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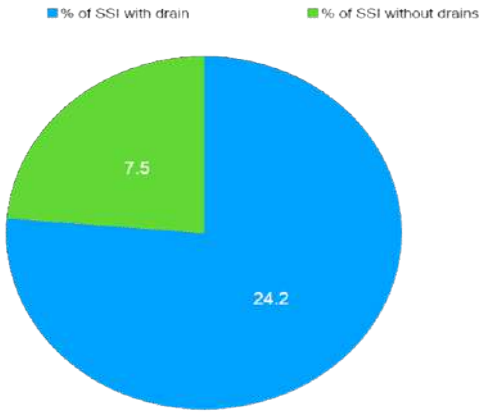
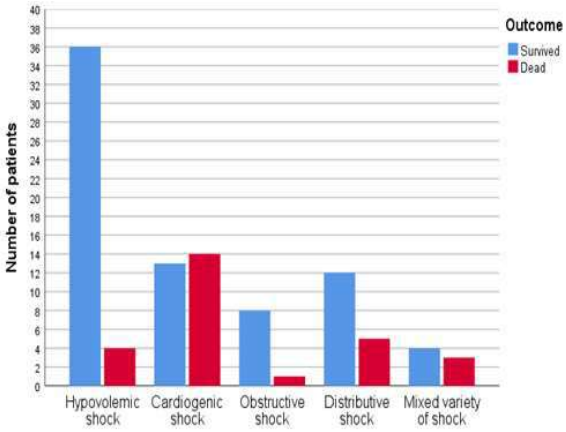
Percentage of patient having SSI with or without drain

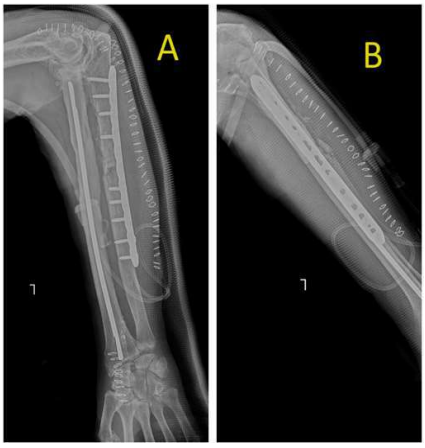


Paradoxical Middle Turbinate

Outcome among different types of shock



Immediate postoperative Anteroposterior (AP)



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EDITORIAL

Differences (Disorders) of Sex Development (DSD): The Quintessence of Perennial Controversies-IV: Genitoplasty for CAH- Management, Socio-cultural and Legal Issues

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In children with differences in sex development (DSD), by and large, it is the parents who make decisions regarding the surgical options. Socio-cultural influences play a significant role in gender assignment. While gender assignment has traditionally been influenced by sex of rearing, the treatment was dependent upon the size of the phallus [1]. The latter still holds, including the developed countries [2]. It is now being increasingly realized that gender identity is a result of complex interaction between genes and environment and it is impossible to predict what gender any child will come to identify with.

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The general trend in belief remains that surgery benefits the patients physically and psychosocially. However, sometimes complications linked to surgical intervention have led to the emergence of a platform for intersex advocacy groups.

Thus, the following 4 groups of caregivers justify the part played by them in the child's welfare at its center. However, a lack of sufficient evidence relegates them to a surrogate role rather than an exemplar:

A. Role of parents

a) Parents have the strong wish to surgically "normalize" their child's sexual anatomy. They view genital surgery as "obvious" and "necessary" to assure their child's positive psychosocial and psychosexual adaptation. The follow-up studies suggest predominantly favorable attitudes toward early feminizing procedures.

b) Parents and the role of Health Care Professionals (HCP): In the initial gender assignment, the HCP interprets the test results, anatomy & physiology (e.g., hormone production, hormone receptors, gross anatomy) & informs the parents. Individual cases are referred to by the institute's ethics committee (IEC)—clinicians, ethicists, members of the law, as well as the community. When IEC finds it difficult to negotiate, the matter is referred to a family court to decide upon the best interest of the child.

B. Role of surgeons

Surgery benefits the patients physically and psychosocially. Atypically developed genitalia affect:

- Physical appearance
- Body image
- Function of the urinary tract
- Gonads &
- Psychological and psychosexual development

Hence, the suggestion that therapeutic management of these patients is limited to 'cosmetic' surgery is not universally true.

Surgery in CAH involves clitoroplasty. This could be in the form of urgent surgery in order to create unobstructed outlets for urine.

- While early clitoral reduction surgery has been categorized as cosmetic and may carry the risk to genital tissue sensitivity, there is less disagreement for clitoroplasty for severe clitoromegaly. The consensus statement and clinical practice guidelines

C. Role of DSD advocacy groups

Their concerns stem from the following beliefs:

a) Parents seek to act before becoming fully informed about all options.
b) Legal and ethical questions are still unclear, and patient's autonomy is not taken into consideration. Therefore, the decision for any intervention should be deferred.
c) Comparative outcomes associated with performing surgery later in life should be known first.

D. Legal issues

These arise primarily around consent for medical interventions, such as genital surgeries, which raise ethical questions about parental authority and the rights of the individuals affected, particularly when considering their capacity to consent as they grow older. This area involves complex intersections of medical ethics and legal standards that often result in intense debates. To ensure that the consent is truly informed, it has to be "qualified and persistent:"

- The consent must be in writing.
- The information provided must be complete.
- The parents must be informed about the dangers of current treatments,
- The possibility of delaying surgeries and giving adequate psychological support to the child.
- The authorization must be given on several occasions over a reasonable time period [3].

The decision to perform surgery early or late would depend upon evidence—Whether later surgery has: Better, Poorer, or Comparable—Physical, Psychosocial, and Psychosexual Outcomes.

It is equally questionable if a general moratorium on all surgeries is justified. It is a common belief that nothing is 100% in medicine, and decisions on individual cases should be taken up on their merit.

In this context, the study by Dsd-LIFE is a laudable effort [4]. This is a multicentre cross-sectional, Clinical evaluation study with:

16 partners and 14 recruiting centres in Germany, France, the Netherlands, Poland, Sweden, and the United Kingdom, of whom 14 were active recruiting sites.

The study was carried out in adolescents (≥ 16 years) and adults with DSD (conforming to the Chicago Consensus). Interview, retrospective chart, and medical examination were carried out, and the following patient-reported outcome questionnaire was filled out and results published:

Clitoroplasty—Effect of timing of Sx on Outcomes (n. 415)

Questionnaire:

Q: General Postponement of Surgery until legal age

i. 51.2% disagreed
ii. 27% agreed
iii. 22% do not know

Q. Appropriate Time for Genital Surgery

i. 46%: infancy
ii. 20%: 4 years to 12 years

Q. Clitoral Reduction is necessary in girls (n. 314)

i. 38.2% agreed
ii. 14% disagreed
iii. 18.8% undecided
iv. 29% don't know

Q. Vaginoplasty: n. 415 Adolescence/Adulthood or Infancy (n. 323)

66% approved of surgery in infancy or childhood

These data suggest that:

- CAH persons predominantly favor interventions in childhood.
- A moratorium —one-for-all solution is not justified
- Case-by-case decision making is better suited [5].
- Efforts in improving information on long-term outcomes, informed consent, and assent.
- Contact between support groups should be strengthened.

If considerable uncertainty exists, parents should be motivated to postpone elective genital surgery.

These data are also in consonance with the ESPU & SPU-stand point (2014), viz., the medical and surgical management aims at:

i. Avoiding potential health hazards—anatomy and function of the urogenital tracts
ii. Meeting parents' expectations
iii. Helping an individual's future satisfactory sexual function.
iv. Consistent with their gender identity

Recent years have seen a shift from calling for shared decision making (SDM) between parents and the young child's healthcare providers, e.g., [6] to appeals for protecting the child's right to bodily autonomy and for the "right to an open future" (interpreted as a deferral of decisions regarding elective gonadal or genital surgery "until the patient himself/herself can participate meaningfully in decision making") [7-10].

Shared decision making: It comprises 3 essential elements:

- Explicit acknowledgment that a decision is required
- Evidence concerning the risks and benefits of each option
- Process takes into account the patient's/family's values and preferences.

Shared decision making: Six steps KON & KARZAKIS, Journal of Endocrinology & Metabolism

- Inclusion of sub-specialists
- Involve parents in decision making
- Parents need help addressing the emotional feelings
- Avoidance of terms referring to genitals
- Providers should strive for objectivity-evidence-based
- Parents should have received unbiased information… hopefully leading to a consensus based on trust and understanding.

Conflicts of interest

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

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ORIGINAL ARTICLE

A Comparative Study of the Incidence and Severity of Surgical Site Infection Following Emergency and Elective Abdominal Surgeries in a Tertiary Care Hospital

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Abstract

Background: Surgical site infection is a medical condition that develops up to 30 days after the surgery if no implants have been placed, and as long as 12 months if the patient has an implant device. SSIs pose a substantial barrier to healing and resumption of normal activities. SSIs and its side-effects have been noted as one of their primary contributors to the morbidity following surgery. This study will look at the incidence and severity of infections at the surgical site after both emergency and elective abdominal surgery. **Methods:** This is prospective observational research in patients who underwent Surgeries in either elective or emergency settings. Southampton wound assessment scale and the ASEPSIS wound scoring system were used in grouping the patients with SSI followed by each patient's SSI type was further recorded. The study also documented other factors, such as hospital stay and interventions. **Results:** There were one fifty participants in this study. 23 patients experienced SSI (6 elective cases and 17 emergency cases), while 127 people did not. The pathogens most commonly cultured were coagulase negative staphylococcus (CoNS, 8 cases), after which came Escheria coli. (4 cases). **Conclusion:** A higher prevalence of SSI is linked to factors including the patient's advancing age, a dirty wound, prolonged surgery, usage of drains, nutritional deficiency, anemia, and diabetes. The hospital personnel need to be more careful about following aseptic procedures and have more awareness of infection management.

Keywords: Abdomen, Laparotomy, Coagulase negative Staphylococcus aureus, Surgical Site Infections, Incidence

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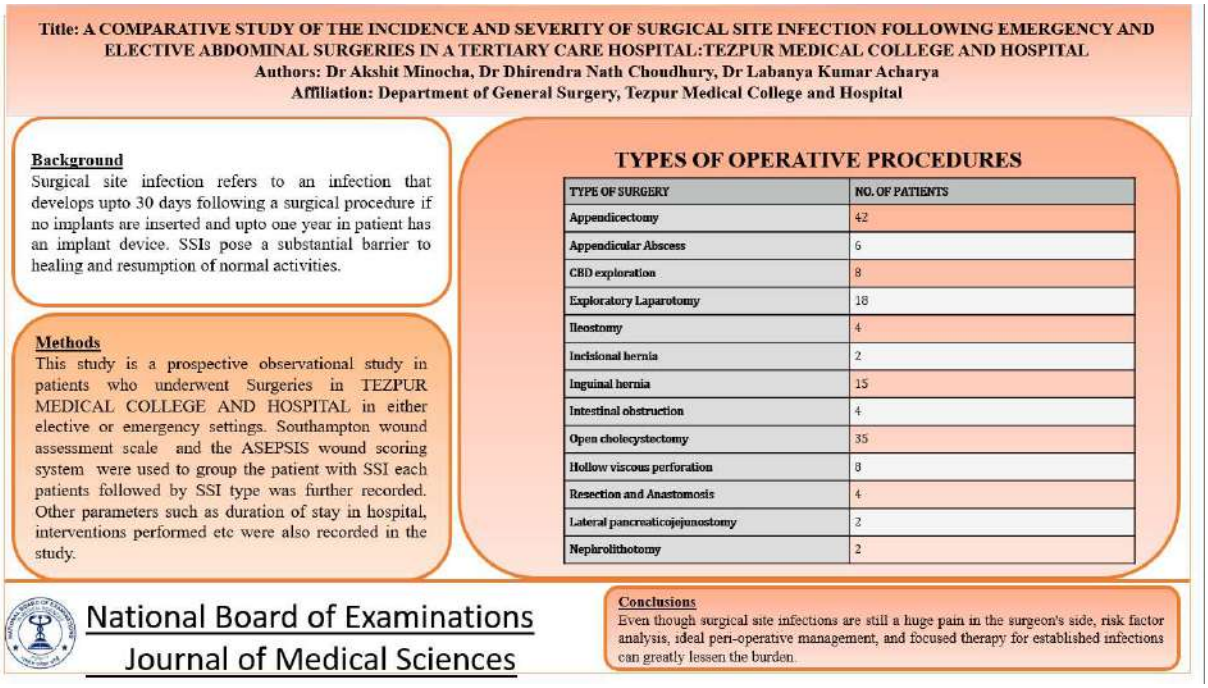
Graphical Abstract



Background

The Centers for Disease Control and Prevention describe surgical site infection as an infection of the wound that arises within a thirty days of the procedure or over a year if a prosthesis is still in place [1]. The infection is thought to have occurred as a result of surgery. SSI are a substantial hindrance to a patient's recovery and return to normalcy. As Osler famously stated, “Typically, patients die from their body's response to infection rather than the infection itself” [2]. Infections were once thought to be a necessary evil, but there has been a gradual but significant paradigm shift in favor of early detection and effective treatment of these infections [3-6].

Methods

This study is a prospective observational research in patients who had Surgery in Tezpur Medical College and Hospital in either elective or emergency settings. Southampton wound assessment scale [7] and the ASEPSIS scoring system [8] were used in grouping the patient with SSI each patient followed by SSI type was further recorded. Other factors, such as length of hospital stay, interventions performed, and so on, were documented in the study.

Inclusion Criteria

Patient with age ≥ twelve years

Patients who agree to engage in the clinical study.

Exclusion Criteria

Patients who have been diagnosed as immune compromised and are being treated with steroids.

Patients under the age of twelve.

Patients with prostheses.

Patients refused to participate in the clinical study.

Data Collection

The presence or absence of surgical site infection was assessed by routine, daily postoperative evaluation of the patient's general condition and a local examination of the patient's laparotomy incision. The

ASEPSIS wound score system was then used to divide patients with SSIs into distinct categories. Seven plus the Southampton Wound Assessment Scale. Each patient's exact SSI type was also documented. Additional parameters such as the length of the patient's hospital stay, their microbiological profile, the interventions they received, and so on were also recorded. Patients with SSIs were evaluated based on the severity of the infection utilizing wound culture and sensitivity, complete blood count, abdominal ultrasonography, and/or computed tomography (CT) abdomen, if needed. There were other tests to assess liver and renal function.

SAMPLE SIZE ESTIMATION

$$N = \frac{((p0q0 + p1q1)(Z\alpha + Z\beta)^2}{(p1 - p0)^2}$$

where,

N = Sample size

Z alpha = Z score of alpha error (i.e 1.96 with an alpha error of 5%)

Z beta= Z score of beta error (i.e. 0.842 with beta error of 20%)

P = prevalence according to study

The overall rate of surgical wound infection was 13.7%, and the infection rate was higher with emergency surgery (29.3%) than with elective surgery, per a retrospective observational study done in the Departments of General Surgery over a 12-month period in a tertiary care center in Tezpur. The sample size after adjusting for changes was 71, comprising 150 patients from Tezpur Medical College and Hospital who were eligible for the study period that was being suggested.

Results

Out of the one fifty participants who signed for the research, the patients' ages ranged from 12 (the lowest age that could be included) to over 80 (mean age of 42.5 and standard deviation of 45.3). Most of the patients clustered in the age range of 21 to 70, with the vast majority falling between 21 and 30 years of age. There were just two patients who were discovered to be older than 80 (Tables 1 to 4).

Table 1. Clinical data of sampled patient

AGE (IN YEARS)	NO. OF PATIENTS
<20	11
21-30	35
31-40	28
41-50	24
51-60	27
61-70	20
71-80	4
>80	2

Table 2. Showing types of operative procedure performed

TYPE OF SURGERY	NO. OF PATIENTS
Appendicectomy	42
Appendicular Abscess	6
CBD exploration	8
Exploratory Laparotomy	18
Ileostomy	4
Incisional hernia	2
Inguinal hernia	15
Intestinal obstruction	4
Open cholecystectomy	35
Hollow viscous perforation	8
Resection and Anastomosis	4
Lateral pancreaticojejunostomy	2
Nephrolithotomy	2

Table 3. 2x2 contingency table

		Surgical site infection		
		Yes	No	Total
Elective surgery	Count	6	69	75
	%within SSI	26%	54%	50%
Emergency surgery	Count	17	58	75
	%within SSI	74%	46%	50%

Analysis of the prevalence of SSIs in planned and emergency procedures. When compared to elective surgery, patients undergoing emergency operations had a higher rate of SSI.

Table 4. Clinical data of organisms growth in elective and emergency procedures

	Organism count	
Organism	Emergency	Elective
Citrobacter	1	0
Coagulase negative staph aureus	6	2
E. coli	3	1
Klebsiella	2	1
MRSA	1	0
Pseudomonas	2	0
Staphylococcus aureus	0	1
Other	2	1

In this study, the use of drains has considerably increased the risk of SSI i.e. 24.2%. More commonly used in contaminated or dirty wounds, as well as in urgent and protracted operations that increase the possibility of the site being infected [9], has also recorded 22.4% cases of drained wounds and 3% of not drained wounds being affected (Figure 1).

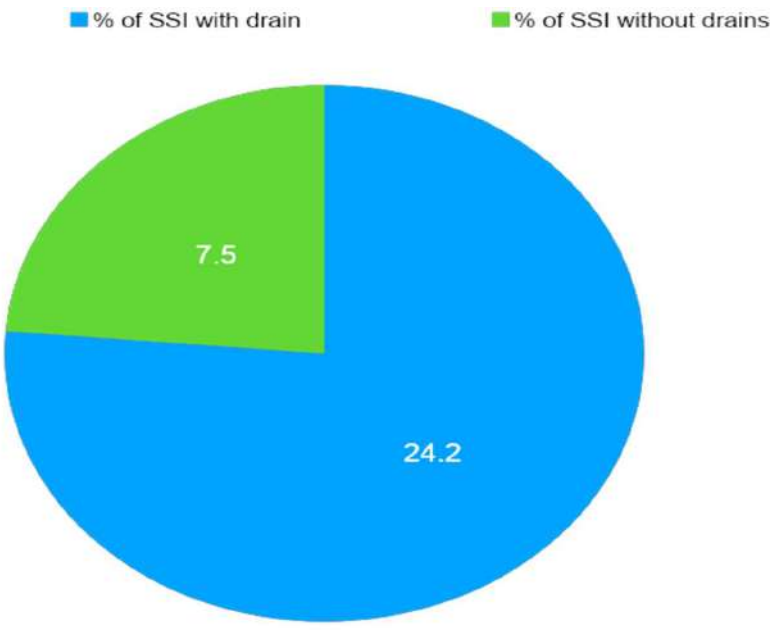


Figure 1. Piechart showing percentage of patient having SSI with or without drain.

The three comorbid conditions under investigation were anemia, hypertension, and diabetes mellitus. The threshold for the anemia in males and females respectively, were 13.5gm% and

12gm% of haemoglobin. 17 (58.6%) of the 29 surgically treated anemic patients developed SSI.

Diabetics and hypertensives, respectively were defined as study participants who were aware of their condition prior to admission and those who received a diagnosis after admission. It was found majority of them have both the condition 18 (75%) patients of 24 diabetics and 16 (72.7%) patients of 22 respectively developed SSI.

Discussion

After surgery wound infection continues to be one of the leading causes of morbidity and among the most prevalent nosocomial infection [10]. SSI rate varies widely both globally and amongst hospitals. Various studies have found SSI rates to range from 2.5% to 41.9% [11-15]. Although high, the current study's incidence of SSI, which is 15.33%, is consistent with previous research.150 patients in all were included and followed up during the course of the trial.

The article has already described the parameters that were taken into account. When taking into account the patients' ages, the vast majority (114 of the total 150 patients) fell into the 20–60 age range, as indicated in Table 1. Numerous studies have shown that age is a separate risk factor. This is most likely clarified by those being treated with concentration in age groups that do not substantially impact their postoperative course, the relative scarcity of patients at the oldest and youngest ages, and potentially because older people have better access to and knowledge of health care. Significant risk factors for SSI included comorbid diseases such anemia, diabetes, and hypertension. In multivariate analysis, diabetes remained a significant predictor. Similar to our study, the National Academy of Science likewise found that patients with diabetes mellitus had a greater rate of infection [16]. The study participants underwent surgical procedures, with an appendectomy being the most frequent surgery. (42 of 150 patients).

This is important since it shows that the results of this study can be applied to a larger group of surgical patients. Table 2 contains a comprehensive list of all the different operations that were carried out. As previously stated, the type of surgery conducted affects the likelihood that SSI will develop; nevertheless, given the small number of cases where SSI did develop and the vast range of procedures carried out, a conclusive association could not be established.

All of the trial participants received preventative antibiotics. Ceftriaxone was the most commonly used antibiotic (42 out of 150), followed by cefuroxime (34 out of 150). This aligns to the hospital's antibiotic regimen. Evidence supporting the use of cephalosporins as a prophylactic precaution. In cases when there is an overwhelming clinical belief that the offending bacterium is present, it is also recommended to switch to other targeted antibiotics. According to subgroup analysis, the majority of patients (8 of 23) who later developed an SSI had ceftriaxone prior to surgery, indicating localized Resistance to antibiotics exists among organisms in the research area.

The most frequently cultured organism in SSIs was CONS (8 out of 23 cases), followed by Escheria coli (4 out of 23 cases). Because of its ubiquity in skin flora, S. aureus is the most often cultured bacterium in SSIs, followed by coagulase-negative staphylococci (CNS) [17,18]. However, This study identified

just two cases of Staphylococcus aureus as indicated in Table 4.

Conclusion

Even while infections at the surgical site remain an important cause of concern for surgeons, risk factor analysis, excellent perioperative care, and focused therapy for existing pathogens can dramatically minimize the burden. Risk elements can be efficiently handled and patients classified by identifying risk variables including the type of procedure done (e.g., emergency vs. planned), existing co-morbidities, the existence or absence of illnesses. This study also looks at the geographic and socioeconomic patterns of SSIs, as well as how the microbial flora involved in SSIs changes, resulting in antibiotic resistance. This enables for adjustments to antimicrobial regimens while emphasizing the importance of improved regional and hospital-based surveillance programs.

Risk factor for prevention and proper therapy for infection that has already taken hold are essential components of the management of SSIs.

Statements and Declarations

Conflicts of interest

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

Funding

No funding was received for conducting this study.

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ORIGINAL ARTICLE

Anatomical Variations on NCCT Nose and Paranasal Sinuses and Their Relation with Symptoms of the Patients: A Retrospective Analysis

Riya Thakral,[1] Abhinav Srivastav,[2] Anshul Chatrath,[3,*] Vishwani Khanna,[4] Sanjeev Awasthi,[5] Vivek Kumar Pathak[6] and Luv Gupta[1]

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Abstract

Background: There are various bones around the nasal cavity that pneumatize to form the paranasal sinuses; namely, maxilla, ethmoid bone, frontal bone, and sphenoid bone. The CT scan of nose and paranasal sinus is the gold standard investigation for the patients of chronic rhino-sinusitis (CRS). **Objective**: This study was conducted with aim to determine the prevalence anatomical variation of Nose and Paranasal Sinuses on CT-scan and their relation with symptoms. **Methods**: A retrospective study was conducted among 200 patients over a period of one year (2022-2023). Patients with various symptoms of chronic rhinosinusitis were subjected to non-contrast enhanced Computed Tomography of nose and paranasal sinuses. **Results**: In our study 56% patients had septal deviation with most common C shaped deviation followed by S shaped deviation. 99.5% patients have agger nasi cells. The attachment of uncinate process was to the lamina papyracea in 83.0%, followed by the base of skull in 13.0%. The least common types were free uncinate process in 1.5%. The prevalence of concha bullosa was found 16.5%. However, paradoxical turbinate was present in 2.0% subjects. The incidence of Haller cells was found to be 5.0% and Onodi cells were found in 4.5%. The type of frontal cell was Agger Nasi followed by a Supra-bullar. In Sphenoid sinus, commonest type was pre-sellar type of pneumatisation. **Conclusion**: Our study concluded these various anatomical variations and its prevalence. The relation of variations with disease symptomatology is inconclusive.

Keywords: Uncinate, lamina papyracea, Concha bullosa, Sphenoid sinus, Haller cells, Onodi cell

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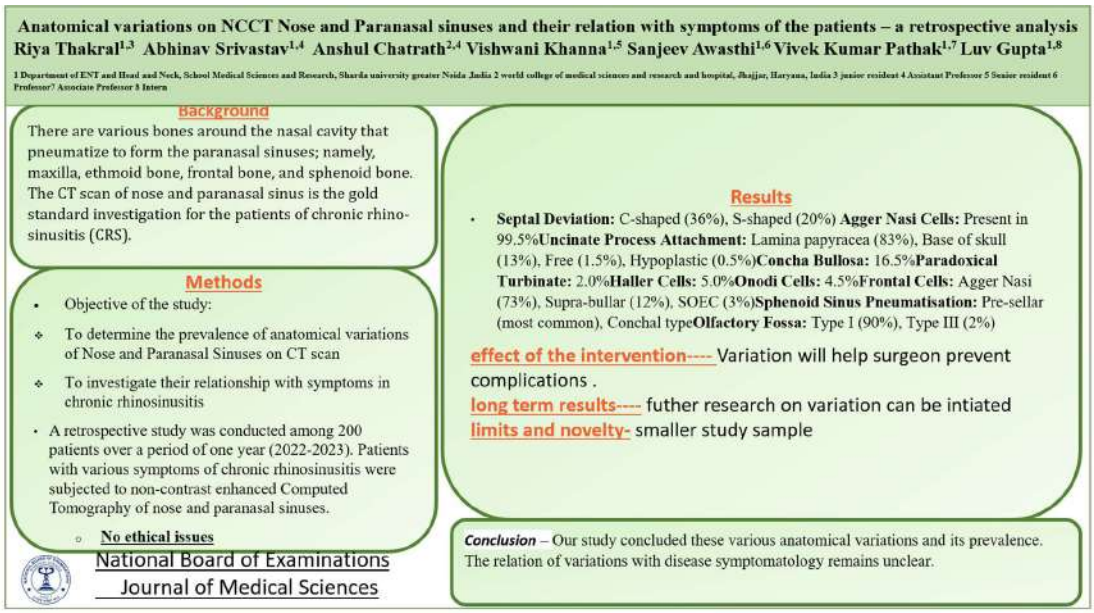
Graphical Abstract



Introduction

There are various bones around the nasal cavity that pneumatize to form the paranasal sinuses; namely, maxilla, ethmoid bone, frontal bone, and sphenoid bone. Persistent inflammation of the sinus or nasal channels lasting longer than 12 weeks at a time is known as chronic rhino-sinusitis (CRS). More than one episode of sinusitis per year is considered as recurrent sinusitis [1].

The CT scan of nose and paranasal sinus is the gold standard investigation for the patients of CRS. Various anatomical variations can be detected with 3mm cut of the CT scans. This occurs due to varying degree of pneumatisation [2]. These anatomical variations may play important role in disease pathogenesis and failure of medical treatment.

In pre-operative planning it is crucial to understand and have knowledge of the various anatomical variations. This will help to create a road map for surgery to prevent injury to adjacent vital tissues like the brain, orbit, optic nerve, carotid artery, etc.

This study was conducted with aim

- To determine the prevalence anatomical variation of Nose and Paranasal Sinuses on CT-scan
- To determine relation of symptoms with anatomical variation in nose and paranasal sinuses

Methodology

A retrospective study was conducted amongst 200 patients over a period of one year (2022-2023) at Sharda hospital Greater Noida. Patients with various symptoms of chronic rhinosinusitis were subjected to non-contrast enhanced Computed Tomography of nose and paranasal sinuses. Anatomic variations of the sinonasal cavities were assessed in the CT images, and prevalence of each was noted. The study included patients with age ≥18 having chronic rhinosinusitis and patient having chronic rhinosinusitis with or without polyposis who were advised NCCT nose and PNS after thorough examination. Patients having any previous nasal surgery or trauma, who did not

consent for the study and patients less than 18 years were excluded from the study.

Results

In our study population of 200 subjects, majority of patients were in the age group of 26-35 years with mean age 34.15±12.67 years. There was male dominance, 58.5%.

In our study, patients showed varying symptoms, most common were nasal obstruction (88%), sneezing (85%), rhinorrhoea (85.5%), poor sleep (78%) and headache (60%).

On clinical examination, majority of the patients showed bilateral hypertrophy of inferior turbinate, 86%. On anterior rhinoscopy, 65 patients had nasal polyps (32.5%).

Various anatomical variations on NCCT are shown in Table 1. The relation of variations with disease pathology remains unclear.

Table 1. Anatomical variations in nose and paranasal sinus

Anatomical variation	**Number of patient N=200**	**Percentage N=200**
Septal deviation		
• **C-shaped**	72	36
• **S- shaped**	40	20
• **Anterior dislocation**	18	9
• **Nasal spur**	38	19
• **Central**	32	16
Agger nasi cell		
• **1 cell**	136	68
• **2 cells**	53	26.5
• **3 cells**	9	4.5
• **Hypoplastic**	1	0.5
	1	0.5
Uncinate process		
• **Attached to base of skull**	26	13
• **Attached to lamina papyracea**	166	83
• **Free**	3	1.5
• **hypoplastic**	1	0.5
• **Pneumatised**	4	2
Middle turbinate		
• **Normal**	158	79
• **Concha bullosa**	33	16.5
• **paradoxical ‘**	4	2
• **Turbinate sinus**	3	1
• **polypoidal**	2	1.5

Ethmoidal sinus • **Pneumatised** • **Extensively pneumatised** • **Hypoplastic** • **Retrobulbar recess** • **Suprabullar recess** • **Sinus lateralis**	140 23 1 9 11 16	70 11.5 0.5 4.5 5.5 8
Ethmoidal air cells • **Hallers cells** • **Onodi cell** • **pneumatized galli**	10 9 8	5 4.5 4
Frontal cell type • **AGN** • **FSC** • **SAC** • **SAFC** • **SBC** • **SBFC** • **SEC**	146 3 8 6 24 7 6	73 15 4 3 1.2 3.5 3
Frontal sinus type of pneumatisation • **Type I** • **Type II** • **Type III** • **Type IV**	5 181 14 0	2.5 90.5 7 0
Olfactory fossa type • **Type I** • **Type II** • **Type III**	180 16 4	90 8 2
Sphenoid sinus type • **Conchal** • **Preseller** • **Sellar**	1 186 13	0.5 93 6.5

Discussion

In humans, there are four pairs of sinuses. These are named after the bones which they pneumatize. They are: The maxillary sinus, ethmoid sinus, frontal sinus and sphenoid sinuses. Sinusitis is an inflammatory process involving the mucus membrane of the paranasal sinuses and/or the bone. Computed tomography plays important role to know anatomical

variations of nose and PNS and the extent of disease [2].

The aetio-pathology of sinusitis can be influenced by a multitude of clinically relevant alterations in the nose and paranasal sinuses. Since they are found in many people, sinonasal anatomic variants are more common than unusual [1]. These variations require CT scans for diagnosis to avoid any complication during endoscopic sinus surgery and various skull base surgeries.

Nasal Septum

Deviated septum is a prevalent physical abnormality. If present, deviation may lead to lateralisation of middle turbinate leading to narrowing of middle meatus and hypertrophy of contralateral turbinate. This leads to obstruction of normal mucous flow, resulting in subsequent inflammation [3,4].

According to literature, prevalence of septal deviation is widely varied. Due to different morphologies, it ranges from 26-97% [5]. In our study 56% patients had septal deviation with most common C shaped deviation followed by S shaped deviation However, not all patients having a deviated septum had complaints of nasal obstruction, headache, or poor sleep.

9% of our patients had Anterior dislocation in which 8% patients had history of trauma and only 3% complaint of cosmetics deformity.

Agger Nasi Cells

The anterior most group of ethmoid air cells are the agger nasi. They can typically be bilateral. Usually, they pneumatise toward the region of frontal recess making it narrow which may lead to sinusitis [13]. For identification, coronal and sagittal views of CT scans are considered ideal [3].

In 1967, Messerklinger et al., reported 10-15% specimens having agger nasi cell during dissection [14] whereas according to a study done in Malaysia, agger nasi is highly prevalent (83.0%) [9]. Their reported prevalence ranges from 10% to 98% [24].

In our study, 99.5% patients have agger nasi cells. One patient had hypoplastic agger nasi cell.

Uncinate Process

The uncinate process is a key bony structure in the lateral nasal wall. Attachment of uncinate process can be variable, such as attached to lamina papyracea, middle turbinate, or base of skull. Sometimes, the uncinate process maybe free-lying or pneumatised as well. In a study conducted by Basak S., recorded variations of the upper end of uncinate in 25% of the CT sections [11].

Our study revealed the most common attachment to be the lamina papyracea, in 83.0%, followed by the base of skull in 13.0%. The least common types were free uncinate process in 1.5% and hypoplastic uncinate process seen in 0.5% of subjects (Figures 1 to 3).

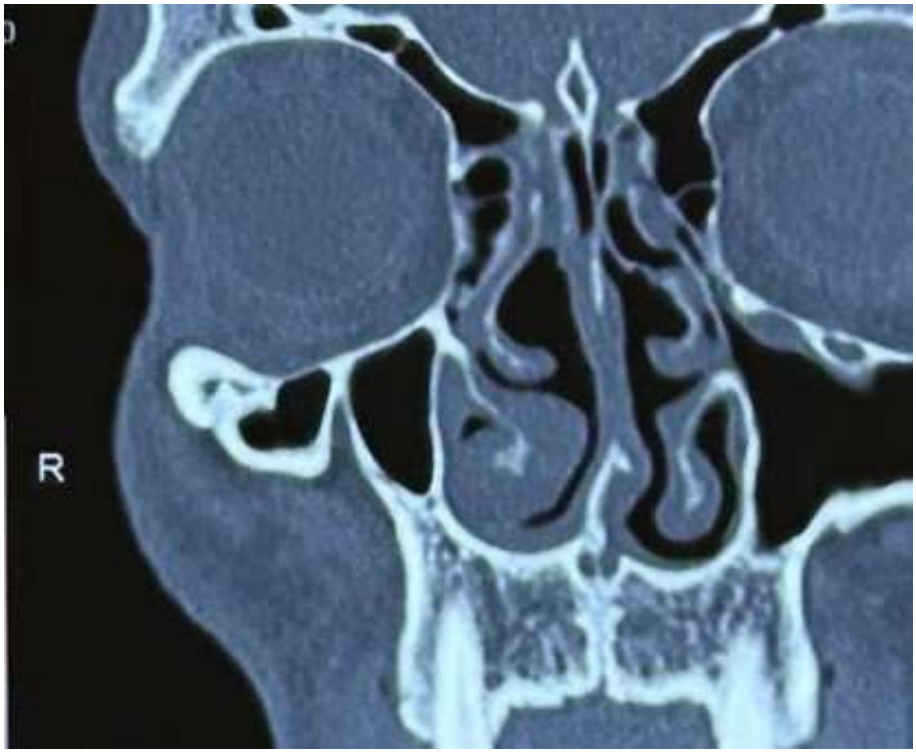


Figure 1. Paradoxical Middle Turbinate

Figure 2. Onodi Cell

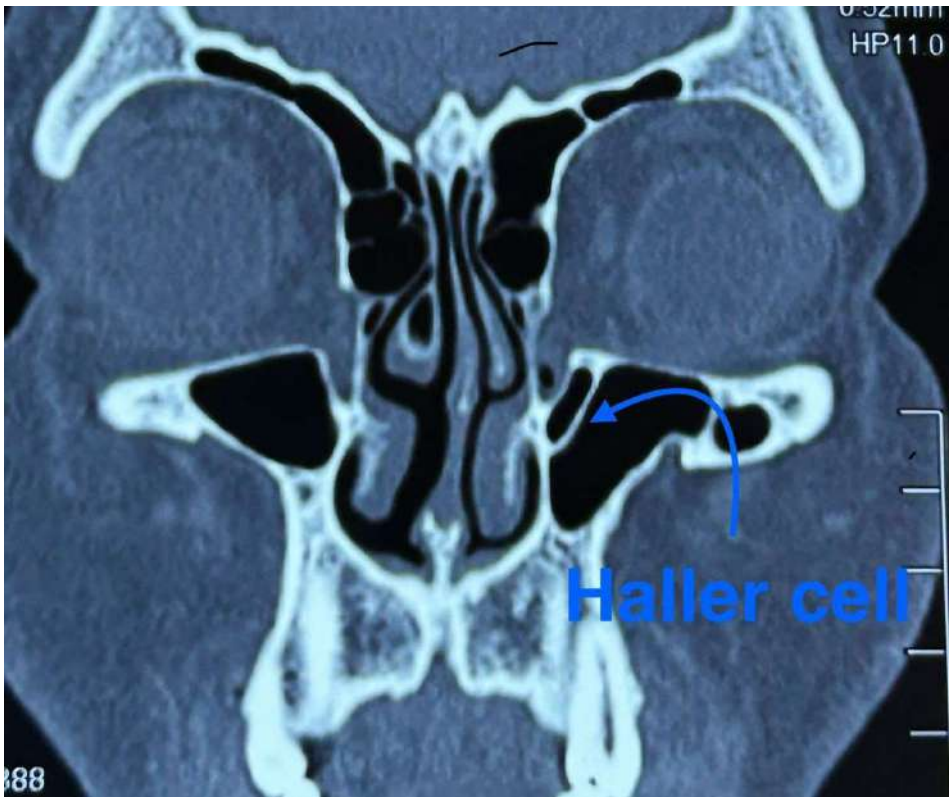


Figure 3. Haller Cell

Aeration of uncinate process is known as pneumatised uncinate or an uncinate bulla. Kennedy et al.'s 1998 study revealed the incidence of this rare variant was 0.4% [12]. Depending on the degree of pneumatisation, there can be significant blockage of the osteo-meatal complex. Along with other variations in anatomy it can intensify the pathogenic impact causing CRS. In our study group, 4 patients (2.0%) showed this rare entity.

Middle turbinate

A concha bullosa is the pneumatisation of the middle concha. Ethmoidal expansion results in pneumatisation of the osseous plate. Its size is mostly variable and can be found on either side or sometimes is bilateral [3]. Patients suffering from chronic rhinosinusitis have the highest reported prevalence, 15-80% [5].

