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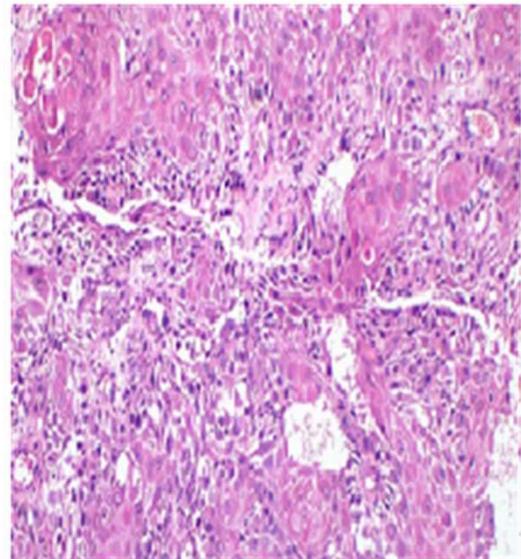


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Separation of the skin and neural elements



Moderately Differentiated "Oral Squamous Cell Carcinoma

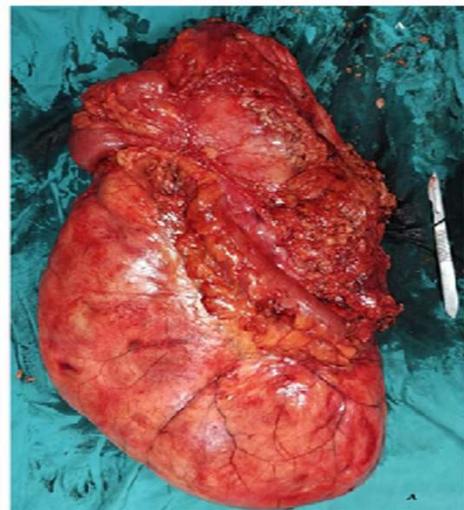


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Primary Closure of wound



Retroperitoneal liposarcoma



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EDITORIAL

Ramping Up India's Critical Care Workforce: Role of NBEMS and the Way Forward

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India has commendably expanded its ICU facilities and critical care beds in recent years. The scaling up continues. High-quality intensive care depends on skilled intensivists, nurses, and support staff. Rapidly developing a critical care workforce has become as important as adding physical ICU beds.

Recognizing India's disease burden, the National Board of Examinations in Medical Sciences (NBEMS) is constantly clambering for specialty training in all fields of medicine, including skill enhancement fellowships (FNB). Respiratory illnesses are a leading health threat. Unsurprisingly, pulmonary medicine and related specialties (e.g., tuberculosis and chest diseases) form a large training pool for critical care. Dozens of medical colleges offer MD or diploma programs in respiratory medicine, collectively producing hundreds of chest specialists annually (for instance, **710** post-graduate

seats in "Tuberculosis & Chest Diseases" were listed across India for 2024). This emphasis reflects the high incidence of asthma, COPD, TB, and other respiratory ailments in India. Many of these pulmonary and chest medicine graduates, along with those from anesthesiology and internal medicine, often staff ICUs or pursue further critical care training. However, until recently, there was no dedicated critical care super-specialty pipeline to adequately channel this pool into formally trained intensivists.

NBEMS has stepped in to fill this void, and what more is needed to ensure accessible, quality critical care for India's 1.46 billion people, including large corporate hospitals and specialty centers, now serving as training sites for DrNB Critical Care, spread across the country. This model has allowed quick scaling-up of training capacity.

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Dominant Role of NBEMS in Critical Care Training

A distinctive feature of India's critical care training landscape is the dominant role played by NBEMS in producing specialists. The Medical Council of India (now NMC) only recognized Critical Care Medicine (CCM) as a distinct super-specialty in 2010–2012, & despite recent efforts, there is a constant backlog in the number of DM (Doctorate of Medicine) critical care seats in government medical colleges, remaining limited. This is in sharp contrast to the growing need. NBEMS has responded by massively upscaling critical care training through its DrNB (Diplomate of National Board) programs. Approximately **90% of all critical care specialist training seats** today are under NBEMS (primarily DrNB Critical Care Medicine), with only a small fraction under traditional university DM programs. This essentially means NBEMS is driving nearly all formal critical care training in India.

Notably, many of the NBEMS training programs are based in private hospitals and dedicated critical care centers. Unlike other specialties that are still largely taught in government medical colleges, critical care has seen a rapid expansion in the private sector. NBEMS has leveraged this momentum by accrediting capable private-sector ICUs to run the 3-year DrNB Critical Care residency.

Eligibility for DrNB/DNB in CCM includes MD/DNB in General Medicine, Paediatrics, Respiratory Medicine, Anaesthesia, and Emergency Medicine. Currently, there are 551 DrNB CCM seats in 211 hospitals accredited with NBEMS. Next in the pipeline are courses in FNB Interventional Pulmonology and DrNB Pulmonary Medicine. With the involvement of private critical care centers, trainees continue to get exposure to high-acuity ICUs with modern equipment and a high volume of patients. Overall, roughly nine out of ten new intensivists in India are now products of NBEMS programs – a testament to the crucial contribution of NBEMS in addressing India's need for specialist training in intensive care.

This reliance on NBEMS and private institutions reflects a pragmatic approach to rapidly expanding specialist education outside the traditional. By empowering NBEMS to accredit any qualified hospital (public or private) for specialist training, the country tapped into a much wider network of facilities. **Pulmonary and critical care medicine** training has particularly benefited: many private hospitals with strong pulmonology and critical care departments joined NBEMS's network, increasing training seats in response to the respiratory disease burden. The epidemiological reality – India has a high morbidity of chronic respiratory

diseases – is thus directly linked to this training strategy.

Partnerships with the Private Sector and COVID-19 Lessons

India's experience during the COVID-19 pandemic vividly demonstrated the value of public-private partnerships in scaling up both critical care resources and specialist manpower. When COVID-19 struck worldwide, an acute shortage of ICU beds, ventilators, and trained ICU staff was realized. In India, the crisis catalyzed cooperation between the government, NBEMS, professional societies, and private healthcare providers. **NBEMS and private**

hospitals together ramped up the training and deployment of specialists in record time. For instance, numerous private hospitals were roped into the COVID response as dedicated critical care centers, bringing their ICU expertise and staff into the fight. Many of these hospitals also host NBEMS training programs – meaning senior residents and recently qualified DrNB intensivists became a frontline workforce during the pandemic surges.

The pandemic also led to innovative *stopgap training* measures. Recognizing the limited availability of formally trained intensivists, some states began upskilling doctors from other specialties. In Kerala, for example, over 300 non-ICU doctors and 180 nurses underwent short critical care training to help staff ICUs during the surge. Similarly, the Health Ministry and AIIMS launched online crash courses on ICU management for any doctors willing to learn. These efforts, while not a substitute for full specialist training, were crucial in extending critical care to areas with no intensivists. They underscore how flexible, tiered training models can quickly bolster capacity – an approach that could be institutionalized for future needs.

Private sector participation proved indispensable in other ways as well. Private hospitals provide the majority of healthcare in India (over 65%–75% of health services), and they owned much of the existing ICU infrastructure when COVID hit. During the first wave, some regions struggled to integrate private hospitals, but others succeeded via novel partnerships. For example, **Odisha state partnered with private hospitals** to set up 17 COVID-dedicated hospitals on a *public-private partnership (PPP)* model, essentially renting private ICUs for public use. The

government paid these hospitals to ensure ICU beds were available to any patient, regardless of occupancy rates. This PPP approach rapidly added critical care capacity in areas that need it.

The key lesson from COVID-19 is that **leveraging all available resources – especially through public-private collaboration – can greatly accelerate the scaling up of critical care services.** NBEMS already embodies this lesson on the education front by training specialists in private centers. During COVID, this model was extended to service delivery: tele-ICU hubs in metro hospitals remotely supported ICUs in smaller towns, private experts worked in tandem with government hospitals, and fast-track training was given to general physicians. Going forward, these examples make a strong case for continued collaboration. The private sector's agility and capacity, when guided by public health priorities and standards, can help bridge gaps in both critical care infrastructure and human resources. However, to sustain such collaborations beyond emergencies, certain challenges need to be addressed – particularly regarding quality control and equitable access.

Challenges in Ensuring Quality and Access

Relying on a rapid scale-up via multiple institutions (many privately run) poses the challenge of maintaining consistent quality and oversight. As India produces more intensivists through NBEMS and other avenues, ensuring they all meet high standards is paramount for patient safety. There is constant focus on quality and accessible critical care, such as:

Accreditation and Oversight

Robust oversight mechanisms are needed to standardize training quality across the diverse array of NBEMS-accredited hospitals. NBEMS has a curriculum and accreditation criteria, but continuous monitoring is essential to ensure that each training center provides adequate case exposure, faculty, and facilities. Similarly, ICUs across the country (in both public and private hospitals) should be subject to common quality standards and audits. The National Medical Commission and bodies like the Indian Society of Critical Care Medicine (ISCCM) ensure the definition of minimum standards for ICU care and staffing.

Training Standards

A critical care specialist in a remote private hospital should be as competent as one trained in a premier institute. Standardized curricula, like the one NBEMS developed, and examination processes help, but there is also a need for uniform clinical exposure.

- Rotations at high-volume centers,
- Simulation-based training,
- Faculty development programs can help equalize training. Alignment between the university (MD/DM) programs and NBEMS programs would ensure that all graduates meet the same competency benchmarks, and
- Continuous medical education and recertification can further ensure skills remain up to date.

Funding

Increasing specialist numbers and ICU capacity will require greater investment. Critical care is resource-

intensive. The **National Health Mission** has aimed to improve access to affordable, quality healthcare, and this mission should explicitly include critical care. This would encourage more medical colleges to start DM Critical Care programs and support state hospitals to hire trained intensivists. Investing in nursing and allied health training for critical care is equally important, as ICU care is a team effort.

Reasonable Distribution of Services

Thus far, most advanced critical care facilities (and trained specialists) are concentrated in urban centers. Bridging this urban-rural gap is a major challenge. It will require creative solutions, like rotation of specialists to peripheral centers, tele-ICU networks, and developing “step-down” high-dependency units staffed by physicians with basic critical care training. Ensuring that the expansion of the workforce translates to **easy access for all segments of the population** – not just those in big cities – is a policy priority. This again may hinge on investments to establish ICU units in district hospitals and improve referral linkages.

Joint Accreditation Programme of NBEMS

Launched in 2023, this programme has the potential to make specialists, both trained and those under training, available at the district level.

Addressing these challenges will require coordinated policy action. Regulations must keep pace with the rapid growth in training programs. Going forward, a strong framework for accreditation, faculty qualification, and periodic review of outcomes (e.g., patient

mortality rates, complication rates in ICUs) can help maintain standards.

The NBEMS motto is that **scaling quantity should not come at the cost of quality**, and strategic support is constantly needed to ensure the two grow hand-in-hand.

The Road Ahead: Recommendations for Scaling Up

India's critical care training programs – primarily driven by NBEMS – have made notable progress in building an expert medical workforce. With the rising demand for ICU services across a nation of 1.46 billion people, these efforts are being regularly upscaled and tailored to India's unique needs.



PERSPECTIVE ARTICLE

Critical Care Training in India vs USA: NBEMS Accounts for 81.89% of Indian Admissions

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Keywords: Critical Care Medicine, NBEMS, Medical Education, India-USA Comparison, Workforce Capacity, Fellowship Training

Background

Over the past three decades, critical care in India has witnessed rapid and remarkable growth. There has been a significant increase in the number of intensive care units with adequately equipped beds, as well as the number of trained healthcare professionals [1]. This expansion followed a well-defined and pragmatic trajectory, ensuring that advancements occur according to a scientifically researched and well-designed framework [1].

In the recent past, a steep rise in medical tourism, particularly for elective and complex surgical procedures [2], has significantly increased the demand for comprehensive critical care and qualified specialists [3]. This need was further established during the COVID-19 pandemic, which brought widespread

awareness of the vital role of intensive care units in modern healthcare [3].

In the United States, Critical Care Medicine is pursued either as a fellowship alone (usually 1–2 years) or in combination with pulmonary medicine (3 years) [4,5]. According to the Accreditation Council for Graduate Medical Education (ACGME), this dual pathway provides a steady pipeline of specialists who are trained to manage ICU patients comprehensively [4,5].

Between 2016 and 2021, U.S. critical care training programs grew by 22.7% (from 413 to 507), while the number of fellows increased by 23.8% (from 2,674 to 3,311) [6]. The majority of fellows (60% in 2020–2021) were enrolled in Pulmonary and Critical Care Medicine (PCCM) programs [6]. Of the 3,311 fellows in 2021, 65.8% were U.S. medical graduates, while 34.2% were international graduates [6].

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In the United States, fellowship programs related to critical care are offered across three main tracks. According to the latest data, standalone Critical Care Medicine programs admit 187 fellows annually [7]. The majority of trainees pursue combined pulmonary disease and Critical Care Medicine programs, accepting 781 fellows annually [7].

The United States, with a population of approximately 340 million,

trains a total of 968 critical care fellows annually, 187 through standalone Critical Care Medicine programs and 781 through combined Pulmonary and Critical Care Medicine programs, as mentioned in Table 1 [7]. This translates to approximately 2.85 critical care fellowship admissions per million people per year, reflecting the country's emphasis on structured, advanced training to meet the growing demand for critical care services [7].

Table 1. Critical Care Fellowship in the USA

Critical Care	187
Pulmonary Critical Care	781
Total Adult Critical Care Positions	968

India, with a population of approximately 1.4 billion, currently has around 591 critical care training seats across various programs, equating to roughly 0.48 seats per million people. This data highlights the growing *need* for critical care training.

Of these, 101 seats are in DM Critical Care Medicine, 6 in DM

Pulmonary Medicine & Critical Care, and 555 in DrNB Critical Care Medicine. Notably, 555 of the 673 seats, or 82.48% of the critical care seats, are produced under NBEMS programs, primarily in private critical care centers as mentioned in Table 2 [8,9]. This distribution highlights the significant role of NBEMS in critical care education in India.

Table 2. Critical Care Seats in India

DM Pulmonary Medicine & Critical Care	6
DM Critical Care Medicine	101
DrNB Critical Care Medicine (NBEMS)	555
Trauma Anaesthesia Critical Care Fellowship (NBEMS)	11
Total Adult Critical Care Seats	673

Discussion

The rapid growth of critical care in India over the past three decades reflects a significant transformation in healthcare infrastructure and specialist training [1]. While the expansion of ICU facilities and critical care beds is commendable, the cornerstone of this progress lies in the development of a trained critical care workforce capable of delivering high-quality care. The United States trains approximately 2.85 critical care fellows per million population annually; NBEMS, too, is constantly upscaling to bridge the gap between demand and supply [7-9].

Pulmonary medicine and related specialties, including TB and chest diseases, constitute a larger training pool, reflecting the epidemiological burden of respiratory illnesses in India [8,9]. It is noteworthy that a distinctive feature of India's critical care training landscape is the dominant role played by the National Board of Examinations in Medical Sciences (NBEMS). Remarkably, approximately 81.89% (555 out of 673) of critical care training seats, primarily DrNB Critical Care Medicine seats, are administered under NBEMS programs, with many situated in private critical care centers [8,9]. This highlights the crucial contribution of NBEMS in addressing the need for specialist training in a country with vast geographic and population diversity. Unlike the United States, where critical care training is often embedded within academic university settings, India's reliance on NBEMS and private institutions reflects a pragmatic approach to rapidly scaling up specialist education outside traditional government-run programs.

India's experience during the COVID-19 pandemic demonstrated the value of partnerships between NBEMS and

the private sector in rapidly increasing the number of medical specialists and resources. However, while this model holds promise, ensuring that people have easy access to quality care will also require strong oversight, consistent training standards, and increased government support.

Looking ahead, India's critical care training programs, primarily driven by the NBEMS, have made notable advancements in designing and building an expert medical workforce. Still, with the rising demand for intensive care across a country of 1.4 billion people, there's a clear need for upscaling the efforts. This means more government funding, stronger collaboration between the public and private sectors, and better infrastructure for education and training.

Conclusion

Learning from international models while customizing solutions to fit India's unique healthcare needs will be key. By doing so, we can strengthen the future of Critical Care Medicine and enhance outcomes for patients nationwide.

Conflicts of interest

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

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Competing Interests

The authors declare no competing financial or non-financial interests related to the work submitted for publication.

Author Contributions

NN: Conceptualization, data collection, comparative analysis, writing

original draft; LE: Literature review, data curation, writing, review & editing; GRC: Literature review, data collection, data curation, writing, review & editing. All authors have read and approved the final version of the manuscript and meet the criteria for authorship.

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ORIGINAL ARTICLE

Delayed Presentation of Meningomyelocele in a Tertiary Care hospital of Northern India

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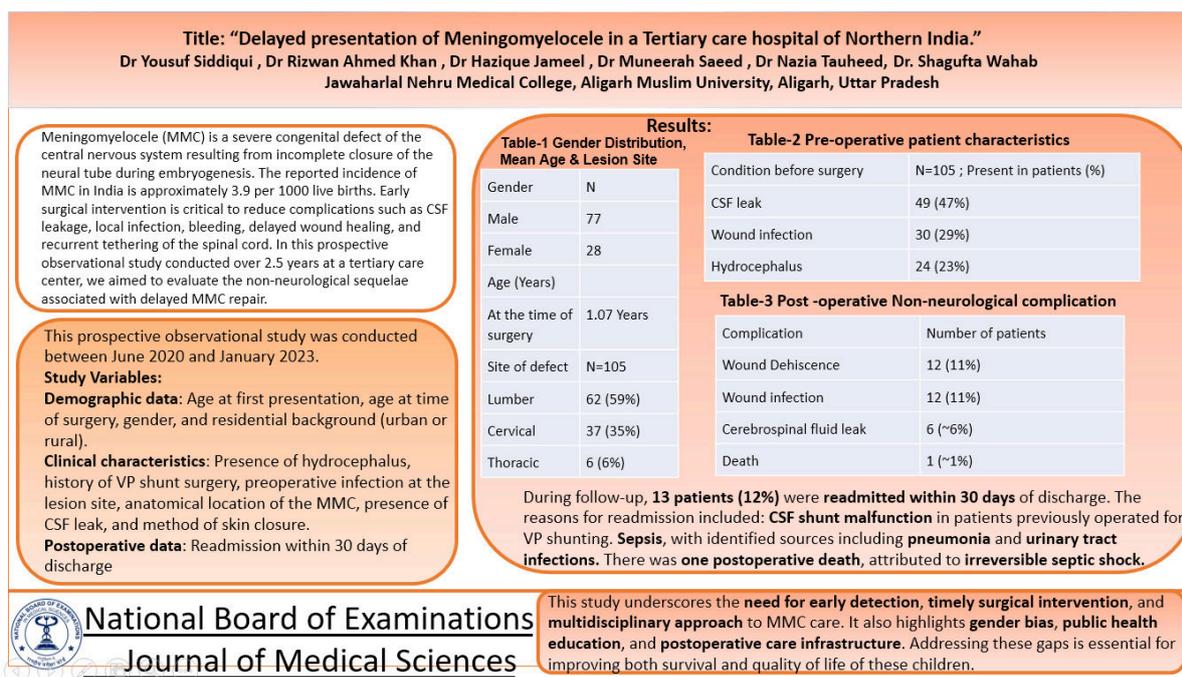
Abstract

Meningomyelocele (MMC) is a severe congenital defect of the central nervous system resulting from incomplete closure of the neural tube during embryogenesis. The reported incidence of MMC in India is approximately 3.9 per 1000 live births (range: 3.6 to 7.48), which is significantly higher than that in developed countries- almost three times greater. Early surgical intervention is critical to reduce complications such as cerebrospinal fluid (CSF) leakage, local infection, bleeding, delayed wound healing, and recurrent tethering of the spinal cord. Unfortunately, due to limited awareness and inadequate healthcare infrastructure, particularly in remote regions, many patients present late and receive suboptimal initial care. In this prospective observational study conducted over 2.5 years at a tertiary care center, we aimed to evaluate the non-neurological sequelae associated with delayed MMC repair. A total of 105 patients were included, comprising 77 males and 28 females, with a mean age at presentation of 1.07 years. The most frequent site of lesion was the lumbosacral region. Postoperative follow-up revealed that wound infection was the most commonly encountered complication. Our findings highlight that delayed presentation of MMC is associated with technically challenging surgeries and a higher incidence of postoperative complications. These observations underscore the need for increased public health awareness, timely diagnosis, and early referral to specialized centers to improve outcomes in affected patients.

Keywords: Meningomyelocele (MMC), surgical outcome, neural tube defect

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Graphical Abstract



Introduction

Meningomyelocele (MMC) is the most severe form of spina bifida, a neural tube defect (NTD) arising from incomplete closure of the spinal cord during early fetal development [1]. It is characterized by a protrusion of the spinal cord and meninges through a defect in the vertebral column, forming a fluid-filled sac on the infant's back [2]. NTDs are particularly prevalent in developing countries and contribute significantly to the global burden of congenital anomalies, both in terms of morbidity and healthcare costs. In low- and middle-income nations, the high incidence of MMC is often attributed to nutritional deficiencies, particularly inadequate maternal intake of micronutrients such as folic acid during the periconceptional period [3–6]. In India, the incidence of NTDs is reported to be approximately 4.5 per 1000 total births, with meningomyelocele accounting for 42% of these cases.

By contrast, developed nations have observed a marked decline in the incidence of MMC, primarily due to improved prenatal care, widespread folic acid supplementation, early antenatal diagnosis of spina bifida, and an increase in medically indicated terminations of affected pregnancies [7]. The management of children with MMC remains complex and resource-intensive. Surgical closure of the defect is a critical intervention aimed at preserving viable neural tissue and preventing complications such as cerebrospinal fluid (CSF) leakage and infection. Early surgical intervention—preferably within the first 48 hours of life—is associated with significantly improved outcomes [8–11]. However, infection at the lesion site, either preoperatively or postoperatively, can be life-threatening [12]. In untreated cases, mortality rates range from 65% to 75% within the first six months of life. Even among treated patients, mortality remains high—30% to 40% in the first year, and up

to 50% to 60% within the first three to five years [13–15].

In Northern India, delayed presentation of MMC is often influenced by socio-economic constraints, cultural and religious beliefs, lack of awareness, and limited access to specialized surgical care. These challenges underscore the urgent need to identify outcome determinants and bridge existing gaps in care delivery.

Material and Methods

Study Design and Data Acquisition

This prospective observational study was conducted at a tertiary care hospital located in a district of Northern India. The study included all patients who underwent surgical repair for meningocele (MMC) between June 2020 and January 2023. All patients were admitted to the Paediatric Surgery ward and followed a standardized institutional protocol for evaluation and management.

Study Variables

The following variables were collected and analyzed:

- **Demographic data:** Age at first presentation, age at time of surgery, gender, and residential background (urban or rural).
- **Clinical characteristics:** Presence of hydrocephalus, history of ventriculoperitoneal (VP) shunt surgery, preoperative infection at the lesion site, anatomical location of the MMC, presence of cerebrospinal fluid (CSF) leak, and method of skin closure.
- **Postoperative data:** Readmission within 30 days of discharge.

Neurological sequelae such as neurogenic bladder or bowel, lower limb weakness, complications from hydrocephalus, or history of meningitis were excluded from the scope of this study.

Perioperative Evaluation and Management

All patients underwent a thorough clinical evaluation and relevant investigations. A non-contrast CT head scan was performed in each case to assess for hydrocephalus. The age of patients at presentation ranged from 5 days to 4 years.

The primary surgical objective was repair of the MMC sac. In cases with local infection, surgical intervention was deferred until infection was controlled. For patients with significant hydrocephalus, a VP shunt was placed prior to MMC repair. Early intervention was prioritized to minimize the risk of complications, including lesion site infection, bleeding, delayed wound healing, recurrent spinal cord tethering, and CSF leak.

Surgical Principles of Myelomeningocele Repair

Timing of Surgery

Whenever feasible, surgical repair was performed within 24–48 hours of birth to reduce the risk of infection and progressive neurological damage.

Surgical Objectives

- Protection of exposed neural placodes and repositioning into the spinal canal.
- Achieving watertight dural closure to prevent CSF leakage.
- Layered closure of muscle and skin to ensure robust coverage, often utilizing V–Y advancement flaps for larger defects.

Multidisciplinary Approach

Management involved a collaborative team comprising pediatric surgeons, neurosurgeons, urologists, and orthopedic specialists to address associated conditions such as hydrocephalus, urinary dysfunction, and skeletal deformities.

Surgical Technique

After induction of general anesthesia, the child is positioned prone. As per institutional protocol, intravenous ceftazidime is administered 30 minutes before incision. The operative field is cleaned with Savlon, followed by triple cleansing with 10% povidone-iodine (Betadine), allowing it to dry before sterile draping.

A standard midline incision is made. Dissection is carried down to expose the dura. Neural placodes are gently detethered and repositioned within the spinal canal (Figure 1). A watertight dural closure is achieved, followed by closure of the paraspinal muscle layers and skin. For large defects, a V-Y plasty technique is employed to facilitate tension-free skin closure (Figure 2).

Postoperative Care

Postoperatively, all patients are nursed in the prone position for five days. Broad-spectrum intravenous antibiotics are continued as per protocol. Wound care, vital monitoring, and serial neurological assessments are performed regularly during hospital stay.

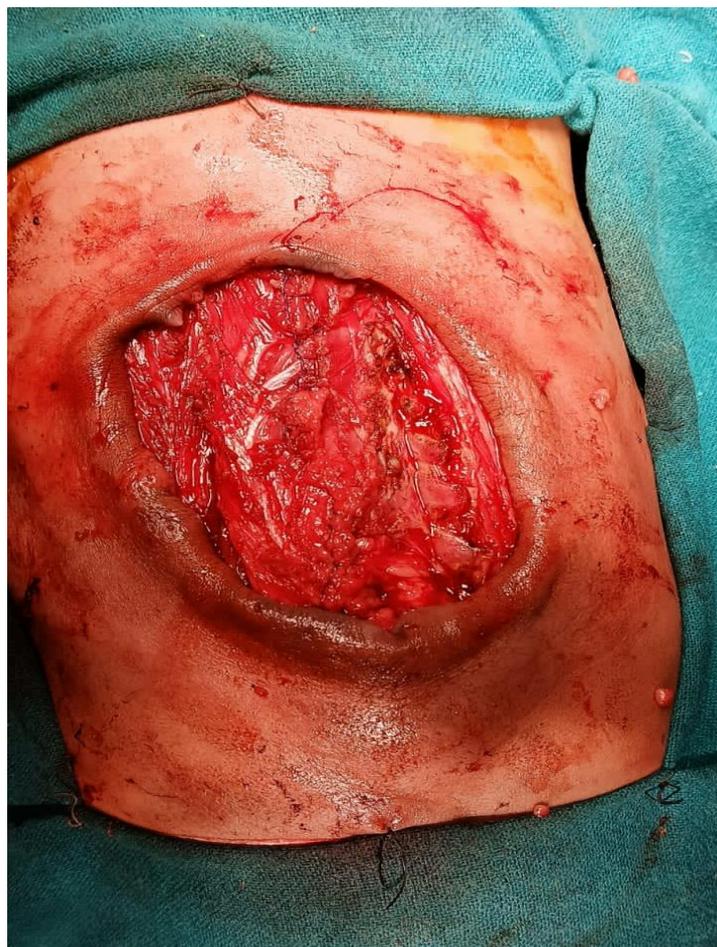


Figure 1. Separation of the skin and neural elements until Dura mater



Figure 2. Closure of the defect with fascia overlying the Para spinal muscles.

Postoperative Period

Post-surgical assessment was conducted immediately following the procedure and subsequently during follow-up visits scheduled at 1.5-month intervals. Preoperative meningomyelocele (MMC) infection was clinically diagnosed based on wound characteristics, such as erythema, discharge, or sloughing. The primary outcomes evaluated were mortality and postoperative non-neurological complications occurring within 30 days of surgery.

Results

A total of **105 patients** were included in the study, comprising **77 males** and **28 females**, yielding a male-to-female ratio of **2.7:1**. The **mean age at presentation** was **1 year and 7 days**, with the oldest patient being **4 years** of age.

Age Distribution at Presentation

- **Neonatal period (≤ 28 days): 23.3%** of patients

- **1 to 6 months: 58.4%**
- **>6 months: 18.3%**

Demographics

- **Rural background: 59%**
- **Urban background: 41%**

Clinical Features at Presentation:

- **Tethering of the spinal cord** was observed in **100%** of patients at presentation.
- **Defect size** varied from **4 × 4 cm to 11 × 9 cm**.
- The **shape of the lesion** was **elliptical** in **93 cases (88.6%)**.
- Lesion site distribution:
 - **Lumbosacral region: 59%**
 - **Cervical region: 35%**
 - **Thoracic region: 6%**

Notably, **none** of the patients underwent surgical repair **within the first three days of life**, which is the ideal window for minimizing complications.





Figure 3. A, B, C, D Gross presentation of Meningomyelocele at various anatomical location

Table 1. Gender Distribution, Mean Age & Lesion Site

Gender	N
Male	77
Female	28
Age (Years)	
At the time of surgery	1.07 Years
Site of defect	N=105
Lumber	62 (59%)
Cervical	37 (35%)
Thoracic	6 (6%)

29% Lesion were infected and 47% had cerebrospinal fluid leak. 23% cases already had hydrocephalus that underwent

ventriculoperitoneal shunting prior to MMC repair (Table 2).

Table 2. Pre-operative patient characteristics

Condition before surgery	N=105 ; Present in patients (%)
CSF leak	49 (47%)
Wound infection	30 (29%)
Hydrocephalus	24 (23%)

In the follow up period, 29% of patients experienced postoperative complication. The most common was wound dehiscence (12 patients) and wound

infection (12 patients). Transient cerebrospinal fluid leak was noted in 6 patients. However most complications were managed conservatively (Table 3).

Table 3. Post -operative Non-neurological complication

Complication	Number of patients
Wound Dehiscence	12 (11%)
Wound infection	12 (11%)
Cerebrospinal fluid leak	6 (~6%)
Death	1 (~1%)

Follow up outcomes

During follow-up, **13 patients (12%)** were **readmitted within 30 days** of discharge. The reasons for readmission included:

- **CSF shunt malfunction** in patients previously operated for ventriculoperitoneal (VP) shunting
- **Sepsis**, with identified sources including **pneumonia** and **urinary tract infections**

There was **one postoperative death**, attributed to **irreversible septic shock** in a patient with a severely infected lesion.

Discussion

This study provides valuable insights into the surgical management and

short-term outcomes of meningocele (MMC) repair in a tertiary care hospital in Northern India. Neural tube defects (NTDs) are significantly more prevalent in Northern India, with a reported incidence of 7.48 per 1000 live births. However, the **true incidence remains underreported**, especially in rural settings, due to the high frequency of home deliveries and limited access to healthcare facilities. In addition, **societal stigma** often results in inadequate postnatal care for both mothers and children with congenital anomalies. This frequently leads to **delayed presentation**, a trend driven by socioeconomic constraints, lack of antenatal awareness, cultural barriers, and gender-based disparities in education and healthcare-seeking behavior [16–18].

