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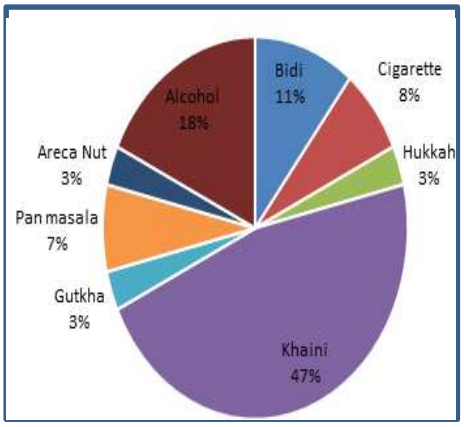
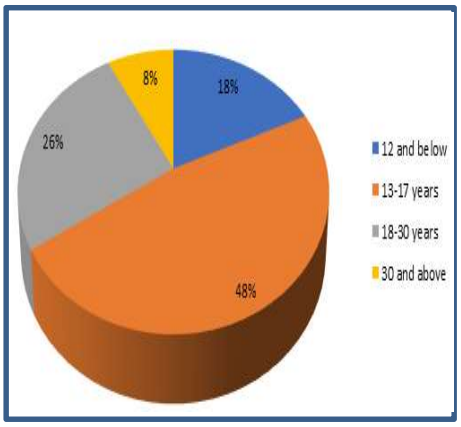
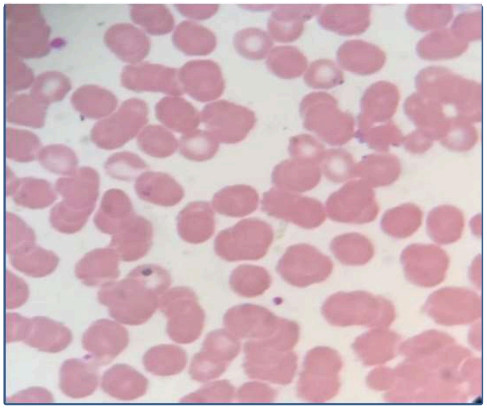
Forms of tobacco habits



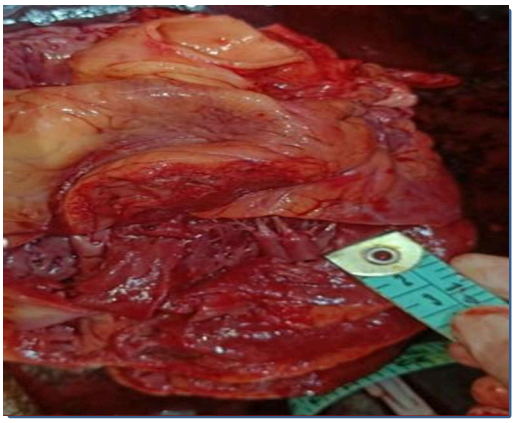
Age distribution of rape survivor



Peripheral Smear



Left ventricle transverse cut section: hypertrophy of heart



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EDITORIAL

Evolving preferences, Digital Healthcare Growth in India & Fintech

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Digital health is driving a revolution, making care convenient, accessible, and tailored

Building strategic partnerships & collaborations: To establish a strong presence in the healthcare landscape, Indian digital healthcare companies are forging strategic partnerships. These alliances enable them to offer a more comprehensive range of services, enhancing their competitiveness and market reach [1].

Supportive policies like Ayushman Bharat Digital Mission (ABDM), telemedicine, etc., are paving the way for a booming digital healthcare industry, making efficient, accessible care a reality for all.

Data privacy and security: ***a paramount need:*** Healthcare providers who invest in robust data management and systems might see initial bumps in cost, but they'll benefit in the long run. Strong security builds trust, and trust drives adoption. Get ready for a healthcare revolution powered by patient privacy.

Compliance consistency for digital healthcare: India's digital healthcare landscape is characterized by a dynamic and rapidly evolving regulatory environment. However, this creates challenges for service providers, who must navigate complex regulations, often leading to confusion and inconsistencies in implementation.

Evolving customer needs

Today's healthcare consumers are actively leveraging online resources to make informed decisions. Increasing awareness of digital tools and wearables, a growing demand for mental health support and personalized wellness plans, and a stronger focus on inclusivity are all reshaping the healthcare landscape. The Digital Fitness & Wellbeing segment is projected to reach USD 8.159 billion in 2024 [2].

