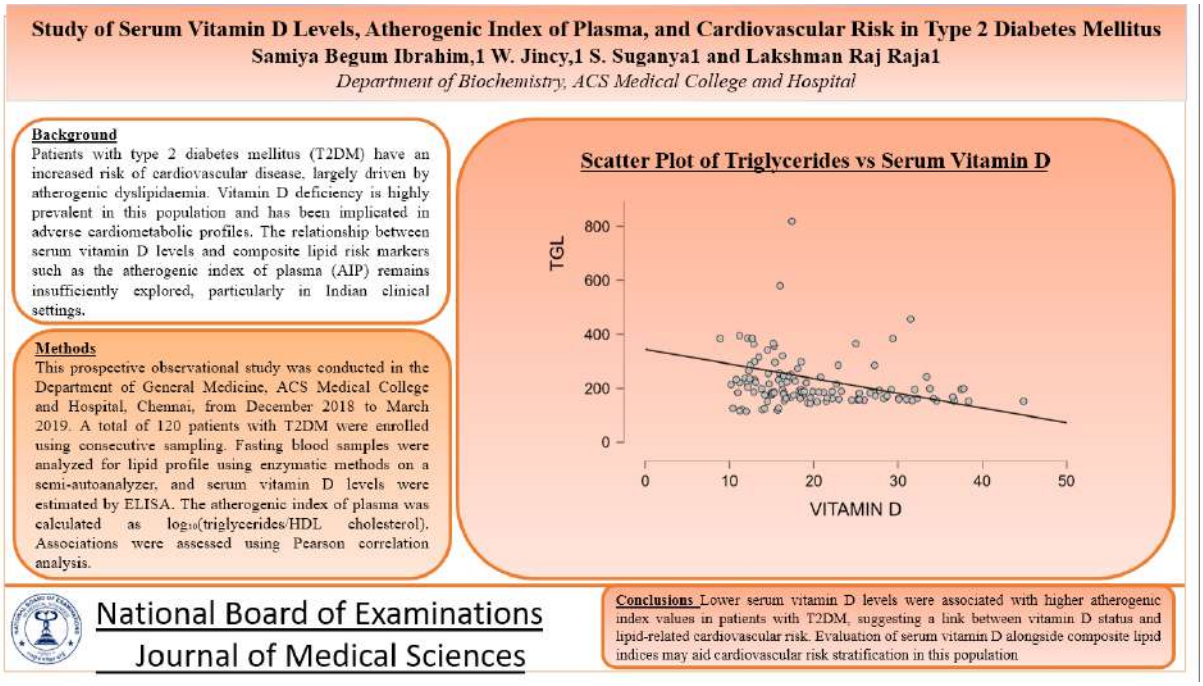
Graphical Abstract



Introduction

Many people around the world are affected by type 2 diabetes mellitus (T2DM); it is one of the most common non-communicable diseases [1,2]. Due to increasing numbers of older adults, urbanization, sedentary lifestyles, and changes in diets, this prevalence of T2DM is increasing [1,2]. The majority of morbidity and mortality from cardiovascular disease (CVD) occurs in people suffering from T2DM, leading to a large proportion of premature deaths and long-term disabilities [3]. A recent meta-analysis of prospective studies indicates that people with T2DM have almost twice the risk of developing coronary artery disease and stroke than people without diabetes, after controlling for all established cardiovascular risk factors [3]. While there have been considerable advances made in glucose-lowering therapies, this excess cardiovascular risk remains, highlighting the need for better risk stratification using clinically accessible markers.

Type 2 Diabetes Mellitus (T2DM) is a major component of the global diabetes burden and is projected to substantially increase over the next several decades [1,2]. Many Indians with T2DM have an abnormal lipid profile that includes elevated triglyceride levels and decreased levels of high-density lipoprotein (HDL) cholesterol along with qualitative abnormalities in low-density lipoprotein (LDL) particles; these characteristics accelerate the rate of atherosclerosis and promote earlier onset of CVD [5]. Although traditional lipid measures can be informative, they do not fully represent the atherogenic lipid environment that is commonly observed in T2DM, especially in populations at high baseline cardiometabolic risk.

The atherogenic index of plasma (AIP), defined as the log ratio of triglycerides to HDL-cholesterol, has emerged as a useful composite measure of atherogenic dyslipidemia [6]. Studies have demonstrated that AIP correlates with

lipoprotein particle size, insulin resistance and cardiovascular risk and therefore provides a more complete evaluation of lipid-related risk than measurement of single lipid fractions [7]. Because AIP uses only lipid parameters that are routinely measured, it has the potential to be a highly useful tool in resource-poor clinical settings for the evaluation of cardiovascular risk in T2DM.

Vitamin D traditionally has been recognized for its role in maintaining skeletal health. It is now increasingly being recognized for its potential to influence other physiological systems, including glucose metabolism, immune system function, endothelial cell function, and cardiovascular health [4]. Receptors for Vitamin D have been identified in pancreatic beta-cells, vascular smooth-muscle cells, and endothelial cells, thereby suggesting a biologically plausible relationship between Vitamin D status and cardiometabolic health. Vitamin D deficiency is present worldwide, but is particularly prevalent in India; despite India's abundance of sunlight, Vitamin D deficiency remains widespread in India due to a variety of reasons including, but not limited to, limited sun exposure, skin pigmentation, inadequate nutrition, and an urban lifestyle [8,9].

Evidence supporting relationships between Vitamin D deficiency and adverse lipid profiles, insulin resistance, and increased cardiovascular risk is provided by observational and interventional studies; however, findings have been inconsistent across different populations [10]. Meta-analyses of randomized-controlled trials in patients with T2DM have shown small improvements in some lipid measures with Vitamin D supplementation, while effects on HDL-cholesterol and total cardiovascular endpoints have varied [10,13]. Moreover, many of the previous studies have focused on individual lipid fractions rather than composite indices that are more representative of atherogenic risk.

There is limited data available concerning the relationship between serum levels of Vitamin D and atherogenic indices, such as AIP, in patients with T2DM. Some studies have demonstrated that Vitamin D status inversely correlates with atherogenic risk markers in diabetic populations, implying that lower Vitamin D levels are associated with more adverse lipid profiles [11]. Associations similar to those described above have been reported in population-based studies evaluating the relationship between serum Vitamin D concentrations and cardiometabolic risk markers, including atherogenic indices [12]. However, there is a paucity of information regarding how Vitamin D relates to atherogenic indices in clinical settings in India, where both the prevalence of T2DM and Vitamin D deficiency are high.

Therefore, we investigated the relationship between serum Vitamin D levels and the atherogenic index in patients with T2DM to gain clinically relevant information about cardiovascular risk assessment using easily obtainable laboratory values. Although the prevalence of both T2DM and vitamin D deficiency are high in India, data specifically addressing the relationship between serum vitamin D levels and composite atherogenic indices such as AIP in an Indian clinical cohort remain limited. Therefore, we hypothesized that lower serum vitamin D levels were independently associated with higher AIP values in patients with T2DM. Therefore, this study was conducted to evaluate whether there exists an association between

serum Vitamin D levels and the atherogenic index of plasma as a marker of cardiovascular risk in patients with type 2 diabetes mellitus.

Materials and Methods

Study Design

This was a prospective observational study.

Study Period

The study was conducted from December 2018 to March 2019.

Study Setting

The study was carried out in the Department of Biochemistry and Department of General Medicine, ACS Medical College and Hospital, Chennai, Tamil Nadu, India. Both outpatients and inpatients attending the department during the study period were screened for eligibility.

Study Population and Sample Size

The sample size was determined based on the ability to detect a statistically significant correlation between serum vitamin D levels and the atherogenic index of plasma. The required sample size for correlation analysis was estimated using **Fisher's z transformation**, according to the formula:

$$n = \left(\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{0.5 \times \ln\left(\frac{1+r}{1-r}\right)} \right)^2 + 3$$

where r represents the anticipated correlation coefficient, α is the type I error, and β is the type II error.

With a **two-sided α of 0.05** and **80% power**, a sample size of **120 participants** was sufficient to detect a minimum correlation coefficient of approximately **r = 0.25** between serum vitamin D levels and the atherogenic index. With **90% power**, the same sample size corresponded to the detection of a correlation coefficient of approximately **r = 0.29**. Accordingly, a total of **120 patients** were included in the study.

A total of **120 patients** diagnosed with **type 2 diabetes mellitus** were included in the study.

Sampling Method

Patients were enrolled using **consecutive sampling**.

Inclusion Criteria

- Adults diagnosed with type 2 diabetes mellitus
- Patients attending the outpatient or inpatient services of the Department of General Medicine during the study period
- Patients who provided informed consent for participation

Exclusion Criteria

- Patients with known **chronic kidney disease**
- Patients with documented **coronary heart disease**
- Patients with acute or chronic illnesses likely to influence lipid metabolism or vitamin D status

Data Collection and Clinical Assessment

After obtaining informed consent, demographic details and clinical data were recorded. Anthropometric measurements including height, weight, and waist circumference were obtained using standard techniques. Blood pressure was measured using a calibrated

sphygmomanometer with the patient in a seated position.

Laboratory Investigations

After an overnight fast, venous blood samples were collected under aseptic precautions.

- Fasting blood glucose and lipid profile parameters (total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol, and VLDL cholesterol) were analyzed using enzymatic methods on a semi-autoanalyzer (Microlab 300).
- Post-prandial blood glucose samples were collected two hours after a standard meal.
- Serum vitamin D levels were estimated using the enzyme-linked immunosorbent assay (ELISA) method.

Statistical Analysis

Data were entered and analyzed using JASP (0.95.4). Continuous variables were expressed as mean ± standard deviation. Prior to correlation analyses, normality of continuous variables was assessed using the Shapiro–Wilk test. For variables that deviated significantly from normality (triglycerides and VLDL cholesterol), Spearman's rank correlation was performed as a supplementary analysis; results were concordant with those from Pearson's analysis. The primary association between serum vitamin D levels, lipid parameters, glycaemic parameters, and the atherogenic index was assessed using Pearson correlation analysis. A p-value < 0.05 was considered statistically significant.

Results

The study population consisted of 120 men and women who averaged 50.1 years old and weighed an average of 70.6 kilograms. The population's mean body mass index (BMI) was 28.9 and ranged from 17 to 43 kg/m². The mean waist circumference of the participants was 108.3 centimeters and ranged from 61 to 153 cm.

Participants' mean systolic blood pressures were 133.7 mmHg, with a range of 90-200 mmHg. Participants' mean diastolic blood pressures were 87.5 mmHg, with a range of 60-140 mmHg. Participants' mean fasting blood glucose levels were 168.5 milligrams per deciliter (mg/dl). Blood glucose values ranged from 47 to 305 mg/dl.

Participants' mean total cholesterol levels were 183.4 mg/dl. Total cholesterol levels ranged from 85 to 275 mg/dl. Mean triglyceride levels among the participants were 233.6 mg/dl. Triglyceride levels ranged from 12 to 1137 mg/dl.

Mean high-density lipoprotein (HDL) cholesterol levels among the participants were 37.9 mg/dl. HDL levels ranged from 14 to 88 mg/dl. Mean low-density lipoprotein (LDL) cholesterol levels among the participants were 100.9 mg/dl. LDL levels ranged from 25 to 206 mg/dl. Mean very-low-density lipoprotein (VLDL) cholesterol levels among the participants were 46.5 mg/dl. VLDL levels ranged from 8 to 163 mg/dl.

Participants' mean vitamin D levels were 20.0 nanograms per milliliter (ng/mL) and ranged from less than 10 to greater than 150 ng/mL. Participants' mean atherogenic indices were 0.74. Atherogenic indices ranged from 0.04 to 3.36. The majority of the study population were men (78 men, 42 women; 65%). This is similar to the mean HDL cholesterol of 37.9 mg/dl found, since male sex is independently related to lower HDL levels; lipid parameter means by gender are provided in Table 5.

There were statistically significant relationships between the participants' serum vitamin D levels and their serum triglycerides (r=-.246, p=0.007), and VLDL cholesterol (r=-.244, p=.007), but no statistically significant relationships between serum vitamin D levels and total cholesterol or HDL cholesterol.

Serum vitamin D levels were inversely correlated with participants' atherogenic indices (r = -.278, p = .002); however, there were no statistically significant relationships between participants' fasting blood glucose or postprandial blood glucose and atherogenic indices.

Table 1. Baseline demographic, anthropometric, and clinical characteristics of the study population

Parameter	**Mean ± SD**
Age (years)	50.1 ± 10.5
Sex (Male/Female)	78/42
Body mass index (kg/m²)	28.9 ± 3.1
Waist circumference (cm)	108.3 ± 8.9
Systolic blood pressure (mmHg)	133.7 ± 16.7
Diastolic blood pressure (mmHg)	87.5 ± 10.1
Fasting blood glucose (mg/dL)	168.5 ± 55.3
Post-prandial blood glucose (mg/dL)	252.9 ± 78.6

Table 2. Lipid profile parameters, serum vitamin D levels, and atherogenic index (n = 120)

Parameter	Mean ± SD
Total cholesterol (mg/dL)	183.4 ± 33.9
Triglycerides (mg/dL)	233.6 ± 168.3
HDL cholesterol (mg/dL)	37.9 ± 4.2
LDL cholesterol (mg/dL)	100.9 ± 35.2
VLDL cholesterol (mg/dL)	46.5 ± 33.7
Serum vitamin D (ng/mL)	20.0 ± 7.8
Atherogenic index	0.74 ± 0.21

Table 3. Correlation between serum vitamin D levels and lipid profile parameters

Lipid parameter	Pearson's r	p-value
Triglycerides	−0.246	**0.007**
Total cholesterol	−0.104	0.260
HDL cholesterol	0.169	0.065
LDL cholesterol	0.061	0.510
VLDL cholesterol	−0.244	**0.007**

Table 4. Correlation of serum vitamin D and glycaemic parameters with atherogenic index

Parameter	Pearson's r	p-value
Serum vitamin D	−0.278	**0.002**
Fasting blood glucose	0.028	0.764
Post-prandial blood glucose	0.088	0.339

Table 5. Sex-stratified lipid profile parameters, serum vitamin D levels, and atherogenic index

Parameter	Male (n=78)	Female (n=42)
Total cholesterol (mg/dL)	181.2 ± 34.6	187.4 ± 32.5
Triglycerides (mg/dL)	241.3 ± 176.4	219.8 ± 152.7
HDL cholesterol (mg/dL)	36.8 ± 4.0	39.9 ± 4.1
LDL cholesterol (mg/dL)	99.1 ± 36.3	104.1 ± 33.4
VLDL cholesterol (mg/dL)	48.3 ± 35.3	43.0 ± 30.5
Serum vitamin D (ng/mL)	19.6 ± 7.9	20.8 ± 7.6
Atherogenic index	0.77 ± 0.22	0.68 ± 0.19

Discussion

This prospective observational study of individuals with type 2 diabetes mellitus (T2DM) found serum vitamin D levels to be inversely associated with lipid-derived cardiovascular risk factors. The population studied had low mean serum vitamin D levels along with a dyslipidemic profile consisting of high triglycerides and low HDL cholesterol. Statistically significant inverse correlations were noted between serum vitamin D and triglycerides, very low-density lipoprotein (VLDL) cholesterol, and the atherogenic index of plasma (AIP). No statistically significant relationships were identified for total cholesterol, low-density lipoprotein (LDL) cholesterol, or glycemic variables. Thus,

these results support the hypothesis that the vitamin D status in T2DM is correlated with atherogenic lipid profiles rather than current measures of glycemic control (Figures 1 and 2).

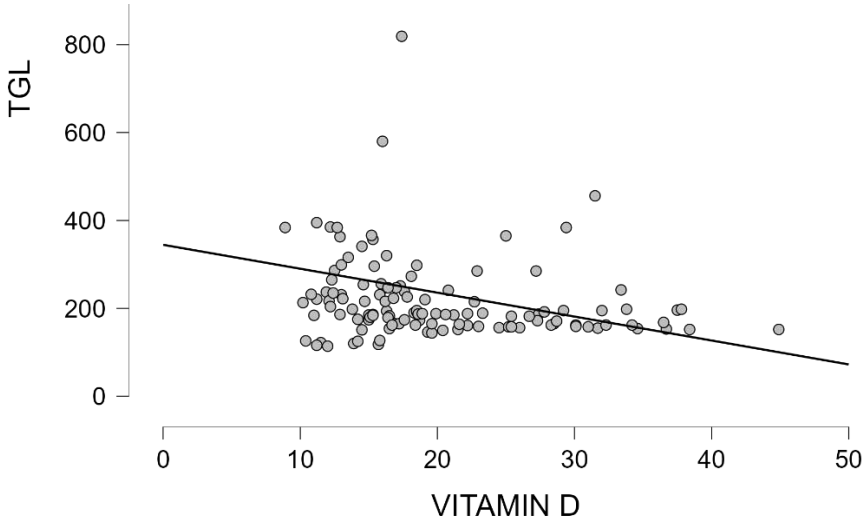


Figure 1. Scatter Plot of Triglycerides vs Serum Vitamin D

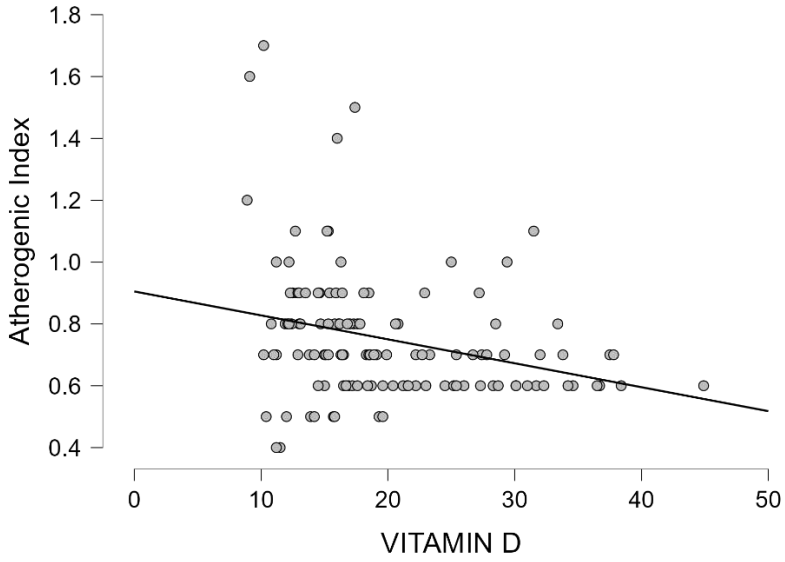


Figure 2. Scatter Plot of Atherogenic Index vs Serum Vitamin D

Comparative Studies with Indian Data

Vitamin D deficiency is widespread in India among individuals with metabolic disease, and has been documented consistently through community and hospital based studies [8,9]. The low mean serum vitamin D levels observed in this study are therefore consistent with prior reports of vitamin D deficiency in India. Dyslipidemia characterized by high triglycerides and low HDL cholesterol is a well-documented feature of Indian patients with T2DM and contributes to a substantial increase in their cardiovascular risk [5].

There are limited Indian studies that have examined the relationship between vitamin D status and composite lipid risk markers in individuals with T2DM. Pokhrel et al. evaluated the relationship between vitamin D deficiency and cardiovascular risk in individuals with diabetes and found that vitamin D deficient subjects had adverse lipid parameters and higher atherogenic indexes compared to non-deficient individuals [11]. While there are methodologic differences in the two studies, the results of Pokhrel et al. demonstrate a similar inverse relationship between serum vitamin D levels and AIP in Indian patients with T2DM.

Comparative Studies with International Data

International data also document a relationship between vitamin D status and cardiometabolic risk; however, the magnitude of the relationship varies between studies. The KERCADR study demonstrated significant inverse relationships between serum vitamin D levels and atherogenic indices in patients with diabetes, and the results of that study are consistent with the inverse relationship we observed between serum vitamin D and AIP in our study [12]. Pokhrel et al. reported higher atherogenic indexes in vitamin D deficient individuals with T2DM, indicating a similar relationship between vitamin D status and atherogenic indices in multiple populations [11].

Meta-analyses of vitamin D supplementation in T2DM have shown modest reductions in triglycerides and total cholesterol, but inconsistent effects on HDL cholesterol [10,13]. Our results support the findings of meta-analyses in that we observed significant relationships between serum vitamin D levels and triglyceride rich lipoproteins, but not with HDL or LDL cholesterol. Collectively, these findings indicate that vitamin D status may affect certain aspects of lipid metabolism, but does not uniformly impact all lipid fractions.

Pathophysiologic Considerations

Several pathophysiologic mechanisms may explain the observed association between low serum vitamin D levels and higher AIP. Vitamin D receptors are present in the liver, adipose tissue, vascular smooth muscle cells, and endothelial cells, suggesting that vitamin D may play a role in lipid metabolism and vascular homeostasis [4]. Deficiency in vitamin D has been associated with increased hepatic production of triglyceride rich lipoproteins and decreased activity of lipoprotein lipase resulting in increased circulating triglycerides.

