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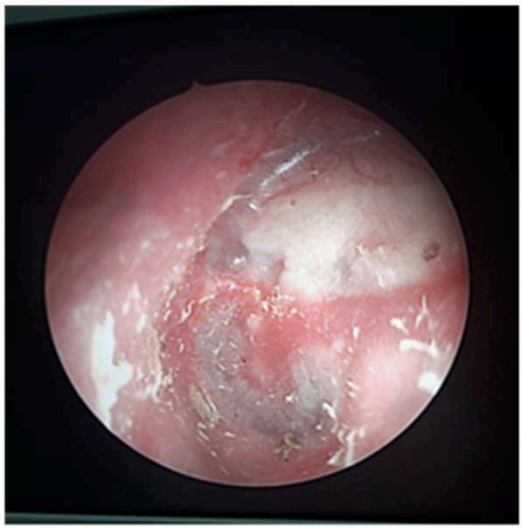
NBEJMS

N B E J M S

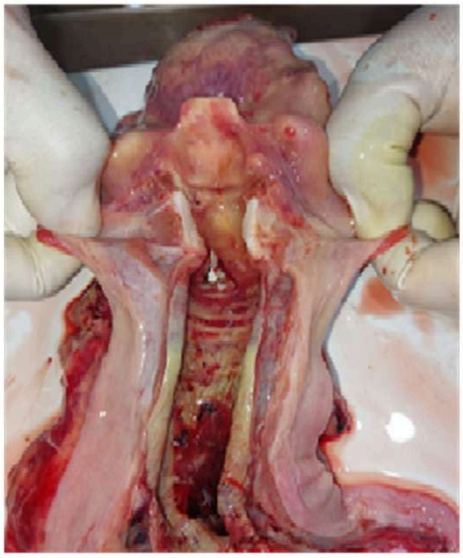
Classical Lichen Planus over trunk

Skin marking on where the point of entry is planned as per the planning CT

Postop otoendoscopy showing healed neotympanum and scutum



Laryngeal oedema at autopsy



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EDITORIAL

The Upscaling Integration of the Private Sector in Meeting the National Healthcare Needs

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India's long-term development roadmap envisions a **developed nation by 2047**, with health as a central pillar. The focus is on **universal health coverage**, digital health transformation, equitable access, and global leadership in healthcare innovation. Corporate hospitals, already a strong pillar of tertiary and quaternary care, will be instrumental in bridging gaps across **infrastructure, workforce, innovation, and global health competitiveness**.

Expectations and Involvement of Corporate Hospitals

Expanding Access & Infrastructure

To establish **quaternary care centers** in tier-2 and tier-3 cities, reduce over-reliance on metros; build **centers of excellence** in oncology, transplant medicine, pediatrics, cardiology, and critical care & support the Government's Ayushman Bharat & PM-JAY schemes by partnering for high-end services.

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Workforce Training & Postgraduate Education

Corporate hospitals can be key **training grounds** under NBEMS/NMC, expanding postgraduate and fellowship seats; play a role in **critical care training**, simulation-based learning, and digital logbooks to meet future workforce demands; structured **mentorship and Entrustable Professional Activity (EPA)-based curricula** can be mainstreamed with corporate hospital–academic partnerships.

Digital Health & Precision Medicine

Drive adoption of **AI, digital twins, wearables, robotics, and tele-ICU networks**; scale up **biobanking and precision medicine platforms**, linking research with clinical care; and lead integration with **NDHM/ABDM (National Digital Health Mission/Ayushman Bharat Digital Mission)** for interoperable, Aadhaar-linked digital health.

Public Health & Community Outreach

Extend **preventive healthcare and wellness programs** beyond hospital walls

(school health, vaccination drives, lifestyle clinics); participate in **chronic disease management programs** using digital therapeutics; improve **emergency & trauma systems**, setting benchmarks in response times and outcomes.

Medical Tourism & Global Leadership

Position India as a **global healthcare hub**, with corporate hospitals leading inbound medical tourism; Ensure international standards in **clinical outcomes, safety, and patient experience;** Promote "Heal in India, Heal by India" by exporting healthcare expertise and telehealth services.

Challenges & Safeguards

Equity–Avoid widening rural–urban and rich–poor gaps. Mandate CSR and PPP models for rural/underserved regions; **Affordability**–Align pricing with **insurance and PM-JAY reimbursements** to ensure inclusivity; **Quality & Standardization**-Strong accreditation (NABH, JCI) and transparent outcomes reporting; **Ethics**-Guard against over-commercialization; reinforce ethics, compassion, and patient-centricity.

Universal Health Coverage & Equitable Access

- Sustaining critical care CCUs in 2-tier cities through the STEP DOWN Model & Hand holding; Learnings from the COVID MODULE
- Centres of excellence in
  - Oncology,
  - Pediatrics,
  - Transplant medicine,
  - Cardiac &
  - Neurosciences
  - Critical care
  - Other emerging fields
- Workforce training: JOINT ACCREDITATION PROGRAMME
- Simulation-based learning: SKILL LABS
- Support the Government in AYUSHMAN B & PMJAY

The private healthcare sector currently contributes over **60–70%** of outpatient care and **50–60%** of inpatient care in India. Leveraging its resources, innovation capacity, and reach will be critical in achieving universal health coverage (UHC) and building a resilient, world-class health system.

Proposed Areas of Contribution

a) Infrastructure Development

- Establish multi-specialty hospitals and diagnostic centres in Tier 2 & 3 cities.
- Partner in building medical colleges and nursing institutions.
- Invest in telemedicine hubs and mobile health units for last-mile access.

b) Health Financing & Insurance

- Support health insurance penetration through low-cost products.
- Co-create risk-pooling mechanisms for catastrophic care.
- Work with the government to expand Ayushman Bharat PM-JAY coverage.

c) Capacity Building

- Joint training programs for doctors, nurses, paramedics, and public health professionals.
- Integrate skill development with National Skill Development Corporation (NSDC) initiatives.
- Promote ethics, quality, and patient safety standards across all facilities.

Strategic Roles of Corporate Hospitals

- Expanding Access and Infrastructure
- Workforce Training and Postgraduate Education
- Digital Health & Innovation
- Public Health and Community Engagement
- Medical Tourism and Global Health Leadership

Way Forward

A multi-stakeholder platform may be considered under NITI Aayog or the Ministry of Health to design a **National Private Sector Engagement Framework** for Viksit Bharat 2047. This should include clear roles, incentives, and accountability mechanisms to ensure alignment with public health goals.

- ***Green & Sustainable Hospitals****:* Net-zero carbon healthcare infrastructure.
- ***Research Leadership****:* Corporate-driven clinical trials, innovation hubs, and AI–biobank ecosystems.
- ***Global Benchmarks****:* Match Mayo, Cleveland, and NHS in quality, outcomes, and innovation.

Corporate hospitals must evolve as **nation-building institutions** within *Viksit Bharat 2047*. Their role is not limited to service delivery but extends to **training the workforce, pioneering innovation, shaping public health, and driving India's emergence as a global healthcare leader**. The following areas need to gather momentum: **Public–Private Partnerships (PPPs)**: Mandate collaboration between corporate and public hospitals for universal coverage; **Green Hospitals 2047**: Encourage investment in **sustainable, net-zero carbon infrastructure; Research & Innovation Hubs**: Incentivize corporate hospitals to establish **AI, biotech, and precision medicine labs; Outcome Transparency**: Enforce reporting of treatment success rates, complications, and patient satisfaction metrics; **Global Competitiveness**: Position India's corporate hospitals alongside leading global institutions (Mayo, Cleveland & NHS).

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ORIGINAL ARTICLE

Association of Lipid Profile with Non-Alcoholic Fatty Liver Disease Diagnosed on Ultrasound

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Abstract

Background: A global prevalence of 25.26% of non-alcoholic fatty liver disease has been reported and it constituted a wide spectrum of chronic hepatic disorders varying from simple steatosis to steato-hepatitis, fibrosis, and cirrhosis, without significant alcohol consumption. The diagnostic tests including MRI and liver biopsy are either costly or invasive as compared to ultrasonography for diagnosis and severity of NAFLD which is more convenient and non-invasive. Thus, the study investigates the association between lipid profiles and NAFLD severity diagnosed by ultrasonography. **Methods:** The study included 126 patients with NAFLD diagnosed on ultrasound, conducted between December 2022 and May 2024 at Government Multispecialty Hospital, Chandigarh. Data tools included socio-demographic information, clinical profile, HbA1c levels, lipid profiles, liver function tests, and ultrasound findings. Statistical analyses, including Chi-square, ANOVA, and multinomial logistic regression, were used to establish associations between variables. **Results:** More than half of the participants (55.6%) had grade I NAFLD, while 31.7% and 12.7% had grade II and III, respectively. Severity of NAFLD was significantly associated with increased levels of total cholesterol levels, TG, LDL, and reduced HDL. ALP and triglycerides were strong predictors of severity of NAFLD. **Conclusion:** The study found significant associations between lipid parameters and NAFLD severity, with ALP and triglycerides as key predictors. Factors like diabetes, gender, and BMI showed no significant correlations, suggesting a complex interplay of metabolic factors in NAFLD severity.

Keywords: Non-alcoholic fatty liver disease, Lipid profile, ultrasonography

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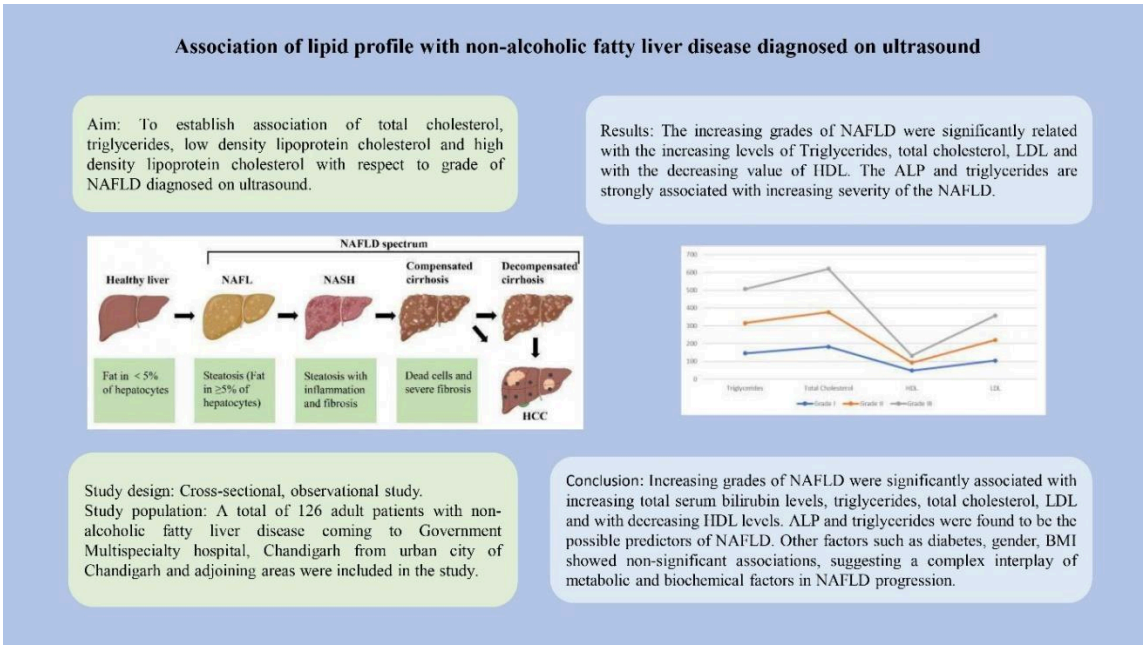
Graphical Abstract



Introduction

Non-alcoholic fatty liver disease (NAFLD) comprises of non-alcoholic fatty liver (NAFL), non-alcoholic steatohepatitis (NASH), and cirrhosis. Up to 15% to 30% of Indians have been found to have fatty liver. Usually, an incidental finding with no clinical manifestations, but few may have discomfort in right upper abdomen, malaise, fatigue, and hepatomegaly on examination. Liver biopsy is the confirmatory test for NAFLD but is an invasive procedure. Thus, ultrasonography being a more convenient and cost-effective method has been used for diagnosing of NAFLD [1]. Non-alcoholic Fatty Liver Disease has become the most common cause of chronic liver disease affecting 2-4% of people worldwide and 17-30% of people in Western nations. While in India, it has been shown to be as high as 15-30% [2-3].

Prevalence of obesity, diabetes, and metabolic syndrome is increasing globally, leading to an increase in the cases of NAFLD, dyslipidaemia being the common eitiology among these. Since the pathognomic feature of NAFLD is the accumulation of fat in the hepatocytes [4].

A diagnosis of fatty liver is made when two out of the following three criteria exist. 1) Liver echotexture is brighter than that of the spleen and kidney; 2) Portal and hepatic vein blending; 3) Decrease in the deep Echo-discontinuous diaphragm.

Grading of hepatic steatosis [5]

Grade 1: Raised hepatic echogenicity associated with normal peri-portal echogenicity and diaphragmatic echogenicity; Grade 2: Raised hepatic echogenicity associated with negligible peri-portal echogenicity and normal visualisation of diaphragm; Grade 3: Non-vsualisation of the diaphragm, undetectable periportal echogenicity, and increased liver echogenicity.

Risk factors for NAFLD

The various etiological factors that lead to NAFLD include genetic factors,

environmental factors, demographic factors, metabolic factors, and gut microbiota. The risk for fatty liver is higher among patients with T2DM, obesity, dyslipidaemia, metabolic syndrome and increasing age [6]. On the other hand, a term "lean NAFLD" has also been defined in literature as hepatic steatosis in people with body mass index (BMI) of less than 25kg/m^2 and around 20% patients of NAFLD are lean. However, lean NAFLD have a better metabolic and histological profile as compared to NAFLD associated with obesity [7].

Dyslipidaemia and NAFLD

The patients with cardiovascular diseases (CVD) risk factors, such as dyslipidaemia and type 2 diabetes mellitus, are more likely to develop NAFLD. Half of patients with type 1 diabetes were also reported to have NAFLD. A strong correlation was found between NAFLD and hypertriglyceridemia, in more than of the patients. The elevated low-density lipoprotein (LDL), very low-density lipoprotein (VLDL), hypertriglyceridemia and reduced high density lipoprotein (HDL) levels are hallmark for NAFLD. The dyslipidaemia associated with NAFLD is pro-atherogenic and CVD is the leading cause of death in these patients. The NAFLD may be used as a one of the features of metabolic syndrome, insulin resistance and CVD risk assessment. Understanding and treating dyslipidaemia is crucial to the overall management of NAFLD patients, to avoid the cardiovascular diseases in these patients [8].

NAFLD and cardiovascular mortality

In recent years, the risk of cardiovascular diseases has increased In NAFLD patients owing to atherosclerosis. The atherogenic dyslipidaemia, systemic inflammation, poor metabolic profile in NAFLD patients increases the risk of atherosclerosis. Due to increasing frequency and severity of cardiovascular events in NAFLD patients, the atherosclerotic cardiovascular diseases risk may be predicted by NAFLD [9].

Among all the different modalities available, MRI is the best imaging for diagnosis of fatty liver. However, it is expensive making its use limited [7]. Ultrasonography (USG), with a sensitivity of 60% to 94% for diagnosing steatosis, is frequently used for population screening and the initial evaluation of patients with suspected NAFLD since it is widely accessible, simple to conduct, and less expensive [10]. The study was done to find out the association of lipid profile with non-alcoholic fatty liver disease diagnosed on ultrasound.

Methods

The study was conducted after taking an approval from the Institutional Ethics committee of Government Medical College and Hospital, Sector 32, Chandigarh. The data were collected from the participants after taking informed consent, between December 2022 to May 2024 at Government Multispecialty Hospital, Sector 16, Chandigarh.

Study Population

126 adult patients of non-alcoholic fatty liver disease coming to Government Multispecialty hospital, Chandigarh from urban city of Chandigarh and adjoining areas were included in the study.

Study design

It was a cross-sectional, observational study.

Inclusion criteria

Those above the age of 18 years, diagnosed to have non-alcoholic fatty liver disease on ultrasound and presented with abdominal complaints in outpatient department or admitted in ward were included.

Exclusion criteria

Patients with fatty liver disease, with a history of significant alcohol consumption and with incomplete hospital records were excluded from the study. Patients taking somatogenic drugs like amiodarone, steroids, diltiazem, methotrexate etc, were also excluded from the study.

Data collection

Eligible patients were explained regarding scope, nature of the study and about the related risks in their own language. After taking an informed consent, the data were collected by detailed history, vital signs and clinical examination. Then they were subjected to ultrasonography using Siemen machine with 3.5-5 MHz transducer. Patients who were diagnosed with fatty liver on ultrasonography were subjected to biochemical testing. Fasting blood samples were taken and lipid profile was estimated in biochemistry lab on fully automated biochemistry analyser XL-1000. Patients were also subjected to other blood investigations like thyroid profile, HBA1c and complete hemogram.

Statistical analysis

Data were analysed using the software statistical package for social sciences (SPSS version 20.0, IBM Corp., Armonk, New York). Univariate analysis included mean (standard deviation) for quantitative variables and frequency (proportions) for qualitative variables. To find out the associations of various grades/severity of non-alcoholic fatty liver disease with socio-demographic details and laboratory investigations, Chi-square, and Analysis of variance (ANOVA) tests were used for qualitative and quantitative variables, respectively. A multinomial logistic regression analysis was done to identify the association of various risk factors with different severities of NAFLD categorised as mild, moderate, and severe. Associations with p-value<0.05 at 95% confidence level were taken as significant.

Results

A total of 126 patients who were diagnosed with non-alcoholic fatty liver disease were included in the study with the mean age of 51.8 (±10.4 SD) years and a range of 25 to 69 years. Approximately, equal number of females (n=65) and males (n=61) were included in the study. Baseline characteristics of clinical examination included blood pressures, body mass index, history of diabetes mellitus and grades of non-alcoholic fatty liver disease as shown on Table 1. Nearly half (48.4%) of the patients were obese and 21% were overweight. More than half (55.6%) of the participants had grade I NAFLD, whereas 31.75% and 12.7% had grades II and III, respectively. Approximately 44% of the participants in the study were diabetics. Mean fasting glucose (120 ± 64.8SD) mg/dl, glycated haemoglobin (HbA1c) (6.1 ± 1.6SD)% were calculated. Distribution of lipid parameters and liver function tests were observed for NAFLD grades (Figure 1).

Table 1. Baseline characteristics of the study participants (n=126).

Variables		Mean ± SD
Age (years)		51.8 ± 10.4
FBG (mg/dl)		120.9 ± 64.8
SBP (mm of Hg)		132.6 ± 16.6
DBP (mm of Hg)		76.3 ± 9.1
HbA1c (%)		6.1 ± 1.6
Variables		Frequency (%)
Gender	Male	65 (51.6)
	Female	61 (48.4
BMI (Kg./m^2)	Obese ≥30)	61 (48.41)
	Overweight (25-29.99)	27 (21.43)
	Normal (18.5-24.99)	37 (29.37)
	Underweight (<18.5)	1 (0.79)
Diabetes mellitus	Present	55 (43.7)
	Absent	71(56.3)
Grades of NAFLD	Grade I	70 (55.6)
	Grade II	40 (31.7)
	Grade III	16 (12.7)

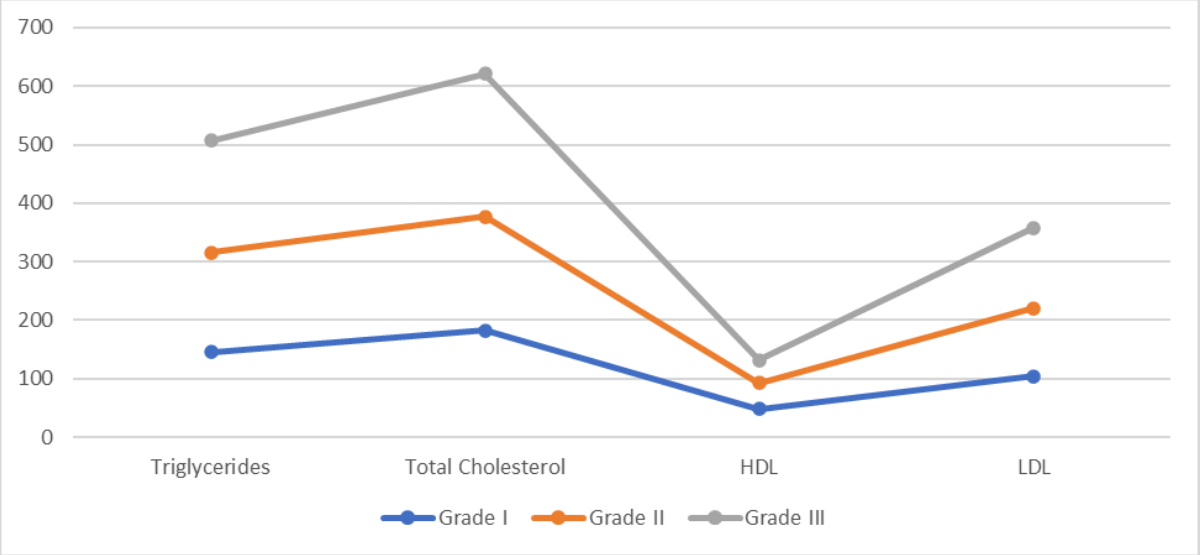


Figure 1. Correlation between NAFLD and serum lipid profile (n=126).

Socio-demographic characteristics and NAFLD

The mean age of the participants in years was 51.26 (10.94 SD), 52.4 (10.04 SD), 52.69 (9.39 SD), for grades I, II, III, of NAFLD, respectively. It was observed that the age of the participants had no association with the severity of NAFLD (p-value=0.847). Gender of the study participants had no association with the severity of disease (p-value=0.985). Likewise, severity of NAFLD was not associated with the body mass index of the participants (p-value=0.406) (Table 2).

Table 2. Association of NAFLD with clinical profile (n=126)

Variables		NAFLD grades [Mean (SD)]			p-value
		Grade I	Grade II	Grade III	
Age		51.26 (10.94)	52.4 (10.04)	52.69 (9.39)	0.847
Gender (%)	Male	34 (55.7)	19 (31.1)	8 (13.1)	0.985
	Female	36 (55.4)	21 (32.3)	8 (12.3)	
Body mass index (%)	Obese	38 (62.3)	19 (31.1)	4 (6.5)	0.406
	Overweight	13 (48.1)	8 (29.6)	6 (22.2)	
	Normal	18 (48.6)	13 (35.1)	6 (16.2)	
	Underweight	1 (100)	0	0	
DM (%)	Present	28 (50.9)	19 (34.5)	8 (14.5)	0.643
	Absent	42 (59.1)	21 (29.6)	8 (11.3)	
Lipid profile	Triglycerides (mg/dl)	145.03 (40.22)	170.53 (61.62)	191.56 (74.56)	**0.002**
	Total Cholesterol (mg/dl)	182.34 (50.39)	194.93 (61.02)	244.25 (107.29)	**0.003**
	HDL (mg/dl)	48.01 (9.43)	44.53 (11.18)	39.03 (11.4)	**0.006**
	LDL (mg/dl)	103.77 (39.99)	116.55 (45.6)	138.06 (54.55)	**0.013**
LFTs	Total serum bilirubin (mg/dl)	40.5 (0.28)	0.82 (0.31)	0.95 (0.52)	**<0.001**
	SGOT (IU/L)	40.5 (22.28)	54.5 (26.5)	59.34 (31.4)	**0.01**
	SGPT (IU/L)	31.43 (17.18)	38.24 (16.14)	32.45 (11.83)	0.099
	ALP (IU/L)	105 (38.65)	146 (69.15)	157 (101.09)	**<0.001**

Clinical profile and NAFLD

Systolic and diastolic blood pressures of the patient were also compared for severity of NAFLD. However, no significant association was observed among the two (p-value= 0.806 and 0.068, respectively). Majority of the diabetic patients, had grade I NAFLD, although the association was not statistically significant (p-value=0.643) Higher mean of parameters of lipid profile was significantly associated with higher grade of NAFLD except HDL levels, where higher level of HDL was associated with lower grade of NAFLD as shown in Figure 1 and Table 2. On comparing the liver function tests with severity of NAFLD, higher mean of the parameters was significantly associated with higher grades of NAFLD except serum glutamic pyruvic transaminase (SGPT) levels (Table 2).

Predictors of non-alcoholic fatty liver disease

Factors significant in bivariate analysis and based on literature, were all included in the multinominal logistic regression (Table 3). Of all these factors, alkaline phosphatase, and triglyceride levels were the significant predictors of moderate (grade II) NAFLD, in which for every unit increase in ALP, the odds of moderate NAFLD compared to mild (grade I) NAFLD increased by 1.017 (95% CI: 1.004-1.031). Similarly, triglycerides also exhibited a significant association indicating a slight increase in the likelihood of moderate NAFLD with rising triglyceride levels with and odds of 1.013 (95% CI: 1.002-1.026). Alkaline phosphatase (ALP) also predicted the likelihood of NAFLD, with higher odds of 1.023 (95% CI: 1.008-1.039) for severe (grade III) NAFLD when compared to mild NAFLD.

Table 3. Predictors for non-alcoholic fatty liver disease among the study participants (n=126)

NAFLD	Predictor	Odds ratio	95% CI
Moderate – mild (Ref.)	SGOT	1.013	0.982 – 1.045
	SGPT	1.004	0.964 – 1.046
	ALP	**1.017**	**1.004 – 1.030**
	Cholesterol	0.995	0.983 – 1.005
	LDL	1.001	0.987 – 1.014
	Triglycerides	**1.013**	**1.002 – 1.025**
	HDL	1.002	0.951 – 1.057
	HbA1c	1.333	0.794 – 2.237
	BMI	0.856	0.676 – 1.083
	Gender	0.782	0.305 – 2.002
	Diabetes Mellitus	0.418	0.305 – 2.002
	Obese-normal weight	1.076	0.165 – 6.991
	Overweight-Normal weight	0.775	0.180 – 3.338
Severe-mild (Ref.)	SGOT	1.024	0.984 – 1.064
	SGPT	0.947	0.881 – 1.016
	ALP	**1.023**	**1.007 – 1.038**
	Cholesterol	1.010	0.994 – 1.024
	LDL	1.007	0.986 – 1.026
	Triglycerides	1.006	0.988 – 1.024
	HDL	0.996	0.929 – 1.066
	HbA1c	1.015	0.481 – 2.142
	BMI	1.089	0.865 – 1.370
	Gender	0.754	0.178 – 3.193
	Diabetes Mellitus	1.170	0.112 – 12.172
	Obese-normal weight	0.124	0.012 – 1.230
	Overweight-Normal weight	1.215	0.208 – 7.087

Model	Deviance	AIC	R^2	X^2	df	P
1	185	245	0.287	54.9	28	**0.002**

Discussion

Non-alcoholic fatty liver disease (NAFLD) along with Non-alcoholic steatohepatitis (NASH) have become one of the major causes of mortality and morbidity in the world. This study was an observational cross-sectional design including 126 participants who had NAFLD diagnosed on the ultrasound, with various grades of the liver damage. The objective was to understand the relationship between lipid parameters and the severity of NAFLD. Majority of the population was in the 5th and the 6th decade of their lives, with a mean age of 51.3 years. Sharma S et al [11] and Mahaling et al [1] showed a mean age of 48.3 years and 49.1 years, respectively, showing the distribution in the same age brackets as the current study. Another study by Bhusal et al [12] also had a similar mean age of 45.39±11.99 years, where most of the study population was in 4th and 5 the decades of life. The mean age in the western studies have been between 41-45 years.

Most of the cases, 55.6% were in grade I of liver damage, followed by grade II in 31.7% of the population and grade III being the least common in the study population, only in 12.7%. Other studies have also shown a similar pattern. One study [12] also showed (n= 100) that 83% had mild fatty liver, and 17% had moderate, while none were having severe fatty liver amongst his study population. Mahaling et al [1] (n= 70) showed that 48.15% of the population had grade I liver

damage, 41.85% had grade II liver damage, while only 10% of the population had grade III liver damage. Sen et al [13] (n= 385) also showed that 83.4% of the study population had grade 0 liver damage, followed by grade I with 11.7%, grade II with 3.1% and the least with grade III, 1.8%. In a study by Baghel et al [14] (n= 50), they showed that there were more cases of grade II (48%) than grade I (40%) and grade III (12%).

In the current study it was found that the serum triglycerides (TG), total cholesterol and LDL were increased in 59.5%, 48.4%and 41.3%, respectively, while HDL was decreased in 58.7% of the study population. Similar findings were seen in the study by Baghelet al [14], and Mahaling et al [1]. Sen et al [13] showed similar trend, but the mean values for the lipid parameters were even higher than seen in the current study. Liver enzymes like alanine transaminase (ALT) and aspartate transaminase (AST) determine the liver function in general. In this study it was observed that the values of total serum Bilirubin, ALP, AST, ALT, were increasing with increase in the severity of the liver disease. Further, the increase in the values of total serum bilirubin (TSB), AST, and ALP had a significant positive correlation with increasing severity of the liver disease ($p< 0.001$, for all), while the change in the values of ALT had no significant correlation with the severity of the disease ($p= 0.099$). In other studies, like Baghel et al [14], Mansour-Ghanaeiet al [15], also found that higher values of lipid parameters were more likely associated with the severity of the liver disease. In another study, Ramesh et al [16] found that the increase serum ALT and dyslipidaemia maybe directly responsible for increase in NAFLD and also supported by Zakeri et al, who reported that elevated ALT and dyslipidaemia may play a role in the development and progression of NAFLD [17]. In this study it was noticed that increased total serum bilirubin was directly and significantly related with the increase in NAFLD chances. The patients included in this study were all diagnosed with NAFLD during the routine ultrasonography subjected to those who presented to opd with complaints such as pain abdomen, anorexia, weight loss, weight gain and patients admitted in wards.

The regression analysis highlighted the importance of ALP and triglycerides as significant predictors of NAFLD severity. ALP consistently demonstrated a stronger association with increasing severity of NAFLD, underscoring its relevance as a marker for disease progression. While triglycerides were associated with moderate NAFLD, their impact on severe NAFLD was not significant. Other factors such as diabetes, sex and BMI showed non-significant associations, suggesting a complex interplay of metabolic and biochemical factors in NAFLD progression.

Study Limitations

The study has several limitations inherent to its design. As a hospital-based, cross-sectional study, there is a possibility of selection bias, and the findings may not be fully generalizable to the broader community. The absence of a control group limits comparative analysis. Additionally, the lack of longitudinal follow-up prevents evaluation of disease progression over time. The relatively short study duration and sample drawn from a single urban setting may also restrict the representativeness of the results.

Conclusion

The study findings revealed that over half of the participants were diagnosed with grade I non-alcoholic fatty liver disease. An upward trend in lipid profile parameters, including low-density lipoprotein, triglycerides, and total cholesterol, was observed with increasing severity of NAFLD. A statistically significant association was found between higher NAFLD grades and elevated levels of total serum bilirubin, triglycerides, total cholesterol, LDL, as well as reduced high-density lipoprotein levels. Among the biochemical markers, alkaline phosphatase and triglycerides emerged as potential risk factors for disease progression. Conversely, variables such as diabetes, gender, and body mass index did not show significant associations, indicating that the development and advancement of NAFLD likely involve a multifaceted interaction of metabolic and biochemical factors.

Statements and Declarations:

Conflicts of interest

The authors declare they do not have conflict of interest.

Funding

No funding was received for conducting this study.

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ORIGINAL ARTICLE

Study of Clinical Variants of Lichen Planus and Its Association with Histopathological Findings in a Tertiary Care Centre

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Abstract

Background: Lichen Planus (LP) is a chronic, immune-mediated papulosquamous disorder with multiple clinical variants. Accurate diagnosis requires taking into account both clinical and histological features and acquire an association between them. **Objective:** To evaluate clinical variants of lichen planus and associate them with histopathological findings. **Methods:** A hospital-based observational study was conducted over 18 months at a tertiary care centre. A total of 70 patients with clinically diagnosed lichen planus were included. Clinical examination and lesional biopsies were performed. Histopathological findings were recorded and compared with clinical diagnoses. **Results:** The study found the highest incidence of LP in the age group of 31-40 years (30%). Females predominated the sample with a male to female ratio of 1:1.56. Most patients presented with lesions of 6–11 months' duration. Histopathological association with clinical diagnosis showed an 83% concordance. Classical LP was the most prevalent form (45%), primarily affecting the lower limbs. Frequently observed histopathological features included inflammatory infiltrate at the dermo-epidermal junction (DEJ) (70%), irregular acanthosis (64%), melanin incontinence (64%), hyperkeratosis (57%), and basal cell vacuolation (53%). **Conclusion:** LP exhibits a varied age-related prevalence with a complex clinical spectrum. This study highlighted the importance of clinical presentation along with histopathological characteristics in order to arrive at a diagnosis, indicating the need for an appropriate diagnostic approach, so as to effectively understand the aspects of LP.

Keywords: Lichen Planus, Autoimmune Disorders, Clinical Variants, Histopathology

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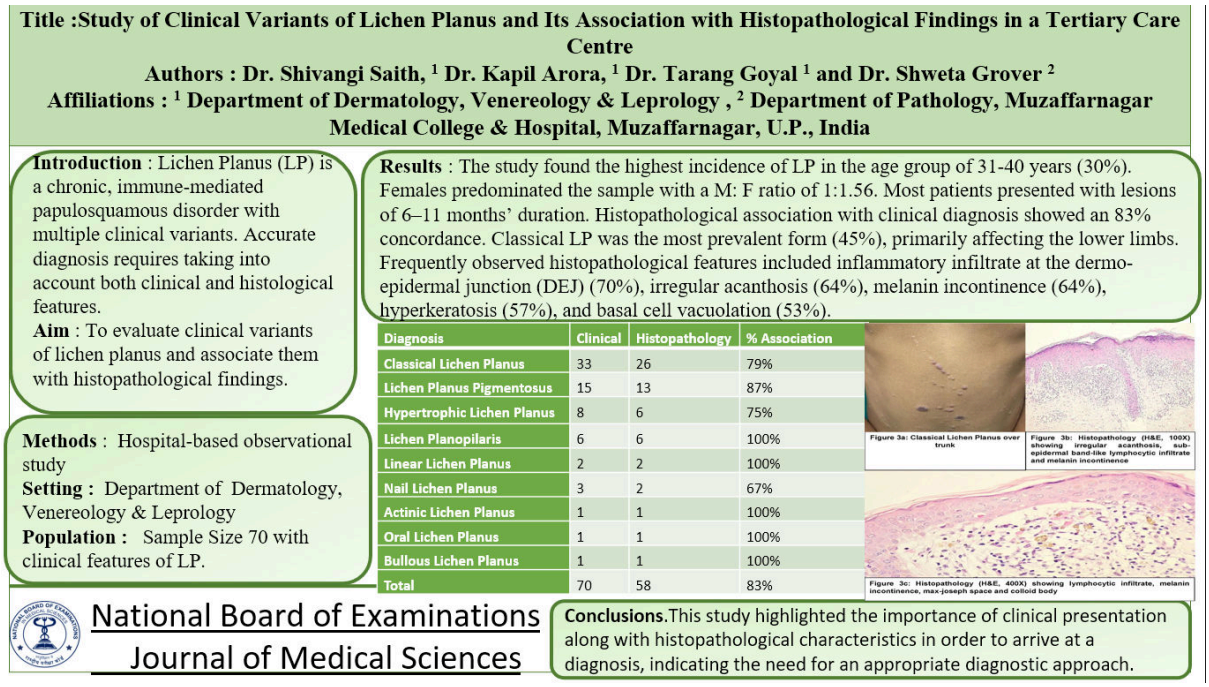
Graphical Abstract



Introduction

LP is a chronic immune-mediated papulosquamous disorder affecting skin, nails, hair, and mucous membranes. It involves a complex interaction between immune system anomalies, environmental stressors, and genetic predisposition [1]. Polygonal, pruritic, violaceous papules are clinical characteristics of classical LP [2]. Other clinical variants include hypertrophic, lichen planus pigmentosus, actinic, linear, follicular, bullous, and mucosal forms [3]. Histologically, Lichen planus is the prototype of lichenoid interface dermatitis, which is defined by a lymphocytic inflammatory infiltrate at the dermo-epidermal junction [4].

Despite well-defined features, LP often mimics other dermatoses, complicating its diagnosis. Histopathology provides diagnostic confirmation, however there are certain similar microscopic patterns that exist among various skin conditions. This study aims to establish a connection between clinical observations and pathological findings to overcome this challenge and achieve an accurate diagnosis. The majority of literature focuses on individual variants with minimal data on clinico-histopathological association across the full spectrum. This study aims to bridge that gap as well.

Materials and Methods

A Hospital-based observational study involving 70 patients with clinical features of LP was conducted in the Department of Dermatology, Venereology, and Leprology at a Tertiary Care Centre for a period of 18 months. Patients of all ages and sexes, presenting with clinical features of lichen planus, who consented to clinical evaluation and provided written informed consent for biopsy, were enrolled in the study. Pregnant or lactating women and those with a history of hypertrophic scarring or keloid formation were excluded.

Study procedure included a detailed history and clinical examination which was followed by a 3–4 mm punch biopsy from

lesional skin following consent from all participants. Samples were fixed in 10% formalin and stained with H&E. Findings were documented and correlated with clinical diagnoses.

Statistical Analysis

This study was a descriptive observational study. As it did not involve hypothesis testing, intervention, or comparative arms, no inferential statistical analysis was performed. The data were summarized using frequency and percentage distributions.

Results

The study comprised of 70 clinically diagnosed cases of LP. Of these, 43 patients (61%) were females and 27 (39%) were males, with a male-to-female ratio of 1:1.56. The most commonly affected age group was 31-40 years, accounting for 21 patients (30%), followed by 11-20 years (n=19, 27%) and 21-30 years (n=15, 21%) (Figure 1). In terms of disease duration, 29 patients (41%) had symptoms lasting for 6-11 months, while 28 patients (40%) presented within 6 months of onset.

Classical LP was the most prevalent variant, occurring in 45% (n=26) of patients, followed by lichen planus pigmentosus (LPP) (n=13, 22%), hypertrophic LP (n=6, 10%), and lichen planopilaris (LPPi) (n=6, 10%). Linear, nail, oral, bullous, and actinic LP were among the less common forms (Figure 2). In terms of site distribution, 70% (n=49) of patients had cutaneous lesions only, while 14% (n=10) had both cutaneous and mucosal involvement. The lower limbs were the most commonly affected anatomical site, accounting for 23% (n=15) of cases.

A clinico-pathological association was assessed for each clinical variant and it was found that among the 33 cases clinically diagnosed of classical lichen planus, 26 (79%) had consistent histopathological features. Of the 15 cases of lichen planus pigmentosus (LPP), 13 (87%) showed histological confirmation. Hypertrophic LP exhibited an association in 6 of 8 cases (75%), and lichen planopilaris (LPPi) demonstrated histological confirmation in all 6 cases (100%). Nail LP showed association in 2 of 3 cases (67%). Furthermore, all cases of linear LP, oral LP, bullous LP, and actinic LP were clinically and histopathologically consistent. Overall, 83% of the patients showed clinico-histopathological concordance (Table 1).

Histopathological examination revealed various epidermal and dermal changes. The most frequently observed epidermal findings were irregular acanthosis (n=45, 64%), followed by hyperkeratosis (n=40, 57%) and hypergranulosis (n=28, 40%). Dermal findings included a band-like inflammatory infiltrate at the DEJ in 49 cases (70%), melanin incontinence in 45 patients (64%), basal cell vacuolation in 37 (53%), and perivascular/peri-adnexal inflammatory infiltrates in 30 cases (42%). Colloid bodies were observed in 14 patients (20%) (Table 2).