Timing of Surgery and Gender Disparity

According to international guidelines—such as those by the **Congress of Neurological Surgeons** and the **Spina Bifida Association**—MMC repair is ideally performed within **48 hours of birth** to reduce infection risk and neurological deterioration. [8–11] However, **none** of the patients in our cohort underwent surgery within the first three days of life, highlighting a significant deviation from global standards. This delay can be attributed to **preoperative infections, unrecognized hydrocephalus,** and limited local surgical resources.

In our study, the **mean age at surgery was 1.07 years,** and **male predominance (73.3%)** was observed. A similar male preponderance was reported in studies from Sub-Saharan Africa by O.E. Down et al. In contrast, Aftab S. et al. in Pakistan reported a female predominance (58.5%). This **regional gender variation** may reflect underlying **cultural attitudes,** especially in parts of Northern India, where gender bias may contribute to healthcare access disparities.

Anatomical Distribution and Complications

The **lumbosacral region** was the most commonly involved anatomical site in our study, consistent with findings by Zoghi et al., Karsonovich et al., and Alruwaili et al., who reported lumbosacral involvement in **22.3% to 55.7%** of cases. Cervical and thoracic MMCs were relatively less frequent.

A key concern in MMC surgery is the **risk of postoperative complications,** particularly wound-related issues. In our cohort, **12% of patients developed wound infections,** often associated with

wound dehiscence and CSF leaks. This is consistent with previous reports:

- **Reynolds R.A. et al. (Zambia)** reported an infection rate of 8% and mortality of 7%.
- **Rebecca et al.** observed wound dehiscence in 10 of 75 cases.
- **A study from Texas** reported wound dehiscence in 11% and infection in 6% of cases.
- **Khan A. et al.** found wound infections in 13.5%, CSF leaks in 23.7%, and hydrocephalus in 22.4% postoperatively.

Our findings highlight the **universally challenging nature of MMC wound care,** especially given the proximity of the lesion to the anal region, which increases the risk of fecal contamination. In developing countries, **malnutrition and poor hygiene** further complicate postoperative recovery. Although nutritional status was not assessed in our study, it remains a key variable for future investigations [18–19].

Mortality and Readmission

The **postoperative mortality rate in our study was 1%,** which is comparatively low. Higher mortality rates have been documented in other resource-limited settings: 6% in Tanzania and 7% in Zambia. A U.S.-based study reported a 3% mortality rate. Our study also recorded a **12% readmission rate** within 30 days, primarily due to **VP shunt malfunction, sepsis,** and **urinary tract infections.**

Limitations and Future Directions

While our study offers a **regional perspective on MMC repair,** it is not without limitations: [20–22].

- **Long-term outcomes**—such as cognitive function, motor ability, and neurogenic bladder/bowel dysfunction—were **not assessed**.
- The **nutritional status** of patients was not documented, although it likely played a role in wound healing.
- The **gender disparity** observed requires further sociological exploration.
- As only **surviving patients** presented to the hospital, the study may not capture the **true burden** of disease or mortality in the community.

Conclusion and Implications

This study underscores the **pressing need for early detection, timely surgical intervention, and a multidisciplinary approach** to MMC care in India. It also highlights broader issues of **gender bias, public health education, and postoperative care infrastructure**. Addressing these gaps is essential for improving both survival and quality of life in children affected by this debilitating congenital anomaly.

Statements and Declarations

Conflicts of interest

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

Funding

No funding was received for conducting this study.

Ethical Approval

Prior to initiation, ethical clearance was obtained from the institutional ethics committee.

Informed Consent

Informed written consent was acquired from the parents or legal guardians of all enrolled patients.

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ORIGINAL ARTICLE

Study of Immunohistochemical Expression of p53 and Ki-67 in Oral Squamous Cell Carcinoma

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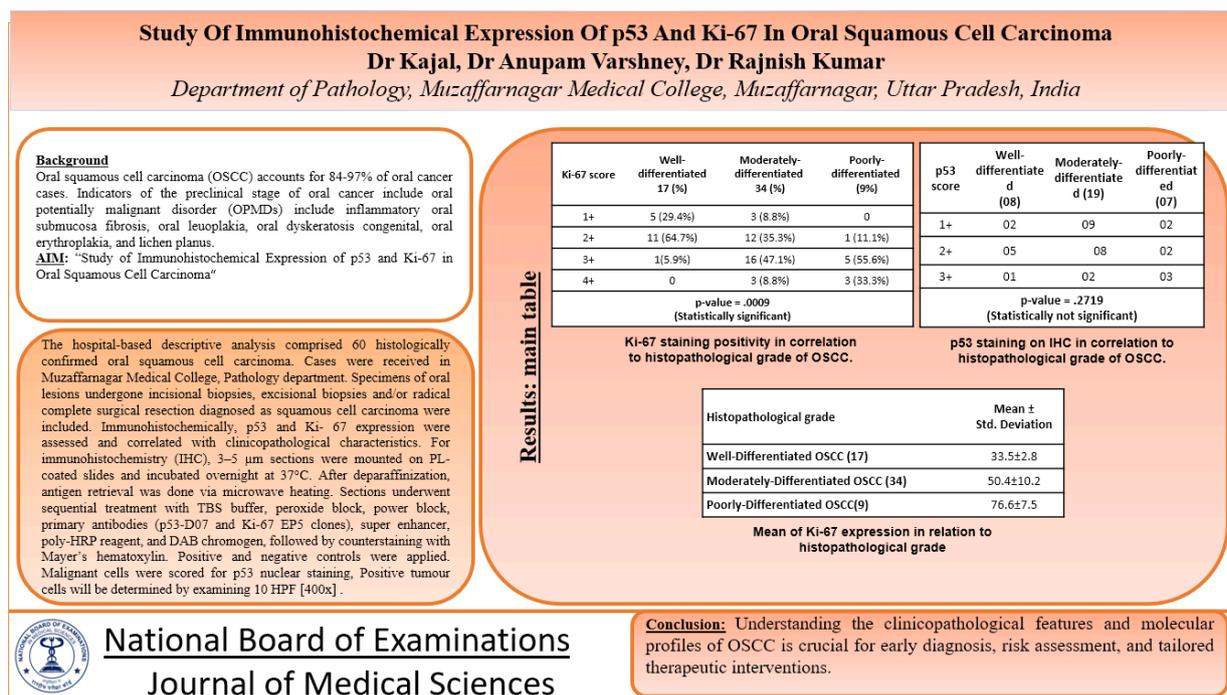
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Objective: “Study of Immunohistochemical Expression of p53 and Ki-67 in Oral Squamous Cell Carcinoma” **Methods:** The descriptive analysis, which was based in a hospital, comprised 60 cases of oral squamous cell carcinoma (OSCC). Cases presented at Muzaffarnagar Medical College, Pathology department. Immunohistochemically, p53 and Ki-67 expression were assessed and correlated with clinicopathological characteristics. **Results:** The Majority of cases having OSCC were in fifth and sixth decades. ‘The tongue is the most common site for OSCC.’ Tobacco use was present in 68.3% of patients. Most OSCC instances were moderately differentiated. p53 and Ki-67 expression were substantially higher in poorly differentiated patients. No significant correlation was seen between age, gender, or histological grade and 56.7% positive p53 expression. A strong correlation existed between age, histological grade, and Ki-67 expression. **Conclusion:** ‘The study highlights the importance of understanding oral squamous cell carcinoma patients' habits and characteristics for improvement of prognosis as well as the treatment options. These markers are recommended for assessing OSCC aggressiveness and progression, but further research is needed to understand their roles in treatment outcomes by incorporating a broader panel of markers.’

Keywords: Oral squamous cell carcinoma, Immunoexpression, p53, Ki-67

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Graphical Abstract



Introduction

Oral carcinoma is considered one of the most common malignancies worldwide, especially in underdeveloped countries. It is a prominent cause of death in India. In India, HPV causes 40% of oral malignancies, compared to 2–4% in Western countries. OSCC prognosis is poor due to delayed diagnosis, despite advances in diagnostic methods. Early identification can boost 5-year survival rates by 80% and improve quality of life [1].

GLOBOCAN 2022 data from the “International Agency for Research on Cancer (IARC)” reported 20million new cancer cases and 9.7million deaths worldwide. Lip and oral cancers were 16th in incidence and 15th in mortality, with 389,485 (2%) new cases and 88,230 (1.9%) deaths [2]. In India, oral cancer led to 75,290 deaths in 2020, accounting for 5.4 deaths per 100,000 population [3]. Central and Southeast Asia, including India, have high age-standardized incidence rates of 14.8/100,000 men and 4.6/100,000 women

[3].

Tobacco and alcohol use are major contributors to the multifactorial etiology of oral cancer, causing genetic and molecular alterations that lead to premalignant lesions [4]. Biomarkers at the molecular level can enhance early diagnosis and prognostic evaluation [5]. Leukoplakia and oral submucous fibrosis (OSMF) are common premalignant lesions that frequently appear before OSCC [1]. Leukoplakia, characterized by white oral mucosal patches, progresses to squamous cell carcinoma (SCC) in 5–43% of cases, depending on dysplasia severity [6].

Tumors are graded using Broder's classification based on differentiation and keratinization: Grade I (>75% “differentiated”), Grade II (>50 to 75%) and Grade III (25 to 50%) [7]. The TP53 gene encodes p53, a tumor suppressor that prevents genetic damage through DNA repair or apoptosis [8]. Mutations in p53, especially in exons 5–8, compromise this function, promoting tumor growth [9]. A

nuclear protein marker called Ki-67 is frequently used to measure tumour growth since it corresponds with cell proliferation [10,11]. This study aims to assess p53 and Ki-67 expression in OSCC using immunohistochemistry (IHC) in India. Emphasis on early detection and prevention remains critical [12].

Material and Methods

The present study, titled “Study of Immunohistochemical Expression of p53 and Ki-67 in Oral Squamous Cell Carcinoma,” had been performed in the Department of Pathology, “Muzaffarnagar Medical College, Muzaffarnagar (U.P.)”. This was a hospital record-based descriptive study for 18 months, including 60 cases of histologically diagnosed OSCC. Both retrospective and prospective samples were examined.

Inclusion criteria: Squamous cell carcinoma was identified in oral lesion specimens that underwent radical total surgical resection, excisional biopsies, or incisional biopsies.

Exclusion criteria: Tissues lacking

viable or representative material. Tissue biopsies of patients treated with radiation therapy and/or chemotherapy after being diagnosed with oral squamous cell carcinoma. Following their fixation in 10% buffered formalin, the samples were embedded in paraffin, processed by employing a semi-automated tissue processor (Thermo Scientific MICROM STP 120), and sectioned at 3–4µm by employing a rotary microtome (Thermo Scientific MICROM HM 325). The normal protocols for H&E (haematoxylin and eosin) staining were followed [13].

For IHC 3–5 µm sections had been mounted on PL-coated slides and incubated overnight at 37°C. After deparaffinization, antigen retrieval was done via microwave heating. TBS buffer, peroxide block, power block, primary antibodies (p53-D07 and Ki-67 EP5 clones), super enhancer, poly-HRP reagent, and DAB chromogen were applied to the sections one after the other. Mayer's haematoxylin was then used as a counterstain. Both negative and positive controls were used. Malignant cells were scored for p53 nuclear staining. Positive tumour cells will be determined by examining 10 HPF [400x] [14] (Table 1).

Table 1. p53 scoring

Score	Percentage
0	Less than 10% of malignant cells positive
1+	10 to 30% of malignant cells are positive
2+	31 to 50% of malignant cells are positive
3+	>50% of malignant cells are positive

Malignant cells had been scored for Ki-67 nuclear staining [Labelling index],

positive cells will be determined by examining 10 HPF [400x] [15] (Table 2).

Table 2. Ki-67 scoring

Score	Percentage
1+	LI=1% to 25% of malignant cells positive
2+	LI=26% to 50% of malignant cells positive
3+	LI=51% to 75% of malignant cells positive
4+	LI=>75% of malignant cells are positive

MedCalc software version 22.020 [16] was employed for statistical analysis and MS Excel was used to generate the data. “Ethical clearance had been obtained from the Institutional Ethics Committee” of Muzaffarnagar Medical College and informed consent had been taken from all patients. Observations were presented in tables and figures and analyzed using relevant statistical tools.

Results

For eighteen months, this descriptive retro-prospective study had been performed in the pathology department of “Muzaffarnagar Medical College and Hospital”. Following ethical approval and established

inclusion/exclusion criteria, sixty cases of OSCC with histological confirmation were included. Haematoxylin and Eosin (H&E) staining, standard processing, and tissue fixation were all performed. The expression of p53 and Ki-67 markers in tumour cells was evaluated by immunohistochemistry (IHC).

Demographic Characteristics

The average age of the patients was 50.68 ± 11.59 yrs., with a range of 30 to 80 years. The fifth decade noted to have highest incidence of 46.7 % followed by sixth decade (18.3%). With a male-to-female ratio of 5:1, males accounted for 83.3% of cases and were the most affected (Figure 1).

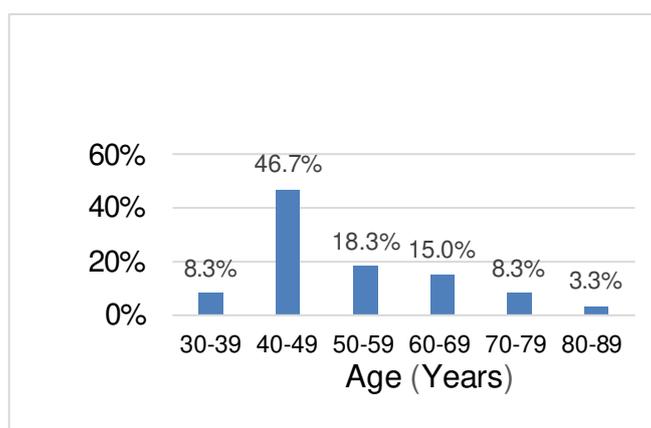


Figure 1. Bar chart showing age-wise distribution of OSCC (%)

Site Distribution

The tongue, especially the left lateral border, was the most frequently impacted region (36.6%). The gingiva

(10%) and buccal mucosa (35.0%) came next. Other less common sites involved the hard palate, lip, floor of the mouth, angle of mouth, and retromolar trigone (Figure 2).

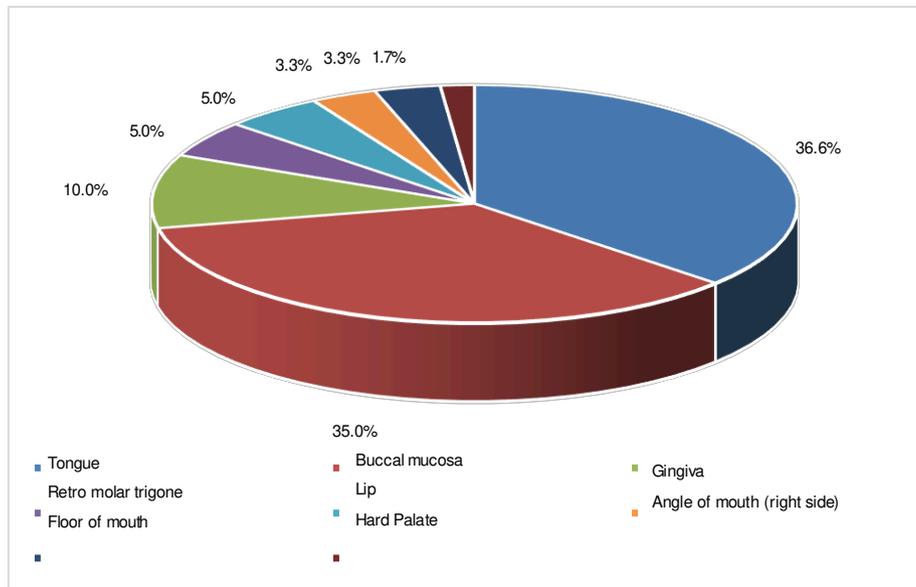


Figure 2. Pie chart showing distribution of OSCC according to sites

Tobacco Use

Tobacco users were categorized into three groups: Only tobacco chewers, only smokers, and both chewers as well as smokers. A significant number of OSCC patients (68.3%) had a history of tobacco use—30% used both chewers as well as smokers. 25% were smokers only, and 13.3% were tobacco chewers only. Non-users comprised 31.7%.

Specimen and Gross Morphology

Of the specimens, 56.7% were incisional biopsies, and 43.3% were

excisional. On gross examination, the ulcero-proliferative type was most common (45%), followed by proliferative (33.3%) and ulcerative (21.7%) types.

Histopathological Grading

Moderately differentiated OSCC was the most common histological grade (56.7%), followed by 28.3% (well-differentiated), and 15% of poorly differentiated type of OSCC. A correlation was observed between higher-grade tumors and use of both tobacco chewers and smokers (Figures 3 to 6).

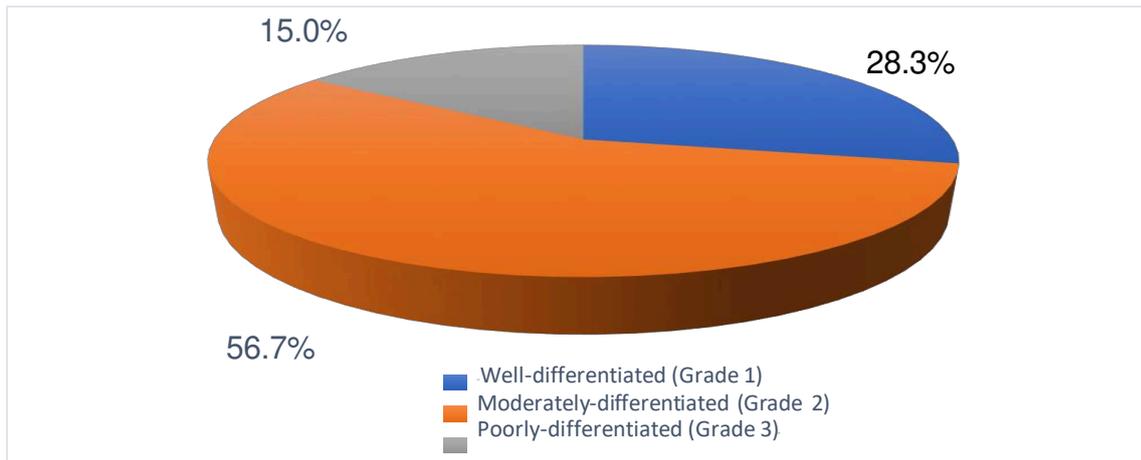


Figure 3. Pie chart showing distribution of study subjects according to histological grades of OSCC

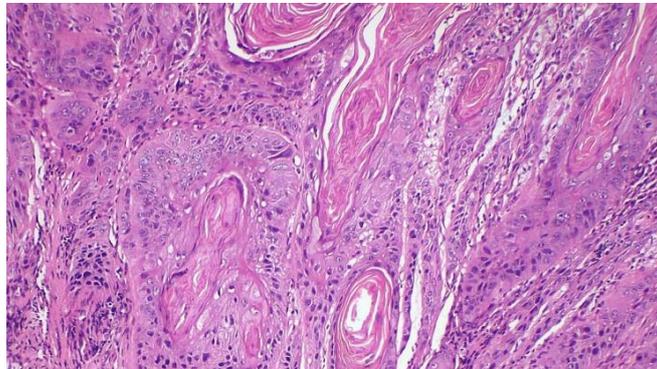


Figure 4. Photomicrograph of Well Differentiated “Oral Squamous Cell Carcinoma” (H&E 100x)

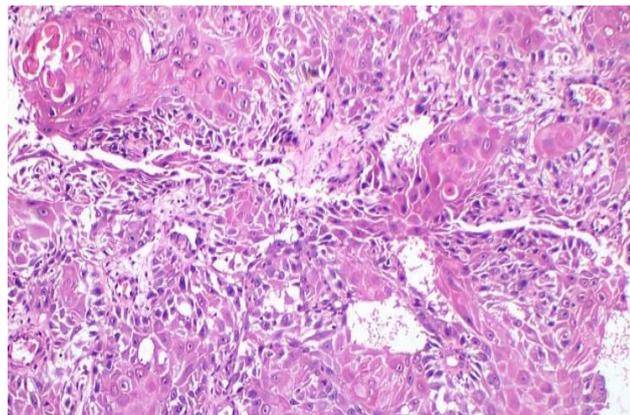


Figure 5. Photomicrograph of Moderately Differentiated “Oral Squamous Cell Carcinoma” (H&E 100x)

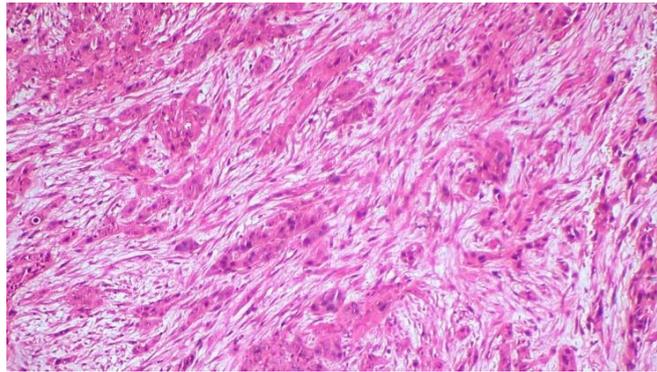


Figure 6. Photomicrograph of Poorly Differentiated OSCC (“Oral Squamous Cell Carcinoma”) (H&E 100X)

p53 Immunohistochemistry

p53 expression on IHC was positive in 56.7% of cases. The most frequent immune-expression was 2+ 15/34(44.1%), followed by 1+ 13/34(38.2%) and 3+ 6/34(17.6%). Positive p53 expression was slightly more prevalent in patients over 50 years (66.7%) compared to those 50 years or younger (50%). Males showed a higher rate of positivity (58%) than females (50%),

although statistical analysis did not show significance ($p > 0.05$). Poorly differentiated OSCC had the greatest p53 positivity among histological grades (77.8%), followed by moderately differentiated (55.9%) and well-differentiated (47%). However, these differences were also statistically nonsignificant (Figures 7 to 10).

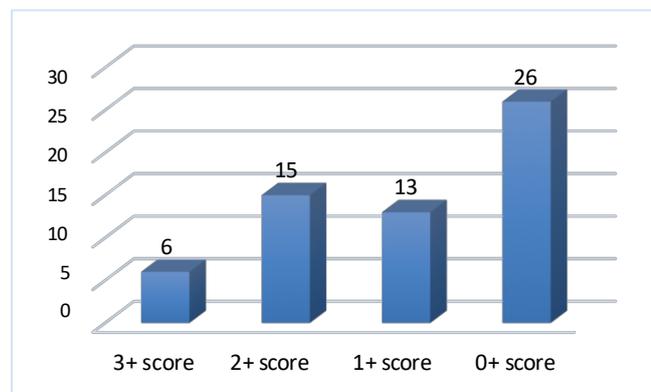


Figure 7. 3D column chart showing total number of cases in p53 score on IHC.

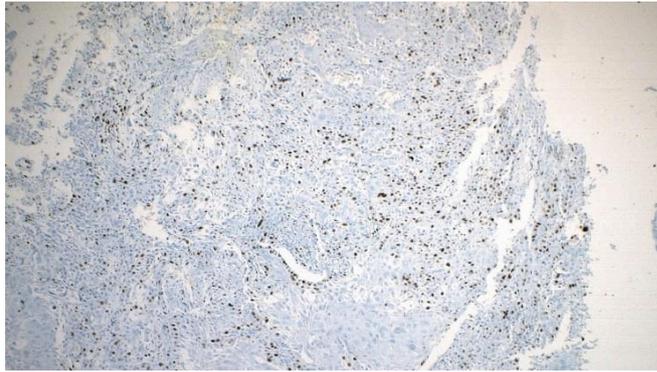


Figure 8. Photomicrograph showing immune-positivity for p53 score 1 (IHC 400x)

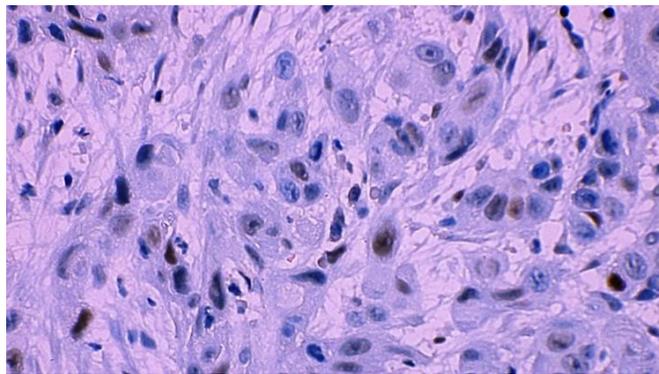


Figure 9. Photomicrograph displaying immunopositivity for p53 score 2 (IHC 40x)

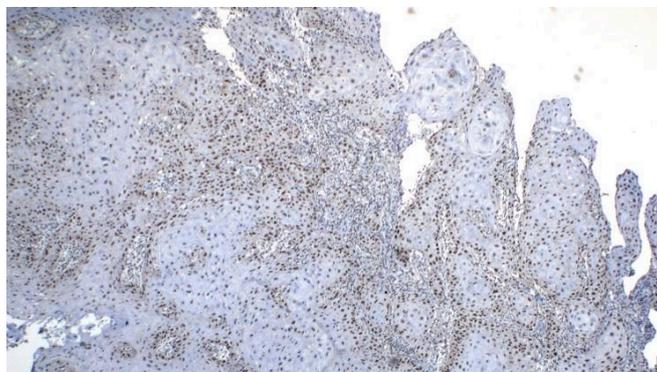


Figure 10. Photomicrograph showing immunopositivity for p53 score 3 (IHC 40x)

Ki-67 Immunohistochemistry

Ki-67 expression on IHC was evaluated. Most patients had moderate 2+ 24/60(40%) to high 3+, 22/60(36.7%) expression. Younger patients (≤ 50 years) had slightly higher Ki-67 positivity. Among histological grades, poorly differentiated

OSCC showed the highest Ki-67 expression (55.5% had 3+ or 4+), indicating a correlation with tumor aggressiveness. Well-differentiated OSCCs mainly showed lower scores (1+ and 2+) (Figures 11 to 14).

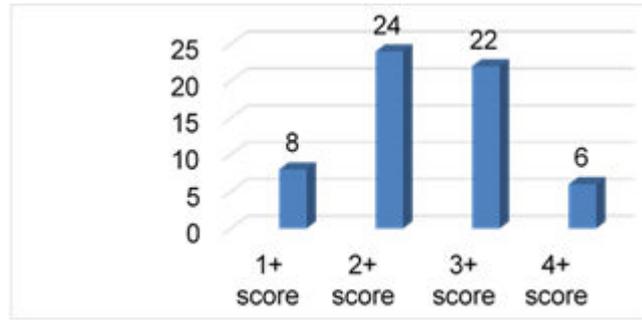


Figure 11. 3D column chart showing total number of cases in Ki-67 score

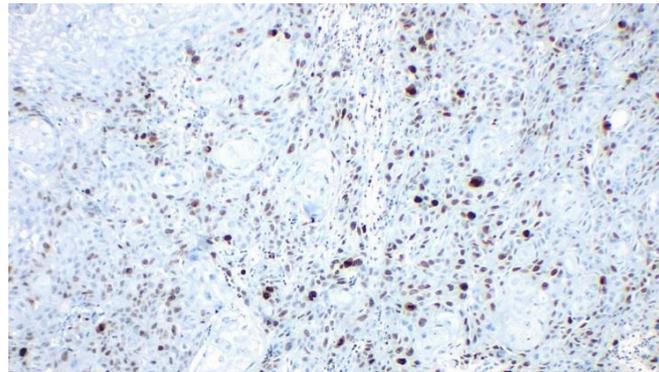


Figure 12. Photomicrograph showing immune positivity for Ki-67 score 2 (IHC 40x)

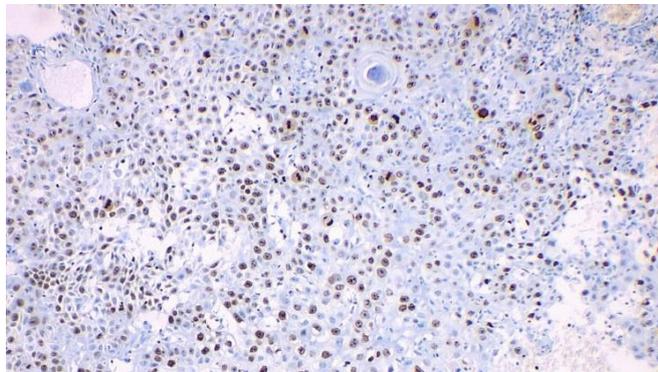


Figure 13. Photomicrograph showing immune positivity for Ki-67 score 3 (IHC 100x)

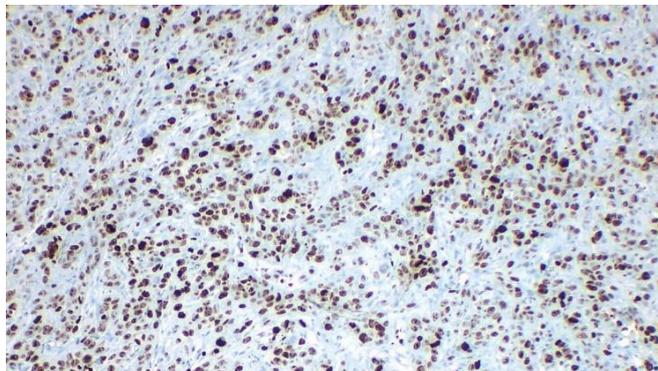


Figure 14. Photomicrograph showing immune positivity for Ki 67 score 4 (IHC 100x)

Discussion

In India, OSCC continues to be a major health burden, and its aetiology is significantly influenced by lifestyle factors including tobacco use. This study, conducted at “Muzaffarnagar Medical College in Uttar Pradesh”, has improved our understanding of the clinic-pathological and immune histochemical characteristics of OSCC. With a male-to-female ratio of 5:1, the disease primarily affects males in their 5th and 6th decades of life, according to a review of 60 histologically verified OSCC cases. The results were in line with those of Sahaf et al. [18] whose mean patient age was 51.8 years and Yasin et al. [17] whose mean diagnostic age was 48 years. Our study revealed a male preponderance in OSCC, which was consistent with results by Singh MP et al. [19] and Chandrakanta et al. [20].

The buccal mucosa, tongue, as well as gingiva were the most often affected anatomical areas, which is consistent with the areas' typical of tobacco chewing. The results aligned with research performed by Singh et al. [19], which observed that the buccal mucosa was the highly affected area in OSCC and that a history of tobacco use was also prevalent. Our findings were similar to those of Chandrakanta et al. [20]. It found that the tongue was the most frequently observed site (50%), followed by the buccal mucosa (18.42%).

The majority of the cases had moderately differentiated tumors, followed by well-differentiated and then poorly-differentiated tumors. The investigation closely resembles research by Yasin et al. [17], which found that moderately differentiated OSCC had the highest number of instances, well-differentiated OSCC had the second-highest number, and poorly differentiated OSCC had the least. The results contrasted with research by Sahaf et al. [18], who found that a large proportion of OSCC was well-differentiated, followed by OSCC that was moderately differentiated, and finally OSCC that was poorly differentiated.

The immune-histochemical analysis for p53 provided important insights into tumor biology. Our study found that p53 expression increased as histopathological grade increased. This result is in close agreement with the discoveries of Mohanapure et al. [15] regarding p53 expression, which showed that p53 expression was positive in 44% of well-differentiated OSCC, 53.8% of moderately-differentiated carcinoma, and 78.9% of poorly-differentiated carcinoma. We can infer that the histological OSCC grade significantly increases the p53 expression. According to a study by Singla et al. [14], p53 positivity was 100% in cases of moderately and poorly differentiated oral squamous cell carcinoma since no case was p53 negative in these situations (Table 3).