In addition, insulin resistance common in T2DM can further contribute to these effects by promoting VLDL production and decreasing HDL cholesterol levels. Since AIP is calculated from triglyceride and HDL cholesterol concentrations, the metabolic changes that occur as a result of low vitamin D status and

insulin resistance will directly alter its value [6,7]. Moreover, low vitamin D status has been associated with low grade inflammation and endothelial dysfunction, and this may contribute to the atherogenic potential of triglyceride rich lipoproteins. The lack of a significant association between vitamin D levels and glycemic parameters in this study indicates that the relationship between vitamin D levels and lipid related cardiovascular risk may be greater than the relationship between vitamin D levels and short term glycemic control.

Implications for Clinical Practice

The findings of this study have several implications for clinical practice. First, the significant inverse association between serum vitamin D levels and AIP indicates that vitamin D status may be used as an adjunctive marker in assessing cardiovascular risk in individuals with T2DM. Both serum vitamin D measurement and AIP calculation can be performed with standard laboratory tests and thus, this approach is feasible and practical for use in everyday clinical practice.

Second, the lack of association between glycemic parameters and AIP underscores the need to assess cardiovascular risk beyond glycemic control. Individuals who have adequate glycemic control may still carry significant atherogenic risk due to dyslipidemia and other micronutrient deficiencies. Therefore, incorporation of vitamin D assessment in metabolic evaluation may help identify individuals at higher cardiovascular risk. It should be noted, however, that the present study was not designed to validate specific clinical cut-off combinations; while published literature has proposed an AIP value of >0.11 as indicating moderate-to-high cardiovascular risk and vitamin D sufficiency is generally defined as ≥20 ng/mL, these thresholds require prospective evaluation before clinical implementation can be recommended.

Limitations

Several limitations of this study should be acknowledged. First, the cross-sectional, observational design precludes any inference of causality between vitamin D status and atherogenic dyslipidaemia. Second, this was a single-centre study conducted at a tertiary care hospital in Chennai, Tamil Nadu, which may limit the generalisability of findings to other geographic regions, ethnicities, or healthcare settings. Third, dietary vitamin D intake and individual sun exposure were not assessed, both of which are important determinants of serum vitamin D levels in the Indian population. Fourth, data on potentially important confounding variables including HbA1c, duration of diabetes, and concurrent use of statins, fibrates, or vitamin D supplements were not systematically collected; their influence on the observed associations cannot therefore be excluded. Fifth, a formal sex-stratified correlation analysis was not performed, and hormonal influences on lipid metabolism and vitamin D status in female participants warrant further investigation. Collectively, these limitations underscore the need for larger, multicentre, prospective studies with comprehensive covariate assessment to confirm and extend the findings of this study.

Conclusion

In this prospective observational study of patients with type 2 diabetes mellitus, lower serum vitamin D levels

were significantly associated with higher atherogenic index values, reflecting an unfavorable lipid-related cardiovascular risk profile. Serum vitamin D demonstrated inverse associations with triglycerides, VLDL cholesterol, and the atherogenic index, while no significant relationships were observed with glycaemic parameters. These findings suggest that vitamin D status may be linked to atherogenic dyslipidaemia in patients with type 2 diabetes mellitus. Assessment of serum vitamin D levels alongside composite lipid indices may serve as a hypothesis-generating observation warranting prospective validation of clinically actionable thresholds. Further longitudinal and interventional studies with comprehensive covariate adjustment are needed to clarify the clinical implications and to determine whether targeting vitamin D deficiency may reduce lipid-related cardiovascular risk in this population.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee of ACS Medical College and Hospital. Written informed consent was obtained from all participants prior to enrollment.

Statements and Declarations

Conflicts of interest

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

Funding

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ORIGINAL ARTICLE

Predictive Ability and Clinical Utility of the SLIC Score for Surgical Decision-Making in Sub Axial Cervical Spine Injuries: A Secondary Data Analysis

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Abstract

Introduction: Sub axial cervical spine injuries (C3–C7) are a major cause of spinal trauma, often resulting from road traffic accidents. The Sub axial Injury Classification (SLIC) system provides a standardized framework for management based on injury morphology, disco-ligamentous complex (DLC) integrity, and neurological status. **Objective**: To evaluate the predictive utility of the SLIC score in determining surgical requirements and assessing its association with neurological recovery among patients with acute Sub axial cervical spine injuries. **Materials and Methods**: This retrospective secondary data analysis reviewed 210 patient records at a tertiary care hospital in Salem (2020–2025). SLIC scores were compared against actual treatment (operative vs. nonoperative) and neurological outcomes (ASIA grade). **Results**: The mean age was 45.21 years with a 69.5% male predominance, primarily due to road traffic accidents (61.0%). Surgical intervention was performed in 61.4% of patients, who had significantly higher mean total SLIC scores compared to those managed conservatively (7.64 vs. 2.98, $p < 0.001$). Overall, 90.9% of patients received SLIC-appropriate management. Neurological improvement was significantly higher in the surgical group (58.1%) compared to the conservative group (30.9%, $p < 0.001$). ROC analysis for predicting surgical requirement (SLIC > 4) demonstrated an AUC of 0.940, with 94.6% sensitivity, 85.2% specificity, and 91.0% overall accuracy. **Conclusion**: The SLIC score is a highly reliable predictor for surgical stabilization and demonstrates excellent diagnostic accuracy. Its strong correlation with neurological recovery and high clinical adherence supports its routine application in high-volume trauma settings.

Keywords: Sub axial cervical spine injury, SLIC score, Surgical stabilization, Neurological outcome

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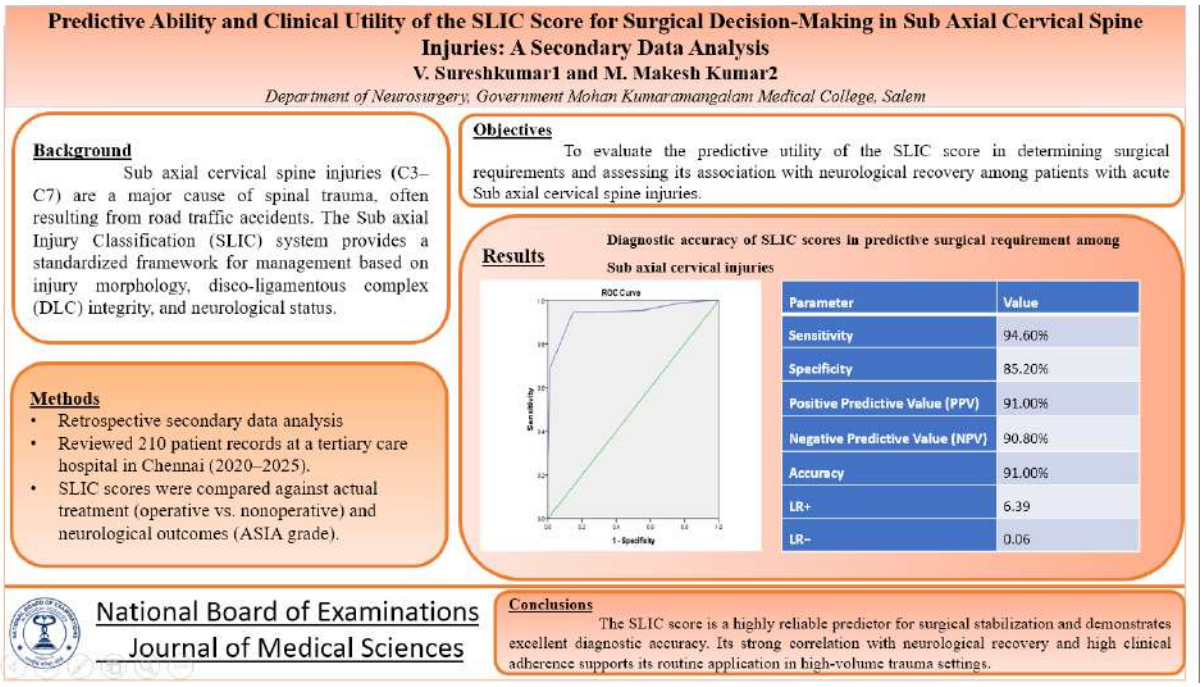
Graphical Abstract



Introduction

Traumatic Sub axial cervical spine injuries (C3–C7) account for a substantial proportion of spinal trauma in low- and middle-income countries, particularly India, where road traffic accidents and falls remain leading etiologies, with mortality rate accounting to 6% [1,2]. Early identification of mechanical instability and neurological compromise is crucial, as these factors directly influence surgical decision-making and long-term functional recovery [3]. In contemporary spine trauma practice, structured injury classification systems are increasingly favored to reduce variability and improve prognostic accuracy [4]. Literatures on Indian tertiary-center data continue to highlight the burden of cervical spine trauma and the need for standardized assessment protocols in high-volume settings [5].

The Sub axial Cervical Spine Injury Classification (SLIC) system, proposed by the Spine Trauma Study Group, integrates three key domains—injury morphology, integrity of the disco-ligamentous complex (DLC), and neurological status—into a cumulative score that guides treatment decisions. Scores ≤3 favor conservative management, ≥5 recommend surgical intervention, and a score of 4 remains equivocal, requiring clinical judgment. [6,7]. Beyond its original intent as a treatment algorithm, multiple contemporary analyses demonstrate that SLIC shows good interobserver reliability and reproducibility in tertiary trauma settings, supporting its routine clinical applicability [8,9].

Literatures from Indian centers suggests that higher SLIC scores correlate with greater mechanical instability, higher likelihood of operative intervention, and more severe baseline neurological deficits, the neurological component of SLIC has demonstrated prognostic relevance, with patients sustaining incomplete spinal cord injuries showing meaningful postoperative neurological improvement following early decompression when appropriately

stratified [10,11]. These findings support the hypothesis that SLIC may serve not only as a decision-making tool but also as a predictor of surgical outcomes.

Despite its widespread adoption in tertiary referral centers—where SLIC scoring is routinely integrated with MRI-based DLC assessment and multidisciplinary trauma evaluation—questions remain regarding its independent predictive strength for postoperative recovery, complication rates, and functional outcomes. Furthermore, recent analyses note that SLIC does not explicitly incorporate patient-specific modifiers such as comorbidities, osteoporosis, or polytrauma burden, which may influence surgical prognosis [4,12,13]. In this context, a structured secondary data review is warranted to critically appraise the application of SLIC scoring in predicting surgical outcomes within real-world tertiary care practice.

Objectives

To evaluate the predictive utility of the Sub axial Cervical Spine Injury Classification and Severity Score (SLIC) in determining the requirement for surgical stabilization among patients with acute Sub axial cervical spine injuries, and to assess the association between baseline SLIC score and postoperative and neurological outcome.

Methodology

This retrospective secondary data analysis was conducted at a tertiary care teaching hospital in Salem. Medical records, operative registers, and radiological databases of cervical spine injury cases were reviewed for a five-year period from January 1, 2020 to December 31, 2025. The study included all patient records (census sampling) with acute Sub axial cervical spine injuries (C3–C7) during the study period. The study utilized routinely recorded clinical and radiological data generated as part of institutional spine trauma management protocols.

Acute traumatic Sub axial cervical spine injury (C3–C7) confirmed on computed tomography (CT) and/or magnetic resonance imaging (MRI) with adequate clinical and radiological documentation to compute SLIC score were included and patients with Upper cervical spine injuries (C0–C2), Pathological fractures (tumor, infection), chronic injuries, or prior cervical instrumentation and Incomplete records precluding reliable SLIC calculation were excluded.

Data were extracted using a standardized data abstraction proforma. Demographic variables (age, sex), mechanism of injury, injury level, radiological findings, neurological outcome as per American Spinal Injury Association [ASIA] grade [14], SLIC score, treatment modality (operative or nonoperative), and in-hospital outcomes (complications) were recorded. Where SLIC score was not explicitly documented in the medical record, it was retrospectively computed from available imaging and neurological documentation according to established SLIC criteria.

SLIC scoring was determined using three components:

1. Injury morphology (based on CT ± MRI)
2. Integrity of the disco-ligamentous complex (preferably MRI-based assessment)
3. Neurological status (ASIA grade at presentation)

Scores were interpreted as follows:

- <4 (nonoperative recommendation),
- 4 (equivocal), and
- >4 (operative recommendation).

Actual treatment decisions were documented as executed under institutional spine trauma protocols.

Of the 251 records retrieved during the study period, based on the completeness of records, inclusion and exclusion criteria, 210 patient records were included for analysis.

Statistical analysis was performed using SPSS v16.0. Continuous variables were summarized as mean ± standard deviation. Categorical variables were presented as frequencies and percentages. Association between SLIC category and Management, Outcome were assessed using the Chi-square test. Diagnostic performance of SLIC cut-offs (>4) was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). A p value <0.05 was considered statistically significant.

Results

The mean age of the patients in our records were 45.21±16.6 years and with a male predominance (69.5%). Road traffic accidents were the leading cause of injury (61.0%), followed by fall from height (20.0%) and ground-level falls (16.2%), indicating that high-energy trauma was the primary mechanism. Associated injuries were present in 42.9% of patients, most commonly head injury (26.7%). The C5 vertebral level was most frequently involved (37.6%), followed by C6 (22.9%) and C4 (21.0%), reflecting the biomechanical susceptibility of the mid-cervical spine. Table 1 shows the distribution of Injury related variables in the study records.

Table 1. Distribution of Injury variables

Injury related Variables		**Frequency**	**Percent**
Mode of Injury	**Assault**	6	2.9
	Fall at Ground Level	34	16.2
	Fall from Height	42	20.0
	RTA	128	61.0
Associated Injury	**Head Injury**	56	26.7
	None	120	57.1
	Polytrauma	21	10.0
	Thoracic Injury	13	6.2

Level of Injury	**C3**	17	8.1
	C4	44	21.0
	C5	79	37.6
	C6	48	22.9
	C7	22	10.5

Regarding management, 129 patients (61.4%) underwent surgical intervention and 81 (38.6%) were treated conservatively. Surgical procedures included combined approaches (18.1%), corpectomy (15.7%), posterior fixation (14.3%), and ACDF (13.3%), suggesting individualized treatment based on instability and neurological status. Complication rates were relatively low, with 69.0% having no complications; infection and pneumonia each occurred in 10.0% of patients, while implant failure and bed sores were infrequent. Table 2 shows the distribution of management and outcome among the study records.

Table 2. Distribution of Management and Outcome

Variable			Frequency	Percent
Management	**Surgical**	**ACDF**	28	13.3
		Corpectomy	33	15.7
		Posterior Fixation	30	14.3
		Combined	38	18.1
	Conservative		81	38.6
Complications	**Bed Sores**		14	6.7
	Implant Failure		9	4.3
	Infection		21	10.0
	None		145	69.0
	Pneumonia		21	10.0

Neurological Outcome (as per ASIA grade)	**Deteriorated**	12	5.7
	Improved	100	47.6
	No Change	98	46.7

The mean SLIC score was 5.84± 2.87 with mean morphology, DLC, neurology scores were 2.60±1.30, 1.43±0.74 and 1.81±1.08. The SLIC score distribution showed that 64% of patients had scores >4, 32% had scores <4, and 4% scored 4. Figure 1 display the distribution of SLIC score among the study records. Surgery was performed in 129 patients and conservative treatment in 81 patients. Figure 2 display the distribution of management approaches done among the study records.

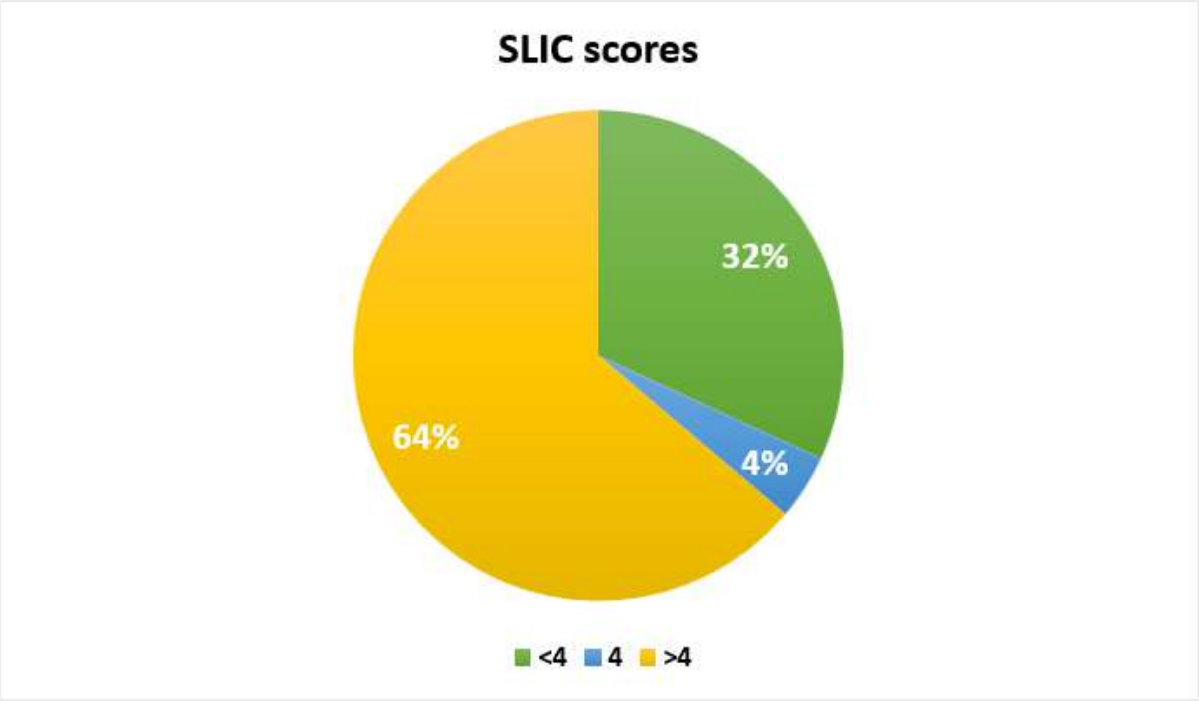


Figure 1. Distribution of SLIC score category among the study records

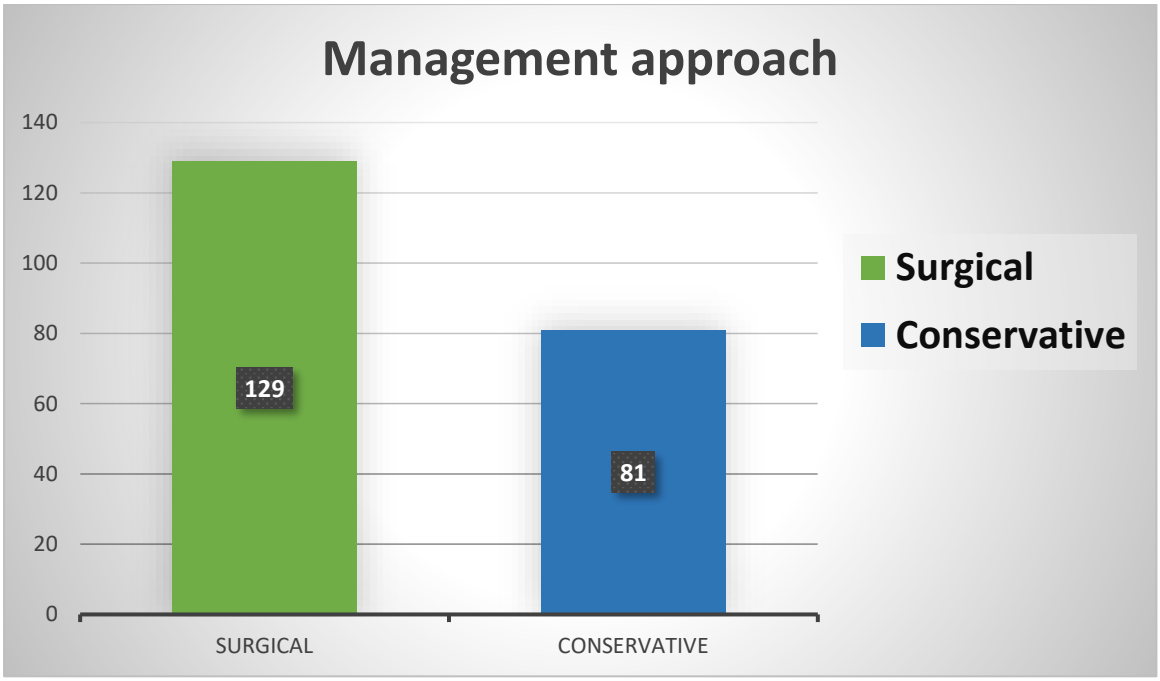


Figure 2. Distribution of management approaches done among the study records

Neurological outcomes were favorable, with 47.6% showing improvement, 46.7% remaining unchanged, and 5.7% deteriorating. Injury morphology was significantly associated with neurological outcome ($\chi^2 = 27.188$, $p = 0.002$), with rotational and translational injuries showing greater improvement. Management modality also showed a significant association ($\chi^2 = 18.14$, $p < 0.001$), as 58.1% of surgically managed patients improved compared to 30.9% in the conservative group. Table 3 shows the association between morphology of the injury and type of management with the Neurological outcome among the study records.