A large concha bullosa with considerable pneumatisation can cause symptoms of headaches, and/or significant nasal obstruction. In such cases, a surgical correction maybe required.

The middle concha's convexity is normally oriented medially, i.e., towards the septum. However, in a paradoxical turbinate, the convexity is laterally faced [6]. Owing to the deformity and obstruction of airflow, it can be presumed as an additional factor for causing sinusitis [7].

According to Mokhasanavisu et al., concha bullosa was found in 64% and 52% of the populations of South and North India, respectively [8]. Azila A. et al., in their recorded concha bullosa in 40.8% subjects having CRS and in 47.5% of control cases [9]. Amongst the Caucasians concha bullosa and paradoxical turbinate have been recorded as 12-31% and 10-22% respectively [10].

In our study, prevalence of concha bullosa was found 16.5%. However, paradoxical turbinate was present in 2.0% subjects.

90% of patients with concha bullosa had symptoms like headache, nasal obstruction, facial pain, which got relieved after surgical correction.

Ethmoid Air cells

Albert von Haller first characterised Haller cells in 1765. They are ethmoid cells above and beside the maxillary sinus ostium growing into the floor of orbit [10]. Their frequency varies astonishingly, from 8% to 57%. The detrimental effect on maxillary sinus airflow is caused by limitation of infundibulum and maxillary ostium. Thus, establishing a link to recurrent maxillary sinusitis, making this variation clinically noteworthy [3].

Furthermore, orbital injuries after ethmoidectomy can be more likely when Haller cells are present [15]. Badia et al. reported the presence of Haller cells in 10-15% Caucasian and 1-9% Chinese group respectively [10].

The Onodi cell (sphenoethmoid air cell), is a posterior ethmoid cell that is closely linked to the optic nerve. It pneumatises far laterally and somewhat superiorly to the sphenoid sinus. The internal carotid artery and optic nerve are more vulnerable to injury when Onodi cells are present. Thus, identification before surgery is of utmost importance [3,7].

Its frequency is reported to fluctuate widely, from 2% to 50% [15]. In Chinese population, presence of Onodi cells has been reported as 20-30 [10]. In the adult group, 48% of Onodi cells were found, according to Bansberg et al. [15].

In the current study, incidence of Haller cells was found in 5.0% and Onodi cells were found in 4.5% of subjects which comparable to previous studies.

Frontal Recess cells

The fronto-ethmoidal cells, are cells located above Agger Nasi. In functional endoscopic sinus surgery, it is essential to comprehend these variances since they impact the likelihood of complications and the operative outcome.

To provide better understanding of the morphology of frontoethmoidal cells and their relationship to frontal recess, the International Frontal Sinus classification (IFSC) was introduced. A study was conducted in Mexico by Bravo-Arteaga, et al., SAFC (Supra- Agger Frontal cell) had a prevalence of 7.88% [18]. In Vietnam, Luan V. reported SBFC (Supra-bullar frontal cell) in 4.3% patients [19], while a study from Malaysia reported a prevalence of 53% [20].

According to Asian analysis, a mere prevalence of 5.4% of SOEC (Supra-orbital ethmoid cell) was observed [21]. In addition to raising the possibility of orbital injury during surgery, the presence of SOEC has been linked to orbital proptosis [9].

Our study revealed the commonest cell type as Agger Nasi (73.0%), followed by a Supra-bullar cell seen in 12.0%. SOEC was prevalent in 3.0% of subjects.

Sphenoid sinus variation

Sphenoid sinus may show extension of pneumatisation laterally to the pterygoids, and can involve the lesser and/or greater wing of sphenoid. The sphenoid sinus was divided into three categories by Hammer and Radberg.

According to their analysis, the sellar variant accounted for 85% of all instances, making it the most prevalent pattern. The presellar and conchal types accounted for 11% and 2.5% of cases, respectively [22]. In the current study, the commonest type was pre-sellar, followed by conchal type of pneumatisation.

Olfactory Fossa

Variations in anatomy can occasionally lead a surgeon to catastrophic outcomes. For instance, if low skull base is not known pre-operatively it may lead to intra-cranial complications post endoscopic surgery. In 1962, Keros classification was given describing the depth olfactory fossa. The cribriform plate and fovea ethmoidalis are taken into consideration. In type III (8-16 mm), the risk of injury to lateral lamella of cribriform plate with subsequent CSF leak is the highest. According to Ali et al., 79% of patients had Keros II [23]. Nouraei et al. reported 92% of patients had Keros type 1 olfactory fossa [24]. In 2014, Al-Abri R et al. 36% patients had type III fossa [2]. In our study, Type I fossa was seen in 90% of the study population, whereas, only 2.0% subjects had type III fossa. The differences in race and ethnicity may contribute to the observed gap.There have been various discussions over the contribution of these anatomical differences to the aetiology of chronic rhinosinusitis. However, the discussions have been inconclusive. In a study conducted in 2020, showed that anatomical variations and symptom severity had a statistically significant relationship [1]. However, according to reports of Asian researchers, no correlation has been established between the two, nor have they shown to worsen pre-existing rhino-sinusitis [16].

Conclusion

Nose and paranasal sinuses are well known for their complicated anatomy. Numerous anatomic variations exist for the sinonasal cavities; some of these variations are widespread and are found incidentally upon use of modern imaging methods.

In our study, patients with mild and those with clinically substantial radiologic evidence of rhinosinusitis did not differ significantly in the incidence of paranasal sinus or nasal cavity variations.

Consequently, unless surgery is planned, it is uncertain whether each routine CT scan of the paranasal sinuses obtained for sinusitis or rhinitis should be analysed for the presence of distinct anatomic variants. Nonetheless, there are some anatomic variations that surgeons should be aware of if they intend to perform functional endoscopic or other skull base surgery.

Ethical Approval

The ethical clearance was taken from institutional ethical committee (Sharda University) ref no SU/SMS&R76-A/2023/172.

Conflicts of interest

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

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Author Contributions

RT Data collection, AS Data collection, Data Analysis; AC Data Collection, Data Analysis, Manuscript Writing, Interpretation of Data; VK Data collection, Manuscript writing, Proof

Reading, Interpretation of Data; SA Proof Reading, Guide; VKP Proof reading; LG Data collection

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ORIGINAL ARTICLE

Prevalence of Mental Morbidities in a Tertiary Care Leprosarium in North India: A Cross-Sectional Study

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Abstract

Background: Leprosy is a chronic infectious disease causing substantial physical and mental morbidity. Every year around 200,000 new cases are reported globally. (WHO) Despite continuous efforts to eradicate leprosy, prevalence of the disease is still a concern especially in India. The treatment of leprosy has always focused on elimination of bacteria, correction of physical deformities and preventive aspects with little emphasis on its psychiatric implications. Therefore, it is imperative to understand the link between the disease and mental health of the patient. This study aims to estimate the prevalence of psychiatric morbidities among leprosy patients admitted in a tertiary care center in north India. **Methods:** Data was collected from patients admitted in a tertiary care leprosy center in North Delhi by using a well-structured questionnaire DASS-21 which included total of 21 questions, 7 questions each pertaining to depression, anxiety and stress. Findings were analyzed using SPSS version 20.0. Frequencies and percentages were used and the association between the variables was tested using the chi-square test. **Results:** Findings suggested that there is causal relationship between leprosy disease and mental health. Prevalence of depression, anxiety and stress was 28%, 56% and 44% respectively which significant. Of note, the prevalence was higher in adults aged between 25-35 years as compared to adults aged 35-45 years. Patients with physical deformities were found to higher prevalence of mental health issues such as depression (18%), anxiety (28%), Stress (24%). **Conclusion:** This study found that there was a significantly high prevalence of depression, anxiety, and stress among individuals affected by leprosy especially among those with physical deformities. Hence, appropriate psychological counselling must be considered as an essential part of therapeutic intervention for leprosy patients.

Keywords: Leprosy, Anxiety, Depression, Stress, DASS-21

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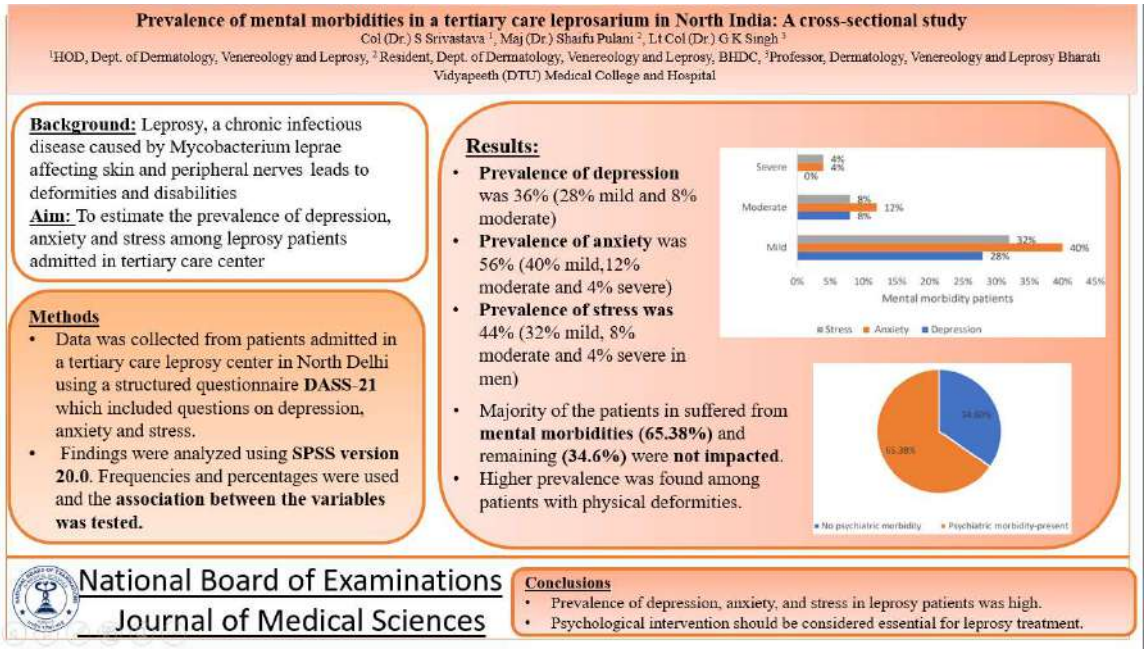
Graphical Abstract



Introduction

Leprosy is a chronic infectious disease caused by Mycobacterium leprae primarily involving peripheral nerves and skin leading to deformities and disabilities. The incubation period of the disease varies between 9 months to 20 years. Although global effort to meet the World Health Organization (WHO) goals of elimination has greatly decreased the burden of Leprosy in recent decades, however, around 200000 new cases are still reported globally every year.

Current WHO targets focus on decreasing the rate of new diagnoses with Grade 2 disability rates. In 2021-22, a total of 61,678 leprosy cases were under treatment with a prevalence rate of 0.45 per 10,000 population and a grade 2 disability rate of 1.36 per million population [1]. Recently, many new leprosy cases have been reported primarily from three countries—India, Brazil, and Indonesia [2].

Leprosy patients not only experience physical deformities but also a lot of psychological and emotional problems affecting their mental health, social adaptability and quality of life (QoL). The main focus of leprosy has always been on treatment, deformity correction surgeries and preventive aspects, with less importance to addressing mental aspects and social stigmas.

Despite all efforts in decreasing the overall burden, Leprosy still continues to be a major cause of physical disabilities. The social stigma is immense leading to mental morbidities. Due to the rising cases of Leprosy in India and its impact on psychological health, it is crucial to understand the current scenario of mental health issues amongst the leprosy patients. Prior research has indicated that leprosy is significantly associated with psychological comorbidities, but there is still lack of awareness and intervention addressing the psychological aspects in a leprosy patient [3-6]. According to Bhatia et al (2006), leprosy affected persons had higher prevalence of psychiatric morbidity (44.4%) than healthy population. [7]

The aim of the study is to ascertain the prevalence of depression, anxiety and stress among leprosy patients admitted in tertiary care center, association of these symptoms with physical deformities/disabilities [8], therefore emphasizing the need of psychological counselling as a therapeutic intervention.

Methods

This cross-sectional study was conducted at a tertiary Leprosy care center in Delhi NCR from June to August 2024. This is a tertiary nodal center with a high caseload of patients with leprosy-associated disability. All the included patients in the study were diagnosed and managed as per WHO guidelines. The patients were classified as per WHO and Ridley Jopling classification. By taking the prevalence of leprosy-patients affected with mental/psychological disability as persons as 0.45, 5% absolute error, and 95% confidence interval, sample size of 43 was calculated which was rounded off to 50.

All the admitted adult patients who were confirmed cases of leprosy on treatment and without any previous co-morbidities were included in the study after an informed consent. Ethical approval was obtained from the Institutional Ethical Committee. A pre-designed structured questionnaire that included questions to evaluate mental health of patients was used to collect data. Depression Anxiety Stress Scale (DASS) 21 which consists of three components: Depression, Anxiety, and Stress was the scale used for assessment [1,9]. Each component included seven questions, with a total of 21 questions (DASS 21, University of Bristol). Participants were asked to indicate how each statement applied to them in the past week, using a 4-point Likert scale (0-3).

Scores for each component were added and multiplied by 2 to obtain the final score, which was then used to grade the severity of depression, anxiety, and stress as mild, moderate, severe, or very severe. The data was entered into Microsoft Excel and analyzed using SPSS version 20.0. Frequencies and percentages were used and the association between the variables was tested using the chi- square test.

Results

Data was collected from 50 patients, all males as per admission policy in our hospital. The mean age among patients was 33.6 years. Figure 1 shows that out of all the included patients, 34.6% (n=50) experienced no psychiatric symptoms whereas 65.38% of them showed psychiatric manifestations.

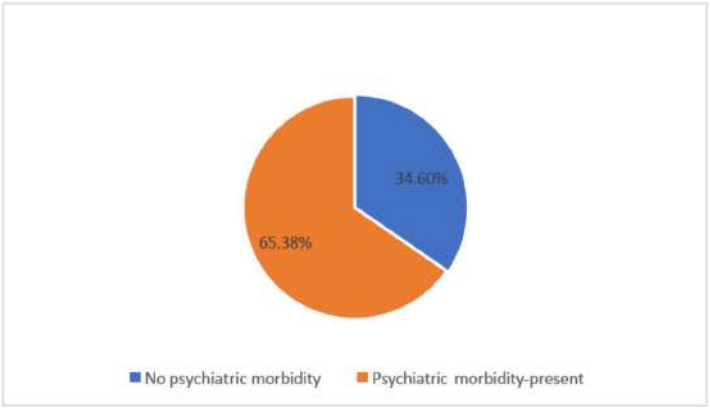


Figure 1. Percentage of population with and without psychiatric morbidity

Figure 2 shows that the prevalence of depression was 36% (28% mild and 8% moderate), the prevalence of anxiety was 56% (40% mild,12% moderate and 4% severe), and that of stress was 44% (32% mild, 8% moderate and 4% severe in men). Majority of the patients had mild forms of psychiatric morbidities.

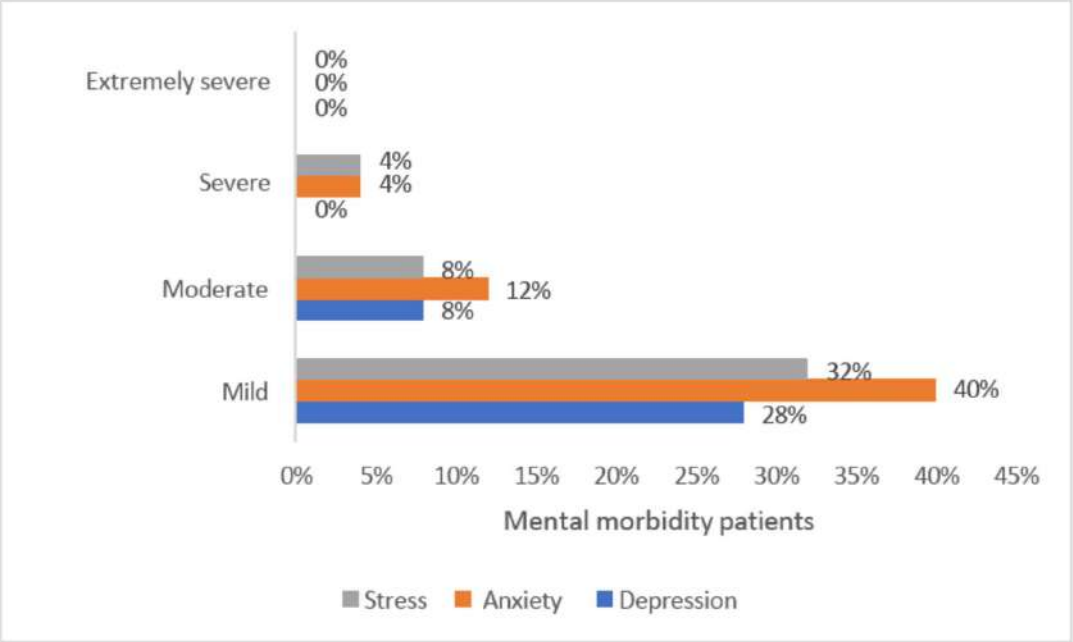


Figure 2: Percentage of population stratified by severity of mental morbidities (`mild, moderate, severe and extremely severe)

Figure 3 shows the prevalence of psychological morbidities was high among age group of 25-35 years as compared to 36-45 years. In the age group of 25-35 years, the prevalence of depression was 24%, anxiety 36% and stress was 28% and amongst age group of 35–45 years, the prevalence of depression was 12%, anxiety 20% and stress 16%.

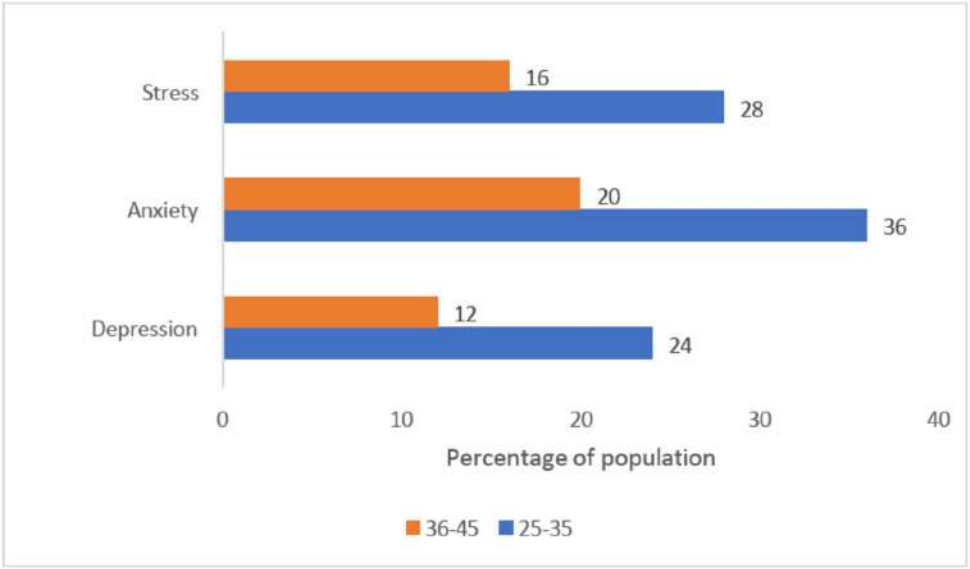


Figure 3. Percentage of patients suffering from mental morbidities stratified by age

All patients were cases of multibacillary leprosy as per WHO classification. All the patients had their family and friends' support. The patients were classified as per Ridley Jopling classification and the patients admitted with us belonged to Borderline tuberculoid, Borderline Lepromatous and lepromatous leprosy along with Pure neuritic cases. It was found that prevalence of depression and stress was equal among borderline leprosy and lepromatous leprosy patients, low among borderline tuberculoid and pure neuritic cases. The prevalence of anxiety was highest among borderline lepromatous followed by lepromatous leprosy (Figure 4).

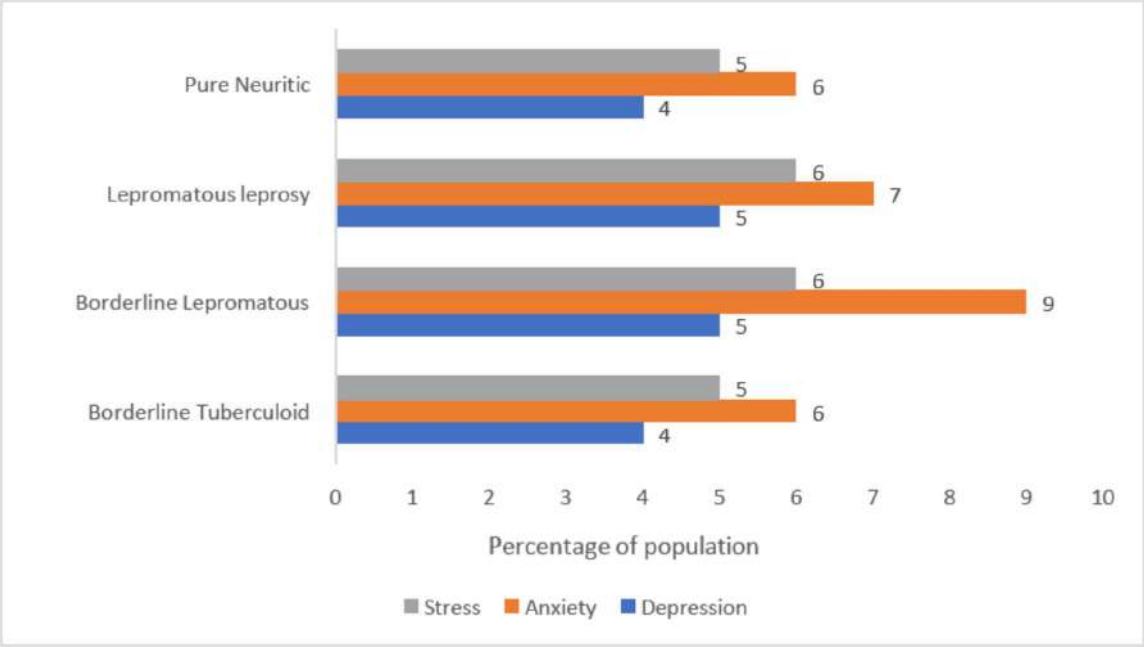


Figure 4. Percentage of population suffering from different classes of leprosy stratified by stress, depression and anxiety.

Figure 5 compares the prevalence of depression, stress and anxiety amongst patients with and without physical deformities/disabilities. It was found that incidence of all three psychological symptoms were more among the patients with physical deformities (Depression 18%, anxiety 28% and stress 24%) and amongst patients without physical deformities, prevalence was 10% for depression, 12% for anxiety and 8% for stress.

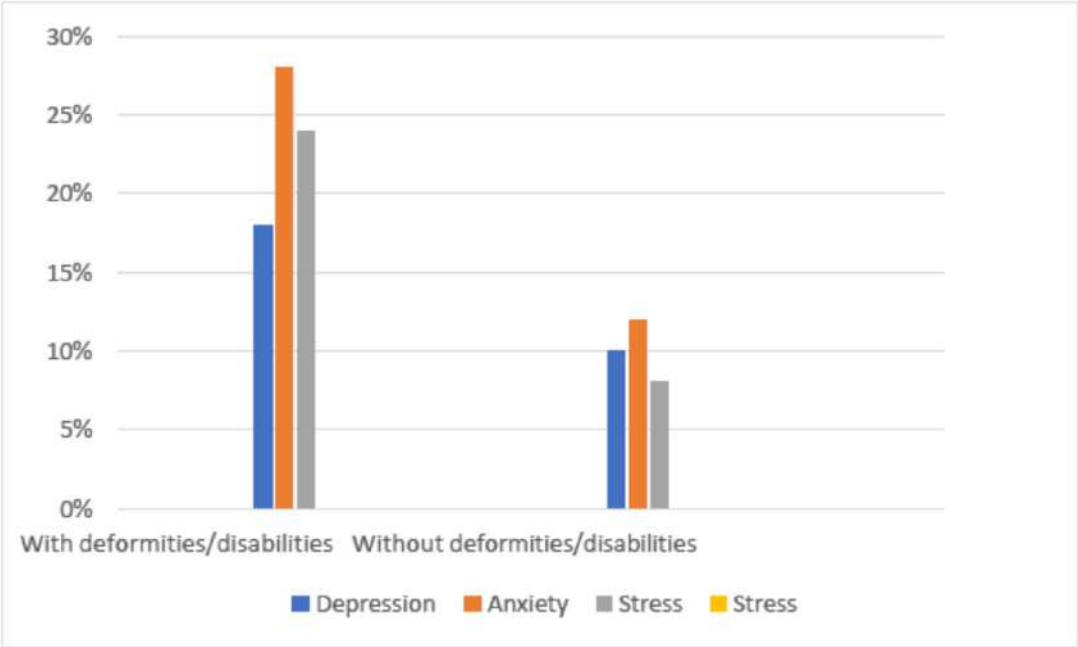


Figure 5. Percentage of mental morbidities amongst patients with and without physical deformities.

Discussion

Leprosy also labelled as Neglected Tropical Disease has existed since pre-biblical times. The stigma associated with the disease, despite effective treatment however still exists. Although, many efforts have been made in the past years to eradicate leprosy, but it continues to contribute a significant burden of disease in India.

The mental well-being in the leprosy patients remains woefully understudied subject. (10) Unlike support groups in chronic diseases like cancer, heart diseases, Diabetes, the psychiatric burden of leprosy patients has not received the attention it deserves.

Despite several evidence-based studies including the present one, demonstrating significant levels of psychiatric morbidity in patients of leprosy, the problem still remains unaddressed.

In this study we collected data from the adult admitted patients to understand the psychological impact of leprosy, free of factors such as poverty, malnutrition and illiteracy.

Majority of the patients in the present study suffered from either depression, anxiety or stress (65.38%) and remaining (34.6%) were not impacted with any psychological morbidity.

The present study indicates that leprosy-affected individuals have a higher prevalence of depression (36%), anxiety

(56%), and stress (44%) compared to the global and Indian prevalence of depression among the general population, which is 3.8% (11) and 5.25% (WHO 2023) [12] respectively. These figures are higher than that reported by Rani, Ritu et al where 20% of patients had depression and 7.14% had anxiety [13] but comparable to the study by Clarissa Iris et al, where 71% of leprosy patients had at least one psychiatric diagnosis [14].

Amongst patients with depression, 28% of patients had mild severity and 8% had depression of moderate severity. 40% had mild anxiety, 12% moderate and 4% severe. Out of the patients experiencing stress, 32% were of mild severity, 8% moderate and 4% severe. The patients with physical deformities/disabilities had high prevalence of these symptoms, 18% with depression, 28% had anxiety and 24% stress. Similar findings were observed by Dian Erisyawanty Batubara et al. [15].

Leprosy-affected individuals also experience feelings of fear and low self-esteem [16]. A higher prevalence of depression was reported by 53% [17], 42.5% [18], 24.6% [19] and prevalence of depression, anxiety and stress reported by Anusha V et al was 12.5%, 19% and 3% [1]. The prevalence of these mental health issues may be influenced by factors such as gender, age, socioeconomic status, religion, underlying co-morbidities and the presence of physical deformities/disabilities. It is essential to target all these psychiatric issues for providing a comprehensive treatment to leprosy patients. Mhasawade et al. demonstrated the positive outcome in mental morbidity of Leprosy patients by employing psychotherapy as a therapeutic tool from time of diagnosis till discharge from treatment [20]. Ima Rahmawati et al by using a simple tool like cognitive behavioral therapy (CBT) managed to reduce level of depression severity in patients of leprosy. This can be incorporated in management protocol for treatment of leprosy [21].

Our observations suggest that there should be regular screening, psychological counselling, and support services for individuals affected by leprosy. Awareness programs at community, school, institutional and district levels should also be conducted to reduce social stigma associated with the disease. Healthcare professionals working at various levels should be adequately trained to identify these mental health issues so that an early diagnosis and prompt intervention can be done. Emphasis should also be laid upon to enhance family, friends and neighborhood support for affected individuals.

Limitations

The various limitations in current study which can induce bias are as follows:

a) Only male patients were enrolled, thus having gender bias (since females and children are not admitted as per existing policy).
b) Since the patients were admitted for supervised treatment, the outpatients were not included.
c) Age: The age group of the subjects in the study ranged from 25-45 years, thus excluding children and elderly.
d) All the patients included in the study were literate and employed. Since Leprosy is associated with poverty, this factor was not applicable to the present study.
e) The duration of the study was small vis-à-vis the natural course of leprosy.
f) Since the inpatient services include provision of well-balanced diet, the

study does not apply to undernourished patients

g) This study only elicited the present mental health status of leprosy-affected persons who did not have any previous co-morbidities.

h) This study was done in a single leprosy tertiary care center and was not carried out as a multi-centric study. Therefore, the findings of the study cannot be generalized to all the populations.

Conclusion

This study found that the prevalence of depression, anxiety, and stress among individuals affected by leprosy was significant in the patients who are not poor, unemployed, malnourished or destitute. The prevalence of depression was 36%, anxiety (56%) and stress (44%) which were significantly high indicating a high burden of psychological impact amongst leprosy patients particularly the patients with physical deformities or disabilities. It can be assumed that the Leprosy per se can impact the mental well-being of a patient. So, as per the findings of the study, we conclude that psychological intervention and counselling should be considered as an important aspect of leprosy treatment.

Statements and Declarations

Ethical Approval

It was obtained from Institutional Ethical Committee at the Institute

Informed Consent

It was obtained from all the patients

Conflict of Interest

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

Funding

No funding was received for conducting this study.

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ORIGINAL ARTICLE

Dental Health Literacy among Highly Skilled Professionals in India: A Pilot Study

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Abstract

Purpose: Research in medical settings has consistently demonstrated that health literacy is essential for patient adherence and comprehension to medical/dental instructions including prescriptions and improving positive holistic health outcomes. Despite its recognized importance, the role of literacy in dentistry has received limited focus. This study aimed to assess the level of oral health literacy among professionals in a multinational company, using the Rapid Estimate of Adult Literacy in Dentistry-30 (REALD-30) as the measurement tool. **Methods**: A convenience sample of 111 adults was recruited from a dental camp held at two locations within an IT firm. Oral health literacy was measured and analysed using the REALD-30 scale. Participants also participated in interviews to collect sociodemographic information, dental visit history, dental needs, global oral health ratings, dental knowledge, practices, and comprehension. Additionally, clinical examinations were conducted to record the DMFT index (Decayed; D component, Missing; M component, and Filled; F component Teeth), as well as the presence of dental stains and calculus. Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 13. **Results:** REALD-30 scores ranged from a low of 8 to a high of 25. Participants who had decayed, missing, or filled teeth, or a DMFT score higher than one, exhibited lower oral health literacy compared to the reference group. Similarly, lower oral health literacy was observed in participants with dental stains or calculus. **Conclusions:** Effective communication with patients is crucial for delivering high-quality dental care. The study concluded that a significant proportion of the highly educated professional group of people has less oral health literacy, which may obstruct their basic ability to understand and process the fundamental oral health information.

Keywords: REALD-30, Oral Health Literacy, Oral Health Outcome, Health Literacy, Communication

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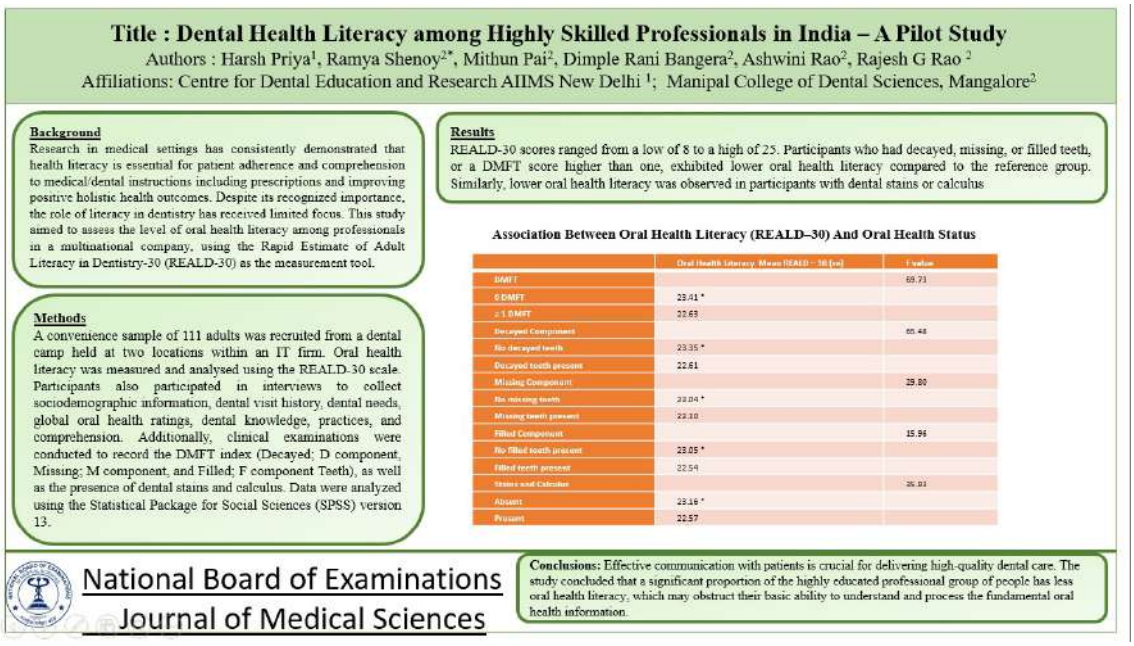
Graphical Abstract



Introduction

Clear and effective communication with patients—through clear information presentation and active listening—is vital for delivering quality dental care and achieving positive oral health outcomes. Oral health outcomes result from various factors that promote oral health and prevent disease. Individual self-maintenance and professional dental care are important alongside community oral health efforts like fluoridation of water, salt, sugar etc. program and dental sealant program in school setting. A patient would require awareness of the current services, and knowledge to access and use them judiciously for availing the benefits of various preventive care and navigation into the complex healthcare system. While patients gather information from many sources, the care and guidance provided by their dentists and dental teams are key in helping them maintain optimal oral health and make informed decisions about their overall health. A visit to the dentist or dental hygienist offers patients the chance to understand essential guidance and develop self-care skills, as well as learn a few extra health services they might need. The communication and soft skills of a professional from dental fraternity significantly enhances a patient's health literacy, ultimately leading to improved and positive health outcomes [1].

Health literacy is vital in preventing and managing non-communicable diseases (NCDs) like diabetes and heart disease too. Individuals with better health literacy can understand risk factors, make informed lifestyle choices, and adhere to treatments. Enhancing health literacy is key to reducing NCD prevalence and improving overall public health outcomes [2].

What is health literacy?

There are multiple ways and organizations to define health literacy. They all emphasize the ability to acquire, comprehend, and apply health information

effectively. The World Health Organization was among the pioneers in defining health literacy, paving the way for subsequent refinements [3]. Healthy People 2010 was the first document to discuss, define and align with the general concept of health literacy: the extent to which individuals can obtain, process, and understand basic health information and services to make appropriate oral health decisions. The crux and central to all definitions are the fundamental idea that better and positive health outcomes can be achieved by improving access to health information and knowledge and the ability to use it effectively and judiciously. Thus, health literacy concept and skills are essential for empowering individuals to enhance their own health [4].

In dental settings, terms like periodontal disease, oral potentially malignant lesions, dental caries, and malocclusion can create hindrances to understanding for many people visiting dental health infrastructure. The language and materials being used to communicate scientific findings, patient information, and health education are vital tools for productive and effective communication [1]. This includes a wide range of materials, such as brochures, newsletters, dental health manuals, consent forms, insurance documents, health histories, information booklets and home care instructions sheets following dental procedures.

Health literacy involves more than just reading skills; it includes writing, listening, numeracy, and oral communication abilities. It also requires navigating a complex healthcare system, influenced by education, culture, and situational context. The emphasis on health literacy is timely, as our nation's demographics change and self-care and healthcare demands increase. Poor or low health literacy is a significant issue, contributing to disease and imposing substantial financial costs on both individuals and the nation. Recent estimates suggest that low health literacy costs between $106 billion and $238 billion annually, accounting for 7% to 17% [1] of all personal healthcare expenses. Individuals with low health literacy are more likely to use emergency services, struggle with diabetes management, and are less likely to engage in preventive care and screenings. Furthermore, health literacy is now recognized as a key determinant of health. These skills vary across different health areas, such as diabetes, cancer, heart disease, and oral health. Understanding health information and knowing how to access services are essential for effective personal health management.

Studies [5,6] have shown that literacy, particularly health literacy, is connected to various aspects of health, including knowledge, health status, outcomes, and the use of services, especially preventive and health-promoting behaviors that impact both medical and dental health. While not yet fully confirmed, this is believed to apply to oral health as well. Low literacy may contribute to health disparities.

Behavioral scientists conducted a study involving 126 men, women, and children from a typical Midwestern community [7], leading to the identification of certain social classes and their attitudes toward dental care. The upper middle class was characterized as professionals and business executives,

well-educated and residing in well-maintained, spacious homes in desirable areas. This group seeks expert advice and, in matters they deem important, follows it diligently. They take a long-term approach to life, focusing on preventing or delaying aging, disease, decay, and death. They highly value their teeth, show interest in preventive dentistry, and actively seek various types of dental care. For them, the dentist is seen not only as someone who repairs teeth and alleviates pain but also as a professional who prevents decay and tooth loss while enhancing the appearance and function of teeth. Members of this class, including those in the present study, are particularly committed to keeping their natural teeth for as long as possible.

While research in medical settings has consistently highlighted the significance of health literacy in patient adherence to medical instructions and improved health outcomes, literacy has received less attention in the field of dentistry [8].

Therefore, the present study aimed to assess oral health literacy among well-educated professionals with B Tech degrees working in a multinational company. The study utilized the REALD-30 instrument, known for its reliability and validity [9], to measure participants' understanding of oral health and their awareness of the importance of maintaining natural teeth.