Table 3. Comparison between p53 positivity with scoring and histological grading

		Present study	Mohanapure et al 2022 [15]	Singla et al. 2016 [14]
Well differentiated	1	25%	36.4%	66.7%
	2	62.5%	63.6%	25.0%
	3	12.5%	0%	0%
Moderately differentiated	1	47.3%	50%	42.1%
	2	42.1%	42.9%	31.6%
	3	10.5%	7.1%	26.3%
Poorly differentiated	1	28.5%	46.6%	0%
	2	28.5%	26.7%	11.1%
	3	42.8%	26.7%	88.8%

The mean Ki-67 LI in the current study was significantly higher for poorly differentiated individuals ($76.6\% \pm 7.4\%$) than for moderately differentiated individuals ($50.4\% \pm 10.2\%$), which was significantly higher than for well-differentiated individuals ($33.5\% \pm 2.8\%$). The results aligned with the research conducted by Chanadrakanta et al. [20], which found that the KI-67 LI was 28.5% in well-differentiated OSCC, 42.8% in moderately-differentiated carcinoma, and 68.5% in poorly-differentiated carcinoma.

Both p53 and Ki-67 markers showed increased expression in poorly differentiated tumors, Ki-67 exhibited a statistically significant correlation with tumor grade, reflecting its role as a proliferation marker. On the other hand, p53 expression, though elevated in more aggressive tumors, did not show a significant association with age, gender, or histological grade, suggesting that its role in OSCC may be more complex and

influenced by additional genetic or environmental factors.

These results demonstrate the potential value of Ki-67 as a trustworthy biomarker for determining the aggressiveness of tumours and forecasting OSCC proliferative behaviour. The variable expression of p53, although not statistically significant in this cohort, indicates a possible involvement in tumor progression that warrants further investigation. Together, these markers may aid in better prognostication and could inform personalized treatment strategies in the future.

Conclusion

In conclusion, understanding the clinic pathological features and molecular profiles of OSCC is crucial for early diagnosis, risk assessment, and tailored therapeutic interventions. This work contributes to the increasing amount of data demonstrating the utility of

immunohistochemistry markers in the assessment of OSCC. Further large-scale, multi-centric studies incorporating a broader panel of biomarkers are recommended to deepen our understanding of OSCC pathogenesis and improve patient outcomes.

Statements and Declarations

Conflicts of interest

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

Funding

No funding was received for conducting this study.

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ORIGINAL ARTICLE

Study of Clinical Profile and Outcome of Neonates on Bubble Continuous Positive Airway Pressure Support vs Heated Humidified High Flow Nasal Cannula Support for Respiratory Distress in a Tertiary Care Hospital

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Abstract

Background: A major clinical problem, neonatal respiratory distress requires immediate action to enhance results. Neonates experiencing respiratory distress are frequently managed with non-invasive respiratory assistance, that includes Continuous Positive Airway Pressure (CPAP) and Heated Humidified High Flow Nasal Cannula (HHHFNC), especially in preterm neonates. CPAP is widely used to maintain airway pressure and prevent atelectasis, while HHHFNC delivers high-flow oxygen therapy with humidification, aiming to reduce the work of breathing. However, there is ongoing debate about relative effectiveness of these interventions. Comparing CPAP and HHHFNC in neonates up to 28 days old requiring non-invasive respiratory support (NIRS) is objective of current research for assessing effects on failure rates, survival, mortality, and duration of respiratory support. **Aim:** This study aims to study the clinical Profile and outcome of Neonates on Bubble Continuous Positive Airway Pressure Support Vs Heated Humidified High Flow Nasal Cannula Support for Respiratory Distress. **Discussion:** Comparing CPAP and HHHFNC in neonates up to 28 days old requiring NIRS is objective of current research to assess effects on failure rates, survival, mortality, and duration of respiratory support. **Conclusion:** In conclusion, current research results underscore distinct advantages and limitations of CPAP and HHHFNC in neonatal care. CPAP demonstrates efficiency and consistency, particularly for preterm and LBW neonates requiring intensive respiratory support. Conversely, HHHFNC offers suitability for term neonates, although with greater variability in clinical outcomes.

Keywords: Nasal Intermittent Positive Pressure Ventilation, Heated Humidified High-Flow Nasal Cannula, Respiratory distress syndrome, Continuous Positive Airway Pressure

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Graphical Abstract

Study Of Clinical Profile and Outcome of Neonates on Bubble Continuous Positive Airway Pressure Support Vs Heated Humidified High Flow Nasal Cannula Support for Respiratory Distress in a Tertiary Care Hospital

Dr. Ankit Kashyap¹, Dr. Manish Agrawal², Dr. Vandana Gupta³, Dr. Amrithesh Ranjan⁴**Background**

Neonates experiencing respiratory distress are frequently managed with non-invasive respiratory assistance, that includes Continuous Positive Airway Pressure (CPAP) and Heated Humidified High Flow Nasal Cannula (HHHFNC), especially in preterm infants. There is ongoing debate about relative effectiveness of these interventions. Comparing CPAP and HHHFNC in neonates up to 28 days old requiring non-invasive respiratory support (NIRS) is objective of current research for assessing effects on failure rates, survival, mortality, and duration of respiratory support.

Aim: This study aims to study the clinical profile and outcome of Neonates on Bubble Continuous Positive Airway Pressure Support Vs Heated Humidified High Flow Nasal Cannula Support for Respiratory Distress.

Methods: A hospital based observational study including neonates experiencing respiratory distress up to 28 days old that visited MMC, Muzaffarnagar's Paediatrics Department.

Sample size: 100 based on the number of admissions in NICU in the hospital.

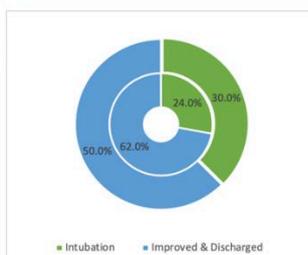
Inclusion Criteria: Even with additional oxygen, neonates with respiratory distress up to 28 days of age who are hospitalized in NICU require NIRS or oxygen saturation < 90%. Detailed history and examination of neonates for Birth weight, Period of gestation, cried immediately after birth or not, Anthropometry, any neonatal illness or death, etc. were taken as per pro-forma attached to find the co-relation between maternal risk factors and neonatal mortality and morbidity. HHHFNC was administered by nasal cannula at flows 1-2L/Kg/min with FiO₂ sufficient for maintaining SpO₂ between 96-98%. At PEEP of 5 cm H₂O, bubble CPAP is initiated, and FiO₂ is regulated for maintaining infants' saturation levels between 92-94%.

Statistical Analysis: Statistics could be conducted with SPSS 25.0 and related significance analyses. P-value of 0.05 indicates statistical significance. Before research commenced, institution's ethical committee gave its approval.

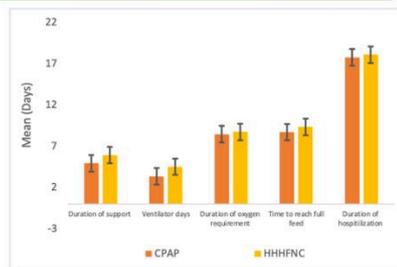
Main Results: CPAP showed more favourable outcomes across several parameters. Intubation was required in 24% of CPAP cases versus 30% in the HHHFNC group. Additionally, 62% of CPAP patients improved and were discharged compared to 50% in the HHHFNC group, suggesting better recovery with CPAP. The failure rates (need for additional non-invasive ventilation) were comparable between both groups (24% for CPAP and 30% for HHHFNC).

Regarding the course of hospital stay, CPAP patients had a significantly shorter mean duration of respiratory support (4.96 vs. 5.96 days), fewer ventilator days (3.38 vs. 4.54), shorter oxygen requirement (8.48 vs. 8.76 days), and faster time to reach full feeds (8.74 vs. 9.38 days), all statistically significant. However, the mean duration of hospitalization showed no significant difference (17.80 days for CPAP vs. 18.12 days for HHHFNC).

Overall, CPAP demonstrated superior clinical outcomes with shorter support durations and higher recovery rates, making it a more effective respiratory support method in this cohort compared to HHHFNC.



Donut Chart for Primary Outcome in CPAP vs HHHFNC



Deviation Bar Chart Comparison of Course of Hospital Stay in CPAP vs HHHFNC



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Conclusion: This study compares CPAP and HHHFNC in managing neonatal respiratory distress, examining maternal and neonatal factors, clinical outcomes, and hospital stay. CPAP showed better outcomes in shorter support duration, quicker feeding, and higher discharge rates. Overall, CPAP may be more effective for preterm and critically ill neonates.

Abbreviations

- APGAR – Appearance, Pulse, Grimace, Activity, Respiration
- ARDS – Acute respiratory distress syndrome
- BPD – Bronchopulmonary Dysplasia
- FiO₂ – Fraction of Inspired Oxygen
- FRC – Functional Residual Capacity
- GA – Gestational” “Age
- HHHFNC – Heated Humidified High-Flow Nasal Cannula
- IPP – Inspiratory Positive Pressure
- MAS – Meconium Aspiration Syndrome
- NICU – Neonatal Intensive Care Unit
- NIPPV – Nasal Intermittent Positive Pressure Ventilation
- PaO₂ – Partial Pressure of Oxygen
- CPAP – Continuous Positive Airway Pressure
- PEEP – Positive End-Expiratory Pressure
- PPHN – Persistent Pulmonary Hypertension of the Newborn
- RDS – Respiratory distress syndrome
- TTN – Transient Tachypnea of the” Newborn

Introduction

The most common problem in newborn globally is **respiratory distress**, affecting 3-7% of live births. It presents as increased work of breathing (WOB), tachypnoea, grunting, and chest retractions. Typical symptoms that indicate respiratory distress in neonates include subcostal and

intercostal retractions, tachypnoea, “grunting, cyanosis, lethargy, and refusal of feed. A healthy newborn's respiratory rate ranges from 40-60 breaths per minute [1,2].

Mortality and morbidity can be decreased in cases of respiratory distress by providing adequate and prompt resuscitation, oxygen supplementation,

maintaining an ideal temperature, prompt referral and providing optimal ventilatory support.” Assisted ventilation is an essential method for management of respiratory distress in neonates. It is an acute, short term intervention that wholly or partially supports the physical process of respiration until the newborn develops the ability to breathe unassisted.

Respiratory distress in neonates has diverse causes, classified by system. **Airway** issues include choanal atresia, micrognathia, Pierre Robin sequence, laryngomalacia, and tracheoesophageal fistula. **Pulmonary** causes include RDS, TTN, MAS, pneumonia, pneumothorax, PPHN, and pulmonary haemorrhage. **Cardiovascular** factors involve congenital heart disease, tamponade, effusion, and failure. **Thoracic** conditions like diaphragmatic hernia and chest wall deformities can impair breathing. **Neuromuscular** causes include HIE, cerebral anomalies, meningitis, haemorrhage, and medication effects. Other causes include sepsis, metabolic abnormalities, and acidosis. Prompt identification of the underlying etiology is essential for targeted management and to improve neonatal outcomes.

Conservative care, breathing support, and surfactant therapy are subsequently employed for ideal “management. Major interventions include:

1. Antenatal corticosteroids.
2. Respiratory support.
3. Exogenous surfactant.
4. Supportive care, that includes nutritional support, antibiotic therapy, fluid and electrolyte management, thermoregulation etc.

In neonates with gestational age of 28–34 weeks, 2 doses of betamethasone 12

mg 24 hrs apart or 4 doses of dexamethasone 6mg 12hrs intervals reduce the incidence of RDS, intraventricular hemorrhage, and mortality [6-7]. Several research projects, including RCTs and systematic reviews that examined impacts of HHHFNC and CPAP, have produced contradictory results in recent years. While certain investigations revealed that HHHFNC had higher failure rate than CPAP, others indicated that HHHFNC was just as effective as CPAP [3-11].

Methodology

Study Design

Hospital-based observational study.

Place of study

Paediatrics Department, Muzaffarnagar Medical College and Hospital.

Study population

Neonates experiencing respiratory distress up to 28 days old that visited MMC, Muzaffarnagar's Paediatrics Department.

Duration of study

18 months (1 year for data collection and 6 months for data analysis).

Sample size

100 based on the number of admissions in NICU in the hospital.

Sampling technique

For the initial 28 days of life, samples are taken from every neonate, whether they are inborn or born, suffering from RDS requires non-invasive respiratory support.

Inclusion Criteria

Even with additional oxygen, neonates with respiratory distress up to 28

days of age who are hospitalized in NICU require NIRS or oxygen saturation < 90%.

Exclusion Criteria

1) Age group for more than 28 days of life. 2) Neonates with significant congenital anomalies or cardiac anomalies. 3) Neonates with unstable cardiovascular status or requiring invasive ventilation on the day of admission. 4) Neonates with prolonged refractory seizures.

Study Procedure

Detailed history and examination of neonates for Birth weight, Period of gestation, cried immediately after birth or not, Anthropometry, any neonatal illness or death, etc. were taken as per pro-forma attached to find the co-relation between maternal risk factors and neonatal mortality and morbidity. Newborns' respiratory distress has been evaluated by Downe's and Silverman-Anderson scoring systems. Clinical respiratory distress is indicated by Downe's score of >4, and imminent respiratory failure is indicated by score of >7. Clinical respiratory distress is indicated by Silverman-Anderson score of >4, and impending respiratory failure is indicated by a score of >8. Scoring systems have been employed for determining extent of respiratory distress. Date and time of applying Bubble CPAP or HHHFNC are noted, and neonates are evaluated every 4 hours thereafter. HHHFNC was administered by nasal cannula at flows 1-2L/Kg/min with FiO₂ sufficient for maintaining SpO₂ between 96-98%. At PEEP of 5 cm H₂O, bubble CPAP is initiated, and FiO₂ is regulated for maintaining neonates' saturation levels between 92-94%. Clinical monitoring is conducted by pulse oximetry, X-rays, and

ABGs for determining requirements for any changes in settings. Notes have been maintained on duration of therapy and the time required to wean off.

Statistical Analysis

Statistics could be conducted with SPSS 25.0 and related significance analyses. P-value of 0.05 indicates statistical significance.

Ethical clearance

Research didn't include any experimentation. Patient's attendant has been informed of process in detail and provided informed consent. Direct or indirect commercial benefits hadn't been provided to anyone, including investigation subject. Before research commenced, institution's ethical committee gave its approval. Statistical analysis has been conducted with SPSS 25.0 software and a relevant statistical significance test. Statistically significant P-value is 0.05.

Results

Current research investigates and compares the clinical profiles and outcomes of neonates managed with two respiratory support modalities: CPAP and HHHFNC. A total of 200 neonates were studied, with 100 cases in each group. Maternal comorbidities were distributed similarly in both groups, with Meconium-Stained Liquor (MSL) being the most common, followed by leaking per vaginum (PV) and pregnancy-induced hypertension (PIH). Statistical analysis revealed no significant difference in distribution of maternal comorbidities in CPAP and HHHFNC groups (p=0.892), suggesting that maternal health factors did not strongly influence the choice of respiratory support.

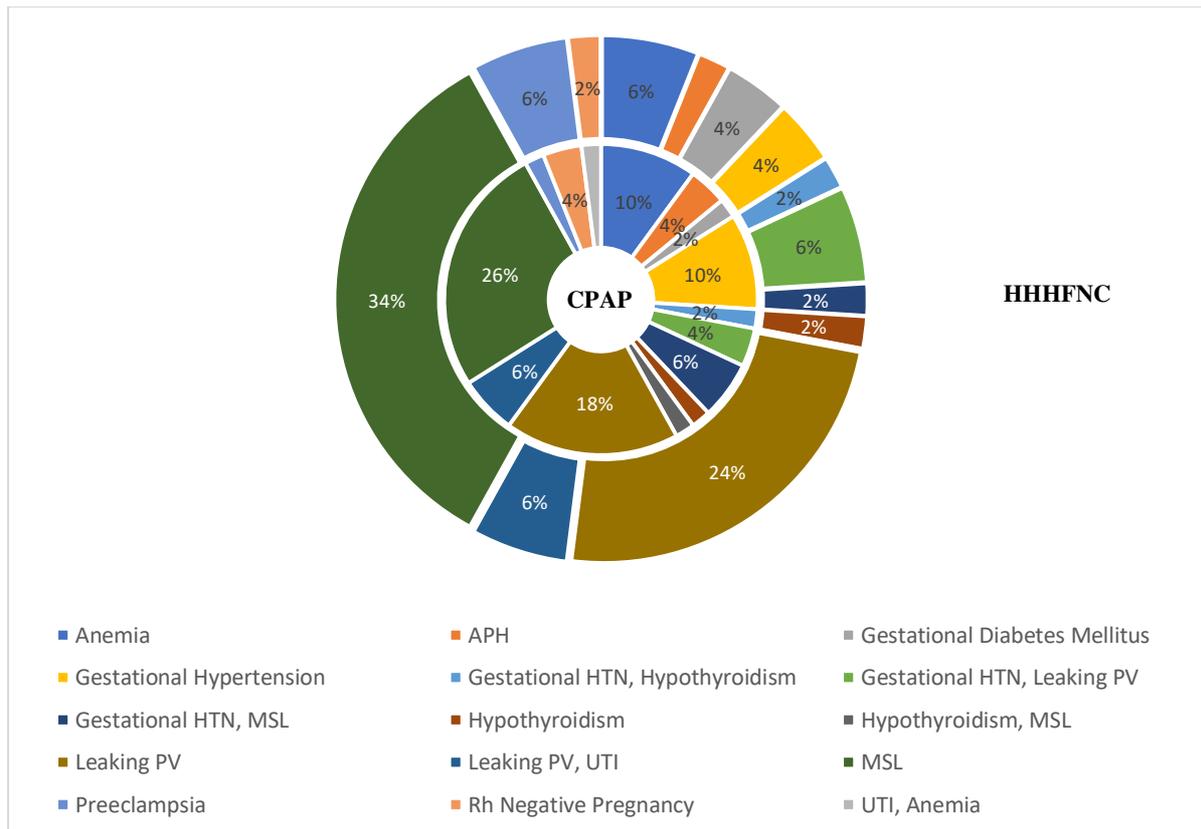


Figure 1. Donut Chart showing Comparison of Maternal Comorbidities in CPAP vs HHHFNC

However, the mode of delivery showed a significant difference. Lower segment cesarean section (LSCS) was far more frequent in HHHFNC group (96%) compared with CPAP group (62%), with statistically significant p-value of 0.001. This may reflect a trend where neonates delivered via cesarean section are more likely to receive HHHFNC, possibly due to milder respiratory distress.

Gender distribution was similar between the groups, indicating no gender-based preference or indication for either modality. In contrast, gestational age and birth weight showed highly significant differences. A higher proportion of preterm and low birth weight (LBW) neonates were managed with CPAP, while term and normal birth weight babies were more often treated with HHHFNC (p=0.001 for both).

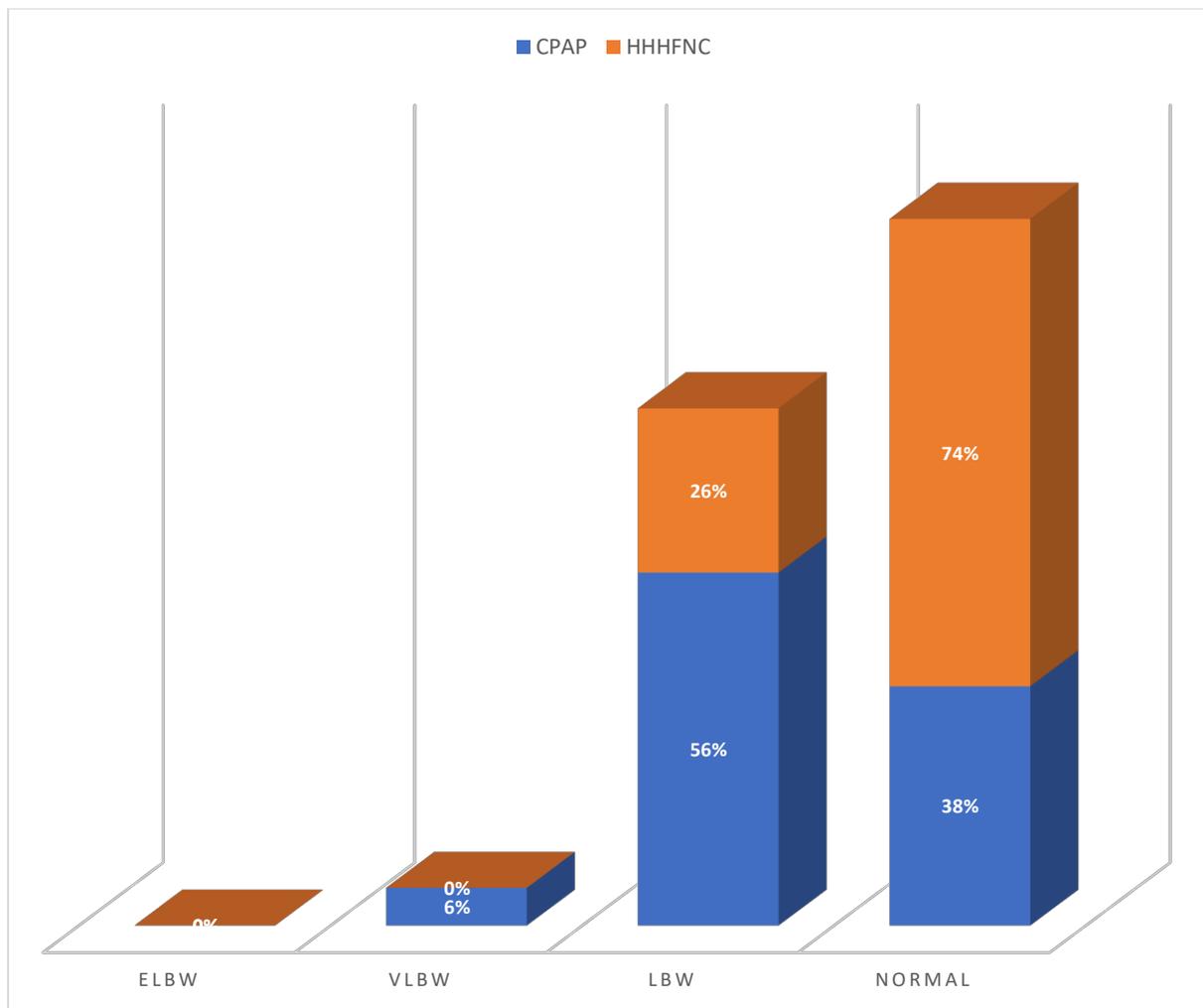


Figure 2. 3D BAR CHART Comparison of Birth Weight of Baby in CPAP vs HHHFNC

Similarly, small for gestational age (SGA) neonates were more commonly managed with CPAP, whereas appropriate for gestational age (AGA) babies have been more likely to receive HHHFNC ($p=0.028$). These results highlight that CPAP is preferred for more vulnerable neonates with higher clinical needs. Results indicate statistically significant difference in

gestational duration across groups ($p=0.001$). Preterm neonates were predominantly treated with CPAP (72%), whereas term neonates were more likely to receive HHHFNC (74%). Post-term neonates were rare in both groups, though slightly more received CPAP (10%) compared to HHHFNC (4%).

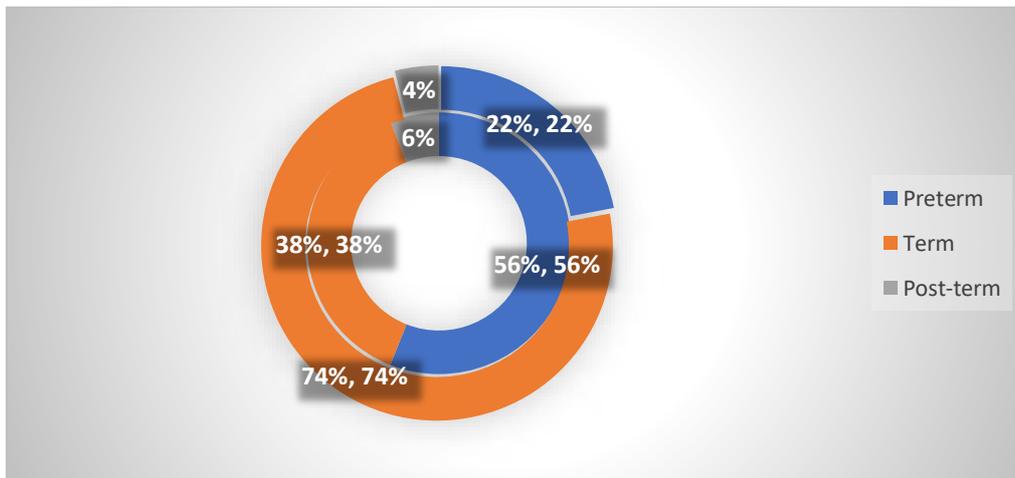


Figure 3. Donut chart Comparing Gestational Age of Baby in CPAP vs HHHFNC

Regarding the causes of respiratory distress, both groups primarily included neonates diagnosed with Meconium Aspiration Syndrome (MAS) and congenital pneumonia, often associated

with neonatal sepsis. While the precise cause of distress varied slightly, there was no significant difference in underlying diagnoses that guided the choice of CPAP or HHHFNC.

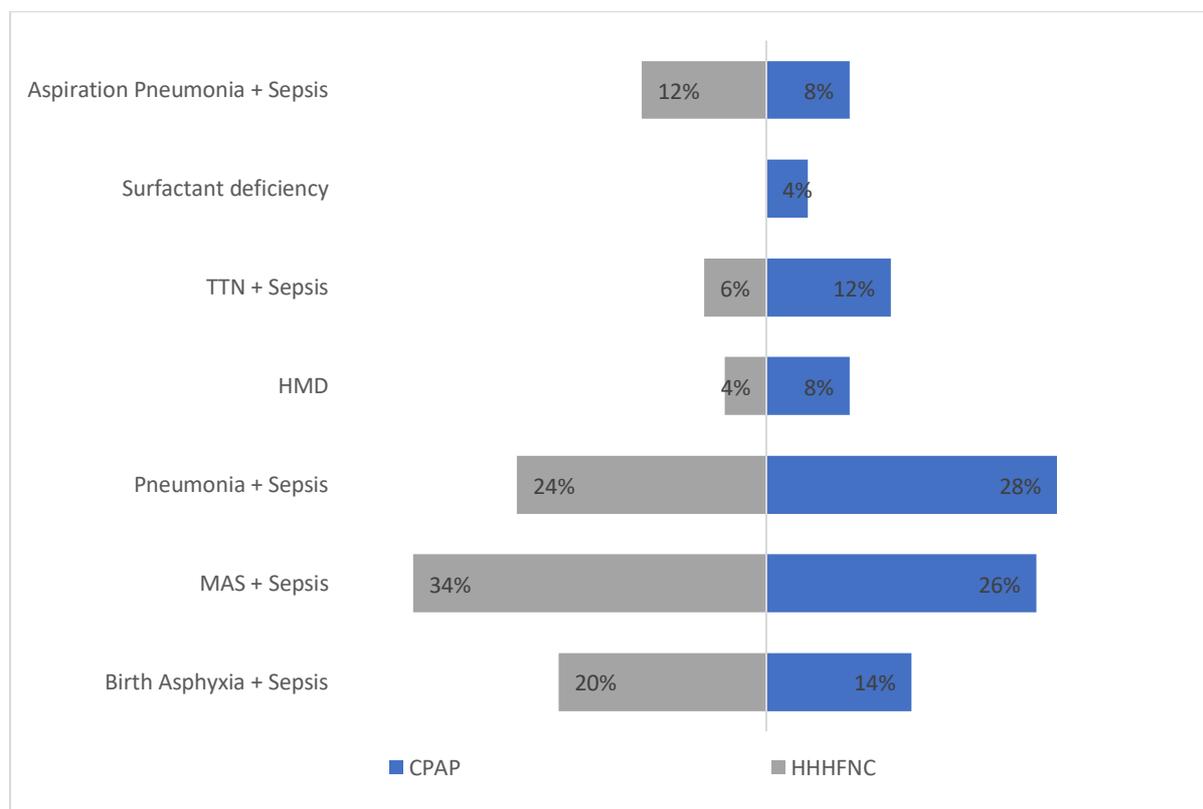


Figure 4. Bi directional chart comparing causes of respiratory distress in neonates on CPAP vs HHHFNC

Socio-economic status, evaluated using Modified Kuppuswamy Classification, showed no significant correlation with the selection of respiratory support modality ($p=0.165$), indicating that clinical condition rather than economic background influenced treatment decisions.

Assessment of respiratory distress using Silverman-Anderson and Downe's scores at admission revealed that neonates treated with CPAP generally presented with more severe respiratory distress compared to those in the HHHFNC group. Over time, both groups showed significant clinical improvement in scores, but the initial severity was higher in the CPAP group.