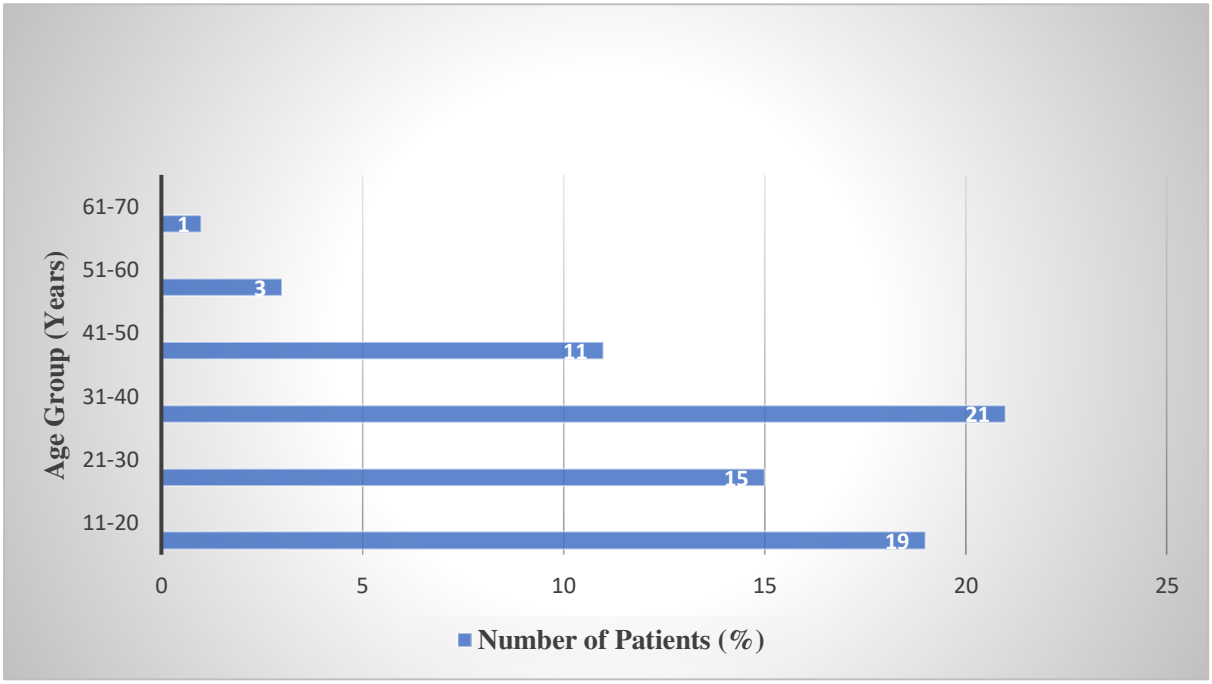


Figure 1. Age wise distribution of Lichen Planus patients

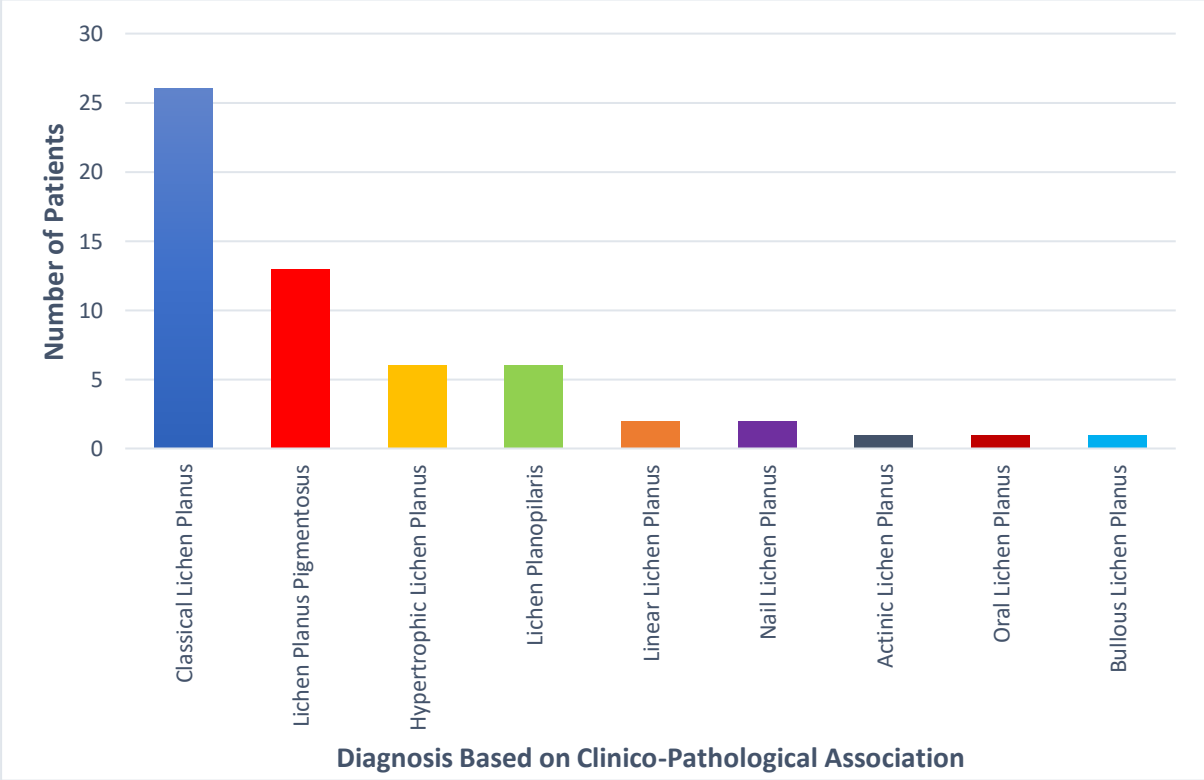


Figure 2. Based on Clinico-Pathological Association

Table 1. Association between Clinical and Histopathological Diagnosis of Lichen Planus

Diagnosis	**Clinical**	**Histopathology**	**% Association**
Classical Lichen Planus	33	26	79%
Lichen Planus Pigmentosus	15	13	87%
Hypertrophic Lichen Planus	8	6	75%
Lichen Planopilaris	6	6	100%
Linear Lichen Planus	2	2	100%
Nail Lichen Planus	3	2	67%
Actinic Lichen Planus	1	1	100%
Oral Lichen Planus	1	1	100%
Bullous Lichen Planus	1	1	100%
Total	**70**	**58**	**83%**

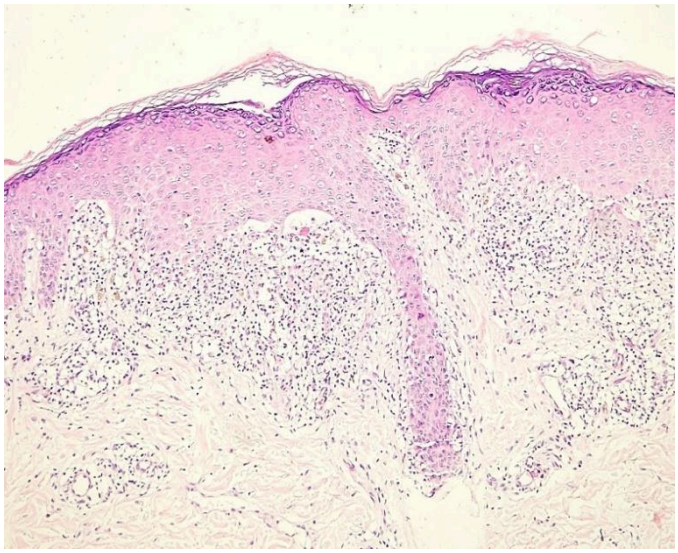
Table 2. Histopathological Findings in all LP patients

	Histopathological Findings	No. of Patients
Epidermal Findings	Hyperkeratosis	40
	Atrophy	4
	Parakeratosis	16
	Hypergranulosis	28
	Irregular Acanthosis	45
	Spongiosis	8
	Saw Tooth Rete Ridges	7
Dermal Findings	Basal cell Vacuolation	37
	Inflammatory Infiltrate at DEJ	49
	Colloid Bodies	14
	Melanin Incontinence	45
	Perivascular and Peri adnexal infiltrate	30
	Peri-follicular fibrosis	6

On variant-wise histopathological evaluation, classical LP predominantly exhibited irregular acanthosis, hyperkeratosis, and interface dermatitis with dense inflammatory infiltrate at the DEJ. LPP showed prominent melanin incontinence and basal cell vacuolation. LPPi was characterized by perifollicular fibrosis and peri-adnexal inflammatory infiltration. Hypertrophic LP commonly displayed hypergranulosis and irregular acanthosis as key histological features (Figures 3 and 4).

(A)

(B)



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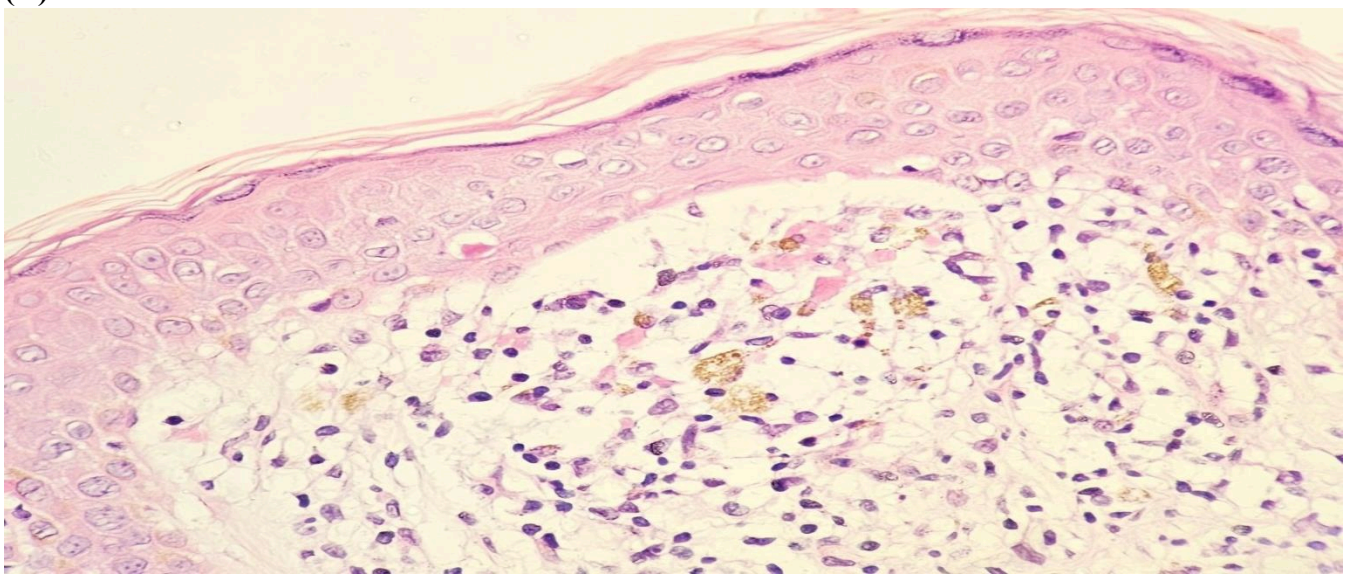
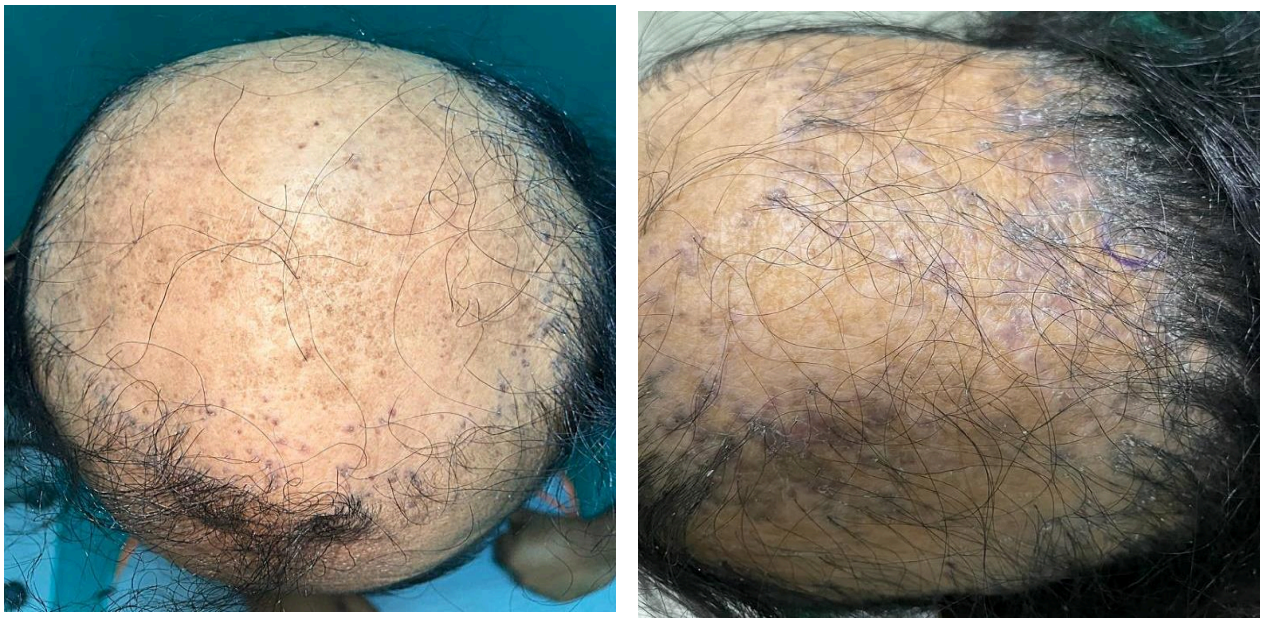


Figure 3: **A** Classical Lichen Planus over trunk; **B** Histopathology (H&E, 100X) showing irregular acanthosis, sub-epidermal band-like lymphocytic infiltrate and melanin incontinence; **C** Histopathology (H&E, 400X) showing lymphocytic infiltrate, melanin incontinence, max-joseph space and colloid body

(A)



(B)

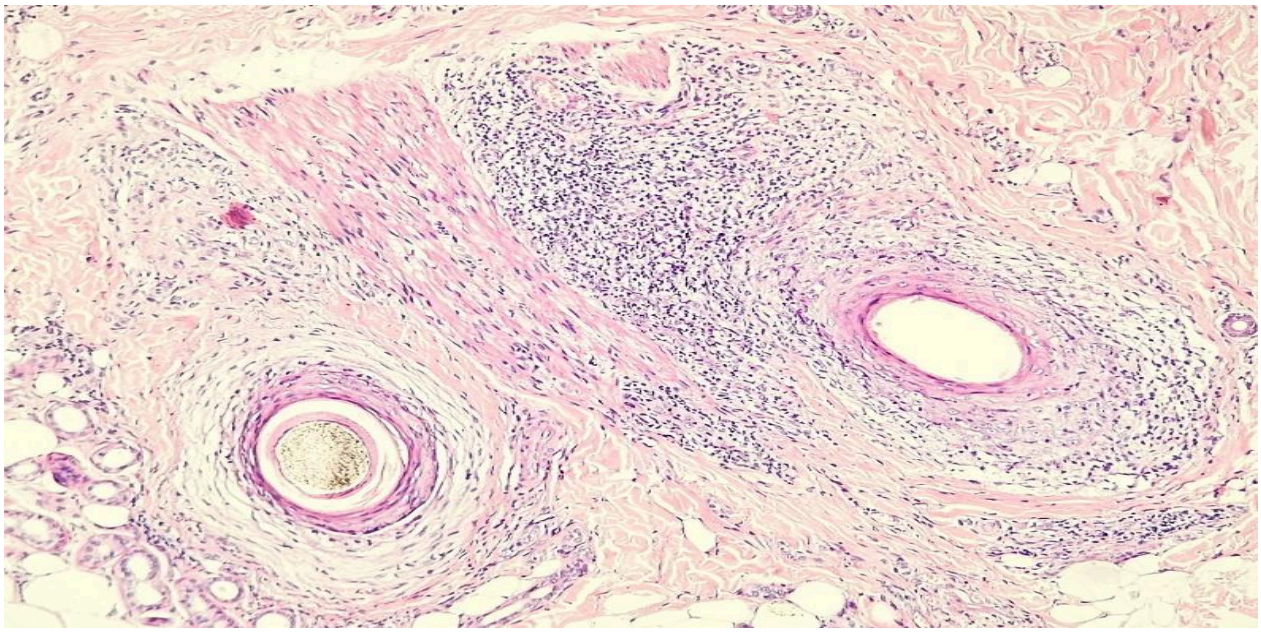


Figure 4. **A** Lichen Planopilaris over scalp; **B** Histopathology (H&E,100X) showing dense perifollicular lymphocytic inflammation and perifollicular concentric fibrosis

Discussion

This study provided a comprehensive evaluation of the clinico-histopathological association across multiple clinical variants of LP which sets it apart from most previous literature, where specific variants were evaluated and reported separately. Our findings not only highlighted LP distribution patterns in Indian population, but also emphasized on the diagnostic importance of combining clinical observations with histopathological

study to improve diagnostic accuracy and treatment outcome.

In this study, LP was found to be most prevalent among individuals aged 31–40 years, accounting for 30% of the total cases, followed by those aged 11–20 years (27%) and 21–30 years (21%). This suggests that LP is commonly seen in younger to middle-aged adults. These results are consistent with findings from studies by Wankhade et al. [5] where the commonly affected group was 30–39 years, and Parihar et al. [6] which also reported the 20–40 years age group as most commonly affected.

The gender distribution revealed a female predominance, with 61% of cases being female and 39% male, resulting in a male-to-female ratio of 1:1.56. This trend was similarly reported by Vani et al. [1] Parihar et al. [6] and Bhagwat et al. [7] showing higher prevalence among females. Disease duration data revealed that 81% of patients had lesions lasting less than one year, with 40% presenting with symptoms for less than 6 months and 41% reporting a duration between 6 and 11 months. Similar findings were reported by Wankhade et al. [5] and Bhattacharya et al. [8] showing that a significant proportion of patients had disease durations of less than one year.

Classical LP was the most common type, accounting for 45% of cases with histopathological confirmation in 79% of cases. Lichen Planus Pigmentosus (LPP) was the second most common variant (22%), with a greater histopathological association of 87%. Hypertrophic LP and Lichen Planopilaris (LPPi) accounted for 10% of patients, with 75% and 100% histological confirmation, respectively. Nail LP had a 67% concordance rate, and all cases of linear, oral, bullous, and actinic LP were confirmed histologically. Overall, clinico-histopathological concordance was found in 83% of cases, which was consistent with the findings of Agarwala et al. [9] and Srivani et al. [10] who reported concordance rates of 85% and 81.6%, respectively.

Cutaneous involvement alone was observed in 70% of patients, while 14% had both cutaneous and mucosal manifestations. These findings were comparable to those of Singh et al. [11] who reported cutaneous-only involvement in 69.6% of cases and combined cutaneous and mucosal presentations in 22.9%. Lower limbs were the most common site of involvement, affecting 23% of patients. This is most likely related to the Koebner phenomenon, which states that trauma-prone areas, such as the lower limbs, are more likely to acquire lesions. Kachhawa et al. [12] (62%) and Parihar et al. [6] (77.2%) reported similar findings.

Histopathological examination showed that among epidermal changes, irregular acanthosis was the most frequently observed feature (45 patients), followed by hyperkeratosis (40 patients), hypergranulosis (28 patients). Saw-toothed rete ridges and epidermal atrophy were less common. Among dermal changes, inflammatory infiltration at the DEJ was most common (49 patients), followed by melanin incontinence (45 patients), basal cell vacuolation (37 patients), perivascular and peri-adnexal infiltrates (30 patients) and colloid bodies (14 patients). Agarwala et al. [9] reported similar findings, noting hypergranulosis and band-like inflammatory infiltrate at the DEJ as key features.

Variant-wise analysis revealed distinct histopathological patterns. In Classical LP, inflammatory infiltrate at the DEJ was observed in all patients (100%),

followed by irregular acanthosis (88%) and hyperkeratosis (81%). These results are in line with those of Parihar et al. [6], who reported high frequencies of orthokeratosis, pigment incontinence, wedge-shaped hypergranulosis, and band-like infiltrate. In LPP, melanin incontinence was the hallmark feature (100%), followed by basal cell vacuolation (85%) and inflammatory infiltrate at the DEJ (62%), indicating an inflammatory process underlying the pigmentation. These findings correspond well with those of Parihar et al. [6] and Wankhade et al. [5]

Lichen Planopilaris (LPPi) demonstrated peri-follicular fibrosis in all patients (100%), with 83% showing perivascular and peri-adnexal infiltrates and 50% showing inflammatory infiltrate at the DEJ. Hypertrophic LP displayed a characteristic triad of inflammatory infiltrate at the DEJ, irregular acanthosis, and hypergranulosis in all patients (100%). Wankhade et al. [5] similarly reported hyperkeratosis, hypergranulosis, and lymphocytic infiltration in most cases.

Histopathological examination of Bullous Lichen Planus demonstrated subepidermal blister formation accompanied by a dense, band-like infiltrate of lymphocytes and histiocytes at the dermo-epidermal junction. These findings align with those reported by Tripathy et al. [13], who also observed subepidermal clefting and interface dermatitis as characteristic features of Bullous LP.

While histopathology serves as a key diagnostic tool, many dermatoses within the spectrum of interface reactions share basal cell damage as a fundamental feature. Distinction relies on thorough analysis of key histological features of each entity along with recognition of pattern of inflammation. Additionally, since clinical features of Lichen Planus may be influenced by prior topical or systemic treatments, it is important to take a detailed treatment history and select the most recent, non-ulcerated lesion for biopsy. Hence, histopathological findings must be interpreted in conjunction with comprehensive clinical evaluation to ensure diagnostic accuracy and guide appropriate management

Limitations

These include a relatively small sample size and a single-centred design, affecting its generalizability. This study may have selection bias due to its dependence on voluntary participation and biopsy consent, possibly excluding less willing candidates.

Conclusion

Lichen Planus presents with diverse morphological patterns. Among the clinical variants, Classical LP was the most prevalent, followed by Lichen Planus Pigmentosus, Hypertrophic LP, and Lichen Planopilaris. Histopathological examination demonstrated an overall clinico-pathological concordance of 83%, highlighting the role of biopsy in diagnostic confirmation.

While histopathology is essential for diagnosing Lichen Planus and distinguishing it from other lichenoid dermatoses through subtle yet definitive microscopic differences, accurate interpretation requires integration with detailed clinical evaluation. A thorough treatment history and biopsy from a recent, untreated lesion are essential to ensure appropriate patient management. This study adds to existing literature by offering a consolidated analysis of individual LP

variants withing a single study. By highlighting the association between clinical and pathological findings, we emphasize the need for a comprehensive approach to diagnosis and treatment.

Conflict of Interest

The authors declare no conflicts of interest.

Ethical Approval

The study was approved by the Institutional Ethics Committee.

Funding

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ORIGINAL ARTICLE

Assessing the Site of Skin Entry in CT Guided Biopsies by an Additional CT Scan with Local Anesthesia Needle in situ

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Abstract

Background and Aims: A guidance system, when integrated into CT-guided procedures, may improve the safety and outcome of the procedure. This study aimed to evaluate the error rate concerning the site of needle entry after planning with the help of an additional scan with the local anaesthetic needle in situ. **Settings and Design:** Consecutive cases booked for CT-guided biopsies were included in the study prospectively from 01 November 2018 to 21 November 2018. An additional CT scan was performed in the region of local anaesthetic infiltration, with needle left in situ. The location of skin entry was compared between the planning CT and the CT after placement of the local anaesthetic needle. This can be easily learned and reproduced in a different centre on different CT machinery. Any mismatch identified was corrected by inserting a local anaesthesia needle into the newly marked site and CT-guided procedure was completed. **Results:** There were 3/71 CT-guided biopsies in which a change in the site of skin entry was detected, out of which one was on the wrong side of the body and two were errors in Z-axis. There were 3 cases of pneumothorax noted post biopsy. There was adequate histopathological yield and radiation dose was within safe limits. **Conclusions:** This novel technique of checking the local needle placement prior to proceeding with the CT-guided procedure with larger needle helps to identify errors in the placement of the needle. This would further help in selecting the correct site of biopsy, improving the yield, and reducing complications.

Keywords: CT guided procedures, Local anaesthesia needle, Yield, Complications

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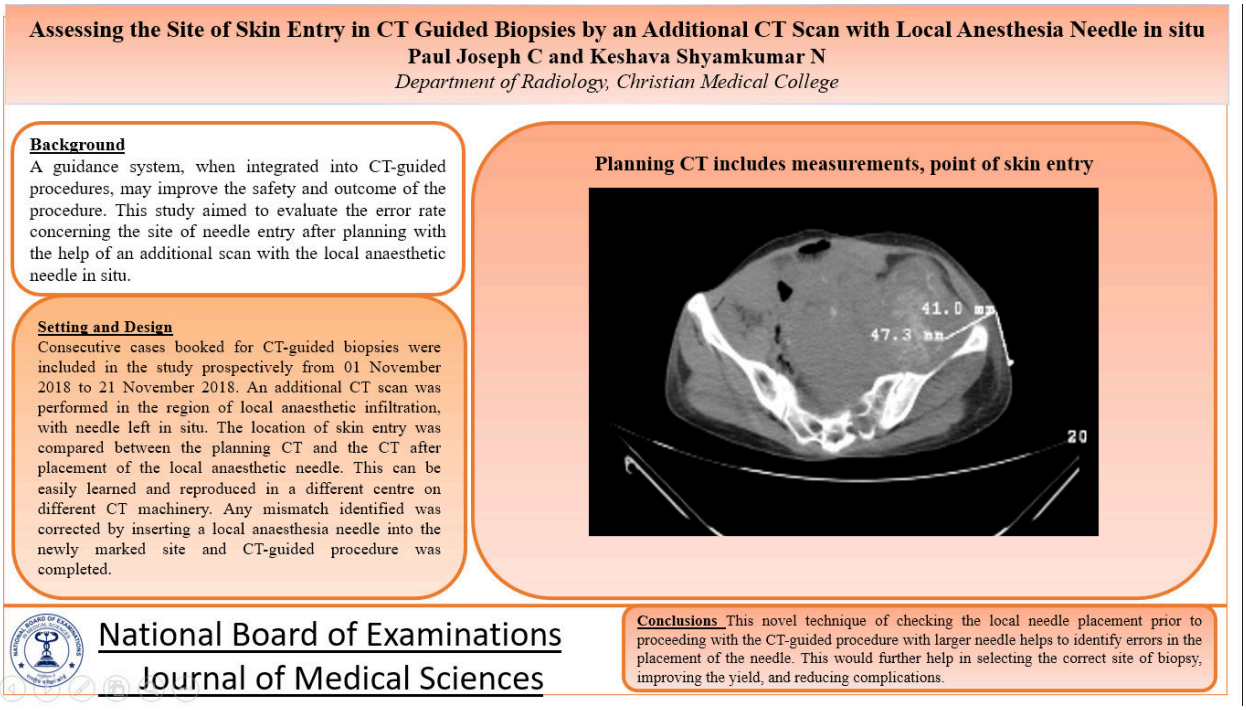
Graphical Abstract



Introduction

Histopathological diagnosis of various lesions can be made using CT-guided biopsy. In addition, clinically inaccessible lesions can undergo biopsy using this technique. Early diagnosis with this modality can reduce morbidity and mortality. For example, for lesions in lung [1] and vertebral bodies, CT-guided biopsy is preferred and largely replaces an open biopsy.

We use a novel approach to guidance by introducing an additional check scan using the local anesthesia needle. This is done after administering local anesthesia at the region of planned skin entry. A check scan is done to confirm the site of planned skin entry and the entry site is adjusted if there is a change in the same.

Methods

Patient Population

All patients undergoing CT-guided procedures with an additional check scan with a local anesthesia needle were recruited for this study. The patients who did not consent were excluded from the study. The study was carried out from 01 November 2018 to 21 November 2018 in a tertiary care center in south India.

Procedure

The study was performed in Philips brilliance CT equipment (402, 4th Floor, Worldmark, Sector 65, Gurugram, Haryana 122018). Hematological parameters like PT/APTT, platelets, and hemoglobin are reviewed and discussed with the hematologist about the need for blood products which is required during and after the procedure. Blood-borne virus screening is done and necessary precautions and segregation of the procedure items which came in contact with the patient's blood are

done by the procedure team. All the procedures are done on an in-patient basis.

CT-guided biopsy can be performed on a routine CT machine. Various guidance systems including laser guidance system [2] and robotic arm are used to improve the success rates. However, guidance systems come with the costs of installing additional equipment and training. We used 2% lignocaine as a local anaesthetic, subcutaneous injection, maximum of 10 ml was injected. Artificial intelligence was not used in this study.

Steps of Procedure

1. Positioning of patient on table:
   The position of the patient is decided based on the location of the lesion and in view of avoiding vital structures.
2. Planning CT with a linear marker on the patient's body:
   The marker is a linear piece of an angiographic catheter, wrapped on adhesive tape and placed on the patient's body before the planning CT. The linear radio-opaque line on the CT is used as a reference point to plan the point of entry of the needle.
3. Planning of the track of biopsy needle:
   The point of skin entry, depth of needle to be inserted, and angle of entry are determined on planning CT (Figure 1). These are done in the console and a separate monitor is available in the procedure room to review the planning CT during the procedure.

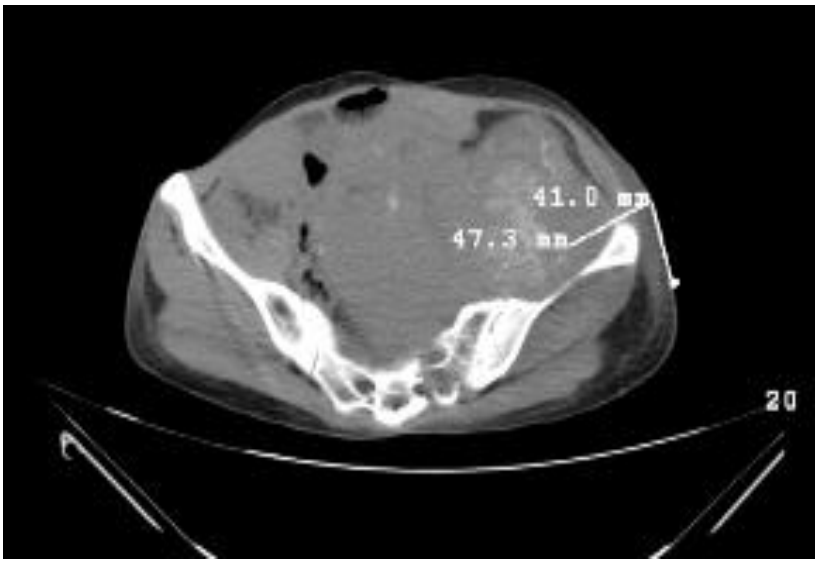


Figure 1. Planning CT includes measurements, point of skin entry, and angle of entry of the needle.

4. Marking on the skin:
   The marking is done on the planned site of needle entry after verbal consent. The marking is usually a cross or in form of a T (Figure 2).

Figure 2. Skin marking on where the point of entry is planned as per the planning CT.

5. Local anesthesia:

The local anesthesia needle is placed at the skin marking. This is a crucial step in this study. The local anesthesia needle is placed according to the angle and at the site of the marking done on the skin as pre-planned in the planning CT (Figure 3). After the local anesthesia is administered, the needle is left in place and at the same orientation as the planned track of biopsy needle.

Figure 3. Local anesthesia needle left in place at the same site of planned skin entry with same angulation.

6. Limited CT with local anesthesia needle in situ:

A check CT is done after the local anesthesia needle is left in place (Figure 4). This additional step is done to confirm the planned track is being followed by the local anesthesia needle and as a reference for the biopsy needle to follow the same orientation. This orientation of the local anesthesia needle is closely studied by the radiologist. The radiologist tries to replicate this while placing the biopsy needle. This helps to home in on the target with accuracy. This improves the yield and avoids complications. This may not add significantly to the procedure time or have additional patient discomfort.

Figure 4. Check CT with the local anesthesia needle.

7. Biopsy needle placement:

The biopsy needle placement is done at the site marked and according to the angle of the planning CT and the orientation of the local anesthesia needle (Figure 5).

Figure 5. Biopsy needle insertion at the same site and angulation of the local anesthesia needle.

8. Check CT:

This step is essential to confirm the position of the biopsy needle tip inside the lesion of interest (Figure 6), to calculate the excursion distance of the biopsy needle and to take the tissue sample.

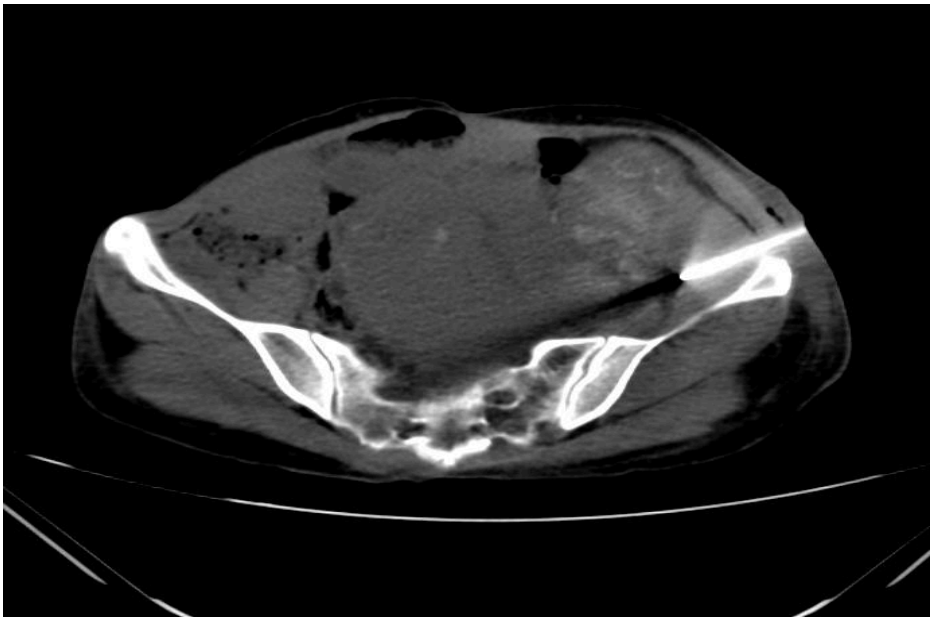


Figure 6. CT check scan with biopsy needle in place

9. Biopsy:

Biopsy is done by the radiologist using the biopsy gun (Figure 7) and the sample is grossly checked for adequate quantity, if there is pus then an aspiration/drainage can be planned.

Figure 7. Biopsy is being performed with a biopsy gun.

10. Check CT:

    This is done to check for complications like pneumothorax, intra-abdominal bleed, to look for the path of the biopsy needle, and to confirm the sample has been taken from the area of interest within the lesion.

Statistical Analyses

The outcome of 71 patients who underwent the procedure using laser guidance was recorded and analyzed. The analyses were in terms of percentage, mean, median, and range.

The difference in the site of skin entry, anatomical location of the lesion, complications, and yield were calculated in terms of percentage. If the change in position of local needle is more than 0.5 cm from the planned CT trajectory, we assume that it is more likely that the biopsy needle may not follow the planned trajectory.

Complications were noted at the time of the procedure from the console and images of the same were sent to the PACS server. The data on the adequacy of the sample (yield) was obtained from the clinical workstation.

Total radiation dose during the procedure (calculated in terms of dose length product) of all the patients from the dose report was sent to PACS at the end of the study. The total radiation doses were presented as mean radiation doses.

Results

There were 71 CT-guided procedures during the study period. There were 35 males and 36 females. The mean age of patients was 46 years, with a range varying between 12-77 years. The number of cases in which changes in the site skin entry of the biopsy site were found on the check scan done with the local anesthesia needle in situ. Change in site of entry was taken only in cases where there was more than 0.5 cm difference between the planned site of skin entry and the actual site of biopsy. 3 such cases were found (Table 1). Out of the three cases found to have a change in skin entry site, one was change in the side of the biopsy in a paravertebral soft tissue biopsy and two were due to change in Z-axis in a cases of biopsy of lung lesions (Table 2). Repositioning of the needles was done in these cases and procedures were carried out successfully.

Table 1. Frequency of significant differences (>0.5 cm) between planned and actual skin entry sites detected on check scan with local anesthesia needle in situ.

Significant difference more than 0.5 cm in site of skin entry					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	68	95.8	95.8	95.8
	Yes	3	4.2	4.2	100.0
	Total	71	100.0	100.0	

Table 2. Distribution of needle position changes detected on check scan, categorized by change of side or change in Z-axis.

Needle position	Frequency	Percent	Valid Percent	Cumulative Percent
no change	68	95.8	95.8	95.8
change of side	1	1.4	1.4	97.2
change in z axis	2	2.8	2.8	100.0
Total	71	100.0	100.0	

Out of the 71 cases, the most common procedure was biopsy of lung lesions (22, 30.9%), followed by vertebral and para-vertebral lesions (18, 25.3%) (Table 3). The yield was calculated based on the histopathology and culture reports retrieved from the hospital clinical workstation. There were no inadequate samples reported from the pathology department (Table 4). The mean radiation dose was 535 mGy-cm (Table 5) with a standard deviation of 272 mGy-cm. There were 3 cases (13.6%) of pneumothorax found (Table 6) during the procedures and they were all managed conservatively.

Table 3. Distribution of biopsy sites among study participants.

Site of procedure	Frequency	Percent	Valid Percent	Cumulative Percent
Lung lesion	22	30.9	30.9	30.9
Vertebral and para-vertebral	18	25.3	25.3	25.3
Mediastinum	5	7.04	7.04	7.04
Renal abscess drainage	4	5.6	5.6	5.6
Others	22	30.9	30.9	30.9
Total	71	100.0	100.0	100.0

Table 4. Adequacy of biopsy yield based on histopathology and culture reports

Yield		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	adequate	62	87.3	87.3	87.3
	not applicable	9	12.7	12.7	100.0
	Total	71	100.0	100.0	

Table 5. Summary statistics (mean, median, range) of radiation dose length product during CT-guided procedures.

Radiation_dose_mGycm		
N	Valid	51
	Missing	20
Mean		535.55
Median		493.00
Std. Deviation		272.651
Minimum		133
Maximum		1646
Percentiles	25	361.00
	50	493.00
	75	674.00

Table 6. Frequency and type of complications observed during CT-guided procedures.

Complications					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	68	95.8	95.8	95.8
	Pneumothorax	3	4.2	4.2	4.2
	Total	71	100.0	100.0	100.0

Discussion

CT-guided procedures have become an inevitable aspect of clinical practice which provides much required histopathological diagnosis. This modality has a high diagnostic accuracy and safety profile [3]. CT-guided procedures are especially useful in intra-thoracic and intra-abdominal lesions [4,5]. Usually, CT-guided procedures are carried out on a normal CT gantry with an additional guidance system. Many guidance systems are studied or used in various centers around the world. Few of them are laser, real-time 3D navigation systems, and smartphone-guided systems [6,7]. However, these guidance systems come with additional costs and software/hardware inclusions to the existing CT machine and console. These procedures can alternatively be carried out by a novel technique by using the local anesthesia needle as a guidance system. This method not only has the advantage of guiding the radiologist to the target lesion but can also find the discrepancy in the site of planned skin entry, thus avoiding inadvertent larger biopsy needle entry. This may prevent complications such as large vessel, ureteric injury, and increase the yield. This technique can be easily adopted and reproduced across different centers and CT platforms.

Further new residents may feel confident when given an additional check scan prior to the actual biopsy.

Our results showed that there were three instances where there was change in the site of skin entry (>0.5 cm) which was detected by this method. There were 3 (13.6%) instances of pneumothorax out of the 22 biopsies performed for lung lesions. A meta-analysis published by Ya Ruth Huo et al showed a pooled rate of pneumothorax after CT-guided lung biopsies to be 25.9% [8]. The p value when compared to a large study of CT guided lung biopsies, was less than 0.5 [10]. Another study in Indian population showed a complication rate of 13.9% [11]. There were no other complications in biopsies involving other organ systems. There was a 100% yield. The mean radiation dose was 535 mGy-cm, with a standard deviation of 276, which is comparable with a study published by Shuai Leng, in which the median dose length product of CT-guided procedures were 657 to 2351 mGy-cm [9]. When compared to laser guided system, our technique showed better results in terms of complications and yield [2].

This technique can be practiced on a routine CT machine. This may improve the safety, yield, reduce the radiation dose and complications. There are no additional consumables required.

The drawback of this study includes a short additional time required for the extra scan with local anesthesia in situ also warn that the length or placement of the needle used for the local anesthesia should be such that it should not reach the pleural space. In cases where a wrong location was identified with the help of local needle, we relocated the correct site, and the procedure was continued. Hence, we do not have a comparison arm to test the complication rate if a coaxial biopsy needle would have been inserted in the wrong location.

Conclusion

Assessing the site of skin entry in patients undergoing CT-guided biopsies by an additional CT scan with local anesthesia needle in situ is a simple technique. In this short series, we identified errors in longitudinal (Z) and transverse (XY) planes. While performing CT-guided procedures, this technique can be easily adapted with no additional consumables in low resource settings. Studies with larger numbers and multicentric trials may be necessary to further assess the yield and reduce the complications.

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Conflict of Interest

No conflicts of interest were declared by the authors.

Ethical Approval

Ethics committee approval for this prospective study was obtained.

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ORIGINAL ARTICLE

Adolescent Mental Health and Teachers' Health Literacy: A Mixed-Methods Exploration and Assessment of Coping and Support Mechanisms in Puducherry Schools

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Abstract

Background: Globally, adolescents face a significant mental health burden, with unique challenges in India. Teachers are pivotal in early identification and support but often lack adequate mental health literacy (MHL). This mixed-methods study assessed the prevalence of mental health problems among adolescents, their coping strategies, and teachers' MHL in Puducherry, India. **Methods**: A convergent parallel design was employed. Cross-sectional surveys using the Strengths and Difficulties Questionnaire (SDQ) were conducted with 420 adolescents (10-19 years) from 4 schools (2 urban, 2 rural). Focus group discussions (FGDs; n=32 students) and in-depth interviews (IDIs; n=16 teachers) explored coping mechanisms, support systems, and MHL. Quantitative data were analysed using SPSS (v21); qualitative data underwent thematic analysis via NVivo 12. **Results**: 35.2% (n=148) of adolescents screened positive for significant mental health difficulties. Peer problems (43.8%), emotional difficulties (25.7%), conduct problems (24%), and hyperactivity (15.7%) were prevalent. Rural adolescents reported significantly higher domestic violence exposure (28.8% vs. 17.1%; p=0.004) and lower psychosocial support (13.6% vs. 39.2%; p<0.001). Key qualitative themes included: 1) Academic/family stress as primary triggers; 2) Predominant use of maladaptive coping (avoidance, emotional suppression); 3) Critical barriers (teacher training gaps, stigma, absent counselling); 4) Variable teacher MHL reliant on experience, not formal training. **Conclusion**: High adolescent mental health needs coexist with insufficient teacher capacity and school support systems. Integrating standardized MHL training into teacher education, deploying school counsellors under national programs (e.g., Ayushman Bharat), and implementing student resilience programs are urgent priorities.