Materials and Methods

Study design

A cross sectional design was used to collect information about oral health literacy in a sample of highly skilled professionals attending dental camp at their workplace. A dental camp was organized in two branches in an IT company situated in the city of Mangalore, India. The human resources department had requested for the dental camp from the Department of Public Health Dentistry through the proper channel. Every Monday, for a period of two months were designated for the dental camp. All the professionals enrolled in the company were informed via e mail regarding the date, duration and venue of the dental camp and were requested to register before hand to ensure smooth functioning. A mobile dental van was used to deliver dental services and was parked at a convenient location outside the main building. The dental check up was done at the health centre inside the main building. A physiotherapist and a physician were regularly present at the health centre. These appointed health personnel's helped regarding the maintenance of record of registered patients. A single interviewer enrolled the participant, conducted the interviews and administered the REALD-30 in a room inside the health centre. A time duration of approximately 10 minutes was required to fill the dental health literacy assessment in privacy of the dental operatory before the patient was examined by the examiner. 15 pretest interviews were completed to refine the data collection methods, calibrate interview and examination protocol and feasibility of the survey. The dental check up was done by the examiner later and the patients were referred for dental treatment as and when required in the mobile dental van.

Survey Instrument

Oral health literacy was evaluated using the Rapid Estimate of Adult Literacy in Dentistry (REALD-30). This is a word

recognition test tailored to gauge oral health literacy. The REALD-30, works principally similar to the Rapid Estimate of Adult Literacy in Medicine (REALM) structure, and is widely used in health set up to pinpoint patients with lesser literacy regarding health [7]. Word-recognition tests like REALD-30 are strongly correlated with general ability to read and comprehend health sector including navigation and instructions. Studies [10,11] have indicated that difficulty pronouncing medical or dental terms, reflecting basic reading skills, often correlates with poorer comprehension and health outcomes. Such tests help clinicians identify patients who might struggle with written and oral communication. The REALD-30 comprises 30 words representing various dental conditions, their ways of prevention, and line of treatment. Participants are asked to read the words aloud, and points are assigned for each correct pronunciation, yielding a score from 0 to 30. In addition to the REALD-30, participants answered a series of questions on socio-demographics, dental visits, dental needs, overall oral health ratings, dental knowledge, practices, comprehension, and self-reported oral health outcomes.

In clinical examination DMFT [12] was recorded for the participants and also presence or absence of stains and calculus was checked. The training and calibration of examiner was done under the guidance and supervision of the senior faculty.

Data Analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS) version 13. Oral health literacy was described using mean scores and frequency distributions of REALD-30 results. For categorical analysis, REALD-30 scores were divided into three groups based on tertiles [12]: high literacy (≥25), moderate literacy (23–24), and low literacy (≤22). The relationship between each covariate and oral health literacy was analyzed using Pearson's χ^2 test for categorical REALD-30 scores and analysis of variance (ANOVA) for mean scores.

Results

Table 1 presents characteristics distribution table of the study population (n = 111). The mean age group was 25.28 years and (standard deviation [3.78]). The minimum REALD – 30 score of 8 and maximum of 25 was reported among the study population. The mean REALD – 30 score for one person was 22.7 ± 2.48. However, when the tertiles were calculated, little less than half of the study population had low literacy level. The percentage distribution of REALD – 30 scores was skewed towards higher scores, but close to 45 percent of the study population scored below 23, defined as low literacy level for purposes of this study. (Figure 1)

Table 1. Association Between Oral Health Literacy (REALD–30) And Oral Health Literacy Related Outcome

	Oral Health Literacy Mean REALD – 30 (se)	**p value**
Dental Visit		0.431
Yes	22.76 (0.28)	
No	22.59 (0.44)	
Oral Health Knowledge		
F Toothpaste		0.297
Correct	22.93 (0.45)	
Incorrect	22.62 (0.29)	
Brushing Time		
Correct	22.35 (0.46)	0.038
Incorrect	22.80 (0.27)	

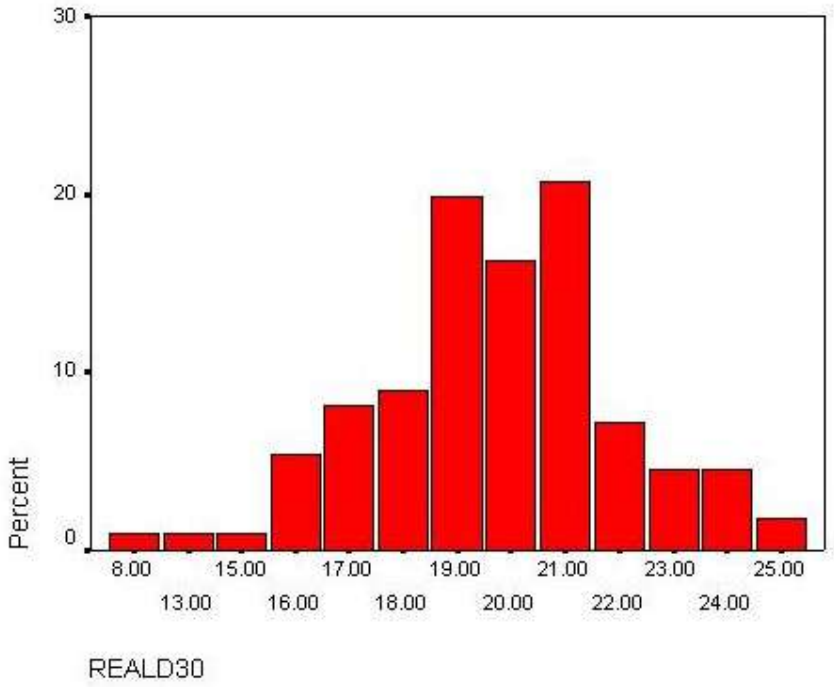


Figure 1. The percentage distribution of REALD – 30 scores

Table 2 presents the bivariate analysis of the mean scores revealed that no significant difference existed in the REALD – 30 scores among any group ($p > 0.05$). However, participants who thought had a gum problem scored higher on the REALD – 30 than did their reference group. This group showed mean scores with a p-value ranging between 0.05 and 0.10. Similarly, the bivariate analysis of the association between REALD-30 categories and covariates indicated comparable relationships, though the statistical significance remained weak. Oral health literacy as assessed by REALD – 30, was lower among participants who had decayed; missing and filled teeth present or an overall DMFT was greater than one as compared to their reference group (Table 3). Also, oral health literacy was lower in participants in who stains or calculus was present.

Table 2. Association Between Oral Health Literacy (REALD–30) and Self Reported Oral Health Outcome

	Oral Health Literacy Mean REALD – 30 (se)	**p value**
Think need extraction		0.41
Yes	21.80 (1.7)	
No	22.75 (0.24)	
Think need filling		0.88
Yes	22.77 (0.50)	
No	22.69 (0.27)	
Think have gum problem		0.06
Yes	23.50 (0.4)	
No	22.46 (0.28)	
Concerned about appearance		0.48
Yes	22.35 (0.42)	
No	22.78 (0.27)	
Self rating oral health		0.50
Good , Very Good and Excellent	22.80 (0.29)	
Fair and poor	22.45 (0.42)	

Table 3. Association Between Oral Health Literacy (REALD–30) And Oral Health Status

	Oral Health Literacy Mean REALD – 30 (se)	**F value**
DMFT		69.73
0 DMFT	23.41 *	
≥ 1 DMFT	22.63	
Decayed Component		65.48
No decayed teeth	23.35 *	
Decayed teeth present	22.61	
Missing Component		29.80
No missing teeth	23.04 *	
Missing teeth present	22.10	
Filled Component		15.96
No filled teeth present	23.05 *	
Filled teeth present	22.54	
Stains and Calculus		35.83
Absent	23.16 *	
Present	22.57	

*p< 0.01

Discussion

The scientific knowledge of oral health literacy is primarily based on a limited number of studies. These studies emphasize a discrepancy between the reading levels needed to understand dental health education materials and the actual reading skills of the users. This area remains under-researched in dentistry, indicating a need for further exploration. Research in medical care highlights the importance of health literacy in influencing health outcomes. Further studies reveal that people with lower education levels tend to exhibit poorer dental habits and overall oral health [14,15]. Just as with general health, maintaining oral health requires the ability to understand, interpret, and act on health information, whether it is presented orally or in writing [16]. This study aims to evaluate the level of oral health literacy, as measured by REALD-30, among professionals working in a multinational company who are attending a dental camp.

All the participants involved completed the interview fully and agreed for the dental check up demonstrating that

the survey was embraced by the community. Present study aimed at measuring the oral health literacy of the professionals and tertiles were calculated of the REALD – 30 scores. The ranges were high literacy level, ≥25; moderate literacy level, 23 – 24 and low literacy level, ≤ 22. However, in another study [13] among adult patients seeking dental care the low literacy level was defined as ≤ 21. This may be attributed to the highly educated participants in the present study. But as far as the overall dental knowledge and reading ability is concerned none of the participant scored cent percent in REALD – 30 scoring. Scores dropped at a low of score 8 on the 30 – point scale, with about 19.8 percent and 20.7 percent of patients being able to correctly pronounce fewer than 19 and 21 words, respectively.

The analytical results suggested that there was no significant association between oral health literacy and the factors that were considered as consequences of poor health literacy. The interpretation cannot be totally negative as other factors might have an influence on oral health literacy which was not considered in this study. Also desirability bias can pave way in this study because of the highly educated and professional study population. The association between oral health literacy and oral health of the study participants was intuitive and supported by literature in the general health realm. Oral health literacy as assessed by REALD – 30, was lower among participants who had decayed; missing and filled teeth present as compared to their reference group. This can be positively interpreted as higher oral health literacy leads to better oral health outcomes. Also, oral health literacy was lower in participants in whom stains or calculus was present. Low health literacy has been linked to increased emergency hospital visits, limited understanding of chronic conditions and their causes, and suboptimal self-care behaviors. Once again, evidence supports the notion that literacy is a crucial factor enabling individuals to process and act on information to enhance their health outcomes and healthcare behaviors [17].

mHealth (mobile health) and health literacy are also interconnected in improving healthcare delivery. mHealth involves the use of mobile devices and apps to enhance health services, from monitoring to communication with healthcare providers. Effective mHealth solutions must consider users' health literacy levels to ensure that information is understandable and actionable. By bridging the gap between technology and comprehension, mHealth can enhance patient engagement, adherence to treatments, and overall health outcomes [18].

Several limitations of our study should be noted. First, the sample was small and convenience-based, which means the findings may not be representative of all highly skilled professionals in multinational companies. Consequently, the study may be underpowered, increasing the risk of a Type II error. Although all participants who attended the dental camp were included, with no refusals, this limitation still applies. Second, the cross-sectional design limits the ability to infer causality. Third, the REALD-30 might not entirely represent oral health literacy in our study population, as it only measures word recognition without evaluating comprehension or functional skills. While

the READLD-30's limitations are acknowledged, including the absence of a comprehension component, few other validated instruments were available. The Test of Functional Health Literacy in Dentistry (TOFHLiD) [19], which assesses broader aspects of oral health literacy such as reading comprehension and numerical ability, was not used due to its potential for a longer administration time.

Conclusion

Effective communication with patients is essential for delivering quality dental care. The study's results indicate that many individuals in the highly educated and professional group exhibit low oral health literacy, which could hinder their ability to comprehend, analyze and process fundamental oral health information. Also, lower the oral health literacy poorer the oral health of the study population. It is the responsibility of the health care provider's team to spot patients who are having difficulty understanding, interpreting and using dental health information and corrective steps should be taken to address their challenges and build strong compliance to their needs. There is dearth of appropriate and up to date knowledge of literacy regarding oro-dental health and urge more relevant and expansive research on this topic. REALD has proved to be a promising instrument or tool for calculating the reading ability dimension of oral health literacy. The concept of a fast estimation for adult literacy in dentistry should be revisited and looked in detail. The goal is to maintain and increase its utility as a measure of oral health literacy. Hence, REALD need to be tested in a more diverse cohorts and population.

Ethical approval

Ethical clearance was obtained from the institutional ethics committee of MCODS Mangalore. Informed consent regarding the interview of study proforma and READLD-30 was obtained verbally.

Conflicts of interest

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

Funding

No funding was received for conducting this study.

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ORIGINAL ARTICLE

Out-of-Pocket Expenditure in Patients admitted to Cardiology Department under AB-PMJAY scheme in a Tertiary Care Hospital in Delhi: A Cross-Sectional Study

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Abstract
Introduction: The recent National Health Accounts 2019-20 data reveals that Out-of-Pocket Expenditure (OOPE) as a percent of Total Health Expenditure is more than 47% which is still higher compared to out-of-pocket health spending in other developing nations. Ayushman Bharat-Pradhan Mantri Jan Aarogya Yojana (AB-PMJAY), the world's largest public-funded social health insurance scheme is a by-product of National Health Policy 2017 recommendations to achieve Universal Health Coverage and reduce OOPE in health. The present study was conducted to know the OOPE among the patients admitted to the Cardiology department under AB-PMJAY scheme in a tertiary care hospital in New Delhi. **Methods:** A descriptive cross-sectional study was carried out from January 2021 to April 2022 among the patients admitted under the PMJAY scheme in the Cardiology Department of Tertiary Care Hospital in New Delhi. A total of 320 patients were interviewed using a structured questionnaire divided into eight sections. The collected data was tabulated in Microsoft Excel and analyzed. **Results:** The study investigated out-of-pocket expenditure (OOPE) for patients, finding the scheme covered doctor consultations, bed charges, physiotherapy, implants, and oxygen, but some patients still faced OOPE for diagnostics (15%), medicines (22.5%), blood transfusions (8.75%), and ambulance with an average direct medical expenditure of approximately Rs. 1511 during the hospital stay at the current hospital. Compared to previous hospitalizations, OOPE for diagnostics, medicines, and blood transfusions significantly decreased under PMJAY. Overall, 60.3% of respondents were satisfied with the PMJAY scheme. **Conclusion:** The PMJAY scheme helped the beneficiaries to reduce the financial burden of health to a great extent. However, few of the beneficiaries continued to make some payments from their pockets for diagnosis, medication, etc. The main reason for this was a lack of knowledge and awareness about the scheme among the beneficiary population.

Keywords: AB-PMJAY Scheme, Out of Pocket Expenditure (OOPE), Cardiology Patients, Public Funded Health Insurance, Universal Health Coverage (UHC)

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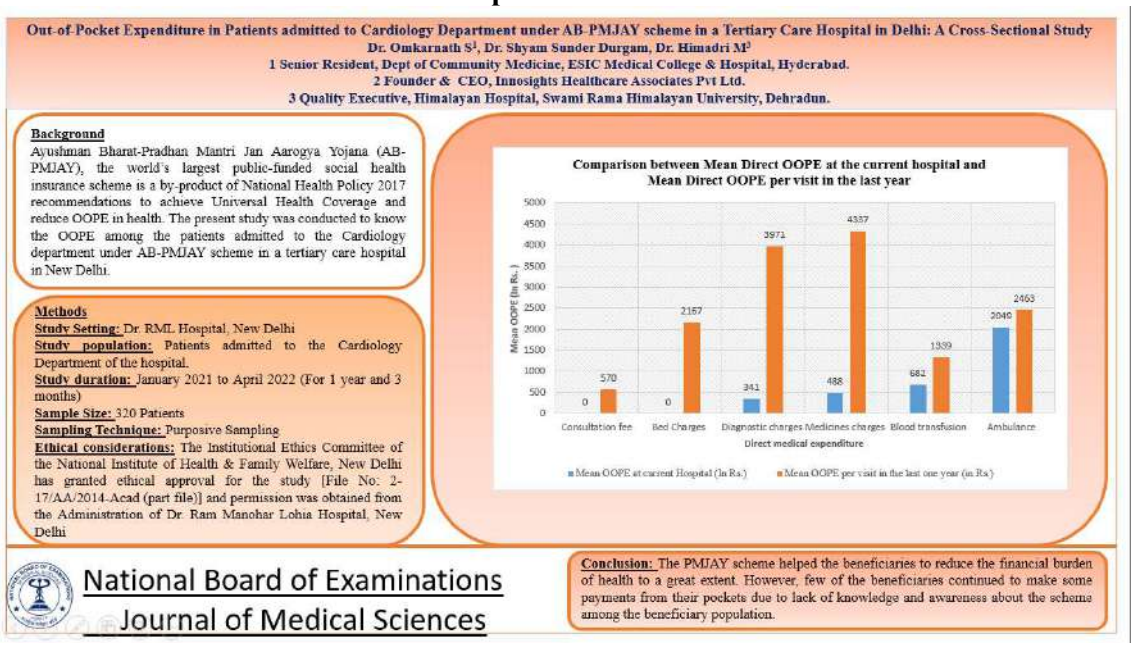
Graphical Abstract



Introduction

The major policy goal in the health sector globally is to achieve Universal Health Coverage (UHC) [1]. The definition of UHC given by the WHO is to provide all people with access to needed health services (Prevention, Promotion, Treatment & Palliation) of sufficient quality to be efficient and ensure that the use of these services doesn't expose the user to financial hardships [2]. Ideally, health care costs should not be paid Out of Pocket (OOP) by users at the time of seeking services but through prepayment mechanisms or tax revenues. Contrary to this, about 60 million Indians fall into poverty annually due to the expenditure on health. Despite the acceptance of UHC at the policy level in India, over 50% of healthcare spending is borne by households in India [3]. The recent National Sample Survey (NSS-75th round) report reveals that only 19.1% of the urban and 14.1% of the rural population is under any health protection coverage [4].

Ayushman Bharat PM-JAY is the largest health assurance scheme in the world which aims at providing a health cover of Rs. 5 lakhs per family per year for secondary and tertiary care hospitalization to over 10.74 crores of poor and vulnerable families (approximately 50 crore beneficiaries) that form the bottom 40% of the Indian population. Except for West Bengal, Odisha, and Delhi, the program is currently being implemented throughout all of India's states and union territories. It aims to provide cashless and paperless health cover up to 5 lacs per family per annum with no cap on family size including 3 days' pre-hospitalization and 15 days' post-hospitalization expenses which covers 1950 procedures and is portable across the country [5]. At the moment, PM-JAY offers 56 cardiac therapy packages with 156 procedures from the cardiology and cardiothoracic and vascular surgery (CTVS) specialties. The study aims to assess the 'Out of Pocket Expenditure' incurred among the Cardiology patients

admitted under PMJAY in a tertiary care hospital in Delhi. The objectives are to assess the direct and indirect health expenditures incurred by the patients admitted in the cardiology department under PMJAY in a tertiary care hospital in Delhi and to compare the expenditure incurred by the patients before PMJAY and after their preauthorization into the scheme.

Methodology and Methods

Study Settings & Design

A Hospital-Based Descriptive Cross-Sectional Study was conducted from January 2021 to April 2022 (For 1 year and 3 months). A purposive method of sampling was applied to select the study area. High inpatient admissions under the PMJAY scheme and the willingness of the hospital authorities to give permission are considered key factors in selecting the study area. The study was undertaken in Dr. Ram Manohar Lohia Hospital, New Delhi after obtaining permission from the concerned hospital authorities.

Study Population

For this hospital-based study, the population comprised of patients who were admitted to the Department of Cardiology to seek treatment under the PMJAY scheme during the study period were interviewed and the relevant information was sought from beneficiaries. The study included patients admitted directly to the Department of Cardiology and those referred from other departments under the PMJAY scheme during the study period whereas severely ill patients, those seeking non-PMJAY treatment packages, ineligible or uncovered patients, and those unwilling to participate were excluded from the study.

Sample size

The sample size was calculated, according to NSSO 75th round [4], OOPE in health is about 66%. Assuming it to be 70%, (p =0.70) and taking a 95% confidence level with ± 5% precision, Using the formula, $n=z^2\ pq/d^2$ where, n= number of participants, Z= Standard normal variant at the confidence level of 95% (Normal value is 1.96) p = prevalence = 0.70 q = 1-p = 0.30, absolute precision (d) = 0.05, Thus, bringing the sample size to 320. Considering the proposed sample size and the average number of In-Patient admissions in the cardiology department in the hospital from the records, all the patients admitted to the department of cardiology during the study period were included in the study to meet the proposed sample size.

Data Collection tool & technique

Data was collected from the patients in the inpatient area, they were approached about their willingness to participate in the current study, and informed consent was obtained, after providing them with a detailed participant information sheet. The data was collected using a pretested, semi-structured interview schedule developed after a thorough literature review and consultation with various stakeholders. Details sought are included in eight sections i.e., Socio-demographic profile of the study population, Patient, Household characteristics, Awareness of the PMJAY scheme, Utilization of the PMJAY scheme, Details of current hospitalization, The total expenditure incurred to avail the treatment of the diagnosed health issue till the admission to the current hospital, OOPE for the last one year for treating the particular illness, Mean OOPE per visit in the last year compared to the OOPE at the current health

facility and the Patient satisfaction with the scheme. The questionnaire was pre-tested as a part of a pilot study before administering the same to the study population. The source of finances to meet the expenses was also recorded. The satisfaction of the patients regarding the scheme was also obtained in a graded manner using a Likert scale. Any queries were promptly addressed during the entire duration of the interview. After the interview was over, the participants were thanked for their valuable time and support in the study.

Data Analysis

All case forms were given a unique Case ID and raw data were tabulated in a Microsoft Excel sheet (MS Office 2019). All entered cases were rechecked for correctness and any typological errors were removed. Any missing information noticed at this juncture was filled out after contacting the participant on a phone call. The personal information was de-linked before doing data analysis. The collected data were tabulated in an Excel sheet (MS Office 2019) and were analyzed using Descriptive statistics such as frequency and percentage to analyze the socio-demographic profile of the subjects. Average OOP expenditure (mean and median) incurred for the period of hospitalization due to illness and up to 1 year before hospitalization for the same diseases was calculated and represented as tables, graphs, and figures.

Results

Socio-demographic Characteristics of Participants

A total of 320 patients admitted to the cardiology department under PMJAY were interviewed for this study. Out of 320 respondents, 63 % of the beneficiaries were male (n=202) and 37% of the beneficiaries were female (n=118). The majority of participants, 33.1% belonged to the age group of 45 to 59 years (n=106) followed by 26.3% of beneficiaries belonging to the age group of 30 to 44 years (n=84), 21.2% of beneficiaries belonging to the age group >60 years (n=68), 12.2% of beneficiaries were belonging to the age group of 15 to 29 years (n=39) and 7.1% of the beneficiaries belonging to the age group <14years (n=23). 77.5% of the beneficiaries were married (n=248), 13.4% were never married and 9.1% of them were married by widowed or divorced (Table 1).

Table 1. Socio-demographic Characteristics of Participants

Characteristics		**Frequency (n)**	**Percentage**
Age	>60	68	21.20%
	45-59	106	33.10%
	30-44	84	26.30%
	15-29	39	12.20%
	<14	23	7.10%

Gender	Male	202	63%
	Female	118	37%
Marital Status	Married	248	77.5%
	Never Married	43	13.4%
	Widowed/Divorced	29	9.1%
History of Chronic Illnesses	Known Chronic illnesses present	233	72.8%
	No History of chronic illness in the recent past	38	11.9%
	Status not known	49	15.3%
	Total	**320**	**100%**

The state-wise distribution of beneficiaries was 43.5% of beneficiaries belonging to Bihar state (n=139) followed by 38.4% of beneficiaries belonging to Uttar Pradesh state (n=123), 5.3% of the beneficiaries belonging to Haryana state (n=17), 4.1% of the beneficiaries belong to Uttarakhand state (n=13), 2.2% of the beneficiaries belong to Madhya Pradesh state (n=7), 6.5% of the beneficiaries belong to Punjab state (n=21). Most of the beneficiaries i.e., about 68.4% are from rural areas (n=219) and 31.6% are from urban areas (n=101). Out of 72.8% of the beneficiaries (n=233) who are suffering from chronic illnesses, 30.3% of the beneficiaries are suffering from only Hypertension (n=97), 19.3% of them are suffering from only Diabetes Mellitus (n=62), 15.9% of them are suffering from both Hypertension and Diabetes Mellitus, and 7.1% of the beneficiaries are suffering from Thyroid related diseases (Both Hypothyroidism and Hyperthyroidism) (Table 2).

Table 2: Educational Status & Occupation of Participants

Characteristics		**Frequency (n)**		**Total**	**Percentage (%)**
		Male	**Female**		
Education	Illiterate	13	22	35	11%
	Literate	44	17	61	19%
	Primary	62	35	97	30.3%
	Junior High School	24	18	42	13.1%
	High School	19	12	31	9.7%
	Intermediate	14	09	25	7.8%
	Graduate	16	05	21	6.6%
	Postgraduate & above	08	00	08	2.5%

Occupation	Unemployed	61	6	67	20.9%
	Student	21	8	29	9.1%
	Housewife	0	51	51	15.9%
	Daily labourer	54	23	77	24.1%
	Farmer	35	19	54	16.9%
	Skilled worker	19	7	26	8.1%
	Self-employed	12	4	16	5%
	Total	**202**	**118**	**320**	**100%**

The majority of the study population about 30.3% have completed their primary education (n=97). Of them, 62 were males and 35 were females. 11% of the respondents, 13 males, and 22 females were illiterate among the study population. 24.1% of the beneficiaries are daily laborers (n=77). Of them, 54 were males and 23 were females. 16.9% of them are farmers (n=54), 8.1% of them are skilled workers (n=26), 9.1% of them are students (n=29), 15.9% are house-wives (n=51), 5% are self-employed (n=16), and 20.9% of the beneficiaries are unemployed (n=67). (Table 3).

Table 3. Average Family Size of the study population

No. of members in the family	**Frequency (n)**		**Total**	**Percentage (%)**
	Rural	**Urban**		
Only Single member	4	7	11	3.4%
2	13	5	18	5.6%
3	23	8	31	9.7%
4	91	37	128	40%
5	77	32	109	34.1%
≥6	11	12	23	7.2%
Total	**219**	**101**	**320**	**100%**

Household Characteristics of the Study Population

It was found that comparatively, the family size in the rural areas is slightly higher than the family size in the urban areas. 39.7% of the respondents are living in the Pucca house (n=127), 17.2% in the semi-pucca house (n=55), 23.1% are living in the serviceable Kutcha house and 20% of them are living in the unserviceable Kutcha house. 74.1% of the beneficiaries are living in their own house (n=237) whereas 25.9% of them are living in a rented house (n=83). It was found that 52.5% of the family had a monthly income of less than Rs. 5,000 (n=168). 34.1% had it between Rs. 5,000-10,000. While 13.4% were those who had a monthly income of more than Rs. 10,000. The monthly per capita income of 41.5% of the family was less than Rs. 1,000. And 37.8% had it between Rs. 1,000-1,500. 11.6% of the beneficiaries had a monthly per capita income of between Rs. 1501-2000, and 3.7% of them had a monthly per capita income between Rs. 2001-2500. While only 5.4% were those who had a monthly per capita of more than Rs. 2,500.

Details of Hospitalization and Health Expenditure to Treat the Particular Illness at the Current Hospital

The majority of patients were diagnosed with Percutaneous Transluminal Coronary Angioplasty with a diagnostic angiogram (n=132), followed by Percutaneous Transluminal Coronary Angioplasty with Double Medicated Stent and diagnostic angiogram (n=56), and Percutaneous Transluminal Coronary Angioplasty with Single Medicated Stent and diagnostic angiogram (n=43). Other diagnoses included Permanent Pacemaker (VVI) implantation (n=31), Permanent Pacemaker implantation - single chamber (n=19), Patent Ductus Arteriosus device closure (n=18), Percutaneous Transluminal Coronary Angioplasty with additional stent (n=7), Atrial Septal Defect device closure (n=5), Temporary Pacemaker implantation (n=4), Permanent Pacemaker (DDR) implantation - double chamber (n=2), Peripheral angiography with medicated stent (n=1), and Unspecified package (n=2) (Figure 1 and Table 4).

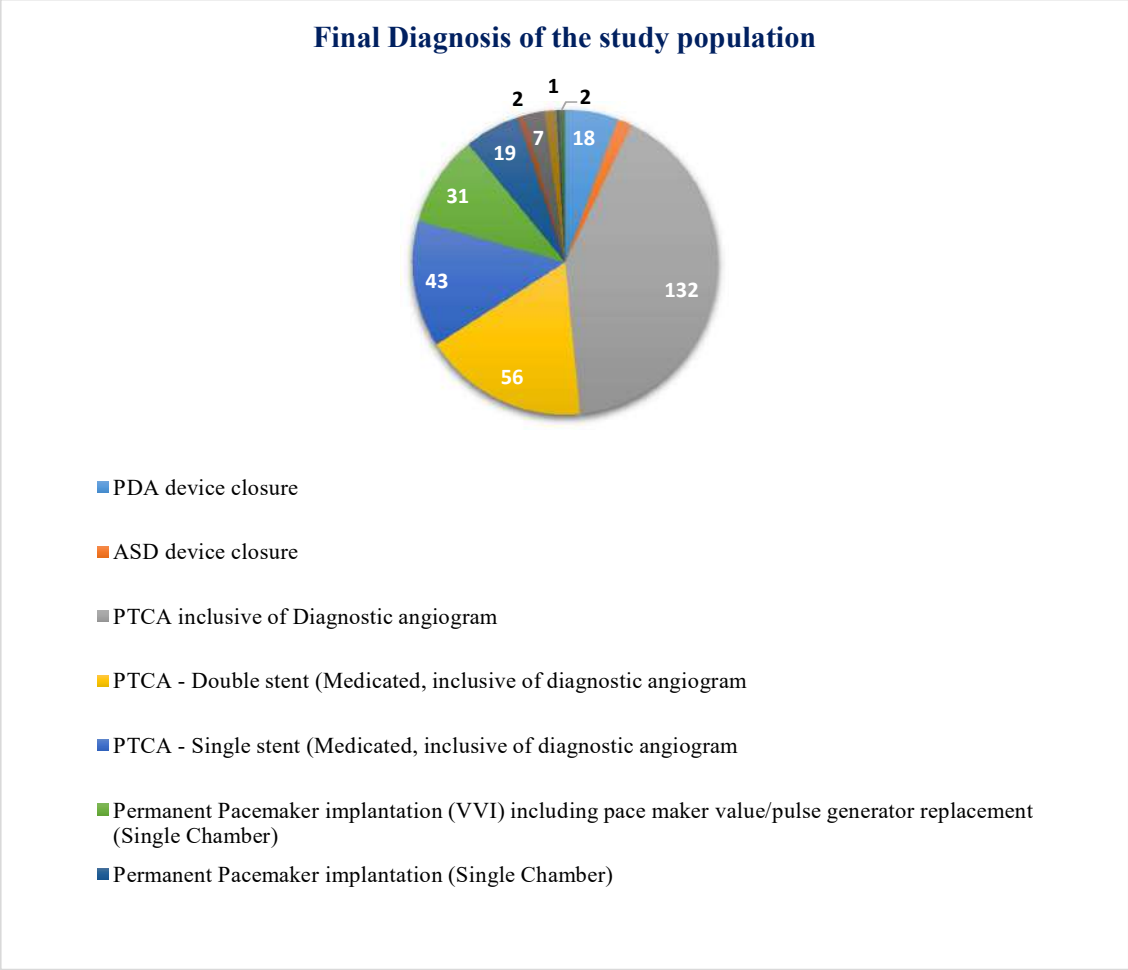


Figure 1. Diagnosis of the patients admitted under the scheme

Table 4. Direct Out-of-Pocket Expenditure by the Patient for availing the treatment

Characteristics		Frequency (n)	Percentage
Duration of hospitalization	Only 1 day	83	26%
	2 days only	117	37%
	3-5 days	71	22%
	6-7 days	32	10%
	>7 days	17	5%
Amount spent on Diagnostic charges	Did not pay any amount	273	85%
	<2000	28	9%
	2001-5000	8	2%
	>5000	7	2%
	Did not pay any amount	247	77.5%

Amount spent to purchase Medicines	<2000	61	19%
	2001-3000	7	2%
	>3000	5	1.5%
Amount spent on Blood Transfusion charges	Blood Transfusion not indicated	293	91.5%
	Did not pay any amount	18	6%
	<2000	5	1.5%
	2001-3000	4	1%
Amount spent on patient transfer by ambulance	Have not utilized Ambulance service	237	79.5%
	Did not pay any amount	21	6.5%
	<2000	15	5%
	2001-3000	33	10%
	>3000	14	4%

The majority of patients (37%) stayed in the hospital for 2 days, 26% for 1 day, 22% for 3-5 days, 10% for 6-7 days, and 5% for more than 7 days. Among the 320 respondents, none paid for doctor consultations or bed charges during their hospital stay. Most patients (85%) did not pay for diagnostic services, but 47 patients (15%) incurred diagnostic test charges. Approximately 22.5% (73 patients) paid for medicines, with 19% (n=61) spending less than Rs. 2000, due to non-availability in the hospital pharmacy, often during emergencies. Of the 27 patients who underwent blood transfusions, 18 did not pay, 5 paid less than Rs. 2000, and 4 paid between Rs. 2000 and Rs. 3000 due to specific blood types being unavailable in the blood bank. Out of 320 patients, 53 required physiotherapy, 188 needed implants or prosthetic devices, and 39 required oxygen support. None of these patients had to pay for these services. Additionally, 83 patients (20.5%) used ambulance services. Of these, 21 used public emergency services without cost, 15 paid less than Rs. 2000, 33 paid between Rs. 2001 and Rs. 3000, and 14 paid more than Rs. 3000 (Table 5).

Table 5. Indirect Out-of-Pocket Expenditure by the Patient for availing the treatment

Characteristics	Amount Paid (In Rs.)	For patient		For attendant(s)	
		Frequency (n)	Percentage	Frequency (n)	Percentage
Amount spent on Food during the hospital stay	Did not pay any amount	142	44.4%	0	0
	<1000	137	42.8%	252	78.8%
	1001-2000	41	12.8%	31	9.7%
Amount spent on accommodation for seeking treatment	Did not pay any amount	289	90.3%	242	75.6%
	<1000	27	8.4%	36	11.2%
	1001-2000	4	1.3%	5	1.6%
Amount spent on transport for seeking treatment	<1000	113	35.3%	104	32.5%
	1001-2000	129	40.3%	137	42.8%
	2001-3000	78	24.4%	42	13.1%
Daily wage loss during treatment	No wage loss	125	39.1%	157	49.1%
	<300	103	32.2%	71	22.1%
	301-500	77	24%	55	17.2%
	>500	15	4.7%	0	0
Total		**320**	**100%**	**283**	**88.4%**

Food for patients was free during the hospital stay, but some had to spend on specific diets like fruits and nutrient-rich food. Food for attendants was not provided, with 78.8% (n=252) spending less than Rs. 1000, and 9.7% (n=31) spending between Rs. 1000 and Rs. 2000. About 9.7% of patients (n=31) incurred accommodation costs. Most attendants (75.6%, n=242) did not spend on accommodation, while 11.2% (n=36) spent less than Rs. 1000, and 1.6% (n=5) spent between Rs. 1001 and Rs. 2000. This was mainly due to waiting times for pre-authorization and subsequent appointments. Regarding travel expenses, 35.3% of patients (n=113) spent less than Rs. 1000, 40.3% (n=129) spent between Rs. 1001 and Rs. 2000, and 24.4% (n=78) spent between Rs. 2001 and Rs. 3000. Among attendants, 32.5% (n=104) spent less than Rs. 1000, 42.8% (n=137) spent between Rs. 1001 and Rs. 2000, and 13.1% (n=42) spent between Rs. 2001 and Rs. 3000. Regarding wage loss, 39.1% of patients (n=125) and 49.1% of attendants (n=157) experienced no wage loss as they were students, housewives, or unemployed. Of those who experienced wage loss, 32.2% of patients (n=71) and 22.1% of attendants (n=71) lost Rs. 300 per day, 24% of patients (n=77) and 17.2% of attendants (n=55) lost between Rs. 301 and Rs. 500 per day. Around 4.7% of patients (n=15) lost over Rs. 500 per day, while no attendants lost more than Rs. 500 per day.

Majority of the patients (n=134) borrowed some money from their friends or relatives, 87 patients spent amount from their wages/salaries, 73 patients utilized their savings while 19 of them had to mortgage some property and 7 of them had to sell their property to meet the expenses at the hospital (Figure 2).

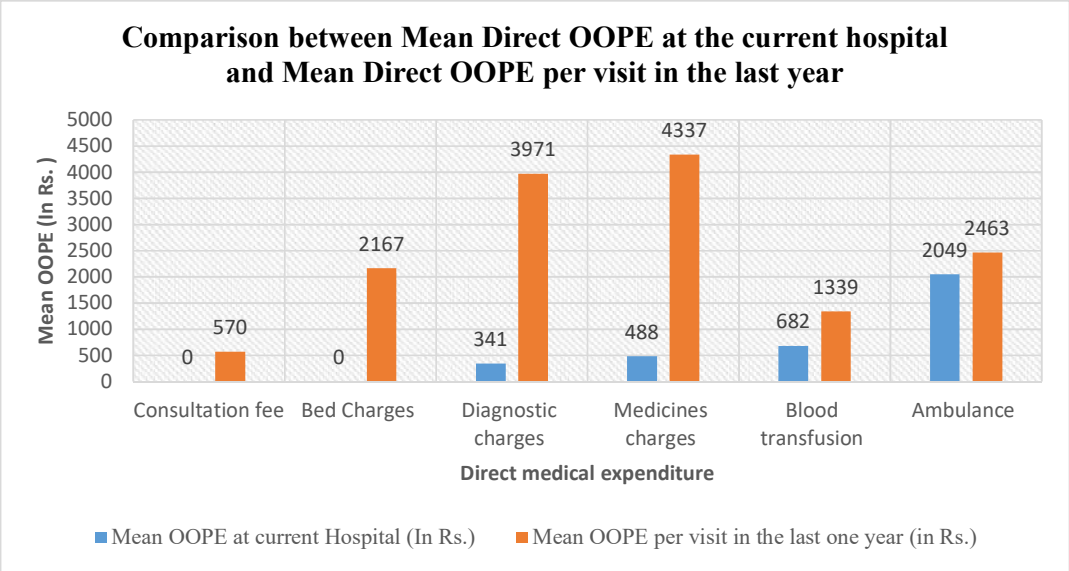


Figure 2. Comparison between Mean Direct OOPE at the current hospital and Mean Direct OOPE per visit in the last year

Comparison of Mean OOPE Per Visit in the Last Year with OOPE at the Current Health Facility

During the study, it was found that none of the respondents had any OOPE on consultation fees and bed charges in the current health facility. It was seen that the mean OOPE at the current hospital on diagnostic charges and medicines charges is drastically decreased by approximately ten-fold and almost halved in the case of blood transfusion when compared with the Mean OOPE per visit in the last year. It was observed that there is no significant change in the OOPE spent on ambulance services. (Figure 3)

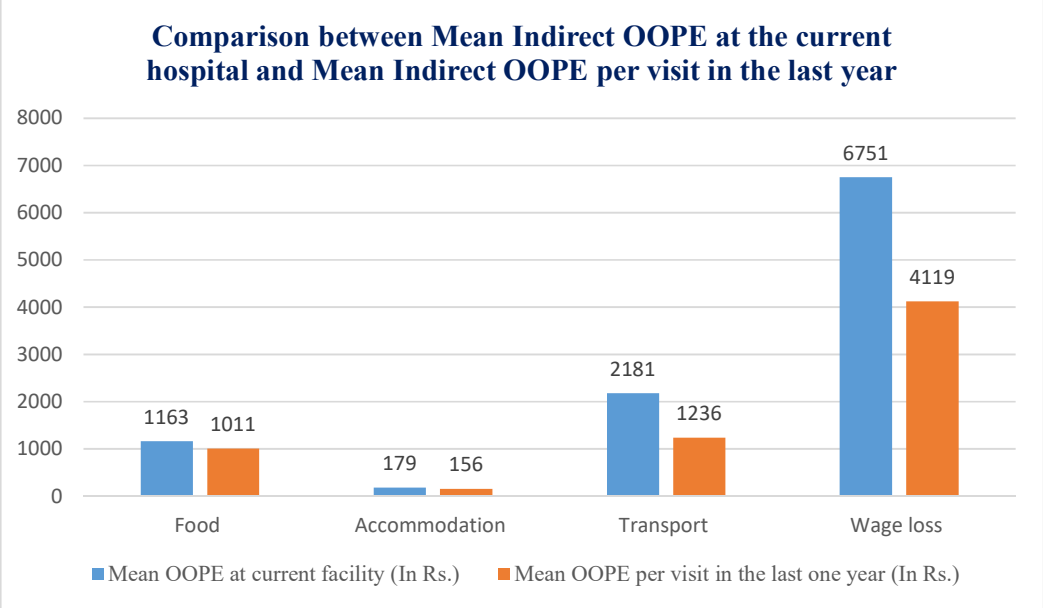


Figure 3. Comparison between Mean Indirect OOPE at the current hospital and Mean Indirect OOPE per visit in the last year

The study revealed that there is no significant change in the indirect OOPE when the Mean Indirect OOPE at the current hospital and Mean OOPE per visit in one year is compared. On the contrary, it was seen that there is a slight increase in the mean OOPE at the current hospital on food, accommodation, transport, and also wage loss. The reason for the increase in indirect health expenditure in the current hospital may be because the majority of the respondents were from surrounding states and they had to travel a long distance, arrange for food and accommodation in Delhi, and also had a greater number of days of wage loss.