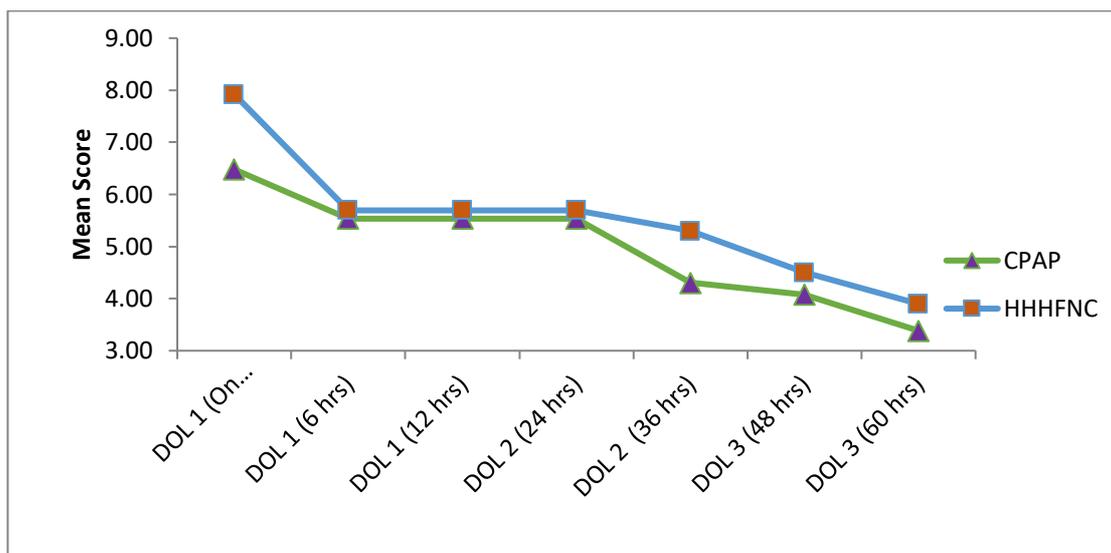


Figure 5. Line graph Comparison of Silverman Anderson's Scoring in CPAP vs HHHFNC

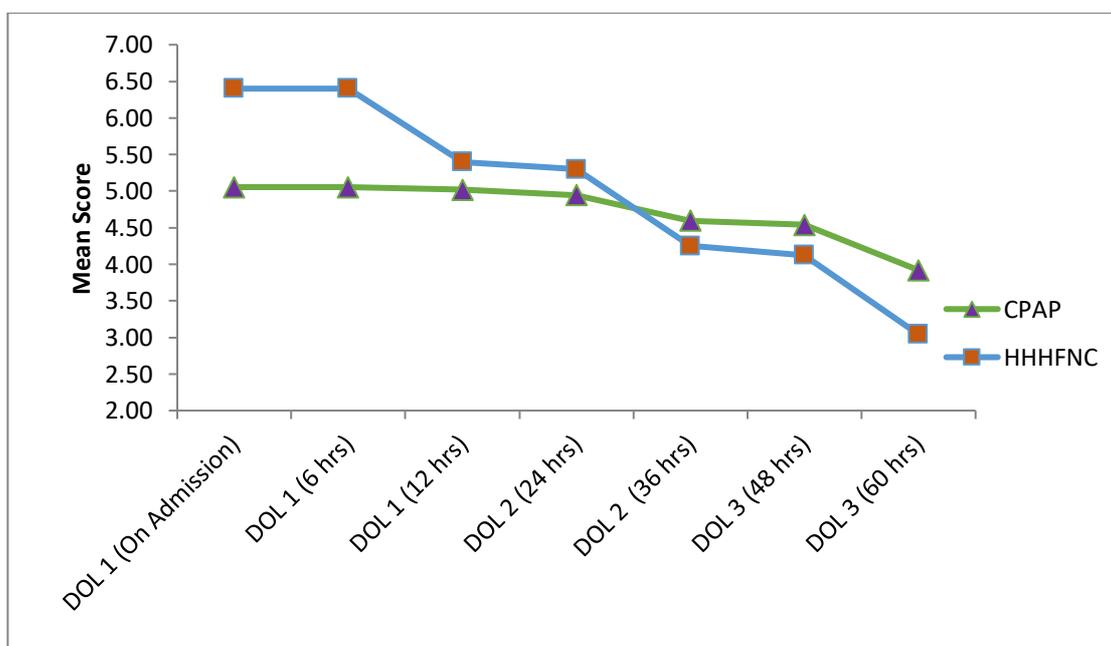


Figure 6. line graph Comparison of Downe's Scoring in CPAP vs HHHFNC

CPAP showed more favourable outcomes across several parameters. Intubation was required in 24% of CPAP cases versus 30% in the HHHFNC group. Additionally, 62% of CPAP patients improved and were discharged compared to

50% in the HHHFNC group, suggesting better recovery with CPAP. The failure rates (need for additional non-invasive ventilation) were comparable between both groups (24% for CPAP and 30% for HHHFNC).

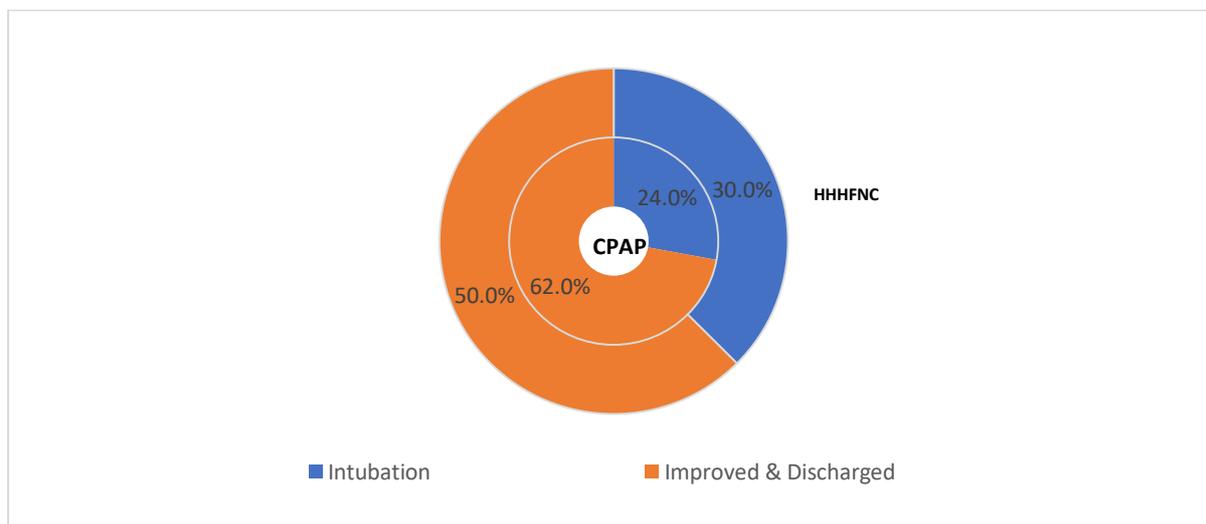


Figure 7. Donut Chart for Primary Outcome in CPAP vs HHHFNC

Regarding the course of hospital stay, CPAP patients had a significantly shorter mean duration of respiratory support (4.96 vs. 5.96 days), fewer ventilator days (3.38 vs. 4.54), shorter oxygen requirement (8.48 vs. 8.76 days),

and faster time to reach full feeds (8.74 vs. 9.38 days), all statistically significant. However, the mean duration of hospitalization showed no significant difference (17.80 days for CPAP vs. 18.12 days for HHHFNC).

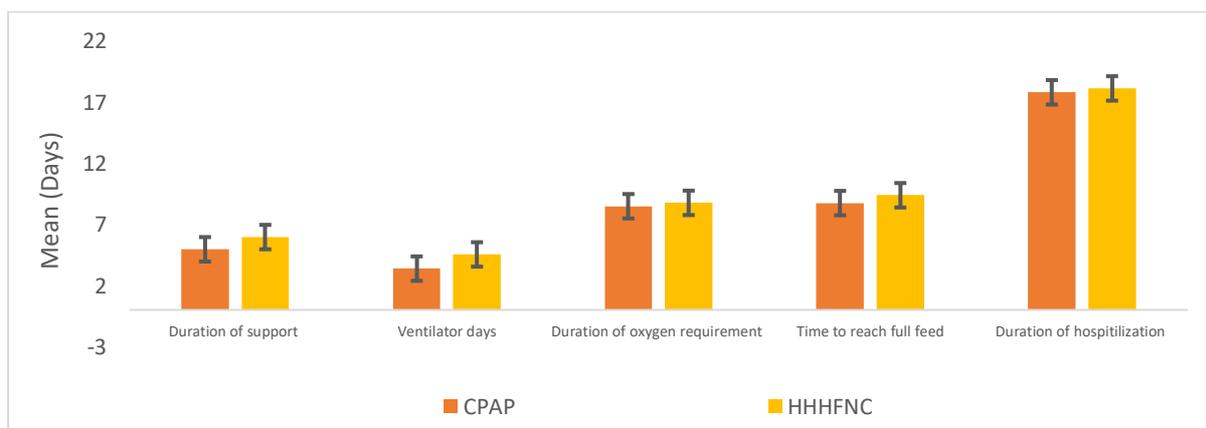


Figure 8. Deviation Bar Chart Comparison of Course of Hospital Stay in CPAP vs HHHFNC

Overall, CPAP demonstrated superior clinical outcomes with shorter support durations and higher recovery rates, making it a more effective respiratory support method in this cohort compared to HHHFNC.

Conclusion

This study compares CPAP and HHHFNC in managing neonatal respiratory distress, examining maternal and neonatal factors, clinical outcomes, and hospital stay. Maternal comorbidities showed no significant influence on treatment choice, while mode of delivery did, with HHHFNC linked to caesarean births and CPAP to vaginal deliveries. CPAP was used more in preterm and low birth weight neonates, while HHHFNC was favoured for term neonates. Both modalities had similar intubation and treatment failure rates, but CPAP showed better outcomes in shorter support duration, quicker feeding, and higher discharge rates. Overall, CPAP may be more effective for preterm and critically ill neonates.

Limitations and Future Scope

Generalizability is restricted by research's single-centre design and small sample size. Selection and exclusion criteria may introduce bias, focusing only on certain neonates. Lack of post-discharge follow-up prevents assessment of long-term outcomes. Additionally, reliance on limited statistical methods may overlook complex clinical interactions.

To increase neonatal respiratory support systems efficacy, future research should focus on improving treatment protocols and assessing long-term results. This work provides a foundation for improving clinical decision-making and advancing the quality of neonatal care.

Statements and Declarations

Conflicts of interest

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

Funding

No funding was received for conducting this study.

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ORIGINAL ARTICLE

A Prospective Comparative Study on the Incidence and Predictors of Difficult Intubation in Cardiac Versus Non-Cardiac Surgical Patients in a Tertiary Care Centre

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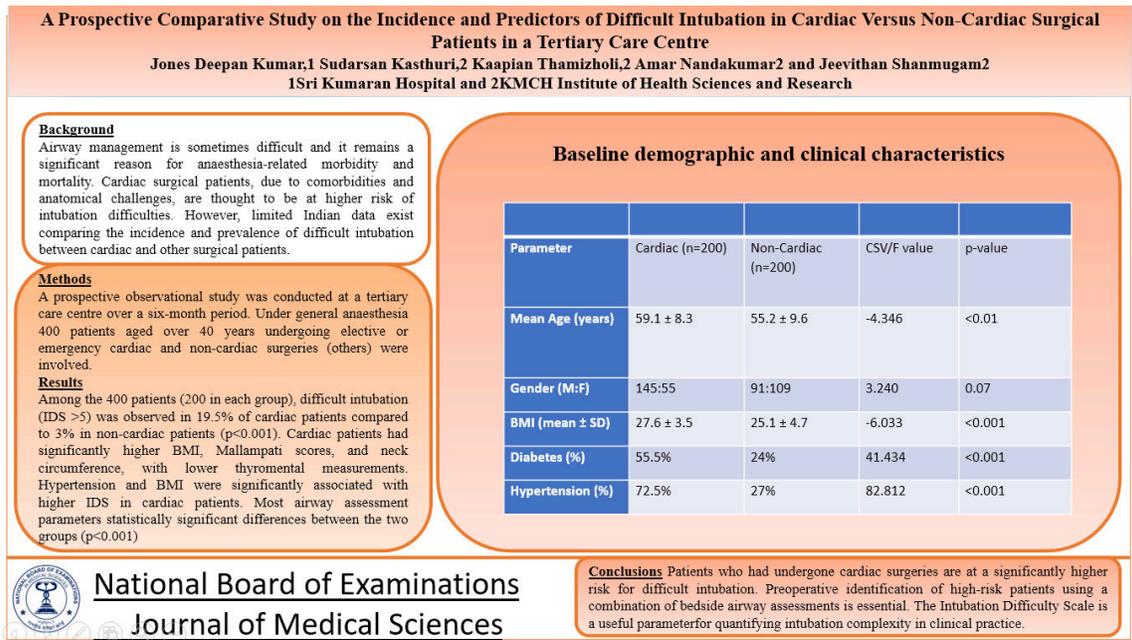
Abstract

Introduction: Airway management is sometimes difficult and it remains a significant reason for anaesthesia-related morbidity and mortality. Cardiac surgical patients, due to comorbidities and anatomical challenges, are thought to be at higher risk of intubation difficulties. However, limited Indian data exist comparing the incidence and prevalence of difficult intubation between cardiac and other surgical patients. The current research aims at assessment and comparison of the incidence and predictors of difficult intubation in these two patient groups. **Materials and Methods:** A prospective observational study was conducted at a tertiary care centre over a six-month period. Under general anaesthesia 400 patients aged over 40 years undergoing elective or emergency cardiac and non-cardiac surgeries (others) were involved. **Results:** Among the 400 patients (200 in each group), difficult intubation (IDS >5) was observed in 19.5% of cardiac patients compared to 3% in non-cardiac patients ($p < 0.001$). Cardiac patients had significantly higher BMI, Mallampati scores, and neck circumference, with lower thyromental measurements. Hypertension and BMI were significantly associated with higher IDS in cardiac patients. Most airway assessment parameters statistically significant differences between the two groups ($p < 0.001$). **Conclusion:** Patients who had undergone cardiac surgeries are at a significantly higher risk for difficult intubation. Preoperative identification of high-risk patients using a combination of bedside airway assessments is essential. The Intubation Difficulty Scale is a useful parameter for quantifying intubation complexity in clinical practice.

Keywords: Difficult intubation, Cardiac anaesthesia, Intubation Difficulty Scale, Airway assessment, Predictive factors

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Graphical Abstract



Introduction

Managing airway safely is the cornerstone of modern anaesthesia practice. Difficult tracheal intubation remains a major contributor to anaesthesia-related morbidity and mortality despite advancements in techniques and devices. Efficient airway control during the induction phase is both a challenge and a measure of success for the anaesthesiologist. A difficult airway is defined as “the clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with facemask ventilation of the upper airway, difficulty with tracheal intubation, or both” [1].

Difficult airway (DA) and intubation are frequently encountered in cardiac anaesthesia, partly due to the demographic profile and anthropometric

measurements of the patients with cardiac conditions [2]. Many cardiovascular surgeries are performed under emergency settings, leaving insufficient time for a comprehensive preoperative airway assessment. Consequently, many difficult intubations in the cardiac operation theatre remain unanticipated [2]. Moreover, patients presenting for cardiac surgery often belong to an older age group and are typically called as American Society of Anesthesiologists (ASA) Physical Status III or above. Comorbidities such as diabetes mellitus, obesity, and hypertension are common in this population. These factors make the induction of anaesthesia particularly precarious, as any hemodynamic disturbance during intubation can be poorly tolerated [1].

These cardiac patients often have fixed cardiac output and impaired compensatory or restoratory mechanisms. Sympathetic responses elicited by laryngoscopy and tracheal intubation—resulting in abrupt changes in heart rate and systemic vascular resistance—can exacerbate hemodynamic instability. Additionally, conditions like diabetes mellitus may lead to limited joint mobility syndrome, including atlanto-occipital joint stiffness, which compromises optimal neck and head extension and increases the risk of difficult laryngoscopy [3].

Adverse outcomes associated with airway mismanagement continue to be a major cause of anaesthesia-related brain injury and mortality. According to closed claims analysis, failure to maintain the airway and subsequent hypoxaemia is the main concern for the majority of irreversible patient harm [4]. Although several bedside assessments such as thyromental distance, the Mallampati classification, and Wilson scoring are widely used [7–9], their accuracy is hindered by observer variability and non-uniform definitions of difficult intubation [5]. Imaging-based assessments, while more precise, are impractical for large-scale preoperative screening [6]. Hence, a comprehensive understanding of the predictors of difficult airway can potentially mitigate life-threatening complications [9–11].

However, predictive outcomes from existing studies have been inconsistent and often evolve over time [12]. In a large-scale analysis of over

21,000 cases using propensity score methods, Heinrich et al. demonstrated a statistically significant higher incidence of difficult laryngoscopy in cardiac surgical patients (7.5%) compared to general surgical patients (5.7%) [2]. In the Indian context, the available literature remains limited. Krishna et al. gave 8.5% incidence of difficult intubation, although their findings were based on optimal Cormack-Lehane grading with external manipulation. Furthermore, individual predictors show only modest sensitivity and specificity when used in isolation. Importantly, the surgical intervention is a potential independent risk factor for difficult intubation which has to be thoroughly investigated [13].

Given the limited data from Indian settings and the growing population of high-risk surgical candidates, this study was undertaken to explore whether patients posted for cardiac surgery face a higher incidence of difficult intubation. The primary objective was to compare the incidence of difficult intubation in patients posted for cardiac versus non-cardiac surgery. Secondary objectives included assessing the relationship between difficult intubation and associated comorbidities, as well as its correlation with laryngoscopic grading.

Materials and Methods

The present study is a prospective observational study conducted at Kovai Medical Centre and Hospital, a tertiary care centre in

Coimbatore, from October 2018 to April 2019. Patients above the age of 40 years who were posted for elective or emergency cardiac and other surgeries under general anesthesia with endotracheal intubation were included. The study was seen and approved by the Institutional Ethics Committee, and an informed written consent was received from the study participants.

Patients diagnosed with cervical spine fractures, upper airway pathology, pregnancy, or a known history of difficult laryngoscopy or with gastroesophageal reflux were not included in the study. A total of 400 patients were enrolled, with 200 in each group. The sample size was calculated based on retrospective data, with a power of 80%, alpha error of 5%, and an expected difference in proportions between the groups. Although the calculated sample size was 211 per group, 200 patients in each group were finally included.

Preoperative airway assessments included Modified Mallampati Score, inter-incisor distance, thyromental height, neck circumference, thyromental distance, range of head and neck movement, mandibular protrusion, and dentition. Standard monitors were applied in all patients. Additional arterial and central venous lines were inserted in cardiac surgery patients as per protocol. Anesthesia was induced with fentanyl, propofol or etomidate, and a muscle relaxant (atracurium or vecuronium). The choice of drugs and laryngoscope blade size were left under the choice of

the attending anesthesiologist who has at least two years of experience.

For 3 minutes, all patients were preoxygenated. Intubation was done in the sniffing position using a Macintosh blade. In accordance with All India Difficult Airway Association guidelines, a difficult airway cart was kept ready. Using the Intubation Difficulty Scale (IDS), the intubation difficulty was evaluated which accounts for operators, number of attempts, alternative techniques, Cormack-Lehane grade, applied lifting force, need for external laryngeal pressure, and vocal cord position. A score of 0 was considered easy, 1–5 moderate difficulty, and >5 very difficult.

The endpoint of the study was an efficient tracheal intubation confirmed by capnography auscultation, chest rise,. Data was recorded in Microsoft Excel and analyzed using SPSS software. Descriptive statistics were used to summarize patient characteristics. Categorical variables were analysed using continuous variables using t-tests or non-parametric equivalents and chi-square or Fisher's exact test, depending on normality. Correlation analysis was performed to assess associations between continuous variables. A p-value of less than 0.05 was considered statistically significant.

Results

In this research, 400 patients were studied, comprising 200 undergoing cardiac surgery and 200 undergoing non-cardiac surgery. The

average age of the study population was 57.2 years (SD \pm 9.3), and 59% were males. The patients who had undergone Cardiac surgery had a higher prevalence of diabetes (55.5% vs. 24%) and hypertension (72.5% vs. 27%). Body Mass Index (BMI) was significantly higher in the cardiac group ($p < 0.001$). No statistically significant difference was observed in gender distribution between the groups ($p = 0.07$),

suggesting that sex did not independently influence intubation difficulty.

Difficult intubation, defined as IDS > 5 , was seen in 19.5% of patients in the cardiac group compared to 3% in the non-cardiac group. The difference found was statistically significant ($\chi^2 = 33.29$, $p < 0.001$), which indicates a strong association between surgical group and intubation difficulty (Table 1).

Table 1. Baseline demographic and clinical characteristics

Parameter	Cardiac (n=200)	Non-Cardiac (n=200)	CSV/F value	p-value
Mean Age (years)	59.1 \pm 8.3	55.2 \pm 9.6	-4.346	<0.01
Gender (M:F)	145:55	91:109	3.240	0.07
BMI (mean \pm SD)	27.6 \pm 3.5	25.1 \pm 4.7	-6.033	<0.001
Diabetes (%)	55.5%	24%	41.434	<0.001
Hypertension (%)	72.5%	27%	82.812	<0.001

Cardiac surgery patients had significantly higher Modified Mallampati Scores and Neck Circumference, with lower Thyromental

Distance and Height, all statistically significant. The Intubation Difficulty Score (IDS) was also higher in the cardiac group (Table 2).

Table 2. Comparison of airway assessment parameters and Intubation Difficulty Score

Airway Parameter	Cardiac (Mean \pm SD)	Non-Cardiac (Mean \pm SD)	F value	p-value
Modified Mallampati Score	2.40 \pm 0.49	2.00 \pm 0.43	-8.677	<0.001
Inter-Incisor Distance (cm)	4.20 \pm 0.32	4.48 \pm 0.62	5.675	<0.001
Thyromental Distance (cm)	6.84 \pm 0.22	7.23 \pm 0.47	10.628	<0.001
Thyromental Height (cm)	4.37 \pm 0.23	4.77 \pm 0.42	11.813	<0.001
Neck	36.46 \pm 2.90	35.22 \pm 2.73	-4.403	<0.001

Circumference (cm)				
Intubation Difficulty Score	4.14 ± 1.25	1.93 ± 1.46	-16.261	<0.001

Further analysis revealed significant positive correlations between BMI and Intubation Difficulty Score ($r = 0.42$, $p < 0.001$), and between Neck Circumference and IDS ($r = 0.38$, $p < 0.001$), suggesting that patients with higher BMI and neck circumference are more likely to experience difficult intubation. Modified Mallampati Score also showed a moderate positive correlation with IDS ($r = 0.47$, $p < 0.001$).

Among patients with IDS >5 , 70% belonged to the cardiac surgery group. The incidence of Cormack-Lehane Grade III or IV view was noted in 22 cardiac patients and only 5 non-cardiac patients. Intraoperative complications such as mucosal trauma and desaturation episodes were more reported in cardiac patients with high IDS scores, though not statistically analyzed in this study. Use of adjuncts like bougie and external laryngeal manipulation was required in 18.5% of cardiac patients versus 4.5% of non-cardiac patients.

This study evaluated 400 patients, evenly distributed between cardiac and non-cardiac surgical groups, to assess predictors and incidence of difficult intubation. The overall mean age was 57.18 years, with males constituting 59% of the cohort. Cardiac patients had more prevalence of

complications like diabetes and hypertension. The incidence of overweight and obesity was also notably higher among cardiac surgical patients. Difficult intubation (IDS >5) was observed in 19.5% of cardiac surgery patients and only 3% in non-cardiac patients, a statistically significant finding. These findings are slightly lower compared to Borde DP et al. who reported an overall incidence of 19.46%, with 24% among cardiac and 14.4% in non-cardiac groups [14].

Airway parameters like Modified Mallampati Score, thyromental distance, inter-incisor distance, thyromental height, and neck circumference were different significantly between the two groups. These measurements were correlated with higher IDS in cardiac patients, especially among those with elevated BMI, older age, and comorbidities. Although various studies suggest these tests individually have limited predictive value [19], combining them provides better diagnostic accuracy.

The Intubation Difficulty Scale (IDS), a validated tool blending subjective and objective criteria, proved effective for stratifying difficulty. Among obese cardiac patients, IDS >5 was found in 28.8% of cases, comparable to the 16.5% incidence reported by Siriussawaku et al. using

IDS [15]. Although laryngoscopy grade heavily influences IDS, poor glottic views do not universally indicate difficult intubation [16,17].

Correlation analysis revealed that both age and BMI correlated with IDS in non-cardiac patients, while in cardiac patients, only BMI showed a significant relationship. The presence of hypertension was significantly associated with IDS among cardiac patients. Smita Prakash et al. similarly identified several predictors including age, gender, Mallampati grade, inter-incisor and thyromental distances, and neck anatomy in an Indian population [18].

Although statistical significance was observed in many parameters, no single airway test was sufficiently predictive. A multifactorial approach remains essential. Complications of difficult airway management include mucosal trauma, hypoxemia, aspiration, and neurological injury, underlining the need for thorough preoperative assessment and preparedness.

Conclusion

This prospective observational study demonstrated a significantly higher incidence of difficult intubation among the cardiac surgery patients compared to non-cardiac surgery patients. Cardiac patients tended to have more comorbid conditions such as diabetes and hypertension, higher BMI, and altered airway anatomy—all contributing to increased intubation difficulty. Although various individual

airway parameters like Mallampati score, neck circumference, and thyromental distance were associated with IDS, none showed adequate predictive power when used alone. Therefore, a composite approach incorporating clinical judgment, multiple bedside assessments, and patient comorbidities remains essential.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

A Retrospective Study of Demographic Profile of Homicide Cases Autopsied at a Teaching Hospital in Nellore, Andhra Pradesh (2023-24)

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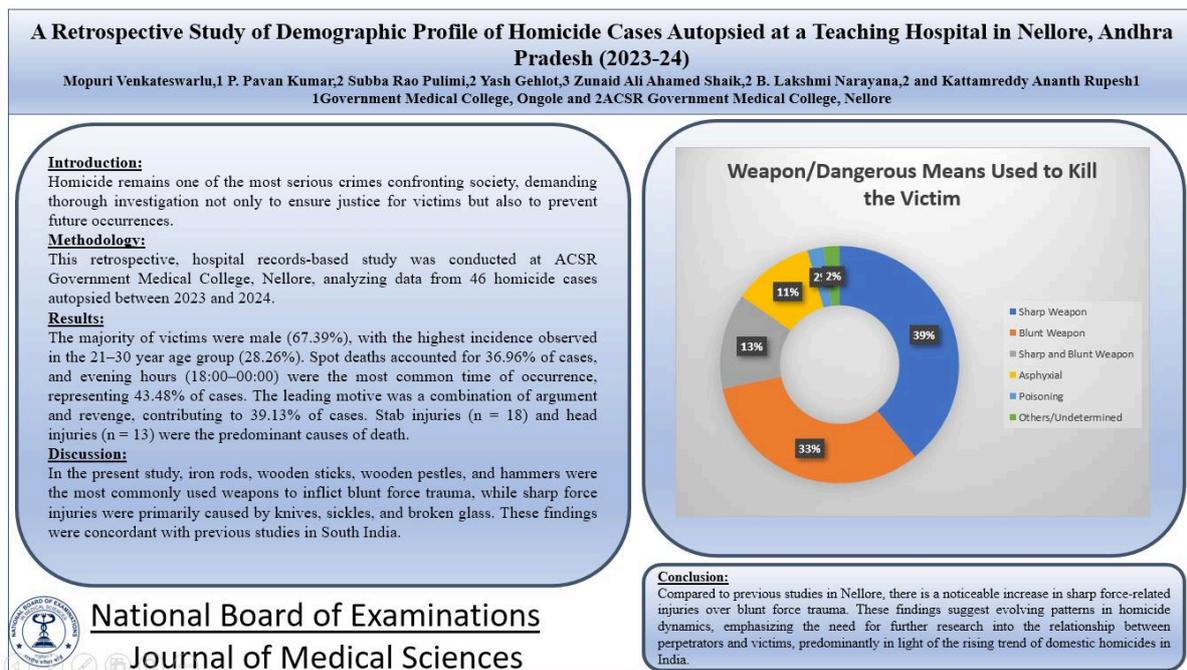
Abstract

Homicide remains one of the most serious crimes confronting society, demanding thorough investigation not only to ensure justice for victims but also to prevent future occurrences. This retrospective, hospital records-based study was conducted at ACSR Government Medical College, Nellore, analyzing data from 46 homicide cases autopsied during the years 2023–2024. The majority of victims were male (67.39%), with the highest incidence observed in the 21–30 year age group (28.26%). Spot deaths accounted for 36.96% of cases, and evening hours (18:00–00:00) were the most common time of occurrence, representing 43.48% of cases. The leading motive was a combination of argument and revenge, contributing to 39.13% of cases. Stab injuries (n = 18) and head injuries (n = 13) were the predominant causes of death. Compared to previous studies in Nellore, there is a noticeable increase in sharp force-related injuries over blunt force trauma. These findings suggest evolving patterns in homicide dynamics, emphasizing the need for further research into the relationship between perpetrators and victims, predominantly in light of the rising trend of domestic homicides in India. Understanding these micro dynamics is essential for developing effective preventive strategies and improving investigative approaches.

Keywords: Homicide, Murder, Unnatural deaths, Forensic autopsy, Domestic homicide

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Graphical Abstract



Introduction

The word *homicide* originates from the Latin *homicidium*, combining *homo* (man) and *caedere* (to kill), meaning the killing of a human being. Ever since the story of Cain and Abel in the Bible and with parallels in Hindu mythology such as the fratricidal war between the Kauravas and Pandavas in the Mahabharata, or the slaying of Vritra by Indra; the act of murder has existed alongside mankind; be it in mythology or recorded legal history.

Overlooking a homicide during autopsy represents one of the most serious failures in medicolegal practice [1]. Hence, it is necessary for a forensic doctor to approach every death with the presumption of homicide until proven otherwise. If a murder is overlooked during autopsy, it constitutes a serious injustice to the deceased and their family. While other manners of death like suicide or accident also warrant thorough evaluation, the level

of scrutiny demanded by a potential homicide must come first.

Although the National Crime Records Bureau (NCRB) data compiles the crude data on homicides; it lacks the finer details which are of paramount importance about identifying local homicide trends. Micro studies on homicides are essential for better understanding of offences against human body in a region and thereby plan preventive measures.

This study aimed to analyze the forensic and sociodemographic characteristics of homicide cases in Nellore, Andhra Pradesh, during the years 2023 and 2024, based on data from autopsy reports and police inquests. On an average 1000 autopsies are conducted at ACSR Government Medical College, Nellore. The jurisdiction of this centre encompasses Nellore city and its suburban areas.

Materials and Methods

This retrospective, records-based study was conducted at ACSR Government Medical College, Nellore, Andhra Pradesh, with the objective of analyzing data pertaining to homicide autopsy cases carried out during the calendar years 2023 and 2024. Data were extracted from autopsy reports and police inquest records, focusing on various parameters including the motive and method of homicide, type of weapon or means employed, sociodemographic characteristics of the victims, period of survival, cause of death, and other relevant medico-legal findings. All cases registered as homicides under the Indian Penal Code (IPC) or Bharatiya Nyaya Sanhita (BNS) and were referred to this medico legal centre for autopsy were

included in the study. Cases with incomplete or missing data were excluded to ensure the reliability of the analysis. Basic descriptive statistical analysis was performed using Microsoft Excel, with frequencies and percentages calculated to summarize categorical variables.

Results

A total of 46 homicide-related autopsies were conducted during the study period 2023–2024, with 21 cases (45.65%) in 2023 and 25 cases (54.35%) in 2024. Of these, 15 victims (32.61%) were female and 31 (67.39%) were male. The age distribution of homicide victims is tabulated in Table 1. Of the total 46 victims, 20 were unmarried (43.48%) and 26 were married (56.52%).

Table 1. Age distribution of Homicide victims

S.No.	Age group in years	No. of victims
1	0-9	2 (4.35%)
2	10-19	0 (0.00%)
3	20-29	13 (28.26%)
4	30-39	9 (19.57%)
5	40-49	8 (17.39%)
6	50-59	6 (13.04%)
7	60-69	5 (10.87%)
8	>70	3 (6.52%)

Among the 46 cases studied, death occurred at the scene (spot death) in 17 cases (36.96%), within less than one day in 12 cases (26.09%), between one to seven days in 7 cases (15.22%), and after more than seven days in 6 cases (13.04%). In 4 cases (8.70%), the survival period following the violent incident could not be ascertained due to unreliable or unavailable history.

Analysis of the time of occurrence of the crime revealed that the majority of cases took place during the evening hours (18:00–00:00), accounting for 20 cases (43.48%). This was followed by afternoon (12:00–18:00) in 11 cases (23.91%), late night (00:00–06:00) in 7 cases (15.22%), and morning (06:00–12:00) in 5 cases (10.87%). In 3 cases (6.52%), the exact

time of crime could not be determined with exactitude.

The most common motive identified was a combination of argument and revenge, accounting for 18 cases (39.13%). Arguments alone were the motive in 8 cases (17.39%), followed by revenge in 7 cases (15.22%). Motives related to property disputes and dowry harassment followed by homicide were observed in 2 cases each (4.35%), while financial reasons were implicated in 1 case (2.17%). In 8 cases (17.39%), the motive could not be clearly established due to factors such as the accused being at large, the victim's identity remaining unknown, or insufficient circumstantial evidence. The category "others" largely included cases of murder for gain and vendetta arising from illicit relationships.