Keywords: Adolescent wellbeing, school health, mental health literacy, teachers

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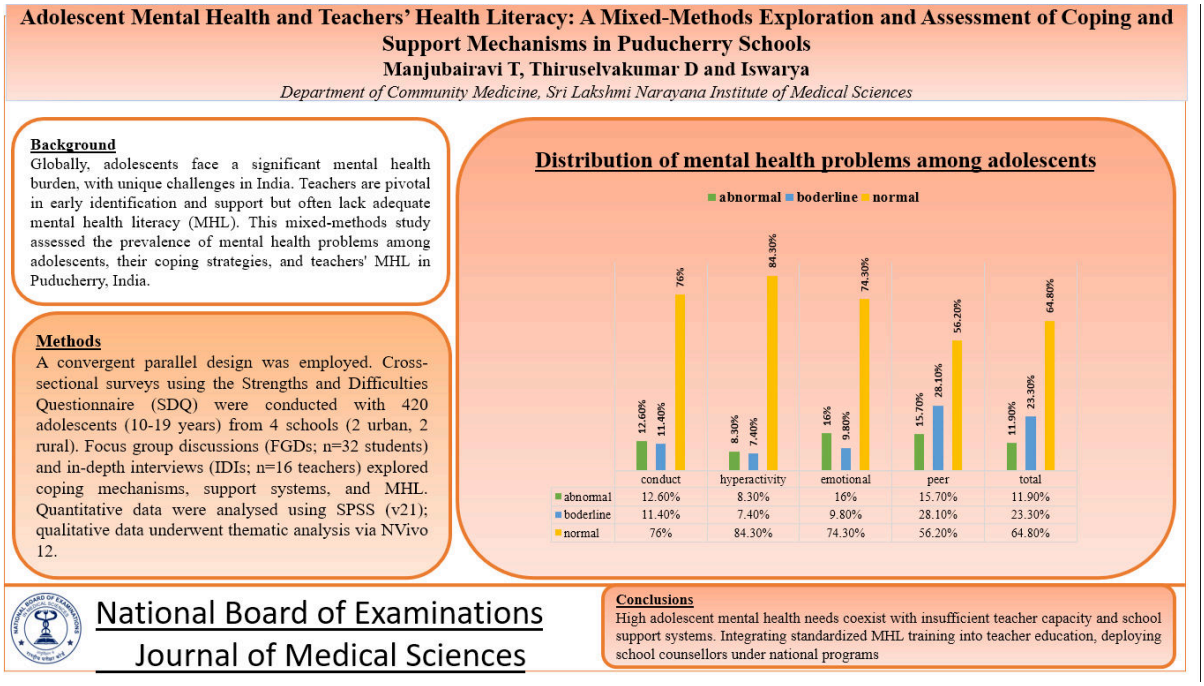
Graphical Abstract



Introduction

Adolescence, a complex and dynamic phase between childhood and adulthood, collectively constitute approximately 23% of the global population, with projections indicating 1.3 billion adolescents (ages 10 to 19) and 0.6 billion young adults (ages 20 to 24) by 2025, notably with India housing the largest adolescent demographic of 397 million [1]. Adolescence represents a formative stage for social, emotional, and cognitive development, a critical window shapes behaviours, relationships, and coping skills that often persist into adulthood. The development of social and emotional behaviours essential for mental health occurs during adolescence. These include learning to control emotions, establishing healthy sleep habits, exercising regularly, and improving interpersonal, coping, and problem-solving abilities [1], have historically received little attention in terms of global health policy and financing [1].

Adolescence is the period of emergence of most mental health disorders. Recent evidence reveals that adolescent mental health problems affect 10-20% of youth worldwide with substantial gaps in prevention, intervention, and support systems. The prevalence of mental diseases in India was 7.3% and was almost equal in both sexes, in the age group of 13 to 17 years. Active interventions are needed for around 9.8 million adolescent Indians aged 13 to 17. In metropolitan areas, the prevalence of mental diseases was almost double (13.5%), compared to rural (6.9%) areas [2]. Despite recognition of this burden, crucial barriers remain: persistent stigma, myths about causation (including supernatural beliefs), and insufficient access to professional mental health services—all of which delay early identification and intervention efforts. These obstacles not only inhibit effective care but also exacerbate psychological distress and negative outcomes [3]. Early identification and intervention help to

achieve favourable outcomes for most students.

Globally, coping mechanisms among adolescents range from adaptive strategies (problem-solving, seeking social support, mindfulness) to maladaptive behaviours (avoidance, substance abuse, self-isolation) [4]. Inappropriate coping strategies, including drug use, liberation from society, and self-harm, are not uncommon [5]. Among adolescents who experience ongoing stress, designing successful interventions to support resilience and mental health requires an understanding of adolescents' coping mechanisms.

Given their significant presence in educational settings, educators play a critical role in recognizing early signs of distress among adolescents and fostering supportive environments, with evidence indicating that enhanced teacher support correlates positively with improved mental health outcomes in teenagers [6]. Teachers have a valuable opportunity to provide mental health education to students in a range of contexts, ultimately benefiting their campus experience; thus, they are able to recognize students at risk for psychological issues and work with colleagues to carry out necessary interventions aimed at promoting both mental health and academic success, while also experiencing difficulties due to limited training and a lack of mental health awareness that constrains their ability to effectively confront these pressing challenges.

Teachers' mental health literacy, grounded in interpersonal interaction theory, is crucial for their professional development and the mental well-being of adolescents, significantly influencing student mental health through teacher-student relationships, as teachers promote positive interactions and problem-solving strategies, enhancing the well-being of both teachers and students and serving as a key outcome of effective classroom instruction [8]. Another study found that even among educated populations, myths such as mental illnesses being caused by supernatural forces persist [9]. Enhancing mental health literacy among teachers is crucial for their own wellness and for cultivating a nurturing atmosphere for students.

The critical importance of adolescent mental health and the indispensable participation of educators are recognized; however, there is a significant absence of localized, detailed research throughout different regions of India. National assessments indicate an overall deficiency in comprehensive school mental health initiatives and qualified personnel throughout India [6].

To date, limited research has holistically explored the full spectrum and prevalence of mental health issues, their interaction between students' coping strategies, available support systems, and the literacy and preparedness of teachers to address emerging mental health concerns and additionally the systemic barriers (cultural, institutional, and personal) inhibiting rapid, effective mental health support in school contexts, considering urban versus rural dynamics. This study aims to address these gaps using a mixed-methods approach, combining quantitative prevalence data with qualitative insights from students and teachers, to inform the design of culturally relevant interventions.

The choice of a mixed-methods design is a deliberate methodological strength, allowing for both precise prevalence estimation and a nuanced, in-depth understanding of underlying

psychosocial determinants, coping strategies, and systemic barriers from the perspectives of both adolescents and teachers. Quantitative data (e.g., SDQ scores, prevalence) identifies the extent and nature of problems, while qualitative data (FGDs, IDIs) explains the underlying reasons and lived experiences, including barriers like stigma and lack of training [1]. This synergy is crucial for developing interventions that are not only statistically supported but also culturally sensitive, contextually relevant, and practically feasible. By elucidating the complexities of mental health in this specific Indian context, the study offers valuable insights transferable to similar low- and middle-income settings grappling with the "hidden burden" of adolescent mental health issues.

Methodology

Study design and setting

The study employed a convergent parallel mixed-methods design, which is a robust approach for comprehensively understanding complex public health phenomena. This design involved an initial quantitative cross-sectional survey among school-going adolescents, followed by a qualitative component comprising focused group discussions (FGDs) with students and in-depth interviews (IDIs) with school teachers. The rationale for this sequence is to first establish the prevalence and statistical associations of mental health issues and mental health literacy quantitatively, and then to use qualitative methods to delve deeper into the underlying reasons, lived experiences, perceptions, and contextual factors that explain these quantitative patterns. For instance, quantitative findings on specific mental health challenges or coping strategies could inform the lines of inquiry in the subsequent qualitative phase, allowing for a richer, more nuanced exploration of the “why” and “how” behind the observed numerical data.

Study Population and Sampling

The study was conducted from July 2023 to October 2023 in four schools (two rural and two urban) selected from the service areas of a tertiary care hospital in Puducherry. The study included two target groups: school-going adolescents aged 10-19 years and school teachers. For the quantitative component, a sample size of 420 students was estimated using the formula

$n=Z2p(1-P)/d2$, with a proportion (P) of 53.6% derived from a prior study in Ghana. While this formula provides a statistical basis, it is important to acknowledge that using a prevalence rate from Ghana as a proxy for Puducherry, India, assumes a degree of epidemiological similarity that may not fully hold. The multistage sampling technique, involving stratification by grades and systematic sampling within each school, for achieving a representative student sample was done.

Concerning the qualitative phase, purposive sampling included a cohort of 48 participants (32 students and 16 teachers). Data collection persisted until saturation was achieved. To enhance qualitative rigor, it is essential to specify the criteria for purposive sampling. For students, criteria encompassed diversity in age, gender, academic performance, and urban/rural background. For teachers, the criteria involved years of experience, subjects taught, and school type (urban/rural). This generally entails detailing the process by which new themes ceased to arise from interviews or focus groups, signifying adequate data collection for understanding the phenomenon under investigation.

Data collection tool and procedure

The data were collected after obtaining permission from the institute's ethics committee. Students were approached during their free period on different dates, and the lead researcher was present to clarify any doubts. Data were collected from 420 students using a strengths and difficulties questionnaire (SDQ) distributed by hand to students after getting informed consent and assent. It is a 25-item behavioural screening questionnaire with 5 scales, with a total score of 0-40. FGDs were conducted among 7- 8 students and IDIs from 3-5 teachers from each school using a semi-structured interview guide till the point of saturation, and it was moderated by 2 researchers. All the interviews were conducted in Tamil, and they were audio recorded.

Data analysis

Quantitative data were processed in MS Excel and subsequently analysed through SPSS version 21. The outcomes were articulated through a combination of descriptive and inferential statistical frameworks. Continuous variables were represented as means alongside standard deviations, while categorical variables were expressed in terms of percentages and proportions. Comparative analyses between groups were conducted utilizing the chi-square test. A p-value threshold of <0.05 was deemed statistically significant. The qualitative data underwent analysis through both deductive and inductive approaches utilizing NVivo 12.

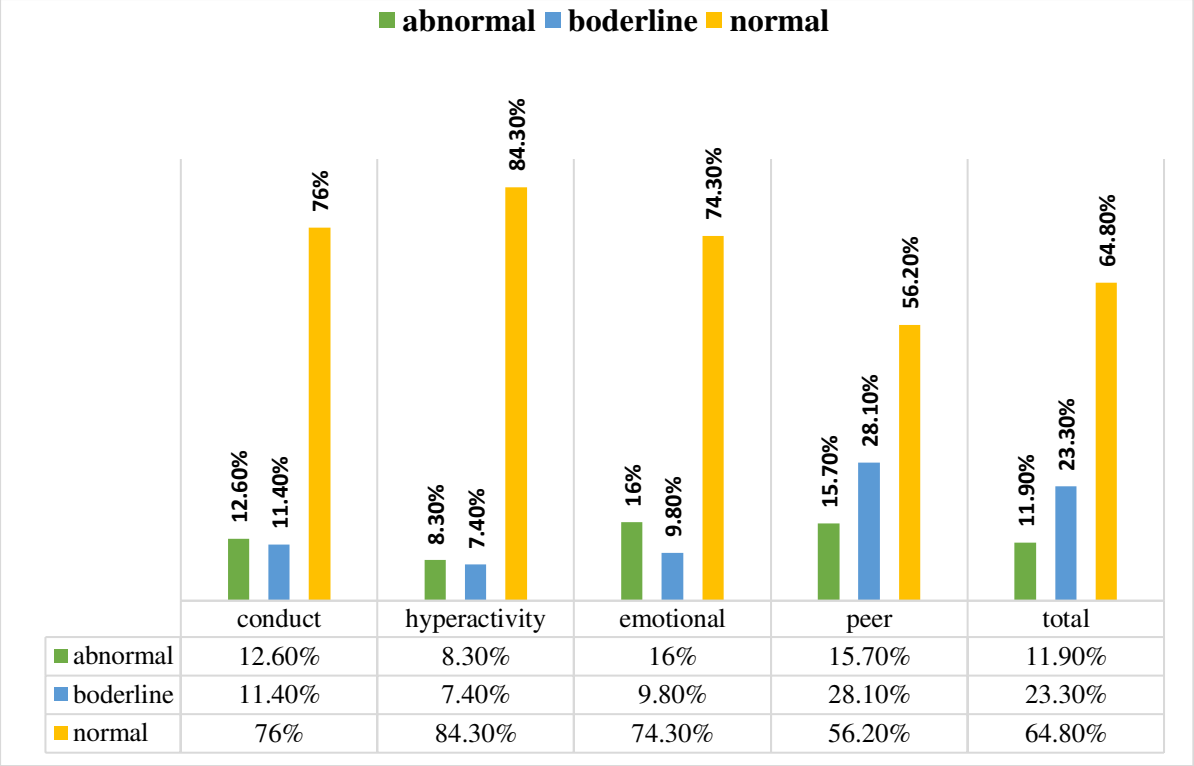
Results

The study sample included 420 school-going adolescents distributed between an urban area with 222 participants and a rural area with 198 participants. Table 1 shows the demographic characteristics of the study participants. The study participants consisted mainly of adolescents from 10 to 19 years with an almost equal gender distribution between male (57.1%) and female groups (42.9%). The results indicated that rural students differed significantly from urban students in their residential status distribution and parent educational level and number of siblings, as well as domestic violence exposure and school bullying and psychosocial support levels ($p < 0.05$).

Table 1. Socio-demographic characteristics of study participants based on the geographical distribution of schools

Variable	Total (n=420)	Urban (222)	Rural (198)	P-Value
Age in years				0.978
10-13	136 (32.4)	72 (32.4)	64 (32.3)	
14-17	146 (34.8)	78 (35.1)	68 (34.3)	
18-19	138 (32.8)	72 (32.5)	66 (33.4)	
Gender				0.866
Male	240 (57.1)	126 (56.8)	114 (57.6)	
Female	180 (42.9)	96 (43.2)	84 (42.4)	
Religion				0.591
Hindu	389 (92.6)	205 (92.3)	184 (93)	
Muslim	24 (5.7)	12 (5.4)	12 (6)	
Christian	7 (1.7)	5 (2.3)	2 (1)	

Grade				0.993
9th	103 (24.5)	55 (24.8)	48 (24.2)	
10th	116 (27.6)	61 (27.5)	55 (27.8)	
11th	108 (25.7)	56 (25.2)	52 (26.3)	
12th	93 (22.2)	50 (22.5)	43 (21.7)	
Residential status				**<0.0001**
Home	304 (72.4)	132 (59.5)	172 (86.9)	
Hostel/relative's house	116 (27.6)	90 (40.5)	26 (13.1)	
Parents marital status				0.610
Living together	394 (93.8)	207 (93.2)	187 (94.4)	
Separated/widowed	26 (6.2)	15 (6.8)	11 (5.6)	
Parents education				**0.001**
Literate	202 (48.1)	135 (60.8)	83 (41.9)	
illiterate	218 (51.9)	87 (39.2)	115 (58.1)	
Academic performance				0.995
Poor	126 (30)	67 (30.2)	59 (29.8)	
Average	138 (32.9)	73 (32.9)	65 (32.8)	
Good	156 (37.1)	82 (36.9)	74 (37.4)	
Number of siblings				**0.005**
No siblings	46 (11)	34 (15.3)	12 (6.0)	
<2	156 (37.1)	84 (37.8)	72 (36.4)	
≥2	218 (51.9)	104 (46.9)	114 (57.6)	
Substance Abuse				0.983
Yes	19 (4.5)	10 (4.5)	9 (4.5)	
No	401 (95.5)	212 (95.5)	189 (95.5)	
Smartphone usage per day				0.087
<2 hours	166 (39.5)	80 (36)	86 (43.4)	
2-4 hours	238 (56.7)	130 (58.6)	108 (54.6)	
>4 hours	16 (3.8)	12 (5.4)	4 (2)	
Domestic violence				**0.004**
Yes	95 (22.6)	38 (17.1)	57 (28.8)	
No	325 (77.4)	184 (82.9)	141 (71.2)	
Bullied in school				**0.005**
Yes	74 (17.6)	50 (22.5)	24 (12.1)	
No	346 (82.4)	172 (77.5)	174 (87.9)	
Suicidal thoughts				0.970
Yes	57 (13.6)	30 (13.5)	27 (13.6)	
No	363 (86.4)	192 (86.5)	171 (86.4)	
Psychosocial support				**0.000**
Yes	114 (27.2)	87 (39.2)	27 (13.6)	
No	306 (72.8)	135 (60.8)	171 (86.4)	



	conduct	hyperactivity	emotional	peer	total
abnormal	12.60%	8.30%	16%	15.70%	11.90%
boderline	11.40%	7.40%	9.80%	28.10%	23.30%
normal	76%	84.30%	74.30%	56.20%	64.80%

Figure 1. Distribution of mental health problems among adolescents

Figure 1 illustrates that a notable proportion of students reported emotional difficulties, conduct problems, hyperactivity, and peer-related issues. In total, 148 students (35.2%) were identified with significant mental health issues on screening. Emotional difficulties were reported by 108 students (25.7%), conduct problems by 101 (24%), hyperactivity by 66 (15.7%), and peer problems by 184 (43.8%).

Table 2 shows the chi-square association between socio-demographic factors and mental health domains. Students with separated/widowed parents showed higher rates of emotional and peer problems. Hyperactivity was significantly higher in only children compared to those with siblings and those with lower grades of education. Substance use and domestic violence exposure were significantly associated with total difficulties, conduct issues, hyperactivity, and emotional problems. School bullying and suicidal thoughts were strongly correlated with emotional and peer problems. Excessive smartphone use (>4 hours/day) showed a significant association with conduct and peer problems. Students with no psychosocial support had more peer problems.

Table 2. Association of mental health problems and sociodemographic determinants using the chi-square test

Variable	Total difficulties (yes) n=148	P value	Emotional (yes) n=108	P value	Conduct (yes) n=101	P value	Hyperactivity (yes) n=66	P value	Peer (yes) n=184	P value
Age										
10-13	54 (39.7)	0.105	33 (24.3)	0.819	32 (23.5)	0.609	22 (16.2)	0.354	56 (41.2)	0.389
14-17	55 (37.7)		37 (25.3)		39 (26.7)		27 (18.5)		61 (41.8)	
18-19	39 (28.3)		38 (27.5)		30 (21.7)		17 (12.3)		67 (48.6)	
Gender										
Male	78 (32.5)	0.175	67 (27.9)	0.233	51 (21.3)	0.121	41 (17.1)	0.373	116 (48.3)	**0.031**
Female	70 (38.9)		41 (22.8)		50 (27.8)		25 (13.9)		68 (37.8)	
Religion										
Hindu	142 (36.5)	0.133	91 (23.4)	**0.001**	98 (25.2)	0.143	60 (15.4)	0.775	172 (44.2)	0.449
Muslim	4 (16.7)		13 (54.2)		2 (8.3)		5 (20.8)		8 (33.3)	
Christian	2 (28.6)		4 (57.1)		1 (14.3)		1 (14.3)		4 (57.1)	
Grade										
9th	42 (40.8)	0.384	24 (23.3)	0.088	23 (22.3)	0.081	16 (15.5)	**0.003**	37 (35.9)	**0.014**
10th	42 (36.2)		23 (19.8)		27 (23.3)		8 (6.9)		43 (37.1)	
11th	37 934.3)		37 (34.3)		35 (32.4)		2 (25)		53 (49.1)	
12th	27 (29)		24 (25.8)		16 (17.2)		15 (16.1)		51 (54.8)	
Residential status										
Home	111 (36.5)	0.376	82 (27)	0.339	76 (25)	0.460	51 (16.8)	0.333	147 (48.4)	**0.002**
Hostel	37 (31.9)		26 (22.4)		25 (21.6)		15 (12.9)		37 (31.9)	
Parents marital status										
Living together	136 (34.5)	0.229	96 (24.4)	**0.014**	91 (23.1)	0.076	60 (15.2)	0.287	167 (42.4)	**0.022**
Separated/ widowed	12 (46.2)		12 (46.2)		10 (38.5)		6 (23.1)		17 (65.4)	
Parents education										
Illiterate	72 (35.6)	0.867	66 (32.7)	**0.002**	51 (25.2)	0.580	34 (16.8)	0.545	91 (45)	0.622
Literate	76 (34.9)		42 (19.3)		50 (22.9)		32 (14.7)		93 (42.7)	
Academic performance										
Poor	51 (40.5)	0.337	36 (28.6)	0.515	37 (29.4)	**0.012**	17 (13.5)	**0.011**	61 (48.4)	0.400
Average	46 (33.3)		31 (22.5)		39 (28.3)		32 (23.2)		60 (43.5)	
Good	51 (32.7)		41 (26.3)		25 (16)		17 (10.9)		63 (40.4)	
Number of siblings										
No siblings	22 (47.8)	0.165	14 (30.4)	0.196	10 (21.7)	0.902	13 (28.3)	**0.017**	19 (41.3)	0.936
<2	52 (33.3)		46 (29.5)		37 (23.7)		27 (17.3)		69 (44.2)	
≥2	74 (33.9)		48 (22)		54 (24.8)		26 (11.9)		96 (44)	
Substance Abuse										
Yes	12 (63.2)	**0.009**	5 (26.3)	0.951	18 (94.7)	**0.000**	5 (26.3)	0.194	9 (47.4)	0.749
No	136 (33.9)		103 (25.7)		83 (20.7)		61 (15.2)		175 (43.6)	
Smartphone usage per day										

<2 hours	53 (31.9)	0.137	37 (22.3)	0.141	38 (22.9)	**0.047**	22 (13.3)	**0.039**	60 (36.1)	**0.020**
2-4 hours	86 (36.1)		64 (26.9)		55 (23.1)		38 (16)		114 (47.9)	
>4 hours	9 (56.3)		7 (43.8)		8 (50)		6 (37.5)		10 (62.5)	
Domestic violence										
Yes	47 (49.5)	**0.001**	38 (40)	**0.000**	27 (28.4)	0.257	38 (40)	**0.000**	43 (45.3)	0.745
No	101 (31.1)		70 (21.5)		74 (22.8)		28 (8.6)		141 (43.4)	
Bullied in school										
Yes	35 (47.3)	**0.017**	37 (50)	**0.000**	18 (24.3)	0.951	20 (27)	**0.003**	53 (71.6)	**0.000**
No	113 (32.7)		71 (20.5)		83 (24)		46 (13.3)		131 (37.9)	
Suicidal thoughts										
Yes	30 (52.6)	**0.003**	27 (47.4)	**0.000**	27 (47.4)	**0.000**	15 (26.3)	**0.018**	31 (54.4)	0.083
No	118 (32.5)		81 (22.3)		74 (20.4)		51 (14)		153 (42.1)	
Psychosocial support										
Yes	38 (33.3)	0.618	24 (21.1)	0.182	22 (19.3)	0.164	17 (14.9)	0.783	44 (38.6)	0.189
No	110 (35.9)		84 (27.5)		79 (25.8)		49 (16)		140 (45.8)	

Table 3: Thematic analysis of teachers' mental health literacy and students' coping mechanisms

Theme	Sub-Themes	Sample Quotes	Frequency
1. Triggering factors for mental health issues	- Behavioural changes - Emotional withdrawal - academic stress - family issues	"Many students seem withdrawn lately." (T1) "Exams give me chest pain… its embarrassing." (S4) "I cry alone… I don't tell my parents." (S2)	Teachers: 2/5 Students: 3/6
2. Coping Mechanisms Used by Students	- Avoidance (e.g., gaming, social media) - Emotional suppression - Seeking support from friends or teachers	"I just scroll through Instagram." (S1) "Sometimes I cry alone." (S2) "My class teacher notices." (S3)	Students: 6/6
3. Barriers to Support	- Lack of training for teachers - Social stigma - Lack of counselling services	"I've not attended any training in mental health." (T1) "It's embarrassing to talk about it to school students." (S4) "We need school counsellors." (T4)	Teachers: 4/5 Students: 4/6
4. Teachers' mental health literacy	- awareness through experience - lack of formal training - willingness to learn	"I usually just listen to them. I feel helpless sometimes" (T1)	Teachers: 3/5

		"I have no training in mental health." (T3)	
5. Desired Improvements	- Inclusion in teacher training - Accessible school-based mental health services - Safe space for students	"Mental health should be in our training modules." (T5) "I wish we had someone to talk to without judgment." (S5)	Teachers: 3/5 Students: 4/6

Students, along with teachers, identified academic strain and family difficulties, together with social detachment, as the main causes of their emotional struggles. Teachers provided evidence of behavioural alterations, which included withdrawal habits along with irritability and absenteeism patterns that occurred specifically during examination times. **T3 (Teacher, 4 years' experience)** said, "One girl started skipping school regularly after her parents divorced. She never said anything, but you could see it."

Students highlighted three main sources of stress that including performance anxiety as well as fear of failure, and insensitivity from adults. **S2 (Student):** "Sometimes, I cry alone. I don't want to tell my parents—they won't get it. They'll just say I'm overreacting."

Teachers demonstrated different comprehension levels regarding mental health, which stem from their varied knowledge backgrounds, their personal experiences, and formal training. Most teachers expressed a lack of preparedness when it came to identifying or assisting with mental health problems. "Some children burst out crying or stop engaging. I feel helpless sometimes. I don't know what to do." Said by **Teacher 2.**

The study participants used various coping strategies, which mainly consisted of solitary avoidance techniques, including social media distraction, video game involvement, and emotional suppression. The students rarely mentioned contacting adults for assistance.

"When I get anxious, I just scroll through Instagram or play games. It takes my mind off things." **Student 1**

"If I am sad, I will remain silent and won't talk to anyone in my class." **Student 5**

Teaching staff, along with students, pointed out important obstacles that prevented an effective response to mental health problems.

"It's hard to talk to teachers or parents. They might say I'm overreacting or just scold me." – **Student 2**

"I've had no training in how to help a student with emotional issues. I usually just listen, but sometimes I worry it's not enough." – **Teacher 1**

The combination of inadequate mental health services in schools, together with a stigma attitude and limited awareness about mental health, became dominant barriers. Students experienced fear of judgment alongside teachers displaying their inability to deal with student mental health issues.

Discussion

This study aligns with national and international literature documenting a high prevalence of emotional, behavioural, and

peer-related problems in adolescent school populations. The findings underscore the significant mental health challenges faced by school children in Puducherry, revealing prevalent coping mechanisms and the current levels of mental health literacy among teachers. Research shows an extensive occurrence of mental health issues that intensifies among groups with specific demographics, along with environmental stress that exists without sufficient institutional support.

35.2% of students reported to have mental health symptoms in the screening, and the most frequently found problems were connected to peers (15.7%), followed by emotional challenges (16%), behaviour concerns (12.6%), and hyperactivity (8.3%). The observed results follow prior Indian studies, which documented an equivalent amount of prevalence. The evaluation of Kerala school children by the SDQ determined peer and behavioural problem prevalence at 13% and 8.3% [11]. The studies by Devika et al. revealed considerable depression and anxiety symptoms among school-going children in Tamil Nadu, which demands immediate identification and intervention strategies [12].

While previous studies have identified family conflict, socio-economic disadvantage, and school environment as risk factors, this work substantively adds to the field by examining urban–rural differences in risk and support, showing higher vulnerabilities among rural students attributable to less-educated parents, reduced psychosocial support, and increased exposure to domestic violence. Residents in rural areas who were young adults experienced elevated risks of domestic abuse with no accessible psychosocial support systems around them. Children developed mental health issues because of parental illiteracy and homes run by single parents who were widowed or separated, alongside substance use and bullying in school, which combined with academic difficulties. The collected data validated results previously obtained from various Indian research studies. Singh et al. analysed how emotional distress interferes with teens who come from families with unstable backgrounds that maintain a low socioeconomic status [13,14]. Chaudary et al reported that adolescent depression develops from family conflicts plus communication breakdown, while also exposing children to violent environments [15].

Students who experienced bullying at school faced increased rates of suicidal thoughts and difficulties with both peers and behaviour, although this connection was recognized as significant for all emotional and social questions. The research findings from Shinde et al. in Bihar confirm that bad school environments and student victimization lead to mental health problems [16]. Young people who spent longer than 4 hours daily using their smartphones experienced an increase in both conduct and peer problems. Research results published in both Tamil Nadu and Maharashtra establish that teenage students who spend more time on screens face sleep disruptions, together with irritability and decreased attention capabilities [17,18].

A small share of respondents (4.5%) admitted to substance use, yet this behaviour is strongly related to conduct problems and total psychological distress, which confirms the findings of Sekar et al. from their study about behavioural issues within Tamil Nadu youth [19]. The students mainly employed avoidance methods such as social media and emotional suppression,

including solitary crying, that combine with peer or teacher informal help for their mental health needs.

According to Parikh et al.'s research, Indian adolescents regularly choose avoidance and distraction, together with denial, as their primary coping methods because they lack appropriate resources or awareness [20]. A small number of interviewed students found benefits in yoga and teacher checking in, but insufficiently organized mental health programs hindered their abilities to properly deal with stressors. The situation emphasizes the necessity to establish formal resilience and life skills training programs for students in the current school curricula.

The teachers in our research discovered emotional and behavioural alterations in students, yet they lacked adequate training and lacked necessary support tools for assistance. Staff members desired to learn about mental health literacy through professional development and stressed the requirement of having school counsellors.

The research by Pratiksha et al. establishes that teachers in West Bengal have limited mental health literacy, although they exhibit strong support intentions toward their students [21]. Brief teacher training courses, according to Siraj et al., proved effective by helping educators spot and assist psychological issues among students [22].

The recognition-to-intervention delay underscores the requirement for systemic mental health education to be integrated into teacher education programs and unveiling the systemic barriers such as stigma, lack of training/resources, absent counselling infrastructure—that impede both early identification and timely response, reinforces the importance of school-based mental health frameworks advocated by leading bodies such as the WHO School Mental Health framework and Indian Psychiatric Society.

Conclusion

This comprehensive mixed-methods study underscores the high burden of mental health challenges among school-going adolescents in Puducherry, marked by suboptimal coping mechanisms and limited psychosocial support. This further underscore the critical importance of integrating mandatory policy-driven, multi-tiered mental health interventions within educational institutions by equipping educators with mental health knowledge and establishing protective environments conducive to students' psychological health. Educators, in collaboration with their students, are often the first to identify mental health challenges in the school setting; however, their capacity to address these issues is hindered by a lack of training, pervasive negative stereotypes, and inadequate formal support systems. School development initiatives ought to entail the integration of mental health curricula for instructors, the creation of counselling services through the appointment of counsellors in educational settings as part of the Ayushman Bharat-school health initiative, and the establishment of life skills programs aimed at promoting supportive learning climates. Such investments yield dual advantages, as they not only enhance the emotional well-being of students but also contribute to improved academic and social outcomes. Subsequent efforts should focus on formulating policies that incorporate research-informed training programs to strengthen these initiatives, ultimately

leading to enhanced resilience in future generations. Addressing these needs will help create safer, more supportive schools and position future research to evaluate the impact of structured interventions at scale.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Comparison of Outcomes in Endoscopic Ear Surgery and Microscopic ear Surgery in Management of Chronic Otitis Media (COM): Squamous Disease in a Tertiary Care Centre: A Randomized Study

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Abstract

Introduction: Chronic otitis media (COM) remains a challenging condition to treat, particularly in its squamous type manifestation. In recent years, there has been increasing interest in the use of endoscopic ear surgery as an alternative to traditional microscope-assisted techniques. This study aimed to compare the efficacy of endoscopic ear surgery with microscope-assisted surgery in terms of disease clearance and hearing improvement among patients with COM-squamous type. **Methodology**: A double-blinded randomised clinical trial was conducted at a tertiary care hospital in South India, involving 112 patients aged 18-50 years. Patients were randomised to either endoscope-assisted or microscope-assisted surgery groups, and disease clearance and hearing improvement were assessed over a 6-month follow-up period. **Results**: All statistical analyses were done using SPSS software version 19.0. Chi Square and paired t tests were used for analysis. There was no statistically significant difference between the two groups in terms of disease clearance ($p = 0.051$). **Conclusion**: It is thus concluded from our study that endoscope assisted ear surgery gives equivalent surgical outcomes when compared to microscopic ear surgery.

Keywords: COM, Chronic Otitis Media, Squamous, Endoscope, Microscope assisted

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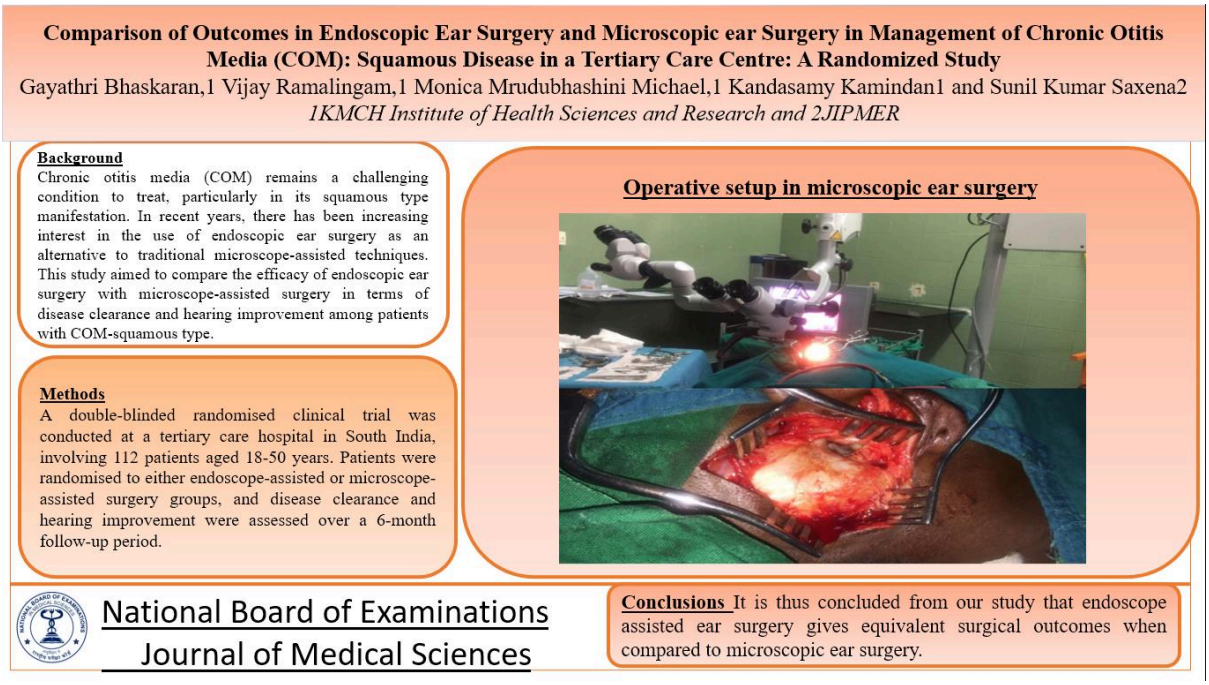
Graphical Abstract



Introduction

Chronic otitis media (COM) is a prevalent condition characterised by inflammation of the middle ear, often resulting in complications such as hearing loss and tympanic membrane defects and it is notorious for severe complications and the associated mortality and morbidity [1,2]. Among its subtypes, COM-squamous type poses unique challenges due to the presence of keratinizing squamous epithelial ingrowths, which can erode bone [3,4] and cause significant morbidity if left untreated. Traditional surgical approaches to COM have primarily involved microscope-assisted techniques, allowing for precise visualisation and manipulation of middle ear structures. However, the advent of endoscopic ear surgery has introduced new possibilities for improved visualisation and less invasive interventions.

Endoscopic ear surgery utilises a narrow-diameter endoscope to provide a magnified view of the middle ear structures, allowing for more precise and minimally invasive procedures. Advantages of endoscopic techniques include better visualisation of hidden areas, reduced need for bone removal, and potentially faster recovery times for patients. While initial studies have shown promising results with endoscopic approaches, further research is needed to compare their efficacy to traditional microscope-assisted techniques.

Methodology

A double-blinded randomised controlled trial was conducted to compare endoscopic ear surgery with microscopic ear surgery in patients with COM-squamous type. After approval from the Institutional Ethics Committee, the study was conducted at a tertiary care hospital in South India, between December 2015 and January 2018 and eligible patients aged 18-50 years were recruited. After informed consent, patients were randomised to receive either endoscopic or microscopic

ear surgery using sealed opaque envelopes with varying block sizes. Exclusion criteria included complicated otitis media, a dead ear, and ear malformations (Figure 1).

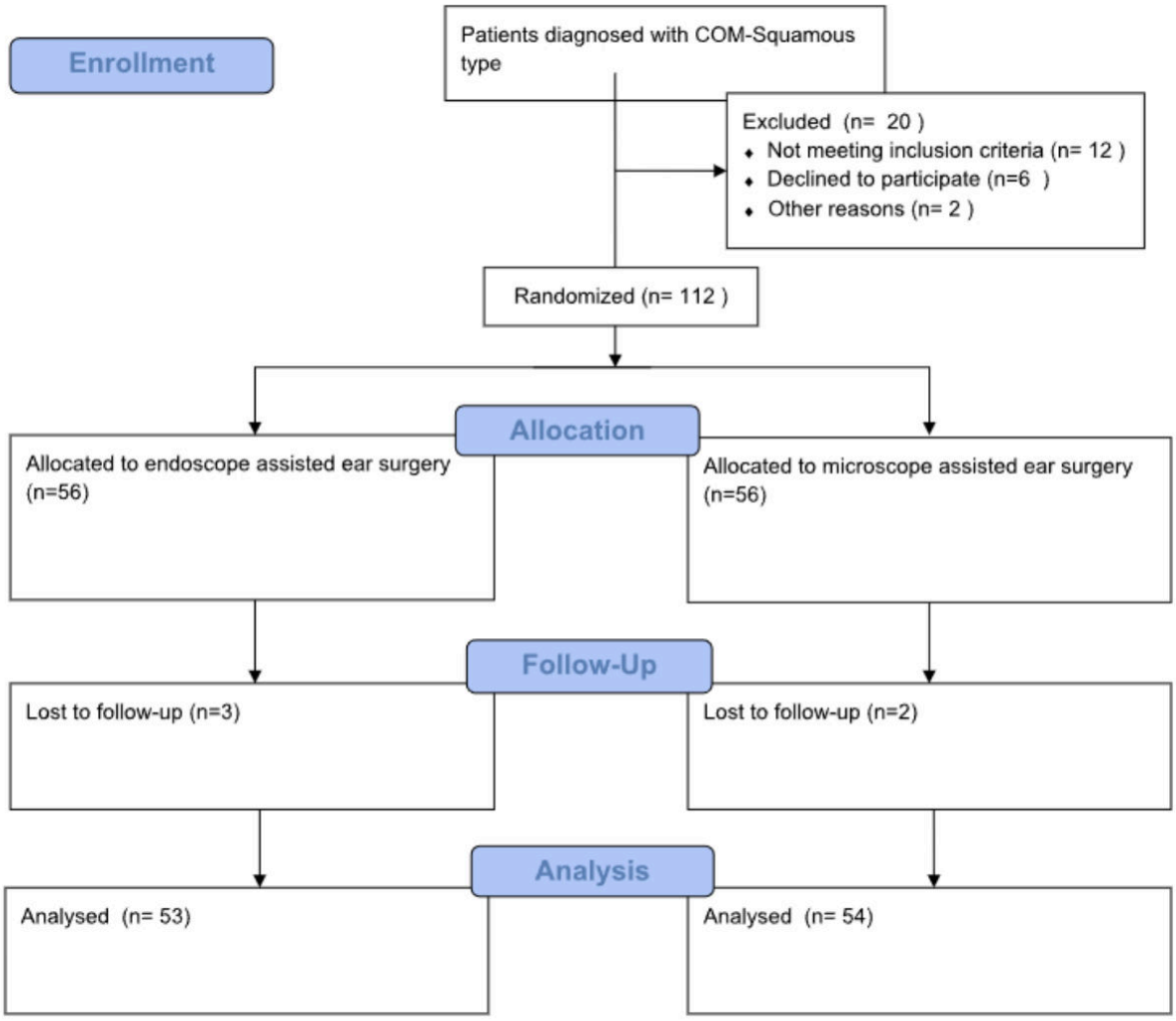


Figure 1. Consort diagram for the randomised clinical trial

Baseline demographic data, including age, sex, and affected ear, were recorded for each patient. Preoperative evaluations included pure tone audiometry and high-resolution computed tomography (HRCT) of the temporal bone to assess disease severity and hearing status, respectively. Surgical fitness was assessed based on clinical and laboratory evaluations, and written informed consent was obtained from all participants.

Patients in the endoscope-assisted surgery group underwent surgery under general anaesthesia, with the entire procedure performed using a 4mm, 18cm 0-degree or 30-degree endoscope and camera system (Figure 2). A wide posterior tympanomeatal flap was elevated, and the cholesteatoma sac was visualised and dissected using endoscopic instruments. The bony canal rim was curetted and drilled for exposure as needed (Figure 3[i to vii]) and appropriate ossicular reconstruction was performed. The ear canal was packed with gelfoam postoperatively.