Patient Satisfaction with the Scheme

Among all participants, 60.3% were very satisfied with the treatment and benefits provided under the scheme, while 25.3% (n=81) were satisfied. Less than 1% (n=2) were very unsatisfied, and around 10% (n=31) had a neutral opinion on the scheme's functioning and services.

Discussion

The results of this study were consistent with a study conducted by Dash et al. (2020) in three states (Bihar, Haryana, and Tamil Nadu) that showed that 71% of the beneficiaries were aware that all the members of the family were eligible to

avail benefits of the PMJAY scheme in the state of Haryana. The study also found that 95% (n = 111) of the beneficiaries were aware that a maximum coverage of 5,00,000 rupees per family per year was being provided under the scheme. The current study found that 77% of the respondents were aware of the maximum amount of coverage under the PMJAY, i.e., annual coverage of up to Rs. 5,00,000 per family [6]. A similar study conducted in the Thanjavur district of Tamil Nadu state by Pugazhenthi (2021) that emphasized mainly awareness of cancer care among the beneficiaries under PMJAY found that the level of awareness among beneficiaries about the amount covered under PMJAY was 42% [7]. In this study, the majority of patients were treated for Percutaneous Transluminal Coronary Angioplasty with diagnostic angiogram (n=132), followed by Double Stent PTCA (n=56), Single Stent PTCA (n=43), and other procedures. These findings align with Pulkit et al.'s study, which highlighted that PTCA with a single stent was the most utilized cardiac package, followed by double-stent PTCA. The top five cardiac packages in their study accounted for over 70% of total cardiac claims under PMJAY [8]. The study found that respondents had no out-of-pocket expenses for consultation fees or bed charges at the current health facility. The mean out-of-pocket expenditure (OOPE) for diagnostic and medicine charges decreased significantly—by about ten-fold—compared to the previous year, and blood transfusion costs were almost halved. This suggests that without the PMJAY scheme, more households might face financial hardship or forgo treatment. However, there was no significant reduction in out-of-pocket costs for ambulance services, which averaged Rs. 2049. This remains a concern since the scheme is supposed to be cashless, with many patients resorting to private ambulances due to a lack of free government services. During the study, it was found that about 22.5% of the beneficiaries (n=73) paid some amount to buy medicines. Ideally, all medicines have to be provided free of cost under the PMJAY scheme. But there are certain instances where the beneficiaries were asked to buy some medicines from outside. The main reason for this is the non-availability of the medicines in the pharmacy attached to the hospital (AMRIT Pharmacy). In some cases, the patients were already on some medication and they preferred to take those medicines from private pharmacies as the drugs given in the hospital are of different brands.

Conclusion

Despite the majority of patients benefiting from cost-free consultations and bed charges, some incurred expenses for diagnostics, medicines, and specific treatments due to service availability issues. The socio-demographic profile revealed that middle-aged males from lower-income rural areas were the majority of users. Although there were gaps in knowledge regarding empaneled hospitals and service providers, awareness of PMJAY's coverage was generally strong. The scheme's effect on financial burdens was demonstrated by the study's comparison of OOPE over time, which revealed a significant decrease in direct expenses at the current hospital, such as diagnostics and medications. To optimize the scheme's benefits, it is essential to address knowledge gaps and provide equal opportunities for rural and lower-income communities. Maintaining PMJAY's aim to provide universal access to

high-quality, reasonably priced healthcare requires continuous improvements and dedicated support systems.

Ethical Considerations

The Institutional Ethics Committee has granted ethical approval for the study [File No: 2-17/AA/2014-Acad (part file)] and permission was obtained from the Administration of Dr. Ram Manohar Lohia Hospital, New Delhi for collecting the data from the patients admitted to the Cardiology Department of the hospital.

Conflicts of interest

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

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ORIGINAL ARTICLE

An Observational Study of Patients Presenting in Hypotension and Shock to Emergency Room by Applying RUSH Protocol

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Abstract

Introduction: Care of the patient with shock can be one of the most challenging issues in emergency medicine. The early use of ultrasound at the bedside in such emergency is a very valuable tool to determine the type of shock. Rapid Ultrasound in SHock (RUSH) protocol done by emergency physicians is one such protocol which is being underused. Hence, we conducted this study to assess the effectiveness of the RUSH protocol for patients presenting with undifferentiated hypotension and shock. **Materials and methods:** This was prospective observational study done on a total of 100 patients presented with hypotension and shock. We performed an early bedside sonographic examination for participants based on RUSH protocol and type of shock was determined. Then the definitive interventions were performed as per the type of shock. The outcome measures were determined either till the survival to discharge from the hospital or till the in-hospital death of the patient. The data was analysed using SPSS version25. **Results:** In this study, the type of shock most commonly found overall was hypovolemic shock (40%) followed by cardiogenic shock (27%) and distributive shock (17%). Contractility of left ventricle, size of right ventricle, inferior venacava caliber, hemoperitoneum, pneumothorax, hemothorax, pulmonary edema, pleural effusion and lungs consolidation were statistically significant in determining the type of shock except cardiac tamponade, abdominal aortic aneurysm/dissection and deep vein thombosis. Majority of the interventions performed were fluid resuscitation (41%), vasopressors and inotropes (28%) and laparotomy (9%) and were statistically significant (p=0.001). Among all patients, 73% survived and 27% died. The outcome was statistically significant (p=0.002). **Conclusion:** RUSH protocol used for undifferentiated hypotension and shock is an effective tool at the bedside as an early approach to diagnose the type of shock. It will also help in determining early definitive interventions in shock states and thereby having better patient outcomes.

Key words: RUSH, Shock, POCUS, Hypotension, Ultrasound

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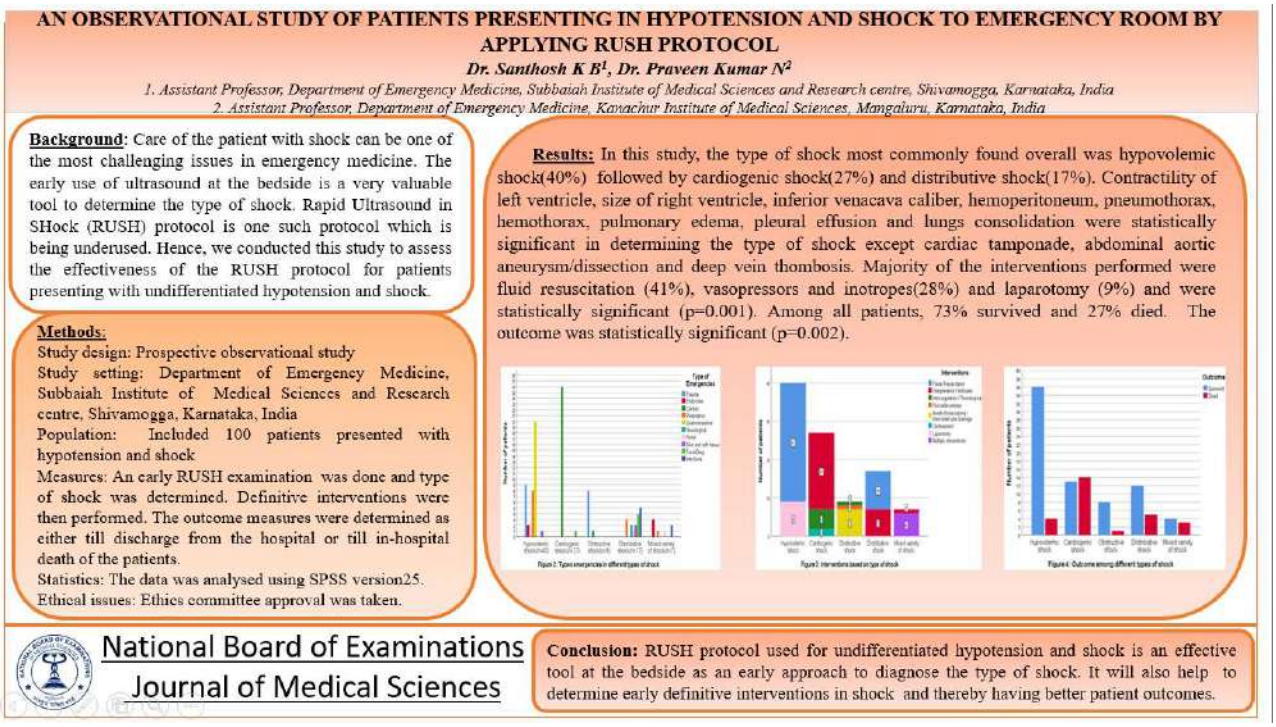
Graphical Abstract



Introduction

Shock is a state of circulatory insufficiency that creates an imbalance between tissue oxygen supply and demand, resulting in end organ dysfunction [1-3]. Shock is typically divided into four categories: hypovolemic, cardiogenic, obstructive, and distributive [4]. Since each type of shock requires a special treatment, we need quick detection techniques for all kinds of shock in the emergency room [5]. In a busy emergency room, the cause of shock and the optimal initial therapeutic approach can still be not clear even for an experienced clinician at the bedside. Traditional physical examination techniques can be misleading given the complex physiology of shock [6]. The longer the duration of hypotension and shock higher is the mortality. Therefore, early diagnosis and initial care must be accurate and prompt to improve the patient outcomes [7]. Failure to make the correct diagnosis and act appropriately can lead to potentially disastrous outcomes and high-risk situations. Laboratory investigations and more specialized investigations such as computed tomography (CT) scan and radiologist performed abdominal ultrasound or echocardiogram which are needed to establish an accurate diagnosis are time consuming and not always readily available especially after hours.

The use of bedside ultrasound has been described in the evaluation of undifferentiated shock for well over two decades [8-12]. In this study, multi-organ point-of-care ultrasound (PoCUS) by using Rapid Ultrasound in SHock (RUSH) protocol was attempted as an early approach to improve the accuracy and to narrow the differential diagnoses thus guiding the

emergency physician (EP) in early goal-directed therapy for better outcome in patients presenting with hypotension/shock.

The need of the study is to assess the effectiveness of RUSH protocol that incorporates a bedside stepped examination for an early approach to undifferentiated hypotension and shock in emergency care.

Materials and Methods

This study was a prospective observational study done from March 2022 to February 2023 conducted on total of 100 patients who presented with hypotension and shock to Emergency Department to Subbaiah Institute of Medical Sciences and Research Centre, Shivamogga, Karnataka. This included patients who had systolic blood pressure of ≤90 mmHg with diastolic blood pressure of ≤60 mmHg. Approval of the ethics committee was taken. The following criterias were used for the selection of patients.

Inclusion Criteria:

a) All patients presenting to emergency department with Hypotension / Shock.
b) Age ≥ 18years
c) Any sex

Exclusion criteria:

a) Patients with chronic heart failure, chronic renal failure, portal hypertension with ascites and hypoproteinemias
b) Any other chronic medical conditions causing accumulation of fluid in third space.
c) Patients with obvious external blood loss causing hypotension/shock.

The clinical evaluation and immediate resuscitation were done according to standard treatment protocols. RUSH examination by a portable ultrasound machine was done along with treatment and also the required investigations were done without delay.

The RUSH protocol involves a three part bedside physiologic assessment simplified as:

Step 1: The pump
Step 2: The tank
Step 3: The pipes

In the evaluation of the Pump, heart was evaluated for its left ventricle (LV) contractility, size of the right ventricle (RV), pericardial effusion and cardiac thrombus. In the evaluation of the Tank, inferior venacava (IVC) caliber, ascites/hemoperitoneum, pleural effusion/hemothorax, pneumothorax were evaluated. In the evaluation of Pipes, Abdominal Aortic aneurysm/dissection (AAA/AAD) and deep vein thrombosis (DVT) were evaluated. After evaluation of all three components of the RUSH protocol, the type of shock was determined based on the findings that are mentioned in the Figure 1 and then patient was started on the definitive interventions. The outcome measures are determined as either till the survival to discharge from the hospital or till the in-hospital death of the patient.

Rapid Ultrasound in SHock (RUSH) protocol: ultrasonographic findings seen with classic shock states

RUSH Evaluation	Hypovolemic Shock	Cardiogenic Shock	Obstructive Shock	Distributive Shock
Pump	Hypercontractile heart Small chamber size	Hypocontractile heart Dilated heart	Hypercontractile heart Pericardial effusion Cardiac tamponade RV strain Cardiac thrombus	Hypercontractile heart (early sepsis) Hypocontractile heart (late sepsis)
Tank	Flat IVC Flat jugular veins Peritoneal fluid (fluid loss) Pleural fluid (fluid loss)	Distended IVC Distended jugular veins Lung rockets (pulmonary edema) Pleural fluid Peritoneal fluid (ascites)	Distended IVC Distended jugular veins Absent lung sliding (pneumothorax)	Normal or small IVC (early sepsis) Peritoneal fluid (sepsis source) Pleural fluid (sepsis source)
Pipes	Abdominal aneurysm Aortic dissection	Normal	DVT	Normal

Figure 1. Ikbal Sasmaz et al. [13]

Statistical Procedures

The data was entered in Microsoft Excel. Then statistical software SPSS version 25 was used for the analysis of the data. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± Standard deviation (Minimum-Maximum) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Chi-square/ Fisher's Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. The results were determined as statistically significant if the p value is </=0.05.

Results

In this study, majority of study participants were in the age group of 51-60 years (22%) followed by 41-50 years (18%). The mean age of the patients was 49.20±17.166 yrs. Minimum age was 18years and maximum age was 85years. Male study participants were 62% and female study participants were 38%. The means of different vitals of the patients in this study were systolic blood pressure (SBP) 74.64±10.93 mmHg, diastolic blood pressure (DBP) 43.86±24.31mmHg, heart rate 130.10±18.00 per minute, respiratory

rate 29.79±5.84 per minute, SpO2 89.71±5.42%, temperature 98.50±2.21°F, capillary refill time 3.20±1.12 seconds and capillary blood glucose 143.55±85.31 mg/dL.

Majority of the presentations were cardiac (27%) followed by gastrointestinal (20%) and trauma (17%) emergencies. The type of shock most commonly found overall was Hypovolemic shock (40%) among which 50% were found in gastrointestinal emergencies, Cardiogenic shock was predominantly found in cardiac emergencies (96.3%) likewise Obstructive shock in Trauma (88.9%), Distributive shock in infections (29.4%) and Mixed variety of shock in Endocrine emergencies (42.9%). The type of emergency was statistically significant in determining the type of shock (p=0.0001). This has been illustrated in the Table 1 and Figure 2.

Table 1. Type of emergencies in different types of shock

Type	Hypovolemic shock	Cardiogenic shock	Obstructive shock	Distributive shock	Mixed variety of shock	Total
Trauma	9(22.5%)	0(0.0%)	8(88.9%)	0(0.0%)	0(0.0%)	17(17.0%)
Endocrine	2(5.0%)	0(0.0%)	0(0.0%)	0(0.0%)	3(42.9%)	5(5.0%)
Cardiac	0(0.0%)	26(96.3%)	1(11.1%)	0(0.0%)	0(0.0%)	27(27.0%)
Respiratory	8(20.0%)	0(0.0%)	0(0.0%)	3(17.6%)	1(14.3%)	12(12.0%)
Gastrointestinal	20(50.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	20(20.0%)
Neurological	0(0.0%)	0(0.0%)	0(0.0%)	2(11.8%)	0(0.0%)	2(2%)
Renal	0(0.0%)	0(0.0%)	0(0.0%)	1(5.9%)	1(14.3%)	2(2.0%)
Skin and soft tissue	1(2.5%)	0(0.0%)	0(0.0%)	2(11.8%)	0(0.0%)	(3.0%)
Toxin/Drug	0(0.0%)	1(3.7%)	0(0.0%)	4(23.5%)	0(0.0%)	5(5.0%)
Infections	0(0.0%)	0(0.0%)	0(0.0%)	5(29.4%)	2(28.6%)	7(7.0%)
Total	**40(100.0%)**	**27(100.0%)**	**9(100.0%)**	**17(100.0%)**	**7(100.0%)**	**100(100.0%)**

Fisher's exact test (p=0.001)

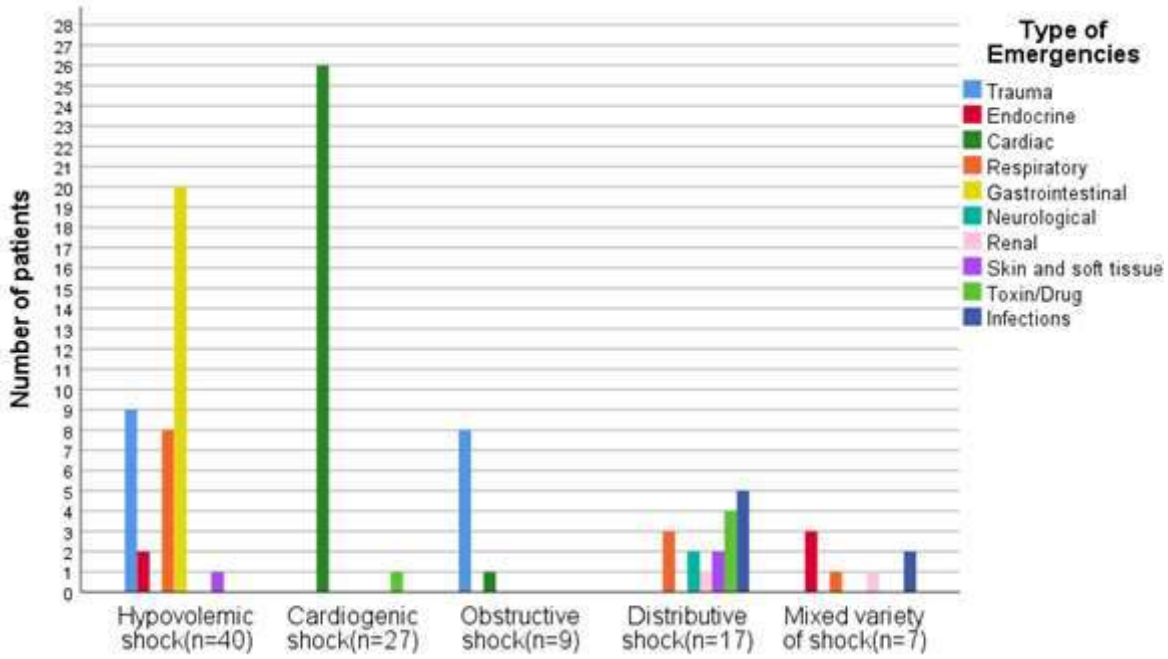


Figure 2. Types of emergencies in different types of shock

1. Findings based on RUSH protocol: The following findings were made by applying the RUSH protocol (Table 2).

a. Pump: LV was hypercontractile in Hypovolemic shock (10%), Cardiogenic shock (7.4%), Distributive shock (52.9%) and hypocontractile in Cardiogenic shock (92.6%), Obstructive shock (22.2%), and mixed variety of shock (85.7%). LV contractility was statistically significant in determining the type of shock (p=0.001). RV was dilated in Cardiogenic shock (55.6%), Obstructive shock (66.7%), Distributive shock (23.5%) and mixed variety of shock (14.3%). RV size was also statistically significant in determining the type of shock (p=0.001). But Cardiac tamponade was present in only Obstructive shock (11.1%) and was statistically not significant in determining the type of shock (p=0.159)

b. Tank: IVC was collapsing in Hypovolemic shock (100%), Distributive shock (64.7%), Mixed variety of shock (85.7%) and dilated in Cardiogenic shock (81.5%), Obstructive shock (66.7%). IVC caliber was statistically significant in determining the type of shock (p=0.001). Hemoperitoneum was present in Hypovolemic shock (22.5%) and was also statistically significant in determining the type of shock (p=0.010).

Pneumothorax was present in Obstructive shock (22.2%) likewise Hemothorax in Obstructive shock (55.6%), Pleural effusion in Hypovolemic shock (2.5%) and mixed variety of shock (14.3%), Pulmonary edema in Cardiogenic shock (29.6%) and Distributive shock (5.9%). Lungs consolidation in Hypovolemic shock (17.5%) and Distributive shock (17.6%). RUSH findings of lungs were statistically significant in determining the type of shock (p=0.001)

c. Pipes: Abdominal aorta aneurysm/dissection (AAA/AAD) was

present in only 2.5% patients having Hypovolemic shock and was statistically not significant in determining the cause of shock (p=1.000). Deep vein thrombosis was present in Obstructive shock (11.1%) and was also statistically not significant in determining the type of shock (p=0.159).

Table 2. Rapid Ultrasound in SHock (RUSH) findings

RUSH Findings		Type of shock						P value
		Hypovolemic shock (n=40)	Cardiogenic shock (n=27)	Obstructive shock (n=9)	Distributive shock (n=17)	Mixed variety of shock (n=7)	Total (n=100)	
LV	Hypercontractile	4(10.0%)	2(7.4%)	0(0.0%)	9(52.9%)	0(0.0%)	15(15.0%)	**0.001***
	Normal	36(90.0%)	0(0.0%)	7(77.8%)	8(47.1%)	1(14.3%)	52(52.0%)	
	Hypocontractile	0(0.0%)	25(92.6%)	2(22.2%)	0(0.0%)	6(85.7%)	33(33.0%)	
RV	Normal	40(100.0%)	12(44.4%)	3(33.3%)	13(76.5%)	6(85.7%)	74(74.0%)	**0.001***
	Dilated	0(0.0%)	15(55.6%)	6(66.7%)	4(23.5%)	1(14.3%)	26(26.0%)	
Cardiac Tamponade	Yes	0(0.0%)	0(0.0%)	1(11.1%)	0(0.0%)	0(0.0%)	1(1.0%)	0.159*
	No	40(100.0%)	27(100.0%)	8(88.9%)	17(100.0%)	7(100.0%)	99(99.0%)	
IVC	Collapsing	40(100.0%)	5(18.5%)	3(33.3%)	11(64.7%)	6(85.7%)	66(66.0%)	**0.001***
	Dilated	0(0.0%)	22(81.5%)	6(66.7%)	6(35.3%)	1(14.3%)	34(34.0%)	
POCUS of Abdomen	Hemoperitoneum	9(22.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	9(9.0%)	**0.010***
	No Hemoperitoneum	31(77.5%)	27(100.0%)	9(100.0%)	17(100.0%)	7(100.0%)	91(91.0%)	
POCUS of Lungs	Normal	32(80.0%)	19(70.4%)	2(22.2%)	13(76.5%)	6(85.7%)	71(71.0%)	**0.001***
	Pneumothorax	0(0.0%)	0(0.0%)	2(22.2%)	0(0.0%)	0(0.0%)	2(2.0%)	
	Hemothorax	0(0.0%)	0(0.0%)	5(55.6%)	0(0.0%)	0(0.0%)	5(5.0%)	
	Consolidation	7(17.5%)	0(0.0%)	0(0.0%)	3(17.6%)	0(0.0%)	10(10.0%)	
	Pleural Effusion	1(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	1(14.3%)	2(2.0%)	
	Pulmonary edema	0(0.0%)	8(29.6%)	0(0.0%)	1(5.9%)	0(0.0%)	9(9.0%)	
AAA/AAD	Positive	1(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.0%)	1.000*
	Negative	39(97.5%)	27(100.0%)	9(100.0%)	17(100.0%)	7(100.0%)	99(99.0%)	
DVT	Positive	0(0.0%)	0(0.0%)	1(11.1%)	0(0.0%)	0(0.0%)	1(1.0%)	0.159*
	Negative	40(100.0%)	27(100.0%)	8(88.9%)	17(100.0%)	7(100.0%)	99(99.0%)	

***Fisher's exact test**

2. Interventions: After determining the type of shock, the following interventions were performed. Hypovolemic shock required fluids resuscitation (77.5%) and laparotomy (22.5%). Cardiogenic shock required Vasopressors/Inotropes (74.1%), Anticoagulation/Thrombolysis (18.5%) and Cardioversion (7.4%). Obstructive shock required Needle thoracostomy / Intercostal tube drainage (77.8%), Anticoagulation/Thrombolysis (11.1%) and Pericardiocentesis (11.1%). Distributive shock required fluids resuscitation (58.8%) and Vasopressors/ Inotropes (41.2%). Mixed variety of shock required Multiple interventions (85.7%) and Vasopressors/Inotropes (14.3%). The interventions done based on the type of shock were statistically significant (p=0.001). These are illustrated in Table 3 and Figure 3.

Table 3. Interventions based on type of shock

Interventions	Hypovolemic shock	Cardiogenic shock	Obstructive shock	Distributive shock	Mixed variety of shock	Total
Fluid Resuscitation	31(77.5%)	0(0.0%)	0(0.0%)	10(58.8%)	0(0.0%)	41(41.0%)
Vasopressors/Inotropes	0(0.0%)	20(74.1%)	0.0%	7(41.2%)	1(14.3%)	28(28.0%)
Anticoagulation and Thrombolysis	0(0.0%)	5(18.5%)	1(11.1%)	0(0.0%)	0(0.0%)	6(6.0%)
Pericardiocentesis	0(0.0%)	0(0.0%)	1(11.1%)	0(0.0%)	0(0.0%)	1(1.0%)
Needle thoracostomy / Intercostal tube drainage	0(0.0%)	0(0.0%)	7(77.8%)	0(0.0%)	0(0.0%)	7(7.0%)
Cardioversion	0(0.0%)	2(7.4%)	0.0%	0(0.0%)	0(0.0%)	2(2.0%)
Laparotomy	9(22.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	9(9.0%)
Multiple interventions	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	6(85.7%)	6(6.0%)
Total	**40(100.0%)**	**27(100.0%)**	**9(100.0%)**	**17(100.0%)**	**7(100.0%)**	**100(100.0%)**

Fisher's exact test (p=0.001)

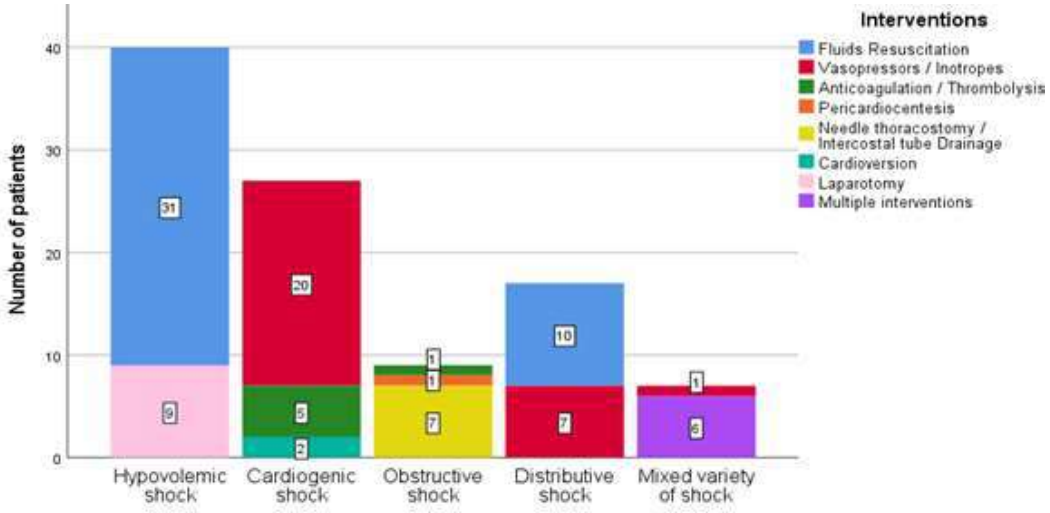


Figure 3. Interventions based on type of shock.

3. Outcome: Among hypovolemic shock patients 90% survived and 10% died as similar to obstructive shock (88.9% and 11.1%, respectively). Among distributive shock patients 70.6% survived and 29.4% died while in cardiogenic shock 48.1% survived and 51.9% died. Among mixed variety of shock patients 57.1% survived and 42.9% died. Overall, 73% of the patients survived and 27% died. This result was statistically significant (p=0.002). This is depicted in Table 4 and Figure 4.

Table 4. Outcome based in type of shock

Outcome	Hypovolemic shock	Cardiogenic shock	Obstructive shock	Distributive shock	Mixed variety of shock	Total
Survived	36(90.0%)	13(48.1%)	8(88.9%)	12(70.6%)	4(57.1%)	73(73.0%)
Dead	4(10.0%)	14(51.9%)	1(11.1%)	5(29.4%)	3(42.9%)	27(27.0%)
Total	**40(100.0%)**	**27(100.0%)**	**9(100.0%)**	**17(100.0%)**	**7(100.0%)**	**100(100.0%)**

Fisher's exact test (p=0.002)

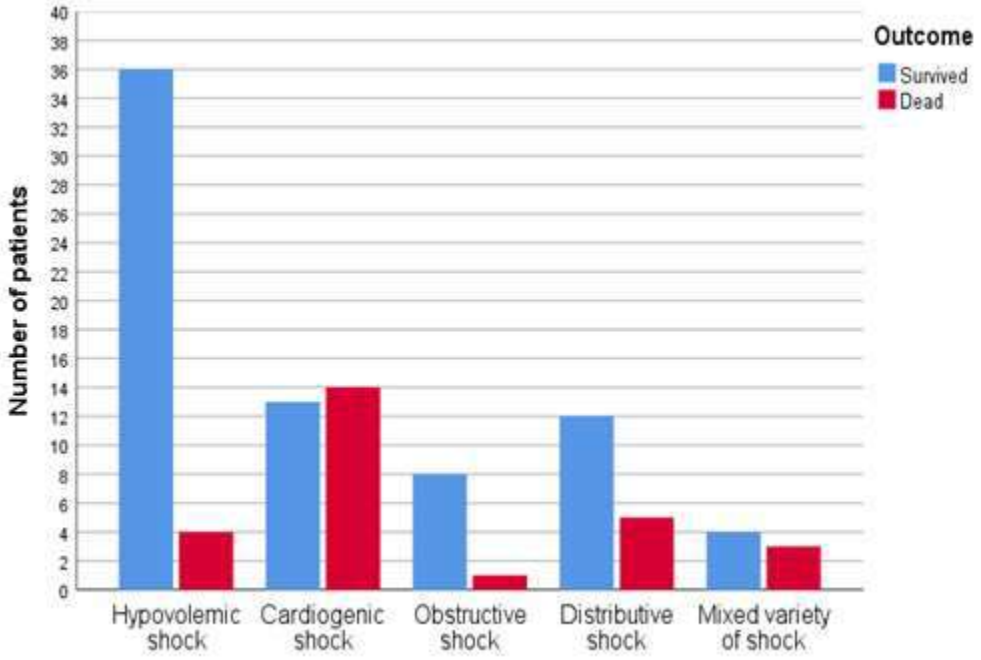


Figure 4. Outcome among different types of shock

Discussion

RUSH is the most recent emergency ultrasound protocol, designed to detect the type of shock at the bedside in a shorter time frame. Appropriate identification of the etiology of shock in early few minutes of patients arrival to emergency room is the essence of the discipline of emergency medicine [6,14]. This study adds to the evidence that a goal-directed point-of-care ultrasound will help emergency physicians (EPs) correctly identify the cause of

symptomatic undifferentiated hypotension [6,15]. In this prospective observational study conducted on 100 patients presenting with undifferentiated hypotension as per the inclusion and exclusion criteria, we applied the RUSH protocol, performed by an emergency physicians in predicting the type of shock in critical patients.

The demographic profile was comparable to a study conducted by Javali et al. [16]. The vitals and clinical characteristics are comparable with studies done by Ginoya et al, which showed similar results [17].

1. RUSH findings

a. Pump: RUSH findings of the heart such as LV contractility and RV size but not cardiac tamponade were able to effectively rule in cardiogenic shock. It had only hypercontractile LV in hypovolemic shock and distributive shock in which the pump cannot be solely used for these diagnosis. Although cardiac tamponade could be easily picked up by RUSH, but was only present in only one of total 8 patients with obstructive shock and was not statistically significant (p=0.159). LV contractility and RV size were statistically significant in determining the type of shock. (p=0.001, p=0.001 respectively)

b. Tank: IVC was effective in diagnosing hypovolemic shock as a direct measure of central blood volume (p=0.001). It was also true in the presence of hemoperitoneum (p=0.010). In cardiogenic, obstructive and distributive shocks, IVC can only help as an associated finding in with the main underlying pathology in the respective conditions.

The presence of pneumothorax, hemothorax were the causes for obstructive shock predominantly in the category. Pulmonary edema in cardiogenic shock was only found in 29.6% of cardiogenic shock and 5.9% of Distributive shock. In distributive shock, the presence of pulmonary edema attributing to the late stage of septic shock with compromised cardiac function. Although lungs consolidation is not included as a finding in RUSH protocol, it was found in lung ultrasound in patients of Hypovolemic shock (17.5%) and Distributive shock(17.6%) which indicates source of sepsis which led to hypovolemia and distribution of central blood volume. Pleural effusion which was bilateral, was present in Hypovolemic shock (2.5%), although it might not solely determine as a cause of shock, as it was reactive pleural effusion. Shock due to pleural effusion which is massive, could lead to obstructive shock rather than hypovolemic shock. Lungs findings were statistically significant in determining the type of shock (p=0.001)

c. Pipes: Abdominal aorta aneurysm/dissection was only in Hypovolemic shock (2.5%) and Deep vein thrombosis causing pulmonary thromboembolism was present in only Obstructive shock (11.1%). Both abdominal aortic aneurysm/dissection and deep vein thrombosis were statistically not significant in determining the type of shock (p=1.000 and p=0.159, respectively) as both of them were present in very less number of patients.

In our study, there were 7 patients which were determined as having mixed variety of shock. The possible reasons for this mixed presentation were due to mixed etiologies, advanced disease states, multiple comorbidities, immune compromised states, etc. While the RUSH findings effectively ruled in the different categories of shock, but for the mixed variety of shock, when there were multiple etiologies resulted in unstable hemodynamic conditions of the patient (for example: cardiogenic and distributive shock, obstructive and cardiogenic shock, hypovolemic and cardiogenic shock), the protocol had the least sensitivity and agreement with the final diagnosis in a study conducted by Ghane et al. [18]. Thus, we strongly suggest that physicians interpret results of this exam with more caution, when they have high clinical suspicion for mixed etiologies.

2. **Interventions**

After the diagnoses of the category of shock were determined using RUSH protocol, interventions were performed. Hypovolemic shock required fluids resuscitation predominantly and but also required blood transfusion and laparotomy for those patients with hemoperitoneum to control the source of internal hemorrhage. Though majority of the Cardiogenic shock patients required Vasopressors/Inotropes, Anticoagulation/Thrombolysis was done for those patients with acute coronary syndrome as the cause of cardiogenic shock and in only two cases (7.4%), cardioversion was done to reverse the tachyarryhthmias with persistent compromised perfusion. Needle thoracostomy (for pneumothorax) and Intercostal tube drainage (for pnemothorax and hemothorax) were done for majority of the obstructive shock patients. An ultrasound guided pericardiocentesis was done for one case of cardiac tamponade which was due to blunt chest trauma. Anticoagulation and Thrombolysis was done for one case of massive pulmonary thromboembolism with shock. Majority of the distributive shock patients either fluids resuscitation or Vasopressors and Inotropes and a very few required both fluids and vasopressors/inotropes as guided by the IVC caliber. Majority of the mixed variety of shock patients required multiple interventions (85.7%) such as fluids replacement, Vasopressors, inotropes and anticoagulation

Use of POCUS in emergency room gives provides information about both abnormal pathology and physiology in a critically ill patient if it is done by expert hands. Thus, emergency physicians with expertise of emergency ultrasound can use this protocol at the bedside and subsequently administer earlier, more goal-directed therapies for these critical patients at the ED. In addition, it will also help them to monitor the effects of interventions performed and if necessary make appropriate adjustments by using RUSH protocol [12,19-21].