Table 3. Association between morphology of the injury and type of management with the Neurological outcome among the study records

Variables		**Neurological Outcome**			**Total**	**Chi Square Value**	**p value**
		Deteriorated	**Improved**	**No Change**			
Morphology Type	**Burst**	2	10	24	36	27.188	**0.002***
		5.6%	27.8%	66.7%	100.0%		
	Compression	2	6	13	21		
		9.5%	28.6%	61.9%	100.0%		

	Distraction	3	39	26	68		
		4.4%	57.4%	38.2%	100.0%		
	No abnormality	4	6	13	23		
		17.4%	26.1%	56.5%	100.0%		
	Rotation	0	18	12	30		
		0.0%	60.0%	40.0%	100.0%		
	Translation	1	21	10	32		
		3.1%	65.6%	31.3%	100.0%		
Management	**Conservative**	9	25	47	81	18.14	**<0.001***
		11.1%	30.9%	58.0%	100.0%		
	Surgical	3	75	51	129		
		2.3%	58.1%	39.5%	100.0%		
SLIC Score Category	**<4**	7	19	41	67	20.816	**<0.001***
		10.4%	28.4%	61.2%	100.0%		
	=4	1	2	6	9		
		11.1%	22.2%	66.7%	100.0%		
	>4	4	79	51	134		
		3.0%	59.0%	38.1%	100.0%		

*p-value<0.05 – Statistically significant

Table 4 presents the distribution of management strategies according to the Subaxial Injury Classification (SLIC) score among the study records (n = 210). Among patients with a SLIC score ≤ 4 (non-operative category), the majority were managed conservatively (90.8%), while only 7 patients (9.2%) underwent surgical intervention. In contrast, among patients with a SLIC score > 4 (surgical category), most were treated surgically (91.0%), with only 12 patients (9.0%) managed conservatively. Overall, 191 patients (90.9%) received SLIC appropriate management, and only 19 patients (9.1%) required management other way. These findings demonstrate a clear association between higher SLIC scores and operative management, indicating good adherence to SLIC-guided treatment choices in the study records.

Table 4. SLIC & Management Distribution

SLIC category	Management done		
	Conservative	Surgical	Grand Total
≤4 - Non-operative	69	7	76
>4 - Surgery	12	122	134
Grand Total	81	129	210

Patients who had surgical management had significantly higher morphology, DLC, neurology, and total SLIC scores ($p < 0.001$) and longer ICU stay (3.60±1.70 vs 1.00±0.00 days). Table 5 shows the SLIC scores and duration of ICU stay among management categories in the study records. ROC analysis demonstrated excellent predictive performance of the total SLIC score for surgical management (AUC = 0.940; sensitivity 94.6%, specificity 85.2%, accuracy 91.0% positive predictive value (PPV) of 91.0%, negative predictive value (NPV) of 90.8%, and overall diagnostic accuracy of 91.0%. The positive likelihood ratio (LR+) of 6.39 and negative likelihood ratio (LR−) of 0.06), confirming its strong clinical utility in guiding treatment of cervical spine injuries. Table 6 presents the diagnostic accuracy of SLIC scores in predicting surgical requirement among Sub axial cervical injuries. The ROC analysis identified a SLIC score of >4 as the optimal threshold (By Youden Index) that provided the best balance between sensitivity and specificity for predicting the outcome in our study population. Figure 3 display the ROC curve for SLIC score >4 as cut off value in predicting surgical management.

Table 5. SLIC and ICU stay across management categories

Variable	Management	N	Mean	t value	p value
Morphology Score	**Conservative**	81	1.42±1.04	-14.827	**<0.001***
	Surgical	129	3.33±0.82		
DLC Score	**Conservative**	81	0.68±0.54	-19.306	**<0.001***
	Surgical	129	1.90±0.37		

Neurology Score	**Conservative**	81	0.88±0.93	-13.631	**<0.001***
	Surgical	129	2.40±0.69		
Total SLIC Score	**Conservative**	81	2.98±1.98	-18.773	**<0.001***
	Surgical	129	7.64±1.59		
ICU Stay days	**Conservative**	42	1.00±0.00	-9.897	**<0.001***
	Surgical	129	3.60±1.70		

*p-value<0.05 – Statistically significant

Table 6. Diagnostic accuracy of SLIC scores in predictive surgical requirement among Sub axial cervical injuries

Parameter	**Value**
Sensitivity	94.60%
Specificity	85.20%
Positive Predictive Value (PPV)	91.00%
Negative Predictive Value (NPV)	90.80%
Accuracy	91.00%
LR+	6.39
LR−	0.06

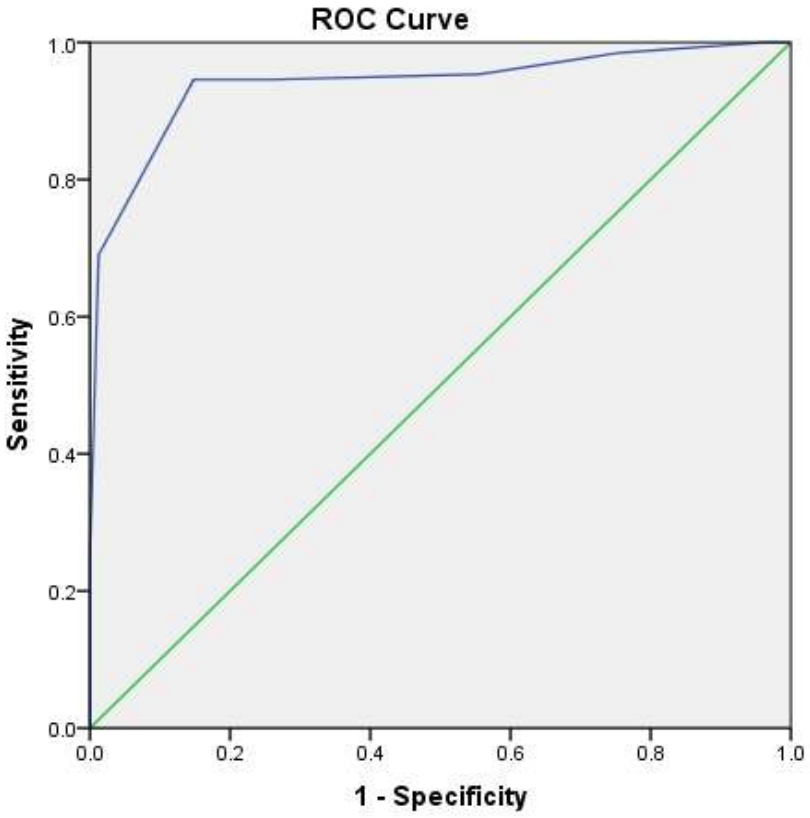


Figure 3. ROC Curve for SLIC >4 in predicting Surgical requirements among Sub axial cervical injuries

Discussion

The application of the Subaxial Injury Classification (SLIC) system as a primary tool for clinical decision-making is reinforced by the findings of this study, which demonstrate high diagnostic accuracy and strong adherence to treatment algorithms.

Our study's mean age of 45.21 years and male predominance (69.5%) align closely with previous literature. Mascarenhas et al. reported a similar average age of 49.4 years with a 76.7% male distribution.[15] In contrast, earlier smaller cohorts by Joaquim et al. observed slightly younger means in their non-surgical (41.1 years) and surgical (44.3 years) groups [16]. The predominance of road traffic accidents (61.0%) as the leading etiology mirrors the findings of Sharif et al., who noted that the subaxial spine is highly predisposed to injury due to its substantial motion, with over 50% of injuries occurring between C5 and C7. Our data specifically identified C5 (37.6%) as the most involved level, consistent with the biomechanical susceptibility noted by Sharif et al [8].

The 90.9% rate of SLIC-appropriate management observed in our study is highly congruent with external validation studies. Joaquim et al. [16] reported a 92.1% match between SLIC-proposed and actual treatment, while Samuel et al. found even higher concordance rates of 93.6% for non-surgical and 96.3% for surgical patients [17]. These results collectively validate the SLIC system as a practical classification that provides a consistent algorithm for diagnosis and management, as emphasized by Sharif et al. [8].

Our finding that patients undergoing surgery had significantly higher mean total SLIC scores (7.64 vs. 2.98, $p < 0.001$) is supported by Samuel et al., who reported a similar significant difference (7.14 vs. 2.22, $p < 0.001$) [17]. Furthermore, our study identified that only 9.2% of patients with a score < 4 underwent surgery, matching the 7.1% to 8.3% outlier rates reported by Joaquim et al. for patients treated outside the standard algorithm due to clinical judgment or head injuries [16].

While our methodology integrated MRI-based DLC assessment, Mascarenhas et al. suggest that CT alone may be sufficient for initial triage, yielding a nearly identical AUC (0.88) compared to combined CT and MRI (0.87) [15]. However, Sharif et al. (WFNS Spine Committee) reached a 100% consensus recommending the use of MRI to achieve a more precise classification [8]. Our study's reliance on MRI for scoring the DLC (mean 1.43) likely contributed to its high diagnostic performance, though Mascarenhas et al. warn that MRI may upstage scores due to its high sensitivity but lower specificity for ligamentous injuries [15].

Our study demonstrates that management modality significantly influences neurological recovery, with 58.1% of surgically managed patients showing improvement compared to 30.9% in the conservative group. This is echoed by Joaquim et al. [16], who found that 72% of patients with incomplete deficits improved their ASIA status post-surgery. Sharif et al. further support early surgical intervention (within 12–72 hours) to improve these outcomes [8].

Additionally, the ROC analysis in our study yielded an AUC of 0.94, indicating excellent predictive performance for surgical requirement. This exceeds the "good" accuracy (AUC 0.87–0.88) reported by Mascarenhas et al. [15] and is very much comparable with the findings by Piazza et.al., among pediatric population [18]. This difference may stem from our study's structured secondary data review in a high-volume tertiary center, which may have tighter adherence to standardized protocols than the retrospective cohorts used in earlier validation studies.

It is also to be taken into account that, the modified SLIC score proposed by Hitti et al. also suggests that time to stabilization is a significant predictor of non-operative failure, a variable not captured in the original SLIC system but relevant for clinical practice [19].

Conclusion

Overall, the findings of this study demonstrate that the SLIC scoring system has high predictive validity, strong diagnostic accuracy, and significant clinical applicability in a tertiary care trauma setting. Higher SLIC scores were consistently associated with surgical management, greater injury severity, and improved neurological outcomes following appropriate intervention, supporting its role as an effective decision-making tool in the management of Sub axial cervical spine trauma.

Limitations

As a retrospective record-based analysis, the study relied on the availability and completeness of existing clinical documentation, which may have limited the inclusion of potential confounders in analysis. Also, interobserver verification of the SLIC scoring was not performed, as the scores were derived from available clinical

and radiological documentation in patient records.

Author Contributions

VS has contributed to the conceptualization, design of the study, literature search, data acquisition, manuscript editing and review. MM contributed towards data acquisition Statistical analysis, Manuscript review and editing. VS acted as the corresponding author for this manuscript

Conflicts of interest

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

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ORIGINAL ARTICLE

Retrospective Analysis of Pediatric Appendicitis Treated in a Tertiary Care Hospital in Puducherry

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Abstract

Introduction: Acute appendicitis is one of the most common surgical emergencies in children and usually presents with characteristic clinical features, with diagnosis supported by laboratory parameters and imaging modalities such as abdominal ultrasound and computed tomography (CT) scans. **Materials and Methods:** This retrospective cohort study was conducted over a period of three years at Sri Manakula Vinayagar Medical College and Hospital, Puducherry, and included all children below 14 years of age who were diagnosed with acute appendicitis and underwent laparoscopic appendicectomy. Demographic details, clinical symptoms, laboratory investigations, radiological findings, operative findings, postoperative complications, and histopathological reports were analyzed. **Results:** A total of 246 children were included in the study. Right lower abdominal pain was the most common presenting symptom, observed in 96.7% (238/246) of children, followed by nausea in 73% (179/246), vomiting in 69.9% (172/246), and fever in 57% (140/246). On abdominal examination, right iliac fossa tenderness was present in 91% (223/246) of patients, rebound tenderness in 83% (204/246), Blumberg's sign in 77% (189/246), and Cope's psoas test was positive in 29% (71/246) of cases. Laboratory investigations revealed leukocytosis in 79% (194/246) of patients. **Conclusion:** Acute appendicitis should be considered in children presenting with acute abdominal pain. The findings of this study emphasize the importance of careful clinical evaluation supported by appropriate laboratory and radiological investigations for early diagnosis and timely management, along with the need for standardized documentation in pediatric appendicitis.

Keywords: Acute appendicitis, Pediatric appendicitis, Laparoscopic appendicectomy, Abdominal pain in children

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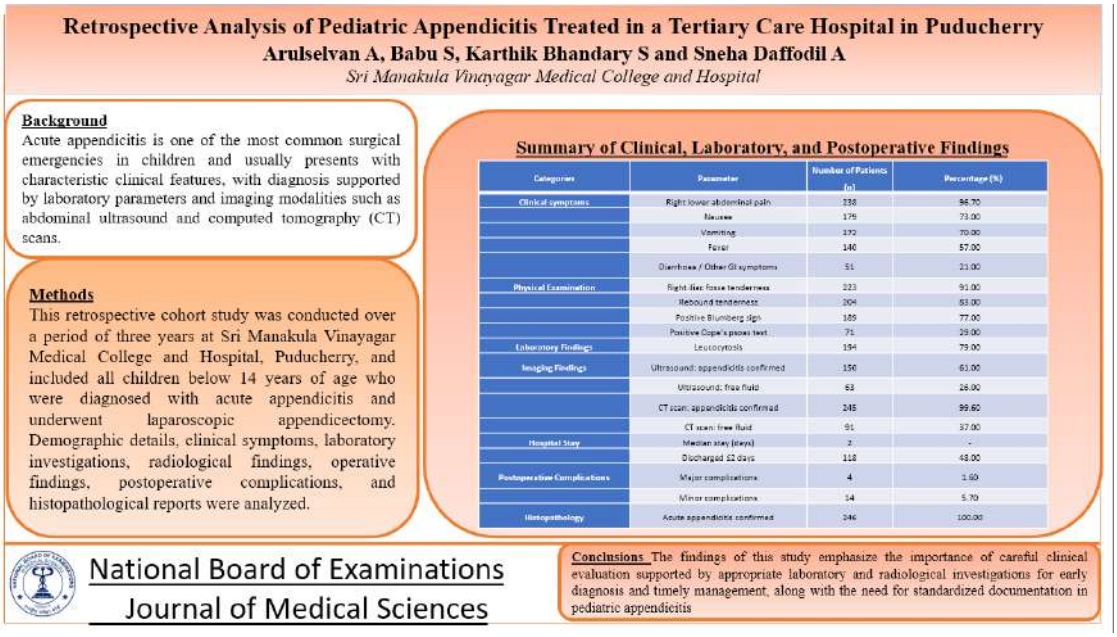
Graphical Abstract



Introduction

Acute appendicitis is one of the most common causes of acute abdominal pain requiring emergency medical attention in children and adolescents. It represents a major proportion of surgical emergencies in the Pediatric population. The estimated lifetime risk of developing appendicitis is approximately 8.6% in males and 6.7% in females. The disease most frequently occurs during the second decade of life and shows an increased risk among the male patients [1-3].

In the United States, appendicitis has been reported as one of the leading causes of children getting hospitalized and ranks among the most common pediatric surgical conditions, with an estimated hospitalization rate of about 97.4 cases per 100,000 children [4]. Globally, the occurrence of acute appendicitis in the pediatric age group has been estimated to range between 100 and 151 cases per 100,000 person-years, although the incidence may vary across worldwide [5].

The diagnosis of appendicitis is mainly based on clinical assessment, including history and physical examination. However, due to the variability of symptoms in children, several clinical scoring systems have been developed to assist clinicians in improving diagnostic accuracy. These scoring methods help in identifying patients who may require further evaluation or surgical management [6-9]. Laboratory investigations are commonly used as supportive tools during the diagnostic process. Tests such as complete blood count, absolute neutrophil count, and measurement of C-reactive protein (CRP) levels are frequently performed to evaluate the presence of inflammation. In addition, imaging techniques including ultrasonography, computed tomography (CT), and magnetic resonance imaging (MRI) are often utilized to help confirm the diagnosis and reduce diagnostic uncertainty. Traditionally, appendicectomy has been considered the standard treatment

for pediatric appendicitis. However, in recent years, non-operative management using antibiotics has gained attention as a potential alternative treatment option in selected patients with uncomplicated appendicitis. Ongoing research continues to evaluate the safety, effectiveness, and long-term outcomes of this conservative treatment [2,3,10].

Our aim is to analyse the symptoms, diagnostic approaches, intraoperative observations, and recovery outcomes of children with acute appendicitis, which is managed by laparoscopic appendicectomy at a tertiary care hospital in Puducherry.

Methodology

This study was a three-year hospital-based retrospective cohort conducted at Sri Manakula Vinayagar Medical College and Hospital, Puducherry. It included all children under 14 years of age who were diagnosed with acute appendicitis and underwent laparoscopic appendicectomy. The minimum sample size was estimated using the single population proportion formula $n=Z^2pq/d^2n = Z^2pq/d^2n=Z^2pq/d^2$. Previous literature (Awuah et al.) [26] reports that acute appendicitis accounts for approximately 8% of abdominal pain cases in children. Considering this expected proportion ($p = 0.08$), a 95% confidence level ($Z = 1.96$), and an absolute precision of 5%, the minimum required sample size was calculated as 113. Since this was a retrospective hospital-based study, all eligible pediatric appendicitis cases managed during the study period were included, yielding a final sample size of 246 patients.

Materials

The following resources were used for data collection and analysis:

1. **Hospital Records:** Medical case files and records.
2. **Demographic Data:** Age, sex, weight, and relevant personal information.
3. **Clinical Assessment Tools:** Standardized forms to record symptoms, duration, and examination findings.
4. **Laboratory Investigations:** Blood tests including complete blood count (CBC), C-reactive protein (CRP), and other routine biochemical parameters.
5. **Radiological Imaging:** Ultrasound and/or CT scan reports confirming acute appendicitis.
6. **Surgical Records:** Operative notes documenting intraoperative findings.
7. **Postoperative Follow-up Data:** Records of complications, duration of hospital stay, and recovery outcomes.
8. **Histopathological Reports:** Analysis of resected appendix confirming diagnosis and pathological grading.
9. **Data Collection Tools:** Pre-designed data sheets and digital spreadsheets for systematic recording and the data collected were entered in Microsoft Excel 2019 and the results were analyzed using SPSS software version 23.0. Quantitative data was expressed in Mean, Range, Frequency and Distribution.

Results

In this retrospective cohort study, a total of 246 Pediatric patients diagnosed with acute appendicitis and managed with laparoscopic appendicectomy were analyzed. The study population predominantly presented with classical

features of appendicitis. Right lower abdominal pain was the most frequently reported symptom, observed in 96.7% (238/246) of children, underscoring the typical clinical presentation of the disease. Gastrointestinal symptoms were also common, with nausea reported in 73% (179/246) and vomiting in 70% (172/246) of cases. Fever was documented in 57% (140/246) of patients, while less frequent symptoms such as diarrhoea or generalized malaise were reported in 21% (51/246) of the cohort.

On physical examination, localized tenderness in the right iliac fossa was present in 91% (223/246) of children, while rebound tenderness was observed in 83% (204/246). A positive Blumberg sign was noted in 77% (189/246), indicating peritoneal irritation, and Cope's psoas test was positive in 29% (71/246), suggestive of retrocecal appendiceal involvement. These findings collectively reinforce the predominance of classic clinical signs in Pediatric acute appendicitis, though atypical presentations were noted in a minority of cases.

Laboratory investigations revealed leucocytosis in 79% (194/246) of patients, serving as a supportive marker for inflammation and aiding in the diagnostic workup. Radiological assessment played a crucial role in confirming the diagnosis: ultrasonography identified appendicitis in 61% (150/246) of patients, with free fluid noted in 26% (63/246), whereas CT imaging demonstrated near-universal diagnostic accuracy, confirming appendicitis in 245 out of 246 patients and detecting free peritoneal fluid in 37% (91/246). These findings highlight the complementary roles of ultrasonography and CT in pediatric appendicitis evaluation.

The postoperative course was generally favourable. The duration of hospital stay ranged from 1 to 6 days, with a median of 2 days, reflecting the minimally invasive nature of laparoscopic management. Nearly half of the patients (48%, 118/246) were discharged within the first two postoperative days. Complications were relatively uncommon, with major complications occurring in only 4 patients and minor complications in 14, demonstrating the safety and efficacy of laparoscopic appendicectomy in the Pediatric population.

Histopathological examination of all resected appendices confirmed to be features consistent with acute appendicitis, including suppurative changes in some specimens. No cases of neoplasia or other unexpected pathology were identified among the specimens included in the study.

Overall, the findings of this study emphasize the classical clinical presentation of acute appendicitis in children, the high diagnostic yield of laboratory and imaging investigations, the effectiveness of laparoscopic appendicectomy, and the favourable postoperative outcomes with minimal complications. These results underscore the importance of early recognition and timely surgical intervention in optimizing Pediatric patient care (Table 1).