Figure 2. Operative setup in endoscopic ear surgery

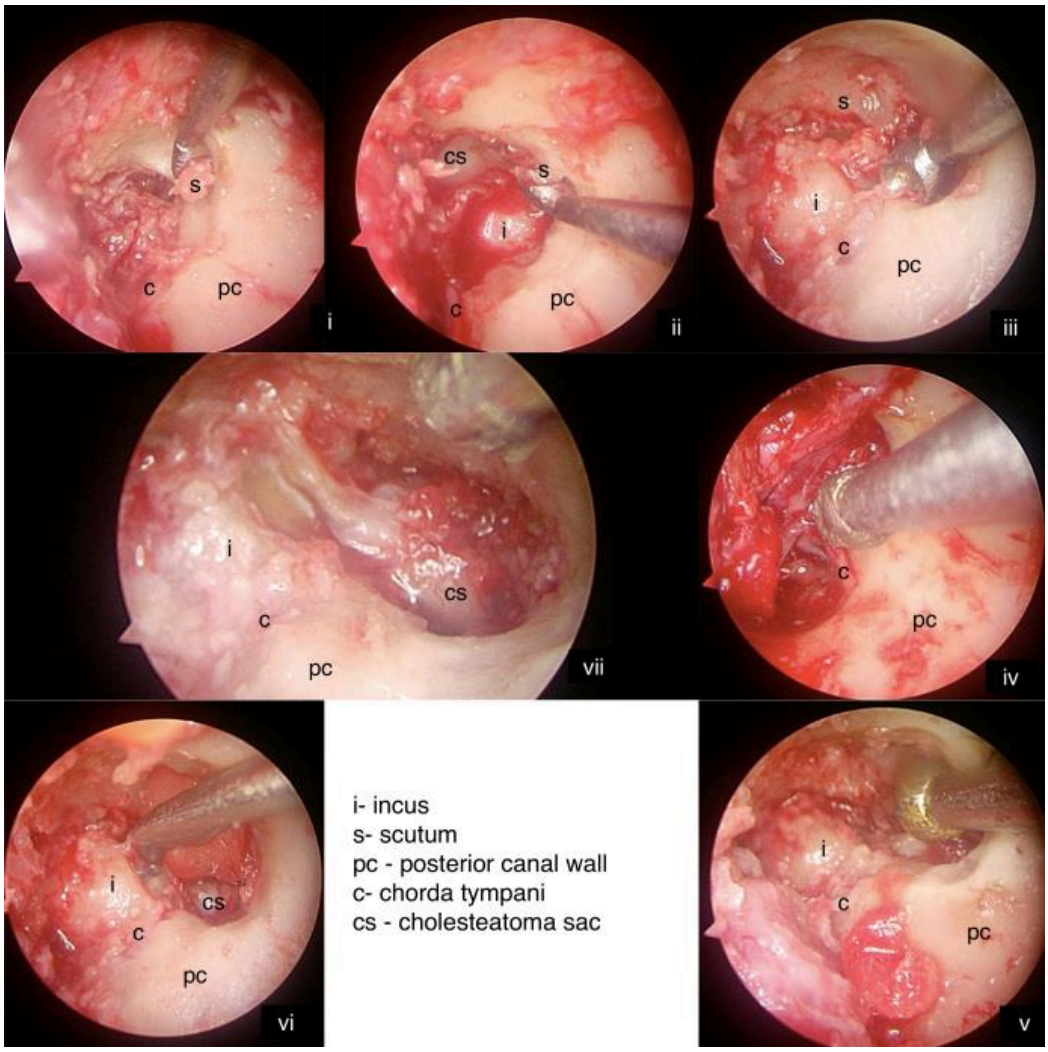


Figure 3. i,ii,iii- identification of chorda tympani(c), scutum(s), incus(i), curetting of the posterior bony canal wall(pc); iv,v,vi,vii- visualisation of aditus ad antrum, identification of cholesteatoma sac (cs) and disease clearance.

Patients in the microscope-assisted surgery group underwent surgery under general anaesthesia with a postaural approach (Figure 4). Under microscope visualisation, the cholesteatoma and granulations were removed, and the mastoid cavity was smoothed with a polishing burr. Temporalis fascia was used for ossicular reconstruction, and the cavity was exteriorized with concho-meatoplasty. A medicated pack was placed in the cavity postoperatively.

Figure 4: Operative setup in microscopic ear surgery

Postoperative care included hospitalisation for three days with administration of intravenous antibiotics, followed by outpatient follow-up visits. Disease clearance were assessed at 6 months post-surgery using HRCT of temporal bone and otoendoscopy (Figure 5) and hearing thresholds using pure tone audiometry.

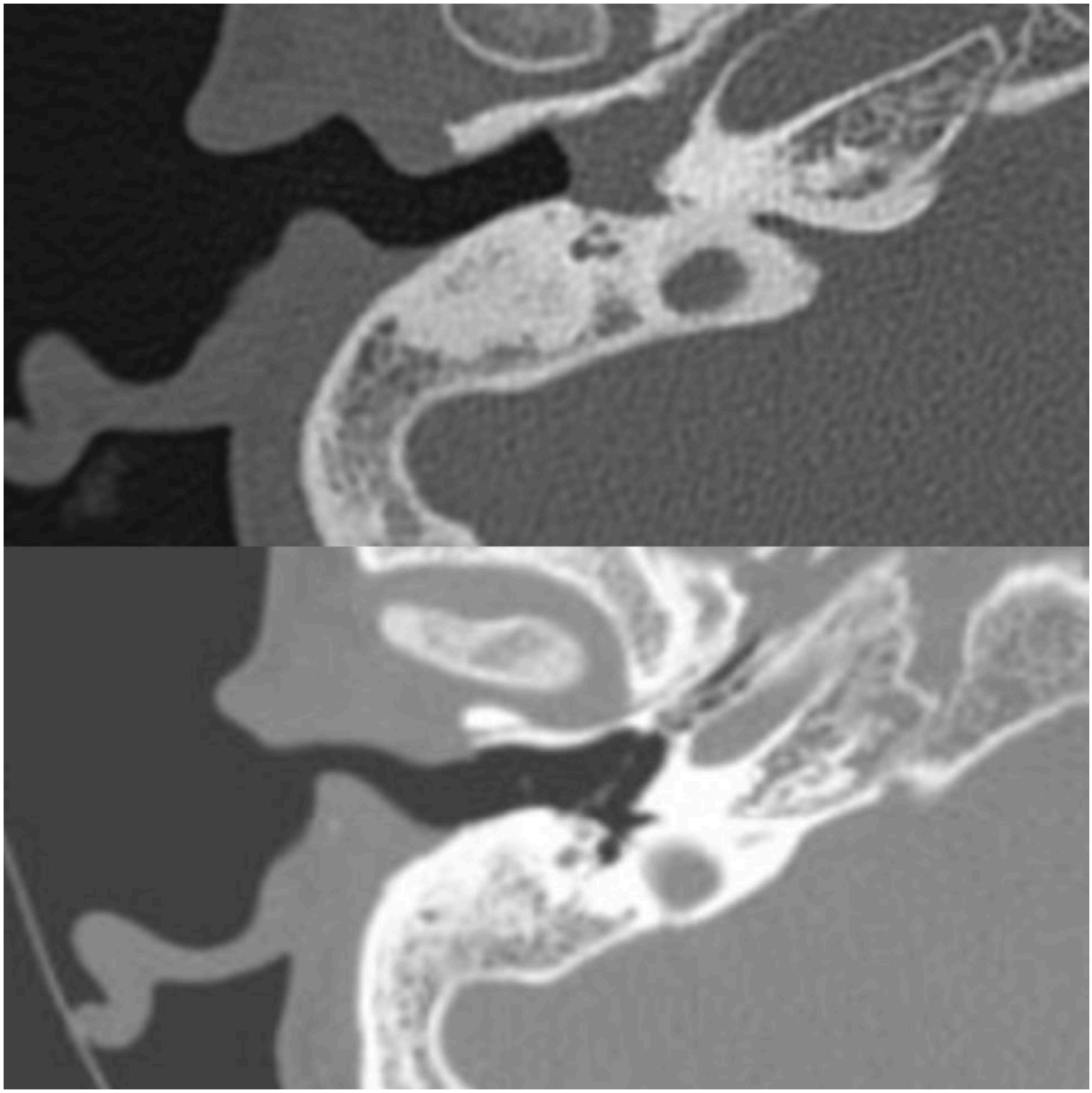


Figure 5. High resolution computed tomography before and after endoscopic ear surgery

Results

A total of 112 patients were recruited and randomised to two groups. 56 patients were subjected to microscopic ear surgery, out of which 54 patients were followed up till 6 months, 2 patients failed to follow up. 56 patients underwent endoscopic ear surgery, 53 patients followed up. 3 failed to follow up. All patients had the disease only in one ear. Baseline demographic characteristics like age were comparable between the two groups. Preoperative audiological characteristics of patients of both groups were similar (Table 1).

Table 1. Comparison of preoperative hearing thresholds between the two groups

Group	Mean (SD) pure tone hearing level in dB	Statistical test
Endoscopic Surgery Group N=56	**41.15(12.23)**	**Independent t test**
Microscopic Surgery Group N=56	**43.34(13.87)**	
p- value		**0.377***

Postoperative Disease clearance

Disease clearance was assessed by a high resolution computed tomography of the temporal bone and otoendoscopy (Figure 6). In our study, it was found that disease clearance after endoscopic ear surgery was not significantly different from microscope-assisted surgery. (Figure 7) Statistical analysis was carried out using Chi-Square test and p-value was found to be 0.05 (Table 2).

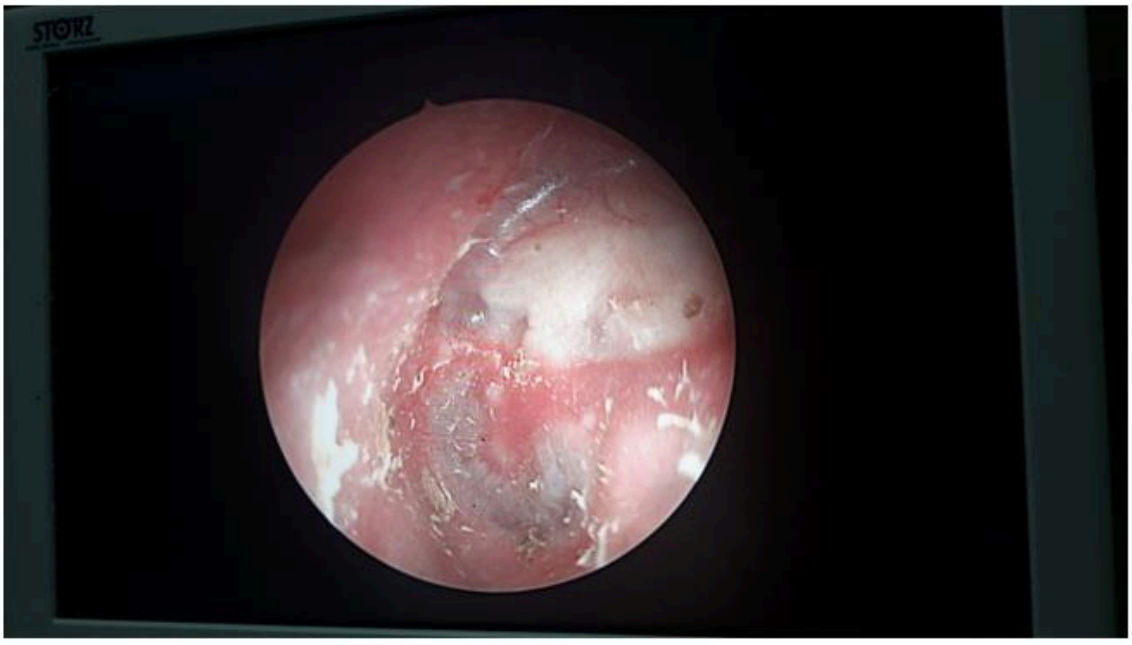


Figure 6. Postop otoendoscopy showing healed neotympanum and scutum reconstructed with conchal cartilage.

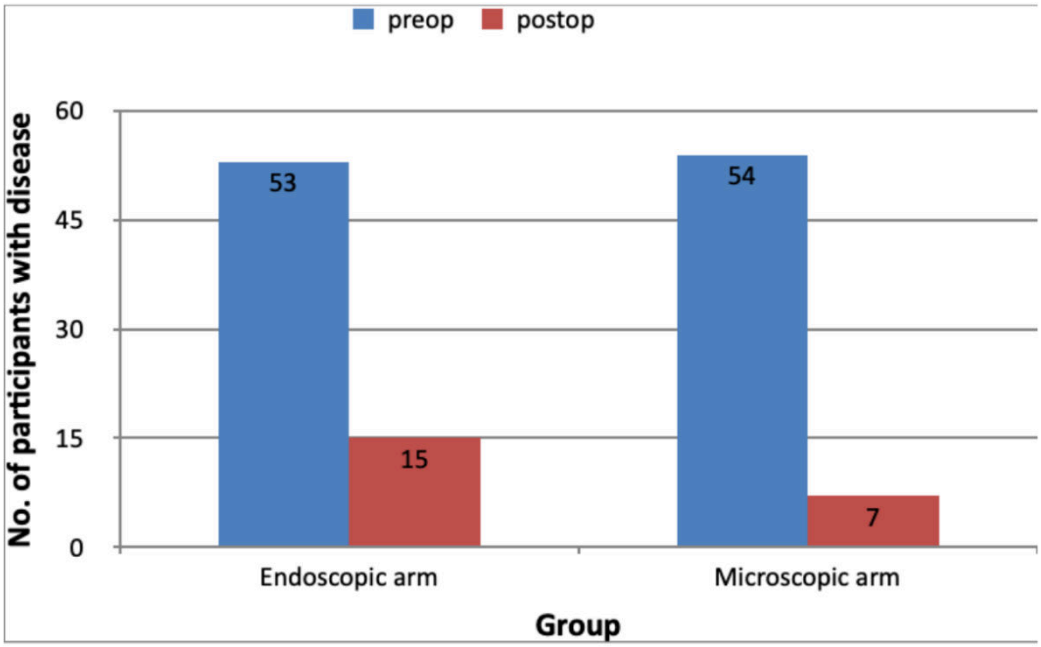


Figure 7. Comparison of disease clearance between the groups

Table 2. Comparison of disease clearance between the groups:

Group		DISEASE present	NO DISEASE	Statistical test used	P value
ENDOSCOPIC Surgery Group	Count	15	38	Chi-Square test	0.05
	% within Group	28.3%	71.7%		
MICROSCOPIC Surgery Group	Count	7	47		
	% within Group	13%	87%		

Hearing improvement between two groups

The hearing improvement was compared between the two groups. The data was found to be normally distributed. Hence comparison was done by independent t test. Both groups individually demonstrated statistically significant improvements in hearing thresholds (Figure 8) postoperatively, although the difference between the groups was not statistically significant ($p = 0.845$). So far, very few studies have compared surgical outcomes between microscope assisted and endoscope assisted surgeries in the management of chronic otitis media – squamous type.

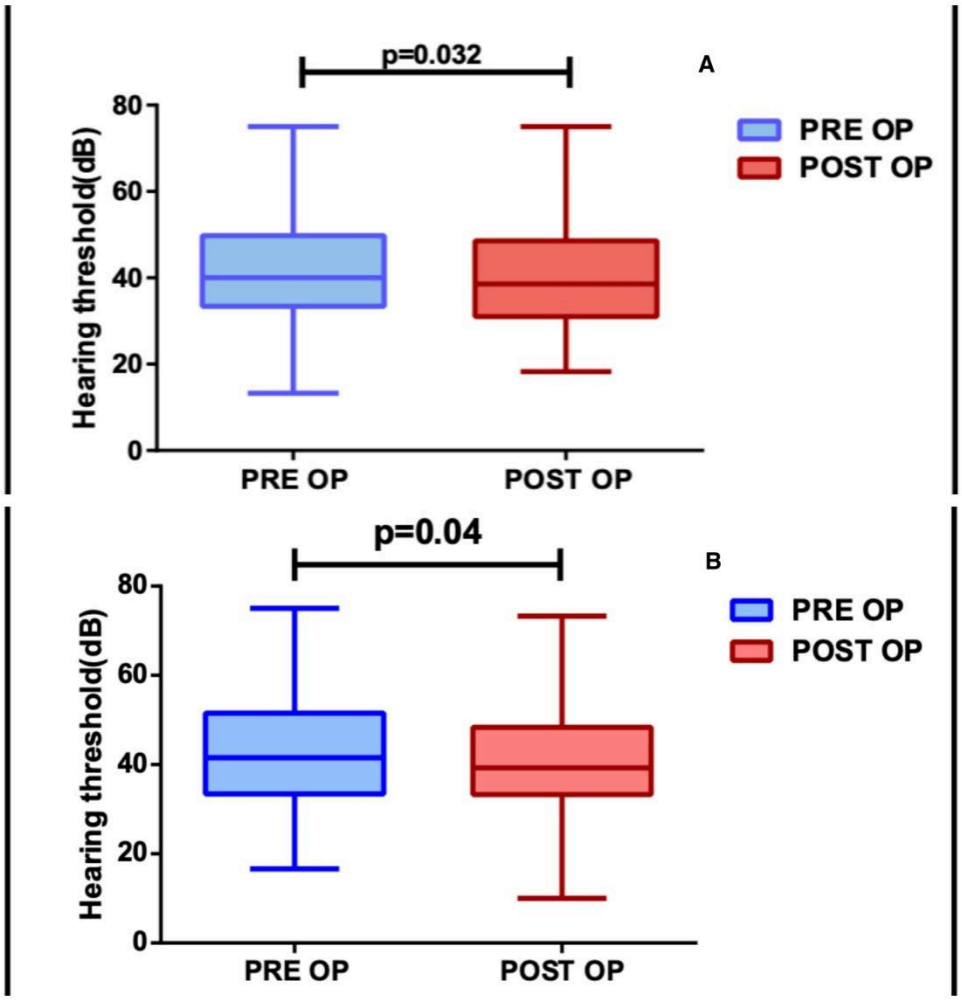


Figure 8. Showing hearing improvement comparison before and after Endoscopic (A) and Microscopic (B) ear surgery

Discussion

The findings of this study suggest that endoscope-assisted ear surgery is comparable to microscope-assisted surgery in terms of disease clearance and hearing improvement among patients with COM-squamous type. These results are consistent with previous studies demonstrating the efficacy of endoscopic techniques in the treatment of COM. While endoscopic surgery offers several potential advantages, including improved visualisation and reduced invasiveness, its effectiveness appears to be similar to that of traditional microscope-assisted techniques.

One possible explanation for the comparable outcomes between endoscope-assisted and microscope-assisted surgery is the meticulous surgical technique employed in both approaches. Both techniques allow for thorough disease clearance and precise reconstruction of middle ear structures, leading to favourable outcomes in terms of disease control and hearing improvement. Additionally, the similarity in outcomes may also be attributed to the surgeon's experience and familiarity with both techniques, ensuring consistent results across the study groups.

Endoscopic ear surgery has gained increasing attention in recent years as a

minimally invasive alternative to traditional microscope-assisted techniques. Studies have reported several potential advantages of endoscopic approaches, including improved visualisation of hidden areas of the middle ear, reduced need for extensive posterior canal wall removal, and potentially augmenting faster recovery times for patients. Tarabichi et al. (2013) conducted a prospective interventional trial evaluating endoscopic ear surgery in 146 patients with chronic otitis media. They reported a high rate of disease clearance (92.5%) and favourable outcomes in terms of hearing improvement. The study demonstrated the feasibility and effectiveness of endoscopic techniques in the management of chronic otitis media [5].

Badr-el-Din et al. (2002) performed a comparative study between endoscopic and microscopic approaches in 75 patients with chronic otitis media. They found that endoscopic ear surgery was associated with better preservation of ossicles and improved functional outcomes compared to microscope-assisted surgery. This study highlighted the potential benefits of endoscopic techniques in preserving middle ear anatomy and function [6].

Pradhan et al. (2015) conducted a study on 28 patients undergoing endoscopic atticotomy >10dB closure of A-B gap and disease clearance at 12-month follow-up, indicating the efficacy of endoscopic approaches in achieving favourable surgical outcomes [7].

It was found in one of the study on benefit of intraoperative usage of endoscopes showed that it gave the surgeon a better visualisation over the pathology, thus leading to proper eradication of disease [8].

In the study Marchioni et al recurrences were defined as re-retraction of the attic requiring revision and residuals were defined as insufficient primary resection of the epidermal matrix. Residuals were also defined by computed tomography just like in our study. CT was performed most frequently at 1-year follow-up. We had a follow up period of 6 months for the computed tomography study [9].

Microscope-assisted ear surgery has been the traditional approach for the management of chronic otitis media and has demonstrated long-standing success in disease clearance and hearing improvement. While endoscopic techniques offer certain advantages, microscope-assisted surgery remains a widely used and effective approach in otologic surgery.

Sasaki et al. (2006) conducted a study comparing outcomes between microscope-assisted and endoscopic surgery in 56 patients with chronic otitis media. They found significant hearing improvement and disease clearance in both groups, with no significant differences observed between the two approaches. This study emphasised the comparable efficacy of microscope-assisted surgery in achieving favourable outcomes [10].

Uyar et al. (2006) retrospectively analysed outcomes in 78 patients undergoing microscope-assisted attico-antrostomy for chronic otitis media. They reported low rates of recurrent disease recurrence and favourable hearing outcomes with microscope-assisted surgery. This study highlighted the effectiveness of traditional surgical techniques in achieving disease control and hearing improvement [11].

Austin et al. (1989) conducted a retrospective study comparing outcomes between canal wall up and canal wall down

procedures in patients with chronic otitis media. They found that canal wall down procedures were associated with lower rates of disease recurrence and better long-term outcomes. This study underscored the importance of good surgical technique in achieving successful outcomes in the management of chronic otitis media [12].

Several studies have compared outcomes between endoscopic and microscope-assisted ear surgery to determine the optimal approach for the management of chronic otitis media. While both techniques have demonstrated efficacy in achieving disease clearance and hearing improvement, differences in surgical technique and patient selection may influence outcomes. In one of the studies it is documented that attic cholesteatoma can be treated completely by a trans-canal approach alone [13]. Another study states that the endoscope allowed a clear understanding of cholesteatoma extension and improved eradication of even residual disease from hidden areas such as anterior epitympanic recess, retrotympanum, and hypotympanum which sometimes may be difficult to visualise with the operating microscope [14].

Mahadevaiah et al. (2008) conducted a comparative study between endoscopic and microscope-assisted surgery in paediatric patients with chronic otitis media. They found comparable outcomes in terms of disease clearance and hearing improvement between the two approaches, highlighting the feasibility of endoscopic techniques in paediatric otologic surgery [15].

Ramalingam et al. (2019) compared outcomes between endoscopic tympanoplasty with and without gelfoam in patients with chronic otitis media. They found similar rates of graft uptake and hearing improvement between the two groups [16].

It was found in one of the studies that an endoscopic technique allows transcanal, minimally invasive surgery and surveillance of cholesteatoma with long-term results that compare well to those of standard post aural methods of treatment [17]. In another study done by Dodson EE et al., the long-term results of an ear with use of endoscope had useful hearing and few problems with chronic medical care and therefore was more gratifying to the operating surgeon on follow up [18]. Overall, the literature supports the efficacy of both endoscopic and microscope-assisted ear surgery in the management of chronic otitis media-squamous type. While endoscopic techniques offer certain advantages, such as improved visualisation and reduced invasiveness, microscope-assisted surgery remains a widely used and effective approach. The postoperative pain and healing seems better results for endoscopic ear surgery patients [19]. In a study by Preyer S, use of endoscopes in ear surgery has been found to reduce the morbidity by reduction of normal bone removal and better chances of conservative surgery by improving visual control [20]. Further research is needed to compare long-term outcomes and determine the optimal approach for individual patients with chronic otitis media.

Conclusion

In conclusion, this randomised controlled trial demonstrates that endoscope-assisted ear surgery is equivalent to microscope-assisted surgery in the treatment of COM-squamous type. Both techniques offer satisfactory outcomes in terms of disease clearance and hearing improvement, with no significant

differences observed between the two groups. These findings support the use of endoscopic techniques as a viable alternative to traditional microscope-assisted surgery in the management of COM. However, further research with longer-term follow-up and larger sample sizes is warranted to confirm these findings and establish the optimal surgical approach for patients with COM-squamous type.

Conflict of interest

There is no conflict of interest involved with any of the authors.

Ethics approval and consent to participate

The ethical committee clearance was obtained in the m from The Institutional Human Ethics Committee (DCGI Reg. no. ECR/342/Inst/PY/2013) with reference no. /JIP/IEC/21/754. An informed consent for willingness to participate in the study was obtained from the patients before recruitment into the study.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

There was no external funding required for the conduct of the study.

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ORIGINAL ARTICLE

Comparative Study of Morbidity Patterns and Sociodemographic Factors among Elderly in Old Age Homes and Residences, Puducherry

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Abstract

Introduction: Growing older is a universal process. The exact boundaries of old age cannot be determined because definitions vary from nation to nation. Aging is a complicated and irreversible process. Unlike earlier life phases, the World Health Organization defines old age as "the period of life when the impairment of physical and mental functions becomes increasingly manifested." Assessing the prevalence of illness patterns among senior persons residing in Puducherry's old age homes and residences is the aim of this study. **Methods:** A two-year community-based comparative cross-sectional study was conducted at senior living facilities and households in the AVMCH field practice area. The sample consisted of 480 people selected using cluster sampling from 8 communities and 8 senior care facilities. Participants were interviewed using a semi-structured, pre-validated questionnaire that covered sociodemographics and patterns of morbidity following informed permission. Excel and SPSS version 28 were used for the data analysis. **Results:** Among the 480 participants in the study, 36% were women and 64% were men. 37.9% of research participants were between the ages of 70 and 80. About 64.4% of people had at least one chronic condition, with 75.4% of those people living in an assisted living facility. 51.5% of the elderly had hypertension, the majority. The majority of sociodemographic variables were found to be important in relation to non-communicable diseases. **Conclusion:** An analysis of the noncommunicable disease morbidity pattern shows that older persons who live in assisted living facilities are more likely to suffer noncommunicable diseases (NCDs) than those who live at home. Most sociodemographic factors were found to have a significant impact on the morbidity pattern of a number of NCDs, including diabetes mellitus, hypertension, cardiovascular disease, chronic kidney disease, stroke, visual impairment, and osteoarthritis.

Keywords: Elderly, Old age home, Residence, Morbidity patterns, Non Communicable Disease

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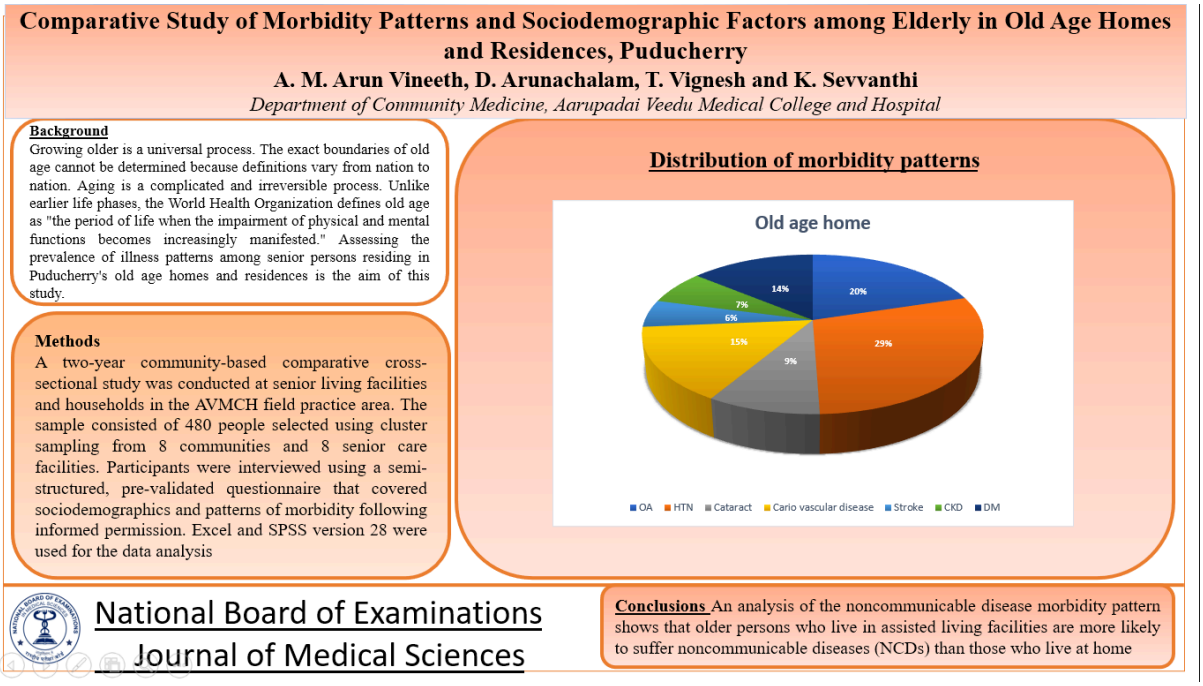
Graphical Abstract



Introduction

The process of aging is universal. According to a quote by Sir James Ross, "You can't heal old age; you have to protect, promote, and extend it." The world population has shifted from a pattern of high birth and death rates to low birth and death rates due to developments in modern medicine and technology, which has resulted in the greying of the population. The process by which the percentage of senior citizens in a society rises is known as “population ageing” [1].

India's population is aging as a result of improved public health and medical facilities, which have reduced fertility and raised life expectancy, respectively. The exact boundaries of old age cannot be determined because definitions vary from nation to nation. In January 1999, the Indian government developed a “National Policy on Older Persons.” According to the regulation, a person is considered a "senior citizen" or "elderly" if they are 60 years of age or older [2]. The process of aging is complex and irreversible [3].

Aging is caused by the cumulative effects of biological damage to molecules and cells. At the physiological level, "aging" refers to the bodily changes caused by a decline in the body's capacity to operate correctly. Numerous chronic illnesses, poor health, issues with vision and hearing, memory loss, trouble eating and digesting food, and an inability to regulate particular physiological processes can all be brought on by these alterations. Ageing is also linked to other life transitions, such as retirement, moving to a more suitable home, and losing friends and companions, in addition to biological changes. Longer life expectancies have been attributed to a number of factors, including improved living conditions, food security, nutritional status, and medical services.

The range of diseases has shifted from communicable to non-communicable due to the prolonged lifespans of the elderly. In terms of morbidity, 50% of India's older population has chronic illnesses, 6% is immobile, and vision and hearing problems are common [5]. In addition to physiological factors, behavioral choices made by individuals and families, genetically inherited health traits, living environment, and changes in socioeconomic status all have an impact on an individual's post-retirement lifestyle, health status in general, and morbidity in particular among the elderly. Therefore, rather than being a random occurrence, factors at the home and community levels influence illness in the elderly [6].

Objectives

1. To examine the differences in morbidity between Puducherry locals and elderly individuals residing in assisted living facilities.
2. To identify the sociodemographic characteristics that affect the pattern of non-communicable disease morbidity among senior citizens residing in Puducherry's old age homes and residences.

Materials and Methods

The elderly residents of AVMCH's field practice areas and those over 60 residing in old age homes participated in a community-based comparative cross-sectional study. According to the inclusion and exclusion criteria, 480 study participants were chosen using the cluster sampling technique, 30 from each hamlet and senior living facility. The sample size, which was 480 (240 in each group), was calculated using the statistical procedure to compare two independent proportions. Morbidity rates for senior adults residing in old age homes were estimated to be 0.80 and 0.90, respectively. It was assumed that the significance and power levels were 80% and 5%, respectively. For reference, LS George et al. [9] conducted a related investigation.

After applying the design effect, we got the sample size of 480 with 240 in each group.

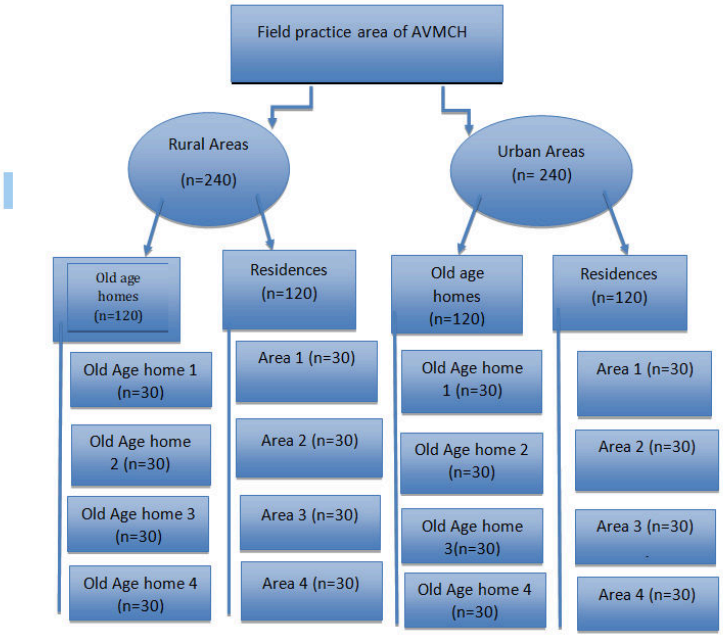


Figure 1. The flowchart of the sampling technique.

The sample method is shown in Figure 1. The samples were selected using the cluster sampling technique. Based on their viability, villages and senior living facilities in both rural and urban areas of our field practice area were selected as our primary sampling unit. A cluster was defined as four communities and four senior homes in both rural and urban locations. The study included a total of sixteen clusters. The probability proportionate to size (PPS) technique was used to determine how many samples should be selected from each cluster for senior homes and residences. Using PPS as the last sampling unit, the study population was randomly selected from each cluster. 240 samples from residences and senior living facilities were eventually selected, presuming a sample.

Assuming a sample size of 480, 240 samples were selected from houses and senior care facilities. Interviewers pre-designed and pretested a semi-structured, validated questionnaire for the older age group that satisfied the inclusion and exclusion criteria. The survey's first segment contained sociodemographic data. The second section of the questionnaire focused on duration and morbidity patterns. Comorbidity history was assessed by asking about a history of diabetes, hypertension, chronic renal illness, cardiovascular disease, stroke, osteoarthritis, and visual impairment.

The survey was distributed after face validity and pilot testing. Data input was done using Microsoft Excel 2021. Data analysis was conducted using SPSS version 28. Frequency charts and bar graphs were used to illustrate the descriptive variables. To investigate the differences between the categorical variables, the chi square test, independent t test, and fischer exact test were employed. A review of sociodemographic characteristics and morbidity patterns was conducted. For statistical significance, a p-value of less than 0.05 was considered.

Results

Over the course of 15 months, from May 2023 to May 2024, residents of the AVMCH field practice regions and senior adults over 60 residing in assisted living facilities took part in a community-based comparative cross-sectional study. The study comprised 480 older people in total, 240 of whom lived in residences and 240 of whom were in old age homes.

Table 1. Association of Socio-demographic characteristics among the elderly in old age homes and residence areas

Variables	Category	Old Age Home	Residences	Total	χ^2	p- value
		n (%)	n (%)	n(%)		
Age	60-70 70-80 >80	76 (31.7) 99 (41.3) 65 (27.1)	81 (33.8) 91 (37.9) 68 (28.3)	81 (33.8) 91 (37.9) 68 (28.3)	0.564	0.754
Sex	Male Female	157(65.4) 83(34.6)	150(62.5) 90(37.5)	307(64.0) 173(36.0)	0.443	0.506

Marital Status	Divorce	1 (0.4)	9 (3.8)	10 (2.1)	15.578	0.004*
	Married	143 (59.6)	158 (65.8)	301 (62.7)		
	Separated	23 (9.6)	13 (5.4)	36 (7.5)		
	Single	35 (14.6)	18 (7.5)	53 (11.0)		
	widow	38 (15.8)	42 (17.5)	80 (16.7)		
Education status	Graduated	47 (19.6)	14 (5.8)	61 (12.7)	30.299	<0.001*
	High	63 (26.3)	59 (24.6)	122 (25.4)		
	Illiterate	19 (7.9)	42 (17.5)	61 (12.7)		
	Middle	50 (25.4)	70 (29.2)	120 (25.0)		
	Primary	61 (25.4)	55 (22.9)	116 (24.2)		
Occupation	Employed	61(25.4)	88(36.7)	149(31.0)	7.095	0.008*
	Unemployed	179(74.6)	152(63.3)	331(69.0)		
Type of Family	Extended	28 (11.7)	15 (6.3)	43 (9.0)	4.865	0.182
	Joint	101 (42.1)	100 (41.7)	201 (41.9)		
	Nuclear	59 (24.6)	69 (28.7)	128 (26.7)		
	Others	52 (21.7)	56 (23.3)	108 (22.5)		
SES	Class I	135 (56.3)	32 (13.3)	167 (34.8)	140.426	<0.001*
	Class II	58 (24.2)	89 (37.1)	147 (30.6)		
	Class III	22 (9.2)	81 (33.8)	103(21.5)		
	Class IV	8 (3.3)	38 (15.8)	46 (9.6)		
	Class V	17(7.1)	0(0)	17(3.5)		

The sociodemographic traits of the elderly living in assisted living facilities and homes are displayed in Table 1. The majority of elderly people in both old age homes and residences are between the ages of 70 and 80. In both groups, married people make up the majority of the elderly (62.7%). With a total of 25.4%, high school was the most prevalent educational level among research participants in both old age homes and residences. 31% of the elderly were employed, the lowest percentage. Approximately 41.9% of research participants are part of a joint family. The highest percentage of research participants in the upper class (Class I) was around 34.8%.

Sociodemographic traits such as occupation, SES, marital status, and educational attainment varied significantly among the senior population in the old age home and the residential area.

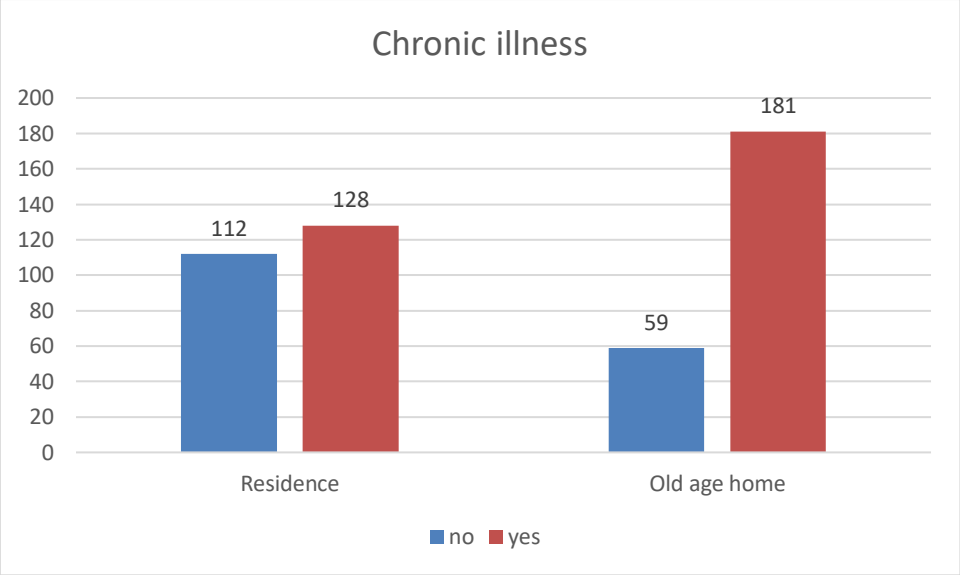


Figure 2. Distribution and comparison of study participants based on place according to the chronic illness

Table 2. Distribution and comparison of study participants based on place according to the chronic illness (N=480)

Chronic illness	Old age home n = 240	Residence n = 240	Total N = 480	χ^2	p- value
	n (%)	n (%)	n (%)		
No	59 (24.6)	112 (46.7)	171 (35.6)	25.518	<0.001*
Yes	181(75.4)	128 (53.3)	309 (64.4)		

*p-value <0.05 shows significance

The largest majority of participants (64.4%) had a chronic condition, according to Table 2, with 75.4% living in assisted living facilities and 53.3% in private homes. This suggests that the majority of people in the research have a chronic condition. A significant correlation (<0.001*) exists between the type of stay and chronic illness.

Table 3. Distribution and comparison of study participants based on place according to number of chronic illness (N=480)

Number of chronic illness	Old age home	Residence	Total	χ^2	p- value
	n (%)	n (%)	n (%)		
0	45 (18.8)	47 (19.6)	92 (19.2)	22.994	<0.001*
1	44 (18.3)	54 (22.5)	98 (20.4)		
2	76 (31.7)	97 (40.4)	173 (36.0)		
3	50 (20.8)	34 (14.2)	84 (17.5)		
4	25 (10.4)	5 (2.1)	30 (6.3)		
5	0 (0)	3 (1.3)	3 (0.6)		

*p-value <0.05 shows significance

The majority of study participants (36.0%) have two chronic conditions, as shown in Table 3, with 40.4% living in houses and 31.7% in assisted living facilities. This indicates that the research population's most prevalent condition is having two chronic illnesses. The least represented group is those with five chronic illnesses (0.6%), with 0% living in assisted living facilities and 1.3% living in homes. There is a significant correlation between the number of chronic illnesses and the type of stay (<0.001*).