3. Outcome

Among hypovolemic shock and distributive shock patients, majority survived owing to its reversibility of shock state if adequate fluid replacement done in early phase of the illness which was done in the current study. Among cardiogenic shock and mixed variety shock patients, the outcomes were equivocal as these patients

which deteriorate rapidly than any other shock types. Most (88.9%) of the obstructive shock patients survived as the interventions done to relieve the obstruction were in time but we lost one patient with cardac tamponade which was due to delayed presentation and overall decreased myocardial contractility. The results of the type of shock and the outcome were statistically significant (p=0.003) which indicates effective implementation of RUSH protocol in the early diagnosis and appropriate interventions as per the type of shock decided by the use of RUSH protocol. We should note that the goal of early use of RUSH protocol in a patient with shock state is to detect the underlying problems that led to shock in shorter time frame or at least to exclude certain life-threatening conditions.

Conclusion

RUSH protocol used for undifferentiated hypotension and shock is an effective tool at the bedside as an early approach to diagnose the type of shock. It will aso help in determining and guiding the early definitive intervention in shock states and thereby having better patient outcomes.

Limitations

This was a single-center study which included only 100 patients. We have considered only consolidation of lungs which was found in lungs ultrasound as foci of sepsis. Other organs with infection were not made an attempt to find it as source of sepsis at the bedside.

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Statements and Declarations

Conflicts of interest

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

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Ethical Clearance

Institutional Ethical clearance approved.

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ORIGINAL ARTICLE

Transcranial Ultrasound Guided Assessment of Brain Midline Shift in Neuro Intensive Care Unit

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Abstract

Background: Neuro Intensive Care Unit (Neuro-ICU) handles neurological emergencies that involve intracranial (IC) hemorrhages. It can be challenging to manage elevated intracranial pressure (ICP) and midline shift (MLS), as they requires constant monitoring and frequent imaging. Trans-cranial Color Coded Sonography (TCCS), a bedside monitoring tool, may be helpful in monitoring MLS under such conditions. **Objectives:** To correlate MLS of the third ventricle in the brain measured by TCCS with CT midline shift. **Method:** A prospective observational study was conducted on patients with IC bleed who were mechanically ventilated and had a head CT done to rule out MLS. Within an hour of doing a CT brain, TCCS-MLS was identified. Data was collected and analyzed. **Results:** A total of fifty patients studied, the MLS (mean ±SD) was 5.3mm ± 3.1 mm using TCCS and 6.7±4.4 mm using CT brain. The calculated midline shift between TCCS and CT brain demonstrated a Pearson's correlation of 0.78 ($P<0.001$). With TCCS, the area under the ROC curve to identify a significant MLS was 0.91 (95%CI=0.8-1). TCCS-MLS of 3.9mm as a cut-off, predicted the occurrence of >5mm MLS on CT scan with a sensitivity of 95% and specificity of 90%. **Conclusions:** This study suggests that TCCS could serve as an alternative bedside monitoring tool in patients whose transportation is risky, in predicting the transcranial MLS >5mm with reasonable accuracy.

Keywords: Transcranial ultrasonography, Neuro-imaging techniques, Midline shift, Neuro critical care

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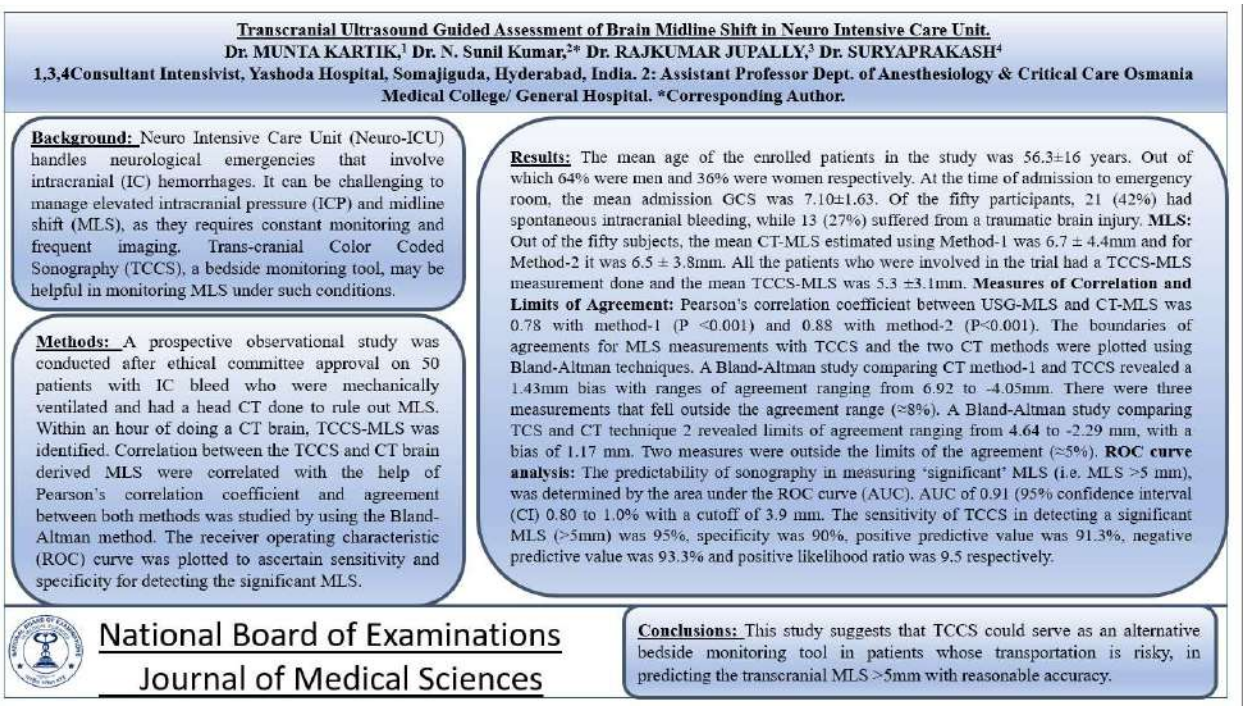
Graphical Abstract



Introduction

Patients with traumatic brain injuries who are admitted to the Neuro-ICU need immediate attention to manage elevated intracranial pressure. Malignant MCA infarcts and spontaneous intracranial bleeding require vigilant observation and prompt decision-making to prevent the adverse effects of elevated ICP. The human head is approximately bilaterally symmetrical; therefore in neuro-radiology small anatomical alterations typically lack a significant clinical influence [1]. One of the most crucial elements in enabling neurosurgeons to take prompt, appropriate action when managing patients with MLS is the accurate assessment of the degree of midline shift on CT brain.

Over the past few decades, the diagnosis of serious neurological conditions has relied on the shift of midline structures. In earlier times, the initial step in MLS detection was to observe a calcified pineal gland on an ordinary X-ray [2]. Since the invention of CT scan technology, it has become an essential aspect of head injury patients' treatment regimens. Currently, CT brain remains a highly reliable method of diagnosing MLS. A number of methods for estimating MLS on CT brain have been reported in the literature. This involves determining the distance between the septum Pellucidum and ideal midline [3,4], the deviation of the pineal body from the center of the brain [5], and the displacement of the third ventricle's center from either side of the skull bone [6]. The latter of which has been shown to correlate well with the outcome.

Marshall and coworkers established a CT scan classification utilizing information from the Traumatic Coma Data Bank. An MLS of greater than 5 mm was one of the elementary criteria for classifying

a degree of a traumatic brain injury according to this classification [7]. A number of CT indicators of injury severity, such as mass lesions, compressed basal cisterns, or traumatic SAH, have been demonstrated to have a strong correlation with the Glasgow Coma Score. [8, 9, 10] Within two weeks of traumatic brain injury, compression of the 3rd ventricle and an MLS exceeding five millimeters were significant predictors of death [11].

According to the Brain Trauma Foundation (BTF) statement, MLS on CT brain is measured at the level of the Foramen of Monro. They recommend for emergency surgical treatment for any traumatic disorder resulting in an MLS greater than 5mm. The risks associated with transferring critically ill patients to radiology units for performing serial CT scans is challenging always [12], for the same reason its value in acute care settings is questionable [13].

Ultrasound is a bedside, repeatable, non-invasive, and radiation-free modality. Its significance in the field of acute critical care settings continues to grow. As the age advances thickness of the temporal bone increases, limiting the application of sonography in this area, for that reason ultrasound is not the preferred diagnostic modality for adult brain imaging. With the advancements in tissue contrast and image resolution, the ability to visualize brain cross sectional images has become possible [14]. Intracranial blood vessels and parenchymal structures can be visualized using TCCS [14]. The display image of cranial ultrasound at the level of temporal bone can help in visualizing cerebrospinal fluid containing the third ventricle along with brain parenchyma. This can be used as an accurate source of information regarding the lateral displacement of the third ventricle in space-occupying lesions of brain, and can be utilized as a diagnostic criterion for MLS [15,16].

The first approach for measuring MLS using TCCS was described by Seidel and colleagues in 1996. Several studies subsequently assessed the method's reliability in providing information about the third ventricle diameter and lateral displacement. Given that MLS measurement may be able to predict outcomes prior to clinical findings in critically ill patient; TCCS can be utilized for repeated monitoring at shorter intervals and even in these patients during the acute phases of their illness [17].

The purpose of our study was to evaluate the correlation between the measurements of the midline shift calculated by TCCS and CT scan among traumatic brain injury, spontaneous intracranial bleeding and acute infarct groups of patients on mechanical ventilator support being admitted to Neuro-ICU.

Methods

This prospective observational study was conducted in a Neuro-ICU of a tertiary care hospital from south India. After obtaining approval from the institutional ethical committee, all those patients who fulfilled the following inclusion criteria were enrolled into the study following the acquisition of a valid informed, written consent from the next of kin of the patients.

Inclusion criteria

i. Patients aged ≥18 years admitted to Neuro-ICU with suspected raised ICP and requiring mechanical ventilator support.

Exclusion criteria:

i. Post de-compressive craniotomy.
ii. Maxillofacial trauma.
iii. Poor image acquisition due to thick temporal bone.

A total of sixty-five mechanically ventilated Neuro-ICU admitted patients of both genders, who have suspected raised ICP were subjected to bedside TCCS. Two sonographers (consultants), who received training in comprehensive ultrasound workshops in ICU and had an experience of around five years performing USG in ICU, performed TCCS. Patients were subjected to CT brain within three hours of conducting a TCCS. Radiologist and investigators were blinded of TCCS and CT brain findings respectively.

Procedure for determining MLS with TCCS

In patients when there is a suspicion of elevated ICP, the ultrasound MLS was conducted using a low frequency (2 to 4 MHz) probe (SonoSite) through the temporal acoustic bone window. Circle of Willis was identified, at the same level adjusting the depth and gain brain stem image was visualized as a butterfly like structure. Tilting the probe to 10 º cephalic at this level third ventricle was visualized as double hyper echoic parallel running lines with hypo echoic centre. The distance between centre of third ventricle and the outer table of the skull bone was measured on either side. (Figure 1) The difference between both the measurements is divided by two to obtain the TCCS-MLS = (B-A)/2.

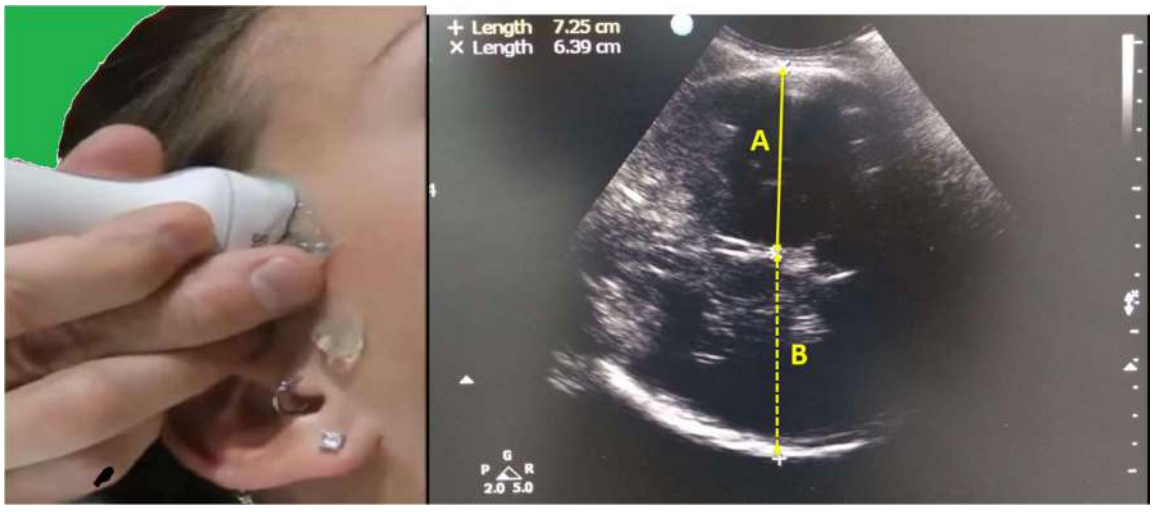


Figure 1. Figure showing placement of Ultrasound probe over Temporal bone (Left), Figure showing Ultrasound image with third ventricle in the center and measurement of MLS (Right). (A- Measurement on ipsilateral side third ventricle distance from skull bone, B- Measurement of distance from third ventricle to contralateral side of skull bone).

Procedure for determining MLS with CT brain

CT method 1

MLS in this method was defined as the distance between the midline determination and the septum pellucidum. It was used as a gold standard and any shift of ≥5mm was considered a significant MLS.

CT method-2

MLS in this method was defined as the distance between the external bone table and the center of the third ventricle at the orbito-meatal plane. [6] These CT methods were performed by the radiologist, who was blinded of TCCS findings. (Figure 2) Data was collected and analyzed for the association.

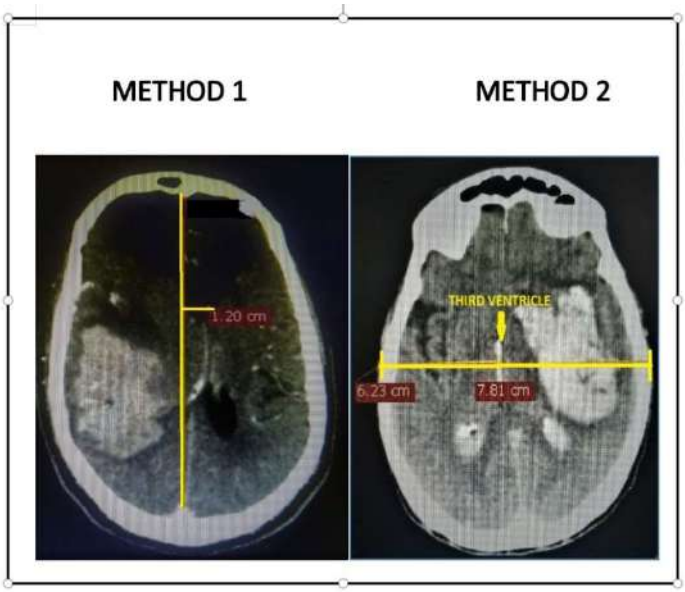


Figure 2. CT scan methods of measuring MLS. (Method-1: Distance between the midline and the septum pellucidum, Method-2: Determining midline from third ventricle).

Statistical analysis of data

Data was collected, tabulated using MS Excel and analysis was done using IBM-SPSS software. Qualitative data was analyzed by calculating percentages and quantitative data was analyzed as mean ±SD. P-value <0.05 was considered significant. Correlation between the TCCS and CT brain derived MLS were correlated with the help of Pearson's correlation coefficient and agreement between both methods was studied by using the Bland-Altman method by measuring the limits of agreement and mean bias. The receiver operating characteristic (ROC) curve was plotted to ascertain sensitivity and specificity for detecting the significant MLS.

Results

A total of sixty five participants were enrolled in the study over the study period. Fifteen individuals (23%) were deemed ineligible for the trial because of the non - visualization of the third ventricle through the skull bone. Remaining fifty patient's data has been collected and analyzed.

Demographic and Etiological data

The mean age of the enrolled patients in the study was 56.3±16 years. Out of which 64% were men and 36% were women respectively. At the time of admission to emergency room, the mean admission GCS was 7.10±1.63. Of the fifty participants, 21 (42%) had spontaneous intracranial bleeding, while 13 (27%) suffered from a traumatic brain injury.

MLS

Out of the fifty subjects, the mean CT-MLS estimated using Method-1 was 6.7 ± 4.4 mm and for Method-2 it was 6.5 ± 3.8 mm. All the patients who were involved in the trial had a TCCS-MLS measurement done and the mean TCCS-MLS was 5.3 ±3.1mm.

Mean midline shift(mm)	Septum pellucidum shift	Third ventricle shift	USG midline shift
	6.75 ± 4.48mm	**6.50 ± 3.80mm**	**5.32 ± 3.15mm**

Figure 3. Mean Midline Shift CT scan methods and Ultrasound Method.

Measures of Correlation and Limits of Agreement

Pearson's correlation coefficient between USG-MLS and CT-MLS was 0.78 with method-1 (P <0.001) and 0.88 with method-2 (P<0.001). The boundaries of agreements for MLS measurements with TCCS and the two CT methods were plotted using Bland-Altman techniques. A Bland-Altman study comparing CT method-1 and TCCS revealed a 1.43mm bias with ranges of agreement ranging from 6.92 to -4.05mm. There were three measurements that fell outside the agreement range (≈8%).

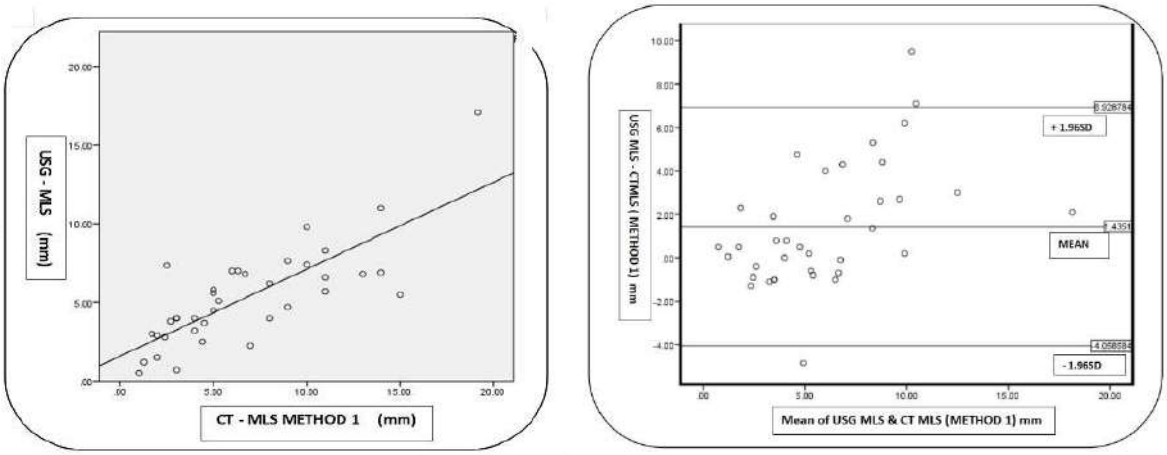


Figure 4. Comparison of CT method-1 and Ultrasound method.

A Bland-Altman study comparing TCS and CT technique 2 revealed limits of agreement ranging from 4.64 to -2.29 mm, with a bias of 1.17 mm. Two measures were outside the limits of the agreement (≈5%).

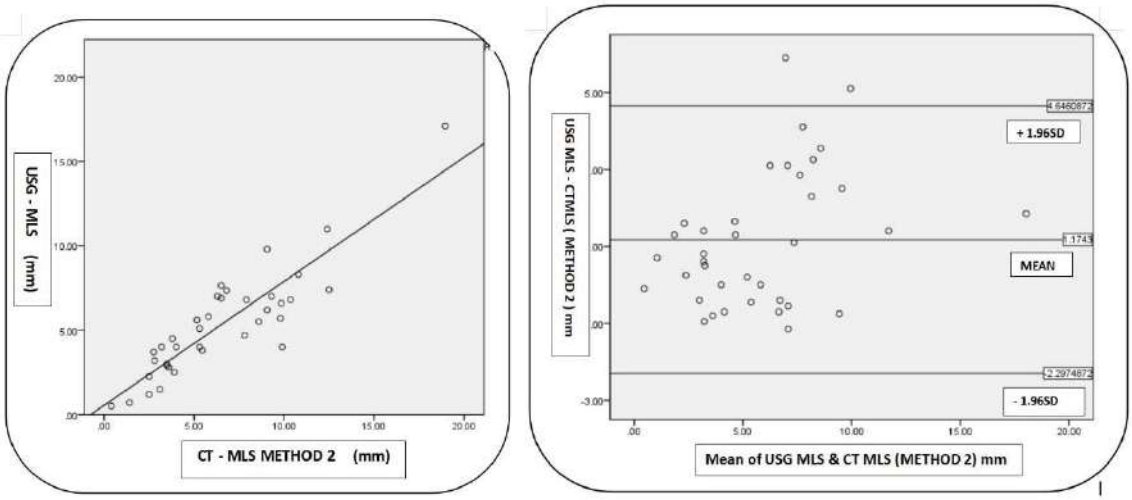


Figure 5. Comparison of CT method-2 and Ultrasound method.

ROC curve analysis

The predictability of sonography in measuring 'significant' MLS (i.e. MLS >5 mm), was determined by the area under the ROC curve (AUC). AUC of 0.91 (95% confidence interval (CI) 0.80 to 1.0% with a cutoff of 3.9 mm. The sensitivity of TCCS in detecting a significant MLS (>5mm) was 95%, specificity was 90%, positive predictive value was 91.3%, negative predictive value was 93.3% and positive likelihood ratio was 9.5 respectively.

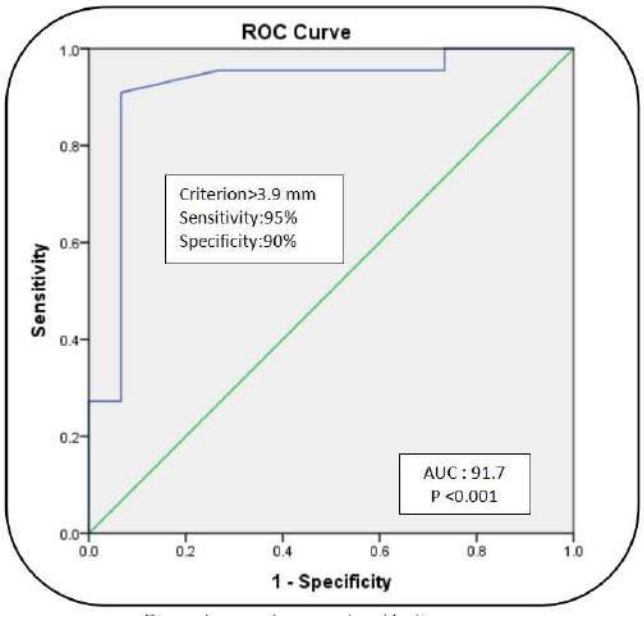


Figure 6. Receiver Operating Characteristic Curve showing Sensitivity and Specificity of Ultrasound.

DISCUSSION

A midline shift of brain parenchyma has been associated with a worsening in sensorium, like drowsiness, stupor and comatose condition. The management for patients with raised ICP has greatly benefited from the detection of horizontal displacement of brain parenchyma from the midline. It is essential to recognize major MLS in Neuro-ICU patients as early as possible for the execution of a suitable management plan. MLS on CT brain correlates well with GCS and magnitude of severity of brain injury [18]. In order to evaluate the precision of MLS determined by USG and assess if the values obtained were consistent with CT brain results, we carried out a prospective observational study.

Bogdhan et al. (1990) were the first to use sonography to identify the brain structures and were able to delineate third ventricle on USG [14]. Subsequently, in 1996, Seidel et al. proposed using sonography to quantify the MLS by using the third ventricle as an essential reference point [15]. They studied on sixty-one patients who presented with acute ischemic stroke (supratentorial infarction) leading to mass effect in brain. The correlation between sonographic measurements of MLS with CT brain in a span of 12-hour time duration was more than 0.9. They showed good reproducibility for the measurements even in the healthy subjects too [15].

Trans-cranial sonography has also been utilized to monitor ventricular width in patients with hydrocephalus. A study conducted by Tamer et al, over a period of one year, on thirty seven individuals concluded that a ventricular width of ≥5.5mm demonstrated a high sensitivity (100%) and specificity (83%) for raised ICP, and a decision was made on the basis of USG observations whether to clamp lumbar or extra-ventricular drainage system or not [19].

An ultrasound MLS of >4 mm within the first 32 hours of the event, was associated with nearly 100% mortality, according to a research by Gerriets et al in 1999, with the exception of patients who had undergone decompressive craniotomy [16]. In 2014, Motel et al. investigated 52 patients in a neurosurgical ICU utilizing sonographic MLS. The brain CT scan and sonography had a Pearson's correlation coefficient (r) of 0.65 ($P<0.001$), with 84.2% sensitivity and 84.8% specificity [18]. Subsequently in 2019 Tamer et al. observed a Pearson's correlation of 0.986 and 0.984 with both the methods of determination of MLS on CT scan with respect to USG and an AUC of 0.98 with a 4mm cut off having 95% sensitivity and 96.6% specificity. These findings suggest that USG guided determination of MLS can serve as a handy bedside tool to facilitate early diagnosis and management of patients with a significant intracranial mass effect [19].

Present study included critically ill patients, with a mean APACHE II of 21 and SOFA score of 10, out of which 48% had a significant MLS on the CT brain. Values of correlation were 0.78 and 0.88 with both the methods of CT-MLS with respect to TCCS and ROC curve analysis showing AUC of 0.91 having a cut-off measure of 3.9mm with a sensitivity of 95% and specificity of 90% respectively, which are comparable to

those observed in earlier studies, even though our study included a versatile group of patients with neurological [20], and neurosurgical [6] issues, unlike prior studies which looked at specific group of patients. About 13(27%) of patients had traumatic brain injury with subcutaneous temporal haematoma, which influenced the measurement of sonography and could be a reason for a slight decrease in correlation values in our study. However, even though MLS may be underestimated by TCCS, the predictability to detect significant MLS (>5mm on CT brain) with TCCS was good in our study, with a sensitivity and specificity around 90%, when using a cut-off for a significant MLS set at 3.9mm. It is important to remember that a significant underestimation of MLS from TCCS in patients with large MLS has also been observed. The difference between sonography and CT brain seemed to increase with a higher value of MLS on CT brain; this was observed in around three patients in the present study [21].

In the literature search and to our knowledge, we could find very few of this kind studies which included versatile patients and second of its kind from an Indian subset of patients studying on bedside utilization of trans-cranial ultrasound in detecting intracranial MLS. Road traffic accidents are the major cause of mortality in developing countries like India, where medical facilities are constrained, and repeated CT imaging may add to morbidity, in such circumstances bedside assessment and monitoring of MLS with sonography adds an additive tool to the armamentarium of patient care in Neuro-ICUs.

There have been a few limitations in the study. First, a single operator performed the TCCS measurements at any given point of time. We could not study inter-observer variability, which could have been of interest to validate this method for clinical use. Second, we excluded nearly 23% of subjects from the study as TCCS could not be done due to poor temporal acoustic bone windows which could have caused selection bias. Thirdly, the location of bleed or infarct could not be captured in the study population which could have explained the variations of MLS. In the present study, the experience in performing brain sonography has been improving with the time duration of the study which might have affected the accuracy of earlier TCCS readings in determining MLS.

Ultrasound could be seen as a reliable bedside alternative modality in measuring midline shift in critically ill patients. It could play an important role in patients, in whom transportation on regular basis is not possible due to unstable clinical conditions and ventilatory support. Owing to its non-invasiveness, repeatability, accuracy, and reliability, it might be used as a prognostication and monitoring tool for raised intracranial pressure; nonetheless, a CT brain would be a more accurate diagnostic tool for MLS. Several more research trials of this kind are needed in the future to support the idea of bedside MLS monitoring for patients who are critically ill.

Conclusion

This study suggests, TCCS might be successful to predict raised intracranial mass effect in Neuro-ICU patients in the form of a

significant midline shift that is comparable to a CT midline shift of >5mm. It may also be an effective bedside tool that can replace CT brain in facilitating early diagnosis of worsening MLS as well as establishing early therapeutic interventions. With more and more literature being published and further development of the technology and experienced skilled operators, TCCS could serve as a potential tool in the armamentarium of critical care physicians in treating critically ill patients.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Assessment of Quality of Life and Determinants Among the Elderly Population in Rural Areas of Puducherry: A Mixed Method Study

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Abstract

Background: Elderly people living in rural areas often faces unique challenges that affect their quality of life (QOL), including limited access to healthcare and social support. Understanding the factors influencing their well-being is essential to improve the quality of life. The study aims to assess the QOL and its determinants among the elderly in rural areas of Puducherry. **Methods:** A community based sequential explanatory mixed method study was conducted among the elderly residing in the rural field practice area of a medical college in Puducherry district. 200 participants were recruited by simple random sampling from the family health records in the Rural Health Training Centre of a medical college. WHO QOL-BREF questionnaire was used to assess the Quality of Life quantitatively and an interview guide to explore its determinants. Data were entered in MS excel and analyzed using SPSS v16.0. **Results:** The mean age of the participants was 68.8± 2.5 years with majority being females. The environmental domain scored the highest mean QOL and psychological domain the lowest mean QOL. The overall mean QOL was 234.8 ± 65.4. The main determinants of poor QOL are age ≥ 75 years, lower socio-economic class, those who are widow/separated and presence of comorbid conditions. The binary logistic regression predicts the factor for poor QOL was age ≥ 75 years with OR (95% CI) as 6.23 (2.44-15.91). **Conclusion:** The overall mean QOL was moderate. The factors identified for poor QOL need to be addressed with key intervention strategies. Quality affordable medical services at door step to improve physical domain and targeted health education for family members and the community, who form the immediate environment around the elderly, can play a crucial role in enhancing the social domain.

Keywords: Quality of Life, Elderly, WHO QOL-BREF

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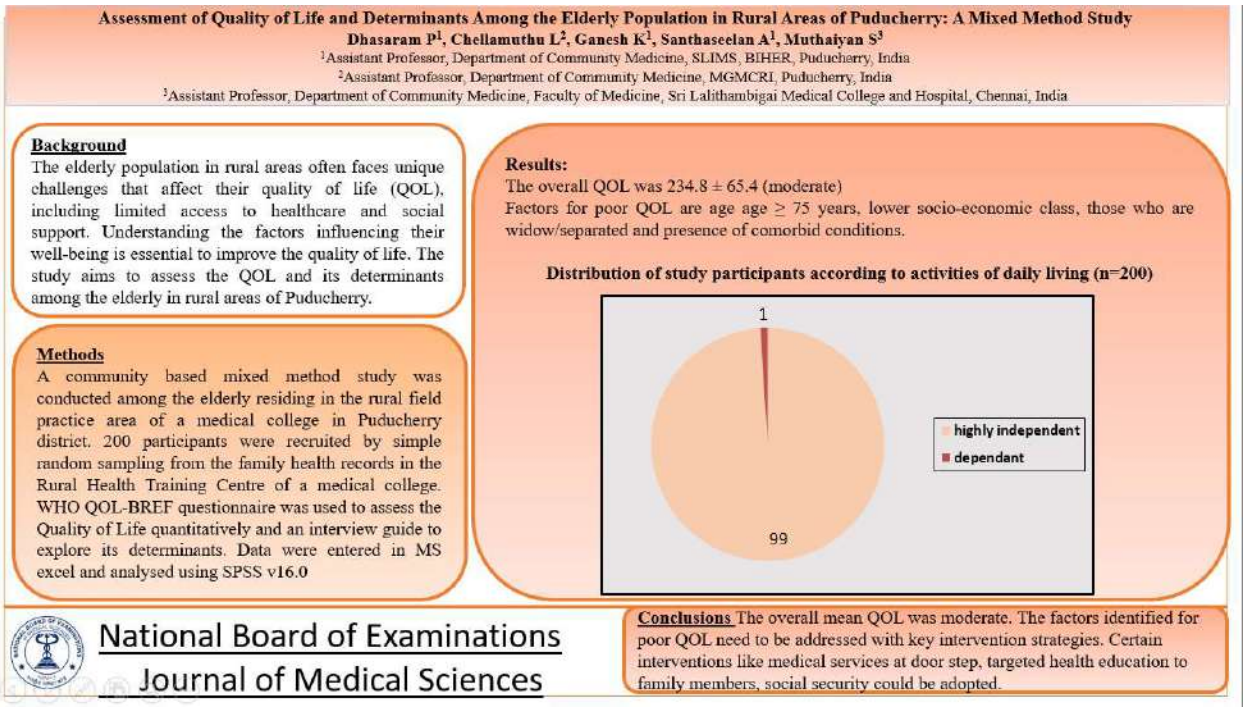
Graphical Abstract



Introduction

Ageing is normal and inevitable phenomenon. In India, as per Census 2011, people with age more than 60 years were 103 million (8.6% of total population) and is predicted to be 319 million (19.5%) in 2050 [1]. With increase in availability, accessibility, affordability of better medical facilities and effective control of infectious diseases the global life expectancy at birth of either gender has reached from 45.5, 48.5 years to 68.5, 73.3 years respectively between 1950 and 2015 [1]. In continuum the UN Population Division predicts that global life expectancy would reach 74.5 years and 79.1 years for males and females respectively by 2050. In addition to this demographic transition, there is also change in the epidemiological trend of overall increase in the prevalence of Non-Communicable Diseases (NCD) and number of NCD Disability Adjusted Life Years with ageing of the population [2]. Almost half (47%) of older Indians have atleast one chronic disease such as arthritis, depression, angina, diabetes, hypertension [3].

The world Health Organization (WHO) has defined Quality of life (QOL) in the context of culture and value system in which he or she lives and in relation of his or her goals, expectation, standard and concerns [4]. QOL among elderly is an important area of concern which reflects the health status and well being of this vulnerable population. QOL is the broad concept covering the individuals physical health, mental health, level of independence, social relationship, spiritual beliefs and environment. In India, around three-fourth (73.3%) of the elderly resides in the rural area with overall literacy rate at 44% [5]. Disabilities such as locomotor and visual also commonly affects

these vulnerable group [6]. Literature review identifies that deterioration of physical health status, mental stress, poor housing conditions, unfriendly neighbors and various other factors affects the QOL of elderly. With this background we planned for quantitative component using WHOBREF tool and Katz activity scale to assess the QOL among elderly and in addition to get insight on perceived psychological and social factors that enhances and deteriorates the QOL we included a qualitative component to the study. The objectives of our study to assess the QOL and explore the factors influencing it among elderly in rural areas of Pondicherry.

Materials and Methods

A community-based sequential explanatory mixed method study was conducted to assess the quality of life among elderly people in rural areas. It was done in villages covered under Rural Health Training Centre (RHTC), attached to the Department of Community Medicine of a private college in Puducherry. The study was conducted for 3 months duration (Jan- March 2024). The participants of 60 years and above living in selected village for more than 6 months were included. Exclusion criteria were elderly participants not willing or not present in house after 2 consecutive visits. Considering from the study by Kumar et al. [7], the standard deviation (SD) of the QOL score in the elderly as 10.2, tolerable error as 1 the minimum sample size estimated was 169. A non-response rate of 20% was added and final sample size calculated was 200. The elderly participants list was collected from family health records maintained in RHTC of the medical college. Simple random sampling using computer generated random number table was applied to select the participants to be included in the study. The data collection tool consists of socio-demographic details, WHO QOL-BREF questionnaire [4] (Tamil translated version) and KATZ ADL (Activities of Daily Living) scale [8]. WHO QOL-BREF questionnaire comprises of four domains, they are physical health, psychological, social and environment with the total of 26 questions. Each of the questions in the scale was rated in a 5 point like scale [4]. As per WHO, the score ranges from 0 to 100, where 0 was the lowest value and 100 was the highest. Katz Index of Independence comprising of 6 questions based on the daily activities was used to assess the ADL. The total score of the scale ranges from 0 to 6, where 6 was the highest score indicating independence in ADL, 0 was the lowest score indicating highly dependent for ADL [8]. In phase I, the data was collected by the principle investigator in the household of the participant after obtaining the written informed consent. Pre-tested semi-structured tool was used to record the information of the participants. All the information collected from the participants are kept confidential. In phase II for qualitative study, the participants with poor QOL were purposely selected. Informed written consent was obtained and the interview were audio recorded. These interviews are conducted by the principle investigator trained in qualitative research techniques using an interview guide in the local language. In-depth Interviews were conducted till the point of saturation in the participants convenient time and place. Each interview lasted for 30-40 minutes and at the

end of the interview the findings of the discussion were disclosed with the participants and validated. Data entry was done in MS excel 2019 and analysis was done using the Statistical Package for Social Sciences (SPSS) version 16.0 software, Chicago, USA. The outcome was represented as mean and SD for continuous variables and proportions for categorial variables. Tests that include Mann Whitney U test and Krushkal Wallis test were applied to find the statistical significance. Transcripts were written in tamil from audio recordings, translated to English and back translated. Inductive approach was applied to identify the codes; to form categories and finally themes were generated by manual content analysis.

Results

In our study of total 200 participants were interviewed and majority were in the age category of 60-74 years 170 (85%). The mean age of study participants was 68.8± 2.48 years. More than two-third were females 139 (69.5%). The distribution of education status among the study participants indicates around 130 (65.0%) were illiterates. Around half of the participants 95 (47.5%) belonged to middle and lower middle class according to modified BG Prasad scale 2023. (Table 1) The major comorbid conditions reported are diabetes, hypertension, osteoarthritis, cardiovascular diseases, asthma, and hemiparesis. The comorbid conditions were validated from medical records and only the chronic conditions were considered as comorbidity.

From Table 2 it was evident that QOL score in environmental domain was the highest 64.6 (±19.3) and psychological domain was the lowest 54.2 (± 17.4). The minimum score in the social domain was 6 followed by psychological domain 13. The total QOL score of the study participants was 234.8 (± 65.4). In overall, the mean QOL of all the domains was average.

Table 1. Shows the socio-demographic characteristics of the study participants (n=200)

Socio-demographic variable		**n (%)**
Age (years)	60-74	170 (85.0)
	≥75	30 (15.0)
Gender	Male	61 (30.5)
	Female	139 (69.5)
Education	Literate	70 (35.0)
	Illiterate	130 (65.0)
Occupation	Working	40 (20.0)
	Not working	160 (80.0)

Socio-economic class*	Upper and upper middle	62 (31.0)
	Middle and Lower middle	95 (47.5)
	Lower	43 (21.5)
Marital status	Married	157 (78.5)
	Widow/separate	43 (21.5)
Family type	Nuclear	142 (71.0)
	Joint/ extended	58 (29.0)
Co-morbidity	Present	80 (40.0)
	Absent	120 (60.0)

*Modified BG Prasad scale 2023

On assessing the ADL, it was found that among 200 participants, 99 % of them were highly independent to carry the activities of daily living and only 1% was dependent of their family members for activities pertaining to daily living based on Katz Index of Independence in Activities of Daily Living.