The weapon or dangerous means used to kill the victim is illustrated in Figure 1. Sharp force injuries were inflicted using both single-edged and double-edged knives. Blunt force injuries resulted from the use of sticks and hammers. Cases

involving ligature strangulation or throttling were categorized under asphyxial deaths. The sole criminal poisoning case involved an agrochemical substance, paraquat. In a few cases [4] the weapon/means remains undetermined.

As per the available history, the victim had consumed alcohol prior to the incident in 3 cases (6.52%), had not consumed alcohol in 40 cases (86.96%), and in 3 cases (6.52%), no reliable history regarding alcohol consumption could be obtained.

The legal sections under which the cases were registered included Section 302 IPC or Section 103 read with other relevant provisions of the Bharatiya Nyaya Sanhita (BNS) in 23 cases, Section 302 read with 34 IPC or Section 103 read with 3(5) BNS in 12 cases, Sections 302 and 201 IPC in 2 cases, and Section 302 IPC along with other sections in 9 cases. The cause of death distribution is shown in Table 2. Of the total 46 homicide cases recorded during 2023–24, 27 were from urban areas and 19 from rural areas.

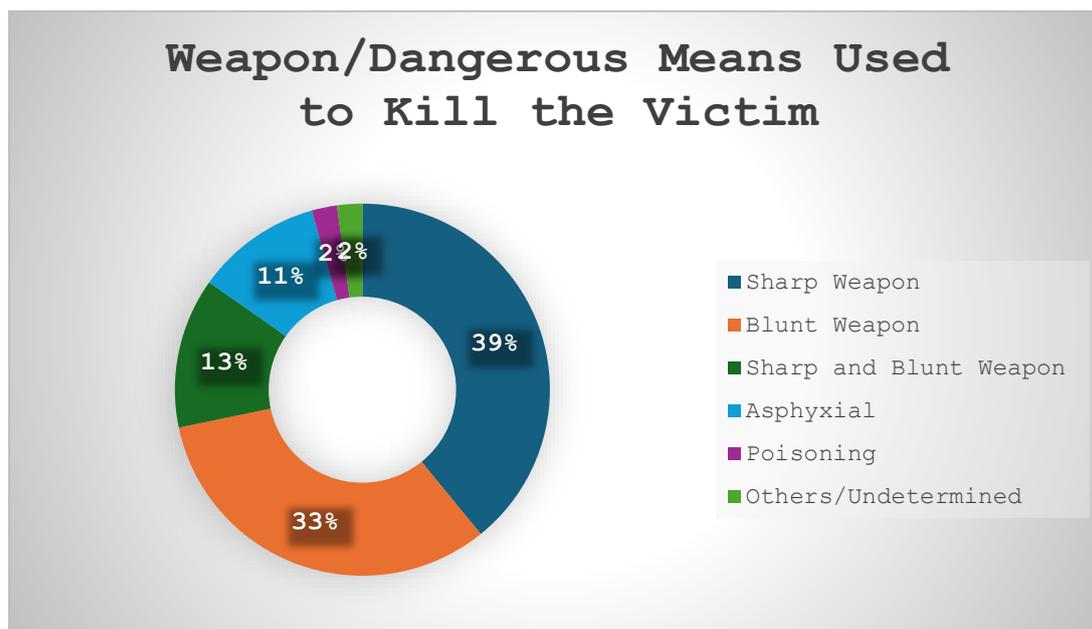


Figure 1. Weapon/Dangerous Means Used to Kill the Victim.

Table 2. Cause of Death in Homicide Cases

S.No.	Cause of death	No. of cases
1	Stab injuries	18
2	Head injury	13
3	Strangulation/Throttling/Chokehold	5
4	Insufficient data/Pending reports	4
5	Cut throat	2
6	Blunt Trauma Abdomen	2
7	Multiple Injuries	1
8	Blunt Trauma Chest	1

Discussion

The present study aimed to understand the forensic characteristics of murder cases autopsied at a tertiary care hospital. Among the victims, 67.39% were male, and 28.26% were within the 20–29 years age group, indicating a higher propensity for young males to become victims of homicidal violence. This trend may be attributed to developmental factors, as individuals in this age group are typically undergoing a phase of individualisation which is often marked by immature decision-making, increased risk-taking behaviour, and increased exposure to interpersonal conflicts [2]. Our results in this aspect were concordant with most of the studies published in literature including Sweekriti et al. [3] and Sumangala et al. [4].

In 36.96% of cases, death occurred at the scene of the incident, indicating the severity and fatal nature of the injuries sustained. A total of 13.04% of the victims survived for more than one week. Most sharp force injuries resulted in rapid fatality due to haemorrhagic shock. Similarly, victims of strangulation typically succumbed immediately to asphyxial mechanisms. In contrast, individuals who sustained blunt force trauma often survived for a variable duration up to a week. The survival period statistics were similar to the

findings reported by Jainik et al. [5] and Sweekriti et al. [3].

A total of 43.48% of the crimes occurred during the evening hours, specifically between 06:00 PM and 12:00 AM. This time period coincides with increased social activity, off-work hours, and a higher likelihood of alcohol consumption, all of which may contribute to interpersonal conflicts and escalation of violence [6]. In contrast, only 10.87% of the incidents occurred during the morning hours between 06:00 AM and 12:00 PM, a period typically associated with structured activities, employment, and lower social interaction, thereby reducing the probability of violent encounters. Evidence from existing literature suggests that stable employment [7] and strong family or social support systems serve as protective factors against involvement in violent behavior [8].

Vengeance and arguments was identified as the most common motive, accounting for 71.14% of the cases, which aligns with findings reported in previous studies [9,10]. Although not identified as prime motive in this study; there appears to be a rising trend in homicides linked to illicit relationships, particularly involving women accused of murdering their younger husbands, often in the context of extramarital affairs [11]. This shift is a grim

reminder of the increasing complexity of intimate partner dynamics and their role in the causation of domestic homicides.

The increased use of sharp force weapons observed during the present study period contrasts with the findings of an earlier study conducted at the same centre in 2019–2020 by Sashikanth [12], which reported blunt force trauma in 48% of homicide cases. Similarly, the previous study [12] at the same centre as mentioned above noted head injuries as the most common type, whereas in the current study, stab injuries were more prevalent, showing the shift in patterns of homicidal violence over time. This could be attributed to increased floating population and expansion of the city over recent years.

The legal classification of the cases in the present study indicates an increased involvement of multiple perpetrators, along with attempts to conceal the crime. The involvement of alcohol in victims is minimal in this study whereas usually it is the accused who is under the influence of alcohol when they resort to violent behaviour [13].

In the present study, as stated earlier, iron rods, wooden sticks, wooden pestle, and hammers were the most commonly used weapons to inflict blunt force trauma, while sharp force injuries were primarily caused by knives, sickles, and broken glass. These findings were concordant with previous studies in south India [14,15].

Conclusion

The present study, conducted on homicide cases autopsied at a teaching medico-legal centre in Nellore during the years 2023–2024, identified a total of 46 cases, with the majority of victims being male and aged between 21 and 40 years.

The peak hours for homicides were observed between 18:00 and 00:00, indicating a temporal pattern in the occurrence of these crimes within Nellore city. A notable shift was observed in the method of homicide, with sharp force injuries surpassing blunt force trauma, which had been more prevalent in previous studies conducted at the same centre. Vengeance and interpersonal arguments remained the predominant motives for murder, and most deaths occurred at the scene of the crime. These findings underscore the need for a deeper exploration of the micro dynamics between perpetrators and victims, which may offer valuable insights for developing targeted strategies to prevent future homicides.

Limitations

The relationship between the accused and the victim, as well as the socioeconomic status of the victims, were not assessed in the present study. Also, the precise location of the crime scene was not documented.

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Conflicts of interest

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

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Ethics committee approval

The study has received ethical clearance from the Institutional Ethics Committee of ACSR Government Medical College, Nellore, Andhra Pradesh vide Ref: No: ECR/961/Inst/AP/2017/RR-20/94-09/25-06-25.

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ORIGINAL ARTICLE

Comparison of Primary vs Secondary Closure Technique after Incision and Drainage of Cutaneous Abscess

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Abstract

Introduction: Historically, cutaneous abscesses have been managed with incision and drainage (I&D), followed by secondary closure, allowing the wound to heal by secondary intention. However, with the availability of modern antibiotics, the feasibility of primary closure in select cases warrants investigation. This study aimed to evaluate and compare the clinical outcomes of primary versus secondary closure following I&D in patients with cutaneous abscesses. **Methods:** A cross-sectional study was conducted over one year at a tertiary care center in Central Gujarat, involving 676 patients diagnosed with cutaneous abscesses. Participants were randomly assigned to undergo either primary closure (Group A) or secondary closure (Group B) following I&D. Key outcome measures included healing duration, length of hospitalization, treatment failure, complications, and patient-reported satisfaction using the Visual Analogue Scale (VAS). A p-value of <0.05 was considered statistically significant. **Results:** Each group consisted of 338 patients. The average healing time in Group A was 8.27 ± 2.23 days, significantly shorter than in Group B. The mean duration of hospital stay for Group A was 2.24 ± 0.87 days, also significantly lower ($p < 0.001$). Group A experienced fewer complications and demonstrated superior cosmetic outcomes compared to Group B, with both differences reaching statistical significance ($p < 0.001$). **Conclusions:** Primary closure after I&D of cutaneous abscesses resulted in improved clinical outcomes, including faster healing, reduced hospital stay, fewer complications, and enhanced cosmetic appearance, when compared to the conventional secondary closure approach.

Keywords: Cutaneous Abscess, Incision and Drainage (I&D), Primary closure, Secondary Closure, Wound Healing Outcomes

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Graphical Abstract

Comparison of Primary vs Secondary Closure Technique after Incision and Drainage of Cutaneous Abscess
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Background
Traditionally cutaneous abscesses were treated through the secondary closure followed by Incision and Drainage (I & D). However, in this era of newer and more effective antibiotics, we need to evaluate whether the same patients can be treated with primary closure. This study was designed to compare the outcome following the primary and secondary closure.

Primary Closure of wound



Methods
A cross-sectional study was carried out at a tertiary care hospital in Central Gujarat among patients of cutaneous abscess over a period of one year. Patients were randomized to primary and secondary closure following to I & D. Outcomes like Healing rate, Duration of treatment, Treatment failure rate, need for hospital admission and Overall patient satisfaction by Visual Analogue Scale [VAS] were compared. P-value less than 0.05 was considered as statistically significant.

Conclusion: Primary closure technique gave better outcome in terms of days required for healing, days required for hospitalization, pain followed by suturing and complication rate as compared to secondary closure technique.



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Introduction

Cutaneous abscess is a focal skin and subcutaneous tissue infection with collection of pus. It generally appears with painful, fluctuant swelling with a central pustule and associated erythema and cellulitis [1,2]. This disease is commonly seen in all ages and both sexes, and is a main load of outpatient and emergency department, which is increased in recent years.

Historically, the treatment of skin abscesses has been I&D with secondary intention healing—leaving the wound open to heal through natural processes of granulation and re-epithelialization. That's the approach favored by major organizations such as the IDSA (Infectious Diseases Society of America), WSES (World Society of Emergency Surgery), and SIS-E (Surgical Infection Society Europe) as well as a number of clinical guidelines [2,3]. The conventional treatment of

cutaneous abscesses has been incision and drainage (I&D) followed by secondary healing in which the open wound is allowed to heal by granulation tissue formation and epithelialization [4].

However, recent literature suggested a change of surgical practice where some clinicians proposed primary closure following I&D. Thus, the trend against primary closure of abscess cavities has been challenged, as recent data support the concept that this modality of therapy may promote more rapid wound healing, less pain, less infection-related morbidity, and better cosmetic results [5]. There are a few reports of good outcomes with this technique in various sites including the breast, neck, axilla, trunk, and extremities [6].

The purpose of this study is to determine the effectiveness and safety of primary closure versus traditional

secondary closure at treating cutaneous abscesses, focusing on outcomes such as time to healing, duration of treatment, failure rate, need for hospital admission, and overall patient satisfaction.

Methodology

Study Design

A cross-sectional comparative investigative study was conducted to evaluate the results of two closure methods post I&D.

Sample Size and Sampling

Two groups of 338 patients each were entered into the analysis, based on an 80% study power and 95% confidence level—Group A patients underwent primary closure and Group B patients entered secondary healing.

The study was conducted in the Department of Surgery of a tertiary care hospital in Central Gujarat - receiving patients from Central and South Gujarat regions and neighbouring states - Maharashtra and Rajasthan.

Eligible patients were those who presented to the ED with localized skin abscesses suitable for I&D. Exclusion criteria were patients with systemic infection (e.g., fever, chills, hypotension), immunosuppressed status (such as diabetes mellitus, HIV, or long-term corticosteroids), large abscesses with surrounding extensive cellulitis (>5 cm) and very tiny ones (<3 cm), and those with conditions that predispose to endocarditis (e.g., congenital heart disease, prosthetic heart valves, IV drug use, pacemaker).

Surgical Techniques

Incision and Drainage (Modified Hilton's) [7]

Diagnosis was established by Aspiration.

The skin was cut at the most prominent and depending part of the collection.

Pus was evacuated with the help of artery forceps or sinus forcep and deep dissection was carried out.

All loculi were broken down by finger dissection. pus sent for culture. The cavity was curetted and irrigated with saline.

Primary Closure Technique [8]

The wound was then closed with 3-0 nylon and a closed suction drain was left in place (Figure 1).

Secondary Healing Method [7]

The cavity was packed with povidone-iodine- and hydrogen peroxide-soaked gauze and allowed to remain open (Figure 2). For larger wounds with good granulation tissue, a secondary suture was performed at a later date.

Antibiotic Regimen

All patients were treated empirically with amoxicillin-clavulanate. Doses for children were 30 mg/kg IV q8h (in patients) and 40 mg/kg/day orally (outpatients). Adults received 1.2 g IV every 12 hours or 625 mg PO twice daily. Antibiotics were changed according to the culture and sensitivity.



Figure 1. Primary Closure of wound



Figure 2. Secondary Closure of Wound

Study Outcomes

Key outcome measures included:

- Healing rate
- Duration of treatment
- Treatment failure rate
- Rate of hospitalization
- Pain on the VAS

Results

A total of 338 patients were randomized in both arms. Demographic profiles (Table 1) demonstrated no statistically significant difference between the groups in the age and sex distribution.

Table 1. Sociodemographic details

Variables	Group A (n-338)	Group B (n-338)	P-value
Age (mean±SD)	37.58± 13.55	37.41 ± 13.92	0.87
Gender			
Male	174 (51.48%)	190 (52.20%)	0.21
Female	164 (48.52%)	148 (43.79%)	

Table 2 shows there was no significant difference between the two groups on the involved anatomy of

abscess and isolated pathogens, and manifestation was also similar.

Table 2. Clinical Profile of the patients

Variables	Group A	Group B	P-value
Site			
Buttock	66 (19.53%)	87 (25.74%)	0.55
Leg	53 (15.68%)	47 (13.91%)	
Breast	50 (14.79%)	44 (13.02%)	
Thigh	46 (13.61%)	49 (14.50%)	
Hand	20 (05.92%)	22 (06.51%)	

Arm	18 (05.33%)	22 (06.51%)	
Forearm	12 (03.55%)	14 (04.14%)	
Back	15 (04.44%)	18 (05.33%)	
Foot	13 (03.85%)	09 (02.66%)	
Chest	05 (01.48%)	04 (01.18%)	
Scalp	18 (05.33%)	10 (02.96%)	
Axilla	13 (03.85%)	07 (02.07%)	
Scrotum	09 (02.66%)	05 (01.48%)	
Organism isolated from the abscess			
Staphylococcus aureus	220 (65.09%)	226 (66.86%)	0.59
Streptococcus	78 (23.08%)	70 (20.71%)	
Proteus	16 (04.73%)	11 (03.25%)	
Klebsiella	05 (01.48%)	09 (02.66%)	
No organism	19 (05.62%)	22 (06.51%)	

Compared outcomes (Table 3) showed statistically significant positive advancements for the primary closure group in most parameters,

hospitalization rates being an only exception to be found at similar levels between the groups.

Table 3. Outcomes

Variables	Group A	Group B	p-value
Time required for healing in days (Mean \pm SD)	8.27 \pm 2.23	9.72 \pm 3.55	<0.001
No of patients required hospitalization	85 (46.96%)	96 (53.04%)	0.33
Days of hospitalization Mean \pm SD	2.24 \pm 0.87	2.93 \pm 0.67	<0.001
VAS Score	Mean (SD)	Mean (SD)	
Day 2	7.56 (0.69)	8.11(0.58)	<0.0001
Day 3	6.00 (0.94)	6.38 (0.81)	<0.0001
Day 5	4.01 (0.95)	4.17 (0.95)	0.03
Day 7	1.96 (0.60)	2.07 (0.76)	0.03
Cosmetic Results			
Good	257 (76.04%)	235 (69.53%)	
Average	72 (21.30%)	67 (19.82%)	0.002
Poor	09 (02.66%)	36 (10.65%)	
Complication			
Yes	85 (40.48%)	125 (59.52%)	<0.0001

No	253 (54.29%)	213 (45.71%)	
Complications			
Secondary suturing	00	67 (53.60%)	
Additional drainage	18 (21.18%)	35 (28.00%)	<0.0001
Readmission	14 (16.47%)	23 (18.40%)	
Suture Reopen	53 (32.35%)	00	

Discussion

In the present study, comparison of primary closure of an acute abscess with negative suction drain versus secondary closure has been done to evaluate and assess. There is a traditional method of treating an acute abscess by incision and drainage, and after that secondary closure. Ellis et al in 1951 was the first person to do a primary closure of an abscess without drain [9]. Now a days of advancement it is debatable that primary closure improves the outcome as compared to secondary closure [10]. In addition, most prior studies were conducted prior to the era of methicillin-resistant *Staphylococcus aureus*. As a result, it is unclear whether the results of prior studies can be generalized to current incision and drainage of cutaneous abscesses (Figure 1 and 2).

In our study we had included equal number of patients (n-388) in each group. Group-A patients had been given primary closure and Group B

patients had been given secondary closure. Both the groups were compared in terms of socio-demographic characteristics and clinical parameters of wound to reduce the chances of confounding and bias. Both the groups were comparable in terms of socio-demographic profile and clinical profile (Tables 1 and 2; $p > 0.05$).

The time required for healing in days was 8.27 ± 2.23 for primary closure and it was 9.72 ± 3.55 in case of secondary closure. The difference was statistically significant. A systemic review by Singer AJ et al had time to healing after primary closure (7.8 days [95% confidence interval {CI}, 7.3-8.3]) and secondary closure (15.0 days [95% CI, 14.3-15.7]) [6]. The difference was statistically significant. Similar findings were there in Dubey et al. in which healing time for patients with primary closure and secondary closure were 7-11 days and 12-36 days respectively. The difference was statistically significant (p value < 0.05)

[8]. Therefore, we could say that primary closure patients required lesser healing time as compared to the secondary closure patients.

The hospitalization was seen in nearly 54 % of patients with secondary closure as compared to the 47% in primary closure. Although we did not find any statistically significant difference in number of hospitalizations in both groups, we found statistically significant difference in the number of days of hospitalization. As it is a newer technique for the management of cutaneous abscess there is lesser literature available in this context. Therefore, we cannot generalize the findings for hospitalization.

There was statistically significant difference between VAS score for each day in both the group. VAS score was lesser in patients with primary closure as compared to the patients with secondary closure. The similar findings were there in a study by AJ singer et al. [11]. There are other studies available which also states that conventional method (secondary suturing) has higher pain score and higher requirement for analgesics [12]. Therefore, we could say that pain was lesser in Group A as compared to Group B.

In our study we found a good cosmetic result in primary closure as compared to secondary closure. A study done by Quinn et al. also had similar finding that primary closure gives better cosmetic results as compared to secondary closure [13]. The complications were less in primary closure as compared to the secondary

closure, especially re-suturing. Re-suturing was only observed in patients with secondary closure. The similar findings were observed in studies done by Singer et al. and Kale et al. which shows complications were more commonly observed in patients with secondary closure as compared to primary closure [11,14].

Thus, we can conclude that primary suturing gives better outcomes in terms of healing rates, hospitalization, reduced pain scores, cosmetic results and complication rates.

Limitations

This study was limited to single-center research, which undermines the generalizability of the results to other regions or general setting. The study did not have a standardized antibiotic regimen, which could be a potential confounding factor. Finally, the patients could not be followed up post-discharge, which may lead to a lack of the assessment of side effects or miserable outcomes that could have developed after discharge.

Conclusion

The findings of this study are supporting primary closure over secondary following incision and drainage of localized cutaneous abscesses through the process being associated with smaller wound size, quicker healing, lower levels of postoperative pain, shorter LOS, less severe wound outcomes, and better cosmetic results. The hospitalization rate was a comparable finding, but all the other points, including patient

satisfaction, were consistently in favor of primary closure. This study challenges the belief behind secondary closure based on comparative evidence for a selective use of primary closure over SC for a well-defined localized cutaneous abscess. However large-scale, multicenter RCT are needed to corroborate the finding of this study.

Conflicts of interest

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

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Author's Contribution

VB Conceptualization, data collection, manuscript drafting; PD: Literature review, data analysis; MB: Study design, critical revision of the manuscript; PT: Manuscript preparation, statistical assistance; PRC: Supervision, guidance on methodology; VDY: Final manuscript editing, corresponding author responsibilities

Ethical Considerations

The study was approved by the Institutional Ethics Committee. Subjects were explained the study protocol and written informed consent was obtained.

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ORIGINAL ARTICLE

Dietary and Lifestyle Patterns Associated with Risk of Obstructive Sleep Apnea in Urban Area of Puducherry: A Case Control Study

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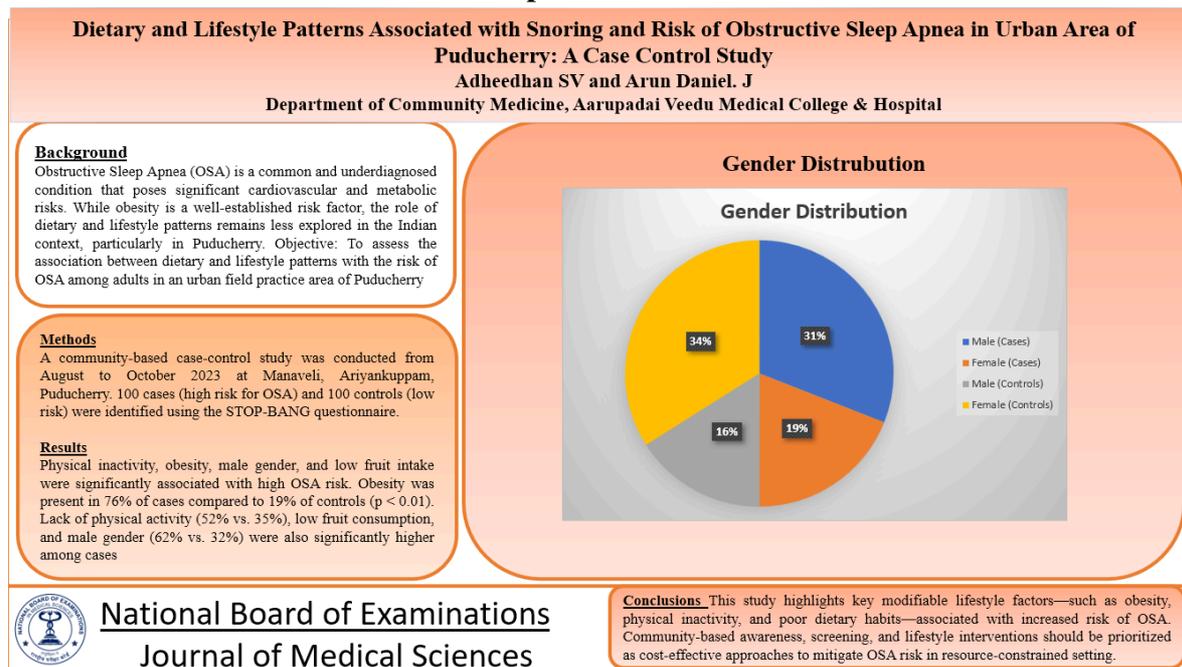
Abstract

Background: Obstructive Sleep Apnea (OSA) is a common and underdiagnosed condition that poses significant cardiovascular and metabolic risks. While obesity is a well-established risk factor, the role of dietary and lifestyle patterns remains less explored in the Indian context, particularly in Puducherry. **Objective:** To assess the association between dietary and lifestyle patterns with the risk of OSA among adults in an urban field practice area of Puducherry. **Methods:** A community-based case-control study was conducted from August to October 2023 at Manaveli, Ariyankuppam, Puducherry. 100 cases (high risk for OSA) and 100 controls (low risk) were identified using the STOP-BANG questionnaire. Participants' sociodemographic, anthropometric, lifestyle, and dietary data were collected using Epicollect5. Statistical analysis included Chi-square tests, Pearson correlation, and multiple logistic regression using SPSS v29. **Results:** Physical inactivity, obesity, male gender, and low fruit intake were significantly associated with high OSA risk. Obesity was present in 76% of cases compared to 19% of controls ($p < 0.01$). Lack of physical activity (52% vs. 35%), low fruit consumption, and male gender (62% vs. 32%) were also significantly higher among cases. **Conclusion:** This study highlights key modifiable lifestyle factors—such as obesity, physical inactivity, and poor dietary habits—associated with increased risk of OSA. Community-based awareness, screening, and lifestyle interventions should be prioritized as cost-effective approaches to mitigate OSA risk in resource-constrained settings.

Keywords: Obstructive Sleep Apnea, Lifestyle, Diet, Obesity, STOP-BANG, Puducherry

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Graphical Abstract



Introduction

Obstructive sleep apnea (OSA) is resulting due to increased collapsibility of the upper airway during sleep causing reduced or cessation of airflow. Compare to women men are more prone to obstructive sleep apnea [1]. The pathogenesis of OSA is multifactorial. Factors contributing OSA is by anatomical cause or non-anatomical cause. Obesity is independent factors contributing OSA. Other than obesity other factors contributing to OSA such as BMI (body mass index), neck circumference, waist circumference and waist hip ratio [1-3]. OSA is associated with high risk of cardio vascular disease. It is estimated around one billion people have OSA globally [4]. The overall prevalence of OSA in India is 11% in that 5% female and 13% male respectively. Even though the awareness about OSA in India is low [5]. The prevalence of OSA is ranging from 4% to 14% and its increasing with age and its commonly observed between the age group of 40 to 65 years.

People with OSA has higher risk of cardiac complications like coronary heart disease, congestive heart failure, myocardial infarction, cardiac arrhythmia [6]. In the age group of > 60 years the prevalence of OSA ranges from 27 to 80%. Severe OSA is an independent risk for cardio vascular mortalities. Mediterranean diet have antioxidant and anti-inflammatory properties that can reduce the mortality rate of major cardio vascular events [7].

The risk factor for OSA are male gender, age above 60 years, Obesity, smoking and family history. The first line treatment of OSA is Continuous positive airway pressure (CPAP), but recent report showed that 50% of patient refuse to continue CPAP treatment in the first year. Since obesity, dietary and lifestyle pattern is a risk factor for OSA. Other measures like dietary management, lifestyle modification and reducing the weight will improve OSA symptoms [8]. A 10% weight

loss reduces apnea-hypopnea index by 26% and improves OSA [9].

The association of dietary and lifestyle patterns with risk of obstructive apnea is not been done in Puducherry recently. In the current study we aim to study the association of dietary and lifestyle patterns with risk of obstructive sleep apnea.

Materials and Methods

It is a case control study which conducted in our field practice area Manaveli, Ariyankuppam, Puducherry. The study was conducted between the period of August 2023 to October 2023.

Inclusion criteria for cases

Age group >18 years of both genders residing at Manaveli with high risk of OSA.

Inclusion criteria for controls

Age group >18 years of both genders residing at Manaveli with low risk of OSA. We have used a STOP BANG questioner for risk assessment for OSA.

Exclusion criteria

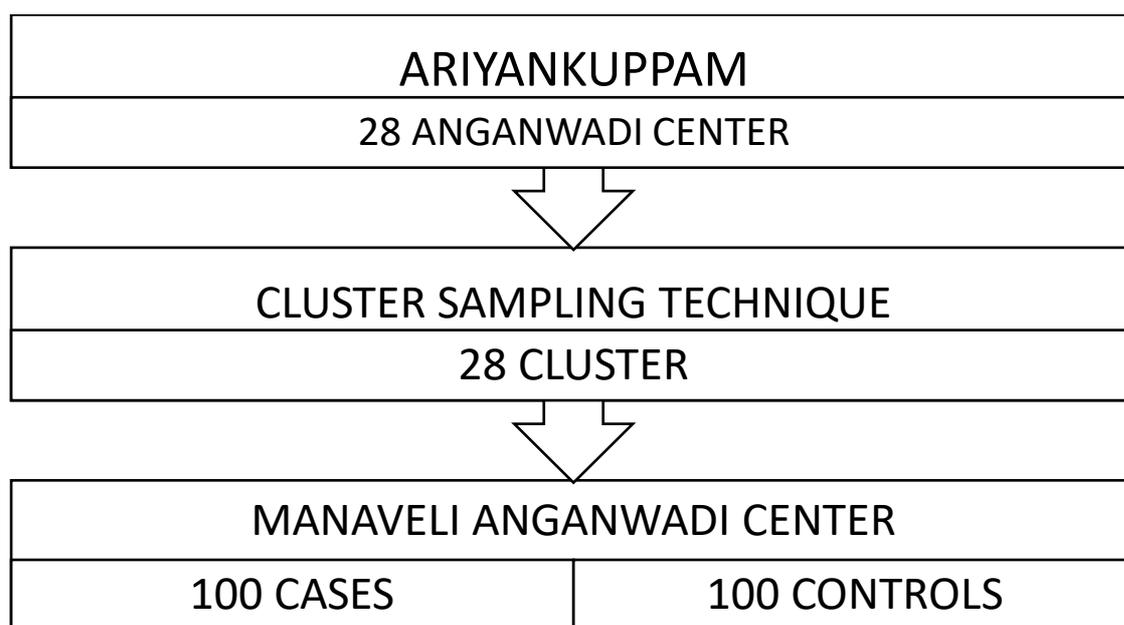
Age more than 60 years of age, people who went recent upper airway surgery and orthognathic surgery/ orthodontic treatment, people who are suffering from hypothyroidism, respiratory malignancy, congestive heart failure, pregnancy, people who are having craniofacial syndrome.

Sample Size Calculation

The sample size 85 cases & controls (170) rounded to 100 cases and 100 controls was calculated based on a similar study by Melaku Y A et al. The expected proportion of high risk of sleep apnea and low risk as 0.25 and 0.50. The level of significance and power were taken as 5% and 90%.

Study procedure

This study will be conducted in Ariyankuppam, our UHTC field practice area, there are around 28 Anganwadi centre in Ariyankuppam, each Angawadi is considered as each cluster, one cluster is randomly selected. Samples will be selected based on our inclusion & exclusion criteria from that cluster.



Data collection methods

After clearly explained about the nature of study in the language known by the people, informed & written consent will be taken from who all are willing to participate in the study. By using Epicollect5 application we have collected the data and extracted in the data in excel sheet. We have collected the sociodemographic profile, height, weight, BMI, dietary and lifestyle pattern, comorbidities, sleep pattern and we have used the STOP BANG questioner for assessing the risk of the OSA. The people with the score of more than 5 are high risk group and people with score of less than 5

will come under moderate and low risk group.