Table 1. Summary of Clinical, Laboratory, and Postoperative Findings in 246 Pediatric Patients with Acute Appendicitis

Categories	Parameter	Number of Patients (n)	Percentage (%)
Clinical symptoms	Right lower abdominal pain	238	96.70
	Nausea	179	73.00
	Vomiting	172	70.00
	Fever	140	57.00
	Diarrhoea / Other GI symptoms	51	21.00
Physical Examination	Right iliac fossa tenderness	223	91.00
	Rebound tenderness	204	83.00
	Positive Blumberg sign	189	77.00
	Positive Cope's psoas test	71	29.00
Laboratory Findings	Leucocytosis	194	79.00
Imaging Findings	Ultrasound: appendicitis confirmed	150	61.00
	Ultrasound: free fluid	63	26.00
	CT scan: appendicitis confirmed	245	99.60
	CT scan: free fluid	91	37.00
Hospital Stay	Median stay (days)	2	-
	Discharged ≤2 days	118	48.00
Postoperative Complications	Major complications	4	1.60
	Minor complications	14	5.70
Histopathology	Acute appendicitis confirmed	246	100.00

Discussion

In our study, the most common symptom and sign of appendicitis were abdominal pain and rebound tenderness, similar to the findings reported by Benabbas et al. [11]. Doctors described abdominal pain in different ways, including “diffuse abdominal pain,” “right lower quadrant pain,” and “pain radiating to the right lower quadrant,” depending on the physical examination and the child’s ability to communicate. All these descriptions were considered indicative of possible appendicitis. Fever was noted either based on the parents’ history or by measuring the child’s temperature at the hospital.

Although tools like the Alvarado Score and can help exclude appendicitis in children [12], our study relied primarily on a high clinical suspicion for children presenting with abdominal pain. According to various clinical scores and guidelines, routine laboratory tests and measurement of inflammatory markers are recommended to evaluate the intensity of inflammation and to determine whether imaging is necessary. In this study, all children suspected of acute appendicitis underwent a complete blood count and CRP measurement. Based on these results, radiological tests were performed to confirm the diagnosis.

Three imaging methods are commonly reported for diagnosing appendicitis: ultrasound, CT scan, and MRI. A systematic review by Doria et al in 2006 found that CT scans were more sensitive than ultrasound in detecting appendicitis in children [13]. Conversely, a recent study by Lee and Yun showed that emergency physician–performed point-of-care ultrasound reached 95% sensitivity and specificity in Pediatric appendicitis [14]. Additionally, Kharbanda et al highlighted that ultrasound is cost-effective, while higher CT use is associated with increased expenses, supporting the use of ultrasound as the initial imaging choice for children [15].

In our hospital, abdominal ultrasound is routinely used as the first-line imaging tool to diagnose appendicitis in children. This was applied to all patients except two, who were referred from another facility with a CT scan already confirming the diagnosis. Ultrasound does have limitations: it requires skilled operators, is dependent on the examiner, can be affected by the child’s body habitus and may yield different results in Pediatric patients compared to adults [15].

CT scans in children with appendicitis have reported sensitivities ranging from 94% to 97% and specificities from 94% to 99%. The main benefits of CT imaging are rapid image acquisition and independence from the operator’s experience. Limitations include limited availability in certain regions, higher costs, and exposure to ionizing radiation [3,16,17]. At our hospital, we coordinate with the radiology team to minimize radiation and reserve CT scans for patients whose ultrasound results are unclear.

MRI has shown sensitivities of 96–97% and specificities of 96–98%, with the major advantage of avoiding radiation exposure [3,18,19]. However, its routine use is limited by longer scan times, higher cost, need for sedation, and restricted availability, making it impractical for standard Pediatric appendicitis diagnosis in our facility.

There is ongoing discussion about treating early or suspected appendicitis non-surgically with antibiotics, reserving surgery for more advanced cases. Possible

advantages of this approach include fewer CT scans, reduced radiation exposure, lower rates of perforation and negative appendicectomy, and decreased risks related to anesthesia and surgery. Potential disadvantages include over-treatment, disease recurrence, and progression [20]. Svensson et al found that nonoperative management can be safe; however, failure rates increase in the presence of an appendicolith, in which case surgical intervention is recommended [2]. In our hospital, Pediatric patients are usually treated surgically, with nonoperative management applied only in selected scenarios and these cases were excluded from this study.

Research indicates that complication rates do not differ significantly between emergent and urgent appendectomies. Therefore, children presenting overnight were admitted and operated on the following day to reduce stress for both patients and staff [3]. Children have a higher risk of appendicitis perforation than adults, with a rate of 7.7% within the first 24 hours, increasing over time. Perforation is more strongly linked to pre-hospital delays than delays within the hospital [21]. Other factors influencing perforation include age, race, socioeconomic status, insurance coverage, and the presence of appendicolith [22,23]. Tan et al. also reported that higher body temperature at admission increases the likelihood of perforation [24]. Kim et al. demonstrated that are operated by Pediatric specialists are associated with shorter operative times, reduced hospital stays, higher rates of laparoscopic procedures, and less peritoneal drainage compared to those performed by general surgeons. However, access to Pediatric surgeons may be limited in certain regions [25].

Conclusion

Acute appendicitis in children remains a largely clinical diagnosis, grounded in careful history-taking and thorough physical examination, with laboratory tests and imaging serving as valuable supportive tools. This study underscores the importance of structured documentation and the selective, judicious use of investigations, which together enhance diagnostic accuracy, guide timely management, and reduce unnecessary interventions. By integrating clinical expertise with targeted testing, healthcare providers can streamline care, minimize complications, and improve outcomes for pediatric patients. Ultimately, adopting a standardized, evidence-based approach ensures safe, efficient, and effective management of appendicitis in children, setting a benchmark for both clinical practice and future research.

Limitations

The study involved a small number of patients. Not all patients underwent the same diagnostic tests, leading to variable data. Only children diagnosed clinically and supported by imaging were included, which may introduce selection bias. Variability in ultrasound results could occur due to different operators performing the scans. Some patients were managed non-surgically and were excluded from the study.

Recommendations

Early clinical suspicion of acute appendicitis in children presenting with abdominal pain is essential for timely diagnosis and management. Clinical

evaluation should be supported by appropriate laboratory investigations and imaging, particularly ultrasound as the first-line modality. Standardized documentation and prompt laparoscopic intervention can help reduce complications and hospital stay. Further multicentric prospective studies are recommended to strengthen the evidence for optimal management of pediatric appendicitis. Future research should focus on large, multicenter prospective studies incorporating clinical scoring systems, advanced imaging, and emerging diagnostic tools such as biomarkers or AI-assisted decision support to further improve the early and accurate diagnosis of acute appendicitis in children.

Statements and Declarations

Conflicts of interest

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

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This study provides regional clinical data on the presentation, diagnostic approaches, and outcomes of pediatric acute appendicitis in a tertiary care setting. The findings emphasize the importance of early clinical suspicion supported by appropriate laboratory and radiological investigations for timely diagnosis and management. The study also contributes to improving standardized documentation and management strategies for pediatric appendicitis in similar healthcare settings.

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Evaluation of Knowledge on Intestinal Parasites and Digestive Wellness Practices Among Healthcare Students in Chennai, South India

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Abstract

Background: Intestinal parasite infection (IPI) is a public health issue in developing countries associated with poverty, illiteracy, hot, humid tropical weather, polluted drinking water, and poor sanitation. Common symptoms include intestinal bleeding, nutritional deficiencies, and tissue damage. Lack of knowledge might contribute to these illnesses. Therefore, this study aimed to explore the attitudes and knowledge of medical and paramedical students regarding IPIs in Chennai. **Methods:** This observational study was conducted among the Medical and paramedical Students from ACS Medical College and Hospital in Chennai. An online questionnaire was administered using Google Forms. The questionnaires included details about the students' information, digestive health, common IPIs, and deworming. The collected data were then analysed. **Results:** Of the 250 participants, 52.8% were female, 69.6% were 18–24 years old, 54.8% were MBBS, and 45.2% were paramedical students. Medical students most commonly practiced hourly handwashing (73.7%), whereas paramedical students more frequently washed hands only after washroom use (26.5%), indicating comparatively better hand hygiene practices among medical students. 82% reported that inadequate sanitation was a reason for IPI spread. 54.4% had no IPI history, 14.4% were unclear, and 31.2% had IPI. **Conclusion:** Our study reveals significant gaps in knowledge, attitudes, and practices concerning gut health and intestinal parasite diseases between medical and paramedical students. Focused curricular improvement, health education, and regular deworming activities are essential for enhancing awareness, promoting preventative behaviours, and improving overall improvement in gut health.

Keywords: Gastrointestinal parasites, Attitude, Knowledge, Deworming, Practices

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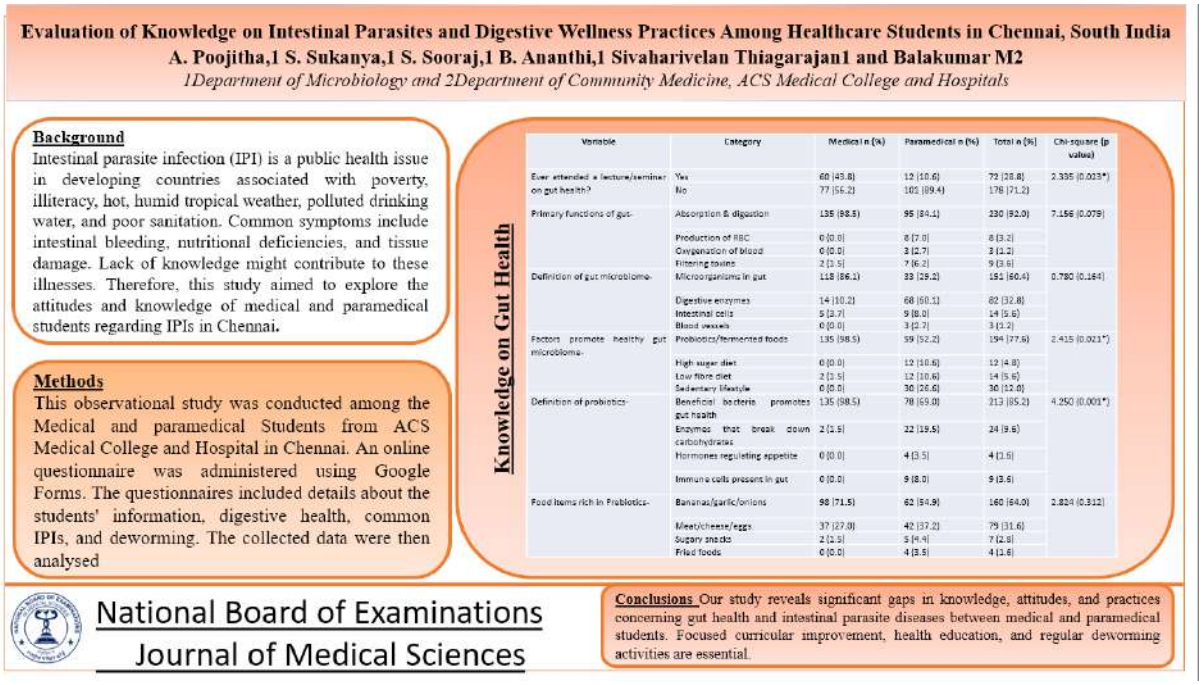
Graphical Abstract



Introduction

Three primary groups of parasites can cause illnesses in humans: helminths, ectoparasites, and protozoa. Ascaris, Entamoeba, Toxoplasma, Cyclospora, Giardia, and Cryptosporidium are among the intestinal parasite infections (IPIs) contributing to the significant disease burden globally [1]. According to the WHO's 2020 Roadmap on Neglected Tropical Diseases (NTDs), soil-transmitted helminth infections (STHI), Ascaris lumbricoides, and Trichuris trichura are classified as one of the 17 NTDs and a significant public health concern [2].

Approximately 3.5 billion people are affected by IPIs, which sicken 450 million individuals, particularly children and women in underdeveloped countries, suffering from the disease. This illness has been linked to 200,000 deaths annually [3]. The high prevalence in developing nations is most likely caused by poor personal hygiene and sanitation. In addition, poverty, illiteracy, hot, humid tropical weather, and polluted drinking water supplies contribute to the incidence of these illnesses [4]. Common symptoms include intestinal bleeding, nutrient malabsorption, nutritional deficiencies, and tissue damage, which can lead to growth retardation and adversely impact the academic performance of students [5].

Removing IPIs is extremely difficult in India due to the wide variety of parasite combinations in different regions. Hookworm infestations are more common in South India than those of T. trichura and A. lumbricoides [6].

The WHO recommends integrated approaches to control IPIs including improved water, sanitation, and hygiene (WASH), behaviour modification, snail control, environmental management, and preventive chemotherapy, which consists of the periodic administration of anthelmintic medications (praziquantel for

schistosomiasis and albendazole or mebendazole) [7].

The Indian government launched a National Deworming Day (NDD) on 10 February and a Mop-up Day on 15 February in 2015 to deworm all pre-school and school children aged 1 to 19 through schools and ICDS facilities. At least once a year, on NDD, children aged 2–19 [8]. Additionally, health education among kids might serve as a preventive measure. A study in India found that younger people's lack of worm knowledge contributes to worm infection [9].

Healthcare students serve as future health educators, making it essential for them to adapt practices that enhance gut health. However, there is a lack of studies assessing knowledge and the adoption of preventive practices regarding this health issue in developing nations, where the curriculum of schools offers limited exposure to gut health. So, this study aimed to assess the parasitic infection knowledge and attitudes among preclinical medical and paramedical students at a Chennai medical school.

The objectives of the study

To analyse the knowledge on Intestinal parasites among medical and paramedical students.

To assess the awareness and practice regarding digestive health and deworming.

Methods

This institute-based cross-sectional study was conducted among preclinical medical and paramedical students at ACS Medical College and Hospital, Chennai, Tamil Nadu, India. The study population included Phase I MBBS students and first-year Allied Health Science students. Phase II, Phase III students and resident doctors were excluded.

A total of 250 students participated in the study. Participants were selected using convenience sampling, as the study targeted students who were readily available and willing to participate during the study period within the institution. This approach was adopted due to feasibility and accessibility of participants. However, convenience sampling may limit the generalizability of the findings to other populations.

Questionnaire Development and Validation

The questionnaire was developed after an extensive review of relevant literature on intestinal parasitic infections, gut health, and deworming practices. The instrument consisted of three sections:

1. Sociodemographic characteristics
2. Knowledge regarding intestinal parasites and gut health
3. Attitudes and practices related to hygiene and deworming

To ensure content validity, the questionnaire was reviewed by subject experts from the Departments of Microbiology and Community Medicine. Necessary modifications were made based on expert suggestions.

Pilot Testing and Reliability

Prior to the main study, the questionnaire was pilot tested among 20 students who were not included in the final analysis to assess clarity, relevance, and feasibility of the questions. Based on feedback from the pilot study, minor revisions were made to improve clarity and comprehension.

The internal consistency of the questionnaire was assessed using Cronbach's alpha, which demonstrated acceptable reliability (>0.70), indicating that the instrument was suitable for assessing knowledge, attitude, and practice variables.

Data Collection

The questionnaire was distributed electronically using Google Forms through institutional email and WhatsApp groups. Participation was voluntary and responses were collected anonymously to maintain confidentiality. Only fully completed responses were included in the final analysis.

Statistical Analysis

Data were exported to Microsoft Excel and analyzed using statistical software. Categorical variables were summarized using frequencies and percentages.

The Chi-square test of independence was used to assess associations between medical students and paramedical students, which constituted the two comparison groups in the study.

The following assumptions of the Chi-square test were considered:

- Independence of observations
- Categorical nature of variables
- Adequate expected cell frequencies

Where small expected cell counts occurred, findings were interpreted cautiously.

A two-tailed p-value <0.05 was considered statistically significant.

Results

In our study, out of the 250 participants, 69.6% were aged 20 years or younger, whereas 30.4% were aged 21 to 25 years. The study comprised 47.2% men and 52.8% women. Of the participants, 45.2% were AHS students, while 54.8% were MBBS students. The responses from each of the subjects regarding their knowledge, perception, and practice of IPIs are displayed in Tables 1, 2, 3 and 4.

Table 1. Knowledge on Gut Health

Variable	**Category**	**Medical n (%)**	**Paramedical n (%)**	**Total n (%)**	**Chi-square (p value)**
Ever attended a lecture/seminar on gut health?	Yes	60 (43.8)	12 (10.6)	72 (28.8)	2.335 (0.023*)
	No	77 (56.2)	101 (89.4)	178 (71.2)	
Primary functions of gut-	Absorption & digestion	135 (98.5)	95 (84.1)	230 (92.0)	7.156 (0.079)
	Production of RBC	0 (0.0)	8 (7.0)	8 (3.2)	
	Oxygenation of blood	0 (0.0)	3 (2.7)	3 (1.2)	
	Filtering toxins	2 (1.5)	7 (6.2)	9 (3.6)	
Definition of	Microorganisms in	118	33 (29.2)	151	0.780

gut microbiome-	gut	(86.1)		(60.4)	(0.164)
	Digestive enzymes	14 (10.2)	68 (60.1)	82 (32.8)	
	Intestinal cells	5 (3.7)	9 (8.0)	14 (5.6)	
	Blood vessels	0 (0.0)	3 (2.7)	3 (1.2)	
Factors promote healthy gut microbiome-	Probiotics/fermented foods	135 (98.5)	59 (52.2)	194 (77.6)	2.415 (0.021*)
	High sugar diet	0 (0.0)	12 (10.6)	12 (4.8)	
	Low fibre diet	2 (1.5)	12 (10.6)	14 (5.6)	
	Sedentary lifestyle	0 (0.0)	30 (26.6)	30 (12.0)	
Definition of probiotics-	Beneficial bacteria promotes gut health	135 (98.5)	78 (69.0)	213 (85.2)	4.250 (0.001*)
	Enzymes that break down carbohydrates	2 (1.5)	22 (19.5)	24 (9.6)	
	Hormones regulating appetite	0 (0.0)	4 (3.5)	4 (1.6)	
	Immune cells present in gut	0 (0.0)	9 (8.0)	9 (3.6)	
Food items rich in Prebiotics-	Bananas/garlic/onions	98 (71.5)	62 (54.9)	160 (64.0)	2.824 (0.312)
	Meat/cheese/eggs	37 (27.0)	42 (37.2)	79 (31.6)	
	Sugary snacks	2 (1.5)	5 (4.4)	7 (2.8)	
	Fried foods	0 (0.0)	4 (3.5)	4 (1.6)	

The table presents the knowledge levels of medical and paramedical students regarding intestinal health. A total of 72 participants (28.8%) had attended a lecture or seminar on gut health, whereas 178 participants (71.2%) had not and p value was 0.023. Two hundred thirty participants (92.0%) indicated that absorption and digestion are the primary functions of the gut. 151 individuals (60.4%) indicated that the gut microbiome consists of bacteria present in the gut. 194 individuals, representing 77.6%, reported that probiotics or fermented foods contributed to the maintenance of their gut flora health with p value 0.01. 213 individuals (85.2%) indicated that probiotics are beneficial bacteria that contribute to gut health. A total of 160 participants, representing 64.0%, reported consuming foods rich in prebiotics, such as bananas, garlic, and onions.