Table 2. Shows the Distribution of QOL Score of study participants (n=200)

Domain	**Maximum possible score**	**Minimum score**	**Maximum score**	**Mean score**	**Standard Deviation**
Physical	100	19	88	56.9	14.9
Psychological	100	13	94	54.2	17.4
Social	100	6	100	59.1	21.2
Environmental	100	25	100	64.6	19.3
Total QOL Score	400	94	363	234.8	65.4

The various socio-demographic factors that includes age, gender, education, occupation, socio-economic class, marital status, family type and comorbidity were compared across all the domains of Quality of Life. It was found that the participants in the age category of 60-74 years had higher mean QOL in all the domains when compared with the participants in the age band of ≥ 75 years (Table 3). On further exploration in qualitative study, the participants perception for this finding was

Respondent 4 (age 77) said*, "as age increases even the son consider us as burden and don't share any information so we will be isolated, frustrated"*

Respondent 7 (age 79) conveyed, "*we will be alone in the house all the time and they never take us to any family functions because of my ill health"*

In socio-economic class the participants in the upper class had higher QOL compared to middle and lower social class. Also, the participants who are married and living with their spouse had higher mean QOL in all the QOL domains except in the psychological health when compared with the participants who are widow or separated. Participants with diagnosed comorbidity had lower QOL compared to those without any comorbid conditions. These differences are also statistically significant (Table 3)

Table 3. Significant socio-demographic factors associated with domains of QOL (n=200)

Socio-demographic Variable	**QOL Domains (Mean ± SD)**				**Total QOL score (Mean ± SD)**
	Physical	**Psychological**	**Social**	**Environmental**	
Age (yrs) †					
60-74	58.2 (13.9)	56.8 (16.2)	62.3 (20.1)	67.0 (18.7)	245.2 (60.7)
≥ 75	43.9 (13.7)	39.9 (17.4)	40.9 (18.2)	51.0 (16.8)	175.7 (60.1)
pValue	0.000*	0.000*	0.000*	0.000*	0.000*
Social class†					
Upper	60.5 (16.2)	59.4 (18.1)	64.8 (19.9)	69.7 (19.9)	254.4 (67.2)
Middle	57.2 (13.4)	53.2 (17.1)	59.8 (19.8)	63.6 (18.5)	233.9 (60.8)
Lower	51.2 (14.6)	49.1 (15.5)	49.3 (22.9)	59.5 (18.6)	209.1 (64.4)
pValue	0.008*	0.011*	0.001*	0.024*	0.003*
Marital status#					
Married	58.2 (14.8)	55.4 (17.3)	61.7 (20.7)	66.4 (19.2)	241.7 (64.3)
Widow	52.2 (14.5)	49.8 (17.2)	49.3 (20.4)	58.2 (18.3)	209.5 (63.7)
pValue	0.023*	0.051	0.001*	0.012*	0.005*

Comorbidity#					
Present	51.1 (14.4)	51.1 (16.3)	54.4 (20.2)	54.4 (20.2)	219.7 (62.8)
Absent	60.8 (13.9)	56.3 (17.9)	62.2 (21.4)	65.6 (20.3)	244.9 (65.4)
pValue	0.000*	0.029*	0.011*	0.316	0.012*

Mann-Whitney test, †Kruskal-Wallis test, *p Value <0.05 is the statistically significance

Table 4. Shows the Predictor variables of Quality of life using binary logistic regression

Variables	**Total n=200**	**Poor QOL n (%)**	**B**	**S.E**	**Wald**	**p-Value**	**Adjusted Odds ratio (95% CI)**
Age (yrs)							
60-74	170	42 (24.7)	1				
≥75	30	22 (73.3)	1.83	0.48	14.61	0.000*	6.23 (2.44-15.91)
Social Class							
Upper	62	16 (25.8)	1				
Middle	94	28 (29.8)	0.43	0.47	0.84	0.360	1.53 (0.61-3.82)
Lower	44	20 (45.5)	0.36	0.42	0.75	0.388	1.44 (0.63-3.29)
Marital status							
Married	157	41 (26.1)	1				
Widow	43	23 (53.5)	0.53	0.42	1.77	0.183	1.74 (0.77-3.93)
Co-morbidity							
Absent	120	37 (30.8)	1				
Present	80	27 (33.7)	0.09	0.34	0.08	0.772	1.10 (0.57-2.14)

*p-Value <0.05 is considered statistically significant

In Multiple Logistic Regression, the age was the predictor of quality of life and it was also statistically significant. The odds of poor quality of life among those who are aged greater than or equal to 75 years is 6.23 time compared to those who are less than 75 years of age (Table 4).

In Quantitative study, the persons belonging to lower socio-economic class had poor mean QOL in physical domain and to support this finding in qualitative interview

Respondent 3 (age 67) said, "*The only person to take care of me is spouse, Because of age either of us could not work and we are managing only with the old age pension (Rs 4000). So, I could not afford for the good quality medical care of my chronic illness"*

In phase I study, the participants with any of the comorbidity had lower mean QOL in all the domains. The inner perspective of the participants for this finding was

Respondent 7 (age 79) said, "*I was bed ridden for past 3 years, so I feel severe ache throughout my body. I am unaware of the things happening in external world"*

Respondent 8 (age 71), revealed "*my daughter in law will scold me, if I ask any money to my son for the treatment of my leg pain"*

Table 5. Participants perspective on factors influencing Quality of Life

Theme	**Good QOL**			
Category	Physical	Psychological	Social	Environmental
Code	Active, Diet restrictions, Sports	Affectionate, Faith Relaxation	Friendly, Hope, Social interaction, Preach, Helping, Dignity, Self-respect	Clean
Theme	**Poor QOL**			
Category	Physical	Psychological	Social	Environmental
Code	Cost of treatment, Tired, Pain, Disability	Memory, Boring, Hallucinations, Depression, Frustrated	Needy, Lonely	Dependable, Burden, Poor, Dirty

The Table 5 represents the themes, categories, and codes. Inductive approach was followed and the factors (codes) explored in the interview were grouped to a category then assigned in either of the appropriate theme good or poor QOL.

Discussion

We conducted a mixed method study among the elderly individuals residing in the rural areas of Puducherry. Totally 200 elderly people were interviewed. Study results shows that overall QOL score of elderly living in the rural setting was average. Similar finding was revealed from the study conducted by Kumar SG et al[7] in the rural area of south India. This similarity is due to geographically near region and study done among geriatrics.

Our study shows higher environmental score shows that the geriatric populations are more satisfied about their environment. Similar findings were revealed from the study conducted by Praveen et al9 done in rural area. The stress free, pollution less, noise free and a more green environment spread in rural areas could be the reason for this higher mean QOL score in environmental domain comparing to other domains. In our study, conversely as age of the participants increases the QOL score decreases. Similar findings noted in a study on quality of life among the elderly residing in the urban area of thirumazhisai (Tamilnadu) which was done by Parasuraman et al. [10]. In our study nearly 99% of the participants scored full in the daily activity of Katz Index of Independence scale. This could be because, majority of our study population was less than 75 years (85%). Parasuraman et al. [10] study also revealed similar findings in the activities of daily living. This similarity could be due to the comparable population characteristics and standardized assessment tools (WHO BREF scale and Katz scale). The educational status in our study population, 52% are illiterate whereas in Shah et al. [11] study conducted among elderly in urban area in Ahmedabad city, Gujarat shows that 35.6% are illiterate. This difference in literacy rate could be attributed to the locality, as our study was carried in rural area whereas shah et al study carried out in the urban area.

In our study age <75 yrs individual has better score in physical health domain. Similarly, Karmakar N Et al[12] conducted study in rural Tripura shows that individual age <70 yrs. have better score in physical domain. Another study by Thadathil et al. [13] in rural kerala showed that mean score of QOL domain was maximum in physical health domain (42.44) followed by the social relationship domain (42.16). Comparably in our study also physical domain has maximum score followed by social relationship domain, this may be due to the similar study population (elderly > 60years). From our study it was evident that physical domain, environmental domain, social relationship score are significantly better among those who are with their spouse than those who are separated, widowed. Barua et al. [14] also conducted a study on the elderly in Karnataka and found that the geriatric population those who are married and living with spouse currently had better quality of life compared to those who are divorced, widowed, separated. In the study by Mudey et al. [15] at Wardha, shows that there was a statistically significant difference in physical and psychological domain QOL score among

rural population with respect to age. This finding correlates with our study where the population in the age category between 60 to 74 has better physical and psychological domain.

The strength of the study is the mixed method design because the qualitative interviews help us to better understand the participant perspective that will help to design strategies to improve the QOL. The limitation of the study is the inclusion of only a small proportion of super senior citizens (80 years and above), which restricts the exploration of quality of life (QOL) in this group.

Conclusion

The overall QOL of the elderly was moderate. The present study revealed that environmental domain had higher mean QOL score in comparison to other domains, and contrastingly physical domain was affected more with low mean QOL score. Key intervention strategies need to planned to improve all the domains of QOL and health holistically. Quality affordable medical facilities at their door steps could improve the physical health. The social domain can also be improved by collective efforts from family members and geriatric support groups in the community.

Conflicts of interest

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

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ORIGINAL ARTICLE

Prevalence of Helicobacter Pylori Infection Among Dyspepsia Patients in a Tertiary Care Hospital of Puducherry

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Abstract

Background: Dyspepsia is a relatively common clinical condition characterized by chronic / recurrent upper abdominal pain or discomfort. Dyspeptic individuals were found to be infected with H-pylori than asymptomatic individuals. Though most individuals are asymptomatic, H. pylori plays a key role in the etiology of many upper gastrointestinal disorder. **Materials and Methods:** This cross-sectional prospective analytical study was done in Department of General surgery, IGMCRI Pondicherry from February 2022 to June 2022. Both male and female patients attending surgery OPD of age 20 to 60 years with upper gastrointestinal symptoms like dyspepsia and epigastric pain were subjected to upper gastrointestinal endoscopy and scopy findings noted and a Rapid urease test done for them. **Results:** The prevalence of H-Pylori was found to be 53%. Gender wise distribution shows more prevalence among females (61%) compared to males (44%). Of the total patients, 72% presented with abdominal pain, 34% presented with associated nausea, vomiting and 50% presented with regurgitation, 47% presented with bloating sensation. 11% present with other associated symptoms like malena and dysphagia. 9 patients with dyspepsia had ulcers in the antral wall and duodenum with 33% RUT positivity. 11 of them presented with pangastritis with 72% RUT positivity, 47 of them had antral gastritis with 66% RUT positivity, and 15 of them were found to have normal endoscopic findings with 33% RUT positivity.47% of the patients with esophageal varices and 20% of the patients with ulceroproliferative growth showed RUT positivity. **Conclusion:** This study validates that more than half the patients with dyspepsia in our population are H-pylori positive. Early referral for Upper GI endoscopy can help diagnose the same and associated clinical condition and initiate an early anti-H. Pylori regimen to achieve quicker symptom relief in these patients.

Keywords: Abdominal pain, Gastritis, RUT, Ulcer

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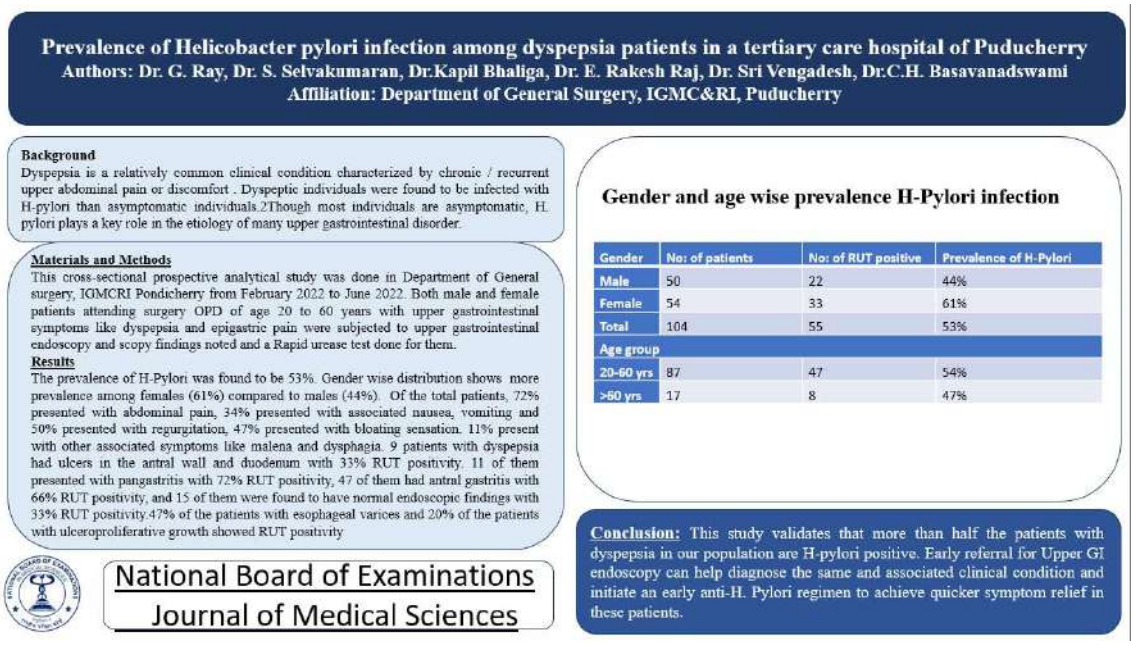
Graphical Abstract



Introduction

Dyspepsia is a relatively common clinical condition characterized by chronic / recurrent upper abdominal pain or discomfort and is often associated with one or more of following symptoms at any given time - upper abdominal pain, burning sensation in the chest or upper abdomen, regurgitation, anorexia and early satiety [1]. Dyspeptic individuals were found to be infected with H-pylori than asymptomatic individuals [2]. Though most individuals are asymptomatic, H. pylori plays a key role in the etiology of many upper gastrointestinal disorders. H. pylori infection is among the leading gastroenterological public health problems in developing countries [1]. Approximately 80% of the population may be infected by the age of 20 [3]. H- pylori infection can be diagnosed invasively using rapid urease test using endoscopic biopsies [4]. Dyspepsia is classified as organic or functional dyspepsia (FD). Organic dyspepsia is defined as dyspepsia induced by known etiology with structural disease like endoscopic lesion. Duodenal or gastric ulcer, erosive gastritis, duodenitis, gastritis, and malignant processes are included under organic dyspepsia. Dyspepsia with the absence of structural disease after the investigation using imaging, endoscopy, or similar method is called functional dyspepsia [5]. Number of invasive and noninvasive techniques though available in the diagnosis of H Pylori, conventional endoscopy is considered a powerful diagnostic tool for upper gastrointestinal tract as it enables the visualization of mucosal lining of the esophagus, stomach and duodenum. The rapid urease test (RUT) provides an opportunity to begin treatment immediately after the test [6]. Though prevalence studies are available in different states of India, data concerning the prevalence of H. pylori infection among dyspeptic patients in Puducherry are scanty; hence, the present study has been undertaken [7-9]. Further response of these patients to standard treatment regimens

would assist the primary care physicians in deciding upon treatment among dyspeptic patients.

Aim and Objectives

The primary objective of the study are to analyze the prevalence of H.pylori infection among patients with dyspepsia and to analyze the treatment response to anti-H.pylori regimen among patients with dyspepsia.

Methodology

This cross-sectional prospective analytical study was done in Department of General surgery, IGMCRI Pondicherry from February 2022 to June 2022. Both male and female patients attending surgery OPD of age 20 to 60 years with upper gastrointestinal symptoms like dyspepsia and epigastric pain willing to undergo endoscopy with tissue biopsy for rapid urease test were included after obtaining written informed consent. Pregnant women, patients diagnosed with bleeding or anxiety disorder, and patients with retroviral or HBV infection will be excluded. Based on the previous study [7], the sample size was calculated to be 93, with alpha error of 5% and an absolute precision of 10%. With 10% failure to follow up the sample size was estimated to be 102. Based on convenient sampling method among the patients attending surgery OPD from Monday to Saturday, 600 patients were diagnosed with dyspepsia, among them 250 patients satisfied the inclusion and exclusion criteria. However, only 104 patients willing to undergo endoscopic procedures were included.

All 104 patients were given appointment on specific dates to undergo upper GI endoscopy. They were advised to report in the endoscopy room after overnight fasting. The procedure was carried out in the endoscopy room under topical lignocaine spray in the Department of General surgery, IGMC & RI, Pondicherry in the morning from 8.30 to 10 am after explaining the procedure completely and getting the written informed consent. Patients were asked to remove the dentures before the procedure. The procedure was repeated after 1 week for willing but non-coperative patients. Patients taking anticoagulants were advised to stop the drug 5 days before the date of appointment. Cardiac fitness was obtained for all the patients on anti-failure treatment. Continuous ECG monitoring was done in these patients till the endoscopic procedure was complete. The esophagus, fundus, greater curvature, lesser curvature and duodenum upto second segment was visualized. Biopsy was taken from edge of the ulcer in patients with ulcer and ulceroproliferative growth. In all others, biopsy was taken from antrum and lesser curvature as it is the preferential site for H-pylori infection. The specimens taken were subject to RUT and the results were obtained within 5 minutes. For patients with ulcer and ulceroproliferative finding specimens were also sent for histopathological examination for further analysis to rule out carcinoma.

Statistical analysis

All the data are tabulated in Microsoft Excel. Analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0 software. The presence of symptoms, prevalence of H Pylori and response to treatment were analysed for descriptive statistics. The findings were expressed as percentage.

Results

Table 1 shows that the prevalence of H-Pylori was 53%. Gender wise distribution shows more prevalence among females (61%) compared to males (44%). Among the total, 87 patients belong to the age group of 20 to 40 years with 54% prevalence and 17 patients belong to 41 to 60 years of age with 47% prevalence. Of the total patients, 72% presented with abdominal pain, 34% presented with associated nausea, vomiting and 50% presented with regurgitation, 47% presented with bloating sensation. 11% present with other associated symptoms like malena and dysphagia.

Table 2 shows the Upper GI endoscopic findings and RUT-positivity, where 9 patients with dyspepsia had ulcers in the antral wall and duodenum with 33% RUT positivity. 11 of them presented with pangastritis with 72% RUT positivity, 47 of them had antral gastritis with 66% RUT positivity, and 15 of them were found to have normal endoscopic findings with 33% RUT positivity.47% of the patients with esophageal varices and 20% of the patients with ulceroproliferative growth showed RUT positivity. Only 55 patients were found to be RUT positive, thus 53% of the dyspeptic patients were found to RUT positive. 90 patients had non-ulcer dyspepsia and 56% of them were infected with H-pylori.

Table 3 shows that all RUT-positive patients with findings of pangastritis, antral gastritis, duodenal ulcer, and normal findings responded 100% to the anti-H-Pylori treatment on follow-up after 4 weeks. However, 7 patients with esophageal varices and 1 with ulceroproliferative growth had persistent symptoms after 21 days and after 4 weeks follow up. 85% of the symptomatic patients with RUT positivity responded to treatment with anti-H Pylori.

Table 1. Gender and age wise prevalence H-Pylori infection

Gender	**No: of patients**	**No: of RUT positive**	**Prevalence of H-Pylori**
Male	50	22	44%
Female	54	33	61%
Total	104	55	53%
Age group			
20-60 yrs	87	47	54%
>60 yrs	17	8	47%

RUT: Rapid urease test, yrs- years

Table 2. RUT positivity in different endoscopic findings of patients with dyspepsia

Endoscopic findings	**No. of patients**	**No. of RUT positive patients**	**% positive**
Pan gastritis	11	8	72%
Antral gastritis	47	31	66%
Normal study	15	5	33%
Duodenitis or ulcer	9	3	33%
Ulceroproliferative growth	5	1	20%
Vascular ectasis	2	0	0 %
Esophageal varices	15	7	47%

Table 3. Response to anti H Pylori treatment among RUT positive patients

Endoscopic findings	**RUT positive patients**	**Asymptomatic Post 4 weeks**	**Treatment response**
Pan gastritis	8	8	100 %
Antral gastritis	31	31	100%
Normal study	5	5	100%
Duodenitis or ulcer	3	3	100%
Ulceroproliferative growth	1	0	0%
Vascular ectasis	0	0	0
Esophageal varices	7	0	0%
Total number of patients	55	47	85%

Discussion

The prevalence of H-pylori infection among dyspeptic patients was found to be 53%. The prevalence was found to be higher when compared to study done in Telangana and Bangladesh which were only 32.9% and 47.8% respectively [10,11]. H. pylori positive patients have a 10–20% risk of developing ulcer and a 1–2% risk of developing gastric cancer in their life time [12]. World Health Organization (WHO) and the International Agency for Research on Cancer has classified H-Pylori as a class 1 carcinogen [13]. In this study, prevalence was found to be higher in females than males, it was found to be higher in the age group of 20 to 60 years. This is similar to the study done by Sharma et al. [7] Treatment for H. pylori infection is recommended in all symptomatic individuals to prevent the development of gastric adenocarcinoma and mucosa-associated lymphoid tissue (MALT) lymphoma [14].

The prevalence of H-pylori infection in non-ulcer dyspepsia was found to be 56%, which is slightly more when compared to the study done by Sharma et al. [7] which was 40%. 72% of patients with pan gastritis were infected with H-Pylori. Among the patients with antral gastritis, 66% were H-Pylori infected. This is similar to the study done by Faintuch et al. which is 61% [15]. RUT positivity among patients with normal endoscopic findings were 33%, which is higher than the study done by Yellapu et al. [16] 47% of the patients with esophageal varices and 20% of the patients with ulceroproliferative growth were infected with H-Pylori.

In this study RUT-positive patients were treated with anti-H-pylori kit for 21 days. The patients were asked to report their dyspeptic symptoms immediately after the completion of treatment and after 4 weeks. 47 RUT-positive patients did not have any symptoms of dyspepsia even after 4 weeks of anti-H-pylori regimen. Thus 85% of symptomatic RUT-positive patients responded to treatment. Similarly, there was 24 to 53% improvement in symptoms among H-Pylori-positive patients in different studies [17,18]. Tanaka et al. reported that 73% of the patients had improvement in the dyspeptic symptoms [19]. This difference could be due to differences in the criteria for improvement of dyspepsia in different studies. Remaining RUT-positive patients with esophageal varices and ulceroproliferative growth were treated with banding and further evaluation for staging of carcinoma respectively. Thus upper GI endoscopic evaluation in patients with more than 4 to 6 weeks of dyspepsia not only help in diagnosing Hpylori infection but also in identifying associated findings like esophageal varices, carcinoma, etc. RUT-negative patients with dyspepsia were treated with oral C. pantoprazole for 3 days or 5 days based on the symptom severity. Follow-up of these patients for 4 weeks did not show any symptom recurrence. All patients were advised to avoid alcoholic beverages and spicy food. They were asked to practice mindful meditation or yoga to reduce their stress level to reduce the recurrence of dyspepsia due to increased gastric secretion.

Conclusion

This study shows anti-H-pylori treatment can be prescribed after upper GI endoscopy and rapid urease test. This finding could assist primary care physicians in deciding on referring patients for upper

GI endoscopy who are not responding to proton pump inhibitors rather than treating them empirically. It also enables them to diagnose other associated findings like esophageal varices and early detection of carcinoma among patients presenting with ulcers.

Strengths & Weakness of the Study

H-Pylori infection was diagnosed with upper GI endoscopic biopsy and RUT, which helps in understanding the prevalence of H-Pylori infection in patients with different endoscopic findings. The study has a few limitations. Post-treatment endoscopy and RUT were not repeated for H-Pylori-infected patients. RUT could be falsely negative among patients treated with proton pump inhibitors. The risk factors like smoking and socioeconomic status were not recorded. Histopathological findings were not correlated with endoscopic findings. This study could be extended with a larger sample size and by scoring the dyspeptic symptoms before and after treatment to clearly define the treatment response.

Statements and Declarations

Conflicts of interest

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

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REVIEW ARTICLE

A Platinum-Graded Green Hospital Building in India during COVID-19 Pandemic: From Planning to Execution and Outcome

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Abstract

Background: A green hospital building has superior qualities over general hospital buildings in terms of energy conservation, use of natural resources, clean indoor air quality, green housekeeping, and other characteristics that improve patient outcomes. During the COVID-19 pandemic, healthcare organizations worldwide faced significant challenges and difficulties running hospitals. These challenges motivated the healthcare administration to find possible solutions for possible protocols for the functioning of the hospital. **Methods:** It was a prospective study conducted at a tertiary care hospital in north India from March 2020 to Feb 2022. After multiple changes in the fields of committee formation, human resource management, training, setting of the donning area and the doffing area, setting of the patient care areas and the infection control practices, equipment utilization, protocols for the support services, patient status updation to family members, and finally maintaining the patient data for the official purpose. **Results:** The hospital statistics showed a recovery rate of 81%, a mortality rate of 18%, and average length of stay of 8 days in COVID-19 patient care. **Conclusion:** The experiences, the challenges learned, and the solutions made to combat this pandemic will be the guide for future pandemics. The green hospital building proved its supremacy in patient outcomes and is recommended by hospital administrators as a future hospital building.

Keywords: COVID-19, Green Hospital Building, Challenges, Solutions, Outcome

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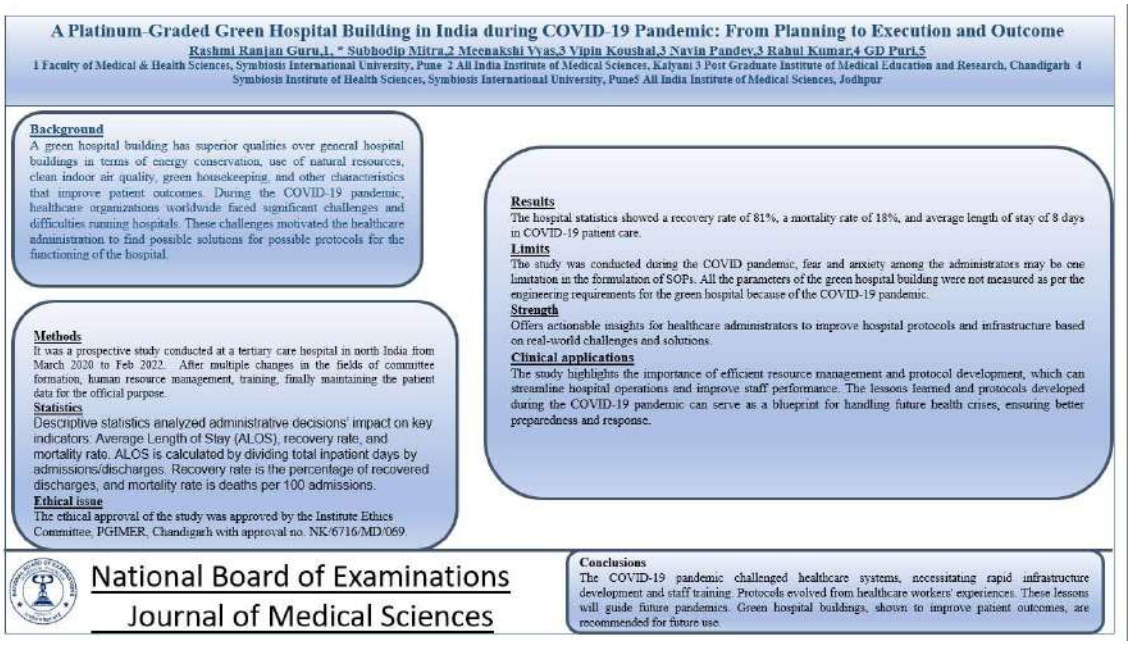
Graphical Abstract



Introduction

The WHO Director-General declared the COVID-19 outbreak as a public health emergency of international concern on 30th January 2020 [1]. Postgraduate Institute of Medical Education and Research (PGIMER) is a tertiary care hospital and a research institute in Chandigarh, India. It is the leading tertiary care hospital in the region of Chandigarh, Punjab, J&K, Himachal Pradesh, and Haryana. PGIMER has state-of-the-art facilities encompassing all specialties and super specialties. It was 21st January 2020, India, one official circular from the Medical Superintendent, PGIMER, Chandigarh was circulated throughout PGIMER on the matter of preparedness for the COVID-19 situation.

On March 14, 2020, the health secretary sent a message t4o start a dedicated COVID hospital within PGIMER as soon as possible and the building, Nehru Hospital Extension (NHE) was chosen for the dedicated COVID Hospital. The hospital was graded as a platinum-graded green hospital building by the Indian Green Building Council (IGBC). A green hospital building has superior characteristics to the general hospital buildings in terms of energy conservation, use of natural resources, clean indoor air quality, green housekeeping, and other characteristics that improve patient outcomes. Transforming the commissioned NHE into a fully functional setup within a fortnight presented an immense challenge for the hospital administrators. A COVID-19 Management Committee was formed, comprising experienced professionals from all departments of the hospital. Their continuous efforts transformed the partially functional hospital into a COVID isolation facility within a short period [2].

The competent authority conducted meetings to establish committees for COVID Management and a team of faculty and residents from different departments took on leadership roles as shown in Figure 1.

Figure 1. Shows COVID-19 Management Committee and the team

A training committee comprising faculties trained the healthcare workers and managed their accommodation, diet, and transportation. Respective departments created rosters and sent HCWs to the training committee. Training sessions were conducted in Lecture theaters adhering to social distancing guidelines as shown in Figure 2.

Figure 2. Shows the training of the HCWs during the COVID-19 pandemic

A CCTV control room with an announcing system directed the movements of the patient and staff. The overall control of all areas was managed by the control room run by the Dept. of Hospital Administration around the clock. The patients were monitored through the facility by camera and televisions in the control room as shown in Figure 3.

Figure 3. Patient Monitoring Control Room in COVID Hospital

Aim of the Study

The article aimed at challenges faced during this preparation and operation phase along with their innovative solutions are being highlighted hereon and its results.

Methodology

It was a prospective study conducted at a tertiary care hospital in north India from March 2020 to Feb 2022. The patients with COVID-19 infection admitted to the hospital were included in the study and the patients without the COVID infection were excluded from the study. A total of 6580 patient admissions were considered as the sample size. The administrative decisions, Standard Operating Procedures, training for the HCWs, and other policies were used as tools for the study. The descriptive statistics were used to analyze how these administrative decisions led to the changes in some crucial indicators such as Average Length of Stay (ALOS), recovery rate and mortality rate, ALOS which is the average number of days that a patient spends in the hospital and was calculated by dividing the total number of days in the hospital for all the patients during a certain period (patient days) by the number of admissions or discharges as shown below:

$$Average\ length\ of\ stay\ (in\ days) = \frac{Total\ inpatient\ days}{Total\ admissions\ or\ discharges}$$

The recovery rate is the percentage of patients discharged from the hospital as successfully recovered and is calculated by dividing the no. of patients discharged as "recovered" by the total no. of discharged patients. The result is multiplied by 100 to convert to a percentage as shown below:

$$Recovery\ rate\ (\%) = \frac{No.of\ patients\ discharged\ as\ "recovered"}{Total\ no.of\ discharged\ patients} \times 100$$

The mortality rate is the number of deaths that occur in a hospital in a given year, it can be seen as the number of deaths per 100 patients admitted in a hospital.

Results

The total number of patients admitted to the COVID hospital was 6580(N). Among them 4063 were male and

2517 were female. 5353 patients were discharged from hospital to home. 1227 number of the patients died during that period. The average number of stays was 8 days, the recovery rate was 81% and the mortality rate was 18.65%. The results are shown in Figure 4.

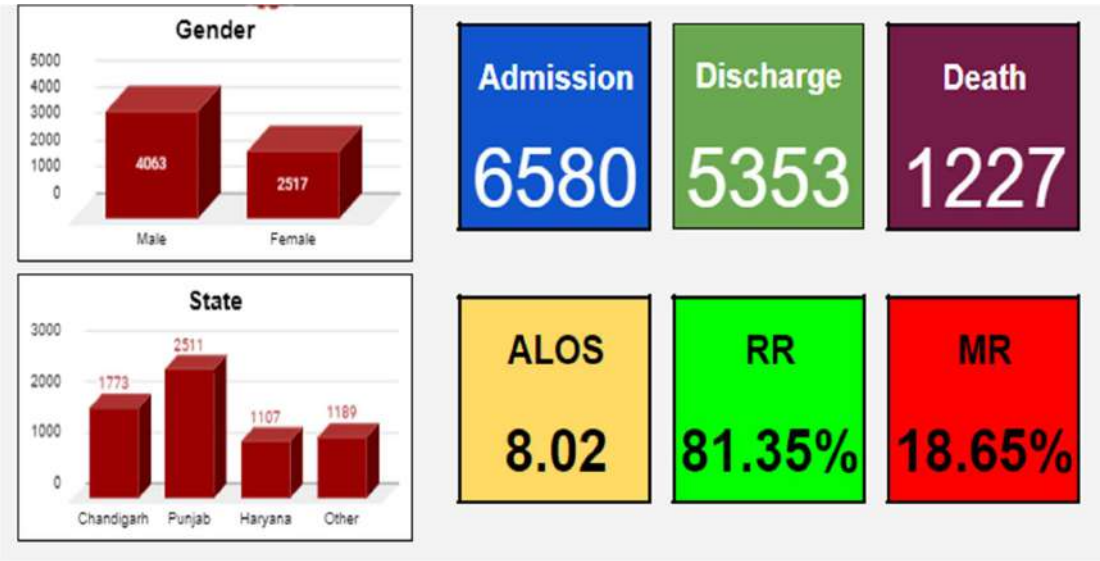


Figure 4. Shows the Hospital Statistics of the COVID-19 Pandemic Era

The Total number of patients admitted to the general hospital building was 2650. Out of the 2650 patients, 2309 number of patients recovered from COVID-19, and 341 deaths occurred. A comparison study is shown in Figure 5.

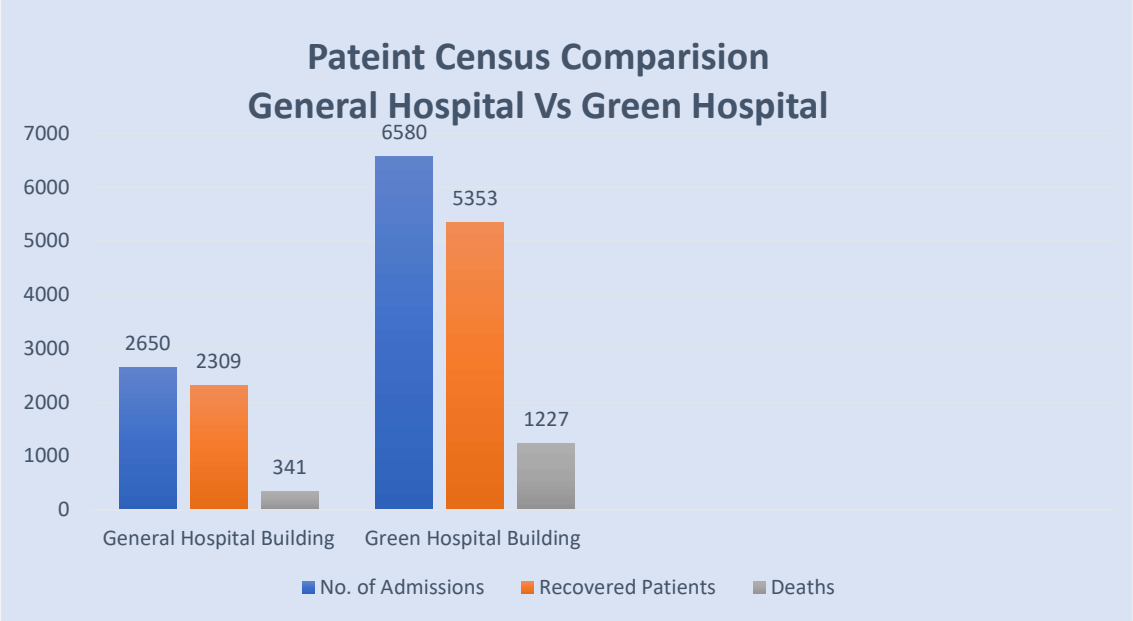


Figure 5. Shows the Hospital Statistics of the COVID-19 Pandemic Era

Discussion

The competent authority conducted meetings to establish committees, for the COVID Management and a team of faculty and residents from different departments took the leadership roles many authors mentioned in their articles [3].

The ICUs of the newly commissioned building were deficient in Heating Ventilation Air Conditioning (HVAC) with negative pressure, RO water supply, UPS backup & generator backup, domestic water supply, water supply to the dialysis facility, drainage of the wastewater of the dialysis machine, hospital information system, radiology workstation, landline telephone connections, remote viewing cameras for the patient care from the control room. The institute's engineering department and the Central Public Works Department (CPWD), Govt of India joined hands to expedite the process. Pre-operative, post-operative, and palliative care unit beds were transformed into 58 fully equipped ICU beds. Ward beds with ventilator connectivity were converted into 108 semi-equipped HDU beds. Additionally, 140 beds were created by utilizing private rooms with patient and attendant beds as step-down beds. This resulted in a total of 306 beds for COVID-19 patients, including a resuscitation area with three beds and a Cath lab mentioned by another author [4].

A training committee comprising faculties trained the healthcare workers and managed their accommodation, diet, and transportation [5]. Training sessions were conducted in Lecture theatres adhering to social distancing guidelines. HCWs received training on various guidelines and protocols, followed by orientation on their duties and responsibilities, and hands-on training on equipment like ventilators. Accommodation was arranged in private rooms within the hospital and hotel rooms provided by the institute at the start of the pandemic but later discontinued. Google forms were used for the booking process of rooms for the staff who were posted for COVID-19 duty every week.

A clean area was designated for administrative work, while contaminated red areas were created by installing glass doors in the hospital building [6]. Separate entry and exit gates were established for staff and patients. Initially, donning and doffing rooms were set up but later converted into donning and doffing corridors to accommodate 450 staff per shift. A doffing control room with real-time remote surveillance and an announcing system for stepwise doffing to minimize errors was established. Senior faculty utilized the facility of cameras installed over ICU beds and HDU cubicles for remote assessment. Patient counselling took place in the reception area, with OPD parking ensuring social distancing. Clinical control rooms enabled daily patient management discussions, while a nursing control room managed consumables and drugs around the clock. A CCTV control room with an announcing system directed patient and staff movements. The overall control of all areas was managed by the control room run by the resident doctors, Dept. of Hospital Administration around the clock.