List variable wise statistical tests to be used for data analysis

Data entry will be done in Microsoft excel 2019 and analysed using SPSS software version 29. Descriptive data will be represented as percentages & frequencies in tables and graphs. The categorical variables will be differentiated using chi-square test. For all statistical tests, alpha error of 5% is available and p value of <0.05 will be considered significant (Table 1).

Results

Table 1. Frequency Table: Case vs Control by Variable

Variable	Cases	Controls	Total
Physical activity (1–2 h)	44	54	98
Physical activity (3–5 h)	4	11	15
Physical activity (none)	52	35	87
Fruit consumption (Daily)	25	34	59
Fruit consumption (Never)	2	0	2
Fruit consumption (Occasionally)	24	23	47
Fruit consumption (Rarely)	6	4	10
Fruit consumption (Several times/week)	43	39	82
Obesity (No)	24	81	105
Obesity (Yes)	76	19	95
Gender (Female)	38	68	106
Gender (Male)	62	32	94

The frequency distribution reveals important patterns related to risk factors for obstructive sleep apnea (OSA). Among the participants, 52 cases reported no physical activity compared to 35 controls, while moderate to higher levels of physical activity (1–2 hours and 3–5 hours per week) were more common among controls, suggesting that inactivity is more prevalent among those at high risk for OSA. In terms of fruit consumption, daily intake was higher among controls (34) than cases (25), and only cases reported never consuming fruits. Several-times-a-week consumption was similar between groups, while occasional and rare intake was slightly

more common in cases. Obesity showed a marked difference, with 76 obese individuals among cases versus only 19 in controls, emphasizing obesity as a strong risk factor. Lastly, gender distribution showed that 62 males were in the case group compared to 32 in the control group, indicating a higher proportion of males among those at risk, while females were more common among controls (68 vs. 38). These frequency patterns suggest that lower physical activity, poor fruit intake, obesity, and male gender are more frequently observed among individuals at high risk for OSA (Figure 1).

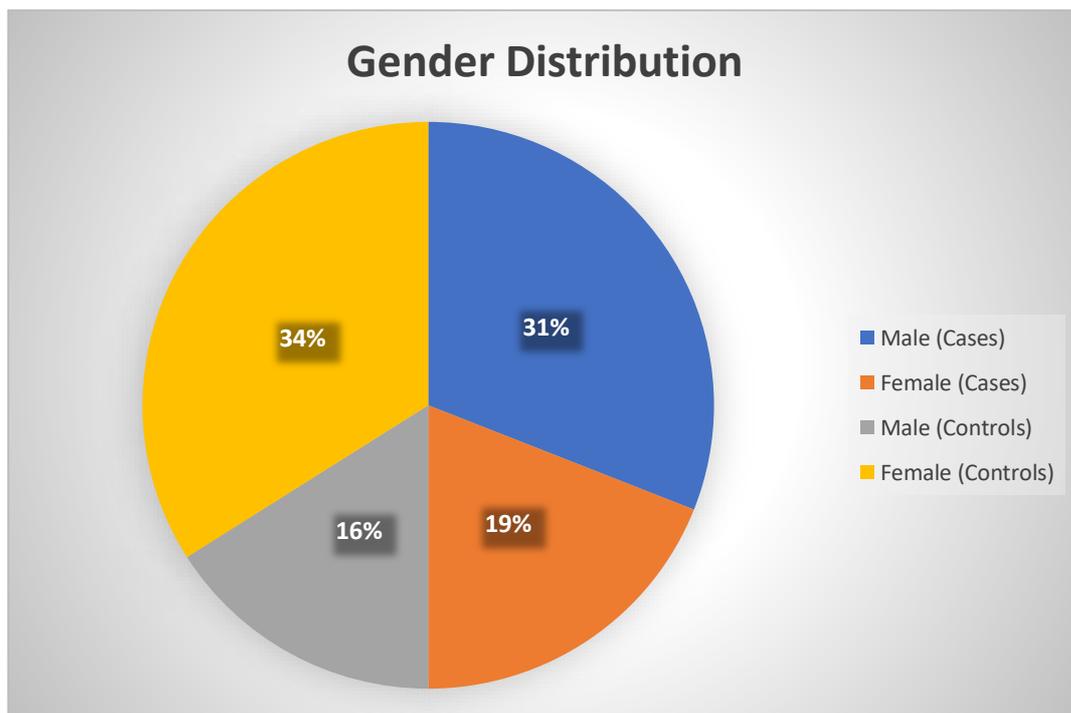


Figure 1. Gender distribution

The pie chart illustrates the gender distribution among cases and controls in the study. It shows that males constitute 31% of the cases and only 16% of the controls, indicating that a higher proportion of males

are at high risk for obstructive sleep apnea (OSA). In contrast, females make up 34% of the controls and 19% of the cases, suggesting that females are less likely to be at high risk for OSA in this population. This

distribution highlights a significant association between gender and OSA status, with male gender emerging as a potential risk factor. These findings align

with existing literature, which suggests that anatomical and hormonal differences contribute to the higher prevalence of OSA in males.

Table 2. Association Between Lifestyle and Demographic Factors with Risk of Obstructive Sleep Apnea (OSA) Among Study Participants (N = 200)

		Case/Control		Total	Chi-Square	p value
		case	control			
Physical activity in a week	1-2 h	44	54	98	4.602	0.021*
	3 - 5	4	11	15		
	none	52	35	87		
Total		100	100	200		
Consumption fruits in a week	Daily	25	34	59	3.989	0.032*
	Never	2	0	2		
	Occasionally	24	23	47		
	Rarely	6	4	10		
	Several times a week	43	39	82		
Total		100	100	200		
Obesity	No	24	81	105	65.143.	0.003**
	Yes	76	19	95		
Total		100	100	200		
Male	No	38	68	106	18.065	0.003**
	Yes	62	32	94		
Total		100	100	200		

There is a statistically significant association between physical activity. A higher percentage of cases (52%) reported doing no physical activity compared to controls (35%). Conversely, a higher percentage of controls reported engaging in some physical activity. This suggests that

lack of physical activity may be associated with being a case. There is a significant association between fruit consumption. Daily and frequent fruit consumption was more common among controls. On the other hand, infrequent or no fruit consumption was slightly more common

among cases. This suggests that lower fruit intake may be associated with being a case.

There is a highly significant association between obesity and being a case. A large majority of the cases (76%) were obese compared to only 19% of controls. In contrast, 81% of controls were not obese. This indicates a strong association between obesity and case status. There is a significant association between gender and case status. A higher proportion of cases were male (62%) compared to controls (32%). Conversely, females were more represented among controls (68%). This suggests that being male may be associated with higher odds of being a case.

Discussion

The present study explores the association between lifestyle and dietary patterns with the risk of obstructive sleep apnea (OSA) in a semi-urban population in Puducherry. It found that physical inactivity, obesity, lower fruit intake, and male gender were significantly associated with higher risk of OSA.

Consistent with previous literature, obesity emerged as a strong risk factor in this study. Among cases, 76% were obese compared to only 19% of controls. This finding supports the existing body of evidence that obesity is one of the most significant modifiable risk factors for OSA [3]. Increased fat deposition, particularly in the neck and upper airway region, contributes to upper airway narrowing and collapsibility, worsening sleep-disordered breathing [7].

The gender difference noted—where 62% of cases were male—also aligns with global and Indian prevalence patterns, where men are consistently more affected than women [2,5]. Hormonal differences, fat distribution, and airway anatomy are

possible explanations for this discrepancy [9].

Importantly, physical inactivity was significantly associated with increased OSA risk. More than half of the cases reported no physical activity, compared to only 35% among controls. Similar associations have been reported in longitudinal studies where low physical activity contributed to both increased BMI and direct worsening of OSA severity [4]. Exercise, independent of weight loss, has been shown to improve sleep architecture and reduce apnea-hypopnea index.

Another noteworthy finding is the association between low fruit intake and OSA. Controls had higher daily or frequent fruit consumption, while cases reported rarer intake. This is supported by findings from [6], who noted that anti-inflammatory dietary patterns, including fruit and vegetable consumption, were associated with reduced OSA severity. Fruits are rich in antioxidants and flavonoids that may counteract systemic inflammation and oxidative stress, both of which are central to OSA pathophysiology.

The STOP-BANG questionnaire used in this study has been validated as a simple yet effective screening tool in primary care and field settings for identifying individuals at risk of OSA [1]. Given the low awareness of OSA in the general Indian population, community-level screening tools remain crucial [5].

This study highlights the need for non-CPAP interventions, particularly in low-resource settings. While CPAP remains the gold standard treatment, nearly half of the patients discontinue it due to discomfort or cost [8]. In such contexts, lifestyle interventions, especially those targeting diet, physical activity, and weight loss, offer practical and sustainable options.

However, some limitations must be noted. The case-control design cannot establish temporality. Dietary data was self-reported, potentially introducing recall bias. Additionally, objective diagnostic tools like polysomnography were not used, which could have added clinical precision to case classification.

Conclusion

This case-control study from Puducherry reveals that male gender, obesity, low physical activity, and poor dietary habits particularly low fruit intake are significantly associated with increased risk of obstructive sleep apnea. These findings underscore the importance of community-level screening and the potential for lifestyle-based interventions in reducing OSA burden. Public health strategies focusing on dietary improvements and physical activity promotion could serve as cost-effective measures in addressing OSA, especially in resource-limited settings.

Strengths

- ✓ The study was conducted in a real-world, community setting (Manaveli, Ariyankuppam, Puducherry), increasing the external validity and generalizability of findings to similar populations.
- ✓ A validated and widely used screening tool for OSA risk, ensuring consistency and ease of use in field settings.
- ✓ Investigated lifestyle and dietary factors that can be changed through public health interventions—making the findings actionable.
- ✓ With 100 cases and 100 controls, the study had sufficient power to detect statistically significant associations.

- ✓ Use of Digital Data Collection Tool (Epicollect5) Minimizes manual errors in data entry and allows for efficient and organized data collection.

Limitations

- ✓ Dietary habits, physical activity, and comorbidities were self-reported, introducing recall bias and social desirability bias.
- ✓ Individuals above 60 years were excluded, yet they are often at highest risk for OSA. This limits generalizability to older populations.
- ✓ Sampling from only one anganwadi cluster limits the geographical and demographic diversity of the sample.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

A Comparative Study of Functional and Anatomical Outcomes in Endoscopic versus Microscopic Type I Tympanoplasty for Chronic Otitis Media Mucosal Disease

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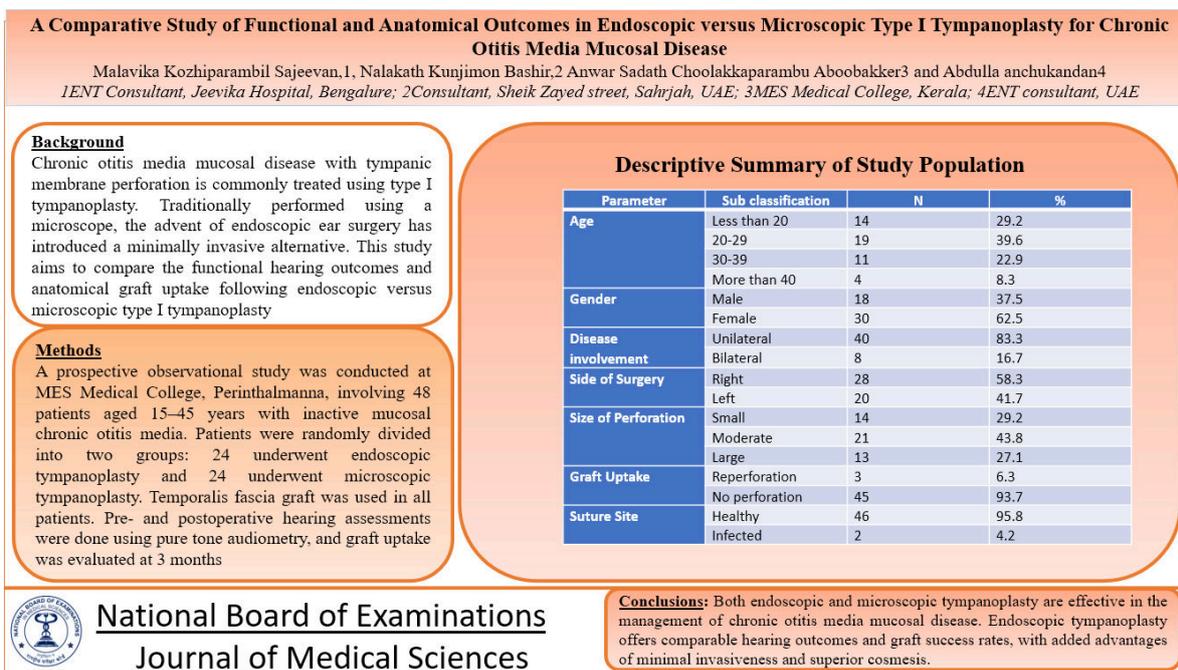
Abstract

Introduction: Chronic otitis media mucosal disease with tympanic membrane perforation is commonly treated using type I tympanoplasty. Traditionally performed using a microscope, the advent of endoscopic ear surgery has introduced a minimally invasive alternative. This study aims to compare the functional hearing outcomes and anatomical graft uptake following endoscopic versus microscopic type I tympanoplasty. **Materials and Methods:** A prospective observational study was conducted at MES Medical College, Perinthalmanna, involving 48 patients aged 15–45 years with inactive mucosal chronic otitis media. Patients were randomly divided into two groups: 24 underwent endoscopic tympanoplasty and 24 underwent microscopic tympanoplasty. Temporalis fascia graft was used in all patients. Pre- and postoperative hearing assessments were done using pure tone audiometry, and graft uptake was evaluated at 3 months. Statistical analysis was performed using SPSS with chi-square and t-tests applied; a p-value < 0.05 was considered significant. **Results:** The mean preoperative air-bone gap (ABG) was 29.71 ± 4.63 dB, which improved significantly postoperatively to 13.25 ± 1.99 dB ($p < 0.001$). The endoscopic and microscopic groups showed similar improvements in ABG ($p = 0.354$). Graft uptake was successful in 95.8% of endoscopic cases and 91.7% of microscopic cases ($p = 0.551$). Two cases of suture site infection were reported, both in the microscopic group. No major complications were observed. **Conclusion:** Both endoscopic and microscopic tympanoplasty are effective in the management of chronic otitis media mucosal disease. Endoscopic tympanoplasty offers comparable hearing outcomes and graft success rates, with added advantages of minimal invasiveness and superior cosmesis.

Keywords: Tympanoplasty, Endoscopic ear surgery, Chronic otitis media, Graft uptake, Hearing outcome

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Graphical Abstract



Introduction

Since the 1950s, microscopic tympanoplasty has been widely accepted as the standard surgical procedure for the repair of tympanic membrane perforations [1]. This technique, which can be performed through postauricular, endaural, or transcanal approaches, allows for precise reconstruction of the tympanic membrane and has consistently demonstrated high graft success rates. A postauricular incision, in particular, offers enhanced visibility and surgical access to the middle ear, making it the preferred route for most surgeons, especially in cases involving restricted ear canal access. The transcanal approach, on the other hand, is generally reserved for patients with smaller perforations and a naturally wider ear canal [2,3].

Despite its established efficacy, microscopic tympanoplasty is not without drawbacks. It typically involves a larger surgical field requiring a deep postauricular incision, general anesthesia, and extended

operative time. These factors contribute to increased patient morbidity and longer recovery periods. Since the late 1990s, however, advancements in minimally invasive techniques have led to a significant increase in the use of endoscopic tympanoplasty as a viable alternative [4]. The primary distinction between the two approaches lies in the surgical field of view. While microscopic surgery is limited by the narrowest segment of the external auditory canal, endoscopy provides a panoramic, wide-angled visualization by bypassing these constraints.

Endoscopic tympanoplasty, performed transcanally using rigid endoscopes, offers several practical advantages over the conventional microscopic method. It eliminates the need for canaloplasty and postauricular incisions, and in many cases, can be performed under local anesthesia, thereby reducing surgical trauma and improving cosmetic outcomes [5-7]. Moreover, the

enhanced visualization afforded by the endoscope facilitates better access to hidden recesses of the middle ear, including the epitympanum, sinus tympani, and hypotympanum—areas often difficult to assess using the microscope [8,9]. These advancements have not only expanded the anatomical reach of transcanal ear surgery but also improved the surgeon's ability to assess and manage chronic otitis media more effectively.

Given these potential benefits, there is a growing body of literature exploring the outcomes of endoscopic versus microscopic tympanoplasty in terms of anatomical closure, functional hearing improvement, operative time, complication rates, and patient satisfaction. However, most comparative studies are limited by varying sample sizes, surgical techniques, and patient selection criteria. In this context, the present study was designed to evaluate the functional and anatomical outcomes of Type 1 tympanoplasty using both endoscopic and microscopic approaches in patients diagnosed with chronic otitis media mucosal disease. This study aimed to provide a comprehensive comparison between the two techniques in a uniform cohort of patients, thereby contributing to the ongoing discourse on the most effective and patient-friendly approach to tympanic membrane reconstruction.

Materials and Methods

This prospective observational study was conducted in the Department of Otorhinolaryngology at MES Medical College, Perinthalmanna, over a period of one year from January 2021 to January 2022. The study included patients presenting with chronic otitis media mucosal disease who fulfilled the inclusion

criteria. Institutional Ethics Committee approval was obtained prior to the commencement of the study (IEC/MES/27/2020). A detailed patient information sheet outlining the study protocol, procedures, potential risks, and benefits was provided to each participant. Written informed consent was then obtained. Data was collected using a pre-validated study proforma.

The study included 48 patients between the ages of 15 and 45 years with inactive mucosal chronic otitis media, defined by a central tympanic membrane perforation with no active discharge for at least three months. Patients with atticointral disease, previous tympanoplasty, sensorineural hearing loss, or an air-bone gap greater than 45 dB were excluded. Each patient underwent thorough clinical evaluation including history, general and systemic examination, and ENT examination. Preoperative investigations included tuning fork tests, X-rays of both mastoids, and pure tone audiometry. The average air conduction threshold was calculated using values at 500 Hz, 1000 Hz, and 2000 Hz.

Participants were randomly assigned into two equal groups of 24 patients each. One group underwent microscopic type I tympanoplasty, and the other underwent endoscopic type I tympanoplasty. All surgeries were performed under general anesthesia by the same surgical team using temporalis fascia grafts. In both techniques, the graft was placed using the underlay method.

In the microscopic group, a postauricular William Wilde's incision was made to harvest the graft, and a standard canal wall approach was used. A self-retaining retractor was inserted to provide exposure. The margins of the perforation

were freshened, and a tympanomeatal flap was elevated from the 6 o'clock to 12 o'clock position. The ossicular chain was assessed for mobility, and gelfoam was placed in the middle ear. The temporalis fascia graft was placed over the middle ear cavity and under the remnant tympanic membrane. Gelfoam was also placed in the external auditory canal, and closure was done in layers using 3-0 vicryl for subcutaneous tissue and 3-0 mersilk for skin.

In the endoscopic group, a similar sequence was followed under direct visualization using a 0-degree rigid endoscope through a transcanal route. The tympanomeatal flap was elevated after freshening the perforation. The handle of the malleus was skeletonized and middle ear inspected. Graft placement was done as underlay with support using gel foam. No postauricular incision or retractor was used in the endoscopic approach. The external canal was packed with gel foam, and skin closure was completed with simple sutures.

Postoperative care was standardized. Patients received intravenous antibiotics for one day preoperatively and continued on oral antibiotics postoperatively for one week. Dressings were removed after one week, and suture removal was performed. Follow-up was done at one week, three weeks, and three months. Graft uptake was assessed via

otoscopic and oto-endoscopic examination. Postoperative hearing assessment was done using PTA at the third month. Functional outcome was measured by the change in air-bone gap.

Data were entered into Microsoft Excel and analysed using SPSS software (trial version). Descriptive statistics were used to summarize demographic variables. Categorical variables were analysed using the Chi-square test or Fisher's Exact Test where applicable. Continuous variables were analysed using independent sample t-tests and paired t-tests. A p-value < 0.05 was considered statistically significant.

Results

The study population comprised 48 patients, with 29.2% aged less than 20 years, 39.6% aged 20–29 years, 22.9% aged 30–39 years, and 8.3% above 40 years. A majority of participants were female (62.5%), while males accounted for 37.5%. Most patients had unilateral disease involvement (83.3%) and underwent surgery on the right ear (58.3%). Regarding perforation size, 43.8% had moderate perforations, 29.2% had small perforations, and 27.1% had large perforations. Graft uptake was successful in 93.7% of cases, while reperforation was noted in 6.3%. The suture site was healthy in 95.8% of the cases, with infection observed in 4.2% (Table 1).

Table 1. Descriptive Summary of Study Population

Parameter	Sub classification	N	%
Age	Less than 20	14	29.2
	20-29	19	39.6
	30-39	11	22.9
	More than 40	4	8.3
Gender	Male	18	37.5
	Female	30	62.5
Disease involvement	Unilateral	40	83.3
	Bilateral	8	16.7
Side of Surgery	Right	28	58.3
	Left	20	41.7
Size of Perforation	Small	14	29.2
	Moderate	21	43.8
	Large	13	27.1
Graft Uptake	Reperforation	3	6.3
	No perforation	45	93.7
Suture Site	Healthy	46	95.8
	Infected	2	4.2

When comparing the microscopic and endoscopic groups, no statistically significant differences were noted in gender distribution ($p = 0.233$), disease status ($p = 0.439$), side of surgery ($p = 1.000$), size of

perforation ($p = 0.571$), graft uptake ($p = 0.551$), or suture site status ($p = 0.149$). Both groups were found to be comparable across these baseline categorical variables (Table 2).

Table 2. Comparison Between Endoscopic and Microscopic Groups (Categorical Variables)

Parameter	Sub classification	Microscopic Group		Endoscopic group		CSV	P Value
		F	%	F	%		
Gender	Male	11	45.8	7	29.2	1.422	0.233
	Female	13	54.2	17	70.8		
Disease status	Bilateral	3	12.5	5	20.8	0.6	0.439
	Unilateral	21	87.5	19	79.2		
Side of Surgery	Left	10	41.7	10	41.7	0	1
	Right	14	58.3	14	58.3		
Size of Perforation	Small	7	29.2	7	29.2	1.121	.571
	Moderate	9	37.5	12	50		
	Large	8	33.3	5	20.8		
Graft Uptake	Reperforation	2	8.3	1	4.2	0.356	0.551
	No perforation	22	91.7	23	95.8		
Suture Site	Healthy	22	91.7	24	100	2.087	0.149
	Infected	2	8.3	0	0		

Significant improvement in hearing was observed postoperatively across all patients. The mean preoperative air-bone gap (ABG) was 29.71 ± 4.63 dB, which reduced to 13.25 ± 1.99 dB postoperatively ($p < 0.001$). In the microscopic group, ABG

reduced from 29.09 ± 5.01 dB to 12.98 ± 2.02 dB ($p < 0.001$), and in the endoscopic group, from 29.24 ± 4.32 dB to 13.52 ± 1.95 dB ($p < 0.001$), indicating a statistically significant functional improvement in both groups (Table 3).

Table 3. Comparison of Preoperative vs Postoperative Air Bone Gap

Parameter	Group	Mean	SD	Mean difference	t value	p-value
Overall	Pre operative	29.71	4.63	15.9	33.98	<0.001
	Post operative	13.25	1.99			
Microscopic Group	Pre operative	29.09	5.01	16.11	22.25	<0.001
	Post operative	12.98	2.02			
Endoscopic Group	Pre operative	29.24	4.32	15.72	25.87	<0.001
	Post operative	13.52	1.95			

Between-group comparisons showed no statistically significant differences in age ($p = 0.472$), preoperative ABG ($p = 0.912$), or postoperative ABG (p

$= 0.354$) between the microscopic and endoscopic groups, confirming that both groups were similar in demographic and functional outcomes (Table 4).

Table 4. Comparison Between Groups on Age and ABG (Pre-op and Post-op)

Parameter	Group	Mean	SD	Mean difference	t value	p-value
AGE	Microscopic Group	27.08	6.63	1.625	0.724	0.472
	Endoscopic Group	25.46	8.75			
Preoperative ABG	Microscopic Group	29.09	5.01	0.14	-0.111	0.912
	Endoscopic Group	29.24	4.31			
Postoperative ABG	Microscopic Group	12.98	2.02	0.54	-0.936	0.354
	Endoscopic Group	13.52	1.95			

No major postoperative complications such as facial palsy, vertigo, or sensorineural hearing loss were reported in either group. The only observed complication was minimal suture site infection in two patients, both of whom belonged to the microscopic group. Additionally, no cases of graft lateralization or blunting were reported.

Discussion

Tympanoplasty is a widely performed procedure for the management of chronic otitis media mucosal disease with tympanic membrane perforation. In this study, we compared the anatomical and functional outcomes of endoscopic versus microscopic type I tympanoplasty. The distribution of disease characteristics such as side of surgery, disease laterality, and size of perforation were similar in both

groups, thereby ensuring a balanced comparison.

In our study, the endoscopic group showed a higher proportion of females (70.8%) compared to the microscopic group (54.2%). The mean age was slightly lower in the endoscopic group (25.45±8.75 years) compared to the microscopic group (27.08±6.63 years), but these differences were not statistically significant. This is comparable to the findings of Jyothi et al., who reported a mean age of 28.5 years in the endoscopic group and 31.4 years in the microscopic group, with similar gender distributions [10]. Likewise, Yang et al. found no statistically significant differences in age or gender between the two groups [11].

The size of tympanic membrane perforation was also similar in both groups, with 43.8% having moderate perforations. Our findings are consistent with the study

by Faruq et al., who also reported no statistically significant association between the size of perforation and surgical outcomes [12].

The mean preoperative AB gap was 29.09 dB in the microscopic group and 29.24 dB in the endoscopic group, and both groups showed statistically significant improvement postoperatively (12.98 dB and 13.52 dB respectively). The mean AB gap closure was 16.11 dB for the microscopic group and 15.72 dB for the endoscopic group, indicating similar functional outcomes. These findings are in agreement with the results of Jyothi et al., where the AB gap closure was 19.54 dB in the microscopic group and 16.16 dB in the endoscopic group [10]. Similar observations were made by Faruq et al. [12] and Maran et al. [13], who documented comparable improvements in AB gap with both approaches.

Regarding anatomical outcomes, the graft uptake rate was 91.7% in the microscopic group and 95.8% in the endoscopic group, with no statistically significant difference. Faruq SAS et al. also reported similar graft uptake rates between groups and concluded that both techniques are equally effective [12]. Better results were also observed in studies done by Harugop et al. [14], Raj et al. [15] and Lakpathi et al. [16]. Patel et al. [17] observed 68% graft uptake. In our study, 2 patients (8.3%) in the microscopic group developed suture site infections, whereas no such complications were observed in the endoscopic group. This may be attributed to the minimally invasive nature of endoscopic tympanoplasty, which avoids postauricular incisions.

Thus, this study demonstrates that both microscopic and endoscopic tympanoplasty are safe and effective

techniques for type 1 tympanoplasty, with comparable graft success rates and hearing outcomes. While the endoscopic approach may offer advantages in terms of reduced soft tissue trauma and better cosmetic outcomes, the choice of technique can be individualized based on surgeon expertise and case-specific anatomical considerations.

This study is limited by its relatively small sample size and single-center design. Future multi-center randomized controlled trials with larger sample sizes and long-term follow-up are recommended to further validate these findings.

Conclusion

The present study demonstrates that both endoscopic and microscopic type I tympanoplasty techniques are effective in achieving favorable anatomical and functional outcomes in patients with chronic otitis media mucosal disease. The graft uptake rates and improvement in air-bone gap were statistically similar between the two groups. Although minor suture site infections were observed in the microscopic group, no major complications occurred in either group. Endoscopic tympanoplasty offers the added advantages of a minimally invasive approach, better cosmetic results, and comparable outcomes to conventional microscopic surgery. Thus, endoscopic tympanoplasty is a viable and equally effective alternative to microscopic tympanoplasty for selected cases of tympanic membrane repair.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Utilization Pattern and satisfaction level of Old Age Pension Scheme Among Elderly in Rural Areas of Puducherry: A Cross Sectional Study

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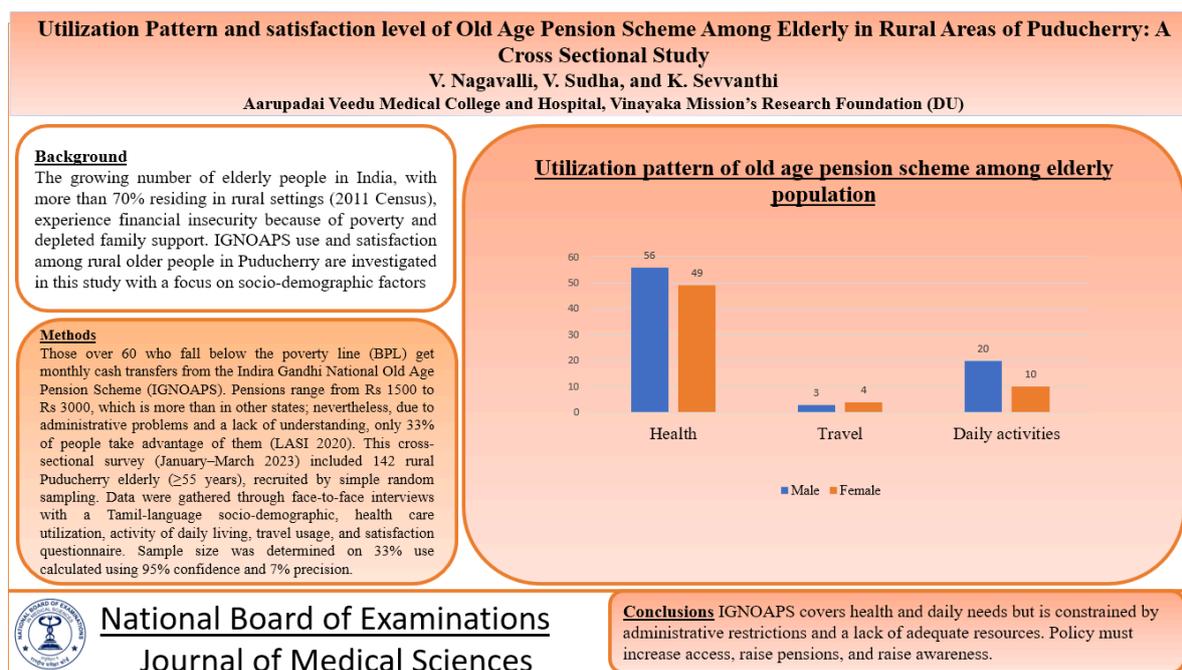
Abstract

Background: The growing number of elderly people in India, with more than 70% residing in rural settings (2011 Census), experience financial insecurity because of poverty and depleted family support. IGNOAPS use and satisfaction among rural older people in Puducherry are investigated in this study with a focus on socio-demographic factors. **Materials and Methods:** Those over 60 who fall below the poverty line (BPL) get monthly cash transfers from the Indira Gandhi National Old Age Pension Scheme (IGNOAPS). Pensions range from Rs 1500 to Rs 3000, which is more than in other states; nevertheless, due to administrative problems and a lack of understanding, only 33% of people take advantage of them (LASI 2020). This cross-sectional survey (January–March 2023) included 142 rural Puducherry elderly (≥ 55 years), recruited by simple random sampling. Data were gathered through face-to-face interviews with a Tamil-language socio-demographic, health care utilization, activity of daily living, travel usage, and satisfaction questionnaire. Sample size was determined on 33% use calculated using 95% confidence and 7% precision. The data were analysed using SPSS 26.0 with descriptive statistics and chi-square tests. Ethical clearance and informed consent were received. **Results:** Study participants (55.6% male, 66.2% literate, 97.9% unemployed) utilized pensions mainly for health (56 males, 49 females) and activities of daily living (20 males, 10 females) with little expenditure on travel. Satisfaction was related to gender ($p=0.019$). Age, education, employment, and health had no significant relationship. **Conclusion:** IGNOAPS covers health and daily needs but is constrained by administrative restrictions and a lack of adequate resources. Policy must increase access, raise pensions, and raise awareness.