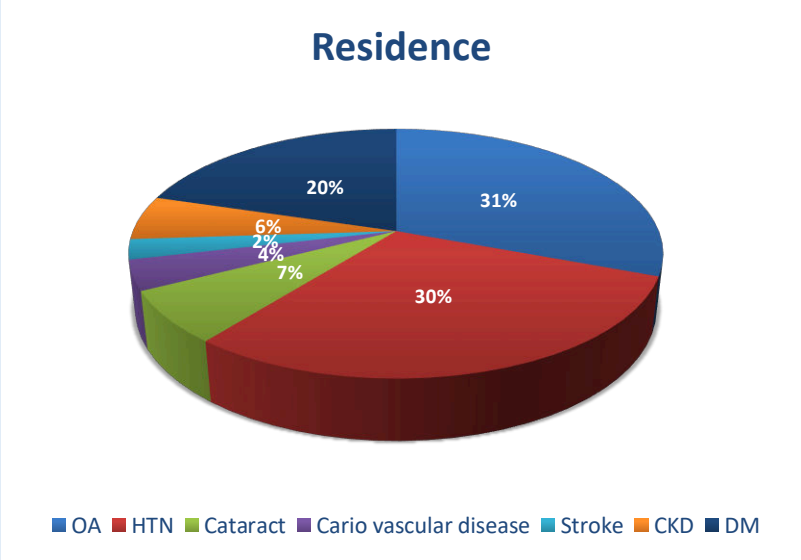


Figure 3. Distribution of morbidity patterns among elderly population in residences

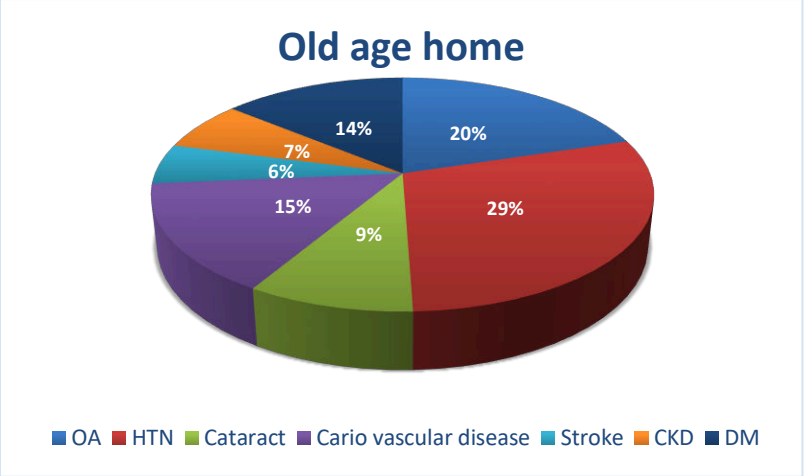


Figure 4. Distribution of morbidity patterns among elderly population in old age homes.

Figures 3 and 4 show that cardiovascular disease, osteoarthritis, diabetes mellitus, and hypertension are more common in both senior living facilities and homes. The two non-communicable diseases that are least common are stroke and chronic kidney disease.

Discussion

This study aims to assess the sociodemographic characteristics and patterns of illness among the elderly population living in the old age homes and residences in Puducherry. In addition to the urban and rural field practice areas of Aarupadai Veedu medical college and hospital, Puducherry, specifically Chinakankanankuppam, Periyakanganan-kuppam, Subaupalavadi, and Uchimedu, this cross-sectional study was carried out in four villages of Ariyankuppam: Chinnaveerampattinam, Manavely, Veerampattinam, and Nagoranthottam. A total of 480 study participants (30 from each village or anganwadi and 30 from each old age home) were chosen based on the inclusion and exclusion criteria, and samples were collected using the cluster sampling technique. A semi-structured validated questionnaire and a pre-validated questionnaire were used to gather data after informed consent.

Demographic distribution of our study participants

Age distribution in our study was approximately 33.8% between 60 and 70 years old, 37.9% between 70 and 80 years old, and 28.3% over 80 years old.

Similar findings were reported in the study conducted in a rural area of south Karnataka by Pooja Anudhar et al. [10], which found that the majority of study participants were between the ages of 60 and 69 (about 38.3%), 70 and 79 (about 38.3%), and over 80 years old (23.4%). The questionnaire was completed after informed consent.

A study by Ramocha et al. [11] reveals that 41% of the participants were in the 60–70 age range. 41.2% of people were between the ages of 71 and 80. The percentage of those over 80 was 17.5%. Conversely, Habatamu Sewunet Mekonnen et al.12 discovered that roughly 67.2% of their study participants were between the ages of 60 and 69, 23.3% were between the ages of 70 and 79, and 9.8% were over the age of 80.

Additionally, in contrast to our findings, George et al. (2010) observed that 70% of the participants were in the 60–69 age category, 27% were in the 70–79 age group, and 3% were beyond 80 years old. The study participants' varied geographic locations could be the cause. Therefore, it may be said that the mortality pattern increases with age.

Gender

Sixty-four percent of the participants in our study were men, and roughly 36 percent were women. Similarly, Sireesha Srinivasa Rao et al. [13] study revealed that 62% of participants were female and 38% were male.

Additionally, the study by Asmita Patnaik et al. [14] revealed that 33.2% of the population were female and 66.8% were male. On the other hand, the majority of study participants in the Sujitha P et al. [15] study were female (52.1%), compared to 47.9% of male individuals. Additionally, approximately 46% of the participants in the study by Sahoo et al. [16] were men, and 54% were women. Geographical variation or the mortality and morbidity pattern of the research region are the main causes of this gender discrepancy.

Marital status

Married individuals made up the largest percentage of survey participants (62.7%), followed by separated individuals (7.5%) and bereaved individuals (16.7%).

Similarly, Clarie Gough et al.'s study from 2017 reveals that 39% of research participants were married, 35% were widowed, 4% were single, and 22% were separated. The majority of the participants in a research by Bincy et al. [18] were married (44%), with 14% being widowed. In contrast, 52% of the study participants in the Sahoo et al. [16] study were widowed, divorced, or separated, while 22% of them were married and 16% were single. Ramocha et al. (2011) found that 57% of people were widowed and 40% of people were married.

Educational status

Most of the study participants had only finished high school (around 25.4%), followed by elementary school (24.2%), middle school (25%), and graduate school (12.7%). Illiteracy rates were 12%. Similarly, Habtamu Sewunet Mekonnen et al. [12] found that 27.7% of people could read and write, 16.9% had completed elementary school, 9.1% had completed middle school, 17.5% had graduated, and 28.8% were illiterate. In contrast, Sujitha et al. [15] survey revealed that around 40.3% were illiterate, 15.8% had finished elementary school, 29.7% had finished middle and upper secondary school, and 14.2% had graduated. According to a research by Ramocha et al. (2011), 16.25% of people had finished their tertiary education, while 11.25% were illiterate. The primary cause of these differences in educational attainment was the differential between residential stays and old age facilities.

Occupation

In our survey, 31% of individuals were employed, whereas roughly 69.0% were unemployed. Similar to this, a study by Sahoo et al. [16] found that 30% of people in urban areas of Raipur, Chhattisgarh, were employed, while 70% of people were unemployed. Conversely, Sujitha et al. [15] study reveals that, based on data from senior living facilities in the

Chengalpattu area, 60.9% of the population was employed and 39.1% was unemployed. The main reasons for this mismatch are the socioeconomic differences across the research sites and the lack of knowledge about government assistance for the elderly.

Socio economic status

According to the modified B.G. Prasad classification, the majority of research participants—34.8%—belonged to the upper class, followed by the upper middle class (30.6%), middle class (21.5%), lower middle class (9.6%), and lower class (less than 1.8%). Similarly, the George LS et al.9 study found that almost 43.9% of the participants were from the lower middle class, followed by the middle class (30.9%) and upper middle class (12.2%), with the lowest percentages from the lower and upper classes (10.4% and 2.6%, respectively). A study by Ruchi Dhar et al. (19), on the other hand, reveals that around 49% of participants in the metropolitan Davengere region were lower middle class, 26% were middle class, 13% were higher middle class, 12% were lower class, and 0% were upper class. Perhaps this discrepancy results from survey participants' ignorance about senior pension schemes' advantages.

Old age home versus Community dwelling old age

The distribution of individuals in our study who were between the ages of 60 and 70 was around 31.7% in the old age home, 33.8% in the residence, and 41.3% in the old age home. People over 80 made up 27.1% of the old age home's population and 28.3% of the dwellings', with 37.9% of the residents being between the ages of 70 and 80.Similarly, the study by Pooja Anudhar et al. [10] reveals that, across all regions of south Karnataka, 59.5% of people in the 60–70 age group lived in residences and 20% in old age homes, 40.5% of people in the 70–80 age group lived in old age homes and 33.5% of people lived in residences, and 39.5% of people over 80 lived in OAH and 7% lived in residences respectively.

The majority of study participants in Raipur, Chhattisgarh's urban areas, on the other hand, were between the ages of 60 and 70, with 37% living in residences and 18% in old age homes; those between the ages of 70 and 80 had 20% in old age homes, 7% in residences, and those over 80 had 12% in OAH and 6% in residences, according to a study by Sahoo et al. [17]. Consequently, it is concluded that the pattern of mortality differs according to the location of stay.

Magnitude of morbidity pattern

Approximately 64.4% of research participants reported that their daily activities were hampered by a chronic disease. Hypertension (51.5%), osteoarthritis (43.5%), cardiovascular disease (17.3%), vision impairment (14%), stroke (7.3%), chronic renal disease (11%), and diabetes mellitus (about 29.4%) comprised the morbidity pattern of chronic illnesses that characterized the majority of research participants. Comparably, a study conducted in the Shimla hills of North India by Deepak Sharma et al.20 revealed that 55% of the participants had osteoarthritis, 30.8% had visual impairment, 40.5% had hypertension, 8% had cardiovascular disease, 5.8% had diabetes mellitus, and 1.5% had stroke.

Also, in the study done by Kiran Bala et al. [21] done Similar to our findings, 56.5% of rural elderly people in

Jammu district had hypertension, 40% had visual issues, 52% had diabetes, 37.5% had osteoarthritis, and 32.5% had cardiovascular disease. In the contrary, the study done by Prabhakar et al. [22] approximately 49.4% of people in Delhi's suburban area had visual impairment, 58% had hypertension, and 30.3% had diabetes mellitus. 32.9% of people with arthritis had it, with one exception. Additionally, according to the LASI survey23, which was carried out in India, about 32.7% of people had hypertension, 14.2% had diabetes mellitus, 5.19% had cardiovascular disease and stroke (2.73%), which was less than what we found, and, on the other hand, only about 19.7% had osteoarthritis (43.5%). Additionally, the Jana et al. study from 24 revealed that almost 35% of participants had high blood pressure, 30% had diabetes, 15% had heart disease, and 3% had stroke. These variations in non-communicable disease prevalence may be due to changes in the morbidity pattern of non-communicable illnesses in connection to their lifestyle and awareness of NCD sickness prevention.

Conclusion

Noncommunicable diseases (NCDs) are more common in assisted living facilities than in the residences of older individuals, according to a comparison of the noncommunicable disease morbidity pattern. Many NCDs, such as diabetes mellitus, hypertension, cardiovascular disease, stroke, chronic renal disease, visual impairment, and osteoarthritis, have morbidity patterns that were found to be significantly influenced by most sociodemographic factors.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

E-pharmacy use among Medical Interns: Insights into Knowledge and Attitude

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Abstract

Background: E-pharmacy is an online pharmacy that offers convenient, cost-effective, and round-the-clock access to medicines, driven by e-prescriptions and the COVID-19 pandemic. However, 95% operate in India illegally, raising concerns about patient safety. There is insufficient evidence on the awareness of E-pharmacy among Compulsory Rotatory Medical Interns (CRMIs). **Objectives:** To assess the knowledge, attitude, and usage pattern of E-pharmacy among CRMIs in a tertiary care hospital. **Materials and Methods:** A prospective online questionnaire (Google Form)-based study was conducted using convenient sampling among 73 CRMIs at a tertiary care hospital in Palakkad for 3 months. Descriptive statistics and chi-square test were used, and the results were reported in the form of numbers and percentages. Statistical Package for the Social Sciences, version 28 for Windows, was used to analyze the data. **Results:** The majority of participants (71%) had poor knowledge and a positive attitude (44%), and a significant association ($P < 0.012$) was found between knowledge and attitude. Despite 78.1% being aware of E-pharmacy, half (53.4%) had never purchased from an online pharmacy, potentially attributable to concerns regarding substandard medication quality (26%) and lack of personal interaction (21.9%). Beauty care products (31.5%) and nonprescription medications (28.8%) were the most often purchased items online. **Conclusion:** Though our interns had a positive attitude towards E-pharmacy, their knowledge was found to be low. Augmenting our interns' knowledge via educational interventions and integrating this subject matter into their curriculum may facilitate the promotion of safe E-pharmacy practices and guide policies for safer digital healthcare delivery.

Keywords: E-pharmacy, Knowledge, Attitude, CRMIs, Online pharmacy

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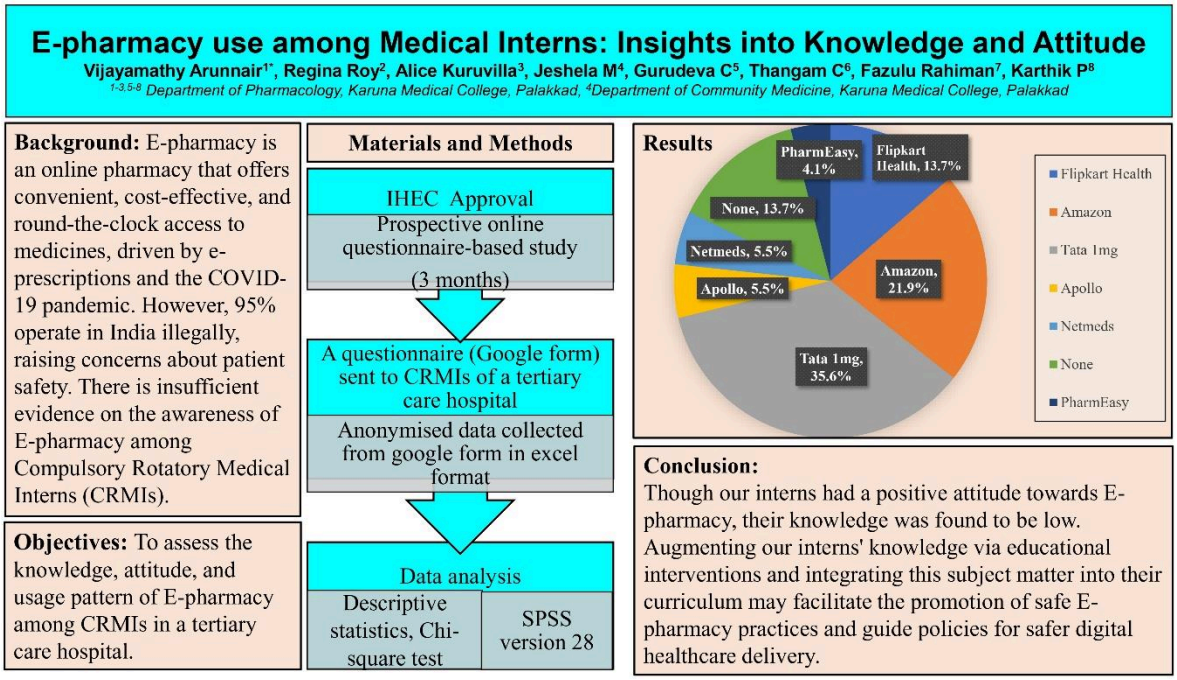
Graphical Abstract



Introduction

E-pharmacy is an online pharmacy that offers convenient medicine delivery to clients, resulting in global demand. The increasing use of e-prescriptions in hospitals has also contributed to the growth of E-pharmacy [1]. The advantages of using an online pharmacy include time and cost savings, convenience for some patients and elderly individuals who are unable to leave their homes, availability around the clock, a greater choice due to the larger selection of medications available, and the ability to receive medications at a chosen time and pace [1,2]. One of the primary forces behind promoting the significance of E-pharmacy has been the COVID-19 pandemic [2].

Approximately 95% of E-pharmacies operate illegally, and there is a lack of legislation or regulations governing online pharmacies in India [1-3]. The World Health Organization (WHO) has raised concerns about the safety of purchasing from E-pharmacies since half of the drugs sold online come from fake websites [1,4]. Online pharmacies without regulations sell counterfeit drugs, posing a significant threat to consumer health [1,4,5]. To recommend safe and reliable online pharmacies to their patients, healthcare providers must be aware of these fraudulent activities and take precautions to avoid them [6].

Research indicates several misconceptions about online pharmacies compared to retail pharmacies [7]. According to an Andhra Pradesh survey, although most medical students were aware of Internet pharmacies, they still favoured offline pharmacies due to concerns about false websites [1]. There are a few KAP (Knowledge, Attitude and Practice) studies in Indian literature about online pharmacy among second MBBS students, physicians, retail pharmacists, and consumers [1,5,7,8]. To the best of our knowledge, there are no such studies involving Compulsory Rotatory Medical Interns (CRMIs), who are budding physicians of tomorrow. Such research may help improve the safety and dependability of E-pharmacy for patient

care in the modern digital environment. Hence, the current study was conducted to analyze the knowledge, attitude, and pattern of use of E-pharmacy among CRMIs in a tertiary care hospital.

Materials and Methods

After approval from the Karuna Medical College (KMC), Institutional Human Ethics Committee (Approval No. KMC/IHEC/22/2024), a prospective observational online questionnaire-based study using convenient sampling was conducted at KMC, Palakkad, for a duration of 3 months (March 2024 to May 2024) among the CRMIs in the academic year 2024 - 2025. We got 73 responses.

Inclusion criteria

All the CRMIs of Karuna Medical College, Palakkad, in the academic year 2024-2025, aged 18 years and above, of either gender

Exclusion criteria

Not willing to participate, and Incomplete responses

Study procedure

A prevalidated questionnaire based on previous studies was sent to all MBBS interns through WhatsApp, utilizing Google Forms as a data collection tool [1,5,8]. An online consent was incorporated at the beginning of the questionnaire (Google Form). The form comprised four sections: the first section contained demographic data, such as age, gender, and regional distribution, while sections two, three, and four each featured ten questions about knowledge, attitude, and usage patterns of E-pharmacy, respectively. Questions were open-ended, closed-ended, and multiple-choice (with the option to add more). Participants' attitudes were assessed using a three-point Likert scale: Agree, Disagree, and Neutral. A score of 1 was assigned to the correct answer and 0 to the wrong answer. The overall knowledge and attitude scores (ranging from 0 to 10) for each participant were determined and classified into three categories of knowledge {high (8-10), moderate (6-7), and low (<6)} and three categories of attitude (positive, neutral, and negative) according to Bloom's cut-off point, and their percentages were calculated [9].

Statistical Analysis

Anonymized data obtained via Google Forms was entered in Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 28. Descriptive and inferential statistics were used, when appropriate, to analyse the results. The association between variables was studied using a chi-square test. Results were presented as numbers (%). Significance was assessed at a 5% level of significance ($p<0.05$).

Results

The majority of participants, 50 (68.5%), were aged 18-25, while the remaining 23(31.5%) were aged 26-35. Most of them were females, 52(71.2%). More than half (54.8%) of the CRMIs belong to urban areas.

Knowledge

The majority (78.1%) were aware of E-pharmacy. Only half of the interns know about reliable online pharmacy websites (47.9%), requirements of prescription (61.6%), medication alerts (50.7%), types of drugs that can be sold (58.9%), and other value-added services (49.3%) like e-consultations, e-diagnostics, details on

medications and illnesses, health insurance services, and patient counselling. Nearly 47.9% were able to recognise safe E-pharmacies. Additionally, 80-95% of the participants had poor knowledge of E-pharmacy laws, including advertisement of drugs (80.8%), E-pharmacy guidelines (94.6%), and reporting of unlawful sales (82.2%) (Table 1).

Table 1. Knowledge of the participants (N=73)

Knowledge-based Questions	**Answers *n* (%)**		
	Yes	**No**	**Don't know**
Do you know about E-pharmacy?	57(78.1)	16(21.9)	0(0)
Do you know about reliable online pharmacy websites?	35(47.9)	30(41.1)	8(11.0)
Advertisement of drugs through E-pharmacy is permitted.	26(35.6)	14(19.2)	33(45.2)
Do you require a prescription for the online purchase of medicines?	45(61.6)	14(19.2)	14(19.2)
Are there any approved E-pharmacy guidelines in India?	31(42.5)	4(5.5)	38(52.1)
E-pharmacies provide medication alerts to doctors and drug reminders to patients.	37(50.7)	3(4.1)	33(45.2)
Narcotics, psychotropic drugs, painkillers, and Schedule X drugs can be sold in online pharmacies.	5(6.8)	43(58.9)	25(34.2)
Are you aware of any other value-added services that E-pharmacies provide?	36(49.3)	19(26)	18(24.7)
Do you know whom to report for unlawful sales of medical products on the Internet in India?	13(17.8)	26(35.6)	34(46.6)
Safe online pharmacies:	Provide a physical address and telephone number in the country	1(1.4)	
	Have a licensed pharmacist on staff to answer your questions.	7(9.6)	
	Offer discounts and deals	1(1.4)	
	Are licensed with the state board of pharmacy	2(2.7)	
	Options 1,2 & 4 are correct	35(47.9)	
	All the above	27(37)	

Attitude

Almost 60-89% of Participants had a positive attitude towards various aspects including the benefit of online pharmacies during COVID-19(87.7%), inclusion in the undergraduate curriculum (86.3%), encouraging others to buy (61.6%), incorporating e-signatures (89%), helping in reducing healthcare expenditure (71.2%), switching to E-pharmacy in the future (74%) and adherence to the country-specific laws (74%). However, individuals expressed negative opinions on the lack of preference for routine medication purchases (64.4%), medicine storage conditions (45.2%), and brand substitution (37%) (Table 2).

Table 2. Attitudes of Participants (N=73)

Attitude-based Questions	**Answers *n* (%)**		
	Agree	**Disagree**	**Neutral**
Do you feel online pharmacies were beneficial during the COVID-19 pandemic?	64(87.7)	7(9.6)	2(2.7)
Non-emergency day-to-day (routine) medicines can be procured offline rather than online.	47(64.4)	19(26.0)	7(9.6)
Should more information on online pharmacies be incorporated into the undergraduate curriculum?	63(86.3)	5(6.8)	5(6.8)
Would you like to encourage patients/ friends/ family members to buy medicine from an E-pharmacy?	45(61.6)	14(19.2)	14(19.2)
Do you feel it is necessary to incorporate the electronic signatures of physicians during purchase through E-pharmacy?	65(89.0)	4(5.5)	4(5.5)
Do you agree that E-pharmacy can reduce overall healthcare expenditure?	52(71.2)	10(13.7)	11(15.1)
Would you like to switch to E-pharmacy in the future?	54(74.0)	7(9.6)	12(16.4)
Do you think the storage conditions of the drugs sold by online pharmacies can be checked?	33(45.2)	19(26.0)	21(28.8)
Do you believe that the pharmacy laws allow a pharmacist to substitute a brand written by a doctor?	27(37.0)	31(42.5)	15(20.5)
Do you think the online pharmacy must be compliant with the laws in both the country of origin and the country of destination?	54(74.0)	5(6.8)	14(19.2)

Pattern of use

Around 74% Participants use the internet frequently and shop online. The most commonly preferred online platform was Tata 1 mg (35.6%, n=26), followed by Amazon (21.9%, n=16) (Figure 1). Most (34.2%, n =25) of the interns stated that they didn't use an online pharmacy for any specific disease. However, E-pharmacy was commonly used for fever (19.2%), followed by diabetes (11%), dermatological disease (6.8%), hypertension (5.5%), and cosmetic purposes (5.5%). While 4.1% and 2.7% used for diabetes along with hypertension, and bronchial asthma, respectively. One participant each used for allergic rhinitis, arthritis, headache, inflammatory bowel disease, hypothyroidism, gastritis, migraine, heart disease, and multiple comorbidities.

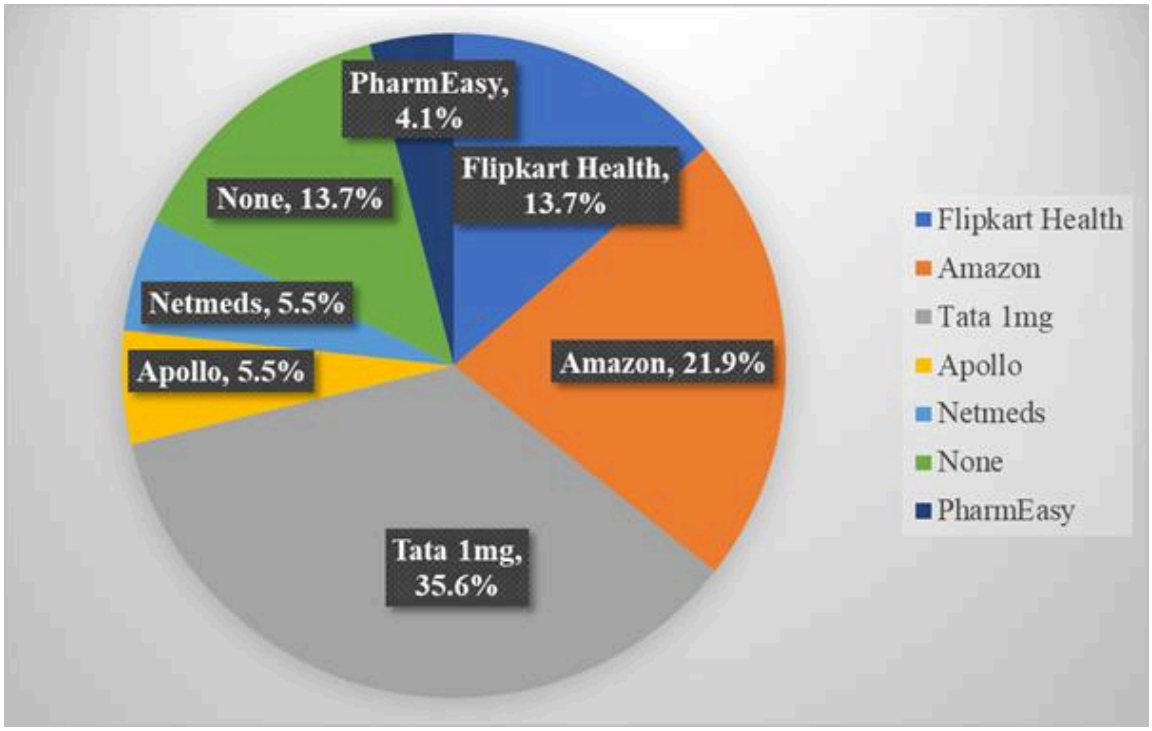


Figure 1. Online platforms for purchasing medicines (N=73)

Considering the frequency of online medicine purchases, the majority (53.4%) never procure, while 24.7% and 20.5% procure monthly and yearly, respectively. Only 1.4% of them bought daily. Participants (27.4%) have been purchasing medicines online for a month to a year, and 21.9% have been buying for over a year. Beauty care products (31.5%), followed by nonprescription drugs (28.8%), were the most common categories of products purchased online; nevertheless, personal care products 5.5% were the least preferred one (Figure 2).

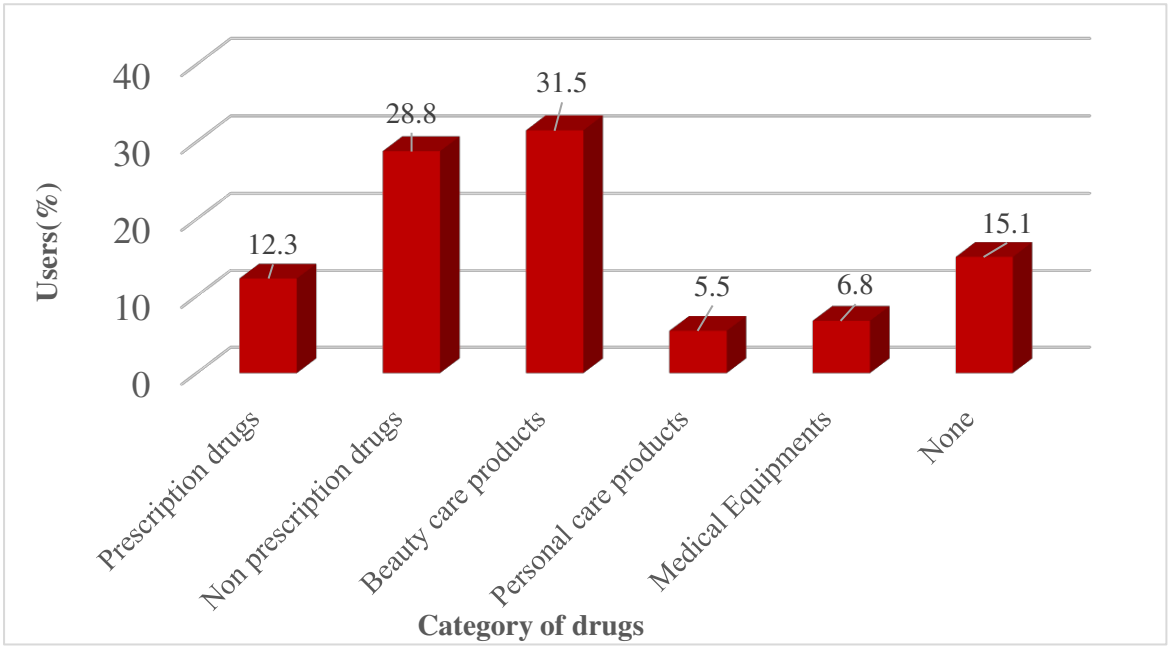


Figure 2. Category of drugs purchased in E-pharmacy (N=73)

Nearly 38.4% (n=28) opted to buy branded medication through an online pharmacy, followed by both branded and generic medications (35.6%, n =26). Only 2.7% preferred generic medicine. More than 87.7% of participants reported no issues, including side effects, poor quality, delays in delivery, or incorrect medication, when purchasing through an E-pharmacy.

The common reasons for choosing E-pharmacy were cheap costs/ special offers (27.4 %) and the lack of certain drugs in offline pharmacies (26%) (Figure 3). Compromised quality of medicine (26%) and lack of face-to-face interaction (21.9%) were the most common reasons for avoiding E-pharmacy (Figure 4).

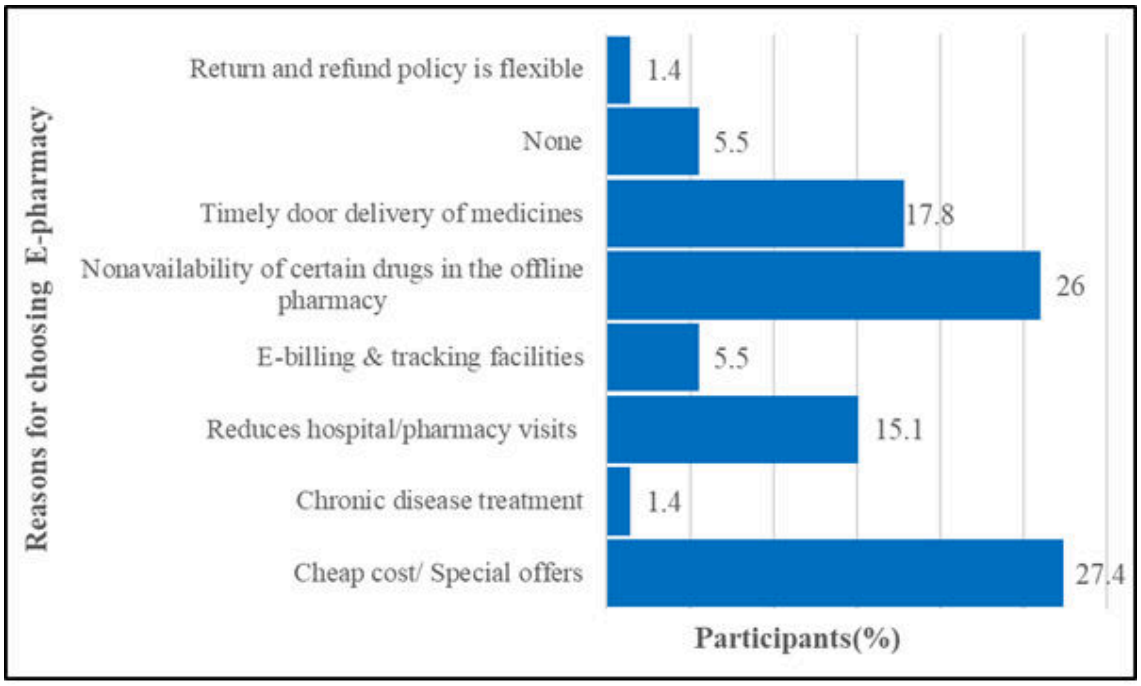


Figure 3. Reasons for choosing E-pharmacy (N=73)

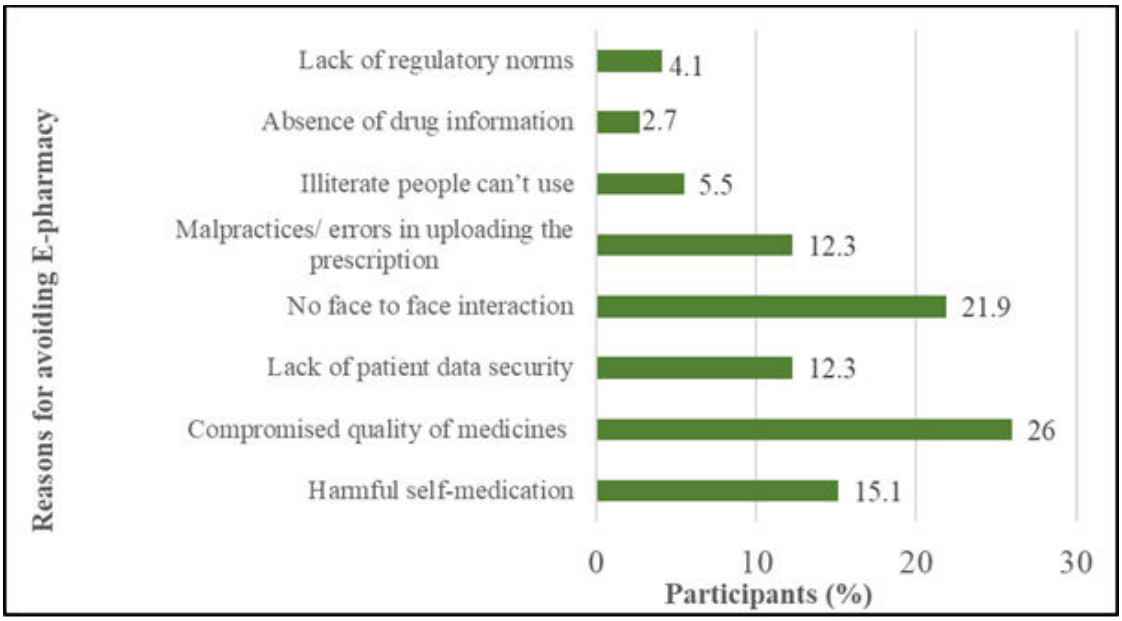


Figure 4. Reasons for avoiding E-pharmacy (N=73)

Knowledge and attitude scores

Students (71%) had low knowledge scores, while 23% and 6% had moderate and high knowledge scores, respectively. A positive attitude was noticed among 44% of students, 18% had a negative attitude; the remaining 38% had a neutral attitude. The Chi-square test found that the relationship between knowledge and attitude was statistically significant. (χ^2 value = 6.241, P <0.012).

Discussion

Though there is a global demand for using E-pharmacy in patient care, the safety and dependability are questionable. Since there is a paucity of studies in Indian literature on the awareness of E-pharmacy among CRMIs who are future doctors, our study is the first of its kind to be done among them. This questionnaire-based study was conducted among 73 medical interns to analyze their knowledge, attitude, and pattern of use of E-pharmacy. The majority of our participants had poor knowledge (71%) and a positive attitude (44%), and a significant association was found between the two.

Most (71.2%) of our study participants were females from urban regions (54.8%), and the majority (68.5%) were between the ages of 18 and 25. Though 78.1% of our interns were aware of online pharmacies, only 46.5% purchased medicines online, consistent with other work [8]. A study by Mrinalini et al., reported that most online customers were found to be graduates, urban residents, and aware of E-pharmacy, but still preferred offline pharmacy purchases [1]. Another study also found that the urban population has higher knowledge and utilization rates of E-pharmacy services, with younger age groups (18-25) more likely to use them [10].

Fewer than half (47.9%) of them only knew about reliable online pharmacy websites. Likewise, in other studies, a lower percentage (37.7%-47.44%) were aware of the trustworthy sites [1,5]. Just 47.9% of our students could identify secure online pharmacies. While in another research, a similar proportion (35-66%) of pharmacy students were able to identify an illegal online pharmacy website; however, following an educational session, the percentage increased to 58-82% [11]. Other study respondents (57%) also stated illegal websites as a major concern [12]. Almost 49.3% of our trainees knew about value-added services, but in a Delhi-based study, 95% of them favoured e-consultations and medication advice [12]. The majority (80-95%) of our interns had poor knowledge of E-pharmacy laws, such as advertisements of drugs (80.8%), E-pharmacy guidelines (94.6%), and reporting of unlawful sales (82.2%). North Indian consumer surveys revealed that only 23%-25.8% of respondents were familiar with E-pharmacy legislation, with varying degrees of familiarity reported in other studies [10,12,13]. Although few articles have stated that the urban population has higher awareness of E-pharmacy, the poor knowledge of our interns could be attributed to their higher preference for offline pharmacies and a lack of practical knowledge about E-pharmacy in their undergraduate curriculum [5,10].

Similar to a previous study, our CRMIs expressed a favourable attitude on the benefit of E-pharmacies during COVID-19 (87.7%) [14]. Nevertheless, like others, our students also preferred an offline pharmacy during non-emergencies [5]. Corresponding to other projects, our

CRMIs also expressed a preference for incorporating E-pharmacy programs into the curricula [11,13,15,16]. Our respondents overwhelmingly supported the use of electronic signatures (89%), citing cost reduction (71.2%), future adoption of E-pharmacies (74%), adherence to country-specific legislation (74%), and encouraging others to use E-pharmacies (61.6%). These findings were consistent with previous studies [1,5,12-13,15-16]. Yet, our students wrongly felt that storage conditions (45.2%) were controlled and brand substitution (37%) was permissible in E-pharmacy. However, some articles have identified doubtful/poor quality of medicines, including counterfeit, substandard, illegal, outdated medicines, and improper storage conditions, as well as nonavailability of specific brands, as the major disadvantages of E-pharmacy [1,5,10,12,16-17]. Although a favourable attitude among medical students is critical for preserving supply chains and protecting consumers from illegal websites, a few factors still require attention.

The majority of our study respondents (74%) were frequent internet users and online shoppers, in line with other research, and frequent internet usage is one of the leading causes for online shopping [12]. Similar to a study by Bansal et al., the most common E-pharmacy website preferred in our study was Tata 1mg (35.6%), followed by Amazon (21.9%) [5]. But, in other studies, Pharmeasy and Netmeds were the most common websites preferred [1,18,19]. In our project, the most common conditions for which online pharmacy was opted were fever (19.2%), diabetes (11%), and dermatological issues (6.8%). A few of the CRMIs used it for chronic health conditions like hypertension, bronchial asthma, and multiple comorbidities, demonstrating the growing interest in online health management.

More than half of our members (53.4%) have never made an online pharmacy purchase, although monthly (24.7%) and annual (20.5%) usage shows a slow shift in favor of E-pharmacy. Contrarily, past studies have depicted only 1- 6% usage of E-pharmacy [12,15]. But a questionnaire-based study conducted among physicians showed 22.35% usage [8]. This increase in purchasing trend seen in our study could be attributed to the time spent by younger generations on the internet and online shopping. In our research, beauty care products (31.5%), followed by nonprescription drugs (28.8%), were the most common category of product purchased online, but in other articles, prescription drugs and cosmetics, followed by dietary supplements, were most commonly purchased [1,5,20]. Considering the type of medicine, 38.4% CRMIs opted to buy branded, followed by both branded and (35.6%) generic, in contrast to other studies in which a greater percentage (59.3%-63.77%) of participants chose both branded and generic [1,5].

More than 87.7% of our participants had not encountered any problems like side effects, poor quality, delay in delivery, or wrong medicine while purchasing through E-pharmacy, in line with an earlier study in which majority (58.9%) didn’t encounter any problem, still rest of them had issues like unavailability of medicine, delay in receiving the medication and wrong medication delivery [15]. Even Jain et al pointed out the chances of wrong medication and delayed delivery in E-pharmacy [21]. Our students chose E-pharmacy due to cheap costs/ special offers (27.4 %) and the unavailability of certain drugs (26%) in offline pharmacies. Various

studies have also supported this finding [1,5,7,12,16,22-24]. Poor medicine quality (26%) and lack of personal interaction (21.9%) discouraged E-pharmacy use among our interns, comparable to numerous other findings [1,5,7,12,13, 25]. As per research, health literacy significantly influences the adoption and usage of E-pharmacy, which could also be an explanation for our respondents' usage pattern [24].

Our CRMIs showed a positive attitude, but poor knowledge, and a significant association between both, which corresponded to a pilot study done among consumers [15]. Nevertheless, a survey of retail pharmacists revealed good knowledge and a positive attitude towards E-pharmacy [7,26]. Another consumer poll found a significant correlation between respondents' education level and their perception of the security of online pharmaceutical services [23]. To address interns' lack of knowledge, formal education on the risks posed by illegal online pharmacies to patient and medication safety is necessary.

Limitations

This study was limited to Interns in a tertiary care hospital with a small sample size, and it can't be generalized to all medical students. Furthermore, the results are entirely subjective and based solely on the responses of the participants. To overcome the shortcomings of the current study, a comparative, multicenter study with an educational intervention involving various target groups (different streams of students) is required. Also, further research is needed to extend the findings to the general public.

Conclusion

This questionnaire-based study has provided valuable insights into the current knowledge, attitude, and pattern of use of E-pharmacy among CRMIs. Though CRMIs had a positive attitude and a gradual inclination towards E-pharmacy usage, poor knowledge was observed. Additionally strong relationship was found between knowledge and attitude. Hence, educational intervention on the guidelines, risks, and benefits of E-pharmacy platforms, as well as their inclusion in the MBBS curriculum, is needed to enhance our CRMIs' knowledge, attitude, and pattern of usage. This may also facilitate the promotion of safe E-pharmacy practices and guide policies for safer digital healthcare delivery. The study's limitations may prompt future research on the impact of E-pharmacy inclusion in medical curriculum, including training and public information.