Table 2. Knowledge on Intestinal Parasitic Infections (All Responses)

Variable	Category	Medical n (%)	Paramedical n (%)	Total n (%)	Chi-square (p value)
Ascaris lumbricoides is a	Protozoa	31 (22.6%)	43 (38.1%)	74 (29.6%)	1.613 (.203)
	Nematode	89 (65.0%)	64 (56.6%)	153 (61.2%)	
	Cestode	8 (5.8%)	6 (5.3%)	14 (5.6%)	
	Trematode	9 (6.6%)	0 (0.0%)	9 (3.6%)	
Common symptoms of worm infestation	Abdominal pain/anaemia/weight loss	123 (89.8)	75 (66.4)	198 (79.2)	6.315 (0.215)
	Headache/fever	11 (8.0)	19 (16.8)	30 (12.0)	
	Joint pain/fatigue	3 (2.2)	10 (8.8)	13 (5.2)	
	Skin rash	0 (0.0)	9 (8.0)	9 (3.6)	
Factors contribute to the spread of parasitic infections	Poor sanitation and hygiene	114 (83.2%)	91 (80.5%)	205 (82.0%)	1.714 (.295)
	Consumption of spicy food	16 (11.7%)	12 (10.6%)	28 (11.2%)	
	Overuse of antibiotics	7 (5.1%)	2 (1.8%)	9 (3.6%)	
	Air pollution	0	8	8	

		(0.0%)	(7.1%)	(3.2%)	
Diagnostic test for gut health	Stool analysis	137 (100.0)	85 (75.2)	222 (88.8)	16.630 (0.001*)
	Blood pressure	0 (0.0)	15 (13.3)	15 (6.0)	
	Lung function test	0 (0.0)	6 (5.3)	6 (2.4)	
	ECG	0 (0.0)	7 (6.2)	7 (2.8)	
Most common Causative agent of amoebiasis in India	Entamoeba histolytica	119 (86.9)	79 (69.9)	198 (79.2)	9.431 (0.076)
	Giardia lamblia	4 (2.9)	15 (13.3)	19 (7.6)	
	Ascaris lumbricoides	14 (10.2)	17 (15.0)	31 (12.4)	
	Trichuris trichiura	0 (0.0)	2 (1.8)	2 (0.8)	
Infections with Ascaris lumbricoides are associated with the following complications?	Liver cirrhosis	22 (16.1%)	16 (14.2%)	38 (15.2%)	3.378 (.290)
	Intestinal obstruction and poor absorption	115 (83.9%)	63 (55.7%)	178 (71.2%)	
	Joint pain	0 (0.0%)	21 (18.6%)	21 (8.4%)	
	Pneumonia	0 (0.0%)	13 (11.5%)	13 (5.2%)	
How is it transmitted?	Ingestion of contaminated food or water	132 (96.4%)	67 (59.3%)	199 (79.6%)	12.083 (.283)
	Blood transfusion	0 (0.0%)	33 (29.2%)	33 (13.2%)	
	Sexual contact	5 (3.6%)	4 (3.5%)	9 (3.6%)	
	Respiratory droplets	0 (0.0%)	9 (8.0%)	9 (3.6%)	
Meaning of deworming	Removal by medication	135 (98.5)	63 (55.8)	198 (79.2)	0.295 (0.439)
	Surgical removal	2 (1.5)	30 (26.5)	32 (12.8)	
	Lab sterilization	0 (0.0)	5 (4.4)	5 (2.0)	
	None of the above	0 (0.0)	15 (13.3)	15 (6.0)	
medication used for deworming-	Albendazole	103 (75.2%)	40 (35.4%)	143 (57.2%)	1.023 (0.751)
	Metronidazole	24	28	52	

		(17.5%)	(24.8%)	(20.8%)	
	Amoxicillin	0 (0.0%)	44 (38.9%)	44 (17.6%)	
	Ciprofloxacin	10 (7.3%)	1 (.9%)	11 (4.4%)	
deworming medications safe for administration during pregnancy-	Yes, but only in the second and third trimesters	61 (44.5%)	42 (37.2%)	103 (41.2%)	3.913 (.430)
	No, deworming is contraindicated in pregnancy	44 (32.1%)	32 (28.3%)	76 (30.4%)	
	Yes, at any stage of pregnancy	20 (14.6%)	15 (13.3%)	35 (14.0%)	
	Only after childbirth	12 (8.8%)	24 (21.2%)	36 (14.4%)	
Hookworm treatment	Penicillin	0 (0.0%)	50 (44.3%)	50 (20.0%)	2.493 (0.844)
	Mebendazole/Albendazole	89 (65.0%)	44 (38.9%)	133 (53.2%)	
	Metronidazole	38 (27.7%)	5 (4.4%)	43 (17.2%)	
	Ciprofloxacin	10 (7.3%)	14 (12.4%)	24 (9.6%)	
Untreated worm infestation in children can results-	Malnutrition and stunted growth	135 (98.5%)	52 (46.0%)	187 (74.8%)	2.641 (0.001)*
	Improved digestion	2 (1.5%)	29 (25.7%)	31 (12.4%)	
	Increased intelligence	0 (0.0%)	21 (18.6%)	21 (8.4%)	
	Bone fractures	0 (0.0%)	11 (9.7%)	11 (4.4%)	

The table presents the knowledge levels of medical and paramedical students regarding intestinal parasitic diseases. One hundred fifty-three individuals (61.2%) of the participants identified Ascaris lumbricoides as a nematode. A total of 198 individuals (79.2%) reported common symptoms, including stomach ache, anemia, and weight loss. Two hundred five respondents (82.0%) attributed the issue to inadequate sanitation and hygiene. Two hundred twenty-two individuals (88.8%) indicated that stool analysis constitutes a diagnostic test. Entamoeba histolytica was identified as the causative agent of amoebiasis by 198 respondents (79.2%) with p value (0.001). Additionally, 178 respondents (71.2%) reported that intestinal blockage and poor absorption were issues. A total of 199 individuals, representing 79.6%, reported that their illness was a result of consuming contaminated food or water. Of the participants, 198 (79.2%) selected deworming as a method for eliminating worms using medication. 143 individuals (57.2%) identified albendazole as a medication effective in eliminating worms. Untreated infestation resulted in malnutrition and stunted growth in 187 cases (74.8%) with p value 0.001.

Table 3. Attitudes and Perceptions on Intestinal Parasitic Infections

Variable	Category	Medical n (%)	Paramedical n (%)	Total n (%)	Chi-square/p-value
Following Practices leading to the transmission of intestinal parasites-	Open defecation	17 (12.4)	19 (16.8)	36 (14.4)	0.932 (0.354)
	Walking barefooted	4 (2.9)	8 (7.1)	12 (4.8)	
	Drinking untreated water	9 (6.6)	17 (15.0)	26 (10.4)	
	Eating soil	0 (0.0)	15 (13.3)	15 (6.0)	
	None of the above	0 (0.0)	3 (2.7)	3 (1.2)	
	All of the above	107 (78.1)	51 (45.1)	158 (63.2)	
Gut health & immunity	The gut plays a crucial role in immune function by housing a large portion of immune cells	96 (70.1%)	80 (70.8%)	176 (70.4%)	17.730 (.721)
	The gut does not interact with the immune system	18 (13.1%)	8 (7.1%)	26 (10.4%)	
	Gut health only affects digestive	23	14	37	

	enzymes, not immunity	(16.8%)	(12.4%)	(14.8%)	
	Poor gut health boosts immune response	0 (0.0%)	11 (9.7%)	11 (4.4%)	
Most effective preventive measure	Using hand sanitizers	13 (9.5)	33 (29.2)	46 (18.4)	0.369 (0.694)
	Boiling drinking water	21 (15.3)	26 (23.0)	47 (18.8)	
	Wearing masks	1 (0.7)	17 (15.0)	18 (7.2)	
	Using insect repellents	0 (0.0)	22 (19.5)	22 (8.8)	
	Boiling water + sanitizers	102 (74.5)	15 (13.3)	117 (46.8)	
Role of public health education	Minor role	14 (10.2)	40 (35.4)	54 (21.6)	1.963 (0.053)
	Crucial role	118 (86.1)	53 (46.9)	171 (68.4)	
	No role	3 (2.2)	12 (10.6)	15 (6.0)	
	Only rural areas	2 (1.5)	8 (7.1)	10 (4.0)	
Does the curriculum place sufficient emphasis on gut health -	Yes	108 (78.8)	12 (10.6)	120 (48.0)	2.466 (0.016)*
	No	2 (1.5)	46 (40.7)	48 (19.2)	
	Not sure	27 (19.7)	55 (48.7)	82 (32.8)	
Gut health is important in preventing chronic diseases-	Very important	128 (93.5)	48 (42.5)	176 (70.4)	5.929 (0.020)*
	Moderately important	7 (5.1)	48 (42.5)	55 (22.0)	
	Slightly important	1 (0.7)	13 (11.5)	14 (5.6)	
	Not important	1 (0.7)	4 (3.5)	5 (2.0)	
A routine deworming program should be conducted in schools-	Yes	121 (88.3)	46 (40.7)	167 (66.8)	9.873 (0.010)*
	No	0 (0.0)	38 (33.6)	38 (15.2)	
	Not sure	16 (11.7)	29 (25.7)	45 (18.0)	
Barriers to	Lack of	55 (40.2)	29 (25.7)	84 (33.6)	0.641

deworming	awareness				(0.821)
	Poor access to medication	17 (12.4)	11 (9.7)	28 (11.2)	
	Cultural beliefs and stigmas	8 (5.8)	6 (5.3)	14 (5.6)	
	Poor infrastructure	3 (2.2)	12 (10.6)	15 (6.0)	
	Lack of awareness + Poor access	3 (2.2)	8 (7.1)	11 (4.4)	
	Lack of awareness + Cultural beliefs	2 (1.4)	11 (9.7)	13 (5.2)	
	Lack of awareness + Poor access + Cultural beliefs + Poor infrastructure	4 (2.9)	1 (0.9)	5 (2.0)	
	Poor access + Cultural beliefs + Poor infrastructure	2 (1.5)	1 (0.9)	3 (1.2)	
	Cultural beliefs + Poor infrastructure	43 (31.4)	34 (30.1)	77 (30.8)	

The table presents the perceptions of medical and paramedical students regarding intestinal parasite infections and gut health. Open defecation accounted for 14.4%, while drinking untreated water constituted 10.4%. Collectively, these practices contributed to 63.2% of the disease transmission. The importance of gut health in preventing chronic diseases was significant (p=0.020). Of the participants, 176 individuals, representing 70.4%, provided correct responses regarding gut health and immunity. Preventive strategies comprised boiling water with sanitizers (46.8%) and utilizing hand sanitizers (18.4%). A statistically significant difference was observed in support for normal school deworming programs (p=0.010). A total of 171 individuals (68.4%) indicated that public health education is of significant importance. A statistically significant association was observed between the curriculum's emphasis on gut health and additional variables (p=0.016).

Table 4. Practice of participants towards gut Health, Hygiene Practices, and Deworming

Variable	Category	Medical n (%)	paramedical n (%)	Total n (%)	Chi-square (P-value)
Are you on diet to improve gut health-	Yes	84 (61.3)	21 (18.6)	105 (42.0)	0.824 (0.072)
	No	12 (8.8)	72 (63.7)	84 (33.6)	
	Plan in future	41 (29.9)	20 (17.7)	61 (24.4)	
Any history of Intestinal parasite infection-	Yes	41 (29.9)	37 (32.7)	78 (31.2)	2.290 (0.041)*
	No	87 (63.5)	49 (43.4)	136 (54.4)	
	Not known	9 (6.6)	27 (23.9)	36 (14.4)	
Regular handwashing practice-	Yes	135 (98.5%)	107 (94.7%)	242 (96.8%)	4.541 (0.041)*
	No	2 (1.5%)	6 (5.3%)	8 (3.2%)	
Frequency of Handwashing usually-	Hourly	101 (73.7%)	37 (32.8%)	138 (55.2%)	1.610 (0.053)
	Once in 2 hours	24 (17.5%)	21 (18.6%)	45 (18.0%)	
	Once in 3 hours	9 (6.6%)	25 (22.1%)	34 (13.6%)	
	Only after washroom	3 (2.2%)	30 (26.5%)	33 (13.2%)	

Ever dewormed	Yes	132 (96.4)	64 (56.6)	196 (78.4)	5.316 (0.001)*
	No	5 (3.6)	49 (43.4)	54 (21.6)	
Deworming every 6 months	Yes	36 (26.3)	6 (5.3)	42 (16.8)	2.226 (0.031)*
	No	96 (70.1)	58 (51.3)	154 (61.6)	
	Never	5 (3.6)	49 (43.4)	54 (21.6)	
Last deworming was done at-	< 6 months	13 (9.5)	3 (2.7)	16 (6.4)	4.562 (0.079)
	6–12 months	38 (27.7)	26 (23.0)	64 (25.6)	
	1–2 years	22 (16.1)	19 (16.8)	41 (16.4)	
	>2 years	56 (40.9)	19 (16.8)	75 (30.0)	
	Never	8 (5.8)	46 (40.7)	54 (21.6)	

The table presents data on the practices of medical and paramedical students regarding gut health, hygiene, and deworming. A total of 105 participants, representing 42.0%, reported making dietary changes for gut health. A history of intestinal parasite infection was reported by 78 individuals (31.2%), and a statistically significant association was observed (p=0.041). A total of 242 individuals (96.8%) reported regular handwashing, a statistically significant finding (p=0.041). Of the participants, 138 individuals (55.2%) reported washing their hands every hour. A total of 196 individuals (78.4%) reported having received deworming, demonstrating a significant correlation (p=0.001). Forty-two individuals (16.8%) reported deworming every six months, a statistically significant finding (p=0.031).

Discussion

Although intestinal parasite infections can occur at any age, they are more common in young children, who may be at higher risk due to malnourishment, a weakened immune system, migration, and poor living conditions. Although intestinal parasite infections are a global issue, they are particularly severe in developing nations due to a persistent lack of basic sanitary facilities, ignorance of the proper mechanism of transmission, and a lack of preventive measures [10].

In this study, students who were not exposed to microbiology in the curriculum were included. The purpose of this study was to assess knowledge, awareness, and practices regarding IPIs. Many other studies have been conducted among schoolchildren and the general population [9,11,12] and this is the only study that included healthcare students. A study conducted in Malaysia included subjects with similar age groups [13].

In our study, most study subjects knew about probiotics and gut bacteria. More than three-quarters of the subjects were aware of the importance of probiotics. Regarding probiotics' usefulness, Aditi et al.'s study [14] found

that 42.1% of students were aware of their benefits. This was in contrast to the findings of a study by Payahoo et al. [15] on Iranian medical science students, which found that 60% of students were aware of probiotics' benefits, which was significantly higher than the findings of our study. In the study among Nigerian healthcare professionals, Amaruche et al. found that over 65% of them were aware [16].

Most study subjects (79.6%) knew how worms spread, and 82% claimed inadequate sanitation and hygiene were the main contributors. Since they knew the infection's source, most subjects blamed soil, walking barefoot, drinking untreated water, and eating undercooked food.

A study of school students found that most don't know how parasites are transmitted. Over 400 parasites have been found, and 45% can be spread by close nonsexual contact, including the fecal-oral route. Knowledge of infection transmission routes is crucial for children's health. Hand-to-hand contact transmits intestinal parasites, while ambient surfaces or food transmit them indirectly. Thus, ignorance about the transmission mechanism is always a risk factor, especially in young children due to poor hygiene [10].

Study subjects knew worms and the signs and symptoms caused by the parasitic infections. Weight loss, abdominal pain, diarrhoea, vomiting, fatigue, lack of appetite, and craving for soil were listed as major signs of worm infection, which is in accordance with the findings of other investigations [17,15].

79.2% of the subjects correctly identified the protozoan that causes amoebiasis (E. histolytica), and nearly two-thirds of them knew something about parasites. Most subjects accurately identified stool analysis as the diagnostic technique. 50% of the subjects recognised the primary medication for amoebiasis treatment (metronidazole), and the majority were aware of the commonly used deworming (albendazole).

Regarding infection prevention, a lot of participants thought that hand washing and drinking purified water were good strategies. Furthermore, almost 90% of the participants had become accustomed to handwashing practice. According to the Yemeni research [19], most participants wash their hands both before eating and after urinating. Compared to the Ethiopian [20] and Colombian [21] research, our findings show better awareness.

Additional steps included drug treatment, general personal hygiene, and appropriate disposal of human waste. The subjects also said that utilizing restrooms and latrines, as well as wearing shoes and receiving health information, will aid in the fight against the infection. Even though the vast majority of survey participants were aware of IP, the mode of transmission, and preventive actions was insufficient. Similar results were obtained in the Malaysian investigation [22]. Active student participation is essential for the effectiveness and sustainability of initiatives like 'Swach Bharat' in educational and healthcare settings.

More than half of the students said they had no history of IP infection, nearly 15% were unsure of the condition, and 31% reported a history of IPI. The Malaysian study and these reports are comparable [13]. This finding contradicts a survey on IP infection conducted among students in Asmara, Eritrea, Africa, which found that 73% of them had prior knowledge of IP infection [10].

When it comes to practice, most of the subjects followed handwashing, and many subjects washed their hands at least once every two hours.

Although more than three-fourths of the subjects in our study had undergone deworming previously, only 16% received it biannually. 54 of the subjects had not previously undergone deworming. The inadequacy of deworming programs may account for this issue. Many of them recommended that deworming and health education activities should be conducted regularly in educational institutions. According to a study done on mothers in Chennai, 35% of them practiced preventing worm infestations inadequately, while 50% of them knew enough about it [23]. 100 mothers participated in a community-based study to gauge their knowledge about worm infestations. The results showed that regarding worm infestations, the majority of the moms had somewhat sufficient knowledge (65%) and moderate behaviours (72%) [24].

According to our report, several subjects mentioned obstacles like taboo traditions, a lack of healthcare resources, and misunderstandings that resulted in underutilization of deworming treatments that were either unavailable or too expensive. According to a Ghanaian study, those who said they had not gone to a hospital or health center because they were poor and their symptoms weren't severe enough cited a lack of funds, with proximity not being a deterrent [25].

According to a study done in the Erode District, Tamil Nadu, schoolchildren have a low degree of understanding, while paramedical workers have a good level. The majority of paramedical personnel have a positive attitude [26].

The results of another deworming study conducted in Tamil Nadu indicate that mothers of under-fives residing in rural areas often lack adequate and frequent deworming practices [20]. Since intestinal parasites are a public health issue, it is essential to implement interventional programs, provide regular monitoring, and educate parents and caregivers on health issues to reduce the disease's prevalence [27].

The study revealed significant gaps in awareness of gut health between medical and paramedical groups. Both groups acknowledged certain gut-related conditions; however, medical students demonstrated significantly greater knowledge. This highlights the necessity for focused educational interventions for paramedical students to address the existing knowledge gap. Health science students should be more knowledgeable about gut health so they can utilize and advocate for probiotics more confidently to treat and prevent stomach problems [28].

Conclusion

This study highlights differences in knowledge, attitudes, and practices related to intestinal parasitic infections and gut health between medical and paramedical students. Although general awareness regarding transmission and prevention was relatively high, gaps remain in structured education and preventive practices. Strengthening curricular components and health education programs may improve awareness and promote better preventive behaviours among future healthcare professionals.

Study Limitations

The primary limitation of this study is its single-centric nature and the fact that subjects are healthcare students, rendering the conclusions non-generalizable to the broader public.

Ethical Approval

Ethical approval for the study was obtained from the Institutional Ethics Committee of ACS Medical College and Hospital.

Conflicts of interest

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

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ORIGINAL ARTICLE

Effect of Low-Dose Dexmedetomidine Infusion on Hemodynamic Responses and Anaesthetic Requirements During Laparoscopic Surgery

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Abstract

Introduction: Laparoscopic surgeries conducted under general anaesthesia are associated with peri-operative hemodynamic stress due to tracheal intubation, laryngoscopy, pneumoperitoneum, and extubation. These responses may lead to hypertension, tachycardia, and increased anaesthetic agent requirements. Dexmedetomidine, a selective alpha-2 adrenergic agonist, has been proved to attenuate the sympathetic responses and to reduce the anaesthetic requirements. **Materials and Methods:** This study was done after getting Institutional Ethics Committee approval and the written informed consent from all the study participants. The patients belonging to ASA physical status I and II and those who undergo the elective laparoscopic surgeries were allocated into two groups randomly: Dexmedetomidine group (DX) and Normal Saline group (NS). The DX group received dexmedetomidine infusion at 0.4 µg/kg/hr, and the Normal Saline group received an equivalent volume of saline. Standard general anaesthesia was administered, and the bispectral index monitored the depth of anaesthesia. **Results:** Baseline demographic data and surgical profiles were compared between the two study groups. The dexmedetomidine group demonstrated significant reduction of blood pressure and heart rate responses during the laryngoscopy, intubation, pneumoperitoneum, and extubation compared to the other group (NS). End-tidal isoflurane concentration, isoflurane, total propofol, and fentanyl requirements were significantly lesser in the dexmedetomidine group ($p < 0.001$). Time of awakening was comparable between groups. **Conclusion:** Low-dose dexmedetomidine infusion at 0.4 µg/kg/hr offers effective reduction of peri-operative hemodynamic stress responses during the laparoscopic surgery, which significantly lessens the anaesthetic drug and opioid requirements. It also improves the cardiovascular stability without delaying the recovery time or without increasing the adverse effects.

Keywords: Dexmedetomidine, Hemodynamic response, Laparoscopic surgery, Anaesthetic requirement, Bispectral index

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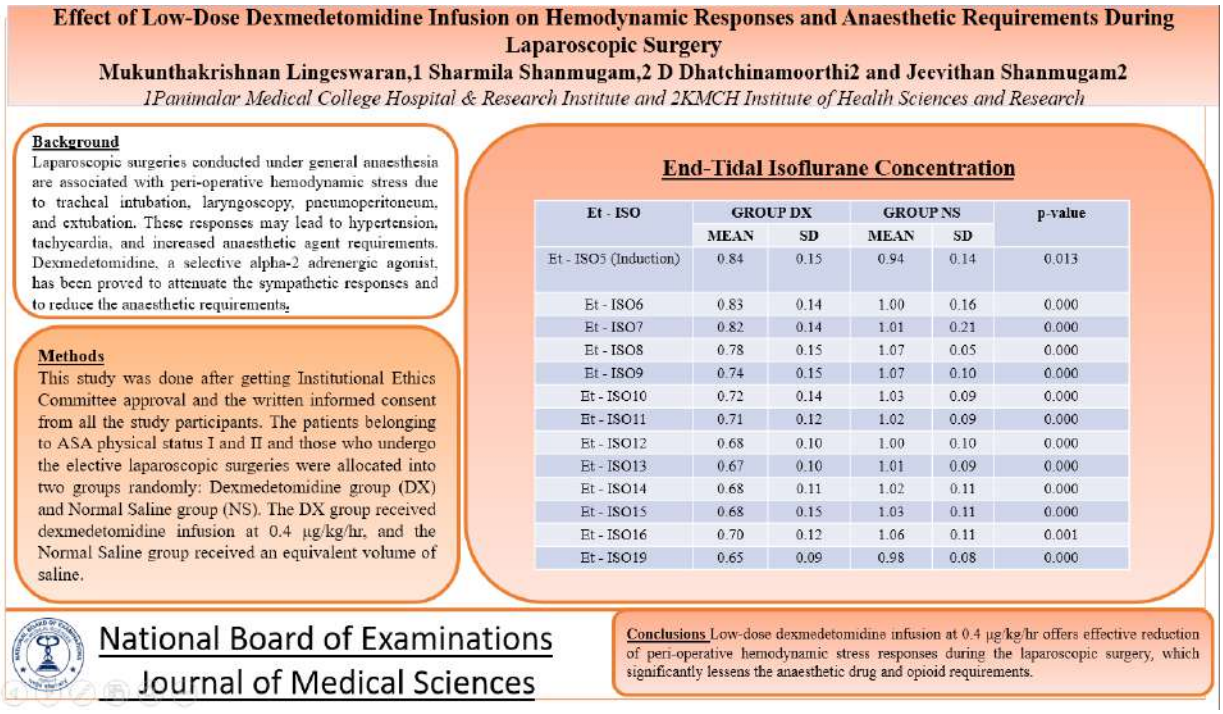
Graphical Abstract



Introduction

Laparoscopic surgery had shown remarkable evolution since the introduction of diagnostic laparoscopy since 1960s. The pioneering work of Muehe E and Semm K in the early 1980s had established laparoscopy as a definitive surgical procedure, leading to its improved adoption across multiple surgical specialties [1]. Owing to the main advantages like, early mobilization, less postoperative pain, shorter hospital stay, and improved cosmetic outcomes, laparoscopic procedures have become the gold standard for various gastrointestinal and gynaecological surgeries [2-5].