The task of sorting lab samples was highly challenging. Initially, the lab samples were sent through a ramp. The physical effort exerted by attendants to climb the ramp caused delays in sample transport and missing of samples which few authors mentioned in their studies [7].

The area near the patient lift, providing access to outside and various labs

and the ABG lab, was chosen as the sample sorting station, which was equipped with CCTV cameras, sample-keeping trays, sorting containers, and a refrigerator to maintain cold chains, it ensured efficient handling of the sample. An LED screen in ABG Lab was used to monitor sample arrival at the laboratory. Vaccine carriers were used to maintain the cold chain during transportation.

With the increase in patients, the number of staff also increases, the new donning corridor is fully equipped with 47 donning stations used for 100 staff going for duty, as mentioned in other studies [8]. The donning area has two attendants deployed to help in donning. The Epicollect-5 surveillance mobile application was used for easy data entry and to speed up the process of donning.

The HVAC system was set to fresh air mode with closed return ducts and exhaust fans initially, but this caused problems in the AC's functionality [9]. To address this, air sampling was conducted multiple times, confirming the absence of the virus in the air at the roof level. Return ducts were opened. Oil heaters were placed near patient beds to maintain the desired room temperature. Precautionary measures were implemented to prevent fire incidents.

In the initial phase of setup, essential equipment such as ventilators, syringe pumps, monitors, ECG machines, ECHO, radiology workstations, portable X-ray machines, sonoclot machines, and portable ABG were needed for patient care. The challenge was to procure and arrange the necessary equipment for patient care. It was decided to temporarily relocate equipment from non-operational patient care areas for use in the COVID hospital until new equipment arrived. Ventilators were later received from the Prime Ministers Care Fund (PM Care), but their unique input system posed challenges for doctors. Regular training sessions were conducted to familiarize residents and nurses with ventilators and other equipment [10].

Initially, due to the building's commissioning stage, the dialysis facility was unavailable. As the first chronic kidney disease (CKD) patient was admitted to the ICU, a dialysis setup was arranged. With the increasing number of dialysis patients, a dedicated room with four fully equipped stations was established. However, during the hot summer, the heat caused the water temperature to rise, resulting in the malfunctioning of the dialysis machines. Reverse Osmosis (RO) water connection was given to the dialysis machines and two storage tanks were kept in the corridor with one pump to provide cool water to the dialysis machine, few authors mentioned in their studies [11].

A CCTV camera was installed at the staff entry gate and near the staff lift to speed up the process of registering for attendance purposes. Staff duties and responsibilities were described during the orientation program. A register was made for the nursing supervisors and sharing shift details on the WhatsApp group for supervision [12].

In root cause analysis for the maintenance of inventory of linen gowns, it was found that the staff put the linen gowns in the yellow color bins (used for disposable items) hence they were misused because they were sent for disposal. As a solution Linen hampers were placed in doffing areas and wards for storing gowns, and the nursing supervisor shared linen records via the WhatsApp group for verification [13].

COVID-positive patients were demotivated during their transfer to the

radiology centre due to the reluctancy shown by the staff. To streamline patient shifting to radiology a dedicated transportation team comprising a resident doctor, nursing officer, hospital attendant, sanitary attendant, and ambulance driver was formed. Coordination was facilitated through the WhatsApp group. A checklist of essential equipment was provided to ensure availability before shifting the patient. Additionally, a specialized radiology team was established to coordinate the patient transfers to radiology procedures [5].

Upon a patient's recovery and medically fit for discharge or obtaining two negative test results, the respective department issued a discharge slip. The hospital administration's control room initiated the discharge process. The COVID area resident then directed the patient to the ambulance bay, facilitating discharge with a discharge file, flowers, and post-COVID care guidelines. Coordinating these steps was a time-consuming challenge. A patient discharge group was made on WhatsApp, and all the staff involved were added for faster information concerning the discharge. This saved time and enabled a faster discharge process.

Sharing COVID patient details with various departments and entities, including the data center, Medical Record department, virology department, ICMR portal for data entry, RT-PCR reporting, laboratories, and clinicians, proved to be a time-consuming process. A dashboard was made by using a Google Excel sheet from where information regarding patient details, admissions, discharges, death and was shared with the departments and institute website. The COVID Hospital in India was a 300 bedded facility under Govt of India serving more than 6850 patients with a mortality rate of 18.65% and recovery rate of 81.35% with average length of stay was 8 days [14].

A hand hygiene chart of different areas was made for comparison between all the ICUs and wards. The chart was posted in all the groups, the clinical rounds, and the training sessions. An hourly announcement via the Public Announcement System was made as a reminder of hand hygiene, and unique steps none of the authors mentioned this but mentioned by the same author [15].

The brachytherapy OT was purposed as a functional Cath lab, with essential equipment such as a C-Arm, echo machine, monitor, defibrillator, OT lights, backup OT spotlight, and a resuscitation trolley. Staff members were assigned, and consumables were arranged, enabling the Cath lab to begin procedures [16].

Coordination delays occurred in sending blood product requests to the blood bank, resulting in prolonged sample receipt, cross-matching, and issue of blood products. Additionally, the absence of a blood return policy led to the wastage of numerous blood units. To reduce paperwork, an option for blood product requests was implemented in the Hospital Information System (HIS). A WhatsApp group was created for efficient coordination with the blood bank doctors. A blood product return policy was established, involving wiping the product with alcohol-based hand sanitizer and disinfecting it in an ultraviolet light box for 30 minutes after 48 hours of issue and then returned to the blood bank from the COVID ward. A dedicated register was maintained by the nursing supervisor in the COVID area to track the blood products returned [17].

Every week, nursing officers, resident doctors, and hospital administration received training in ICU

procedures and job responsibilities. Additionally, a mega critical care workshop was conducted providing training to a group of around 85 resident doctors and nursing officers at a time keeping social distancing measures [18].

A multidisciplinary team of doctors was formed, with round-the-clock receptionists to address family calls. Junior doctors utilized a dedicated phone to update family members on the status of stable patients while for critical patients, physical meetings were arranged at the hospital's spacious reception area to ensure social distancing.

The green hospital building has superior qualities to the general hospital buildings in terms of energy conservation, use of natural resources, clean indoor air quality, green housekeeping, and other characteristics that improved patient outcomes in terms of increased recovery rate and decreased mortality rate shown in figure 5.0 [19,20].

Limitation

The study was conducted during the COVID pandemic, fear and anxiety among the administrators may be one limitation in the formulation of SOPs. All the parameters of the green hospital building were not measured as per the engineering requirements for the green hospital because of the COVID-19 pandemic.

Recommendation

The formulation of the administrative rules and the Standard operative procedures are recommended to be made before starting any work in the hospital. The Green hospital buildings are recommended for their superior characteristics in terms of energy savings, infection prevention methods, and use of natural resources.

Conclusion

The COVID pandemic has presented an unprecedented challenge to healthcare systems. Healthcare organizations faced challenges in various aspects, including infrastructure development and staff training. Protocols were developed based on experiences faced by the healthcare workers. The experiences, the challenges learned, and the solutions made to combat this pandemic will be the guide for future pandemics. The green hospital building proved its supremacy in patient outcomes and is recommended by hospital administrators as a future hospital.

Statements and Declarations

Ethical Approval

The ethical approval of the study was approved by the Institute Ethics Committee, PGIMER, Chandigarh with approval no. NK/6716/MD/069.

Competing Interests and Funding

The authors declare that they do not have any financial or non-financial interests that are directly or indirectly related to this article.

Conflicts of interest

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

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CASE REPORT

Management of a Five-Decades-Old Nonunion of the Ulna: A Rare Case Report

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Abstract

Introduction: Chronic nonunion of fractures, especially of long-duration standing, is challenging to manage. The nonunion of forearm bones is now often effectively treated with open reduction and internal fixation using a plate. **Case report**: A 71-year-old male was presented with a nonunion of the ulna following the fractures of radius and ulna, 51 years ago, which was treated with open reduction and internal fixation, using square nails. Later, an attempt to remove the broken ulnar nail was successful partially. Now, the patient presented with stiffness and decreased range of motion of the elbow and wrist joints, along with features of ulnar nerve palsy. We managed this case by open reduction and internal fixation of the ulna fractures, removal of broken square nail and bone grafting. Additionally, anterior ulnar nerve transposition was done. This treatment resulted in fracture union and neurological improvement. **Conclusion**: This rare case is the longest nonunion ever reported. It demonstrates the complexity of managing long-standing nonunions, through a combined approach of providing mechanical stability and biological augmentation.

Keywords: Fracture fixation; Non union; Ulna fractures; Elbow; Treatment outcomes

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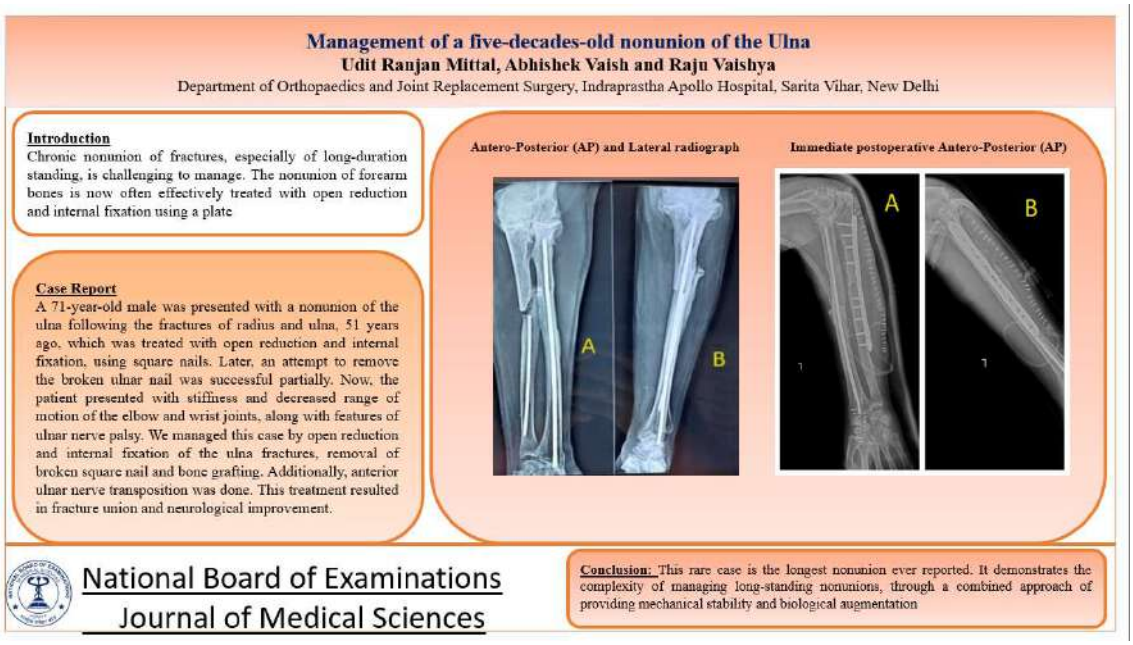
Graphical Abstract



Introduction

Chronic nonunion of long bones, especially of the ulna, presents significant clinical challenges. Nonunion is defined as the failure of a fracture to heal within the expected timeframe, generally between six to nine months [1]. Nonunions lead to a substantial burden to the patients with pain, loss of function and psychological distress with very high medical expenses leading to significant financial loss [2], and these can be of hypertrophic or atrophic types [3].

Around 2-10% of all forearm fractures may complicate and lead to nonunion. Forearm nonunions are problematic due to poor bone mass, previous implants, and joint stiffness due to prolonged immobilization [4]. The fractures occurring in the middle third of the ulna shaft are most prone to nonunion as this region has the poorest blood supply [5]. Forearm nonunion is mostly atrophic and results in a bony defect after removing all the sclerotic bone at the site of un-united bone [6]. In most cases, forearm nonunions can be successfully treated by plate fixation, irrespective of whether it involves the radius, ulna or both bones. Additional bone grafting can be done in cases of atrophic nonunion to enhance the local blood supply [7]. Forearm nonunion is challenging to treat as it requires restoration of length, axis and rotation of the ulna and radius to preserve the stabilizing effect of the soft tissue. With dynamic or locking compression plates, the nonunion rates have been reduced to less than 5% [8]. Intermedullary nails (IM nails) were traditionally used to treat forearm fractures. However, they are generally inappropriate as they cannot provide sufficient rotational stability to this region, leading to higher nonunion rates and the need for additional long-term fixation [9].

We present a rare and significant case report of a 51-year-old long nonunion of the ulna, making it the longest reported and managed nonunion date. This case adds to our understanding of nonunion management and underscores the potential for successful treatment, even in the most challenging cases.

Case report

A 71-year-old male patient presented to us with complaints of inability to lift heavy objects from his left upper limb. He also had stiffness in the left elbow and wrist joints. His complaints started after suffering from an injury to his left forearm, causing fractures of the radius and ulna of the left side around 51 years back, which were surgically managed by open reduction and internal fixation. Initially, his symptoms were not that severe, and he was able to do his day-to-day work, but they started progressing gradually in the last ten years. He also started having progressive weakness in his left hand, which decreased sensations over his little finger and ring finger. His complaints progressed with time and became so severe that he faced difficulties in his day-to-day activities. A healed surgical scar mark was present over the forearm and wrist. There was no tenderness. The range of motion at the elbow joint, especially pronation, supination and elbow flexion, was severely restricted (pronation and supination of 40°, elbow flexion of 50°). His wrist range of motion was also severely restricted.

A wasting of hypothenar muscles and web space was present, along with decreased sensations in the little finger and ring fingers. Mild clawing of the fingers was present. Froment's and ‘card’ signs were present. These findings were suggestive of high ulnar nerve palsy (due to the early elbow injury).

Plain radiographs revealed a nonunion ulnar shaft fracture with a partially removed broken nail in the distal Ulna. The radial fracture was united with an existing nail in situ. The left elbow and wrist joints had evidence of osteoarthritis (OA), with the radial nail impinging the carpal bones (Figure 1). The nerve conduction studies confirmed the diagnosis of chronic sensory-motor axonal neuropathy of the ulnar nerve in the elbow region.

Figure 1. Antero-Posterior (AP) and Lateral radiograph of the forearm showing nonunion of the ulna shaft with a broken nail in the distal fragment and a nail in the radius, with associated arthritic changes seen in the elbow and wrist joint.

Chronic nonunion of ulnar fracture was managed by removing the broken remanent nail and fixing the fracture after freshening the fracture ends and reaming the intramedullary canal of the ulna with one 11-hole low-contact dynamic compression plate (LCDCP) (Figure 2). Autogenous cortico-cancellous bone grafts (harvested from the iliac crest) were also placed around the nonunion site. Left ulnar nerve decompression and anterior transposition were also done.

The postoperative period was uneventful, and the wounds healed by primary intention. Hand, wrist and elbow physiotherapy was started to gain the range of motion (ROM) and muscle strength. Left ulnar nerve palsy started showing an early recovery in the hand sensation. The neurological recovery was significant at three months, and the ulnar fracture showed signs of union (Figure 3).

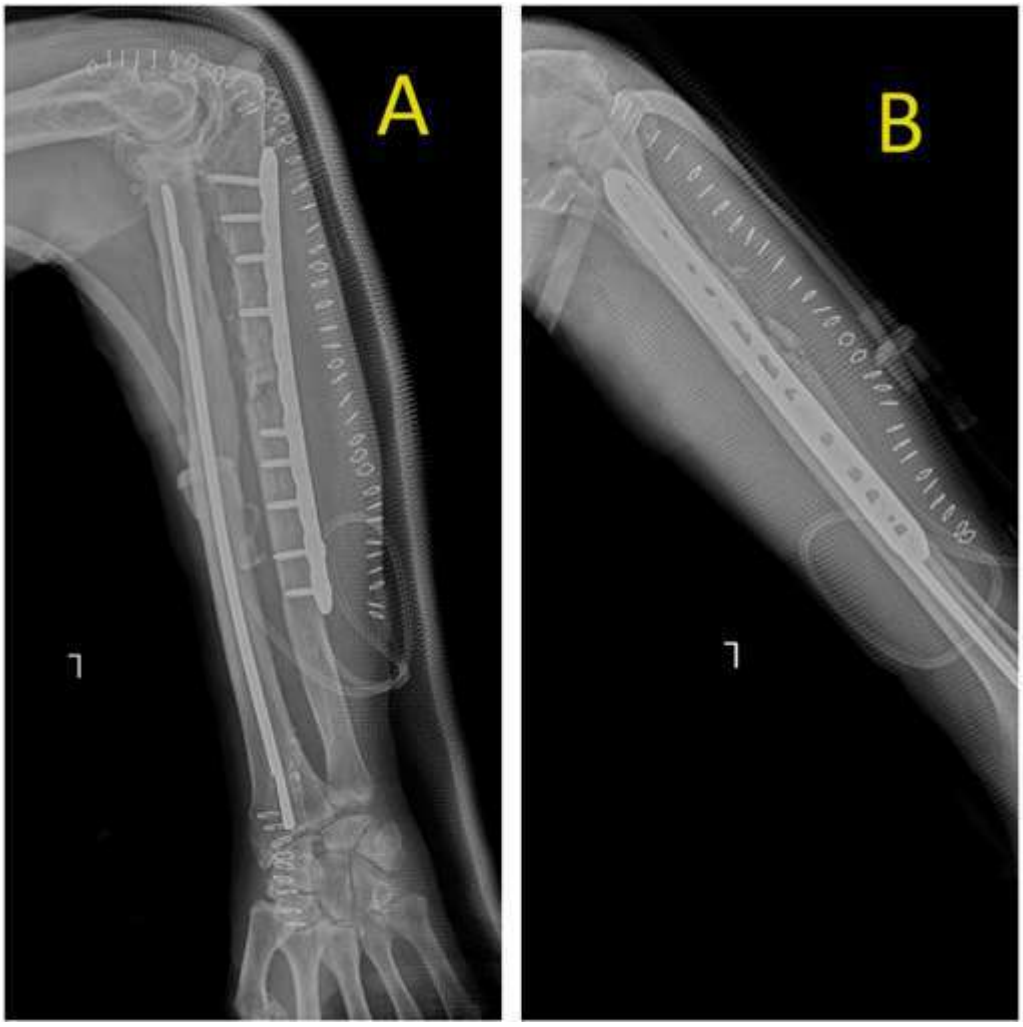


Figure 2. Immediate postoperative Anteroposterior (AP) and lateral forearm radiographs showing fixation of ulnar nonunion with a plate.

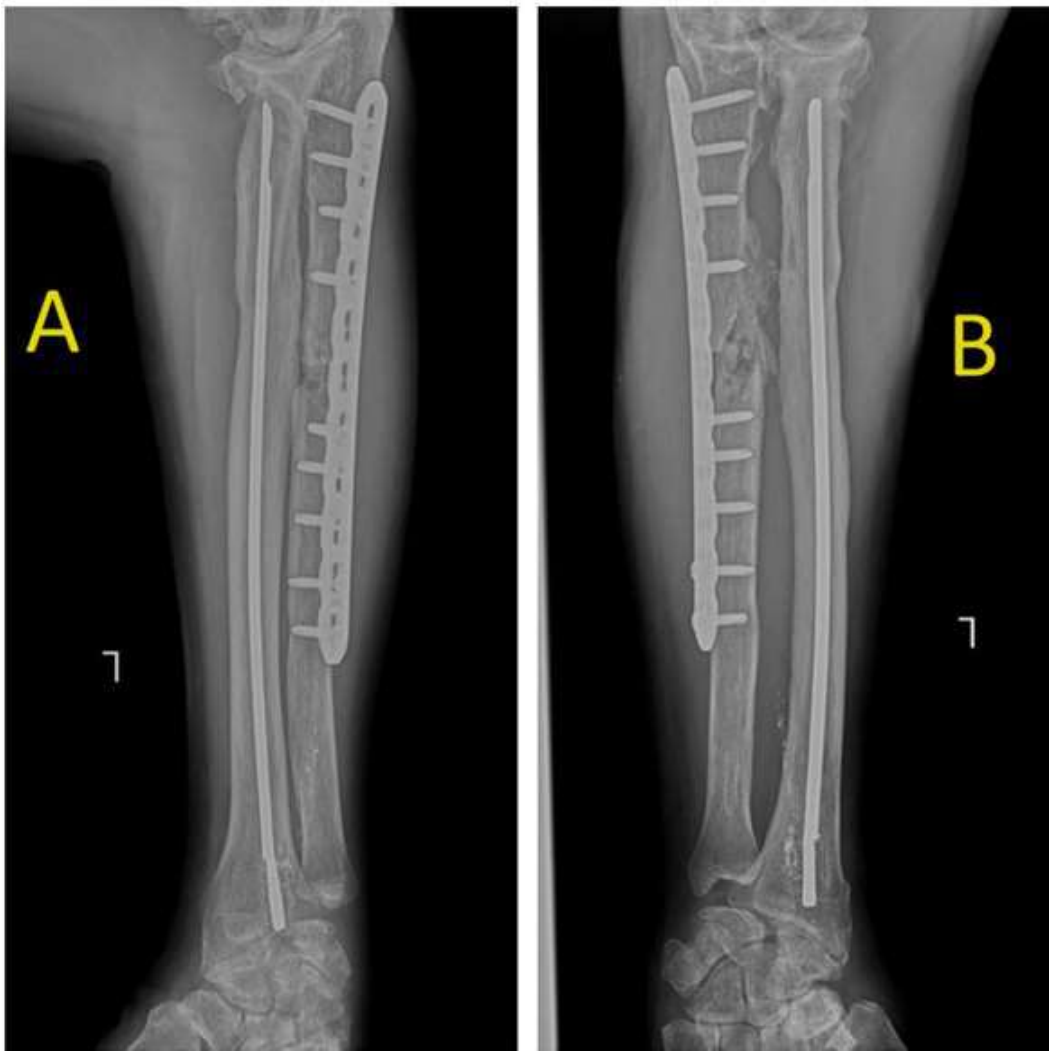


Figure 3. The anteroposterior (A) and lateral (B) X-rays of the forearm at three months follow up showing good progress and signs of union.

Discussion

This case exemplifies the difficulties encountered in managing chronic nonunion of the ulna, given that the forearm represents a distinct anatomical region where all associated bones and structures function as an intricate unit. The primary objective of surgical intervention for forearm nonunion is to restore appropriate bone length, anatomical integrity, and functional capability while alleviating pain. To achieve a favourable outcome in the treatment of forearm nonunion, it is essential to optimize the fracture's biology and the nonunion site's stability [10]. Contributing factors to nonunion may include insufficient initial treatment, biological variables, and the presence of comorbidities in the patient. Surgical approaches incorporating stable fixation and bone grafting have demonstrated efficacy in facilitating union.

In this case, the primary fixation was done with square intramedullary (IM) nails (Stainless steel- Talwalkar's nail). The IM nailing may have certain advantages,

such as lower risks of infection, lesser duration of surgery and small scars, but older implants, like square nails, did not provide adequate rotational stability and had nonunion rates of more than 10% [11], which are comparable to non-operative management [12,13].

The reported long-duration nonunion of long bones is relatively rare and often anecdotal. Cases of nonunion persisting for decades have been documented, but specific durations can vary widely**.** For instance, some reports have documented nonunions persisting for over 30 years. The 51-year duration of nonunion described in our case report is among the most protracted documented cases. Initial displacement in cases of ulna fracture is directly related to the chances of nonunion. There is a 20% chance of nonunion if the displacement is more than half of the diameter of the shaft [5].

Kloen et al. [14] conducted a comprehensive review of a substantial cohort of forearm nonunions, with durations ranging from 2 to 312 months. Their treatment approach involved meticulous debridement, the removal of unsuccessful hardware, and the restoration of proper alignment, length, and rotation. They emphasized the importance of stable fixation, preferably through compression, and optimising a conducive environment for bone formation, including bone grafting when necessary. This multifaceted strategy facilitated the healing of all nonunions within 18 months following the initial procedure.

A debate exists between the use of a plate or a nail. Plating requires extensive soft tissue dissection that compromises the blood supply. Also, osteoporosis at the fracture site may result in inadequate screw purchase leading to inadequate fixation making it less suitable for fixation in older patients. Hong et al. [15] treated 26 diaphyseal fracture nonunions of forearm bones, with IM nailing (‘Foresight’ interlocking intermedullary nail system (Smith and Nephew, Memphis)) resulted in 96% of radiological union with a mean healing time of 14-15 weeks for radius and Ulna. Interlocking IM nailing adds to anti-rotational control, preventing the nail from backing out**.** It is a stress-sharing device that increases peri osteal vascular reaction, leading to better healing than standard interference-fit-forearm nails. However, this technique was inferior to the plate and screw fixation as it required prolonged immobilization, which led to loss of function and stiffness.

Nonunion epidemiology is variable and could be related to patient-dependent and independent risk factors (Table 1).

Table 1. Factors related to Nonunion of Fractures

NonunionFactors	Risk factors
Patient Dependent	• Advancing age • Steroid use • Smoking • Metabolic diseases • Nutritional deficiency

Patient Independent	• Fracture pattern and location • Severity of soft tissue injury • Bone loss • Infection • Quality of surgical fixation

Successful management of chronic nonunion requires a comprehensive strategy incorporating surgical procedures, biological enhancement, and careful postoperative management. The "diamond concept" also emphasizes the significance of mechanical stability and the biological milieu, equally. The healing of a fracture is dependent on the favourable biological environment at the fracture site like the availability of molecular mediators, progenitor cells, extracellular matrix, and immunoregulatory cells etc. An optimal mechanical environment is also equally crucial by providing adequate fracture stability, thereby promoting a physiological process that allows fracture healing [1].

Conclusion

We present a rare case of a 51-year-old chronic ulna nonunion, It was successfully managed by employing a combination of biological and mechanical strategies. The prolonged duration of this nonunion highlights the effectiveness of surgical principles in addressing even the most resistant and chronic cases.

Statements and Declarations

Conflicts of interest

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

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CASE REPORT

Obscure Rare Cause of Recurrent Angina in Post CABG Patient: Coronary-Subclavian Steal Syndrome

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Abstract
Coronary subclavian steal syndrome (CSSS) is a rare and unrecognized complication of coronary bypass grafting surgery when a left internal mammary artery (LIMA) graft is utilized for left anterior descending (LAD) artery revascularization without knowing left subclavian artery status. We describe a case of a 67-year-old male, with a known history of triple vessel coronary artery disease (CAD) managed with CABGx3 in March 2003. The patient presented after 16 years with complaints of recurrent angina for the past 15 years which aggravates on exertion, especially of left hand. Recurrent hospitalizations and repeated Coronary angiograms (CAG) as well as CT Coronary angiography failed to diagnose the cause of angina. Subclavian angiography and subsequent methodical clinical examination during the present admission revealed left subclavian origin stenosis which was successfully revascularized by deployment of a stent resulting in convincing relief in the patient's angina.

Keywords: Coronary subclavian steal syndrome, left internal mammary artery, coronary artery bypass graft surgery, coronary artery disease

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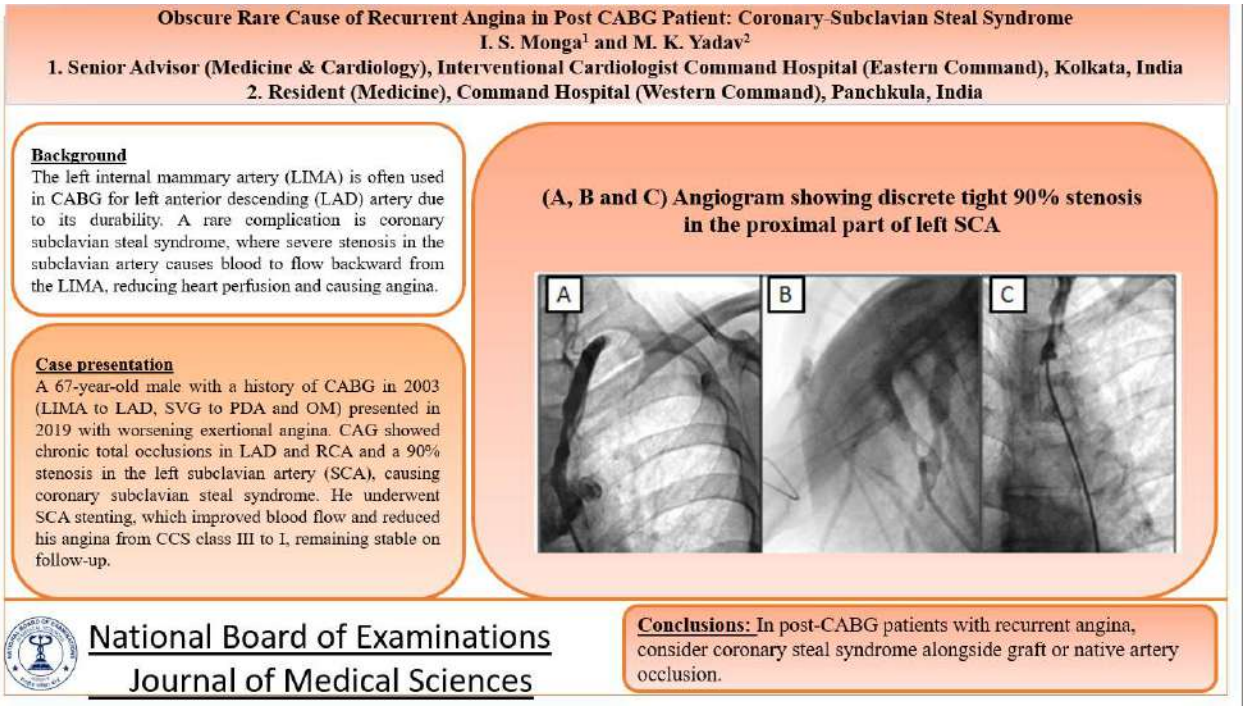
Graphical Abstract



Introduction

The left internal mammary artery (LIMA) is frequently used as a graft for left anterior descending (LAD) artery revascularization during coronary artery bypass graft surgery (CABG) because of long-term graft survival and superior patency rates [1]. Rare complications of CABG surgery with LIMA as the graft is coronary subclavian steal syndrome. It is characterized by severe stenosis of the proximal subclavian artery (SCA) which results in decreased myocardial perfusion due to retrograde blood flow from LIMA to the proximal subclavian artery for maintaining perfusion of upper extremity. This 'stealing' of blood by retrograde flow to subclavian artery through LIMA induces ischemia and results in angina due to compromised myocardial perfusion.

Case Presentation

We describe a case of a 67-year-old male, reformed smoker with a history of hypertension and triple vessel coronary artery disease (CAD) with a history of CABGx3 in March 2003 (LIMA to LAD and SVG to PDA and OM) who presented to cardiology OPD at this hospital on 01 Oct 2019 with moderate intensity left sided recurrent anginal chest pain since 2004 which aggravates on exertion, especially with left hand. For the initial year after CABG patient was right when he developed angina on exertion which was managed conservatively with anti-anginal medications with some symptomatic relief. However, he continued to be symptomatic with gradually progressive exertional angina and presented to the cardiac center in June 2011. His check coronary angiography (CAG) revealed complete total occlusion (CTO) of mid-LAD, proximal right

coronary artery (RCA), and patent LIMA and reversed saphenous vein graft (rSVG) to PDA and OM. His 2D Echocardiography revealed a left ventricular ejection fraction of 45%. So he was continued on antianginal drug therapy only. He was again admitted in Jan 2017 with similar complaints of worsening exertional angina and a check CAG (04 Jan 2017) again revealed CTO of LAD and RCA, 50-60% lesion in proximal left circumflex artery (LCX), 50% lesion in the proximal ramus, ostial LMCA plaque with patent LIMA to LAD and blocked rSVG to PDA and OM from ostium. The patient was therefore sent for CT Coronary angio before deciding on any further invasive treatment. Coronary CT angiography showed patent LIMA to LAD graft with normal caliber and adequate distal opacification and non-opacification of rSVG graft to PDA. Thereafter he was sent for stress myocardial perfusion imaging (MPI) with ^{99m}Tc MIBI (Feb 2017) showing fixed perfusion defect in the apex, adjoining septal and inferior wall, and left ventricular dysfunction which was aggravated on stress. He was still kept on maximal medical management siting fixed perfusion defect in RCA and OM territory. However, he continued to have progressive symptoms despite maximal medical therapy and reported to cardio OPD on 01 Oct 2019. This time we admitted him for check CAG given severe anginal symptoms despite maximal medical therapy.

Routine hematological and biochemical investigation revealed elevated serum urea (69 mg/dL), and creatine (1.96 mg/dL). Total cholesterol- 255 mg/dL (LDL 172 and triglyceride- 210 mg/dL), CKMB- 28 IU/L and LDH- 513 U/L. Urine routine and microscopic tests were within normal range. His USG KUB revealed a small-sized left kidney with increased cortical echogenicity with loss of cortico-medullary differentiation. Electrocardiogram (ECG) revealed sinus bradycardia, QS in V_1-V_4, T wave inversion in I, aVL, and V_2-V_6(no new ST or T wave changes compared to previous ECG). 2- D echocardiography revealed left ventricular ejection fraction (LVEF) of 45% with anterior wall hypokinesia, concentric left ventricular hypertrophy (LVH) and mild mitral regurgitation.

CAG was done after contrast-induced nephrotoxicity (CIN) prophylaxis on 03 Oct 2019 which revealed CTO of mid-LAD and distal-RCA, 50% plaque in proximal ramus and ostial LMCA (Figure 1A), patent LIMA to LAD (Figure 1B) and complete ostial occlusion of rSVG to PDA and OM (absolutely no change in status since CAG done in Jan 2017). However, after profiling of LIMA, as the diagnostic JR catheter was being pulled back into the aorta, a highly significant pull-back gradient ≥ 90 mm Hg was noted at the origin of the left SCA. Further profiling of the left SCA with the same catheter at the ostia of Lt SCA revealed discrete tight 90% stenosis in the proximal part of the left SCA (Figure 2). Therefore, this patient was now found to be suffering from focal stenosis at the first part of Lt SCA as the cause of his recurrent angina and was planned for peripheral angioplasty of Lt SCA at a subsequent date. Detailed physical examination was carried out which was probably missed during all previous OPD or IPD visits. Physical examination revealed a feeble left radial and brachial pulse. An inter-arm blood pressure difference of 95 mmHg

systolic (187/85 mmHg in the right arm and 92/53 mmHg in the left arm) was present. However, no supraclavicular bruit could be heard. On direct questioning, the patient also gave a history of an increase in angina pain while using the left upper limb.

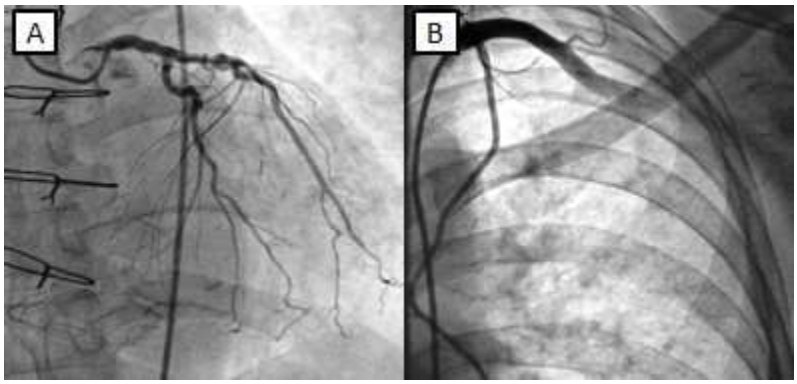


Figure 1. Coronary angiogram showing CTO of mid-LAD and distal-RCA filling retrogradely, 50% plaque in proximal ramus and ostial LMCA (A), patent LIMA to LAD (B)

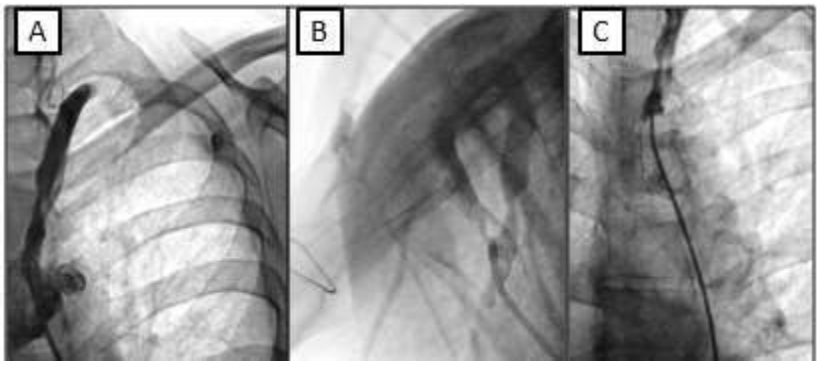


Figure 2. (A, B and C) Angiogram showing discrete tight 90% stenosis in the proximal part of left SCA

Thus, our patient was diagnosed with coronary subclavian steal syndrome as a rare and obscure but treatable cause of recurrent angina among patients who had undergone CABG in the past. He was therefore managed by left subclavian artery stenting on 10 Oct 2019 at our hospital with an 8x37 mm scuba BMS stent (Figure 3). Post procedure good flow was achieved across the stent and through LIMA graft. The patient also showed symptomatic improvement from CCS class III to CCS class I post-procedure. He was on regular follow-ups at 1, 3, 6, and 11 months and continues to be in CCS class 1 despite reducing his anti-anginal therapy.