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Authors' Contributions

All the authors contributed to the concept, design, data collection, data analysis, and interpretation, drafting of the article, critical revision of the article, and final approval of the version to be published.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the research, authorship, and publication of this article

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ORIGINAL ARTICLE

Comparison of Ultrasound Guided Femoral Nerve Block and Fascia Iliaca Compartment Block for Pain Relief During Positioning and Postoperative Analgesia in Proximal Femur Fracture

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Abstract

Introduction: Proximal femur fractures are usually associated with pain, which poses a challenge for patient positioning for subarachnoid block (SAB). The femoral nerve block (FNB) which is a regional anaesthetic technique such as and fascia iliaca compartment block (FICB) are widely utilised to alleviate this pain. While both the techniques are efficient, there is limited comparative data regarding their efficacy under ultrasound guidance. **Materials and Methods:** This observational comparative study included 44 adult patients who undergo elective surgery for isolated proximal femur fractures under spinal anaesthesia. The study participants were divided into two groups: Group 1 (n = 22) who received ultrasound-guided FNB with 20 mL of 0.25% Ropivacaine, and Group 2 (n = 22) who received ultrasound-guided FICB with 30 mL of 0.25% Ropivacaine. Pain was assessed using a 10 cm Visual Analog Scale (VAS) before the block and at 5-minute intervals up to 40 minutes post-block. Patients were positioned for SAB when VAS < 3. **Results:** VAS scores were comparable between the groups up to 10 minutes after block administration. From 15 to 35 minutes, the FNB group showed significantly lower VAS scores compared to the FICB group ($p < 0.05$), indicating a faster onset of analgesia. The mean time for VAS to regress to 3 was significantly shorter in the FNB group (29.32 ± 3.87 minutes) compared to the FICB group (35.00 ± 3.45 minutes; $p < 0.001$). **Conclusion:** Both ultrasound-guided FNB and FICB are effective in managing preoperative pain during positioning for SAB in patients with proximal femur fractures. FNB offers a faster onset of analgesia, making it preferable for early positioning, while FICB provides longer-lasting postoperative pain relief. The choice of block can be tailored to meet specific perioperative analgesic goals.

Keywords: Femoral nerve block, Fascia iliaca block, Proximal femur fracture, Ultrasound guidance, Postoperative analgesia

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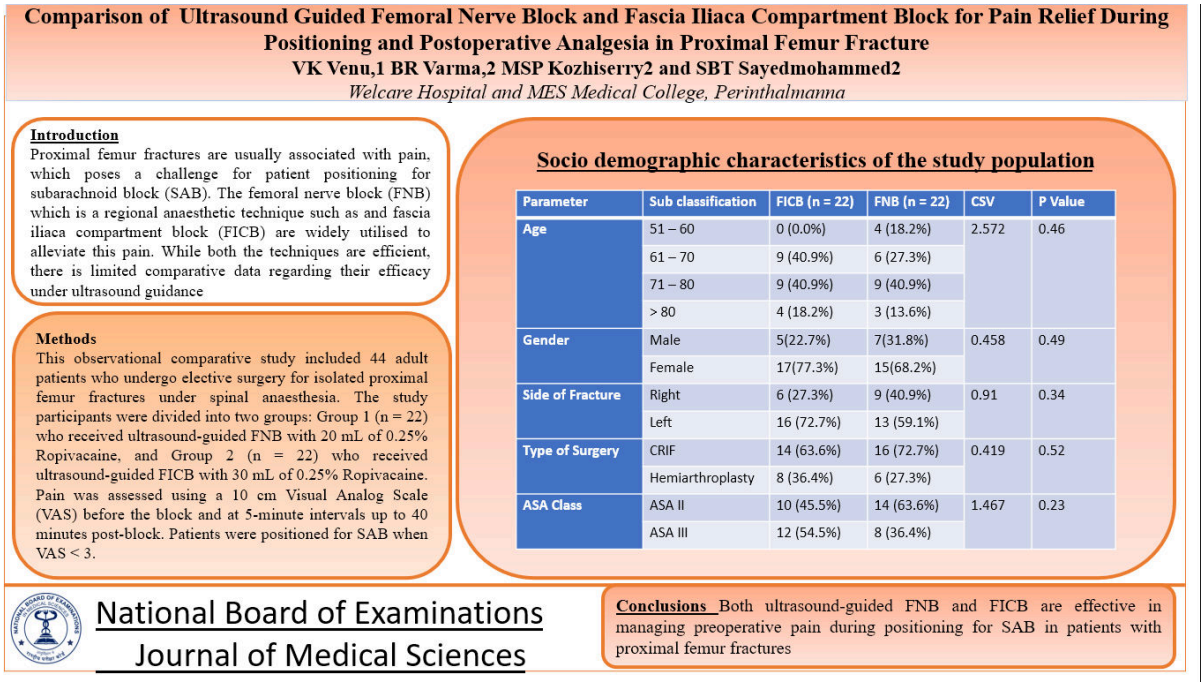
Graphical Abstract



Introduction

Fractures of the proximal femur, including the neck of femur and intertrochanteric fractures, are among the most common orthopaedic emergencies encountered in the elderly population. These injuries are associated with severe pain and significant functional limitations, often necessitating early surgical intervention under regional anaesthesia, particularly spinal anaesthesia, to minimize perioperative complications and enhance recovery [1-3]. However, the intense pain experienced by these patients frequently makes positioning for subarachnoid block (SAB) extremely challenging, potentially reducing the success rate of the regional technique and increasing the risk of haemodynamic fluctuations due to catecholamine surges [1,4,5]. A pain free, calm and quiet patient improves the ease of doing block and gives the chance for an earlier successful SAB.

To address this issue, various analgesic strategies have been employed to facilitate patient positioning. This comprises of systemic analgesics like intravenous opioids as well as peripheral nerve blocks. Among the latter, the femoral nerve block (FNB) and the fascia iliaca compartment block (FICB) are widely practiced and have shown promise in providing effective preoperative analgesia for femur fracture surgeries [1]. Both techniques aim to nerves supplying proximal part of femur, thereby reducing pain during positioning for spinal anaesthesia.

Although several studies have evaluated the analgesic effects of FNB and FICB individually, only a limited number of comparative studies have been conducted under ultrasound guidance. Ghirmire et al. [6] found that FICB resulted in greater VAS score reduction compared to FNB using lignocaine with adrenaline. In contrast, Jain et al. [7] reported that ultrasound-guided FNB with Ropivacaine provided more effective pain relief than FICB in femur fracture patients. Meeta Gupta et al. [1]

observed that FICB resulted in significantly lower VAS scores at various intervals after the block and offered longer postoperative analgesia than FNB. Liang et al. [5] also proved that FNB had a faster onset compared to FICB, although both techniques were ultimately effective.

With the arrived mixed results and the lack of consensus, especially in the South Indian patient population, further research on these types of comparative studies are warranted. The current research aims to compare the analgesic efficacy of ultrasound-guided FICB and FNB in patients with proximal femur fractures undergoing surgery under spinal anaesthesia, specifically assessing their role in facilitating positioning and providing postoperative analgesia.

Materials and Methods

This comparative observational study was done at MES Medical College, Perinthalmanna, after getting IHEC clearance. The present study aimed to compare the efficacy of analgesia between ultrasound (USG)-guided femoral nerve block (FNB) and fascia iliaca compartment block (FICB) in patients with proximal femur fractures planned for corrective surgery under spinal anaesthesia. A total of 44 participants, aged above 18 years, of both the gender, belonging to the American Society of Anaesthesiologists (ASA) physical status from I to III, were included for the study.

The exclusion criteria includes patient with coagulopathies, infection at the injection site, polytrauma or multiple fractures, a history of lower limb nerve block within the preceding 48 hours, suspected compartment syndrome, were anxious or agitated or, were unwilling to participate in the study.

All the patients were provided with a detailed explanation of the study objectives, procedures, risks, and benefits in their native language before including them in the study. The consent process was conducted in a quiet and private setting, ensuring that each participant had adequate time to ask questions and clarify any doubts. Patients were informed about their right to withdraw at any stage without affecting their treatment. A written informed consent form, approved by the Ethics Committee and available in the local language, was signed by each participant. In cases where patients had difficulty writing, a thumb impression was obtained in the presence of a witness, as per institutional norms.

Patients were allocated into two groups by non-probability sampling. Group 1 (n = 22) received an ultrasound-guided femoral nerve block with 20 mL of 0.25% Ropivacaine, while Group 2 (n = 22) received an USG-guided fascia iliaca compartment block with 30 mL of 0.25% Ropivacaine. This volume difference follows a similar pattern of several previous similar studies, which used higher volume for fascial plane blocks [7-10]. The procedures were performed in a supine position under strict aseptic precautions by the principal investigator, with the assistance of an experienced anaesthesiologist. In the FNB group, the femoral artery was identified under USG guidance using a high-frequency linear probe, and the needle was introduced in-plane to deposit the local anaesthetic adjacent to the femoral nerve. In the FICB group, under ultrasound guidance femoral artery and femoral Nerve are identified in an “in plane technique”. Psoas muscle lies lateral to the femoral nerve and is covered by the iliacus fascia, which lies beneath the

fascia lata. The needle was advanced through the fascia lata and fascia iliaca until two characteristic "pops" were felt, and the local anaesthetic was deposited beneath the fascia iliaca after confirming negative aspiration.

Pain intensity was assessed using a 10 cm Visual Analog Scale (VAS), where 0 indicated no pain and 10 represented the worst possible pain. VAS scores were recorded before the block, immediately after the block, and at 5-minute intervals up to 40 minutes. Patients were considered ready for spinal anaesthesia when the VAS score dropped below 3. After the surgical procedure, postoperative pain scores were recorded at 0, 2, 4, 6, 8, 10 and 12 hours. Rescue analgesia was administered when the VAS score was 4 or more, and the time to the first analgesic request was noted.

The data collected was entered into Microsoft Excel, coded and analysed using SPSS software. Continuous variables such as age and VAS was expressed as mean ± standard deviation (M±SD), and categorical variables like gender, ASA classification, and type of fracture were presented as frequencies and percentages. Independent t-test was performed for normally distributed continuous data and Mann-Whitney U test for non-parametric data, and the chi-square test for association between categorical variables. A p-value of less than 0.05 was considered statistically significant.

Results

Table 1 shows the sociodemographic characteristics of the study population, including age distribution, gender, side and site of fracture, type of surgery, and ASA classification. The mean age was comparable between groups (72.6 ± 6.93 years in FICB and 70.7 ± 11.3 years in FNB), with no statistically significant difference across age strata ($p = 0.46$). The gender distribution was also similar, with females forming the majority in both groups (77.3% in FICB vs. 68.2% in FNB; $p = 0.49$). The side of fracture (right or left), type of surgery (CRIF or hemiarthroplasty), and ASA class distribution between FICB and FNB groups were not significantly different ($p > 0.05$ for all), suggesting that both groups were well-matched demographically and clinically at baseline (Table 1).

Table 1. Socio demographic characteristics of the study population

Parameter	**Sub classification**	**FICB (n = 22)**	**FNB (n = 22)**	**CSV**	**P Value**
Age	51 – 60	0 (0.0%)	4 (18.2%)	2.572	0.46
	61 – 70	9 (40.9%)	6 (27.3%)		
	71 – 80	9 (40.9%)	9 (40.9%)		
	> 80	4 (18.2%)	3 (13.6%)		
Gender	Male	5(22.7%)	7(31.8%)	0.458	0.49
	Female	17(77.3%)	15(68.2%)		
Side of Fracture	Right	6 (27.3%)	9 (40.9%)	0.91	0.34
	Left	16 (72.7%)	13 (59.1%)		
	CRIF	14 (63.6%)	16 (72.7%)	0.419	0.52

Type of Surgery	Hemiarthroplasty	8 (36.4%)	6 (27.3%)		
ASA Class	ASA II	10 (45.5%)	14 (63.6%)	1.467	0.23
	ASA III	12 (54.5%)	8 (36.4%)		

The comparison of pain scores using the Visual Analog Scale (VAS) before and after administration of the block is presented in Table 2. Before the block and up to 10 minutes afterward, VAS scores were not significantly different between FICB and FNB groups ($p > 0.05$). However, starting from 15 minutes post-block, the FNB group demonstrated significantly lower VAS scores, with the difference persisting up to 35 minutes ($p < 0.05$). At 40 minutes post-block, VAS scores in both groups converged to 3.0, showing no statistical difference ($p = 1.000$). This indicates that while both blocks are eventually effective, FNB achieves pain relief faster, making it more suitable for early positioning before spinal anaesthesia (Table 2).

Table 2. Comparison of Pre-op and During Procedure VAS between FICB and FNB

Pre-op VAS	**FICB**	**FNB**	**p-value**
Before Procedure	7.09 ± 0.81	6.86 ± 0.71	0.327
After Block			
5 Minutes	7.09 ± 0.81	6.86 ± 0.71	0.327
10 Minutes	6.91 ± 0.75	6.86 ± 0.71	0.849
15 Minutes	6.36 ± 0.79	5.73 ± 0.77	0.014
20 Minutes	5.64 ± 0.73	4.86 ± 1.04	0.009
25 Minutes	4.82 ± 0.85	3.86 ± 0.77	0.001
30 Minutes	4.05 ± 0.79	3.14 ± 0.35	0.000
35 Minutes	3.23 ± 0.43	3.00 ± 0.00	0.019
40 Minutes	3.00 ± 0.00	3.00 ± 0.00	1.000
Post-op VAS			
0 Hours	0.00 ± 0.00	0.00 ± 0.00	1.000
2 Hours	0.36 ± 0.58	1.68 ± 0.65	0.000
4 Hours	1.36 ± 0.79	2.64 ± 0.73	0.000
6 Hours	2.19 ± 0.68	3.65 ± 0.59	0.000
8 Hours	2.65 ± 0.67	3.83 ± 0.41	0.002
10 Hours	3.33 ± 0.69	4.00 ± 0.00	0.313
12 Hours	3.65 ± 0.75	4.13 ± 0.32	0.321

Mann-Whitney test was performed.

Postoperative VAS scores recorded from 0 to 14 hours show that immediately after surgery, pain scores were identical in both groups (VAS 0.00 ± 0.00). However, beginning at 2 hours postoperatively, patients in the FICB group experienced significantly lower VAS scores compared to the FNB group up to 8 hours ($p < 0.05$). By 10 hours, the difference was not statistically significant. VAS scores beyond 12 hours were not recorded, as the majority of patients in both groups had required rescue analgesia by then (Table 2).

The comparison of the time to regression of VAS score to 3 and the duration of postoperative analgesia is presented in Table 3. Patients in the FNB group reached a VAS score of 3 significantly earlier (29.32 ± 3.87 minutes) than those in the FICB group (35.00 ± 3.45 minutes), suggesting a faster onset of action with FNB. In contrast, the time to first postoperative analgesic request was significantly longer in the FICB group (10.45 ± 2.39 hours) compared to the FNB group (6.46 ± 1.37 hours), highlighting that FICB provided a longer duration of pain relief after surgery (Table 3).

Table 3. Comparison of Time to Pain Regression and Duration of Postoperative Analgesia between FICB and FNB

Parameter Measured	FICB		FNB		P Value
	M	SD	M	SD	
Time Taken for Regression of VAS Score to 3 (min)	35	3.45	29.32	3.872	<0.001
Time Taken for First Analgesia post op(hrs)	10.45	2.385	6.455	1.371	<0.001

Discussion

Patients presenting with proximal femoral fractures often endure severe pain that complicates positioning for subarachnoid block (SAB). In order to effectively manage the positioning pain, different analgesic modalities have been suggested, including intravenous opioids and regional nerve blocks. Out of these, femoral nerve block (FNB) and fascia iliaca compartment block (FICB) are two frequently employed regional techniques for providing preoperative analgesia.

In the current research, both FNB and FICB were evaluated for their efficacy in pain relief during positioning for SAB and their subsequent postoperative analgesic effects. The findings emphasized that while both techniques provided effective analgesia, FNB resulted in a quick onset of pain relief. This was made evident from significantly lower Visual Analog Scale (VAS) scores observed from 15 to 35 minutes after the block in the FNB group, when compared to the FICB group. But the VAS scores became similar in both groups by the 40-minute mark, suggesting that the overall analgesic effectiveness equilibrated after a certain period.

These findings are in similar with the results reported by Liang et al. [5], who showed that FNB provided significantly lower VAS scores at 3 and 5 minutes after the block compared to FICB. But, at 8 and 10 minutes, the analgesic effect of both blocks was found to be same, indicating that FNB has a quicker onset but comparable efficacy in the longer term. Similarly, Jain et al. [9] also proved that the lower VAS scores during positioning for SAB in patients receiving ultrasound-guided FNB compared to those who received FICB, showing the evidence of faster onset with FNB.

In contrast, postoperative analgesia duration was shown to be significantly longer in the FICB group in the present study. This was shown by a longer time for the VAS score to reach 3 and a significantly delayed request for the first rescue analgesic in the FICB group compared to the FNB group. The above findings align with those of Meeta Gupta et al. [1], who showed that FICB resulted in prolonged postoperative analgesia with delayed rescue analgesia requirements. Thus, the superior duration of analgesia with FICB could be attributed to its anatomical distribution, which may encompass the femoral nerve, lateral cutaneous nerve of thigh (LCNT), and obturator nerve (ON), thus providing a broader and longer-lasting pain control in these cases [8,9].

Ghirmire et al. [6] in contrast, reported that FICB provided more effective VAS score reduction than FNB at 20 minutes after the block when utilising the lignocaine with adrenaline. The variation in these findings may be attributed to differences in the volume and concentration of local anaesthetic used, the use of ultrasound guidance, and patient-specific anatomical factors. In our study, both blocks were administered under ultrasound guidance using 0.25% Ropivacaine, enhancing the accuracy and consistency of nerve localization and drug delivery [10,11].

The present findings further proved the relevance of choosing the appropriate block based on clinical objectives. For faster patient positioning before spinal anaesthesia, FNB may be the preferred technique due to its quicker onset. However, when prolonged postoperative analgesia is desired, FICB appears to be more advantageous. As both blocks were performed using ultrasound guidance, the risk of complications was minimized, and precision was improved, potentially enhancing the efficacy of both techniques [10,13].

Overall, while both blocks serve their intended purposes well, tailoring the choice based on patient needs, urgency of SAB, and expected postoperative pain requirements would lead to better outcomes. Given the limited comparative data in South Indian populations, this study adds valuable evidence to the existing literature and supports the integration of ultrasound-guided regional techniques in the perioperative management of femoral fractures.

Conclusion

Both ultrasound-guided femoral nerve block (FNB) and fascia iliaca compartment block (FICB) are effective techniques for providing analgesia during positioning in patients with proximal femur fractures undergoing spinal anaesthesia. FNB was associated with a faster onset of pain relief, facilitating quicker and more comfortable patient positioning for subarachnoid block. On the other hand, FICB offered significantly prolonged

postoperative analgesia, as evidenced by delayed onset of pain and a longer duration before the first request for rescue analgesia. These findings suggest that the choice between FNB and FICB can be guided by the specific clinical goals—FNB being more suitable for rapid procedural preparation, and FICB being more advantageous for extended postoperative pain control. Both blocks, when administered under ultrasound guidance, offer a safe, reliable, and patient-friendly alternative to systemic analgesics. Further large-scale, multicentre studies are warranted to validate these findings and refine regional anaesthesia protocols for optimal perioperative pain management in femoral fracture patients.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Diagnostic Evaluation and Staging of Carcinoma Cervix by Magnetic Resonance Imaging

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Abstract

Background: Cervical cancer is one of the top five most common cancers in the world. Cervical carcinoma ranks fourth among all cancers worldwide annually impacting millions of women, making it a significant public health issue. Globally, cervical cancer is the primary cause of cancer-related illness and death among women. Smoking, socioeconomic circumstances, and Human Papilloma Virus (HPV) infection are risk factors for cervical cancer. **Objective:** The objective of the study is to assess the role of magnetic resonance imaging in evaluating carcinoma cervix. Magnetic resonance imaging evaluation of cervical carcinoma is considered best modality due to higher soft tissue and contrast resolution. **Material and Methods:** In Staging of Cervical Carcinoma, MRI imaging plays vital role in. It provides a practical approach in evaluation of cervical cancer from initial diagnosis to restaging of the recurrence. MRI Imaging is very accurate in assessment of the extent of the disease and for staging of the disease. A total of sixty-three cases newly diagnosed, histopathologically confirmed with carcinoma of uterine cervix and treated with chemotherepy/radiotherapy were included. All of the sixty-three study participants were subjected to MRI pelvis performed with 1.5 tesla machine. The staging is classified by international federation of gynecology and obstetrics staging (an updated FIGO). **Conclusion:** MRI provides a valuable stool in evaluating carcinoma cervix, providing accurate staging, detecting parametrical involvement, lymph node metastasis and helping in guiding treatment planning and follow up.

Keywords: cervical cancer, MRI staging, Magnetic Resonance Imaging, Diagnostic

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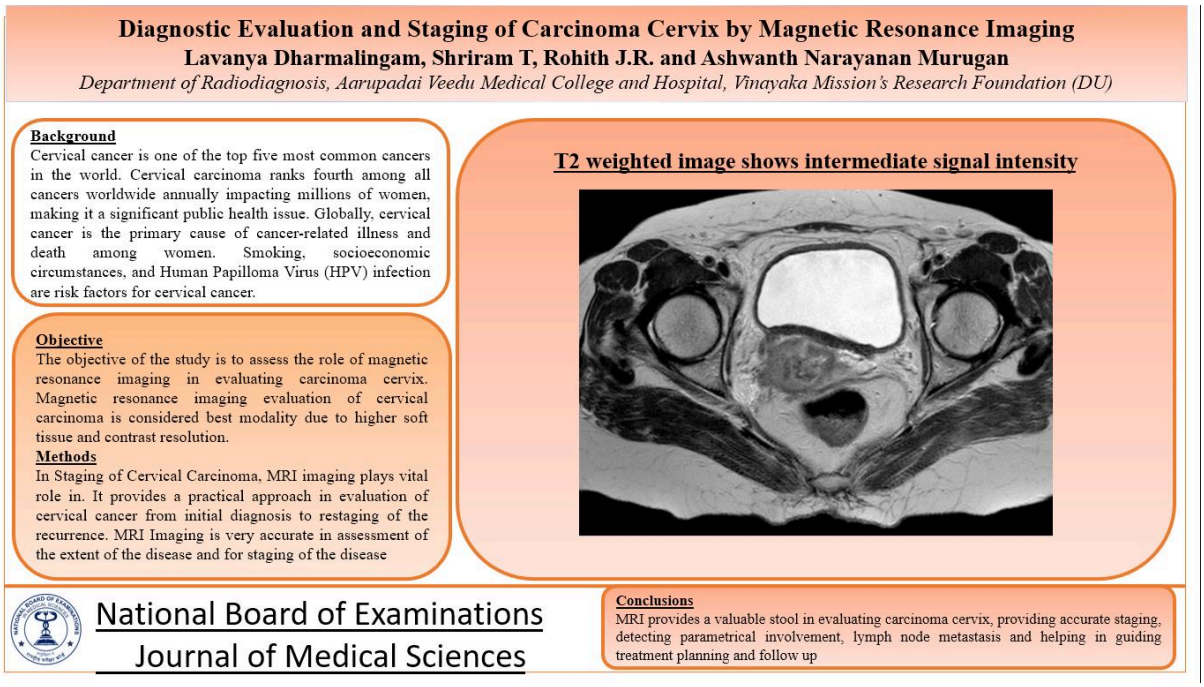
Graphical Abstract



Introduction

The primary cause of cancer-related mortality for women in developing nations is cervical carcinoma [1]. After lung, colon, and breast cancer, cervical cancer is the fourth most frequent type. Women of all ages are susceptible to cervical cancer, although incidence rates differ by region [1]. Persistent infection with a high-risk human papillomavirus (HPV) type, various sexual patterns, tobacco use, smoking, and a compromised immune system are risk factors [2]. Most cervical cancer cases happen in developing countries with limited access to screening and treatment. Due to restricted access to HPV vaccination and screening, the incidence rate is still high in underdeveloped nations [3].

The imaging modalities for cervical cancer are magnetic resonance imaging and computed tomography. In terms of cervical cancer staging, the International Federation of Gynecology and Obstetrics is the most widely used [4]. Vaginal hemorrhage, pelvic pain, and dyspareunia are possible symptoms of cervical cancer, or it may be asymptomatic. Research indicates that magnetic resonance imaging (MRI) is a highly accurate diagnostic method for evaluating cases of cervical cancer in its early stages. we will evaluate in details of uterine cervical carcinoma by magnetic resonance imaging and correlate with FIGO staging which be useful for treatment planning

Material and Methods

The study was conducted in department of radiodiagnosis, Aarupadai Veedu Medical college (AVMC & H) hospital from January 2024 to March 2025. The design of study was cross sectional observational study and the images were examined by the radiologist of Aarupadai Veedu medical college. The data of the patients were collected, patient with newly

diagnosed, histopathologically confirmed with carcinoma of uterine cervix, patient on post treatment willing to participitate are involved in the study. The study participants with adequate renal function subjected to MRI pelvis 1.5 tesla machine.

Informed consent was obtained from all the cases. All the participants subjected to MRI 1.5 tesla, following protocol sequence will be taken. MRI protocol done in our study are T2 weighted, T1 weighted, STIR or fat sequences. T2weighted saggital is to access tumour extent (size, shape and extent). T2W axial to evaluate the parametrial, T1w, STIR or fat saturation for detecting the fat planes and assessing the lymph node, helps in identifying haemorrhage or proteinaceous material Stir sequence suppress fat signal, increasing visibility of tumours, helps in detecting lymph nodes and accessing tumour extent. Diffusion weighted imaging with apparent diffusion coefficient can be more effective in detecting cervical cancer and grading its severity. DWI can also help in assess the response to treatment.

The 1.5 tesla philips MRI machine was used for the studies. TR/TE time of 650/22 milliseconds were used to generate the T1 and T2 weighted (saggital and axial sequence)2600/90 was used to obtain the T2 weighted images. For T1 and T2, the acquisition matrix was 192 x 256 and 256 x 256, respectively with a field of view of 260 mm (pixel size -1.02 mm) for saggital pictures, the slice thickness and inter -slice gap were 4mm and 0.4mm, whereas for the axial slice they were 3mm and 0.3mm.

Results

The fourth most prevalent gynecological cancer in women worldwide is cervical cancer. Adenocarcinoma is the second most prevalent cervical carcinoma after squamous cell carcinoma. The internal federation of obstetrics and gynecology staging classification for cervical cancer is generally recognized. MRI is a diagnostic and staging tool for cervical cancer that also aids in treatment.

A total of sixty-three case in which newly diagnosed cases are fourty nine (78%), recurrence is fourteen (22%) in number. Out of fourteen cases follow up post chemotherapy and post radiotherapy recurrence are eight cases (57%) and six cases (43%) there is no growth (Figure 1).

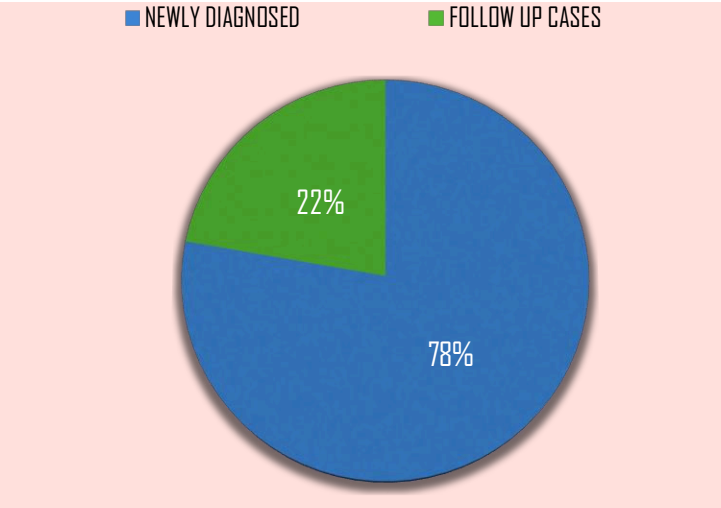


Figure 1. Total Number of Case.

Majority of cases were in between age group 51-60 years (22%), followed by 30-40 years (13%) and 41-50 years (12%), 61-70 years (12%) and 71-80 years (2%) and 81-90 years (2%) (Figure 2).

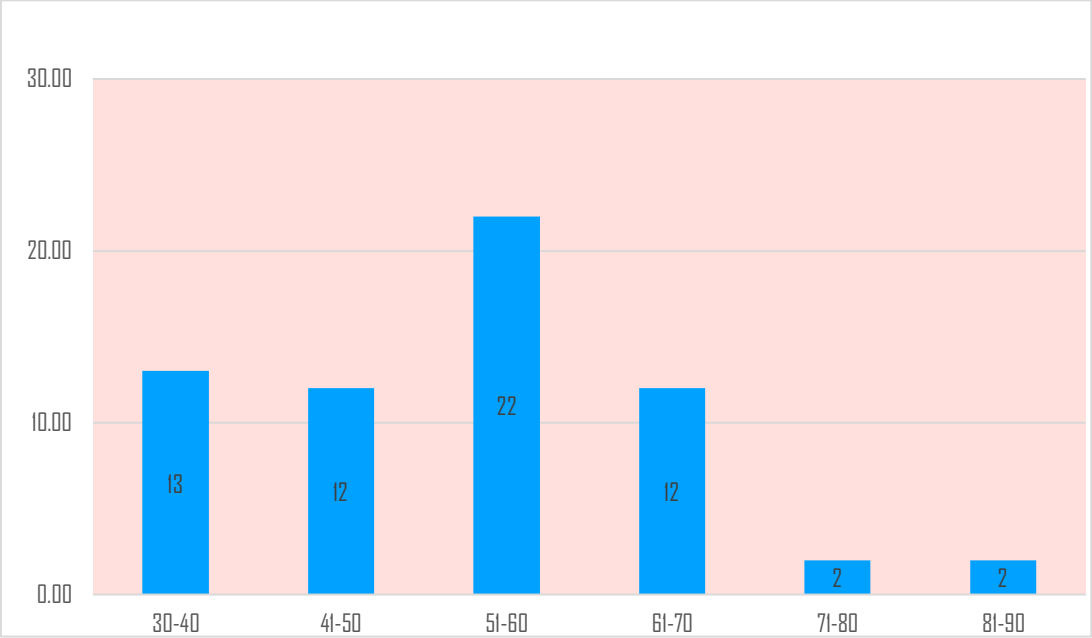


Figure 2. Age Wise Distribution

Incidence of carcinoma cervix were more in between age group 30-40 years and the figure was equal for 41-50 years and 61-70 years with peak incident between 51-60 years. The symptoms of carcinoma cervix in our study are asyptomatic, pain abdomen, white discharge, per vaginal bleeding and mass per vagina.

In our study patient presenting with mass per vagina in a newly diagnosed patients 2 percent and patients on chemotherapy/radiotheraphy were 9 percent and patient with no specific complaints were 29 percent (asymptomatic)with post menopausal bleeding complaint 15 percent, and those who came up for master health check up was 8 percent. According to FIGO classification, in our study, none of the stage IA cases were found on MRI, Stage IB in our study is eleven cases involved. Stage II tumour extends beyond the cervix upto two third of vagina. In this stage out of 25 patients were presented with stage II FIGO classification. Eight of the 25 cases of stage II tumors were in IIA, and 17 were in IIB. Seven cases of stage III tumors have spread to the pelvic wall, affecting the lower third of the vagina, and result in hydronephrosis or non-functions kidney. Of the 13 cases reported in stage III of this study, 10 cases involve no expansion to the pelvic wall, and III A comprises the lower part of the vagina. There are three examples of III B extending to the pelvic wall and/or causing hydronephosis.

In this stage the tumour extends to the bladder or rectal masses is considered as stage IV according to FIGO classification. In IV stage, IV A involves the bladder and rectal invasion and IV B the spread of tumour to liver, spleen, pancreas, kidney

and GI track Thus IV A includes seven cases and IV B includes 1 case. After post radiotherapy and post chemotherapy for follow up scan, there were no recurrence found in six cases. In newly diagnosed cases, primary group lymph nodes (illiic, parametrial and obtrurator) were involved in 18 cases. In carcinoma cervix, lymph node spread occurs usually along the obturator, external iliac, common iliac and paraaortic node (Figures 3 and 4).

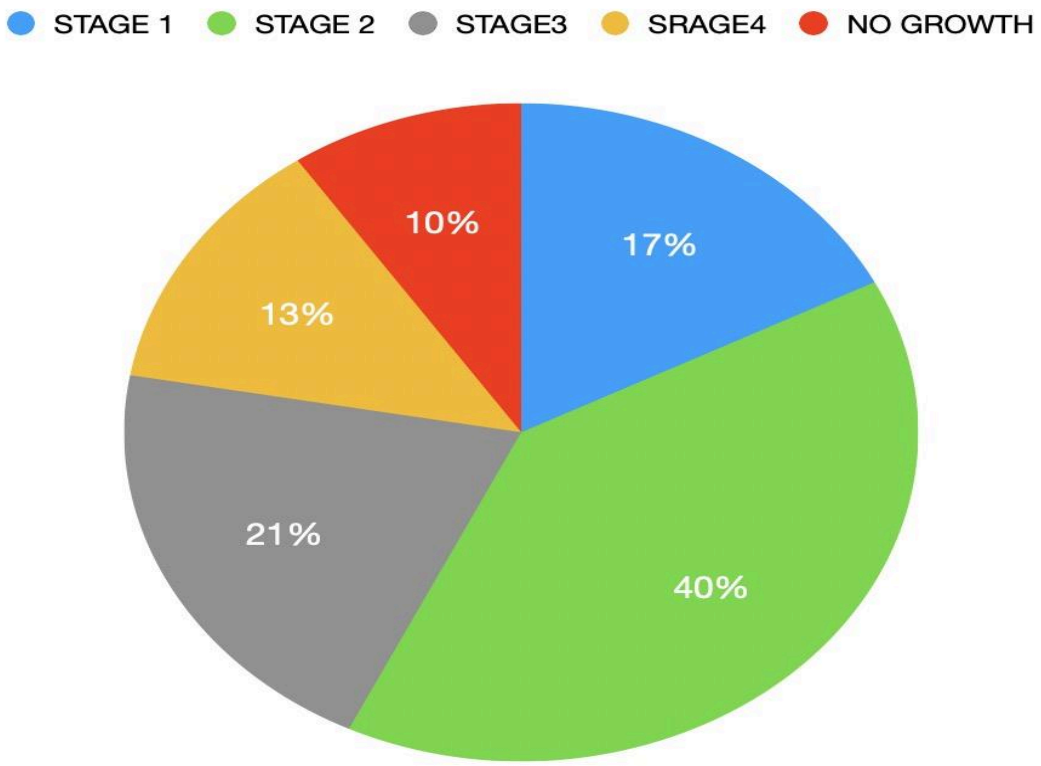


Figure 3. Total Number of Cases Categorized according to FIGO classification and data of no recurrence growth

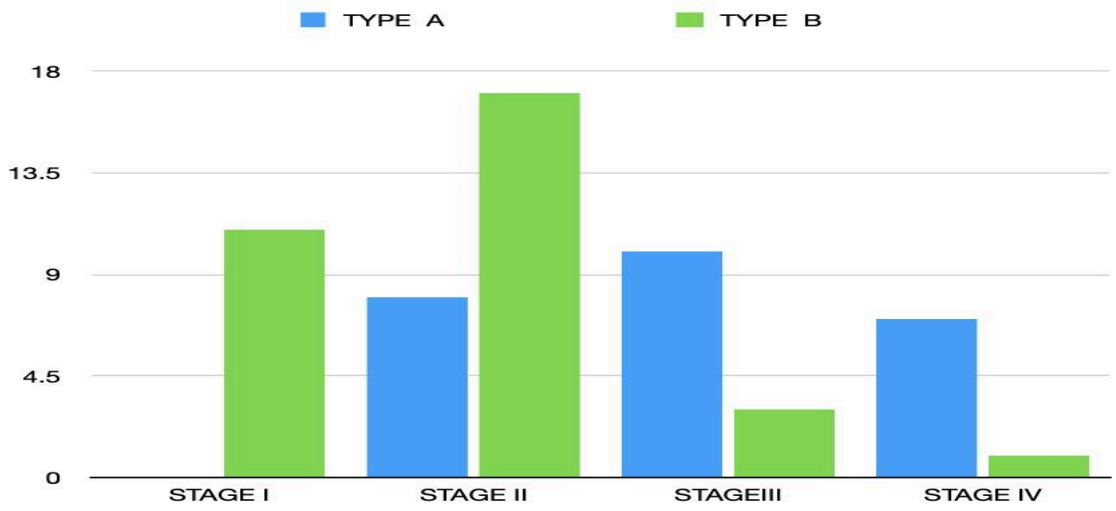


Figure 4. Total Number of Cases Categorized Subdivision of Figo Stages.

Discussion

Cervical cancer is the fourth most frequent gynecological cancer in women worldwide. In our research phase, patients are instructed to fast for four hours before the scan and to void an hour beforehand in order to acquire the best possible MRI image quality.

The preferred method for determining the size of the tumor, parametrial involvement, pelvic side wall expansion, and invasion of nearby organs is magnetic resonance imaging (MRI) with excellent soft tissue contrast. An expansile or infiltratic mass shows on the T2 weighted picture without fat suppression. The cervical stoma's signal intensity is contrasted with the mass's signal intensity. Another crucial prognostic factor in determining the phases is the tumor's size [7].

Because of its high soft tissue contrast, multi-planar imaging capacity, lack of radiation exposure, and accuracy in identifying tiny tumors and parametrial invasion, magnetic resonance imaging (MRI) is the diagnostic technique of choice for detecting cervical carcinoma. Because of its superior soft tissue resolution, MRI outperforms CT and PET/CT in terms of staging accuracy. Transvaginal ultrasonography is dependent on the operator and has depth penetration limitations [8]. Thus MRI is extremely useful in early diagnosis, staging of cervical cancer and evaluating post treatment stasis [9]. The appearance of carcinoma cervix in MRI, T1 weighted imaging tumour are usually isointense mass, T2weighted are usually hyper intense mass easily distinguishable from low signal intensity cervical stroma (Figures 5 to 8).

Figure 5. T2 weighted image shows intermediate signal intensity with right parametrial involvement

Figure 6 Sagittal T2W hyperintense mass in the cervix extending into upper third of vagina along the anterior and posterior walls

Figure:7. Axial T2W images show hypointense mass noted in the cervix

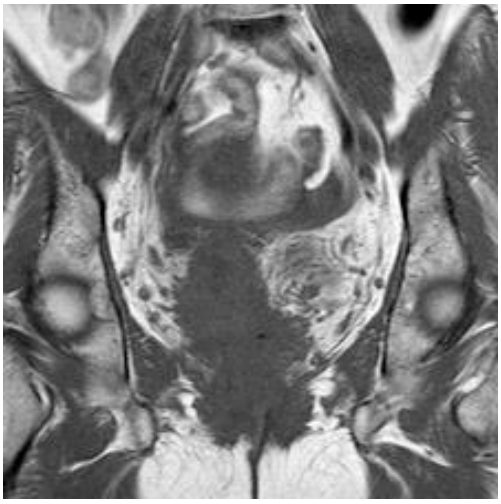


Figure 8. T1weighted images show hypointense mass noted in the cervix extending into the vagina

According to the updated FIGO classification, a stage 1 tumor is one that has been confirmed to be located on the cervix. A stage IA1 tumor has stromal invasion that is 3 mm or less deep and has a horizontal spread of 7 mm or less. A stage IA2 tumor has stromal invasion that is more than 3 mm but not more than 5 mm, with a horizontal spread of 7 mm or less. MRI cannot assess stage IA. Invasive cancer with a measured deepest invasion of >4 mm is included in stage IB.

In stage II, the tumor has spread outside the uterus, but not to the side walls of the pelvis or the bottom third of the vagina. There is no parametrial invasion in stage II A, and the tumor extends into the parametrium in stage IIB, disrupting the outer T2 hypointense cervical storm.

Stage III tumors induce hydronephrosis, or a malfunctioning kidney, and/or affect the pelvis, as well as the lower portion of the vagina. The lower third of the vagina is affected in stage IIIA, although the lateral pelvic wall is not extended. Stage IIIB occurs when the tumor is less than 3 mm from the pelvic wall, encases the iliac vessel, and penetrates the obturator internus, pyriformis, or elevator muscle.

Stage IVA is when the normally observed low signal intensity bladder wall is disrupted; bladder invasion is more common than rectal invasion; Stage IV involves invasion of bladder or rectal masses or distant metasis; and Stage IVB involves distant spread of tumors to the lungs, liver, peritoneum, paraaortic, and inguinal lymph nodes [12]. According to our research, a cancer recurrence occurs when the treated lesion recedes at least six months later and there are regrowth or distant metastases.