However, laparoscopic surgery under general anaesthesia is commonly associated with significant peri-operative hemodynamic stress. Laryngoscopy, tracheal intubation, pneumoperitoneum, and extubation are the main noxious stimuli which provoke the sympathoadrenal activation, leading to hypertension and tachycardia. The creation of carbon dioxide pneumoperitoneum further leads to hemodynamic instability through increased vasopressin, increased catecholamine release, increased intra-abdominal pressure, and diaphragmatic elevation, causing increased systemic and pulmonary vascular resistance and reduced cardiac output [6-11].

Different pharmacological agents have been tried to reduce these responses, including calcium channel blockers [12,13], beta-blockers [12,14,15], opioids [16], vasodilators [17-18] and lignocaine [16,19]. Among these, alpha-2 adrenergic agonists have gained considerable attention due to their sympatholytic properties. Both clonidine and dexmedetomidine have demonstrated efficacy in blunting peri-operative hemodynamic responses [20-23].

Dexmedetomidine is a highly selective alpha-2 adrenoceptor agonist with an α_2:α_1 selectivity ratio of 1620:1, significantly higher than that of clonidine

[24]. Its pharmacological effects include sedation, anxiolysis, analgesia, and reduction of sympathetic outflow. Several studies have shown that dexmedetomidine reduces anaesthetic requirements and decreases the minimum alveolar concentration of volatile anaesthetics by approximately 30–35% [25]. However, higher doses or rapid bolus administration have been associated with adverse effects such as hypotension and bradycardia [24,26,27-38].

An additional concern with anaesthetic dose reduction is the potential risk of inadequate depth of anaesthesia and intra-operative awareness. Objective monitoring of anaesthetic depth using bispectral index has therefore been advocated to ensure adequate hypnosis during surgery [39-42].

The present study was undertaken to evaluate the efficacy of low-dose dexmedetomidine infusion (0.4 μg/kg/hr) in attenuating hemodynamic responses to laryngoscopy, tracheal intubation, pneumoperitoneum, and extubation in patients undergoing laparoscopic surgery, while assessing its effect on anaesthetic requirements, recovery characteristics, and peri-operative adverse events under bispectral index monitoring.

Materials and Methods

After getting the Institutional Ethics Committee approval, this prospective study was done in patients undergoing elective laparoscopic surgeries under general anaesthesia. The study procedure was explained in detail to all the eligible participants during the pre-anaesthetic evaluation. Written informed consent was obtained from all the willing participants explaining the study objectives, procedures involved, potential benefits, and possible risks. Ethical principles outlined in the Declaration of Helsinki were strictly followed throughout the study. Confidentiality of patient data were maintained, and the participation was purely voluntary, with the option to withdraw at any stage of the study without affecting clinical care.

Sample size was calculated based on expected differences in peri-operative heart rate and mean arterial pressure between the two groups from Ghodki et al. [20]. Assuming an effect size of 0.8, a power of 80%, and an alpha error of 0.05, the minimum required sample size was calculated to be 22 patients per group. To compensate for possible dropouts, 25 patients were recruited in each group, giving a total sample size of 50 patients.

Adult patients of either sex belonging to American Society of Anaesthesiologists (ASA) physical status I and II scheduled for elective laparoscopic procedures were enrolled in the study. Patients with known hypersensitivity to the study drugs, significant cardiovascular, hepatic, renal, or neurological disease, anticipated difficult airway, or those receiving medications affecting autonomic function were excluded. Eligible patients were randomly allocated into two groups using a computer-generated random number table. Allocation concealment was ensured using sealed opaque envelopes, which were opened only at the time of initiation of the study drug. The anesthesiologist administering anaesthesia was aware of group allocation, while the investigator recording hemodynamic parameters and postoperative outcomes was blinded to group assignment.

All the participants had undergone standard pre-anaesthetic evaluation and they were kept nil per oral as per the

institutional protocol. During the surgery, standard monitoring including non-invasive blood pressure, electrocardiography, pulse oximetry, end-tidal carbon dioxide, and bispectral index monitoring were utilised. Baseline heart rate, blood pressure, and bispectral index values were recorded. An intravenous line (IV) was secured, and participants in the DX group received dexmedetomidine infusion at a rate of 0.4 μg/kg/hr, while the participants in the NS group received an equivalent volume of normal saline. The infusion was started, just prior to the induction and it continued throughout the intra-operative period.

Anaesthesia was induced with intravenous (IV) propofol, titrated to loss of consciousness, and guided by bispectral index monitoring to maintain the necessary depth of anaesthesia. Neuromuscular blockade was done using a suitable muscle relaxant to perform tracheal intubation and Fentanyl was administered for analgesia. Laryngoscopy and endotracheal intubation were conducted using standard techniques. Anaesthesia was maintained with air, oxygen and isoflurane, with end-tidal isoflurane concentration adjusted to maintain an appropriate bispectral index range. Pneumoperitoneum was created using carbon dioxide, and intra-abdominal pressure was maintained within acceptable standards as per the surgical requirements.

Hemodynamic parameters including systolic blood pressure, diastolic blood pressure, heart rate, and mean arterial pressure were noted at predefined intervals: At the Baseline, after administering the drug, following the induction, after laryngoscopy and intubation, during the period of pneumoperitoneum (CO_2) at regular intervals, after release of the pneumoperitoneum, and following the extubation. Total consumption of isoflurane, propofol, and fentanyl were recorded. Recovery parameters including the time to awakening were recorded. Episodes of tachycardia, hypertension, hypotension, and bradycardia were noted and managed according to the institutional standard protocols.

The primary outcome was the peri-operative hemodynamic response like heart rate and blood pressure changes. Secondary outcomes included anaesthetic and opioid requirements, recovery characteristics, and incidence of adverse events.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) software version 27. Continuous variables were expressed as mean and standard deviation (SD), while categorical variables were expressed as frequencies and percentages. The independent sample t-test was used for Intergroup comparisons for continuous variables and categorical variables were assessed using the Fisher's exact test or Chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

Table 1 shows that both the Dexmedetomidine (DX) group and the Normal Saline (NS) group were comparable with respect to baseline demographic and operative parameters. The average age of patients in the DX group was 40.92 ± 13.07 years when compared to 42.36 ± 11.22 years in the NS group ($p = 0.678$). Mean body weight (72.28 ± 7.94 kg vs. 71.36 ± 9.83 kg; $p = 0.717$) and body mass index (27.33 ± 3.31 vs. 27.08 ± 2.68; $p = 0.973$) were also statistically comparable between the two groups. The duration of surgery was nearly same (74.6 ± 13.30 minutes in DX group vs. 74.4 ±

19.33 minutes in NS group; p = 0.966). The intergroup differences in anaesthetic requirements and hemodynamic responses can be attributed to the study drug rather than the baseline confounding variables.

Table 1. Baseline Demographic and Operative Characteristics

Parameter	Dexmedetomidine gp		Normal saline gp		P value
	Mean	SD	Mean	SD	
AGE	40.92	13.07	42.36	11.22	0.678
Body weight	72.28	7.94	71.36	9.83	0.717
BMI	27.33	3.31	27.08	2.68	0.973
Duration of surgery	74.6	13.30	74.4	19.33	0.966

Table 2 gives an even distribution of categorical variables between the study groups. Both groups had similar sex distribution, with males constituting females 13 patients (52%) and 12 patients (48%in each group). **ASA physical status I** is accounted for 18 patients (72%) in the NS group 19 patients (76%) in the DX group, while **ASA status II** comprised of 7 patients (28%) in the NS group, and 6 patients (24%) in the DX group. (p = 0.753). The types of laparoscopic procedures were also well matched, with laparoscopic appendicectomy, cholecystectomy, inguinal hernia repair, and umbilical hernia repair being similarly distributed between groups (p = 0.90).

Table 2. Distribution of Sex, ASA Status, and Type of Surgical Procedure

Parameter	Sub classification	Dexmedetomidine gp		Normal saline gp		P Value
		F	%	F	%	
Sex	Male	12	48	12	48	1
	Female	13	52	13	52	
ASA	1	19	76.00%	18	72.00%	0.753
	2	6	24.00%	7	28.00%	
Type of Surgical Procedure	Laparoscopic appendicectomy	5	20	4	16	0.90
	Laparoscopic cholecystectomy	8	32	7	28	
	Laparoscopic inguinal hernia repair	8	32	8	32	
	Laparoscopic umbilical hernia repair	4	16	6	24	

This balanced distribution ensures homogeneity of surgical stress and anaesthetic exposure, strengthening the internal validity of the comparative outcomes.

Analysis of systolic blood pressure, diastolic blood pressure, heart rate, and mean arterial pressure across the critical peri-operative time periods revealed a significant reduction of hemodynamic stress responses in the Dexmedetomidine group compared to the Normal Saline group. Following the laryngoscopy, tracheal intubation, pneumoperitoneum, and extubation, the NS group showed marked hypertensive and tachycardia responses, whereas these changes were blunted significantly in the DX group. The intergroup differences were observed immediately after intubation, during the early pneumoperitoneum, and following extubation, with various comparisons reaching the statistical significance ($p < 0.001$). Over time, hemodynamic parameters in both the groups had gradually returned towards the baseline values (Figure 1).

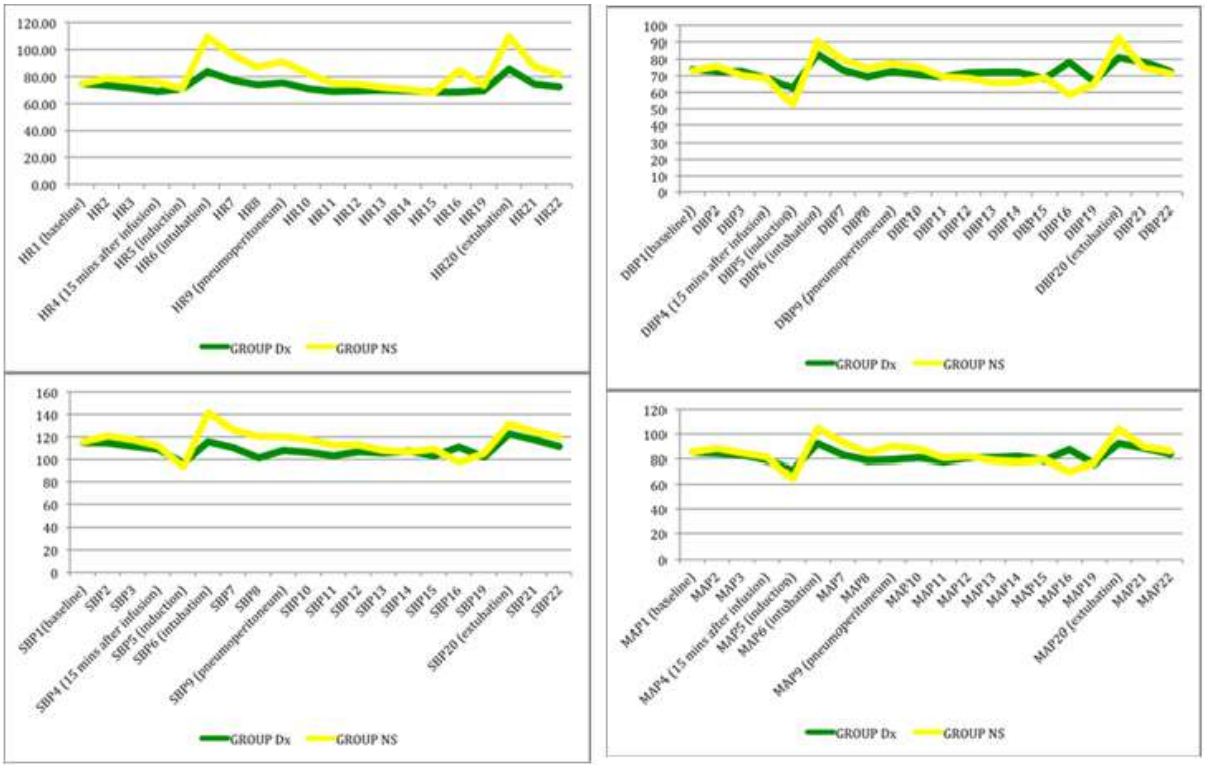


Figure 1. Peri-operative Hemodynamic Responses

Table 3 shows consistently lower end-tidal isoflurane requirement in the Dexmedetomidine group throughout the anaesthesia maintenance. From induction onwards, the mean end-tidal isoflurane concentrations were significantly decreased in the DX group, when compared to the NS group at all the measured intervals, with p-values reaching the significant statistical significance ($p \leq 0.001$) at most of the time periods. These results clearly indicate a dose-sparing effect of dexmedetomidine on the inhalational anaesthetic requirements, showing its anaesthetic-adjunct properties while maintaining the expected depth of anaesthesia.

Table 3. End-Tidal Isoflurane Concentration

Et - ISO	GROUP DX		GROUP NS		p-value
	MEAN	SD	MEAN	SD	
Et - ISO5 (Induction)	0.84	0.15	0.94	0.14	0.013
Et - ISO6	0.83	0.14	1.00	0.16	0.000
Et - ISO7	0.82	0.14	1.01	0.21	0.000
Et - ISO8	0.78	0.15	1.07	0.05	0.000
Et - ISO9	0.74	0.15	1.07	0.10	0.000
Et - ISO10	0.72	0.14	1.03	0.09	0.000
Et - ISO11	0.71	0.12	1.02	0.09	0.000
Et - ISO12	0.68	0.10	1.00	0.10	0.000
Et - ISO13	0.67	0.10	1.01	0.09	0.000
Et - ISO14	0.68	0.11	1.02	0.11	0.000
Et - ISO15	0.68	0.15	1.03	0.11	0.000
Et - ISO16	0.70	0.12	1.06	0.11	0.001
Et - ISO19	0.65	0.09	0.98	0.08	0.000

Table 4 demonstrates a significant reduction in opioid and anaesthetic consumption in patients receiving dexmedetomidine. The average propofol requirement in the DX group (75.60 ± 13.56 mg) was significantly lesser than in the NS group (135.60 ± 15.30 mg; $p < 0.001$). Similarly, total isoflurane consumption (11.88 ± 2.33 vs. 15.92 ± 1.61; $p < 0.001$) and total fentanyl requirement (2.29 ± 0.26 vs. 3.47 ± 0.44; $p < 0.001$) were significantly reduced in the DX group. Despite reduced anaesthetic dosing, time to awakening was comparable between the two study groups ($p = 0.751$), indicating that dexmedetomidine did not delay recovery while providing effective anaesthetic sparing.

Table 4: Anesthetic Drug Requirements and Recovery Profile

Parameter	Dexmedetomidine gp		Normal saline gp		P value
	Mean	SD	Mean	SD	
Time to Awakening	5.92	1.32	6.04	1.34	0.751
Propofol requirement	75.60	13.56	135.60	15.30	<0.001
TOTAL ISOFLURANE REQUIRED	11.88	2.33	15.92	1.61	<0.001
TOTAL FENTANYL REQUIRED	2.29	0.26	3.47	0.44	<0.001

Table 5 demonstrates a marked reduction in episodes of hypertension and tachycardia in the Dexmedetomidine group. 18 patients (72%) in the DX group, experienced no episodes of hypertension, compared to only 2 patients (8%) in the NS group (p = 0.002). Multiple episodes of hypertension were frequently seen in the NS group, with 12 patients (48%) experiencing two episodes in the DX group.

Table 5. Incidence of Hemodynamic Adverse Events

Parameter	Sub classification	Dexmedetomidine gp		Normal saline gp		P Value
		F	%	F	%	
Episodes of hypertension	0	18	72.00	2	8.00	0.002
	1	3	12.00	8	32.00	
	2	4	16.00	12	48.00	
	3	0	0.00	2	8.00	
	4	0	0	1	4	
Episodes of Tachycardia	0	15	60.00	1	4.00	<0.001
	1	9	36.00	2	8.00	
	2	1	4.00	4	16.00	
	3	0	0.00	12	48.00	
	4	0	0.00	5	20.00	
	6	0	0.00	1	4.00	
Episodes of hypotension	0	20	80.00	14	56.00	0.21
	1	4	16.00	11	44.00	
	2	1	4.00	0	0.00	
Episodes of bradycardia	Nil	25	100.00	25	100.00	1

Similarly, No tachycardia was observed in 15 patients (60%) in the DX group compared to only 1 patient (4%) in the NS group (p < 0.001), while recurrent tachycardia episodes were seen notably in the NS group. Episodes of hypotension were comparable between groups (p = 0.21), and no episodes of bradycardia were observed in both the groups (100% in both).

Discussion

The current study assessed the effectiveness of low-dose dexmedetomidine infusion (0.4 µg/kg/hr) in suppressing the peri-operative hemodynamic responses and reducing anaesthetic requirements in patients undergoing laparoscopic surgery under general anaesthesia. The findings of the current study prove that dexmedetomidine offered the excellent hemodynamic stability during the critical peri-operative events such as laryngoscopy, tracheal intubation, pneumoperitoneum (CO_2), and extubation, without increasing the recovery period or increasing the adverse events.

Laparoscopic surgery provokes significant sympathoadrenal responses due to airway manipulation and carbon dioxide pneumoperitoneum, leading to hypertension and tachycardia [6-11]. In the current research, the patients in the normal

saline (NS) group showed, significant raise in blood pressure and heart rate following intubation, during the pneumoperitoneum, and after extubation. In contrast, the dexmedetomidine group show cased, significant decrease in these responses, particularly during intubation, early pneumoperitoneum, and extubation. These results prove the sympatholytic effect of dexmedetomidine, which is mediated through central alpha-2 adrenoceptor activation, leading to reduced sympathetic outflow [20-23].

The observed hemodynamic stability with dexmedetomidine in this research is consistent with earlier findings showing reduction of pressor responses to laryngoscopy and intubation [24,26-29,35]. Previous studies evaluating the dexmedetomidine during the laparoscopic surgery have reported similarly with tachycardia and arterial pressure responses during pneumoperitoneum [21,37,42]. The present study reinforces these findings using a low-dose continuous infusion, thereby minimizing the risk of adverse cardiovascular effects reported with higher doses or rapid bolus administration [24,26,27].

An important finding of this study was the significant reduction in anaesthetic and opioid requirements in the dexmedetomidine group. End-tidal isoflurane concentrations were consistently lower throughout the intra-operative period, and total consumption of propofol, isoflurane, and fentanyl was significantly reduced. This anaesthetic-sparing effect of dexmedetomidine has been well documented in previous studies, which have demonstrated reductions in minimum alveolar concentration and total anaesthetic consumption [24,25,35,36]. The current study proves that even low-dose dexmedetomidine infusion can bring meaningful reduction in anaesthetic dosage.

Despite the decrease in anaesthetic requirements, the recovery characteristics were not affected so much. Time to awakening was similar between the two groups, indicating that dexmedetomidine did not delay the early emergence from anaesthesia. Similar observations were reported in the earlier studies, where dexmedetomidine provided anaesthetic and hemodynamic benefits without prolonging the recovery period [29,36,37]. The present study used the bispectral index monitoring and ensured the adequate depth of anaesthesia despite reduction in the anaesthetic dosing, addressing concerns regarding intra-operative awareness [39-42].

The incidence of less adverse hemodynamic events supports the safety profile of the drug low-dose dexmedetomidine. Episodes of tachycardia and hypertension were significantly lesser in the dexmedetomidine group compared to the normal saline group, while the incidence of hypotension was comparable between the two groups. Notably, no episodes of bradycardia were observed in either of the groups. These findings contrast with the studies using more bolus doses of dexmedetomidine initially, where hypotension and bradycardia were more frequently noted [24,26,27,35] and showcased the advantage of low-dose infusion in maintaining the cardiovascular stability.

This study has certain limitations. It was conducted in ASA I–II patients only, limiting generalizability to higher-risk populations. Blinding of the anaesthesiologist was not feasible. Neuroendocrine markers were not

measured, and hemodynamic parameters were used as indirect indicators of stress response. Larger multicentre studies are required to confirm these findings.