Keywords: Old age pension, Rural elderly, Utilization, Satisfaction, Puducherry

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Graphical Abstract



Introduction

India's aging population is increasing at a fast pace with rising life expectancy and falling fertility rates, with more than 70% of them living in rural regions, as indicated by the 2011 Census [1]. This population transition presents formidable challenges for the economic protection of the elderly, many of whom suffer from financial insecurity arising from poverty, poor access to formal sector employment, and erosion of traditional family support networks [2]. Indira Gandhi National Old Age Pension Scheme (IGNOAPS), initiated in 2007 under the National Social Assistance Programme (NSAP), offers monthly cash benefits to Below Poverty Line (BPL) people aged 60 years and above to overcome these issues [3]. In Puducherry, a Union Territory with robust socio-economic parameters, the state adds to the central pension value, distributing Rs 1500 to 3000 depending on age categories, which is higher compared to several other states. This provides

Puducherry as a suitable context to observe pension utilization trends [4].

Even with its intentions, the IGNOAPS has some setbacks in rural areas, which according to studies, has poor take-up resulting from hindrances such as low awareness, cumbersome administrative procedures, and delay in disbursement of pension [2]. The Longitudinal Ageing Study in India (LASI, 2020) revealed that only a third of rural BPL elderly who are eligible receive the benefits of IGNOAPS, with challenges such as documentation issues and low awareness creating barriers to access [1]. In rural Puducherry, where multimorbidity and chronic conditions are prevalent among the older population, there is a need to understand how pension money is utilized, whether for healthcare, day-to-day needs, or maintenance of family and evaluate the scheme's role in quality of life (QOL) [1,2]. Recent findings indicate that receiving pensions can enhance economic empowerment and health-seeking behavior,

but contextual utilization patterns are least explored in rural settings [2].

The goal of this study is to investigate usage patterns, degree of satisfaction with the IGNOAPS among the older population in rural Puducherry, spending habits on health, daily living, social needs, and family support, as well as the social and demographic factors influencing such patterns. In filling these lacunae, the study offers evidence-based recommendations for maximizing the effectiveness of the scheme and guiding policy interventions for the rural elderly.

Methodology

This cross-sectional descriptive, community-based study was carried out among the elderly age group of 55 years and above residing in the rural field practice areas of a Private Medical College in Puducherry, India. The purpose of this study was to explore the utilization patterns and satisfaction levels of the Indira Gandhi National Old Age Pension Scheme (IGNOAPS) among this age group, particularly considering how pension money is spent and the socio-demographic determinants of these patterns.

The research was conducted among chosen rural villages under field practice areas of the Rural Health Training Centre of the tertiary care institute in Puducherry between January and March 2023. Puducherry was selected because it has a comparatively high pension grant of Rs 1500 to 3000 every month based on, as compared to many other states, and it has high human development indices, offering a special setting for testing the usage of pension. The study sample consisted of older adults aged 55 years and older, who had been living in the chosen rural communities for one year or more and were

registered in or eligible for the IGNOAPS. Those with severe cognitive impairment or who were not willing to give informed consent were excluded.

Sample size was calculated based on a study from 2020, which showed that 33% of rural Below Poverty Line (BPL) elderly who were eligible used the IGNOAPS [2]. Applying the cross-sectional study formula, $n = (Z\alpha/2)^2 * p * (1-p) / d^2$, where $Z\alpha/2 = 1.96$ (95% level of confidence), $p = 0.33$ (proportion of use), and $d = 0.07$ (absolute precision), the sample size needed was found to be around 129. Adding a non-response rate of 10%, a total of 142 participants were approached. A simple random sampling method was used, a list of eligible old people that was provided by household records kept by the Rural Health Training Centre. Out of this list, 142 participants were selected randomly with the help of a random number generator in order to have a random selection process.

Data were gathered using face-to-face interviews by means of a pretested semi-structured questionnaire. The questionnaire elicited socio-demographic factors (age, gender, education, marital status, socioeconomic status, pension use information (cognitive awareness of IGNOAPS, having received pension, amount received, and spending pattern in health, everyday activities, social requirements, and family support), morbidity and utilization behavior (self-reported chronic conditions and utilization of pension amounts for medical expenses), Interviews were carried out in Tamil to procure cultural and linguistic sensitivity. Quantitative data were processed with SPSS software version 26.0. Descriptive statistics, such as percentages, means, and standard deviations, were applied to present

socio-demographic characteristics and patterns of pension utilization. Comparisons between the relationships between socioeconomic factors and pension usage were made using chi-square

tests. The Institutional Ethics Committee of the Private Medical College approved the study, and written informed consent was taken from all participants, ensuring confidentiality throughout the study.

Results

Table 1. Distribution of study participants based on sociodemographic profile

Demographic characteristics	Frequency	percentage
Age		
55-59	41	28.9
60-79	52	36.6
≥80	49	34.5
Gender		
Male	79	55.6
female	63	44.4
Education		
Illiterate	48	33.8
literate	94	66.2
Occupation		
Employed	3	2.1
unemployed	139	97.9
Type of family		
Nuclear	119	83.8
Joint	23	16.2
Religion		
Hindu	132	93.7
Christian	8	5.6
Muslim	2	1.4

According to the demographic data in table 1, the study participants was predominantly made up of elderly individuals, with 36.6% of respondents falling between the ages of 60 and 79, 34.5% between the ages of 80 and older, and 28.9% between the ages of 55 and 59, indicating a predominantly elderly population. The gender pattern was slightly male-dominated at 55.6% versus 44.4% female. The education levels showed that 66.2% were literate and 33.8% were illiterate, implying a fairly educated

population. Occupation-wise, a very large participants 97.9% were unemployed, and just 2.1% were employed, most likely corresponding with the age groups retirement status. Family-wise, the majority was strongly nuclear (83.8%), while merely 16.2% lived in joint families. Religiously, the overwhelming majority were Hindu (93.7%), with a minuscule minority of Christians (5.6%) and Muslims (1.4%), corresponding to a largely Hindu population with little religious diversity.

Table 2. Association between Sociodemographic factors and Satisfaction level of old age pension scheme

Variables	Satisfied N=70		Dissatisfied N=72		Chi-square value	P value
Age						
≤75 Years	30	42.9%	32	44.4%	0.757	0.384
≥75 Years	50	71.4%	40	55.6%		
Sex						
Male	32	45.7%	47	65.3%	5.504	0.019*
Female	38	54.3%	25	34.7%		
Education						
Illiterate	19	27.1%	29	40.3%	2.737	0.098
literate	51	72.9%	43	59.7%		
Occupation						
Employed	2	2.9%	1	1.4%	0.37	0.543
unemployed	68	97.1%	71	98.6%		
Socio economic status						
Class I & II	33	47.1%	23	31.9%	3.486	0.062
Class III & IV	28	40.0%	36	50.0%		
Class V	9	12.9%	13	18.1%		
Health condition						
Chronic disease	42	60.0%	39	54.2%	0.493	0.483
Normal	28	40.0%	33	45.8%		

The Table 2 depicts the examination of the association between sociodemographic and satisfaction with the previous old age pension scheme

demonstrated different patterns. There was no significant correlation with age ($p=0.384$), with 42.9% of ≤75 years old and 71.4% of ≥75 years old satisfied, in contrast

to 44.4% and 55.6% dissatisfied, respectively. Gender was highly significant ($p=0.019$), 45.7% of males being satisfied and 65.3% dissatisfied, and 54.3% of females being satisfied and 34.7% dissatisfied. Education level also revealed no significant association ($p=0.098$), with 27.1% of literate respondents being satisfied and 40.3% dissatisfied, and 72.9% of illiterate respondents satisfied and 59.7% dissatisfied. Occupation was not found to be significantly associated ($p=0.543$), with 97.1% of unemployed respondents being

satisfied and 98.6% dissatisfied. Socioeconomic status was not significantly related ($p=0.062$), with satisfaction levels being 47.1% for Class I & II and 40% for Class III & IV, respectively, as compared to dissatisfaction levels of 31.9% and 50%, respectively. Health condition was also not significantly related ($p=0.483$), with 60% of patients having chronic diseases satisfied as compared to 54.2% dissatisfied, and 40% of patients having normal health satisfied as compared to 45.8% dissatisfied.

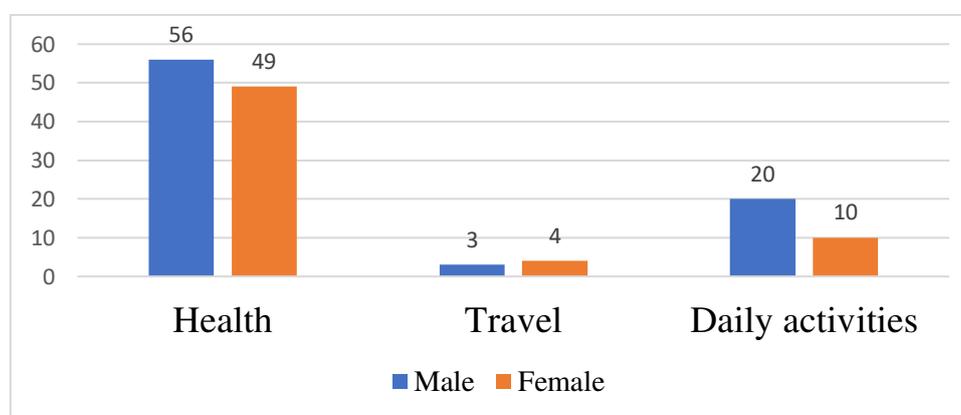


Figure 1. Utilization pattern of old age pension scheme among elderly population.

The Figure 1 depicted an old age pension scheme utilization pattern among aged people, gender-segmented (Male and Female) in three categories: Health, Travel, and Daily Activities. Under the category of Health, males had a higher utilization rate of 56 as compared to females at 49, which showed a significant preference among males for this activity. On the other hand, the Travel category registered low usage for both genders, with women leading at 4 while men trailed at 3. Daily Activities saw men again take the lead with an adoption rate of 20, followed by women at 10, indicating a moderate inclination among men here as well. In general, the statistics depicted a trend where men used the

pension scheme more than women, with the greatest usage coming from Health, followed by Daily Activities, and minimal use in Travel for both sexes.

Discussion

The cross-sectional study found the patterns of use and satisfaction levels with the Indira Gandhi National Old Age Pension Scheme (IGNOAPS) among the elderly people of rural Puducherry and generated meaningful knowledge regarding the scheme's ability to meet the economic and healthcare needs of the elderly. The age structure of the study sample was seen to be largely elderly, with 36.6% in the age range of 60–79 years and 34.5% in the over 80

years' age group, reflecting rural India's aging population trends evident from the 2011 Census [6]. The male overrepresentation (55.6%) and high unemployment level (97.9%) correspond to the anticipated retirement status of this age group, in line with the Longitudinal Ageing Study in India (LASI, 2020), emphasizing the economic dependency of rural older populations [1]. The prevalence of nuclear families (83.8%) compared to joint families (16.2%) indicates change from traditional family forms, possibly leading to greater dependence on social security programs such as IGNOAPS with declining family support structures [1,2].

The research identified gender as strong predictors of satisfaction with the IGNOAPS ($p=0.019$). Interestingly, there was a higher likelihood of females expressing discontent (54.3%) than males (27.1%), which is contrary to some earlier findings reporting females gained more from pension schemes because of higher economic vulnerability [5]. This difference may be due to greater expectations from males or varying access to information and administrative procedures in rural Puducherry. Conversely, literate respondents were more inclined to express dissatisfaction (72.9%) than illiterate respondents (27.1%), perhaps due to higher levels of awareness of procedural inefficiencies or greater expectations of the scheme's rewards among educated participants [3]. These results support the significance of socio-demographic variables in influencing perceptions of social security schemes, as proposed by Ravi et al. (2025), who emphasize the role of education and gender in pension scheme participation [2].

The age, education, profession, socioeconomic status, and medical status

had no relationship with satisfaction ($p>0.05$). The absence of correlation with age ($p=0.384$) indicates that younger (≤ 75 years) and older (≥ 75 years) elderly do not differ significantly in their level of satisfaction, which could reflect similar difficulties in receiving or utilizing the pension regardless of age [1]. The lack of a strong correlation with occupation ($p=0.585$) comes as no surprise in the light of near-total unemployment (97.9%) among this aging population, consistent with economic dependence observed in Pandey and Kumar (2023) [5]. Correspondingly, socioeconomic status ($p=0.817$) and health status ($p=0.655$) did not have a significant effect, indicating that the existence of chronic conditions (91.1% of satisfied respondents) does not have a strong effect on satisfaction, possibly due to the fact that pension sizes are inadequate to meet healthcare expenses in rural Puducherry, where multimorbidity is common [1,5].

The poor take-up of IGNOAPS, where less than a third of the rural BPL elderly eligible were covered as per LASI (2020), was echoed in the problems expressed in this study, including unawareness and administrative complexities [1]. These issues will probably account for the high levels of dissatisfaction, especially in males and literate people, who may face or even perceive more procedural obstacles. The dominance of nuclear families (83.8%) could also further increase pressures on finances, since traditional joint family support networks are less accessible, with greater reliance on pensions for day-to-day needs, healthcare, and social care [2]. Yet the evidence of the research implies that the pension value (Rs 1500–3000) in Puducherry, although greater than in most

states, could still be insufficient to make a real difference in terms of quality of life, especially for healthcare needs, considering the high rates of chronic disease [5,6,7].

The religious distribution, with 93.7% Hindu respondents, illustrates the population profile of rural Puducherry and could shape cultural perspectives on the use of pensions, although this was not measured directly [6]. The qualitative aspect of the study in the form of in-depth interviews with Anganwadi workers, non-beneficiaries, and beneficiaries would additionally shed light on such barriers as delay in pension disbursement and documentation hassles, observed in earlier studies [1,2]. Future research should investigate these qualitative findings to craft evidence-based interventions, e.g., streamlined application procedures or sensitization campaigns, to address IGNOAPS uptake and satisfaction.

The pattern of utilization of the Indira Gandhi National Old Age Pension Scheme (IGNOAPS) by rural elderly in Puducherry was such that most of the male and female beneficiaries utilized their pension towards health care expenses, given the prevalent high prevalence of chronic diseases and poor access to geriatric healthcare in rural settings [1,5]. Few employed the pension for travel (3 men, 4 women), possibly because of mobility restrictions or prioritization of basic needs [2]. Notably, more men (n=20) employed the pension for everyday activities than women (n=10), indicating potential differences in financial independence or household function [2,5]. These conclusions reinforce the necessity for gender-sensitive delivery of pensions and increased protection of healthcare cover to limit dependence on the pension for medicine needs [1,4,7].

The strengths and limitations of this research are limited sample size (n=142) and reliance on patient reported data, and such reliance could have introduced recall bias. In addition, the research failed to investigate certain spending patterns (e.g., percentage of pension allocated to healthcare vs. living expenses), which may yield more in-depth utilization insights. Notwithstanding these shortcomings, the research adds to the sparse literature on utilization of IGNOAPS in rural settings, in a high-pension state such as Puducherry [7]. The study emphasizes the requirement of policy measures to overcome administrative hurdles and raise pension values to suit the healthcare and economic requirements of the rural elderly.

Conclusion

This research underscored the pivotal role of the Indira Gandhi National Old Age Pension Scheme (IGNOAPS) in enabling elderly men and women in Puducherry's rural areas to access healthcare and cover other needs of everyday living. Although the scheme ensured basic financial relief particularly for healthcare spending levels of satisfaction differed widely according to gender and education, with educated and male respondents expressing higher levels of dissatisfaction. While Puducherry provided relatively higher amounts of pensions compared to most other states, the results indicated that the financial assistance was still inadequate to address the larger needs of the older persons, especially those with chronic diseases. Travel utilization was low, and gender variations in expenditure on routine activities indicated underlying socio-cultural issues and mobility constraints. The effectiveness of the scheme was also

limited by administrative constraints, ignorance, and weakening traditional familial support. According to the research, measures needed to better address the financial and health care requirements of elderly people in rural areas include better access mechanisms, more initiatives to increase awareness, and a possible rise in the number of pensions. Future research using qualitative methods was suggested to examine greater depth regarding the lived experience and issues confronting beneficiaries.

Statements and Declarations

Conflicts of interest

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

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REVIEW ARTICLE

The Scope of 4D Printing in Endodontics

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Abstract

Three-dimensional printing has revolutionized modern dentistry by enabling personalized, digitally driven procedures. However, its static constructs fail to mimic the dynamic behavior of oral tissues. Four-dimensional printing—an evolution of 3D technology—introduces time-responsive smart materials that can change shape or function in response to external stimuli. This narrative review explores the progression from three-dimensional to four-dimensional printing, highlighting the potential applications of 4D technology in endodontics. Emphasis is placed on how four-dimensional printing may address current limitations in regenerative endodontic scaffolds, intracanal drug delivery, and adaptive obturation systems. Given the lack of direct clinical implementation, this review outlines the theoretical and experimental scope of 4D printing in endodontics.

Keywords: 3D printing, 4D printing, Dentistry, smart materials, shape memory polymers, regenerative dentistry

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Introduction: The Rise of Additive Manufacturing in Dentistry

The three-dimensional (3D) printing has played a pivotal role in various dimensions of dentistry, such as preparation of surgical guides, rapid and accurate fabrication of prosthesis and modification of various devices, etc. [1,2]. It has also been used in endodontics mainly for the development of customized guides for doing access cavity preparation in calcified canals, for making training models, and for modifying and optimizing scaffolds for regenerative endodontics [3]. Nevertheless, despite these advances, this technique has not been able to be explored to its full potential in endodontics. This is primarily because 3D printing cannot maintain the dynamism in its output, resulting in static outcomes. There is no possibility of changing or adapting the geometry and configuration of the output after printing [4]. Furthermore, the regenerative capability of static scaffolds is limited because they are not able to adjust to changing internal anatomy or healing environments [5]. These drawbacks highlight the need for a technology that can capable of producing biomimetic, dynamic, and stimulus-responsive structures.

4D Printing: Evolution and Definition

The concept of four-dimensional (4D) printing was first presented by Skylar Tibbitts at MIT in 2013. He defined it as 3D printing that has been improved with smart materials that allow

for gradual change in shape or property over time [6]. Time, the fourth dimension, makes the structures dynamic and functionally adaptive by allowing them to react to stimuli such as heat, moisture, pH, or magnetic fields [7]. In contrast to 3D models, 4D printed devices can transform after printing, offering real-time interaction with biological environments [8].

Materials and Mechanisms of 4D Printing

Various smart materials have been used in 4D printing, such as shape-memory polymers (SMPs), hydrogels, and composites, sensitive to various stimuli [9]. When heated, SMPs can return to a predefined form, making them suitable for space-adapting scaffolds and root canal obturation [10]. Hydrogels have superior biocompatibility and tunable properties, which make them suitable for dental applications, especially in regenerative endodontic strategies [11]. These materials are printed using advanced stereolithography systems or multi-material extrusion, making them capable of creating structures with integrated functionality. However, there are certain limitations to using hydrogels and shape-memory polymers in dentistry. Hydrogels often lack mechanical strength and tend to lose their effectiveness over time as they swell and shrink repeatedly. Shape-memory polymers also respond to changes in temperature, but they may go back to their original shape too quickly or in an unexpected way, which can make them

less useful in complicated clinical situations [6].

Applications of 4D Printing in Dentistry

4D printing in dentistry is currently utilized for corroborative tasks in creating self-adjusting orthodontic aligners, smart implants, adaptive prosthesis, and consumptive drug-releasing devices [5,9]. In periodontics, smart scaffolds are emerging for tissue regeneration under biomechanical load [12]. In Prosthodontics, removable dentures are developed to adapt to mucosal changes, and dynamic implants that integrate better with bone are studied in oral surgery [13]. Even though most of these applications are at an experimental stage, they are advanced steps toward a dynamic and personalized form of dentistry.

Potential Applications in Endodontics

Despite a lack of direct research on 4D printing in endodontics, its potential is vast. Smart scaffolds made with 4D technology could release therapeutic agents in response to inflammation or infection, improve healing through programmed degradation, and be able to adjust to irregular root canal anatomy [10,11]. The major application of 4D in endodontics can be in the form of root canal fillings, which can better adapt to irregularities of the root canal by changing the shape after insertion. This increases the chance of root canal sealing in all dimensions, which will further reduce the chance of

treatment failure by bacterial leakage. Shape-memory obturation materials may improve canal sealing by extending into small lateral canals when heated [7]. To improve treatment outcomes, future systems might incorporate intelligent intracanal drug delivery platforms that release medication in response to microbial activity.

Limitations and Future Scope

High fabrication costs, limited clinical-grade smart materials, and lack of data on long-term biocompatibility present difficulties for 4D printing despite its transformative potential [14]. Printing resolution and response predictability are still major technical challenges. More in vitro and in vivo studies are needed in endodontics to validate mechanical performance, therapeutic impact, and material safety. As interdisciplinary research progresses, the integration of artificial intelligence with 4D printing may further enhance material responsiveness and procedural customization.

Conclusion

4D printing brings intelligent, dynamic, responsive constructions to dentistry. Although its application in endodontics is still hypothetical, its capacity to overcome important constraints of 3D-printed systems makes it a future tool of promise. 4D printing is expected to revolutionize regenerative endodontics, drug delivery, and biomaterial-based therapies as studies on dental smart materials expand.

Statements and Declarations

Conflicts of interest

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

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REVIEW ARTICLE

The Role of Clinical Pharmacologists in Hospital Administration: A Strategic Leadership Perspective

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Abstract

Background: Clinical pharmacologists possess a unique blend of deep drug-therapy expertise and a crucial systems-based perspective on healthcare delivery. Despite their comprehensive training, the potential leadership contributions of these individuals in hospital administration, particularly at strategic levels, remain significantly underutilised across many healthcare systems. This frequently results in lost chances to improve hospital financial results, patient safety, and operational efficiency. **Objectives:** The purpose of this narrative review is to examine and synthesize the available data regarding the various ways that clinical pharmacologists currently impact and can strategically contribute to important aspects of hospital governance, formulary decisions, medication safety programs, and general strategic management. We aim to draw attention to their demonstrated influence and point out avenues for deeper integration. **Methods:** A comprehensive narrative review of English-language literature published between 2000 and 2025 was conducted across major bibliographic databases, including PubMed, Scopus, and Google Scholar. Search terms combined "clinical pharmacologist" with "hospital administration," "leadership," "formulary management," "medication safety," "Pharmacoeconomics," and "strategic governance." Inclusion criteria focused on peer-reviewed studies, observational and interventional studies, narrative and systematic reviews, and policy papers directly addressing clinical pharmacologists' leadership roles in hospital settings. Articles not related to hospital-based or preclinical pharmacology were excluded. **Conclusion:** It is proven that patient safety, clinical results, and operational efficiency are all improved when clinical pharmacologists are promoted to official, strategic leadership positions within hospital administration. Hospitals and healthcare policymakers should proactively formalise these roles through targeted leadership training, explicit policy development, and careful organisational design with the goal of maximising their expertise at the highest levels of hospital governance.

Keywords: Clinical pharmacologist; hospital administration; leadership; formulary management; medication safety; Pharmacoeconomics; strategic governance

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Introduction

Fundamentally, the scientific field of clinical pharmacology is devoted to comprehending how medications affect people and improving drug treatment. Direct patient care, including complex pharmacotherapy consultations, therapeutic drug monitoring, and managing adverse drug reactions, has historically been the primary responsibility of the clinical pharmacologist in hospitals [1]. Their extensive knowledge of drug interactions, pharmacokinetics, pharmacodynamics, and therapeutic efficacy makes them invaluable in the management of individual patients, particularly those with complicated comorbidities or difficult drug schedules.

Clinical pharmacology's scope has been gradually growing beyond these conventional direct patient care roles. Significant contributions to pharmacovigilance, the creation of clinical practice guidelines, and involvement in drug development and research within academic medical centres are examples of emerging roles today [2]. They are in a unique position to close the knowledge gap between the fundamentals of pharmacological sciences and their practical use at the bedside and, more and more, at the systemic level of healthcare delivery.

Clinical pharmacologists continue to be remarkably underrepresented in strategic hospital leadership and administrative roles, despite having a wealth of knowledge that includes both the subtle complexities of contemporary therapeutics and an innate understanding of healthcare systems [1]. Although they are frequently consulted on particular drug-related matters, their wider ability to impact hospital governance, resource distribution, and policy formation is overlooked. This

underrepresentation constitutes a significant gap, hindering hospitals from fully leveraging a unique talent pool capable of driving substantial improvements in quality, safety, and financial stewardship.

This review's objective is to methodically investigate and support the strategic leadership positions that clinical pharmacologists can and ought to hold in hospital administration. Our goal is to draw attention to their demonstrated contributions in a number of important areas and offer workable plans for their formal incorporation into hospital governance. By doing this, we hope to show that giving clinical pharmacologists strategic administrative authority is not just a theoretical ideal but also a necessary step toward improving patient care and hospital performance in an increasingly complicated healthcare environment.

Methods

This narrative review was conducted to synthesize existing literature on the strategic leadership roles of clinical pharmacologists in hospital administration. The methodology employed aimed for a comprehensive yet focused exploration of relevant evidence.

Literature Search

A thorough search of English-language literature published between January 1, 2000, and June 30, 2025, was performed across three major electronic bibliographic databases: PubMed, Scopus, and Google Scholar. The broad temporal scope was chosen to capture two and a half decades of evolving roles and administrative practices in hospital settings. The search strategy employed a combination of keywords, including

"clinical pharmacologist," "hospital administration," "leadership," "formulary management," "medication safety," "Pharmacoeconomics," and "strategic governance," along with their synonyms and related terms (e.g., "pharmacology department head," "drug policy committee," "adverse drug events," "antimicrobial stewardship director," "health economics"). Boolean operators (AND, OR) were used to combine these terms effectively.

Inclusion Criteria

Articles were included if they met the following criteria:

- Peer-reviewed studies published in scientific journals.
- Original research (observational studies, interventional studies) that explored the roles or impact of clinical pharmacologists in hospital administration or leadership.
- Review articles (narrative reviews, systematic reviews, meta-analyses) that synthesised evidence on the topic.
- Policy papers, guidelines, or consensus statements from professional organizations or governmental bodies addressing the administrative or leadership contributions of clinical pharmacologists in hospitals.
- Studies specifically focusing on leadership, administrative, or governance roles of clinical pharmacologists within hospital or healthcare system contexts.

Exclusion Criteria

Articles were excluded if they:

- Focused solely on preclinical pharmacology research without direct relevance to hospital administration or clinical practice.

- Discussed the roles of clinical pharmacologists primarily outside of hospital settings (e.g., pharmaceutical industry, regulatory agencies, private clinics, academic research without hospital linkage).
- Were editorials, letters to the editor, conference abstracts, or book chapters unless they provided unique, substantiated evidence not available elsewhere.
- They were not available in English.

The initial search results were screened based on titles and abstracts for relevance. Full-text articles (n = 105) were then retrieved for a more detailed assessment against the inclusion and exclusion criteria. Data relevant to the objectives were extracted and synthesised thematically for discussion in the subsequent sections.

The Strategic Roles of Clinical Pharmacologists

Clinical pharmacologists, with their unique dual training in medicine and therapeutics, are exceptionally well-positioned to assume strategic leadership roles that transcend traditional clinical practice. Their expertise allows them to impact various facets of hospital administration, from direct patient safety to broader financial and operational efficiencies.

Formulary and P&T Committee Leadership

Clinical pharmacologists play a pivotal role in Formulary and Pharmacy & Therapeutics (P&T) Committees, which are central to drug selection and management within hospitals. Their scientific rigour and understanding of evidence-based medicine are crucial for evaluating new drugs,

assessing their efficacy, safety, and cost-effectiveness [4].

Evidence on their involvement includes their leadership in developing drug monographs, setting criteria for restricted drug use, and creating therapeutic guidelines that standardise prescribing practices. They are instrumental in supplier negotiation and cost management, advising on bulk purchasing agreements, advocating for generic substitutions where appropriate, and negotiating with pharmaceutical companies to secure favourable pricing without compromising patient care quality.

Demonstrable financial impacts can be seen through case studies of rational procurement. For example, a clinical pharmacologist's analysis might reveal that a slightly more expensive but significantly more effective antibiotic can lead to shorter hospital stays and reduced complication rates, ultimately yielding net cost savings due to decreased overall treatment expenses [4]. Their expertise in Pharmacoeconomics is directly applied here to make informed decisions that balance clinical need with fiscal responsibility, preventing the unnecessary expenditure on less effective or overly priced medications.

Medication Safety and ADR Reporting

Medication safety is a cornerstone of patient care, and clinical pharmacologists are uniquely equipped to lead initiatives in this critical area. Their deep understanding of pharmacology allows them to identify potential drug-related risks, design safer medication processes, and effectively manage adverse drug reactions (ADRs) [5].

Their role in improving adverse drug reaction systems is paramount. Clinical pharmacologists often design and implement hospital-wide ADR reporting

protocols, ensuring comprehensive data collection and thorough causality assessment [5]. They can recommend dosage adjustments, specific patient monitoring protocols, or even the removal of the drug from the formulary if safer alternatives exist. They are instrumental in analysing reported incidents to identify systemic issues rather than isolated errors.

Their role has a direct impact on reducing medication errors, such as implementing smart pump technology with drug libraries, developing order sets with built-in safety alerts, or providing targeted education to prescribing physicians and nursing staff on high-alert medications [5]. These interventions are directly linked to national and joint quality standards and hospital accreditation frameworks.

Organisations like the Joint Commission (JCI) or the National Accreditation Board for Hospitals & Healthcare Providers (NABH) emphasise robust medication safety practices. Clinical pharmacologists ensure that hospitals not only meet but exceed these standards by proactively identifying and mitigating risks, thereby enhancing the hospital's reputation for patient safety and facilitating successful accreditation.

Antimicrobial Stewardship Programs (ASP)

The rising threat of antimicrobial resistance (AMR) has made Antimicrobial Stewardship Programs (ASPs) a mandatory and critical component of modern hospital operations. Clinical pharmacologists are ideally suited to provide leadership in designing, monitoring, and evaluating ASPs due to their comprehensive knowledge of microbiology, infectious diseases, and pharmacokinetics/pharmacodynamics of antimicrobials [6].