Conclusion

MRI is essential for optimal carcinoma cervix patient care due to its accuracy, details, ability to detect tumour spread, lymphadenopathy and distant metastasis. It guides in treatment planning and predicts patient outcome. Thus MRI is the gold standard imaging modality for carcinoma cervix staging, assessment and treatment planning.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Comparison of Accuracy in Central Venous Catheter Tip Placement in Right Sided Internal Jugular Vein Using Clinical and Endocavitory ECG Method in Elective Surgeries in a Tertiary Care Center

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Abstract

Introduction: Central venous catheter (CVC) insertion is a common and essential procedure in perioperative and critical care management. Accurate catheter tip placement is critical to avoid malposition and complications such as arrhythmia, vascular injury, and thrombosis. Conventionally, chest radiography has been used for confirmation, though it has limitations including time delay and radiation exposure. **Materials and Methods:** This prospective comparative study was conducted after obtaining Institutional Human Ethics Committee approval. A total of 90 patients undergoing elective cardiac surgery were randomized into two groups: Group A (fixed-depth insertion, n=45) and Group B (endocavitary ECG-guided insertion, n=45). Demographic details, type of procedure, number of attempts, threading difficulty, and complications were documented. **Results:** The baseline demographics, including age (59.5 ± 9.4 years in Group A vs. 60 ± 11.9 years in Group B, p=0.822), weight (66 ± 8.2 vs. 69.8 ± 16.9, p=0.207), and height (159 ± 5.1 vs. 161 ± 8.0, p=0.406), were comparable between groups. Most patients underwent CABG (84.4% vs. 91.1%). First-attempt success rates were similar (73.3% vs. 66.7%, p=0.49). Difficult threading occurred in 20% of Group A and 28.9% of Group B. **Conclusion:** Both fixed-depth and ECG-guided CVC insertions were safe and effective, with comparable complication rates. However, ECG guidance demonstrated a higher proportion of catheters positioned optimally at the SVC–RA junction, suggesting its value as a practical, real-time, and radiation-free method to improve accuracy and safety in CVC placement.

Keywords: central venous catheter, endocavitary ECG, tip position, chest radiography, cardiac surgery

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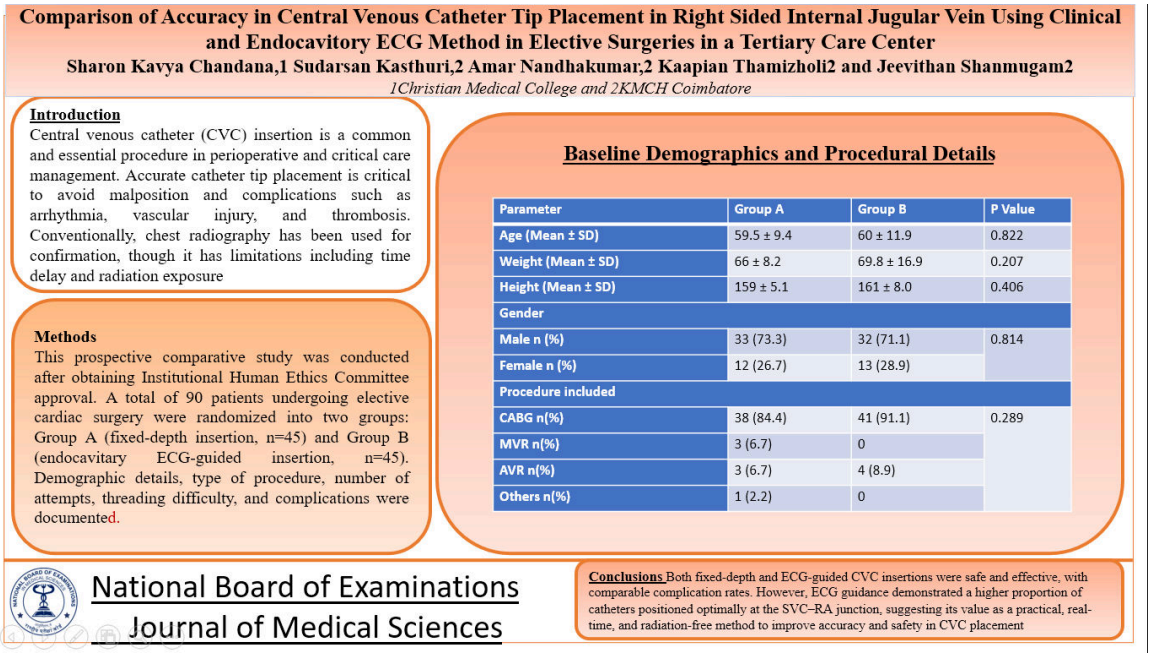
Graphical Abstract



Introduction

Central venous catheter (CVC) insertion is one of the most common invasive procedures performed, not only in operation theatres and intensive care units but also extended to bedside placements in chemotherapy and medical wards. Though central venous catheterization offers multifarious benefits, the procedure is associated with adverse events that may be hazardous to patients [1,2].

Meticulous care and adjuncts such as ultrasound and fluoroscopy substantially improve the success of central venous catheter placement. Nevertheless, a considerable number of catheter-related complications still occur in day-to-day practice [3–7].

The common adverse events associated with CVC insertion in the neck and thorax have been extensively reported in the literature and include infection, hematoma, and pneumothorax. Other recognized complications of CVC placement include hemothorax, chylothorax, extravasation of infusate, unrecognized arterial placement, cardiac tamponade, and mediastinal hemorrhage (8). A less commonly described but important complication is malpositioning of the catheter tip in a vessel other than the superior vena cava (SVC), reported in approximately 7% of thoracic CVC placements, and capable of leading to serious sequelae. Malposition enhances the risks of catheter wedging, erosion or perforation of vessel walls, local venous thrombosis, and catheter dysfunction [1,10,11].

Over-insertion of the catheter tip can result in life-threatening cardiac tamponade or precipitate arrhythmias, whereas inadequate depth of insertion may lead to thrombus formation and increased rates of infection. More than

100 cases of cardiac perforation due to a malpositioned CVC tip have been reported in the literature, highlighting the critical importance of accurate tip positioning [11–13].

Despite advancements in imaging techniques and procedural protocols, malposition and related complications of central venous catheter placement remain clinically significant and under-reported in routine practice. Accurate positioning of the catheter tip is crucial for patient safety, effective therapy, and reduction of morbidity and mortality associated with CVC use. This study was therefore undertaken to assess the demographic and procedural factors, technical difficulties, complications, and radiological outcomes associated with CVC insertion, with the objective of identifying predictors of safe and successful placement and minimizing malposition-related risks.

Materials and Methods

This was a prospective cross sectional comparative study conducted at a tertiary care centre. The study was carried out between August 2018 and November 2018. Ninety patients requiring central venous catheter placement for elective surgeries were included. They were randomly allocated into two equal groups of 45 each (Group A and Group B) using computer-generated block randomization sequences. All patients requiring central venous catheter placement for elective surgical procedures were eligible. Patients with arrhythmias, pacemaker rhythms, deranged coagulation profiles, local infection at the insertion site, anatomical chest or neck deformities, or those aged below 18 years were excluded.

Prior to enrolment, a patient information sheet describing the study protocol, benefits, and possible risks was provided, and written informed consent was obtained. Ethical clearance was secured from the Institutional Human Ethics Committee (IHEC) before initiating the study.

In Group A, the depth of catheter insertion was determined by the anesthetist's judgment following institutional guidelines. For right internal jugular vein cannulations, the catheter fixation depth was typically 12–13 cm for males and 11–12 cm for females, a depth validated in Indian populations to minimize malpositions, particularly inadvertent intra-atrial placements [14,15].

In Group B, catheter depth was guided using endocavitary electrocardiography (ECG). This technique utilized a specialized adaptor (e.g., Braun) connected between the guidewire and ECG monitor, allowing the operator to switch between surface and intracavitary ECG. Lead II was mainly used for visualization of P-wave changes. The method relied on distinct ECG patterns as the catheter advanced:

- A normal upright P-wave indicated placement in the upper SVC.

- A P-wave of half the surface amplitude indicated position in the lower SVC.
- A maximal upright P-wave suggested the catheter tip at the cavo-atrial junction.
- Biphasic or negative P-wave deflections signified advancement into the right atrium [16,17].

Thus, intracavitary ECG provided a real-time physiological marker of tip position, improving precision over conventional depth-based methods.

Outcome assessment was performed using postoperative chest radiographs in the intensive care unit or post-anesthesia care unit. These X-rays confirmed the catheter tip position and identified any misplacements. In addition, complications such as carotid puncture or hematoma were documented.

Sample size calculation was based on retrospective data from 438 eligible cases over a six-month period. With a 95% confidence interval, 5% margin of error, and response distribution of 5%, the sample size was estimated as 90. Block randomization with a block size of six ensured balanced distribution between the study arms.

Statistical analysis: Data were coded and entered in Microsoft Excel, and statistical analysis was performed using SPSS software (version 27). Continuous variables such as age, height, and weight were expressed as mean ± standard deviation (SD) and compared between groups using the Student's t-test. Categorical variables such as gender, number of attempts, complications, and radiographic outcomes were expressed as percentages and compared using the Chi-square test or Fisher's exact test where appropriate. A p-value <0.05 was considered statistically significant.

Results

The mean age of patients was 59.5 ± 9.4 years in Group A and 60 ± 11.9 years in Group B ($p = 0.822$), while the mean weight was 66 ± 8.2 kg in Group A and 69.8 ± 16.9 kg in Group B ($p = 0.207$). The mean height was also comparable between the two groups (159 ± 5.1 cm vs. 161 ± 8.0 cm, $p = 0.406$). Male patients predominated in both groups, with 73.3% in Group A and 71.1% in Group B, while females constituted 26.7% and 28.9% respectively ($p = 0.814$). In terms of procedures, CABG was the most common, performed in 84.4% of patients in Group A and 91.1% in Group B, while other procedures such as MVR (6.7% vs. 0%), AVR (6.7% vs. 8.9%), and miscellaneous surgeries (2.2% vs. 0%) formed the minority. No significant differences were observed between the groups in baseline or procedural characteristics, indicating comparability of study populations (Table 1).

Table 1. Baseline Demographics and Procedural Details

Parameter	**Group A**	**Group B**	**P Value**
Age (Mean ± SD)	59.5 ± 9.4	60 ± 11.9	0.822
Weight (Mean ± SD)	66 ± 8.2	69.8 ± 16.9	0.207
Height (Mean ± SD)	159 ± 5.1	161 ± 8.0	0.406
Gender			
Male n (%)	33 (73.3)	32 (71.1)	0.814
Female n (%)	12 (26.7)	13 (28.9)	
Procedure included			
CABG n(%)	38 (84.4)	41 (91.1)	0.289
MVR n(%)	3 (6.7)	0	
AVR n(%)	3 (6.7)	4 (8.9)	
Others n(%)	1 (2.2)	0	

The first-attempt catheterization was successful in 73.3% of Group A and 66.7% of Group B, while 26.7% and 33.3% respectively required a second attempt (p = 0.49). Difficulty in threading was reported in 20% of cases in Group A and 28.9% in Group B (p = 0.327). Complications were infrequent overall, with carotid puncture seen in one case (2.2%) in Group A and none in Group B, while hematoma occurred in 6.7% of Group A and 4.4% of Group B (p = 0.438). Importantly, pneumothorax did not occur in either group. These findings highlight that the technical aspects of cannulation and complications were comparable across both groups, with low complication rates overall (Table 2).

Table 2. Technical Aspects and Complications

Parameter	Sub Classification	Group A N (%)	Group B N (%)	P Value
Attempts	First	33 (73.3)	30 (66.7)	0.49
	Second	12 (26.7)	15 (33.3)	
Difficulty threading	No	36 (80.0)	32 (71.1)	0.327
	Yes	9 (20.0)	13 (28.9)	
Complications Encountered	Carotid Puncture	1(2.22)	0	0.438
	Hematoma	3(6.66)	2(4.44)	

Radiological evaluation of catheter tip placement showed that in Group A, 31.1% were 2.1–3.5 cm below the carina, 40% were 0.1–2.0 cm below, 22.2% were at the carina, and 6.7% were above the carina; while in Group B, 40.9% were 2.1–3.5 cm below, 43.2% were 0.1–2.0 cm below, 15.9% were at the carina, and none were above ($p = 0.31$). Regarding the final location of catheter tips on chest X-rays, 11.1% in Group A and 8.8% in Group B were in the upper SVC, 73% and 84% respectively were at the SVC-RA junction, and 15% versus 6.6% extended into the right atrium ($p = 0.19$). These results show that although not statistically significant, ECG guidance resulted in a higher proportion of tips at the optimal SVC-RA junction and fewer malpositions into the right atrium compared to the clinical method (Table 3).

Table 3: Radiological Outcomes

Parameter	Sub Classification	Group A N (%)	Group B N (%)	P Value
Distance of tip from Carina	2.1–3.5 cm below carina	14 (31.1)	18 (40.9)	0.31
	0.1–2.0 cm below carina	18 (40.0)	19 (43.2)	
	At the level of carina	10 (22.2)	7 (15.9)	
	0.1–2.0 cm above carina	3 (6.7)	0 (0.0)	
Location of catheter tip in both groups on chest x-rays	Upper SVC tip	5 (11.1)	4 (8.8)	0.19
	SVC-RA junction tip	33 (73)	38 (84)	
	RA Tip	7 (15)	3 (6.6)	

Discussion

Central venous catheter (CVC) insertion is a ubiquitous invasive procedure, often lifesaving in diverse clinical scenarios. Despite its wide use, the procedure is still associated with potentially serious complications, some of which may be life-threatening. Real-time ultrasound guidance has revolutionized central venous access, making the technique safer than traditional landmark-based approaches, as demonstrated in numerous studies [14,18]. The addition of fluoroscopy has further increased success rates in selected settings. Nevertheless, complications remain inevitable even in expert hands, highlighting the need for adjunctive strategies to improve safety.

There is no clear consensus on the ideal CVC tip position; however, it is generally agreed that the optimal site is at the cavo-atrial junction (CAJ), the region between the superior vena cava (SVC) and right atrium [15]. Traditionally, chest radiography has been the most widely employed method to confirm CVC tip placement and rule out malposition or complications such as pneumothorax [19]. However, post-procedural chest X-ray is not a real-time modality and often diagnoses malposition after catheter insertion is complete, thereby failing to prevent adverse events. Moreover, chest X-rays are subject to drawbacks, including time delay, radiation exposure, variable image quality, and difficulties in interpretation due to patient positioning, rotation, or poor exposure.

In routine practice, clinicians often adopt empirical methods to determine insertion depth, such as using fixed formulae, approximations based on patient height, or institutional standards of 13 cm in males and 12 cm in females [20,21]. Although convenient, these methods are prone to inaccuracies, as factors such as patient height, puncture site variation, and neck thickness significantly affect precision. This underlines the need for a real-time, reliable method for confirming catheter tip position.

Among bedside techniques, endocavitary ECG has emerged as a promising approach. This technique enables real-time visualization of P-wave morphology to indicate proximity to the right atrium, thereby allowing adjustment of insertion depth before fixation [16]. Studies have demonstrated its effectiveness in minimizing malposition, reducing complications, and improving procedural success rates [22,23].

In the present study, demographic characteristics such as age, height, and weight were comparable between the two groups, with no statistically significant differences ($p>0.05$). The mean age was 59.5 ± 9.4 years in Group A and 60 ± 11.9 years in Group B, while mean heights were 159.1 ± 5.1 cm and 161 ± 8.0 cm, respectively. This comparability in baseline characteristics ensured that group differences in outcomes were unlikely to be attributable to demographic confounders. Similarly, the gender

distribution and type of surgical procedures (predominantly CABG in both groups) were balanced, indicating that the groups were homogeneous at baseline.

Technical aspects, such as the number of attempts and difficulty in threading, showed no significant differences between groups. Complications were minimal, with only a few cases of carotid puncture and hematoma, again with no statistically significant differences. Importantly, radiological confirmation of catheter tip location demonstrated that Group B (endocavitary ECG-guided placement) achieved a higher proportion of tips positioned at the SVC–RA junction compared to Group A, which relied on fixed-depth institutional protocols. Although not statistically significant in this study, this trend reflects findings from previous reports that have highlighted the superior accuracy of ECG-guided placement in achieving optimal catheter positioning [17].

Conclusion

The present study demonstrated that demographic and procedural characteristics were comparable between the groups, ensuring homogeneity. Technical difficulties and complications were minimal and not significantly different between the groups. Importantly, radiological evaluation indicated that the use of endocavitary ECG guidance resulted in a higher proportion of catheter tips positioned at the superior vena cava–right atrial junction, which is considered the optimal site, compared to the conventional fixed-depth method.

Although the differences did not reach statistical significance, the findings align with existing evidence that ECG guidance offers a real-time, cost-effective, and reliable method for accurate tip localization. This approach may reduce malposition-related complications and the need for repositioning. Thus, integrating endocavitary ECG into routine practice has the potential to improve safety and efficacy in central venous catheter placement, particularly in resource-limited settings where fluoroscopy is not feasible.

Statements and Declarations

Conflicts of interest

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

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SYSTEMATIC REVIEW

Impact Analysis of Diagnostic Errors on Healthcare Delivery: A Systematic Review

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Abstract

Background: There is need to collate the evidences on the prevalence of diagnostic errors and their influence on hazardous outcomes to affect efficiency, cost and safety in healthcare delivery. **Objectives**: This review addressed diagnostic errors in terms of epidemiology, hazards, impacts, challenges to suggest holistic recommendations to all the stakeholders, researchers and administrators. **Methods**: Electronic public domains viz. PubMed, SCOPUS, GoogleScholar, ResearchGate. and manual search on diagnostic errors and interventions implemented by clinician in clinical environment, searched for literatures published between January 2005 and June 2025 for common errors concerning the diagnosis in the practice directed towards the patient, direct and indirect repercussions on health and financial and operational aspects of healthcare, challenges, research and interventions to improve patient safety by checklists using PRISMA reporting guidelines. **Results**: A total of 291 articles were screened of which 28 studies met inclusion criteria of our review. Data extraction was done by two groups, each group comprising two independent investigators from Review (n=20), Cohort study (n=2), Cross-sectional, (n=3), Controlled intervention (n=2), Invited Commentary (n=1). WHO check list, digitalization and AI are showing potential solution for error reduction amid ethical, legal, quality assurance issues. **Conclusions**: Our analyses revealed evidence on prevalence, risk correlates and interventions to limit DEs being feasible in clinical settings across High Income Countries (HICs) and Low and Middle Income Countries (LMICs). A comprehensive approach is needed to ensure safety by quality of care at every patient interface, capacity building and systems approach to enhance accuracy and ensure updating.

Keywords: Diagnostic error, impact, healthcare, patient safety, remedial measures

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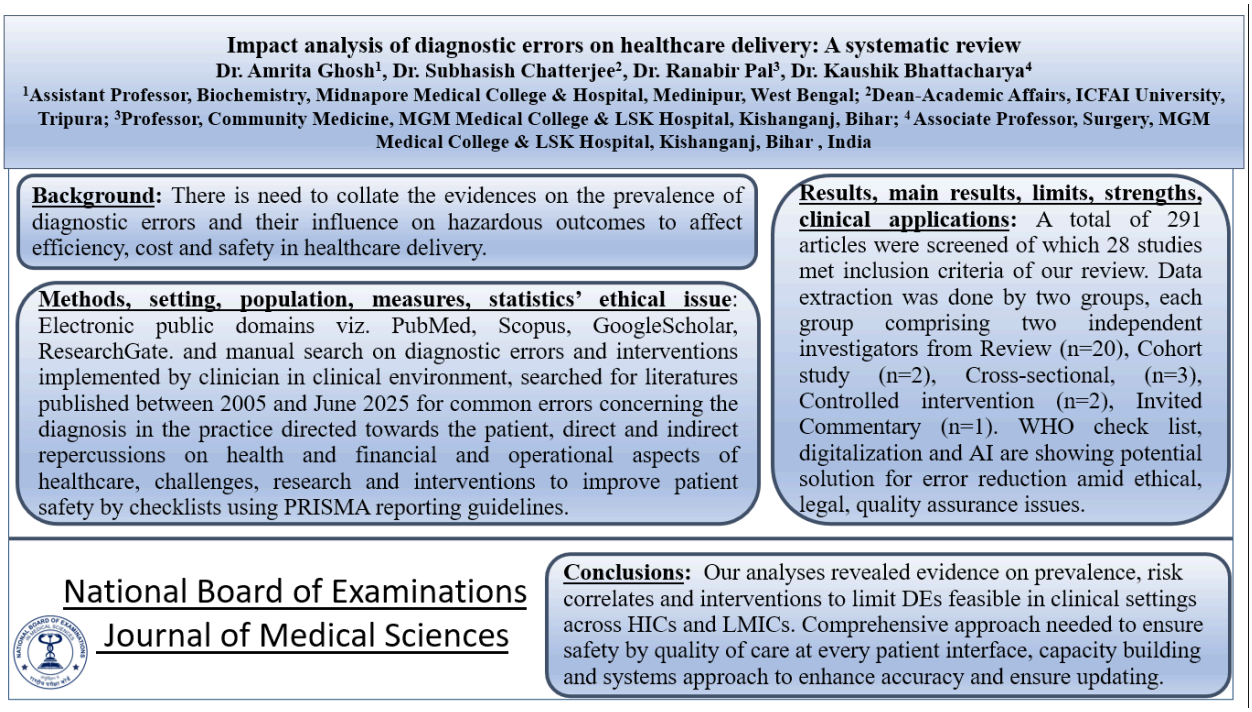
Graphical Abstract



Introduction

WHO promulgated "First, do no harm" is the key principle of health care. Across geographical or temporal boundaries in evolving junctures of paramount importance on diagnostic errors (DEs), precise and timely diagnosis is ever more vital milestones supported with prompt interventions to limit hazards amid optimum prognostication [1]. National Academy of Medicine defined DEs as "the failure to (a) establish precise and timely explanation of patient's health issues or (b) share an explanation with the patient" [2]. Healthcare workers (HCW) accept DEs as preventable hazards that endanger patients and ruin invaluable resources at every set up and level of health system to reflect unsafe issue and optimally address at right time and right place [3]. Deficient competencies, technical skills, and cognitive illusions encourage DEs which lead to wrong procedures, longer treatment time or cause lasting injuries. These un-or under-diagnosed pathophysiology add suffering to the care-seekers with delays in treatment initiation, under- or overtreatment, or worsening morbidity and disability with or without mortality [4]. The negative consequences of DEs have placed attention on research on its causes and outcomes. Failures in diagnostic processes adversely affect the safety of patients; also leads to wastage of resources due to increased rates of re-admission, excess length of stay and increased expenses in health care. Such trends of work focus on the relevant education of healthcare professionals as a measure of control, adoption of various more effective diagnostic techniques, and the need of digitalization [5]. DEs are failure to do & communicate precise and apt clarification of

health matter to the care seekers [6]. The rationale for this review lies in the context to sensitize on upgrading knowledge solving issues as pivotal to mitigate hazards and enhance safety in health care dimensions limiting diagnostic errors in medicine viz. Epidemiology, Hazards, Impact, Interventions, Researcher and Challenges to suggest best current measures.

Methods

Eligibility Criteria

Inclusion Criteria: Studies published in English peer reviewed journals related to DEs (i.e. error type: undiagnosed, wrong diagnosis, late diagnosis), Studies investigating the effects of DEs on healthcare outcome (e.g. mortality, morbidity, hospitalization rates, duration of stay), focus on economic/resource impact (e.g. additional costs, excess tests, waiting time for treatment); qualitative and quantitative research: (cohort, case-control, cross-sectional and interventional studies) and reviews. Exclusion Criteria: Literatures on other issues excluding errors, not in English language, conference and grey literatures.

Information Sources

This review put effort to find information from offline and online databases. Bibliographic search and consultation were initiated since 2005 from dependable sources from public domain viz. PubMed, SCOPUS, GoogleScholar, ResearchGate and others viz. databases, registers, websites, media, and news portals. Reference lists from potentially eligible studies that contained relevant information were explored.

Search Strategy

MeSH search terms and Boolean operators were used: “Diagnosis” [all fields]). Search strategy was constructed using Medical Subject Heading terms combined with Boolean operators: (“Diagnosis” [all fields] OR “Errors” [all fields] AND (“Hazards” [all fields]) OR “Outcomes” OR “Adverse events” OR “Impacts” OR “Complications) AND “Checklists.” 291 articles were screened of which 28 studies met inclusion criteria of this systematic review.

Selection Process

Following a methodical search through databases, 178 literatures were identified and 113 from articles in the list of references. After duplication check 146 records were removed; 145 were considered potentially eligible based on the title or abstract, both title and abstract. After full-text review, 28 studies were eligible as 117 full texts were unavailable; summary table included 21 literatures; 7 enriched manuscript (Figure 1, Table 1).

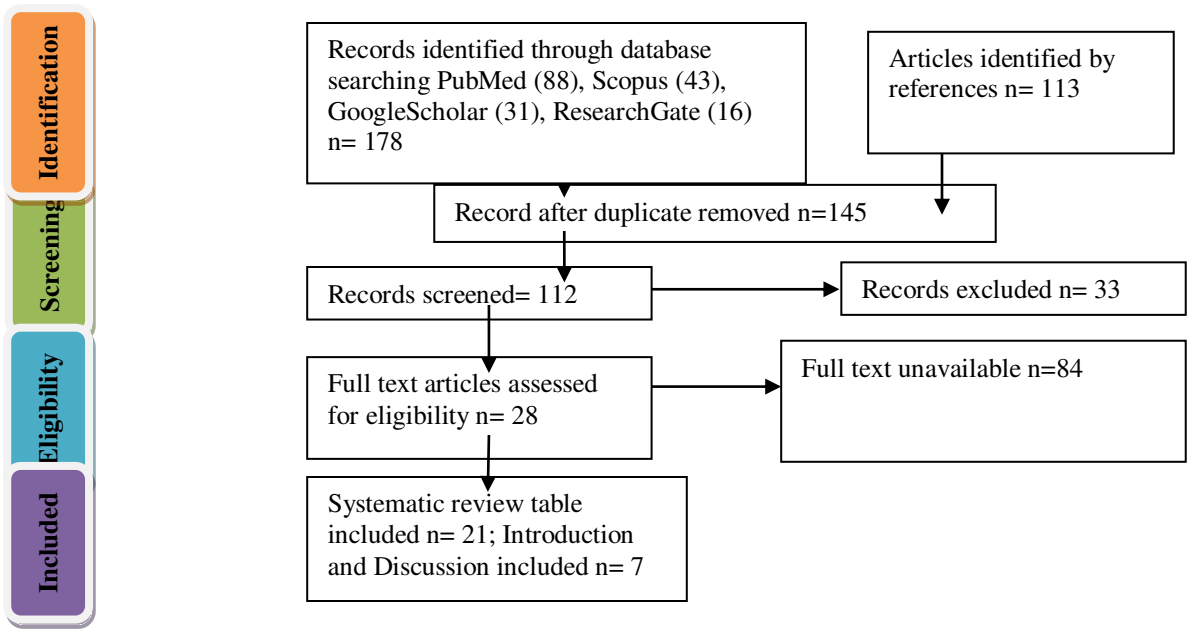


Figure 1. Impact of diagnostic errors on the healthcare delivery: A systematic review- Preferred reporting items for systematic reviews and meta-analyses (PRISMA) diagram

Table 1. Literature included in 'Impact analysis of diagnostic errors on healthcare delivery: A systematic review' (n =21)

Authors and Type of study	**Salient findings in the study**
Betsy Lehman Center for Patient Safety Annual Report (2024) [6].	Factors of DEs: System-level factors, Cognitive bias, Incomplete/inaccurate patient information, Limited time with patient, Patient factor
Auerbach AD et al (2024) Multicenter retrospective cohort study by EHRs (2023-2024) [7].	High rates of DEs among critically ill adult ICU transfer & in-hospital deaths; imply targetted interventions within hospital settings transferred to ICU or who died with harmful & underlying causes to design future intervention
White Paper on human & financial loss of DEs (2016) [8].	Abridge data of 2.5 lacs indoor US cases; all with lifetime incident; loss of million labor days, demise upto 80,000 and U.S. $750 billion each year.
Invited Commentary on DEs in primary care (2013) [9].	Focus on measurement & classification with individualized intervention of causative factors of DEs viz. issues of cognition, communication, resources, priority in preventing DEs in primary care settings.
Graber et al. Review on intervention to reduce DEs (2012) [10].	Cognitive interventions to reduce diagnostic error: a narrative review.

Singh H et al DEs in primary care levels (2013) [11].	Frequency DEs in clinical conditions process breakdowns, contributory factors, and harm; compared patient and practitioner variables in primary care visits with and without errors; patient characteristics as proportions.
WHO Patient safety. Key facts. 2023 [12].	Document discussed on DEs on salient facts, common sources and factors, System approach to patient safety, "Global action on patient safety", "Global Patient Safety Action Plan 2021–2030", "World Patient Safety Day", WHO Flagship initiative "A Decade of Patient Safety 2021–2030"
Cheraghi-Sohi et al Cohort study 2021 [13].	DEs were <5% among primary care consultations, extrapolated nationally is millions potentially at risk of avoidable harm by multifactorial risk yearly; need to develop & evaluate multipronged intervention with policy changes.
Singh et al. Review 2014 [14].	Impact of DEs on Primary and domiciliary care in USAs was reviewed by yielded a rate of 5.08%, or 12 million US adults every year or 1 in 20
Ely JW, et al. Review Expert consensus 2011 [15].	Implementation of checklists and decision support systems significantly reduced diagnostic errors in clinical settings.
Abimanyi-Ochom et al Review 2019 [16].	26 studies were classified as communication or audit strategies to reduce DEs in clinical settings; technology-based systems (62%) and in acute care setting (57%); limited evidence on interventions being practical.
Berner et al Analytic review 2008 [17].	Study covers scale and impact of DEs correlated to doctor's overconfidence, approach to improve diagnostic precision and scope of futuristic research.
Slawomirski et al 2025 OECD Health Working Papers No. 176 [18].	DEs in chronic cases use 5% of total health exchequer in member countries; 17.5% direct pooled fiscal burden of mis-, under- and over-diagnosis
Newman-Toker et al 2013 [19].	Challenges in DEs are A. Omission: depriving EBM, B. Commission: Quaternary prevention of a. Overuse of b. Misuse of diagnostic tests
NHSRC Diagnostic Safety Review [20]	Study finds DEs in five strata viz. settings and level of care with optimum knowledge; measure diagnostic safety; assess source of hazard; system approach instead of point of care health; updating. Right test and processing of samples are vital mitigation measures to combat DEs from lab medicine.
Graber ML et al Cross-sectional (2005) [21]	DEs are commonly multi-factorial involving system-related and cognitive factors. There is need to develop comprehensive taxonomy to classify DEs.

National Academies of Sciences Engineering & Medicine Literature review: Expert Panel 2015 [22]	'Improving Diagnosis in Health Care': Lesser than 10 years diagnosing treatment frameworks versus period 2010-2015 variables. The article argued that diagnostic training and system improvement could reduce errors.
Materiovigilance Programme of India (MvPI) (2025) [23]	Medical Device Adverse Events database under the National Materiovigilance Programme (MvPI) ADR Monitoring System (ADRMS) report adverse events from medicine, vaccine & medical device.
Choudhury et al. Review (2025) [24]	DEs in India are missed, incorrect, or delayed diagnoses; impact outcome, well-being, quality of life; regarded as No-fault, System, Cognitive errors.
Mishra M et al Review (2017) [25]	Indian research group suggested training of medical students to evade cognitive and system factors that trigger DEs imperceptible to HCWs.
Sharma A. Interview with expert (2020) [26]	DEs can be averted by right technology like boost mobile devices, grow communications, nurture personalized healthcare

Data Collection Process

Each publication was scrupulously and thoroughly scrutinized following our strategy by at least two investigators of our interprofessional research group on the full text screening to guarantee preset inclusion and exclusion criteria with weightage on quality than mere quantity of information to minimize ambiguity.

Data Items

This review has primary thematic search problem as 'How much spells of hazards does the healthcare system imbibe from diagnostic errors in medicine?'

Effect Measures

All the reviewers studied and assessed literatures independently and later on worked together for each outcome variable in data abstraction and analysis viz. What are most often the types of error in the diagnosis directed towards the patient? What are the repercussions of these errors on the health of the patient? What economic impacts do misdiagnoses on the financial and operational aspects of healthcare? How are we tackling to lessen the incident misdiagnoses? What are the unsolved issues and innovative ideas to curtail diagnostic errors?

Synthesis Methods

Data extraction and synthesis was done from the publications that satisfied the recommended eligibility criteria on diagnostic error: year, title, author/s, clinical instrument/s, variable/s, duration, findings. Systematic search for information viz. literature supports, and full-text reviews was conducted using the strategy to search by agreements, relying bibliographic reliable citations, namely - 14 from Journals publications, 7 from web sources.

Reporting Bias Assessment

Risk of bias was assessed using National Heart, Lung, and Blood Institute Study Quality Assessment Tools (NHLBI) (https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools) viz. Quality Assessment Tool for Observational Cohort and Cross-sectional, Controlled Intervention Studies and Reviews. Data were sourced from truthful sources of good publishing group and webpages transparent in publication ethics; Good: 6, 7, 8, 9, 10, 12, 14, 15, 17, 18, 19, 20, 21, 22, 26; Fair: 11, 13, 16, 23, 24, 25 (Table 1 and Table 2).

Table 2. Results of quality assessment tool of Cohort, RCT and Review studies included in 'Literature included in 'Impact analysis of diagnostic errors on healthcare delivery: A systematic review' (n =21)

Authors and study type	**Q 1**	**Q 2**	**Q 3**	**Q 4**	**Q 5**	**Q 6**	**Q 7**	**Q 8**	**Q9**	**Q 10**	**Q 11**	**Q 12**	**Q 13**	**Q1 4**
€ Cohort														
Auerbach AD et al (2024).[7]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No
Cheraghi-Sohi et al 2021 [13]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes
€ Cross-sectional														
Singh H et al (2013) [11]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Singh et al Review 2014 [14]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Graber ML et al [2005] [21]	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No
₹ Controlled intervention	**Q 1**	**Q 2**	**Q 3**	**Q 4**	**Q 5**	**Q 6**	**Q 7**	**Q 8**	**Q9**	**Q 10**	**Q 11**	**Q 12**	**Q 13**	**Q1 4**
Graber et al. Intervention to reduce DEs (2012) [10]	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Ely JW, et al. Review Expert consensus 2011 [15]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
¾ Review	**Q 1**	**Q 2**	**Q 3**	**Q 4**	**Q 5**	**Q 6**	**Q 7**	**Q 8**						

Betsy Lehman Center for Patient Safety Annual Report (2024) [6]	Yes	NA	NA	NA	NA	NA	NA	NA						
White paper (2016) [8]	Yes	Yes	No	No	Yes	Yes	Yes	Yes						
Newman-Toker DE Invited commentary (2015) [9]	Yes	Yes	No	No	No	Yes	No	NA						
WHO Patient safety. Key facts. 2023 [12]	Yes	NA	NA	NA	NA	NA	NA	NA						
Abimanyi-Ochom J et al Review 2019 [16]	Yes	Yes	No	No	Yes	Yes	Yes	Yes						
Berner et al Analytic review 2008 [17]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
Slawomirski et al 2025 Working Papers [18]	Yes	Yes	No	No	Yes	Yes	Yes	Yes						
Newman-Toker et al 2013 [19]	Yes	Yes	No	No	Yes	Yes	Yes	Yes						
NHSRC Diagnostic Safety Review [20]	Yes	NA	Yes	NA	NA	Yes	NA	NA						
National Academies of Sciences	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes						

Engineering & Medicine Literature review: Expert Panel 2015 [22]														
Materiovigilance Programme of India (MvPI). [2025] [23]	Yes	NA	No	NA	NA	Yes	NA	NA						
Choudhury R et al. Review [2025] [24]	Yes	No	Yes	No	Yes	Yes	No	Yes						
Mishra M et al Review [2017] [25]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes						
Sharma A. Review based on Interview [2020] [26]	Yes	NA	NA	NA	NA	NA	NA	NA						

Main Outcomes and Measures

Epidemiology, Hazards of outcomes, Economic Impact, Interventions and Challenges of diagnostic errors in medicine.

Certainty of Evidence

To establish the highest quality of review, we limited search from high quality peer reviewed indexed journals from legendary publishing houses who bring out literature after being certain of the quality of evidence available in the public domain freely; we are content on conventional trustworthy data sources viz. PubMed, SCOPUS, GoogleScholar, ResearchGate. Most of the documents within this review focus on DEs: their types, causes and consequences on the patients, effects on the economy of healthcare system and policy in general.

Ethical Considerations

Because this is a systematic review of previously published literature, no ethical approval was sought.

Databases Searched

Databases including PubMed, SCOPUS, GoogleScholar, ResearchGate were searched also manually looking through the reference list of the articles.

Search Strategy

The systematic review was conducted in compliance with the PRISMA guidelines. Additional resources viz. reference list of studies included in our review, which aimed at seeking additional papers, as well as databases, were also searched for. In addition, the following gestalt has been formulated so as to provide a method for searching literature using Medical Subject Heading terms incorporated with Boolean features: "Diagnostic" [all fields]).

Data Extraction

The research was organized based on common information gathering forms prepared for each included work, namely: Year, Title, Research group, Study Instruments, Variables, Time Period, and Salient Observations. Our interprofessional research group attempted to classify diagnostic errors in five broad headings viz. Epidemiology, Hazards of outcomes, Economic Impact, Interventions and Challenges of diagnostic errors in medicine.

Results

Data abstraction and analysis

Our interprofessional research team classified DEs on magnitude, underlying causes and associated harms to suggest holistic remedies in five broad headings viz. Epidemiology, Hazards of outcomes, Economic Impact, Interventions and Challenges of diagnostic errors in medicine.

Study Characteristics

Our study analyzed DEs in medicine from Review (n=20), Cohort study (n=2), Cross-sectional, (n=3), Controlled intervention (n=2), Commentary (n=1).

Results of Individual Studies

Our study outlined extent, character and consequences of hazards of DEs in medicine in time, place and person distribution, interventions, research and developments on protocols, checklist, digitalization, ethical issues and challenges.

Results of Syntheses

Diagnosis is not a one-point decision. Rather it evolutes over days and weeks in a process of initiation and continuation of ideas over development of symptoms and signs. Based on initial assessment by clinical acumen, the treating healthcare team providers kick-off 'Provisional diagnoses' and initial interventions. These are corroborated by supporting highly structured battery of laboratory medicine and imaging studies when 'Final diagnosis' is reached amid prognostication. Further, in the capricious pathogenesis vis-a-vis salutogenesis trail of events, 'Syndromic', 'Etiological', 'Differential', 'Working' diagnosis mar the vignette with origin of DEs in 'Primary' to 'Quinary' levels till individuals return to normal health.

DEs originates from System (communication barriers, flawed investigation, manpower), Perception (mindset and decision block), Imperfect data transfer (partial data sharing), Overload (unable to obtain history, clinical profile and review records), Patient (failure to share chronological symptoms to beget apt care) [6]. A 'Electronic Health Records Analysis'

used random sample of adults from 29 facilities admitted in medical wards in United States assessed volume, aetiology, and hazards of DEs among transferee to intensive care unit (ICU) or expired; classified harms and correlated those with risk factors by 'adjusted proportion attributable fraction [7]. United States (US) White paper analyzed 2.5 Lacs indoor cases; all experiences DE once in lifetime; yearly loss of million labour days, deaths of 80,000 and economic cost U.S. $750 billion [8].

Study stressed criticality to quantify and classify DEs in primary health to improve precision and safety by mitigation plan to manage mis- and delayed diagnosis; spot and roadmap rate and nature; explore and target intervention of core and non-core risks emanating from cognitive bias, communication barriers, and resource-poor set-ups; prioritize the critical issues of DEs culminate to reduce errors and improve safety in healthcare [9]. Graber et al noted 16% of preventable harm globally from delayed, incorrect or missed DEs at every set-ups of healthcare from both HCWs and patients from array of risks specially in Low and Middle Income Countries (LMICs) viz. access, competency, fragmented care, communication, patient issue, technology, cognitive bias, system and process like follow-up [10].

In the primary care DEs take toll of millions from public health problems viz. Infective: acute respiratory infections and acute diarrhea (usually viral infections, treated with superfluous antimicrobials), Malaria, Tuberculosis (TB); Cardiovascular disease: Myocardial Infarction (MI), Stroke; Cancer; Preventable Child health issues. DEs crop up from affordability, health literacy, access to quality care due to crunch and misdistribution of resources; solutions include competent HCWs, team approach, lab back-up infrastructure; lack communication, health informatics, follow-up, culture and cognition of updating; patient characteristics and practitioner variables with and without error compared [11]. In 'Patient safety' document WHO discussed DEs on facts, sources and factors. Globally patient-doctor encounter harm are commonest sources of DEs (20%), adult admissions (0.7%); once in lifetime; health hazards of 3 million yearly, LMICs even higher (25%); cut global economic growth by 0.7%; cost US dollars of trillions [12]. UK retrospective data mining study re-defined DEs as "missed diagnostic opportunities"; 4.3% from history taking, examination or ordering tests (68%), analyzing tests (35%), follow-up (48%); 37% were moderate to severe [13].

Impact of DEs on Primary and domiciliary care in United States was reviewed by Singh et al.; noted outpatient DEs of 5.08%, or approximately 12 million US adults every year. This population-based estimate noted that half of DEs as potentially harmful and affected 1 in 20 US adults; suggested all the stakeholder viz. policymakers, healthcare organisations and researchers to find prevalence and interventions to improve patient safety [14]. DEs are linked to cognitive bias and mental shortcuts (faulty thinking) are common in high-risk and high-reliability healthcare; mitigation to be done by supplementing clinical acumen with checklists especially in Operation Theatres (OTs) and ICUs.

Checklists analyzed a. general checklist (to optimize cognition), b. differential diagnosis checklist (to avoid failure to find correct diagnosis), c. checklist of common pitfall and cognitive forcing function (evaluate selected issue). Checklists need rigorous appraisal to support intuition and memory in critical thinking n problem solving uncertainty in real time [15].