Conclusion

The findings of this research have significant clinical implications. Low-dose dexmedetomidine infusion offers effective reduction in peri-operative stress responses, decreases opioid and anaesthetic requirements. It also improves hemodynamic stability without compromising the recovery time. This makes dexmedetomidine infusion, an essential anaesthetic adjuvant, particularly in laparoscopic surgeries where the sympathetic stimulation is pronounced.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Immediate Total Knee Replacement Plus Standardized Non-Surgical Management Versus Standardized Non-Surgical Management Alone in Patients Eligible for TKR: A Prospective Comparative Cohort Study of Functional Outcomes and Predictors of Recovery

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Abstract

Background: Optimal timing of total knee replacement (TKR) in patients with advanced knee osteoarthritis (OA) remains debated. Whether immediate TKR combined with standardized non-surgical management provides superior functional outcomes compared with continued non-surgical management alone is uncertain particularly in Indian population. Aim is to compare outcomes of immediate total knee replacement versus non-surgical management and identify predictors of recovery. **Methods:** This prospective, observational comparative cohort study enrolled 60 patients (50-80 years) with Kellgren-Lawrence grade III-IV knee OA who were eligible for TKR. Participants were allocated based on clinical decision and patient preference into immediate TKR plus standardized non-surgical management or standardized non-surgical management alone. The primary outcome was change in KOOS4 score from baseline to 12 months. Secondary outcomes included KOOS subscales, Timed Up and Go (TUG) test, 20-m walk test, patient satisfaction, adverse events and predictors of recovery. Analyses followed intention-to-treat principles. **Results:** Baseline characteristics were comparable between groups. At 12 months the immediate TKR group demonstrated significantly greater improvement in KOOS4 compared with the non-surgical group (78.6 ± 7.4 vs. 60.9 ± 10.2; between-group difference +17.7; 95% CI 12.3–23.1; $p<0.001$). Secondary outcomes including KOOS pain, activities of daily living, quality of life, TUG and 20-m walk test were all significantly better in the immediate TKR group ($p<0.001$). A higher proportion of patients undergoing immediate TKR achieved the minimal clinically important difference for KOOS4 (86.7% vs. 46.7%; $p=0.003$) and reported greater satisfaction and functional independence. **Conclusion:** Immediate TKR combined with standardized non-surgical management results in superior functional outcomes and patient-reported benefits compared with non-surgical management alone at 12 months.

Keywords: Total knee replacement, Knee osteoarthritis, KOOS4 score, Kellgren–Lawrence grading

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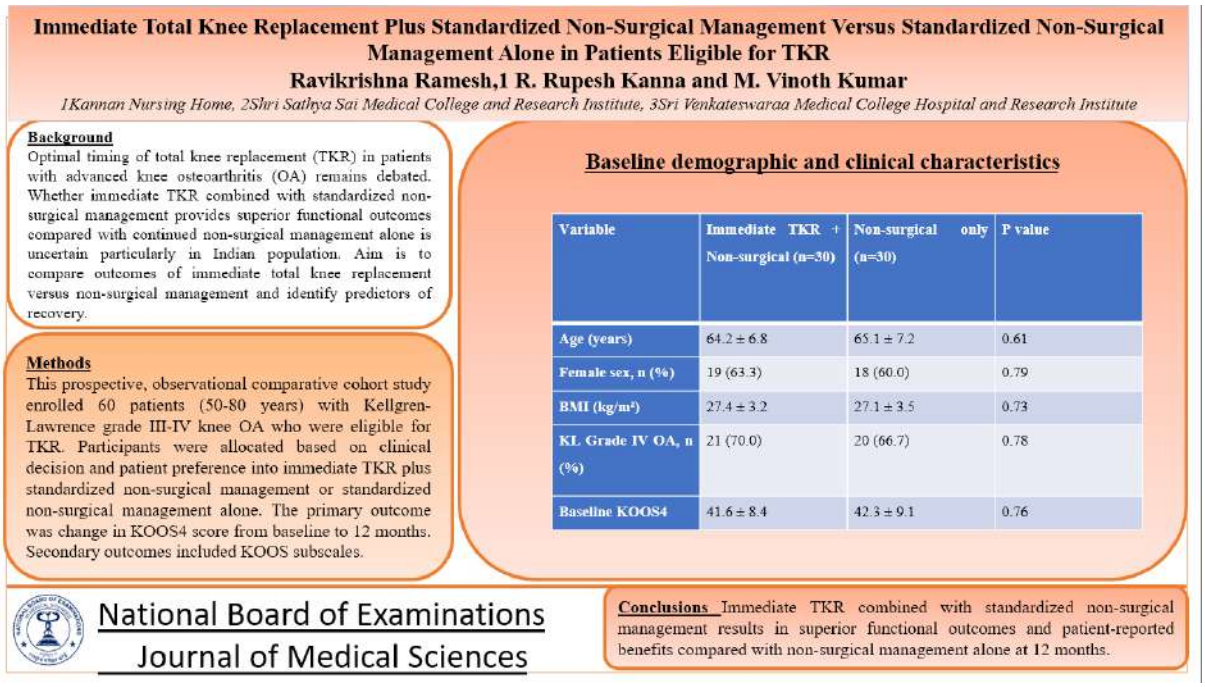
Graphical Abstract



Introduction

The most common cause of disability in the elderly population is osteoarthritis (OA) a degenerative joint disease affecting the cartilage and surrounding tissues [1,2]. All joints can be affected by OA however the knee is the most frequently affected (OA knee) followed by the hand and hip [3]. Globally 10% of men and 13% of women 60 years of age and older have symptomatic osteoarthritis in their knees [4]. For those older than 70 years the incidence rises to 40 percent and the prevalence of OA in older adults (>65 years) varies widely [17-60.6%] with rural areas having a higher point prevalence than urban areas according to data from community surveys conducted in both rural and urban areas of India [5-7]. OA knee symptoms include stiffness that gets better after activity and discomfort that becomes worse with use and gets better with rest. Physical examination reveal deformity, edema and crepitus [8]. A clinical and radiographic evaluation such as MRI, CT scan or X-ray is used to diagnose OA knee. The Kellgren Lawrence (KL) grading system can be used to classify OA knee into four classes based on radiological evidence. In general grade 1 refers to uncertain joint space narrowing, grade 2 to probable joint space narrowing and definite osteophytes, grade 3 to definite joint space narrowing and sclerosis, grade 4 to severe sclerosis, definite deformity and massive osteophytes [9]. Both conservative and surgical methods can be used to treat OA knee [10]. Physiotherapy and medications are part of conservative treatment for OA knee [11]. In terms of surgery total knee replacement (TKR) is a tried and true method of treating osteoarthritis of the knee that has been shown to significantly reduce symptoms resulting in significant patient satisfaction and an enhanced quality of life [12]. For a long time TKR has been used to treat OA knee. Over time there have been numerous advancements primarily in the quality of prostheses and surgical methods. Numerous publications have been

published that regularly highlight TKR's clinical efficacy and how it has changed over time [13,14]. The number of TKR procedures carried out in India rose from 25,215 in 2014-15 to 43,905 in 2018-19 indicating a growth rate of 13.22% according to the National Health Profile 2020. The age range of 60 to 69 years old has the highest number of TKR operations [15]. Although TKR has consistently shown improvement compared with pre-operative status there remains uncertainty whether immediate TKR combined with structured non-surgical management offers superior functional and patient reported outcomes compared with continuation of standardized non-surgical management alone. Delayed surgery may expose patients to persistent pain, reduced mobility and caregiver burden while early surgery involves cost and procedural risks. Establishing such evidence will help determine optimal timing of TKR, strengthen integrated care pathways and allow identification of predictors of recovery such as age, BMI, comorbidities, baseline range of motion and quadriceps strength. The objective of the present study is to evaluate the addition of immediate total knee replacement to a program of standardized non-surgical management results in better pain relief, physical function and health-related quality of life when compared with standardized non-surgical management alone among patients already considered eligible for TKR while also exploring baseline factors that predict recovery and in-hospital and post-trial adverse events.

Materials and Methods

Study Design

This investigation is designed as a prospective, observational comparative cohort study conducted in a single Ortho care hospital in Tamil Nadu, India. Participants were allocated based on clinical decision and patient preference into: either immediate TKR plus standardized non-surgical management (maximal intervention) or standardized non-surgical management alone (moderate intervention) was based on the shared decision-making between patient and treating surgeon, considering clinical indications, patient preference, and affordability.

Participants

Adult patients aged 50–80 years with symptomatic advanced knee osteoarthritis presenting to the Department of Orthopaedics will be screened for eligibility. Inclusion criteria will include: clinical eligibility for total knee replacement as determined by high-volume knee surgeons based on pain severity, functional limitation and radiographic findings, radiographic knee OA of Kellgren–Lawrence grade III or IV, mean knee pain during the previous week ≥40 mm on a 100-mm visual analogue scale and KOOS4 score ≤75. Exclusion criteria will comprise inflammatory arthritides, previous knee replacement on the index side, requirement for simultaneous bilateral TKR, active infection, severe cardiopulmonary or systemic illness precluding surgery, inability to comply with follow-up visits or unwillingness to participate. Written informed consent will be obtained from all eligible participants prior to enrollment.

Interventions

Participants in the surgical arm will undergo total knee replacement within two weeks using a standardized operative

technique by experienced arthroplasty surgeons. Postoperatively these participants will receive the same structured non-surgical program. The standardized non-surgical management will consist of 12 weeks of supervised exercise therapy focusing on neuromuscular control and muscle strengthening delivered in twice-weekly 60-minute group-based sessions, structured patient education on disease characteristics and self-help, individually fitted insoles with a 4° lateral wedge when indicated by the single-limb mini squat test, dietary counseling targeting at least 5% weight loss in patients with BMI ≥25 and stepwise analgesic optimization using paracetamol and NSAIDs if required. Participants in the non-surgical-only arm will receive this identical program without surgery. Monthly telephone booster contacts will support long-term adherence following the supervised period.

Outcome Measures

The primary outcome will be the between-group difference in change from baseline to 12-month follow-up in KOOS4, covering pain, symptoms, activities of daily living and knee-related quality of life (0–100, worst to best). Secondary outcom**es** will include individual KOOS subscales (including function in sport and recreation), Timed Up & Go test, 20-m walk test, knee range of motion, quadriceps strength, patient satisfaction, return to activities of daily living and adverse events such as wound complications, deep venous thrombosis, manipulation under anaesthesia, readmissions, revision surgery and mortality. Assessments will be conducted at baseline, discharge, 3 months, 6 months and 12 months in person by specifically trained blinded assessors.

Sample Size

The sample size was determined pragmatically at 60 participants (30 per group) consistent with previous study demonstrating that approximately 41 patients per arm were required to detect a 10-point difference in KOOS4 (SD 14) with 90% power and alpha 0.05. Considering feasibility and to generate preliminary Indian data, a total of 60 eligible patients will therefore be enrolled in the present study.

Statistical Analysis

All analyses will follow intention-to-treat principles. Continuous variables will be summarized as mean ± SD or median (IQR) depending on distribution. Between-group comparisons for KOOS4, TUG and 20-m walk test will be performed using linear mixed-effects models with patient and follow-up time and treatment arm as fixed factors. Categorical outcomes will be compared using chi-square accounting for clustering at the patient level. Multivariable linear regression was constructed to identify predictors of recovery and complications including age, sex, BMI, comorbidities, and baseline ROM. A two-sided p value ≤0.05 will be considered statistically significant. Data will be analysed using SPSS version 25 and Stata when required.

Results

Table 1. Baseline demographic and clinical characteristics

Variable	Immediate TKR + Non-surgical (n=30)	Non-surgical only (n=30)	P value
Age (years)	64.2 ± 6.8	65.1 ± 7.2	0.61
Female sex, n (%)	19 (63.3)	18 (60.0)	0.79
BMI (kg/m²)	27.4 ± 3.2	27.1 ± 3.5	0.73
KL Grade IV OA, n (%)	21 (70.0)	20 (66.7)	0.78
Baseline KOOS4	41.6 ± 8.4	42.3 ± 9.1	0.76

A total of 60 participants were involved in the study with 30 patients each in the immediate total knee replacement plus non-surgical management group and the non-surgical management only group. Table 1 baseline demographic and clinical characteristics of both groups were comparable. The mean age was 64.2 ± 6.8 years in the immediate TKR group versus 65.1 ± 7.2 years in the non-surgical group with no statistically significant difference between the two groups (p = 0.61). Female participants comprised 63.3% of the immediate TKR group and 60.0% of the non-surgical group (p = 0.79).

The mean BMI was no different between groups 27.4 ± 3.2 kg/m² vs 27.1 ± 3.5 kg/m²; p = 0.73. There was a similar percentage of patients with KL grade IV osteoarthritis in both groups: 70.0% of patients with immediate TKR, 66.7% in the non-surgical group, p = 0.78. Baseline knee-related symptoms, as measured by the KOOS4 score, were similar between the two groups: 41.6 ± 8.4 vs. 42.3 ± 9.1, p = 0.76.

Table 2. Change in KOOS4 score over time

Time point	Immediate TKR	Non-surgical	P value
Baseline	41.6 ± 8.4	42.3 ± 9.1	-
3 months	64.8 ± 9.2	50.7 ± 8.6	<0.001
6 months	71.9 ± 8.1	55.8 ± 9.4	<0.001
12 months	78.6 ± 7.4	60.9 ± 10.2	<0.001

The changes observed in knee-related measures over time, as calculated by the KOOS4 score are presented in Table 2. There was no significant difference observed between the baseline KOOS4 score of the immediate TKR group and the non-surgical group. In comparison to the non-surgical group, the immediate group

showed a significant difference in KOOS4 score at three months of follow-up (64.8 ± 9.2 vs. 50.7 ± 8.6, $p < 0.001$).

This difference was still significant at six months with a higher score of 71.9 ± 8.1 for the immediate TKR procedure and 55.8 ± 9.4 for the non-surgical procedure ($p < 0.001$). Patients who had the immediate TKR procedure still reported a superior score to the non-surgical procedure at a 12-month follow-up. These patients reported a higher score of 78.6 ± 7.4 as opposed to 60.9 ± 10.2 reported by the non-surgical procedure patients ($p < 0.001$). Patients with the immediate procedure reported a higher improvement in symptoms of the knee region throughout the whole of the follow-up procedure.

Table 3. Secondary functional outcomes at 12 months

Outcome	Immediate TKR	Non-surgical	P value
KOOS Pain	82.4 ± 7.1	64.5 ± 9.6	<0.001
KOOS ADL	79.6 ± 8.3	61.8 ± 10.4	<0.001
KOOS QoL	76.8 ± 9.2	58.1 ± 11.1	<0.001
TUG (s)	9.8 ± 1.6	12.4 ± 2.1	<0.001
20-m walk test (s)	18.6 ± 2.9	22.3 ± 3.4	<0.001

The secondary functional outcomes reported at 12 months are provided in Table 3. The outcomes reported by patients in the immediate total knee replacement (TKR) group were found to be significantly better than in the non-surgical management group. The KOOS Pain scores were higher in the immediate TKR group than in the non-surgical management group (82.4 ± 7.1 vs. 64.5 ± 9.6; $p < 0.001$). There were better outcomes in the KOOS ADL (Activities of Daily Living) scores (79.6 ± 8.3 vs. 61.8 ± 10.4; $p < 0.001$) and KOOS QoL (Quality of Life) scores (76.8 ± 9.2 vs. 58.1 ± 11.1; $p < 0.001$) in the immediate TKR group.

The objective functional measurements were also in favor of the immediate TKR group. The results of the timed-up-and-go test indicated that the mean time to complete the test was significantly shorter in the immediate TKR group as compared to the non-surgical group (9.8 ± 1.6 s vs. 12.4 ± 2.1 s, $p < 0.001$). The results of the 20-meter walk tests were also in favor of the immediate TKR group as the completion times were shorter in the TKR groups as compared to the non-surgical groups.

Table 4. Adverse events and complications

Event	Immediate TKR (n=30)	Non-surgical (n=30)
Surgical site infection	2 (6.7%)	0
Deep venous thrombosis	1 (3.3%)	0

Manipulation under anesthesia	2 (6.7%)	—
Hospital readmission	2 (6.7%)	1 (3.3%)
Mortality	0	0

Adverse events and complications of both groups during the study period are outlined in Table 4. In the immediate TKR group surgical site infection was seen in two patients (6.7%) and deep venous thrombosis occurred in one patient (3.3%). Two patients (6.7%) in the immediate TKR group required manipulation under anesthesia for postoperative stiffness. In the immediate TKR group two patients (6.7%) reported hospital readmission in the non-surgical management group there was one patient (3.3%). There was no record of mortality in either group during the study period.

Table 5. Predictors of good functional recovery (KOOS4 ≥75 at 12 months)

Predictor	Adjusted OR	95% CI	P value
Immediate TKR	4.32	1.68–11.14	0.002
Age <65 years	2.11	1.03–4.35	0.041
BMI <30 kg/m²	1.94	1.01–3.75	0.047
Baseline ROM ≥100°	2.76	1.29–5.91	0.009
No diabetes	2.23	1.08–4.60	0.030

Multivariable logistic regression analysis was also used to identify the predictor of good functional recovery which was determined as a KOOS4 score ≥75 at 12 months (Table 5). Immediate total knee replacement (TKR) surgery showed a significant association with a greater likelihood of good functional recovery (adjusted OR: 4.32, 95% CI: 1.68–11.14, p = 0.002). Patients who were <65 years old showed a significant likelihood of good functional recovery (adjusted OR: 2.11, 95% CI: 1.03–4.35, p = 0.041).

Lower body mass index (<30 kg/m²) was significantly related to good functional recovery (adjusted OR 1.94; 95% CI: 1.01-3.75; p = 0.047). A baseline knee range of motion of ≥100° was another predictor of functional recovery (adjusted OR 2.76; 95% CI: 1.29-5.91; p = 0.009). The lack of diabetes mellitus was independently related to functional outcomes at 12 months (adjusted OR 2.23; 95% CI: 1.08-4.60; p = 0.030).

Table 6. Within-group changes over time

Outcome	Group	Baseline	12 months	P value
KOOS4	**Immediate TKR**	41.6 ± 8.4	78.6 ± 7.4	<0.001
KOOS4	**Non-surgical**	42.3 ± 9.1	60.9 ± 10.2	<0.001
TUG (s)	**Immediate TKR**	14.8 ± 2.6	9.8 ± 1.6	<0.001
TUG (s)	**Non-surgical**	14.6 ± 2.5	12.4 ± 2.1	0.004

Within-group changes in functional outcomes from baseline to 12 months are given in Table 6. For the immediate total knee replacement group, there was a significant improvement in the KOOS4 score from baseline (41.6 ± 8.4) to 12 months (78.6 ± 7.4) ($p < 0.001$). Significant improvements in the KOOS4 score from baseline (42.3 ± 9.1) to 12 months (60.9 ± 10.2) in the non-surgical management group were observed ($p < 0.001$).

The objective functional performance as indicated by the Timed Up and Go test showed considerable improvement in both groups. For the immediate TKR group there was a significant reduction in the time taken to perform the Timed Up and Go test. This time decreased from 14.8 ± 2.6 seconds at baseline to 9.8 ± 1.6 seconds at the end of 12 months. The non-surgical group showed significant reductions in the time taken to perform the Timed Up and Go test. In the non-surgical group, the time taken to perform the Timed Up and Go test decreased from 14.6 ± 2.5 seconds to 12.4 ± 2.1 seconds at the end of 12 months.

Table 7. Between-group differences (mixed-effects model)

Outcome	Mean difference	95% CI	P value
KOOS4	+17.7	12.3–23.1	<0.001
TUG (s)	−2.6	−3.4–−1.8	<0.001
20-m walk (s)	−3.7	−4.8–−2.6	<0.001

To investigate the difference with regard to the functional outcomes, a mixed effect model was utilized the results of which are presented in Table 7. Patients from the immediate total knee replacement (TKR) group showed significant differences with regard to the KOOS4 results with a marked improvement of +17.7 on the score (95% CI: 12.3 to 23.1, $p < 0.001$).

There were also objective functional performance benefits for the immediate TKR group. The mean time taken by the participants to perform the Timed Up and Go (TUG) test was substantially lower in the immediate TKR group as compared to the non-surgical

group as revealed by the -2.6 seconds between-group difference (95% CI -3.4 to -1.8, $p < 0.001$). The results revealed that performance of the 20-meter walk test also reflected a significant between-group difference of -3.7 seconds (95% CI -4.8 to -2.6, $p < 0.001$).

Table 8. MCID achievement at 12 months

Outcome	Immediate TKR	Non-surgical	P value
KOOS4 ≥10	26 (86.7%)	14 (46.7%)	0.003
KOOS Pain ≥10	25 (83.3%)	13 (43.3%)	0.002
TUG ≥3 s improvement	22 (73.3%)	11 (36.7%)	0.006

Achievement of the minimal clinically important difference (MCID) in the 12-month follow-up is depicted in Table 8. A significantly higher percentage in the immediate total knee replacement group compared with the non-surgical intervention group achieved a clinically important improvement in the KOOS4 scores ≥ 10 points (86.7% vs. 46.7%, $p = 0.003$). Achievement of the minimal clinically important difference for the KOOS Pain scores ≥ 10 points showed a significant higher percentage in the non-surgical intervention group compared with the immediate total knee replacement group (83.3% vs. 43.3%, $p = 0.002$).