They are typically at the forefront of developing evidence-based guidelines for appropriate antibiotic use, restricting broad-spectrum antibiotics, and promoting de-escalation of therapy. For example, a clinical pharmacologist might establish a protocol for "antibiotic time-outs". where prescribing physicians are prompted to reassess antibiotic therapy after 48-72 hours based on culture results. They lead multidisciplinary teams, including infectious disease specialists, microbiologists, and pharmacists, to implement these strategies effectively.

The impact of their leadership in ASPs is multifold. It directly aligns with significant cost savings by reducing unnecessary antibiotic prescriptions, shortening lengths of hospital stay, and decreasing the incidence of *Clostridioides difficile* infections [6]. Moreover, it demonstrably improves Key Performance Indicator (KPI) performance related to healthcare-associated infections and readmission rates. Crucially, their work in ASPs ensures AMR policy compliance with national and international guidelines.

Pharmacoeconomics in Hospital Budgets

In an era of escalating healthcare costs and finite resources, the application of Pharmacoeconomics in hospital budgets is indispensable. Clinical pharmacologists, with their quantitative skills and understanding of both clinical outcomes and economic principles, are uniquely positioned to apply cost-effectiveness and budgetary analysis to high-cost therapies and new medical technologies.

They conduct pharmacoeconomic evaluations, such as cost-effectiveness analyses (CEAs), cost-utility analyses (CUAs), and budget impact analyses (BIAs), for new drugs or treatment

protocols [7]. This allows them to quantify the value proposition of different therapeutic options, going beyond mere acquisition cost to consider the full economic impact, including effects on length of stay, readmission rates, and long-term patient outcomes. For instance, when evaluating a new biological agent for an autoimmune disease, a clinical pharmacologist would not only consider its price but also its potential to reduce hospitalisations and improve patient productivity, thereby justifying its cost [7].

This expertise directly ties into formulary decisions and capital investment. Their pharmacoeconomic analyses provide P&T committees with data-driven insights to make rational decisions about drug inclusion and purchasing, ensuring that the hospital invests in therapies that offer the best value for money [4].

Clinical Trial Management & Research Administration

Clinical pharmacologists commonly take on key operational functions in clinical trials sponsored by hospitals and research administration generally. Their scientific expertise and knowledge of regulations render them indispensable in translating new therapies from the research setting to the bedside [2].

They are frequently engaged in feasibility assessments of new clinical trials, determining the feasibility of performing studies through the hospital's current infrastructure and patient base. Their pharmacological and drug development pathway expertise enables them to act as regulatory liaisons and ensure compliance with local, national, and international regulations (e.g., ICH-GCP guidelines, ethical review board requirements [2]). This includes managing

the intricacies of informed consent, patient safety reporting, and data integrity. In addition, clinical pharmacologists make important contributions to quality governance in clinical research.

They create strong monitoring plans, monitor data collection to maintain accuracy and completeness, and apply quality controls to protect patient safety and trial integrity.

Human Resource and Organisational Change

In addition to their clinical and scientific functions, clinical pharmacologists may also act as effective hospital leaders in human resources and organisational change management. Their knowledge of the intricate health system as well as their ability to facilitate clinical and administrative change perspectives, enables them to be successful change agents [3].

They contribute significantly to training pharmacists and clinicians on new drug therapies, medication safety protocols, and evidence-based prescribing practices. Continuous education is vital for maintaining high standards of care and integrating new knowledge into daily practice. For instance, a clinical pharmacologist may design and provide training modules for new residents in rational antibiotic prescribing or for nurses in safely administering high-risk medication. As a leader, they are skilled in the management of change within hospital settings, particularly with the introduction of new technologies or treatment models.

They also assist in monitoring performance measures associated with the use of medication, safety, and efficiency, utilising data to determine areas of improvement and inform strategic decision-making [3].

Organisational Models & Integration Strategies

The effective integration of clinical pharmacologists into hospital administration requires thoughtful organisational design. While their roles vary across institutions, several models exist for incorporating their expertise, ranging from advisory positions to formal leadership appointments.

Overview of Models

- **Independent Departments:** In some larger academic medical centres, clinical pharmacology may exist as a standalone department. This model provides a strong academic and research focus, allowing clinical pharmacologists to lead their initiatives and maintain a distinct professional identity.
- **Divisions within Clinical Departments:** More commonly, clinical pharmacology might be a division within a larger clinical department or a pharmacology unit. This model offers close ties to direct patient care and medical education but might limit direct administrative authority or influence over hospital-wide policies.
- **Integrated within Pharmacy Services:** In other models, clinical pharmacologists may work closely with, or be formally integrated into, the Department of Pharmacy. While beneficial for medication management and formulary control, this model might not fully leverage their broader medical and systems-based expertise for strategic governance beyond drug-related issues.
- **Direct Administrative Appointments:** A growing, albeit less common, model involves direct administrative

appointments, such as a Chief Medical Officer with a background in clinical pharmacology, or dedicated roles within quality and safety departments. This model offers the most direct strategic influence but requires a clear understanding of the unique value proposition of clinical pharmacologists by hospital leadership.

Recommendation for Formal Leadership Positions

To fully harness the strategic capabilities of clinical pharmacologists, hospitals should actively pursue the creation of formal leadership positions with defined responsibilities and clear lines of authority. Recommended roles include:

- Medication Safety Officer (MSO): A dedicated MSO with a clinical pharmacology background can lead all medication safety initiatives, from error prevention and reporting to root cause analysis and implementing corrective actions [5].
- Antimicrobial Stewardship Program (ASP) Director: Formalising this role for a clinical pharmacologist ensures consistent leadership, strategic planning, and effective implementation of ASPs crucial for combating antimicrobial resistance [6].
- Chair or Co-Chair of the Pharmacy & Therapeutics (P&T) Committee: Elevating a clinical pharmacologist to a formal leadership position within the P&T committee solidifies their influence over formulary decisions, drug procurement, and pharmaco-economic evaluations [4].
- Director of Pharmacoeconomics/Value Analysis: A dedicated role focused on assessing the cost-effectiveness and budgetary impact of therapies, directly

informing hospital financial strategy [7].

- Chief Quality and Safety Officer: For a broader impact, a clinical pharmacologist can assume a hospital-wide leadership role focusing on overall quality improvement and patient safety, leveraging their systems-based thinking.

Outline of Competencies Needed

Beyond their foundational clinical and pharmacological expertise, clinical pharmacologists aspiring to strategic leadership roles need to cultivate a broader set of competencies:

- Health Economics and Finance: A strong understanding of healthcare economics, budgeting, cost accounting, and financial management to effectively contribute to strategic resource allocation and demonstrate return on investment (ROI) [7].
- Negotiation Skills: Proficiency in negotiation, particularly with pharmaceutical companies, suppliers, and external partners, to secure favourable terms for drug procurement and technology adoption.
- Data Analytics and Informatics: Advanced skills in data collection, analysis, interpretation, and visualisation to drive evidence-based decision-making in areas like medication safety, formulary management, and operational efficiency. Familiarity with electronic health record (EHR) systems and health informatics is crucial.
- Quality and Safety Accreditation Know-How: In-depth knowledge of national and international quality and safety standards and accreditation processes, enabling them to lead

initiatives that ensure compliance and drive continuous improvement [5].

- **Leadership and Management:** Training in organisational behaviour, change management, team leadership, strategic planning, and human resource management to effectively lead multidisciplinary teams and implement organisational change
- **Communication and Advocacy:** Excellent communication skills to articulate complex scientific and financial concepts to diverse audiences, including clinicians, administrators, and policymakers, and to advocate for evidence-based policies. Developing these competencies through formal education (e.g., MBA programs), specialised certifications, and mentorship is crucial for clinical pharmacologists to successfully transition into and excel in strategic administrative positions.

Challenges & Enablers

While the strategic value of clinical pharmacologists in hospital administration is clear, their full integration is often hampered by significant barriers, yet facilitated by identifiable enablers.

Barriers

- **Lack of Formal Roles and Job Descriptions:** A primary barrier is the absence of clearly defined, formal administrative or leadership positions specifically designed for clinical pharmacologists within many hospital organisational charts. This leads to their expertise being utilised on an ad hoc basis rather than being structurally embedded
- **Variable Administrative Recognition:** There is often a lack of consistent

administrative recognition of the unique value proposition that clinical pharmacologists bring beyond direct patient care. Hospital executives may not fully grasp their potential contributions to financial stewardship, quality improvement, and strategic planning.

- **Funding Issues and Resource Constraints:** Hospitals, particularly those with tight budgets, may perceive the creation of new, dedicated administrative positions as an added cost rather than a strategic investment. Funding for specialised training or dual degrees (e.g., MD/MBA) can also be a significant limitation.
- **Limited Managerial and Leadership Training:** Traditional clinical pharmacology training pathways often focus heavily on scientific and clinical aspects, with less emphasis on formal management, leadership, health economics, or organisational development skills. This can make the transition into administrative roles challenging
- **Siloed Organisational Structures:** Many hospitals operate with siloed departments, making it difficult for a professional from one speciality (clinical pharmacology) to exert influence across multiple administrative domains without a clear mandate or formal integration.
- **Resistance to Change:** Existing administrative structures and traditional hierarchies may exhibit resistance to integrating new roles or empowering non-traditional leaders, preferring to maintain the status quo.

Enablers

- **Dual Training (MD + MBA/MHA):** Clinical pharmacologists who pursue advanced degrees in business administration (MBA) or health administration (MHA) are exceptionally well-equipped to bridge the clinical and administrative worlds. This dual training provides them with both medical credibility and the necessary managerial and financial acumen.
- **Mentorship in Leadership:** Opportunities for mentorship by experienced hospital executives, particularly those who understand the value of clinical expertise in administration, can significantly accelerate the development of leadership skills and provide pathways to strategic roles.
- **Supportive Policy Frameworks:** National or regional healthcare policies that mandate or incentivise specific roles (e.g., requiring an ASP director) or emphasise pharmacoeconomic evaluations can create the necessary impetus for hospitals to formalise clinical pharmacologist positions [6,7].
- **Demonstration of Return on Investment (ROI):** Crucially, the ability of clinical pharmacologists to demonstrate the tangible ROI of their interventions (e.g., quantifiable cost savings from formulary management, reduced medication errors leading to fewer readmissions, improved patient outcomes from ASPs) is the most powerful enabler [4-6].
- **Accreditation Body Requirements:** Requirements from accreditation bodies related to medication safety, quality improvement, and antimicrobial stewardship can necessitate the

expertise of clinical pharmacologists, thereby creating demand for their formal inclusion in administrative roles [5].

- **Advocacy by Professional Organisations:** Strong advocacy from professional organisations representing clinical pharmacologists can raise awareness among hospital administrators and policymakers about their strategic contributions, pushing for greater recognition and integration.

Overcoming the barriers requires a concerted effort from both the clinical pharmacology community and hospital leadership, recognising the mutual benefits of greater integration.

Recommendations for Hospitals & Policy Makers

To fully capitalise on the strategic expertise of clinical pharmacologists, a multi-pronged approach involving hospitals, academic institutions, and policymakers is essential. These recommendations aim to formalise roles, foster leadership development, and ensure accountability.

For Hospitals

Embed Clinical Pharmacologists in Hospital Governance with Defined Role Descriptions

- **Create Formal Positions:** Establish specific administrative and leadership roles for clinical pharmacologists within the hospital's organisational structure, such as Chief Pharmacologist Officer, Director of Medication Safety, Head of Antimicrobial Stewardship, or Chair of the P&T Committee.
- **Develop Clear Job Descriptions:** For these roles, articulate comprehensive

job descriptions that go beyond clinical responsibilities to include strategic planning, policy development, financial oversight, quality improvement initiatives, and interdepartmental collaboration.

- Ensure Representation on Key Committees: Mandate their presence and active participation on critical hospital committees, including the executive board, quality assurance committees, finance committees, and risk management teams, ensuring their insights inform high-level decision-making.

Provide Structured Leadership Development

- Sponsor Advanced Education: Invest in clinical pharmacologists by sponsoring or supporting their enrolment in MBA, MHA, or other relevant master's programs focused on healthcare administration, health economics, and leadership.
- Offer Mentorship Programs: Establish formal mentorship programs where senior hospital administrators mentor clinical pharmacologists interested in leadership roles, guiding strategic thinking, organisational dynamics, and effective management.
- Provide Continuous Professional Development: Fund and encourage participation in workshops, seminars, and certifications focused on quality improvement, patient safety, data analytics, negotiation skills, and change management.

Monitor Impact via Key Metrics

- Track Formulary Cost Savings: Implement robust systems to quantify

the financial impact of formulary decisions influenced by clinical pharmacologists, including drug acquisition cost reductions, waste minimisation, and efficiency gains [4].

- Measure Reduced Medication Errors and Adverse Drug Events (ADEs): Systematically collect and analyse data on medication errors, near misses, and ADEs, correlating reductions with clinical pharmacist-led safety initiatives [5].
- Assess ASP Effectiveness: Utilise key performance indicators (KPIs) for antimicrobial stewardship, such as reductions in broad-spectrum antibiotic use, Clostridioides difficile infection rates, and length of hospital stay attributed to infections, to demonstrate the value of clinical pharmacist leadership.
- Evaluate Patient Outcomes: Monitor improvements in patient outcomes, such as reduced readmission rates, decreased morbidity and mortality linked to optimised pharmacotherapy, and enhanced patient satisfaction.

For Policy Makers and Professional Bodies

Encourage National-Level Frameworks to Formalise Leadership Roles

- Develop Accreditation Standards: Regulatory and accreditation bodies should integrate requirements for specific roles within hospital accreditation standards [5].
- Issue Guidance Documents: National health ministries or professional organisations should publish guidance documents outlining the recommended strategic roles for clinical pharmacologists in various hospital

settings, emphasising their contributions to public health goals (e.g., AMR combat) [6].

- **Incentivise Integration:** Consider financial incentives or recognition programs for hospitals that successfully integrate clinical pharmacologists into senior administrative positions and demonstrate positive outcomes.

Integrate Administrative and Leadership Training into Clinical Pharmacology Curricula

- **Update Postgraduate Training:** Medical and pharmacology training programs should revise their curricula to include core competencies in health economics, hospital management, quality improvement, and leadership, preparing future clinical pharmacologists for broader administrative roles.
- **Promote Dual Degree Pathways:** Encourage and support pathways for clinical pharmacologists to pursue dual degrees (e.g., MD/MBA) from an earlier stage in their careers.

By implementing these recommendations, hospitals can unlock significant value, improving financial performance, enhancing patient safety, and fostering a culture of evidence-based, high-quality care, while policymakers can lay the groundwork for a more strategically optimised healthcare system.

Conclusion

Clinical pharmacologists possess an unparalleled combination of medical expertise, scientific rigour in therapeutics, and a crucial systems-based understanding of healthcare delivery. This unique skill set positions them as invaluable, yet often

underutilised, assets in hospital administration. As this review has demonstrated, when empowered with strategic roles, clinical pharmacologists can significantly enhance hospital performance across multiple critical domains, including formulary management, medication safety, antimicrobial stewardship, pharmaco-economic optimisation, clinical trial oversight, and organisational change.

Their direct contributions lead to tangible improvements: rationalising drug procurement for substantial cost savings, mitigating adverse drug reactions to bolster patient safety, judiciously managing antimicrobials to combat resistance, and embedding economic analyses to ensure fiscal responsibility contributions extend beyond individual patient care, influencing the very operational efficiency, quality outcomes, and strategic trajectory of the entire institution.

To fully leverage the profound skills of clinical pharmacologists, healthcare institutions and regulatory bodies must champion their structural integration into leadership and governance frameworks. This requires a proactive shift from viewing them solely as clinical consultants to recognising and formalising their potential as strategic leaders. By defining explicit administrative roles, investing in leadership development, and establishing robust mechanisms for monitoring their impact, hospitals can unlock significant value. Ultimately, empowering clinical pharmacologists in strategic administrative roles is not just an organisational enhancement; it is a critical investment in the future of safe, efficient, and financially sustainable patient care.

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Conflicts of Interest

The authors declare no conflicts of interest relevant to the content of this article. All authors have completed the ICMJE Uniform Disclosure Form for Potential Conflicts of Interest.

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CASE SERIES

Giants Within: A Tale of Two Rare Abdominal Behemoths

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Abstract

Hidden deep within the abdomen, giants can grow in silence—unseen, unfelt, and often undetected until they command attention with mass effect or incidental discovery. We present two such formidable entities: a rare giant adrenal angiomyolipoma and an enormous retroperitoneal liposarcoma—each a pathological paradox, pushing anatomical boundaries and clinical expectations. Their sheer size, silent progression, and rarity challenge diagnostic acumen and surgical dexterity alike. These cases are not mere enlargements of common pathologies; they are singular narratives of stealth, size, and surgical spectacle. Through them, we explore the thin line between benign and malignant, routine and extraordinary in retroperitoneal tumours.

Keywords: angiomyolipoma, retroperitoneal liposarcoma (RPLS), imaging, computed tomography (CT)

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Introduction

Retroperitoneal liposarcoma is a malignant tumor that often presents late due to its deep-seated location and indolent growth [1]. Adrenal angiomyolipoma (AML) is a rare benign tumor, usually discovered incidentally during imaging for unrelated symptoms [2]. Both pose unique diagnostic and management challenges. We present a case series of two distinct and unrelated cases illustrating these rare entities.

Case1

A 61-year-old female presented with a two-year history of progressive abdominal swelling, which had rapidly increased over the past six months, accompanied by abdominal discomfort and exertional dyspnea. She was a known hypothyroid on regular medication. There was no history of prior abdominal surgery. Her bowel and bladder habits remained normal. Obstetric history included a single full-term vaginal delivery 30 years ago.

On examination, she was normotensive and general physical examination was unremarkable. Abdominal examination revealed a massive, generalized distension. Abdomen was soft, cystic and non-tender. Abdomen was dull to percussion with resonance in the right flank. Bowel sounds were audible in the right flank. No abnormalities were noted on systemic examination.

A provisional diagnosis of a large ovarian cyst was made. However, contrast-enhanced computed tomography (CECT) of the abdomen revealed a 31 × 18 cm retroperitoneal fatty mass containing a 7 × 5 cm contrast-enhancing, hyperdense area with fibrous components, suggestive of liposarcoma (Fig. 1). The mass displaced the intestines and left kidney laterally.

Laboratory investigations, including hematological parameters and CA-125, were within normal limits. Chest X-ray, electrocardiogram, and echocardiography showed no abnormalities. Following preoperative optimization, the patient underwent exploratory laparotomy and a large retroperitoneal fatty tumor with areas of central necrosis was excised completely (10 kg) (Fig. 2). A drain was placed in the left paracolic gutter.

Postoperative recovery was uneventful. The patient was discharged on the tenth postoperative day after suture removal. Histopathological examination confirmed the diagnosis of well differentiated low grade retroperitoneal liposarcoma. However, MDM2 could not be demonstrated on IHC. At three-month follow-up, the patient remained asymptomatic and was referred to the oncology department for further management.

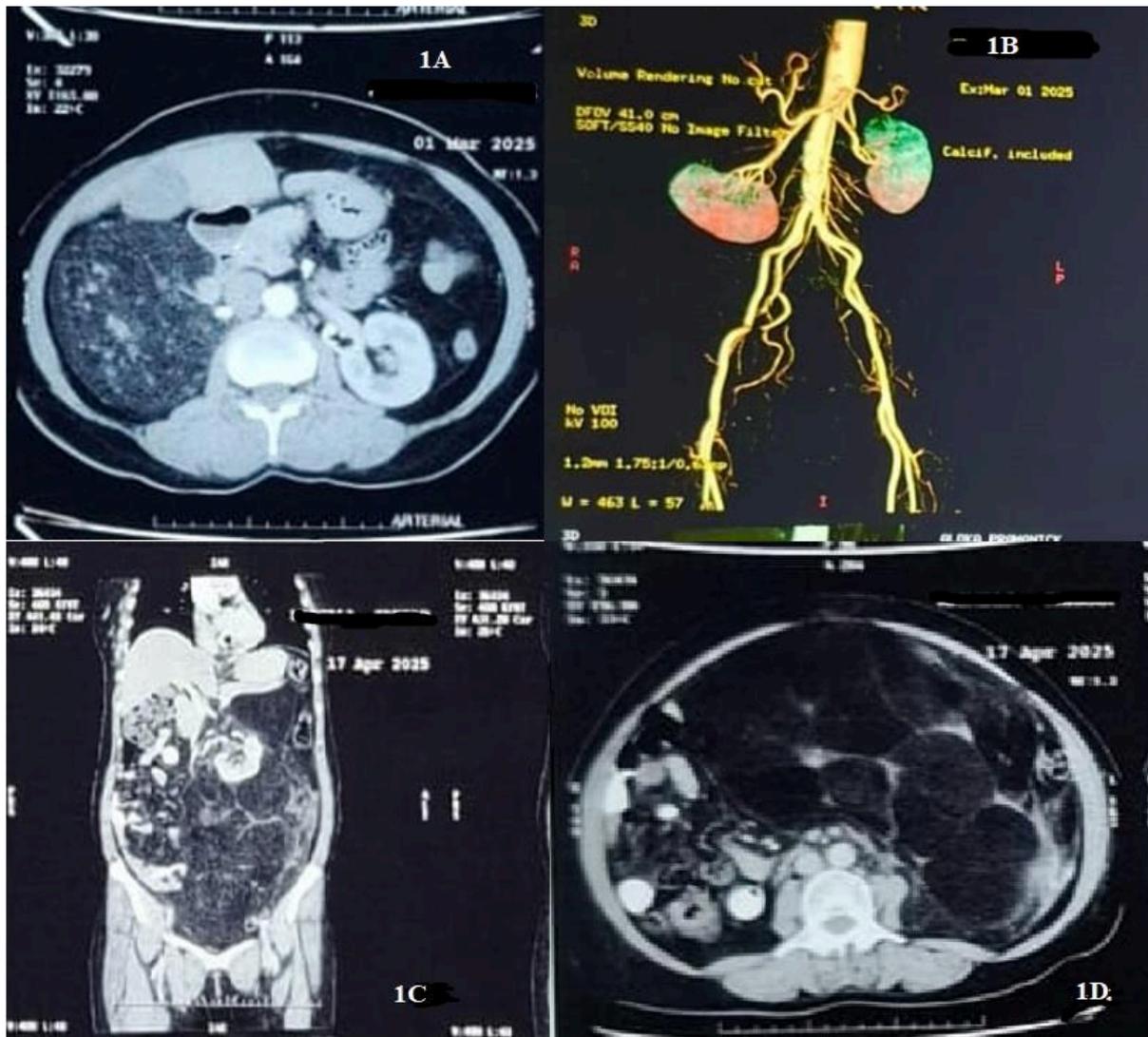


Figure 1. **A** - CT frame showing giant adrenal angiomyolipoma, **B** – CT angiography showing displaced kidney by the mass, **C** & **D** – CT frames showing giant retroperitoneal liposarcoma displacing the intestines and kidney to the right

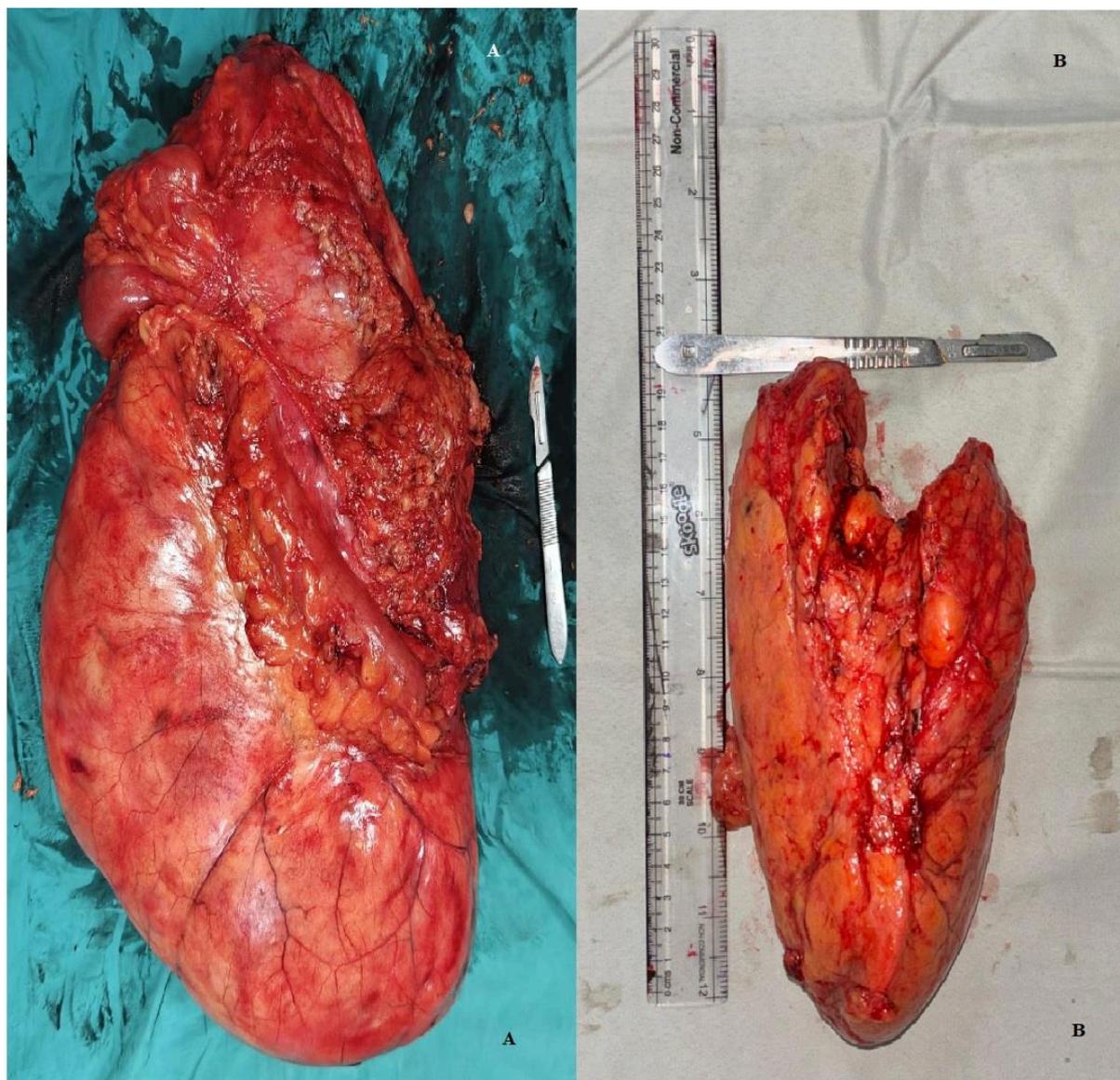


Figure 2. Postoperative specimen of giant **A**. Retroperitoneal liposarcoma, **B**. Adrenal angiomyolipoma

Case 2

A 64-year-old woman presented to the outpatient department with complaints of dull aching pain and abdominal discomfort localized to the right lower quadrant for the past 8–10 months. She had no associated symptoms and no history of comorbidities such as hypertension, diabetes, or thyroid dysfunction. Urine and stool were normal.

On general examination, all vital parameters were within normal limits. Abdominal examination revealed a firm, non-tender, ballotable mass measuring approximately 10 × 6 cm in the right lumbar region. A provisional diagnosis of renal lump was made.

Routine hematological investigations were normal. Endocrine evaluation, including 24-hour urinary metanephrines and normetanephrines, as well as serum cortisol, were within normal limits.

Ultrasound of the abdomen showed a 15 × 7 × 9.7 cm hyperechoic, heterogeneous, well-circumscribed lesion adjacent to the right kidney, with minimal internal vascularity and no invasion of the renal parenchyma. Contrast-enhanced CT of the abdomen revealed a predominantly fat-containing lesion measuring 15.1 × 10.1 × 9.3 cm at the upper pole of the right kidney, displacing the kidney inferiorly (Fig 1). Internal soft tissue and vascular components were noted, and the lesion was radiologically suggestive of an adrenal angiomyolipoma.

Exploratory laparotomy revealed a large mass arising from the adrenal gland above the right kidney. The mass was excised completely after ligating the adrenal vein and separating it from the kidney (Fig 2). The specimen weighed 2.5

kg and was sent for histopathological evaluation.

The postoperative course was uneventful. The patient was discharged on the 10th postoperative day following stitch removal. Histopathology confirmed the diagnosis of adrenal angiomyolipoma. At 3-month follow-up, the patient remained asymptomatic and well.

Discussion

Retroperitoneal liposarcoma and adrenal angiomyolipoma, though vastly different in behaviour, represent rare but significant abdominal masses. Liposarcoma, the most common retroperitoneal sarcoma, comprises over 50% of RPS and presents in four variants—well-differentiated being the most indolent with >90% 5-year survival [1]. Management hinges on surgical excision, as biopsy is often avoided. Recurrence and prognosis depend on tumor subtype, size, and resectability, while the role of adjunct therapies remains selective and debated [3,4].

Adrenal AML, by contrast, are benign, nonfunctional tumors accounting for 6–16% of adrenal incidentalomas, increasingly detected due to widespread imaging [2]. Typically, asymptomatic, larger lesions (>7 cm) risk rupture or hemorrhage and warrant surgical intervention, especially if symptomatic or radiologically suspicious. AML can be Classic or Triphasic AML, Epithelioid AML, Fat poor AML, Cystic AML, Extrarenal AML, AML associated with TSC which may require genetic screening [5,6].

Together, these cases highlight the diagnostic and therapeutic nuances of managing large retroperitoneal masses. Timely imaging, clinical vigilance, and

individualized surgical strategy remain key to optimal outcomes in these abdominal behemoths.

Author contributions

Concept: UD; Data collection: KK, AK; Writeup: KK, AK; Editing: UD; Final approval: UD, AK, KK

Statements and Declarations

Consent for publication

Written informed consent was obtained from the patient for publication of their clinical details and associated images.

Conflict of interest

The authors declare no conflicts of interest related to this publication.

Data availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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IMAGES IN SURGERY

Comprehensive 3D CT Imaging of Horseshoe Kidney with Anatomical Details

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Abstract

A 3D CT scan should be the investigation of choice in case of congenital anomalies like Horseshoe kidney, as it guides the surgeon precisely before any major surgical intervention.

Keywords: Horseshoe kidney, 3D CT imaging, Colorectal cancer

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A 30 year male patient came with hematuria along with recurrent urinary tract infection of more than a decade. Ultrasound revealed a horseshoe kidney with fusion of the lower pole. Three-dimensional (3D) CT revealed a horseshoe kidney with left ureteric calculi (Figure 1). The patient underwent surgery initially for the ureteric calculi and at present under follow-up.

Horseshoe kidney is a congenital renal fusion abnormality, having an incidence of 0.25–0.5% of the population, where abnormal renal anatomy with atypical vasculature poses an operative challenge and complicates tumour resection, especially during colorectal tumours. The renal vasculature, tumour

vasculature, and tumour involvement of the pelvicalyceal system are difficult to assess with two-dimensional (2D) images, but with Three-dimensional (3D) reconstructions of the horseshoe kidney, the subjective knowledge of surgical anatomy increases the surgeons' confidence and improves the surgical intraoperative decision. The 3D virtual reconstruction is used as an investigation of choice for laparoscopic and robotic-assisted partial nephrectomy [1]. With the help of 3D CT, precise vascular anatomy around the horseshoe kidney was delineated and used during partial nephrectomy in renal cell carcinoma [2].



Figure 1. 3D CT showing horseshoe kidney with calculus left ureter.

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Conflicts of interest

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