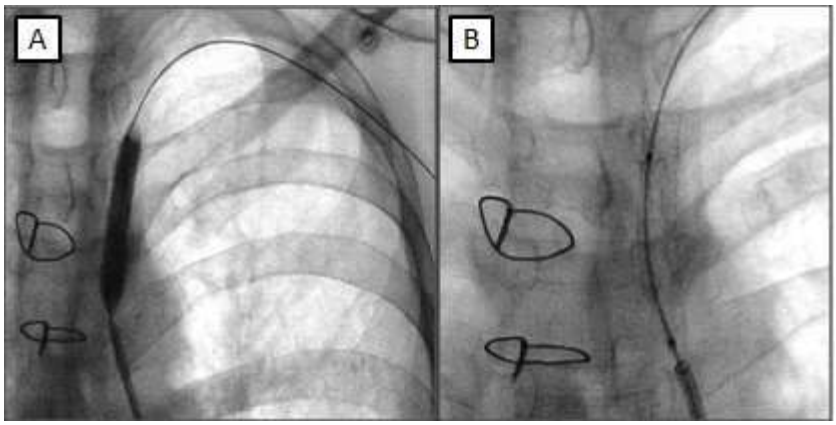


Figure 3. (A and B) Left subclavian artery stenting with 8x37 mm scuba BMS stent

Discussion

Coronary subclavian steal syndrome (CSSS) is caused by atherosclerotic stenosis of the proximal part of the subclavian artery before the LIMA graft. Reversal of blood flow from LIMA to left SCA results in myocardial ischemia in post-CABG patients [2]. Atherosclerosis of native coronary vessels and disease in the graft vessels are the main causes of angina in post-CABG patients. Compromised myocardial perfusion due to CSSS should be kept in differentials for angina in the post-CABG patient [3]. Harjola and Valle first described coronary subclavian steal syndrome in 1974 [4].

Although CSSS commonly presents as recurrent episodes of angina after upper limb stress it may be asymptomatic occasionally and can manifest with a myocardial infraction, heart failure, silent ischemia, vertebrobasilar insufficiency symptoms such as dizziness, ataxia, syncope, blurring vision, ataxia, numbness, drop attacks and upper extremity claudication. Individuals have been reported to present with symptoms between 2-31 years following intervention and presentation within a year following CABG is suggestive of the missed stenotic lesion during initial surgery [5]. Various causes of CSSS include ipsilateral subclavian artery stenosis, Takayasu arteritis, radiation arteritis, and hemodialysis AV fistula [6,7]. The various risk factors for CSSS include advanced age, smoking, hypertension, diabetes mellitus, and non-subclavian vascular calcification [8,9]. CSSS should be suspected in an individual with a history of peripheral vascular disease associated with the presence of more than 20 mmHg inter-arm pressure difference [10]. Noninvasive imaging modalities for CSSS include duplex ultrasonography of supra-aortic vessels, computed tomography and MRI. Proximal aortic arch arteriography is gold standard for the definitive diagnosis of CSSS which shows the presence of flow reversal, including complete retrograde flow in the LIMA.

CSSS can be avoided by using vein conduits and radial artery conduits for CABG. Surgical and radiological-guided endovascular procedures are available methods for the management of CSSS. Preoperatively detected SCA stenosis can be combined with direct subclavian artery bypass surgery. Post-operatively diagnosed

SCA stenosis should be managed with percutaneous angioplasty and stenting like in our case. The radiological endovascular revascularization approach with percutaneous transluminal angioplasty (PTA) and peripheral stenting is the first line of treatment for SCA stenosis [11,12]. These radiological procedures do not require general anesthesia, are minimally invasive, have a shorter hospital stay, and decrease morbidity and mortality [11,13] when compared to surgical bypass techniques. Recurrent stenosis rate is low with stenting as compared to angioplasty [13,14]. In patients with complete occlusion of SCA, surgical procedures such as carotid-axillary, carotid-subclavian, aorta-subclavian, and axilla-axillary bypasses, as well as transposition of the internal mammary artery could be done [15,16]. These are the only option for revascularization despite the relatively high risk of procedures, as Carotid-subclavian bypass has a mortality rate of 0% at 30 days, 82% symptom-free survival rate at 5 years and 92% and 95 % primary and secondary patency rate at 10 years [16,17]. Indications for surgical bypass procedure include complete occlusion near the ostium of the vertebral artery, severe calcification of lesion with a length more than 5 cm, and concomitant brachiocephalic and coronary artery disease [15,18]. Peripheral stenting was preferred over carotid subclavian artery bypass in our patient as it is more feasible, minimally invasive and technically less difficult.

Conclusion

In post-CABG patients presenting with recurrent episodes of angina, a differential of coronary steal syndrome should always be kept in mind other than native coronary artery or graft vessel occlusion. History followed by a thorough physical examination is generally sufficient to diagnose CSSS. However, due to the heavy workload of OPD patients, clinical examination is generally overlooked leading to diagnostic dilemmas like in the present case. Moreover, LIMA ostium and subclavian artery ostium must always be profiled before referring patients for CABG and we should always look for pull back gradient while withdrawing the catheter in our case, this was the only clue that helped us reach the diagnosis. CT Coronary angiography if done in post-CABG patients should also include the ostial part of grafts as well as the subclavian artery to rule out significant stenosis. Such patients once diagnosed can be managed with peripheral stenting as in our case.

Statements and Declarations

Conflicts of interest

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

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Authors Contributions

All the authors have contributed equally to the work and fulfil ICMJE authorship criteria. All the authors have reviewed the final draft and approved the same.

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CASE REPORT

Death Due to Homicidal Paraquat Poisnong: A Case Report

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Abstract

Background: Paraquat is a widely used herbicide that raises a significant public health concern due to its extreme toxicity even at low doses and its potential for criminal poisoning. However, most of the research is concentrated on pulmonary toxicity of the compound so far, ignoring its other systemic effects. Moreover, a perfect antidote for this poisoning remains still at large. **Case Presentation:** In this case report, we present probably the first case of criminal paraquat poisoning in India, involving a 40-year-old man who was poisoned by family members with paraquat-laced alcohol. Although the patient initially appeared to be recovering, his condition worsened, and he died from multi-organ dysfunction syndrome (MODS). **Discussion:** Paraquat poisoning presents with a spectrum of clinical features, mainly affecting the lungs and kidneys, often leading to respiratory and renal failure. However, its toxicity extends to other organs like liver causing toxic hepatitis that prompts us for a proper diagnosis and management. Current research and management protocols tend to neglect the hepatic and renal toxicities, focusing primarily on pulmonary fibrosis. The manufacture and sale of paraquat in India needs to be reviewed in the light of increasing global bans of this compound. There is also a pressing need for antidote research in dealing with agrochemical substance abuse, particularly paraquat. **Conclusion:** The emergence of paraquat as a lethal homicidal poison highlights the need for stringent regulations and proactive measures to safeguard public health. The whole saga of chemical/pesticide regulation in our country is very naïve when compared to the global standard. It is time to foster collaboration between regulatory bodies, healthcare professionals, and researchers to address the menace of *'paraquat deaths'* in India.

Keywords: Paraquat, Criminal poisoning, Homicide, Herbicide, Dithionate test, Forensic Toxicology

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Introduction

Paraquat dichloride, scientifically labelled as N,N′-dimethyl-4,4′-bipyridinium dichloride, is an organic compound with the chemical formula [(C6H7N)2]Cl2 [1]. It is extensively utilized across the globe as an herbicide in agriculture. The mechanism of action of paraquat is due to its uptake by cells where it produces toxic reactive oxygen species, leading to oxidative stress and cellular damage/death.

Paraquat (PQ) is emerging as a one of the largely abused agrochemical for self-harm in India. It has always been a matter of concern for clinicians because this compound is extremely lethal in even small doses (5-10 ml/one sip) and the research community is equally worried about developing a reliable antidote for this. In addition, there were instances of accidental exposure to PQ during agricultural activities or while handling it at manufacturing sites. Although PQ was sporadically misused for criminal poisoning in other parts of the world, there were no documented cases of its intentional use for homicide in India, except for an unsuccessful attempt involving a child [2]. Here, we present the first documented case of fatal homicidal PQ poisoning in an adult in India.

Case Report

A 40-year-old man was poisoned with paraquat while consuming alcohol by his family members, who colluded to permanently eliminate him. According to the deceased's statement, his wife had engaged in an extramarital affair, leading to heated arguments and marital discord between them. Subsequently, his wife, father-in-law, and brother-in-law conspired together and mixed paraquat into the alcohol consumed by the deceased. The incident took place at the deceased's residence. The investigation revealed that the motive for the murder was to get rid of him due to his constant questioning of his wife's fidelity, his lack of involvement in any gainful employment to contribute to the family expenses, and his excessive spending on alcohol. However, the deceased remained unaware of this until his condition deteriorated, leading to his hospitalization four days later. Additionally, the deceased had been attacked by his father-in-law and brother-in-law six years earlier, resulting in a scuffle and the deceased sustained an upper limb fracture (specific details regarding the site and side of the fracture are unavailable).

The deceased presented at the healthcare facility with complaints of abdominal pain, decreased urine output, yellowish discoloration of conjunctivae and urine, and vomiting for the past 4-5 days. There is no significant past medical history available on record. He is a known alcoholic for the past 10 years. On physical examination, icterus was present, and the blood pressure was 99/60 mmHg. Cardiovascular, central nervous system, and respiratory system examinations were normal. Laboratory data at the time of admission showed TC: 16,700/µL, RFT: serum creatinine at 9.2 mg/dL, blood urea at 264 mg/dL, LFT: AST at 381 IU/L, ALT at 481 IU/L, ALP at 202 IU/L, total bilirubin at 12.8 mg/dL, and RVAB 1 and 2 non-reactive. Serum electrolytes were within normal limits and coagulation profile data is unavailable. The ultrasound of the abdomen and pelvis detected grade 1 renal parenchymal disease and a 6mm calculus in the right kidney (the exact location is not mentioned by the radiologist), thickened gall bladder, and

minimal free fluid in the pelvis. The initial working diagnosis was acute febrile illness with acute kidney injury, and attempts were made to rule out leptospirosis, scrub typhus and other related diseases with similar presentation. However, the associated upper GI bleed and oral mucosal erosions made the attending physician become sceptical about the infectious aetiology. Eventually, the diagnosis of poisoning of unknown origin was made through a thorough history collection process by the physician. The case was subsequently registered as a Medico-Legal Case (MLC), involving police authorities. The deceased himself went to the police station and lodged a complaint about the issue after the attending physician raised suspicions of poisoning in this case during his hospital stay before his condition worsened. Further investigation revealed that the deceased was criminally poisoned with paraquat laced with alcohol. The deceased succumbed to Multi-Organ Dysfunction Syndrome resulting from Acute Kidney Injury and Toxic hepatitis one week after admission to the hospital despite several attempts of haemodialysis and transfusion of fresh frozen plasma. An autopsy was conducted accordingly to ascertain the exact cause of death.

At autopsy, the deceased appeared moderately built and moderately nourished. The body exhibited a yellowish tinge overall, with yellowish conjunctivae. Brownish-red fluid was observed emanating from the mouth and nostrils. Ulcerations were noted throughout the oral mucosa and lips. Upon dissection, both lungs were deeply congested and emitted brownish-red fluid upon sectioning. The liver appeared yellow, enlarged, and gritty upon sectioning. Both the kidneys appeared grossly congested on cutsection. The left ventricular wall of the heart measured 2.4 cm. The lumens of both coronary arteries were patent, with thickened walls, and the aorta exhibited atherosclerotic changes at some sites. Approximately 50 ml of brownish-red fluid was found in the stomach. Viscera were preserved for chemical analysis, including the liver, kidney, stomach and its contents, small intestine and its contents, and blood. Histopathological examination of the lung revealed features of congestion and dilated alveolar spaces. The liver showed congestion and fatty changes histologically whereas the kidneys also showed congestion and oedematous parenchyma. Chemical analysis of the viscera tested positive for paraquat (qualitative analysis) even at about 2 weeks post poisoning. Similarly, a glass of paraquat-laced liquor was seized at the crime scene after autopsy, which also revealed paraquat and ethyl alcohol upon chemical analysis. Quantitative analysis of paraquat was not possible due to resource constraints, both for clinical and forensic purposes. Additionally, the urine dithionate test was not performed during the hospital stay. The cause of death in this case was opined as *"due to paraquat poisoning as per available evidence on record"*. All the accused in this case later admitted to poisoning the deceased while he was consuming alcohol, intending to kill him due to his disruptive and irresponsible behaviour towards family members. Consequently, they were charged with homicide, and the case is currently under legal proceedings.

Discussion

In this case, the patient initially appeared normal for four days after being criminally poisoned with paraquat which is

quite commonplace in practice. The reason why poisoned victims may appear normal after consumption can be attributed to the variations in both the concentration and quantity of PQ consumed. This variability scientifically explains the differing onset times for symptoms, ranging from immediate effects to delayed manifestations. It's common for paraquat poisoning patients to remain asymptomatic for a considerable period (a few hours to days) before the prodromal acute gastroenteric illness-like symptoms begin to manifest. These symptoms then slowly transform into renal failure and respiratory failure/ Multi Organ Dysfunction Syndrome (MODS) as the condition worsens. This is a critical consideration to be borne in mind when discharging patients with paraquat poisoning from hospitals. Point-of-care physicians may occasionally discharge seemingly stable patients who later return in a deteriorated condition. Furthermore, there is an increasing trend of concealed paraquat poisonings in India. Urban, well-educated individuals are obtaining paraquat from online markets, consuming it in small doses for committing suicide, and keeping it undisclosed to others. They only inform their treating doctors about it when the situation deteriorates further and are on the verge of death. This has become a method of clandestine suicide poisoning for some individuals who wish to make their deaths appear as though it was caused by illness rather than intentional poisoning [3].

Paraquat poisoning can mimic various pathological conditions, and incidents of using this lethal herbicide for criminal purposes are increasing globally, with several reported cases [4-9]. The signs and symptoms of paraquat ingestion can resemble other conditions and need differentiation. Paraquat poisoning manifests with a spectrum of clinical features, with pulmonary and renal toxicities being predominant and often contributing to mortality. Gastrointestinal symptoms, though common, are sometimes overlooked as a cause of mortality due to erosion and perforation. Early signs may include the characteristic "Paraquat tongue," along with oesophageal and gastric erosion, accompanied by nausea and vomiting. Pulmonary complications arise due to paraquat distribution to pneumocytes, leading to pneumonitis, Acute Respiratory Distress Syndrome and, in delayed cases, pulmonary fibrosis. Finally, it may result in a multiorgan failure which is usually associated with acute renal injury, hepatic shut down, myocardial injury and internal bleeding. Timely identification and management are crucial in reducing the fatal outcomes of paraquat poisoning.

Oropharyngeal burns, a major sign, can also occur in other herbicidal ingestions, burns, infections like aphthous ulcers, herpes simplex, tonsillitis, and chemotherapy induced toxicity. Acute dyspnoea must be differentiated from emergent pulmonary conditions such as airway obstruction, aspiration, cor-pulmonale, pneumonia, pulmonary embolism, pulmonary hypertension, tension pneumothorax, cystic fibrosis, and cardiac conditions like cardiac tamponade, cardiogenic pulmonary oedema, myocarditis [1]. The diagnostic dilemma in recognising paraquat poisoning lies in the initial clinical presentation of nonspecific symptoms like buccopharyngeal ulcers, sore throat, and vomiting that mimic a natural illness. The treating physician might misdiagnose it as influenza, diphtheria, or dermatitis, leading to delays in PQ

poisoning management. The point of care medical officers should have a high index of suspicion to think on the lines of poisoning especially in cases where proper history isn't available.

If we look at the medical literature, ongoing research, and poisoning management protocols, much is discussed about paraquat lung, while the toxic effects on the kidneys and liver have often not been given proper consideration. Instead, disproportionate attention has been given to Acute Respiratory Distress Syndrome and lung fibrosis. The initial impact of paraquat poisoning is typically observed in the kidneys, resulting in acute kidney injury, often followed by toxic hepatitis in many patients. However, in cases of minor dosage consumption, renal toxicity tends to be self-limiting, with patients exhibiting favourable responses to haemodialysis and avoiding further progression to Multi-Organ Dysfunction Syndrome (MODS). This has led some practitioners to rigorously pursue haemodialysis, although its benefits in high dose/concentration paraquat poisoning are equivocal [11]. There is a pressing need for research on prognostic and mortality indicators in the management of paraquat poisoning. It has been observed by several physicians that aspiration of paraquat during ingestion and extensive GI burns are a few indicators of worse prognosis [1].

As paraquat increasingly becomes a tool for homicide, it is imperative to reconsider regulations regarding its sale in India. Given its significant toxicity to humans, it warrants classification as a highly toxic compound, necessitating a national emphasis on research aimed at minimizing its usage, addressing packaging and labelling concerns, and ultimately phasing it out with sustainable alternatives in agriculture practices. The packaging should prominently display hazard indicators like it is usually displayed on tobacco products. Furthermore, the implementation of technology-based consumer tracking and the employment of digital suicide prevention surveillance are essential in the current context. The ongoing debate about the connection between paraquat exposure and Parkinson's disease remains a controversial issue and adds weight to paraquat ban argument [12].

Various potential antidotes have been identified for management of paraquat poisoning, but antidote research faces limitations due to the substance's unique mechanism of action involving redox cycling and the generation of reactive oxygen species, which are highly toxic at the cellular level. Effective antidotes should aim to either bind to the substance and render it inert or disrupt the cascade of events leading to cellular and molecular toxicity. Further research in mechanistic toxicology of PQ is necessary.

In a medico-legal setting, relying solely on qualitative toxicology data may not suffice. Quantitative data regarding paraquat levels is preferable, despite literature indicating that even a small amount can be lethal. The challenges in quantifying paraquat or its residues in bodily fluids, attributed to factors such as time elapsed and metabolism, are significant considerations within the domain of autopsy toxicology. However, a clinically positive dithionate test, coupled with paraquat detection in body fluids before death, can significantly aid forensic pathologists in determining the cause of death, apart from utilizing the chemical analysis of viscera following autopsy. It's worth noting that while a pathologist can confidently identify the cause of death,

establishing the method/manner of poisoning rests with the law enforcement agencies and always requires additional evidence.

This case report represents the first documented instance of homicidal poisoning involving paraquat in India. It is noteworthy in the context of forensic toxicology and public health awareness. The only other comparable reported incident involved an unsuccessful attempt by a grandmother to poison her 4-year-old grandchild with paraquat [2]. This case underscores the importance of vigilance in detecting and managing paraquat poisoning, particularly in cases involving deliberate harm.

Conclusion

With paraquat emerging as a lethal homicidal weapon, urgent measures are warranted to regulate its sale and use in India. Considering its potential for self-harm and homicide, a ban on this substance should be seriously considered, with efforts directed towards identifying economical alternatives in agriculture. Emergency physicians must remain vigilant, as paraquat poisoning can masquerade as a medical illness, necessitating a high index of suspicion for accurate diagnosis. In cases of uncertainty, the urine dithionate test stands as a crucial point-of-care diagnostic tool, guiding appropriate treatment protocols. However, the persistent lack of an effective antidote for paraquat underscores the pressing need for further research in this area. As we navigate these challenges, it's imperative that regulatory bodies, healthcare professionals, and researchers collaborate closely to mitigate the grave consequences of paraquat poisoning and safeguard public health.

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Conflicts of Interest

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

Ethical Considerations

All ethical concerns should be addressed to the authors.

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CASE SERIES

Rare Chromosomal Variants in Males with Hypogonadism: A Case Series From Tertiary Hospital in India

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Abstract
Male hypogonadism refers to decrease in testosterone levels due to diminished activity of testes. Hypogonadism will result in infertility, absent or poor secondary sexual characteristics and abnormal genitalia. One of the important causes of male hypogonadism is sex chromosomal abnormalities. In present study we discuss 5 cases of hypogonadism which has resulted due to rare sex chromosomal abnormalities. Identification of these abnormalities is very important in management of these patients.

Keywords: Hypogonadism, sex chromosomal abnormalities, infertility, Klinefelter syndrome

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Introduction

Male hypogonadism results from decreased activity of testes resulting in inadequate production of testosterone. In primary hypogonadism, there will be low testosterone levels with higher or normal FSH and LH levels. Main causes of primary hypogonadism include Klinefelter syndrome, anatomic causes, iatrogenic injuries, and tumors. In secondary hypogonadism, there will be low testosterone with low to low-normal LH and FSH levels. Main cause of this type of hypogonadism lies in defects related to pituitary gland. Chromosomal abnormalities resulting in altered sex hormone levels are one of the important causes of male hypogonadism. Common sex chromosomal abnormality resulting in hypogonadism is Klinefelter syndrome [1,2]. Klinefelter syndrome is the most frequent genetic cause of male infertility, and is found in 11% of azoospermic men and 4% of infertile men [3]. In consanguineous marriage, mutation in genes causing meiotic disjunction can result in chromosomal abnormalities resulting in hypogonadism. Identification of causes of hypogonadism will help clinician for hormone replacement therapy as well as to decide on assisted reproductive techniques in cases of infertility.

Case Series

We present 5 cases of hypogonadism showing rare sex chromosomal abnormalities who presented to Division of human genetics, Department of Anatomy, St. John's medical college, Bangalore from 2020-2021.Out of 5 cases, 3 cases presented as primary infertility and 2 cases presented as abnormal external genitalia. As a routine, hormonal levels were performed in these patients which showed low testosterone levels. Ethical clearance was taken from institutional ethics committee and informed consent was taken from the patients. A detailed history was taken and both general and systemic examination was carried out. The patients denied any personal history of mumps, HIV, or testicular torsion, no exposure to radiation, chemotherapy and chronic medications. This ruled out acquired causes of primary hypogonadism. Blood samples of these patients were subjected to standard protocol for karyotyping and Fluorescent in situ hybridization (FISH) to screen for chromosomal abnormalities.

Case 1

34-year-old male, born to third degree consanguineous parents, married for 3 years presented with complain of primary infertility. On examination, secondary sexual characteristics were not well developed. He had proximal hypospadias, chordee with bilateral atrophic scrotal testes. Investigation showed low levels of testosterone. Scrotal scan showed bilateral small sized testes, bilateral varicocele. His karyotype was 46,XX confirming 46,XX testicular disorder of sex development (Figure 1). Karyotype of wife was normal.

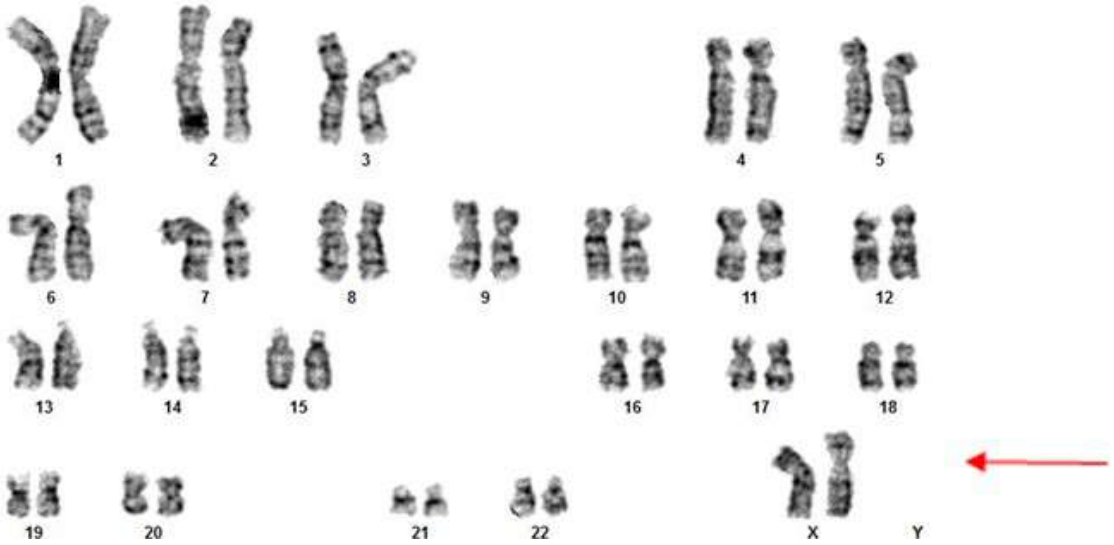


Figure 1. Karyotype of a male patient with hypogonadism showing 46,XX karyotype(Case 1).

Case 2

17-year-old male child born to a non-consanguineous marriage was referred for karyotyping with ambiguous genitalia. Hormonal profile showed low testosterone levels. Scrotal scan revealed bilateral small volume testis. Chromosomal analysis showed mosaic pattern with 29 cells with 45,X Karyotype and 21 cells showing 46,X,+mar. Marker was identified as Y chromosome with deletion on the Yq in mosaic pattern with positive SRY gene on marker. Presence of Y chromosome confirmed diagnosis of mixed gonadal dysgenesis (Figure 2).

Case 3

43-year-old male married for 7 years was referred for karyotyping with history of primary infertility. On examination he had bilateral gynecomastia and absent secondary sexual characteristics. His semen analysis showed azoospermia. Karyotyping showed mosaic variant of Klinefelter syndrome. Out of 25 metaphase spreads analysed, 4 spreads showed a normal 46,XY karyotype and 21 spreads with 47,XXY karyotype. Karyotype of wife was normal (Figure 3).

Case 4

38yr old male, married (consanguineous) for 13yrs was referred for karyotyping with history of primary Infertility. On examination he had bilateral gynecomastia and absent secondary sexual characteristics. Hormonal profile showed decreased testosterone levels with high FSH and LH levels. Semen analysis showed Azoospermia/ cryptozoospermia. Chromosomal analysis showed mosaicism with 47,XXY [33]/48,XXY,+mar[17] suggestive of Klinefelter syndrome. FISH probes (X/Y centromeric and X/Y WCP) were used to identify the marker chromosome, but both probes did not hybridize on the marker and normal signals for X and Y was seen. Y microdeletion studies was also done and it showed the presence of all the 3 regions on the Y chromosome. Spectral karyotyping was suggested to find out origin of marker chromosome. Spectral karyotyping showed

marker chromosome as a part of Chromosome 5. Karyotype of wife was normal (Figure 4).

Case 5

19-year-old male, second born to a non-consanguineous couple was referred for karyotyping with history of small sized testis and diminished secondary sexual characteristics. Hormonal profile showed increased FSH, LH and decreased Testosterone levels. Chromosomal analysis showed 48,XXYY karyotype suggestive of a Klinefelter variant. FISH studies were also done using X/Y centromeric probes - 2 green signals and two red signals indicating the presence of two X and two Y chromosomes were seen respectively (Figure 5).

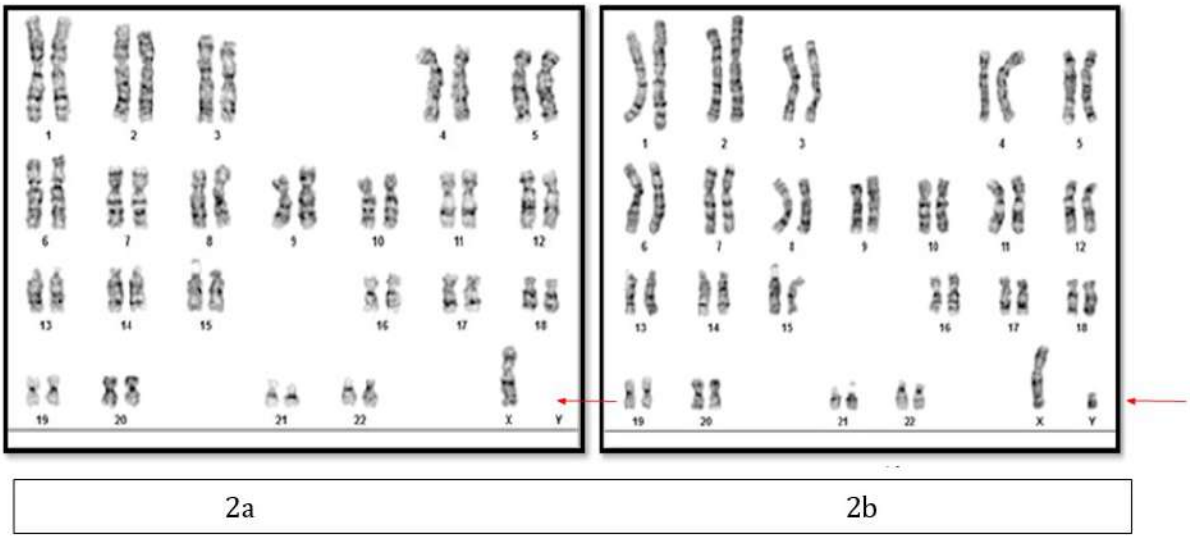


Figure 2. Karyotype showing mosaic chromosomal variant with mixed gonadal dysgenesis in hypogonadism, 2a showing 45,X karyotype, 2b showing 46,X,+mar karyotype(Case 2)

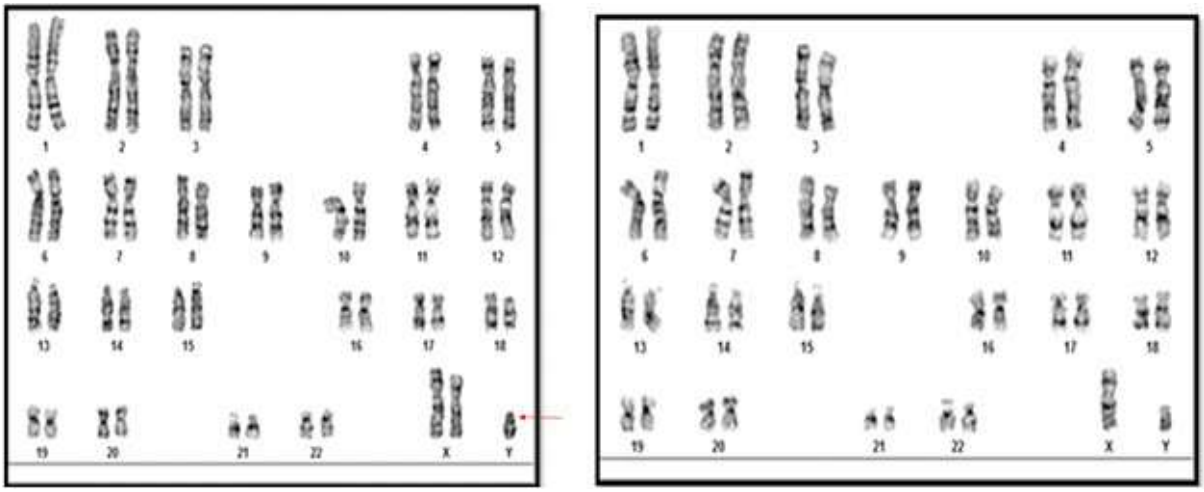
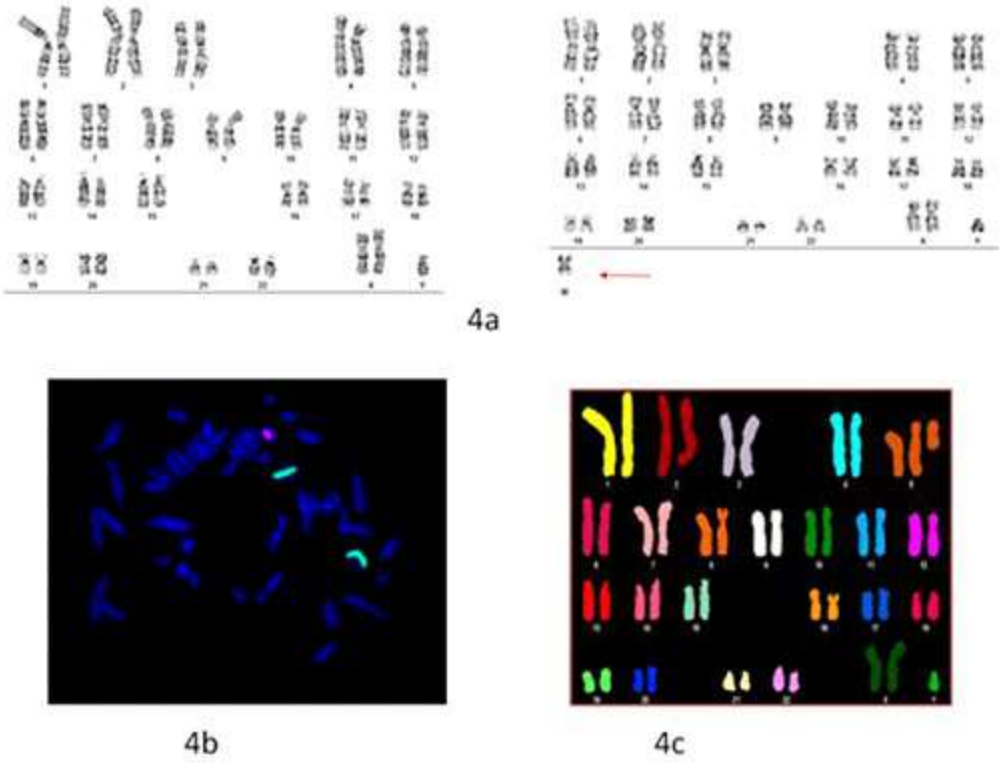


Figure 3. Karyotype of a male patient showing mosaic pattern for Klinefelter syndrome-21 spreads with 47,XXY karyotype (3a) and 4 spreads showed normal 46,XY karyotype (3b) (Case 3)

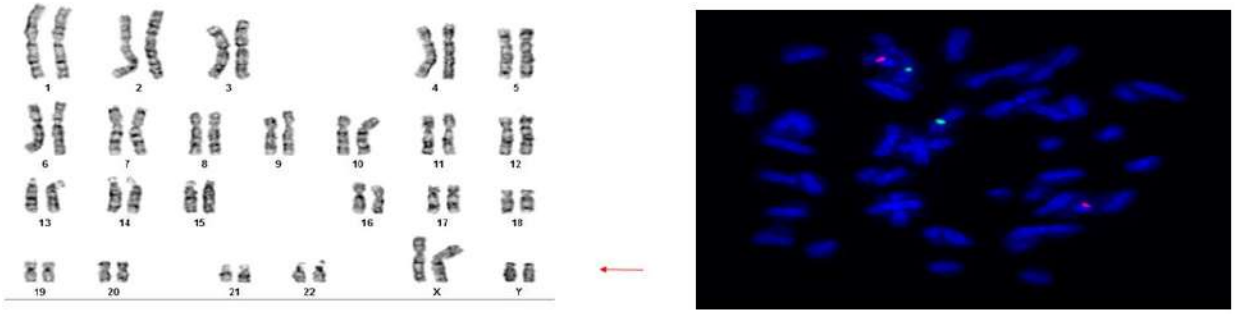


4a

4b

4c

Figure 4. Karyotype (4a) was 47,XXY[33]/48,XXY,+mar[17] suggestive of Klinefelter syndrome. Metaphase (4b) FISH showing 2 green (X) & 1 red (Y) signal. In High SKY (4c) marker got confirmed as derivative of chromosome 5 (Case 4).



5a

5b

Figure 5. Karyotype (5a) - 48,XXYY. Metaphase spread (5b) showing 2 green (X) & 2 red (Y) signal (Case 5)

Discussion

Main pathophysiology behind the chromosomal abnormalities is mutation in genes during meiotic disjunction. This will result in either additional X or Y chromosome or translocation of genes within chromosomes in germ cells. During conception, if these germ cells fertilize, resulting embryo will have chromosomal abnormalities. In all above cases there were

features of hypogonadism like gynecomastia, underdeveloped gonads, and low testosterone levels. Also, most of these cases presented with infertility. Systemic examination of cardiovascular, respiratory and nervous system was normal. Ambiguity in genitalia was limited to small size of testis and in one case hypospadias was present.

First case had 46,XX testicular disorder of sex development. Incidence of such cases is one in 20,000 male births. Alteration in location of SRY gene is main reason for 46,XX testicular disorder. During spermatogenesis, as a random event there is translocation of SRY gene to X chromosome. If fertilization occurs with sperm having X chromosome with SRY gene the fetus will develop as male even if Y chromosome does not exist. This usually happens in 80% of patients and is termed as SRY positive cases. In rest 20% there is SRY negative reason for which is not known. If Y chromosomal material is detected in such cases there are higher chances of neoplastic transformation. Hence surgical removal of gonads is suggested [4]. Tulsi Sharma et al., reported a case of male hypogonadism with 46,XX karyotype and one of the X chromosomes had an apparent deletion of Xp22.33 to Xpter and addition of chromatin material. FISH analysis demonstrated that the male sex-determining region of the Y chromosome, SRY, is present on the short arm of X chromosome [5].

Another important case which presented with hypogonadism was a case of mixed gonadal dysgenesis (case 2). Here karyotype was 45,X/46,X,+mar with underdeveloped external genitalia. In these cases, it is very important to identify status of gonads whether it is testis or streak ovaries. According to literature, risk of development of germ cell tumor in these patients is 15-35%. During providing treatment options, certain issues like malignancy risk, infertility, gender identity and dysphoria, family dynamics, social adaptation and coping skills should be considered [6,7].

Presence of extra X chromosome in males attributes to diagnosis of Klinefelter syndrome [8]. In present study we had three cases out of five who had chromosomal variants of Klinefelter syndrome. According to literature, Klinefelter syndrome is most common cause for hypogonadism. In study done by Osman et al karyotype of total of 64 individuals with hypogonadism was analysed. Chromosomal abnormalities were detected in 18.8% of all individuals. Klinefelter syndrome was the most common sex chromosomal abnormality [9]. In mosaic type of Klinefelter syndrome (case 3) there were few cells had normal male karyotype and few cells had extra X chromosome. In these individuals it is very important to conduct a testicular biopsy to confirm level of mosaicism in gonads to plan management especially in terms of infertility. Artificial reproductive techniques can help in these patients if sperms are of good quality. We had a rare type of variant of Klinefelter syndrome (case 4) with marker chromosome 5. Even with presence of marker chromosome, patient had no dysmorphism and had only presented with hypogonadism and infertility.

Another case with 48,XXYY (case 5) had features similar to classical

Klinefelter syndrome. The incidence of 48,XXYY syndrome is 1/18000–1/40000 [10]. Patients with 48,XXYY syndrome was widely studied by Tartaglia et al. In their study, they reported wide range of medical conditions with varying presentations in these patients. Almost all patients with 48,XXYY syndrome received aid for speech problems as well as intellectual disabilities [11]. Hanley et al., compared MRI scans of 25 subjects with 48,XXYY karyotype with normal male individuals and concluded that XXYY males have smaller brain than normal males and more often XXYY have abnormalities in white matter and in the ventricular system [12]. In above case MRI brain and psychologist opinion was suggested to the patient for further treatment.

It is evident from above cases that karyotyping and FISH plays very important role in diagnosis and management of patients with hypogonadism. Early diagnosis will help in better management with appropriate surgical and medical treatment along with hormonal therapy. Genetic counseling will help patient and his family to plan for future options. With regards to fertility, patient can opt for artificial insemination or in vitro fertilization using donor sperm or deciding on adoption.

Conclusion

Detection of sex chromosomal abnormalities by karyotyping and FISH plays vital role in early management of cases who are diagnosed with hypogonadism.

Conflicts of interest

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

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