Functional improvement indicated by an increase of at least 3 seconds in the Timed Up and Go (TUG) test was also found in a substantially larger number of immediately TKR-treated patients compared to the non-surgically treated group (73.3% vs. 36.7%, $p = 0.006$).

Table 9. Patient satisfaction and functional recovery

Outcome	Immediate TKR	Non-surgical	P value
Satisfied/Very satisfied	24 (80.0%)	13 (43.3%)	0.004
Independent ADL	26 (86.7%)	18 (60.0%)	0.02
Outdoor walking	23 (76.7%)	15 (50.0%)	0.03

The patient self-report of satisfaction and functional recovery at 12 months is summarized in Table 9. A significantly greater proportion of patients treated with immediate TKR reported being satisfied or very satisfied with the treatment outcome than patients managed nonsurgically (80.0% vs. 43.3%, $p = 0.004$). Functional independence in ADL was achieved more frequently by patients who received immediate TKR compared to those managed nonsurgically (86.7% vs. 60.0%, $p = 0.02$).

The ability to walk outdoors independently was reported by a significantly higher number of patients in the early TKR group compared to the non-surgical group, at 76.7% versus 50.0% respectively (p = 0.03) representing better functional recovery among the patients who had early surgical intervention.

Table 10. Health-care utilization

Variable	Immediate TKR	Non-surgical	P value
Hospital stay (days)	7 (6–9)	2 (1–3)	<0.001
OPD visits	5.2 ± 1.4	6.8 ± 1.9	0.001
Analgesic use	6 (20.0%)	17 (56.7%)	0.004

The health care utilization outcomes are given in Table 10. Patients in the immediate total knee replacement group had a prolonged median length of hospital stay compared with the non-surgical intervention group. The median days of hospitalization in the immediate total knee replacement group were 7 days (interquartile range 6-9 days) compared with the non-surgical intervention group at 2 days (interquartile range 1-3 days) p < 0.001. The number of outpatient department visits in the non-surgical intervention group was statistically higher compared with the immediate total knee replacement intervention group with 6.8 ± 1.9 outpatient department visits compared with 5.2 ± 1.4.

The analgesic use rate at 12 months was found to be significantly higher in surgically managed cases than in immediately TKR-treated patients (56.7% vs. 20.0%, p = 0.004) suggesting that pain management needs were higher in the former despite their shorter hospital stay.

Table 11. Subgroup analysis: KOOS4 improvement

Subgroup	Immediate TKR	Non-surgical	Interaction P
Age <65	39.2 ± 10.1	20.4 ± 9.8	0.01
Age ≥65	32.8 ± 9.6	17.1 ± 8.7	0.03
BMI <30	38.4 ± 9.3	22.1 ± 10.4	0.02
BMI ≥30	30.6 ± 11.2	15.9 ± 9.1	0.04

A subgroup analysis of KOOS4 improvements at 12 months showed that there was a greater functional benefit associated with immediate TKR compared with non-surgical management at all prespecified subgroups (Table 11). When considering individuals under the age of 65 years there was a significant increase in mean KOOS4 improvement for those undergoing immediate TKR compared with non-surgical management (39.2 ± 10.1 vs. 20.4 ± 9.8). There was a significant

interaction (p = 0.01). When looking at subgroup analysis for those aged 65 years and above, there was significant increase in KOOS4 improvements for those undergoing immediate TKR compared with those undergoing non-surgical management (32.8 ± 9.6 vs. 17.1 ± 8.7), there was a significant interaction (p = 0.03).

For patients stratified based on body mass index (BMI) category with BMI <30 kg/m² where immediate TKR was performed these patients had superior improvement in KOOS4 when compared to those managed non-surgically (38.4 ± 9.3 vs. 22.1 ± 10.4, p value interaction = 0.02). In the BMI category ≥30 kg/m² better functional improvement was seen when immediate TKR was performed when compared to non-surgical management (30.6 ± 11.2 vs. 15.9 ± 9.1, p value interaction = 0.04).

Discussion

The prospective cohort study demonstrated immediate TKR plus non-surgical management to non-surgical management alone in patients with end stage knee osteoarthritis and reported significantly better functional and PROs for the immediate TKR group over a 12-month follow-up period. The results continue to add to the mounting evidence supporting early surgical intervention in carefully selected patients with end stage osteoarthritis.

The matching demographic and clinical data of the participants in both groups was comparable with regard to age, sex distribution, body mass index, Kellgren-Lawrence grade as well as baseline KOOS4 scores thus showing that there was group comparability reducing any effect of bias that would have otherwise been present due to demographic differences between the groups as has been demonstrated in previous studies on early versus late TKR surgery [16–18].

One of the significant findings of the present study was the enhanced degree of improvements with regard to the KOOS4 scores in the immediate TKR group as compared to the non-surgical group. At the end of 12 months the mean KOOS4 score for the immediate TKR group was found to be significantly higher compared to the non-surgical group. At the end of 12 months the mean KOOS4 scores for the immediate TKR and the non-surgical groups were 78.6 ± 7.4 and 60.9 ± 10.2 respectively. These findings align with the study by Skou et al. and Katz et al., who found significant improvements in pain, function and quality of life for patients undergoing early TKR compared with those receiving non-surgical management alone [19].

The increasing trend over time observed in the immediate TKR group points to the durability of the surgical benefit which has also been demonstrated in studies assessing the long-term follow-up of the results of TKR [20,21]. Though the non-surgical group demonstrated significant improvement the clinical inferiority of the result supports the proposition that non-surgical approaches alone may not be adequate for advanced osteoarthritis.

In terms of secondary outcomes such as KOOS pain, ADL and QoL a better outcome was observed in the immediate TKR group in these areas compared to other groups at 12 months. The functional outcomes of TU (Timed Up) and 20-m walk tests were also better in the immediate TKR group compared to other groups. The results are in accordance with previous studies, which have also shown that gait,

functional activities and functional independence improve with TKR [22–24].

Enhanced PBOs are of special significance for the elderly population, as mobility is heavily linked with the incidence of falls, disability and loss of independence. Previous studies have reported a significant reduction in TUG time after TKR suggesting enhanced neuromuscular control with improved functional stability [25].

Although the immediate TKR group had procedure-related complications such as surgical site infection, deep venous thrombosis and requirement of manipulation under anaesthesia overall complication rates were comparable to existing literature [26,27]. There was no mortality for either group, and the benefits seemed to outweigh the risks in appropriately selected patients. This is consistent with evidence that suggests that although TKR carries its inherent surgical risks, overall complication rates remain acceptable in modern practice [28].

Multivariable analysis revealed immediate TKR, age under 65 years, BMI <30 kg/m², superior preoperative ROM and absence of diabetes all to be highly significant modifiers of good functional outcome. Such predictors of satisfactory outcome have been noted previously in relation to TKR. In those studies, younger age at surgery, lower BMI, and fewer comorbid diseases correlated with postoperative outcome [29-31].

A notably larger percentage of patients in the immediate TKR group reached the MCID for KOOS4, KOOS pain and TUG improvement. The MCID was considered important because it represents clinically meaningful improvement from the patient's perspective. Previous studies have also identified higher MCID attainment rates following TKR compared to conservative therapy [32].

Patient satisfaction and functional independence were also significantly higher in the immediate TKR group. High satisfaction rates following TKR have constantly been reported in literature and are closely linked with pain relief, functional improvement and restored mobility [33,34].

Although the immediate TKR group had longer initial hospital stays, more visits were required with the non-surgical group. In the non-surgical group long-term analgesic consumption was higher. This is in agreement with previous studies that suggested that prolonged time to surgical intervention might produce cumulative healthcare expenditures and analgesic dependence [35]. Definitive surgical intervention reduces overall healthcare costs in the long term despite higher overall cost during the acute period.

Further subgroup analysis showed that immediate TKR was associated with better improvement in KOOS4 across all categories of age and BMI. These results support the existing literature, which indicates that the benefits of TKR apply across all groups though the magnitude of improvement may vary [36,37].

Conclusion

This prospective comparative cohort study suggests that immediate total knee replacement combined with standardized non-surgical management leads to significantly greater improvements in pain relief, physical function, quality of life and objective mobility outcomes compared with standardized non-surgical management alone in patients eligible for TKR. The benefits were clinically meaningful, sustained over 12 months and

accompanied by higher patient satisfaction and functional independence. Although surgery was associated with procedure-related complications and longer initial hospitalization overall adverse events were acceptable and consistent with contemporary arthroplasty literature. Immediate TKR emerged as the strongest independent predictor of good functional recovery, alongside younger age, lower BMI, better baseline knee range of motion and absence of diabetes. These findings support early surgical intervention in carefully selected patients with advanced knee osteoarthritis rather than prolonged conservative management. Integrating patient selection criteria with standardized perioperative non-surgical care may optimize outcomes and guide evidence-based decision-making regarding the timing of total knee replacement

Statements and Declarations

Conflicts of interest

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

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CASE REPORT

A Rare Case of Primary Mucinous Adenocarcinoma of the Urinary Bladder

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Abstract

Globally, bladder cancer accounts for substantial cancer-related morbidity and mortality ranking in 9th position. Transitional cell carcinoma constitutes the majority of such cases, accounting for approximately 90–95%, while non-urothelial bladder cancers, comprising epithelial and non-epithelial subtypes, are relatively rare. Adenocarcinoma, one of the epithelial non-urothelial types, constitutes only 0.5–2% of all primary bladder cancers, and the mucinous subtype is extremely rare. In this article, we present a rare case of primary mucinous adenocarcinoma of the urinary bladder.

Keywords: Bladder cancer, Adenocarcinoma, Histopathology, Mucicarmine, CK7, CK20

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Introduction

Bladder cancer is one of the leading causes of cancer-related morbidity and mortality worldwide, primarily affecting the males of sixth and seventh decades. Epidemiologically, bladder cancer ranks within the top ten cancers worldwide. Bladder cancers can be broadly classified as either urothelial or non-urothelial based on histology. Nearly nine out of ten bladder cancers are of urothelial origin [1].

Non-urothelial bladder tumours represent a rare subset and are further divided into epithelial and non-epithelial tumors. Epithelial subtypes include squamous cell carcinoma, adenocarcinoma, and small cell carcinoma, while non-epithelial variants encompass rare entities such as sarcomas, paragangliomas, melanomas, and lymphomas. Among these, Adenocarcinoma forms a very small proportion of primary bladder malignancies, with the mucinous subtype representing a small fraction of these cases. Primary bladder adenocarcinoma (PBA) is most frequently diagnosed in individuals aged 5^{th}-6^{th} decade and may be associated with risk factors such as persistent urachal remnants, bladder exstrophy, and long-standing mucosal irritation resulting in glandular metaplastic changes [2].

Mucinous adenocarcinoma of the bladder is rare and often presents with nonspecific symptoms such as hematuria, dysuria, and suprapubic pain. Due to its poor response to chemotherapy and radiotherapy, surgical excision remains the most effective management. The diagnostic approach typically involves imaging, cystoscopy, urine cytology, and biopsy, followed by histopathological and immunohistochemical evaluation to differentiate it from secondary adenocarcinomas originating from the gastrointestinal tract [2].

Although it is histologically distinct from urothelial carcinomas, there is limited literature on the clinicopathological behavior, treatment strategies, and prognosis of mucinous PBA. Therefore, we report a rare case of primary mucinous adenocarcinoma of the bladder with atypical location involving the bladder dome and anterior wall to add to the existing body of literature on this subject [3].

Case Report

A 64-year-old male presented with complaints of suprapubic pain, dysuria, and haematuria for one month. He also had a chronic smoking history. On clinical examination, gross anaemia was noted. Local examination elicited suprapubic tenderness; however, no palpable abdominal mass was detected. On ultrasonography, a distended urinary bladder with an irregular mass measuring 5 × 3.4 cm involving the dome and anterior wall; (the third dimension could not be clearly assessed) was reported. Following appropriate diagnostic workup and multidisciplinary tumour board review, the patient underwent radical cystectomy. The resected specimen, sent for histopathological confirmation, consisted of a urinary bladder measuring 9 × 4 × 3 cm. On cut section, the bladder wall was markedly thickened and showed abundant gelatinous material along with a solid area measuring 3 × 2 cm (Figure 1).

Figure 1. Radical Cystectomy specimen showing large mucinous pools and solid area

Sections studied microscopically showed abundant extracellular mucin with pleomorphic floating signet ring cells arranged singly and in glandular patterns. The tumour cells also exhibited a high nuclear-to-cytoplasmic ratio and infiltrated the muscularis propria. The cells were characterized by eccentrically placed, hyperchromatic nuclei compressed by intracytoplasmic mucin vacuoles (Figure 2-5).

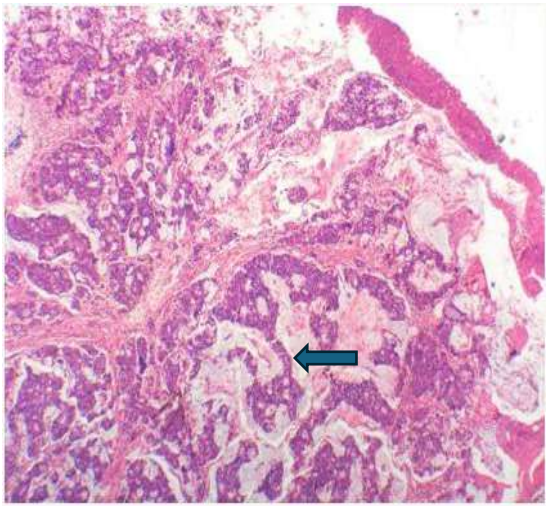

Figure 2. 4X H&E Pleomorphic tumor cells in glandular pattern and abundant mucinous pools

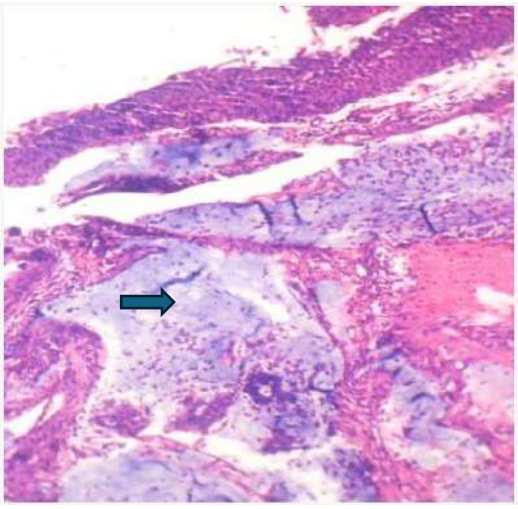

Figure 3. 10X H&E Abundant mucinous pools with floating tumor cells

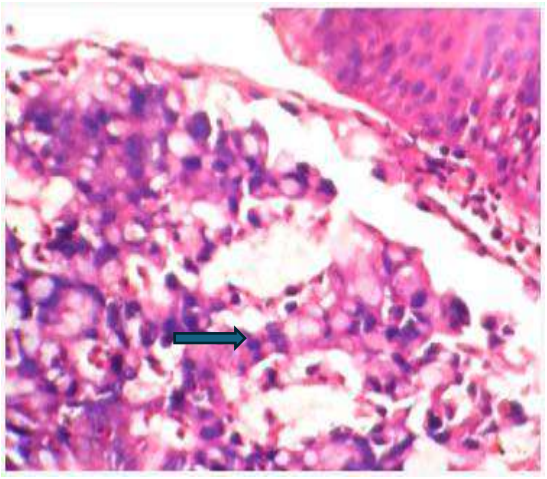

Figure 4. 40X H&E Mucin secreting pleomorphic tumor cells arranged in glandular pattern

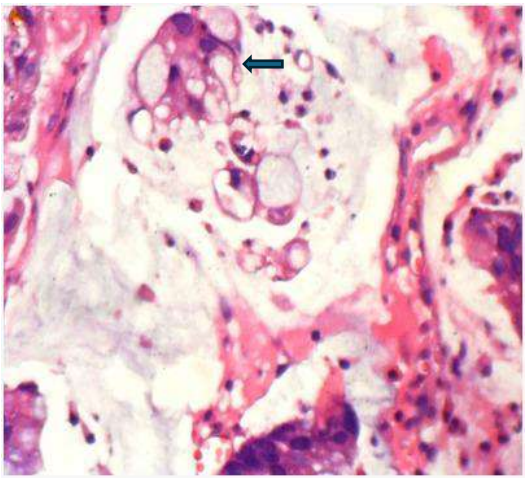

Figure 5. 40X H&E Large Mucinous pools with floating tumor cells

Considering the patient's age and the tumour location at the dome and anterior wall of the bladder, the differential diagnoses included primary mucinous adenocarcinoma of the bladder, urachal carcinoma, secondary bladder involvement from prostatic or colorectal adenocarcinoma, and metastatic mucinous adenocarcinoma from the gastrointestinal tract.

Special histochemical staining was performed in this case. Mucicarmine staining demonstrated strong positivity, highlighting abundant extracellular mucin pools as well as intracytoplasmic mucin within the tumour cells. These findings confirmed the mucinous nature of the neoplasm. The presence of mucicarmine-positive material supported the diagnosis of mucinous adenocarcinoma and aided in differentiating it from other bladder malignancies, such as urothelial carcinoma with glandular differentiation, which typically lacks extensive mucin production. Immunohistochemical analysis showed the tumour cells to be positive for CK7 and CK20, while CDX2 and GATA3 were negative, further supporting the diagnosis of primary mucinous adenocarcinoma of the urinary bladder.

Discussion

Primary bladder adenocarcinoma is an infrequently diagnosed malignancy accounting for less than 2% of all bladder cancers. It is classified into three categories based on origin: primary, urachal, and metastatic. Among these, the mucinous variant is particularly rare. The tumour most commonly arises at the bladder base or urachal region, especially at the dome and anterior wall, and predominantly affects men in the sixth to eighth decades of life. The incidence is higher in schistosomiasis-endemic areas and in patients with bladder exstrophy [4].

Two principal mechanisms have been proposed for its pathogenesis: persistence of embryonal glandular remnants or glandular metaplasia of the urothelium secondary to chronic irritation, infection, or urinary stasis. Chronic conditions such as cystitis glandularis, recurrent urinary tract infections, and persistent urachal remnants are recognized precursors of malignant transformation.

Clinically, haematuria is the most frequent presenting symptom, often accompanied by dysuria, frequency, or suprapubic pain. Cystoscopic examination commonly demonstrates a solitary mass lesion, indistinguishable from urothelial carcinomas. Due to their deep infiltration, most cases present at stage T2 or T3 at diagnosis [5].

Morphologically, bladder adenocarcinomas exhibit diverse histological patterns: not otherwise specified, enteric type, signet ring cell, mucinous, clear cell, hepatoid, and mixed types. Most are well to moderately differentiated and produce variable amounts of mucin. Abundant extracellular mucin lakes are a hallmark of the mucinous subtype containing clusters of malignant epithelial cells, often with signet ring morphology. These features closely resemble metastatic colorectal adenocarcinoma, posing a diagnostic challenge [5].

Special stain particularly mucicarmine, serves as an important adjunct in confirming the mucinous nature of adenocarcinomas. Mucicarmine specifically stains epithelial mucins, producing a deep rose-pink coloration of intracellular and extracellular mucin pools. In mucinous adenocarcinoma of the

bladder, strong mucicarmine positivity highlights abundant mucin production by malignant epithelial cells, supporting the diagnosis and helping to differentiate it from urothelial carcinoma with glandular differentiation, which usually shows minimal or absent mucin staining [6].

Immunohistochemistry (IHC) is essential to confirm the primary origin. Primary bladder adenocarcinomas typically express CK7, CK20, and CEA, whereas metastatic colorectal carcinomas are CK20-positive, CK7-negative, and show nuclear β-catenin and CDX2 expression. Urothelial carcinomas with glandular differentiation produce less mucin and lack prominent signet ring cells, while PSA and GATA3 positivity support prostatic and urothelial origins, respectively [6].

Distinguishing between urachal and non-urachal adenocarcinomas is vital for management and prognosis. Urachal carcinomas, usually centred at the dome, have a relatively favourable prognosis and can be treated by partial cystectomy with en bloc urachectomy. Non-urachal tumours require radical cystectomy with pelvic lymph node dissection, as they tend to present at an advanced stage. The role of adjuvant therapy remains uncertain; limited evidence suggests modest benefit from postoperative radiotherapy, while chemotherapy has shown minimal survival improvement [7].

Conclusion

Primary mucinous adenocarcinoma of the bladder is a rare but distinct pathological entity that can mimic metastatic gastrointestinal malignancy both morphologically and immunohistochemically. Accurate diagnosis through clinicopathological and immunohistochemical correlation is essential, as prognosis and management differ markedly between primary, urachal, and secondary adenocarcinomas.

Limitations

Complete clinical details and follow-up data were unavailable for the patient. Immunohistochemistry was performed; however, the slides could not be retrieved at the time of manuscript submission.

Conflicts of interest

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

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Ethics committee approval

All ethical concerns including informed consent were addressed by the authors.

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