Abimanyi-Ochom et al favoured communication and audit reduce DEs by intervention viz. technology-based (62%) and in acute care setting (57%); computer-based and alert system-based algorithms reduce delay and imprecision; review team approach in trauma care and radiology limit DEs [16]. Bulk of correct final diagnosis stem from normal cognition except when cerebral process fail, usually unappreciated from intrinsic and systemic reinforced factor related overconfidence [17]. Organisation for Economic Co-operation and Development (OECD) estimated DEs in chronic illnesses slice 5% of health expenditure in member countries; 17.5% direct pooled fiscal burden of mis-, under- and over-diagnosis [18].

Challenges in diagnostic services are A. Omission: Incapacity to do a test with probability of benefit viz. Failure to screen cervical smears to eligible women. B. Commission: Quaternary prevention of a. Overuse of diagnostic test when potential harm exceeds benefit viz. Battery of test in common ailments, angiography in uncomplicated headaches etc. b. Misuse of diagnostic test to deprive full potential benefit of evidenced based medicine viz. pulmonary angiography in dyspnoea without taking past history of allergy to contrast dye [19]. Other study finds DEs in five strata viz. settings and care with optimum knowledge; assay diagnostic safety; find source of hazard; system approach instead of point of care health; updating. Choosing correct test and right processing of samples are most important mitigation measures to combat DEs from lab medicine [20]. A record and patient study noted relative role of system-related and cognitive components on comprehensive taxonomy “no fault”, “system-related”, and “cognitive”. System-related factors (policy, procedure, inefficiency, teamwork, and communication) 65%, cognitive factors 74% [21]. ‘Improving Diagnosis in Health Care’ study on diagnosing treatment framework on 2010-2015 variables found utility of diagnostic training and system improvement to reduce Des [22].

India lacks culture of reporting and recording precise medical data specially DEs. Medical Device Adverse Event Monitoring Centres (MDMCs) enhance reporting quality. Lack of communication and continuum of care to patients of abnormal test results lead to DEs of delay. Medical Device Adverse Events database under National Materiovigilance Programme (MvPI) acts as repository of adverse events reported by MDMCs. Under MvPI 174 MDMCs report adverse events from medical devices voluntarily; “Adverse Drug Reactions Monitoring System (ADRMS)” locate adverse events from application of drug, vaccine & medical device [23].

Millions of annual preventable deaths and injuries in India include missed, incorrect, or delayed diagnoses impacting treatment, well-being, and quality of life; 5.2

million medical errors occur annually and 3 million preventable death. Risk factors of DEs are poor knowledge and competency, problems in data acquisition, and synthesis of information; categorized as "No-fault", "System" and Cognitive errors; involve missing, incorrect, or delayed diagnosis leading to psycho-somatic and financial ramification. DE mitigation entails multifaceted approach to improve care, enhancing communication, and promoting culture of safety within health systems; to focus on capacity building, live teamwork and communication, updating infrastructure [24]. DEs harm to crop "medical negligence claims" viz. "Cognitive", "System", "No-fault errors". Indian research group suggested - how medical students can evade intricate interplay of cognitive and system factors that trigger DEs imperceptible to HCWs [25]. Medical mistakes including DEs mostly outcome of human factors, right technology may beat the threats by viz. augmenting mobile devices, staff communications, personalized healthcare [26].

Summary of Evidence

This systematic review outlined the burden posed by instability and errors in diagnosis on health systems, outcome, costs and care efficiency from 21 full text literatures that varied in High Income Countries (HICs) and LMICs to different disciplines and levels of healthcare.

Discussions

To champion patient safety we need training, updating, live communication among HCWs, system approach on accessibility and affordability, check lists, infrastructure upgrading and throbbing work culture in healthy Evidenced Based Medicine (EBM) based environment, create awareness on reporting of DEs in threat-free milleau. Empowering care-seekers to share negative feedbacks amid health system strengthening by digitalization, strong referral and weightage on prognostication supported by innovative telemedicine network.

WHO stressed on conceptual "System approach to patient safety" within the broader healthcare system context involving patients to advance with agenda viz. "Global action on patient safety", "Global Patient Safety Action Plan 2021–2030", "World Patient Safety Day", WHO Flagship initiative "A Decade of Patient Safety 2021–2030" [12]. WHO experts feel that DEs should be universal priority to minimize unwelcome outcomes of care in nearly half of the countries [27].

World Patient Safety Day (WPSD) is observed every year on 17 September for solidarity and united global action on patient safety and preventing hazards of health care [28].

Suggested Remedies

Enhanced Diagnostic Training

One way to solve this problem is by offering more in-depth training to clinicians, with a focus on the cognitive biases that affect diagnosis and how to mitigate them. Training should include the use of standard diagnostic checklists and protocols to reduce practice variation among the practitioners.

System Improvement

To systems need to prioritise effective communication between the members of healthcare teams and resolve workflow disruptions as a means of reducing the occurrence of diagnostic errors. Real-time decision support systems and interdisciplinary communication tools will prove useful in this scenario.

Integration of AI with Caution

Incorporation of tools of artificial intelligence into the process of diagnosis should be done gradually. We need to contain bias, caused by AI and maintain the interaction between AI and clinician, in particular, in a multicultural situation.

Checklists and Decision Support

The implementation of standard diagnostic checklists, clinical pathways, and decision support systems in the spheres of high diagnostic uncertainty, such as the emergency and intensive care medicine, will help in decreasing the prevalence of DEs to guarantee all clinicians follow best practices in every diagnosis situation.

Second Opinions and Standardization

Obtaining a second opinion for complex diagnosis cases, especially in dark areas like radiology and pathology, and standardising practice amongst the healthcare system minimizes variations and enhances diagnostic performance levels.

Targeted Approach

Focused disease model approach help reduce error rate up to 50% in conditions with a high propensity for DEs, such as strokes, sepsis, pneumonia, and cancer.

Integrated Approach Within Care

It's important to improve multidisciplinary and multi-team communication to perform the correct diagnosis. In a team-based approach, improving communication and documentation about diagnostic interpretation can help decrease the diagnostic errors in the interpretation of the patient's data.

Alerts on Quaternary and Quinary Prevention

Quaternary prevention, the fourth level public health that prevents over-diagnosis, and over-interventions; prevent iatrogenesis and ensure ethical care. Quinary prevention is latest concept in public health prevention that combats the negative effects of misinformation and pseudoscience that affect all levels of prevention from 'Primordial', Primary', Secondary', 'Tertiary', 'Quaternary' and 'Quinary' levels. It prevents optimum diagnosis with prognosis for uncertain disease progression.

Morbidity, Disability, Mortality and Diagnostic Error Audit

Diagnosis is a high risk area for errors in primary care, performing and interpreting diagnostic tests, follow-up and tracking of diagnostic information, referral-related communication and coordination, and patient behaviour, adherence and engagement. Audit at each of these points have potential to reduce DEs in difficult

clinical situations with rare disease or rare presentation.

Implications of Results for Practice, Policy and Future Research

Healthcare systems can forge ahead by using the information from this comprehensive research and implementing realizable measures to elevate patient safety and heighten health outcomes. Healthcare education courses and curriculum must receive attention to incorporate clinical decision-making skills and simulated-based learning to competencies. This includes drill of safe practice checklists with enhanced coordination, cooperation, information transfer and adherence to preventive protocol to minimize mistakes and deficiencies in compliance.

Error prevention strategies need to be incorporated in the system and tools are improvised through upgrading, regular monitoring and corrective action limit avoidable complications with focus on simulation-based training to improve technical skills and teamwork. The exchanges of messages between patients and providers are improved and plans are needed to present various risks and complications that arise from patient care. Interdisciplinary and multidisciplinary concepts are promoted to manage complicated conditions to provide integrated provision of both the biological and social aspects that influence the healing of the patients. Prospective readers will benefit from practical advice on current and crucial information on mitigation of man-made hazards to the special circumstances of tropical and LMIC countries. Summarizing data to date, this study looked into settling the great question of how mistakes affect the patients, including the overall level of care costs and inefficiency in systems to suggest creation of improved protocols, updating for staff and stronger monitoring mechanisms to enhance quality of service.

Conclusions

Healthcare hazards have downstream human, moral, ethical and financial connotation in which errors in diagnosis by healthcare provider have major chunk of contribution. Our analyses revealed scale of evidence, hazards and cost-effective interventions to limit DEs being feasible in clinical settings across HICs and LMICs. A systems approach is needed to guarantee patient safety by optimizing quality of care at every encounter with healthcare seekers, training and re-training, infrastructure development to boost precision and updating in line with the developments of science and technology.

'Once we realize that imperfect understanding is the human condition, there is no shame in being wrong, only in failing to correct our mistakes' - George Soros.

Diagnosis is *"the most critical of a physician's skills. It is every doctor's measure of his abilities. It is the most important ingredient in his professional self-image"*. Sherwin Nuland 1993

Not only are they wrong but physicians are "walking…in a fog of misplaced optimism" with regard to their confidence—Fran Lowry 1995

Author's Contribution

Concept of study (SC, RP), literature search (RP, KB), study design (RP, KB), data acquisition (AG, SC, RP), data analysis (AG, SC, RP), manuscript drafting (AG, SC, RP, KB), manuscript review, editing and final approval (AG, SC, RP, KB).

Registration and Protocol

Review was not registered and protocol was not prepared

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Conflict of Interest

All authors declare no competing interest regarding this review.

Availability of Data, Code and Other Materials

We have collected all the literature freely available to use for academic purpose from the public domain and analyzed using PRISMA checklist using data from included studies.

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CASE REPORT

Syphilitic Alopecia Through the Dermoscope: A Series of two Cases

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Abstract

Syphilitic alopecia (SA) is an uncommon manifestation of secondary syphilis which mimics common non-cicatricial alopecias. Dermoscopy/trichoscopy has been increasingly used as a non-invasive tool for the diagnosis of hair disorders. In some cases, specific dermoscopic features instantaneously clinch the diagnosis while in most other cases including syphilitic alopecia the findings are supportive. We report two cases of syphilitic alopecia with characteristic dermoscopic findings. Dermoscopy of both the patients showed alopecic patches with empty hair follicles, vellus hairs, hypopigmented to depigmented hairs and telangiectasias in a diffuse erythematous background. The absence of exclamation mark hairs as seen in alopecia areata, cork-screw hairs in tinea capitis, and lack of trichoptilosis, flame hairs and tulip hairs in trichotillomania makes the diagnosis of SA more likely. The case series highlights some valuable dermoscopic features of SA, a sparsely researched entity. Since syphilis, the great mimicker, has resurged, SA is gradually turning into a major mimicker in dermoscopy as well. Meticulous use of this non-invasive tool will help efface common hair disorders that simulate SA for prompt diagnosis and favourable therapeutic outcomes.

Keywords: Syphilitic alopecia, Non-cicatricial alopecia, Dermoscopy, Trichoscopy

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Introduction

Syphilitic alopecia (SA) is an uncommon manifestation of secondary syphilis which mimics common non-cicatricial alopecias. Most cases are asymptomatic, and the absence of specific histopathological findings results in under-diagnosis of the entity. Dermoscopy/trichoscopy has been increasingly used as a non-invasive tool for the diagnosis of hair disorders. In some cases, specific dermoscopic features instantaneously clinch the diagnosis while in most other cases including syphilitic alopecia the findings are supportive. There has been a resurgence of syphilis in the past two decades and in tandem with that, trichoscopic findings are studied and utilized to diagnose syphilitic alopecia. [1,2] Herein we report two cases of syphilitic alopecia with characteristic dermoscopic findings.

Case 1

A 28-year-old man presented with a five-month history of patchy alopecia over the parieto-occipital scalp (Figure 1A) along with mildly erythematous and scaly patches over the palms and soles. Dermoscopy of the alopecic patches revealed empty hair follicles, vellus hairs, hypopigmented to depigmented hairs and telangiectasias in a diffuse erythematous background (Figure 1). A biopsy from the palmoplantar lesion revealed parakeratosis, lichenoid infiltrate along with plasma cells and endothelial cell swelling of the dermal blood vessels. Additionally, the Venereal diseases research laboratory (VDRL) test was positive with titers of 1:128 and *Treponema pallidum* haem-agglutination (TPHA) was also positive. The patient was treated for secondary syphilis with benzathine penicillin, which was followed by complete hair regrowth in three months and resolution of palmoplantar lesions.

Case 2

A 36-year-old man visited the dermatology clinic for a maculopapular rash over the trunk of two months duration. On examination, subtle patches of non-cicatricial alopecia were incidentally observed. (Figure 1B) On further probing, the patient gave a history of a painless genital ulcer four months back that healed on its own without any sequelae. Dermoscopy of these patches revealed empty hair follicles, depigmented hairs, and telangiectasias. A VDRL was positive with titers of 1:256 and TPHA was positive. The patient was managed as secondary syphilis with syphilitic alopecia with a single shot of benzathine penicillin resulting in complete resolution.

Syphilitic alopecia (SA) is an uncommon manifestation of secondary syphilis with a prevalence ranging from 2.9-7%. In 1940, McCarthy described two forms of SA; symptomatic and essential, the former being associated with other cutaneous lesions of syphilis. Moth-eaten or patchy non-cicatricial alopecia is the commonest presentation, whilst diffuse and mixed patterns can occur too. The pathophysiology of SA is still enigmatic, but immune-mediated reaction to Treponema pallidum antigens centred around hair follicles is the best-proposed hypothesis. Alopecia areata, tinea capitis, and trichotillomania feature as the main differentials for moth-eaten alopecia, while telogen effluvium mimics diffuse SA [1].

Although there is no telltale dermoscopic feature of SA but ruling out differentials by confirming the absence of specific signs is the main aim while performing trichoscopy in this entity. The

absence of exclamation mark hairs in alopecia areata, cork-screw hairs in tinea capitis, and lack of trichoptilosis, flame hairs and tulip hairs in trichotillomania makes the diagnosis of SA more likely. Decreased hair follicles per unit, short regrowing hairs, empty follicles, peripheral black dots, follicular scaling, and hypopigmented hairs are some dermoscopic findings of SA described by Piraccini et al. Pomsoong et al in a study describing dermoscopy in SA pointed out that background uniform erythema is a key finding along with the previously described features to assuredly rule in SA, which was prominent in the first case [2,3]. The case series highlights some valuable dermoscopic features of SA, a sparsely researched entity. Syphilis, the great mimicker, has resurged, so SA is slowly becoming a great mimicker in dermoscopy too. Meticulous use of this non-invasive tool will help efface common hair disorders that simulate SA for prompt diagnosis and favourable therapeutic outcomes.

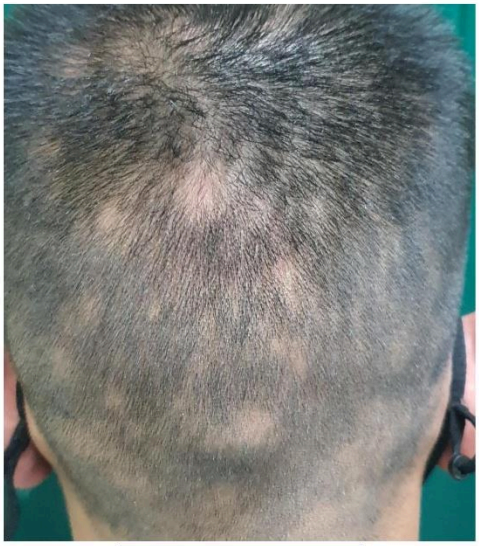

Figure 1A

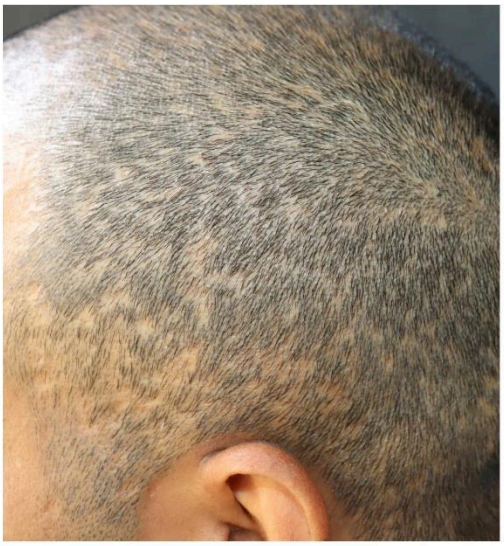

Figure 1B

Figure 1. **A** Multiple ill-defined patches of non-cicatricial alopecia over the occipital scalp; **B**: Multiple ill-defined patches of non-cicatricial alopecia over the temporal and parietal scalp

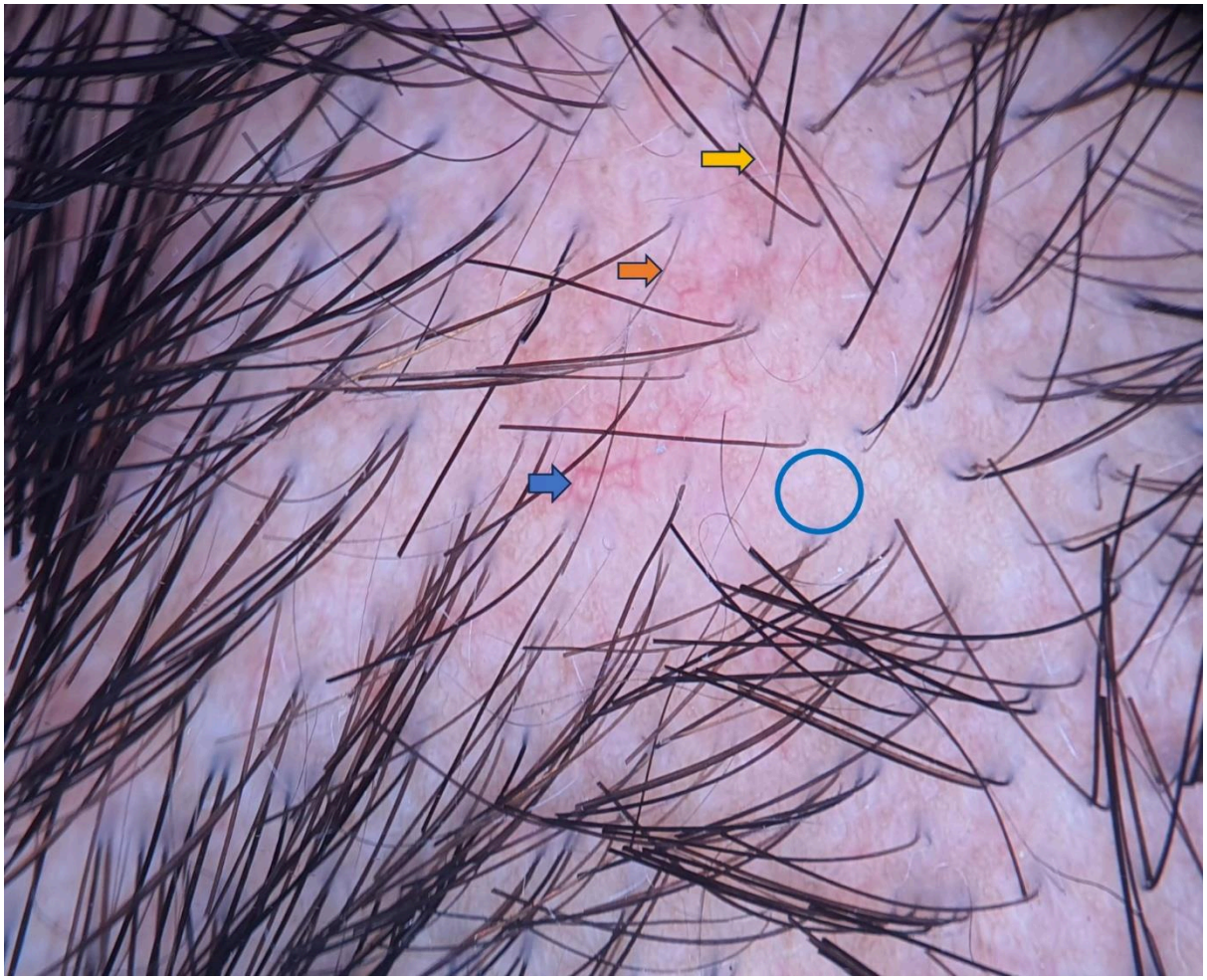

Figure 2: Dermoscopy (Dermlite DL4, polarized, 10 X) of the alopecic patches shows empty hair follicles (blue circle), vellus hairs (orange arrow), depigmented hairs (yellow arrow), and telengiectasia (blue arrow).

Acknowledgement

The patient in the manuscript has given written informed consent to the publication of case details and photographs.

Data availability statement

The authors declare that data supporting the findings of this case are available within the article and its supplementary information file.

Author contribution statement

The manuscript has been read and approved by all the authors. The requirements for authorship have been met, and each author believes that the manuscript represents honest work. In addition, we declare that the manuscript is original and it is not being published or submitted for publication elsewhere

Conflicts of interest

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

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CASE SERIES

Fatal Super Vasmol 33 Hair Dye Poisoning

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Abstract

Super Vasmol 33 is a widely used hair dye in India which contains paraphenylene diamine (PPD), a coal-tar derivative known for its toxic and allergenic properties. In this article we present four fatal cases of Super Vasmol ingestion, stressing its misuse as a method of deliberate self-harm. About10g of PPD is lethally toxic to cause death. Clinically, poisoning manifests with a characteristic triad: cervicofacial edema, rhabdomyolysis, and acute kidney injury. All four cases showed early onset of airway compromise due to laryngeal edema, requiring emergency airway management. At autopsy, histopathology showed pulmonary edema in lungs, acute tubular necrosis in the kidneys, and hepatic zone III necrosis in liver. Despite aggressive supportive care which included tracheostomy, corticosteroids, and dialysis, the mortality remained high. In Case 1, PPD was not detected in analytical toxicology likely due to metabolism and elimination as the survival period is long. The other three cases confirmed PPD presence in the chemical analysis of viscera. Immediate airway management and renal care (dialysis) remain as vital components of treatment. These cases underscore the systemic toxicity of PPD and the lack of a specific antidote. While banned in several countries, PPD remains easily accessible in India, raising concerns over its misuse. Safer alternatives like para-Toluenediamine sulfate (PTDS) may reduce hypersensitivity risks in dermatological practice. However, the toxicity of PTDS when ingested is not known. Enhanced public awareness, regulation, and substitution with less toxic compounds are essential to curb the growing incidence of hair dye poisoning in India.

Keywords: Paraphenylenediamine (PPD), Super Vasmol 33, Hair dye poisoning, Acute tubular necrosis (ATN), Rhabdomyolysis, Angioneurotic edema, Acute kidney injury (AKI).

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Introduction

Super Vasmol 33 hair dye contains a mixture of chemical compounds, with paraphenyl-diamine (PPD) being the most significant concerning toxicity, along with other chemicals like propylene glycol, resorcinol, cetostearyl alcohol, sodium lauryl sulphate, sodium ethylenediaminetetraacetic acid, liquid paraffin, preservatives, and perfumes [1,2]. PPD is an aromatic amine derived from coal tar, widely used in hair dyes for its effective colour enhancement properties.

When pure, PPD appears as white crystals, but it rapidly turns brown upon exposure to air due to oxidation. Its molecular weight is approximately 108 Daltons, and it has a boiling point of around 267°C and a melting point of approximately 140°C. The CAS number for para-phenylenediamine (also known as 1,4-Phenylenediamine) is 106-50-3. PPD is highly soluble in organic solvents such as ethanol, ether, benzene, chloroform, and acetone, which facilitates its absorption during use. It is only partially soluble in water, especially with agitation, which can influence its absorption during oral ingestion.

The concentration of PPD in hair dyes varies significantly depending on the formulation. In stone hair dyes, PPD can constitute between 70% to 90%, whereas in branded or commercial dyes, the concentration is usually between 2% to 10%. For instance, a typical 100-milliliter bottle of Super Vasmol 33 contains approximately 12 grams of PPD, demonstrating its relatively high concentration. The toxicity of PPD is notable; ingestion of as little as 3 grams can produce systemic poisoning symptoms, and doses of 7 grams or more are potentially fatal [3]. Because of its widespread use and toxicity, accidental or intentional oral ingestion of PPD-containing products like Super Vasmol 33 can lead to severe health consequences.

Once ingested, PPD is rapidly absorbed through the mucous membranes of the digestive tract into the bloodstream and also absorbed through skin (dermal route) and inhalation in industrial settings. It is then metabolized primarily into N-acetyl-PPD and N,N-diacetyl-PPD, which are relatively less toxic than the parent compound, yet can still cause systemic toxicity. These metabolites are subsequently eliminated through the urine. The quick absorption and metabolism of PPD are responsible for its potent toxic effects, which can include severe allergic reactions, skin and mucous membrane burns, swelling of the face and throat, and systemic complications affecting multiple organs, depending on the concentration. Given its affordability and availability, Super Vasmol 33 remains a popular choice among consumers, despite the health risks associated with PPD exposure.

Case details

Case 1

A 31-year-old female presented to the hospital with a history of consuming Super-Vasmol 33 hair dye. Her initial symptoms included a sudden onset of shortness of breath, sublingual edema, and stridor. She underwent emergency tracheostomy and supportive care, and was treated with diuretics, antibiotics, antihistamines, corticosteroids, and nebulization for 4 days during which her platelet counts, and total leucocyte counts declined, and serum creatinine, blood urea, and total bilirubin elevated (Table 1). Despite receiving treatment, her condition deteriorated rapidly and developed acute

tubular necrosis (ATN) and acute respiratory distress syndrome (ARDS), and she succumbed to the poisoning because of multi organ dysfunction syndrome. Upon autopsy, externally facial and neck swelling was noted. The brain, kidneys, and lungs along with other internal organs were congested. Laryngeal oedema was noted (Figure 1). There were no external injuries on the body. Viscera were preserved and sent for chemical analysis, which tested negative for Paraphenylenediamine (PPD). Histopathology of lung showed pulmonary edema (Figure 2) and kidneys showed acute tubular necrosis (Figure 3).

Table 1. Clinical Parameters of Case 1 While Undergoing Treatment.

Parameters And Normal Values	**Day 1**	**Day 2**	**Day 3**	**Day 4**
Hemoglobin (11.6 to 15 g/dl)	9.4	11	8.8	7.1
Platelets (1.5 to 4.5 lakhs/microliter)	2.75L	4.48L	2.59L	1.2L
TLC (4000-11000 /microliter)	8700	25500	20500	15400
Serum creatinine (0.7-1.3mg/dL)	0.9	4.2	6.1	6.9
Blood urea (6-21 mg/dL)	20	72	117	131
Total Bilirubin (0.2-1.3 mg/dL)	0.9	0.9	1.3	1.8

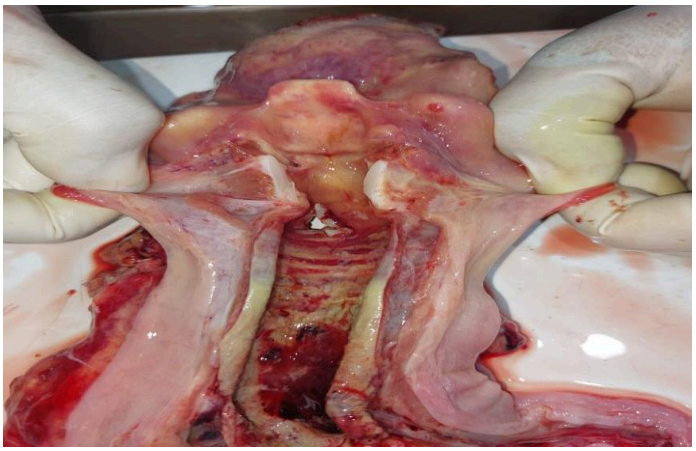

Figure 1. Laryngeal oedema at autopsy in case 1

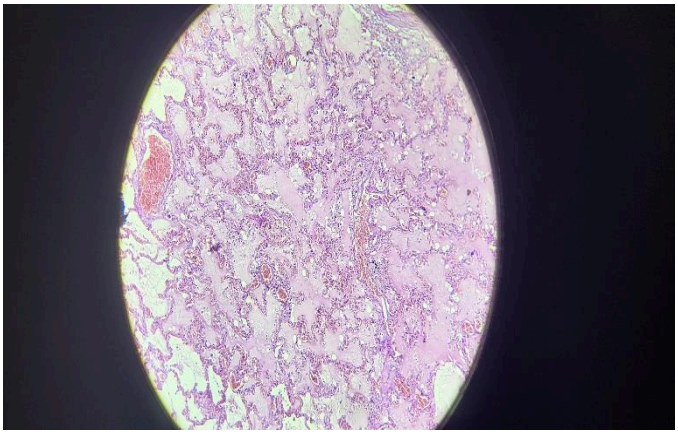

Figure 2. Pinkish exudates in alveolar spaces (H and E staining low power) in case 1.

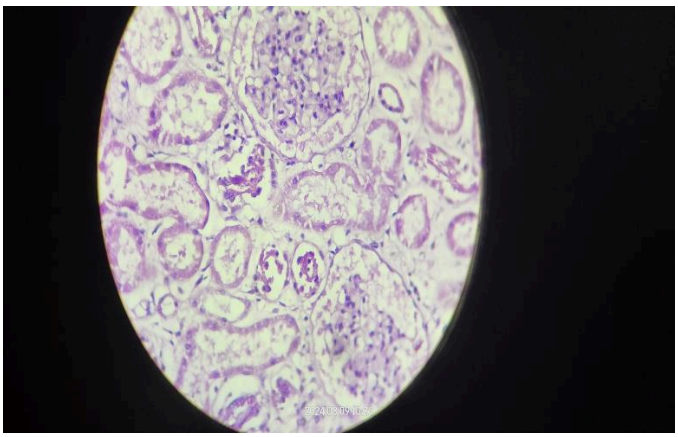

Figure 3. Separation of the basement membrane of collecting tubules and glomerulus (H and E staining low power).

Case 2

A 32-year-old female was admitted to the hospital in an unconscious state with a history of Super Vasmol 33 hair dye ingestion and died during treatment within five hours of consumption. Upon autopsy, external appearance showed congested conjunctivae, and the tongue was stained brown. Internal examination showed laryngeal edema, the trachea was congested, 100ml of greenish brown colour fluid was noted in the stomach (Figure 4), and the mucosa of the stomach was congested. Lungs, liver, and kidneys were congested. Viscera was sent for chemical analysis, and turned positive for PPD.

Figure 4. Congested stomach mucosa and greenish brown stomach content in case 2

Histopathology of lung tissue revealed pulmonary edema (Figure 5), kidneys showed acute tubular necrosis (Figure 6), and liver showed predominant zone III necrosis, central vein dilatation, and periportal inflammation (Figure 7).

A super vasmol 33 bottle containing PPD was seized at crime scene in case 2 (Figure 8).

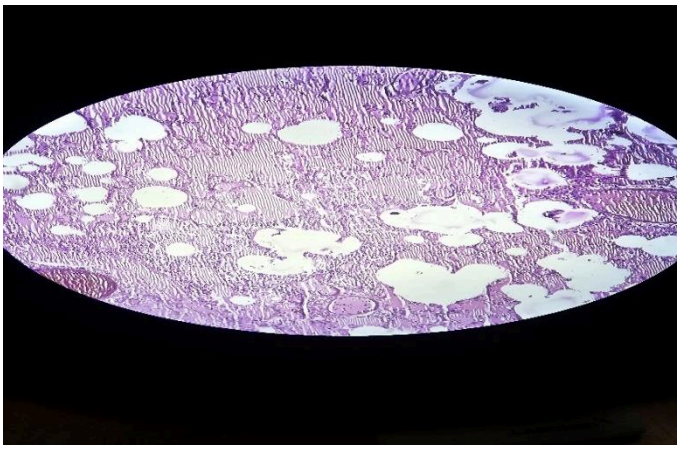

Figure 5. Pulmonary edema in case 2 (H and E staining low power).

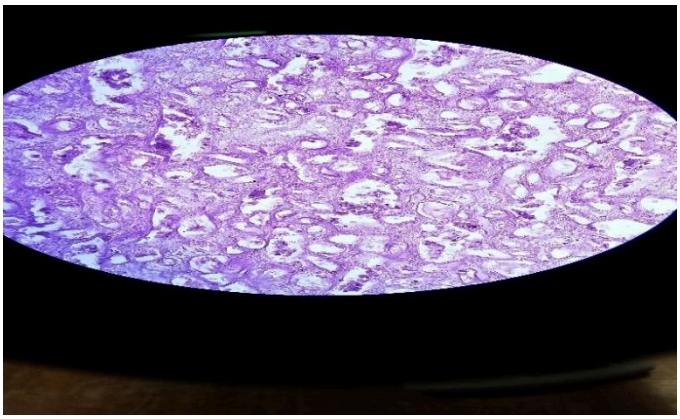

Figure 6. Tubular dilatation, cell damage and interstitial edema in case 2 (H and E staining low power).

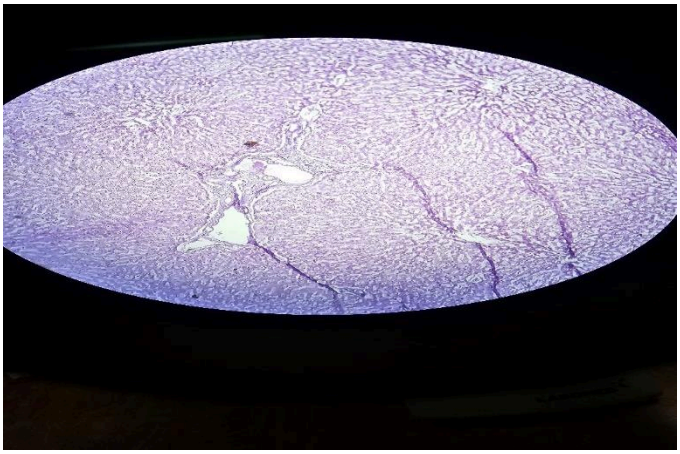

Figure 7. Liver showing central venous dilatation, periportal inflammation, zone 3 necrosis (H and E staining low power).

Figure 8. A super vasmol bottle seized at the crime scene in case 2.

Case 3

A 22-year-old female consumed Super Vasmol 33 hair dye to commit suicide and was brought to the hospital, where she received timely treatment, including an emergency tracheostomy; however, despite medical intervention, she survived only for six hours. At autopsy, faciocervical swelling was noted (Figure 9). Internally, laryngeal edema was noted. The stomach was empty, and the mucosa showed congestion. The brain, lungs, and both kidneys were congested. Viscera was sent for chemical examination, and the result was positive for PPD.

Figure 9. Photograph showing Faciocervical swelling and surgically sutured tracheostomy wound.

Case 4

A 39-year-old male presented with a history of consuming Super-Vasmol 33 hair dye and was rushed to the hospital, and died after 2 days while undergoing treatment. The body was brought to the KGH mortuary for autopsy. Externally, Facio cervical swelling was noted. Internally, Laryngeal edema was present, about 20ml of greenish brown fluid was present in the stomach, and the mucosa was congested. The brain, Lungs, and both kidneys were congested. Laboratory investigations prior to death showed elevated serum creatinine and blood urea levels. Viscera was sent for chemical analysis and was positive for PPD.

Discussion

Super Vasmol 33 hair dye contains a mixture of chemical compounds, with paraphenyl-diamine (PPD) being the most significant concerning toxicity, along with other chemicals like propylene glycol, liquid paraffin, resorcinol, cetostearyl alcohol, sodium lauryl sulphate, sodium ethylenediaminetetraacetic acid, preservatives, and perfumes [1,2].

Paraphenylenediamine (PPD), a hazardous derivative of coal tar, undergoes oxidation to form Bandrowski's base, a trimeric compound known for its strong allergenic potential and suspected mutagenic and cytotoxic properties [4-6]. Exposure to PPD can trigger severe allergic reactions, including angioedema, muscular edema, rhabdomyolysis, and potentially life-threatening shock.

Resorcinol, another ingredient found in hair dyes, is a powerful phenolic compound (1,3-dihydroxybenzene or 3-hydroxyphenol) that is highly corrosive and can cause haemoglobinuria, resulting in urine that appears chocolate-colored. However, in the cases studied here where clinical records are available, there is no such finding of chocolate coloured urine documented.

Propylene glycol, commonly used as a solvent in hair dyes, also contributes to the toxicity of these products. Among the active ingredients in Super Vasmol, PPD, resorcinol, and propylene glycol stand out for their potential to cause systemic toxicity and life-threatening effects [7]. It is key to be informed about these dangers and

consider the implications of using such products. However, in all the cases mentioned in this case series, the manifest toxic effects appear to be due to PPD more predominantly compared to the other common ingredients mentioned herein above.

PPD (Paraphenylenediamine) poisoning follows a distinct three-stage progression. During the first three days, an inflammatory stress response is observed, characterized by relative immunosuppression. From the third to the sixth day, a proinflammatory state emerges, primarily due to rhabdomyolysis. After the sixth day, immunomodulatory effects are seen, attributed to oxidative metabolism. The poisoning induces a systemic inflammatory reaction driven by cytotoxic effects on cells. Several pathophysiological mechanisms are involved, including increased free radical formation, skeletal and cardiac muscle necrosis (scattered coagulation necrosis), the generation of quinone diamine (a highly nephrotoxic oxidative metabolite of PPD), renal tubular occlusion from myoglobin casts, and acute tubular necrosis. The clinical picture of case 1 showed a similar complex systemic toxicity due to PPD poisoning.

Clinically, PPD toxicity can present with a wide spectrum of symptoms, including hoarseness of voice, pneumothorax, hepatitis, convulsions, coma, cardiac toxicity, hypotension, and sudden cardiac death [8,9]. The fatal dose ranges from 6 to 12 grams, with 100 ml of PPD-containing solution typically containing around 12 grams. The fatal period depends on the quantity ingested and the time between ingestion and treatment initiation. Currently, there is no known antidote for PPD poisoning. A single high dose concentration is generally considered to be more fatal because of the upper airway oedema and rhabdomyolysis induced renal failure. However, there have also been fatal outcomes in cases with low dose exposure where the treatment was delayed.

Super Vasmol poisoning presents with a characteristic triad comprising early angioneurotic edema of the face and neck, rhabdomyolysis, and acute kidney injury (AKI). The angioneurotic edema typically manifests early, with symptoms including hoarseness of voice, stridor, a swollen and hard protruding tongue, and an edematous “bull neck.” These orofacial swellings are often the first clinical signs following ingestion of the dye. Rhabdomyolysis is marked by the presence of dark brown-colored urine, while AKI develops as a consequence of muscle breakdown products accumulating in the kidneys [10-12].

The management of Super Vasmol poisoning is primarily supportive and depends on the patient’s clinical status. Maintaining airway patency is of utmost importance. Early or prophylactic endotracheal intubation is recommended to prevent airway compromise and reduce the need for surgical intervention. In cases of significant neck swelling, where anatomical landmarks are obscured, tracheostomy is preferred over cricothyroidotomy as an emergency surgical airway. Antihistamines and corticosteroids are commonly used to treat airway edema, possibly due to hypersensitivity to para-phenylenediamine (PPD), although there is no definitive evidence supporting their efficacy. To prevent AKI resulting from rhabdomyolysis, early initiation of alkaline diuresis with isotonic saline, sodium bicarbonate, and osmotic diuretics is crucial, along with ensuring a high urine output.

This article presents four cases: Two are fatal within hours (case 2,3) and the other two cases surviving for four days (case 1) and two days (case 4). Toxicological analysis confirmed the presence of p-phenylenediamine (PPD) in the viscera in Case 2,3,4 while Case 1 tested negative, possibly due to early treatment, metabolism, or elimination of the toxin [13-15].

Misuse of hair dye containing PPD is being increased as a means of suicidal poisoning [10] and homicidal poisoning. In Punjab, India kala pathar was used as homicidal poison to kill eleven children [17].

PPD is either fully banned or subject to strict restrictions in several countries, such as Germany, France, Sweden, and Sudan, because of its toxic and allergenic effects. In Sudan, the ban is particularly motivated by its frequent misuse in suicide attempts and the high risk of accidental paediatric poisoning. PPD is a potent skin sensitizer known to cause severe allergic contact dermatitis and Type IV hypersensitivity reactions. Additionally, it exhibits selective cytotoxicity toward skin fibroblast cells [18]. For dermatological use, para-toluenediamine sulfate (PTDS) is considered a safer and more affordable alternative to paraphenylenediamine (PPD) in hair dyes and cosmetics, as it is less likely to trigger allergic reactions [19].

Instances of accidental hair dye poisoning in children has been a source of concern [20]. Super vasmol poisoning was common in the Rayalaseema region of Andhra Pradesh for a long period of time and this trend is being now a days observed in coastal areas of Andhra Pradesh as well. It is necessary to reduce the over the counter availability of these toxic dyes and herbal and less toxic alternatives should be explored in the interest of public safety [21].

In medico-legal cases it is important to consider sending biological samples during treatment for qualitative and quantitative analysis of PPD as the chances of detecting the same at autopsy decreases as survival period increases.

Conclusion

As hair dyes become increasingly misused as a means of poisoning either in cases of suicide or homicide, the number of related incidents has been rising in several regions across the country [10]. In all cases presented here, facial and laryngeal edema were noted similar to the earlier documented literature [10-12]. Gross findings showed congestion of the stomach mucosa and congestion of other organs. Histopathological findings showed pulmonary edema of the lungs, tubular necrosis of the kidneys, and zone 3 necrosis and periportal inflammation in the liver. There is a need for searching for safer alternatives to this toxic ingredient in hair dyes. In addition, community awareness and health education help towards early diagnosis and prevention to some extent.

Conflict of Interest

None to declare

Financial Support

Not applicable.

Ethical Considerations

Consent for conducting medicolegal autopsy was obtained from law enforcement agencies. All ethical considerations were addressed by the authors.

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