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India's telemedicine market is experiencing rapid growth, projected to surge from USD 830 million in 2022 to USD 5.5 billion by 2025—a remarkable annual growth rate of 31%.

Prioritizing a high-quality "phygital" (physical + digital) healthcare experience is essential for users. Online consumer feedback, especially patient reviews and ratings, has become a key factor influencing healthcare decisions. Numerous studies underscore the critical role of patient reviews in shaping healthcare choices.

FINTECH- Improve efficiency, access, and outcomes in healthcare

Fintech in healthcare is a rapidly growing field that integrates financial technology with medical services to enhance efficiency, access, and outcomes in healthcare.

Some key areas where fintech is making an impact:

Payment Processing and Management: Fintech solutions streamline billing and payment processes, making it easier for patients to pay their bills, manage insurance claims, and handle medical expenses. This includes automated billing, digital payment platforms, and flexible payment plans.

Insurance Technology (Insurtech): Insurtech innovations improve underwriting, pricing, and management of health insurance. Advanced data analytics enable personalized insurance plans, faster claims processing, and greater transparency.

Telemedicine Payments: As telemedicine grows, fintech solutions integrate payment gateways into virtual care platforms, ensuring seamless and secure transactions for remote consultations.

Health Savings Accounts (HSAs) and Flexible Spending Accounts (FSAs): Fintech tools help patients track expenses, contribute funds, and optimize tax benefits through HSAs and FSAs, making healthcare costs more manageable.

Patient Financing: Medical credit cards, instalments plans, and specialized healthcare loans provide patients with financial flexibility to cover high medical expenses.

Data Security and Compliance: Fintech enhances security measures to protect sensitive health data, ensuring compliance with regulations like (Health Insurance Portability and Accountability Act) and safeguarding patient information from breaches.

Health Data Analytics: Fintech leverages data analytics to provide insights into patient health trends, treatment costs, and financial risk management, aiding informed decision-making.

Blockchain and Smart Contracts: Blockchain technology secures medical records, streamlines claims processing, and enhances transparency in healthcare financial transactions.

Predictive Analytics for Cost Management: By using predictive analytics, fintech helps forecast healthcare costs, allowing patients and providers to plan and manage expenses more effectively.

Integration with Electronic Health Records (EHRs): Seamless integration with EHRs synchronizes financial and health data, improving billing accuracy and operational efficiency.

The Future of Fintech in Healthcare

Fintech advancements are revolutionizing how healthcare is paid for, managed, and delivered—ultimately making it more accessible, affordable, and efficient for all stakeholders.

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1. Digital Fitness & Well being - India | Statista - 2024
2. India’s growing Telemedicine market - India Briefing - 2022

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ORIGINAL ARTICLE

Oral Health Status and Anxiety Level Amongst the Borderline Security Force Personnel and Their Family Members

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Abstract

The primary role of border security personnel is to safeguard borders against illegal trans-border activities during peacetime and provide military support during wartime. Medical facilities are available to residents, offering direct oral care for minor procedures, with comprehensive dental treatments managed through empanelled clinics under a government insurance system. This study aimed to evaluate the oral health status, treatment needs, and prevalence of oral pre-malignant conditions among security forces personnel and their families at training centres in Delhi NCR. A multi-centric cross-sectional study was conducted at three training centres. Permission was obtained from BSF headquarters for the oral health screening program. Oral health education topics included oral cancer screening, early detection, oral diseases, their prevention, and tobacco cessation. Brief explanations of dental procedures, such as pit and fissure sealants, dental caries restoration, and root canal treatments, were provided. Demonstrations of proper brushing techniques and oral hygiene maintenance measures were conducted. Participants were encouraged to discuss experiences and challenges, which were addressed by attending clinicians. Following the sessions, oral screenings identified oral diseases and pre-malignant lesions. Affected participants were informed about their condition and referred for treatment. Those using tobacco were counselled, provided with educational materials, and motivated to quit. The study concluded that the oral health status of BSF personnel was comparable to the general population, possibly due to the rigorous physical and medical fitness criteria required during recruitment.

Keywords: Oral Health, Anxiety, Military Oral Health, Army Oral Health, Tobacco

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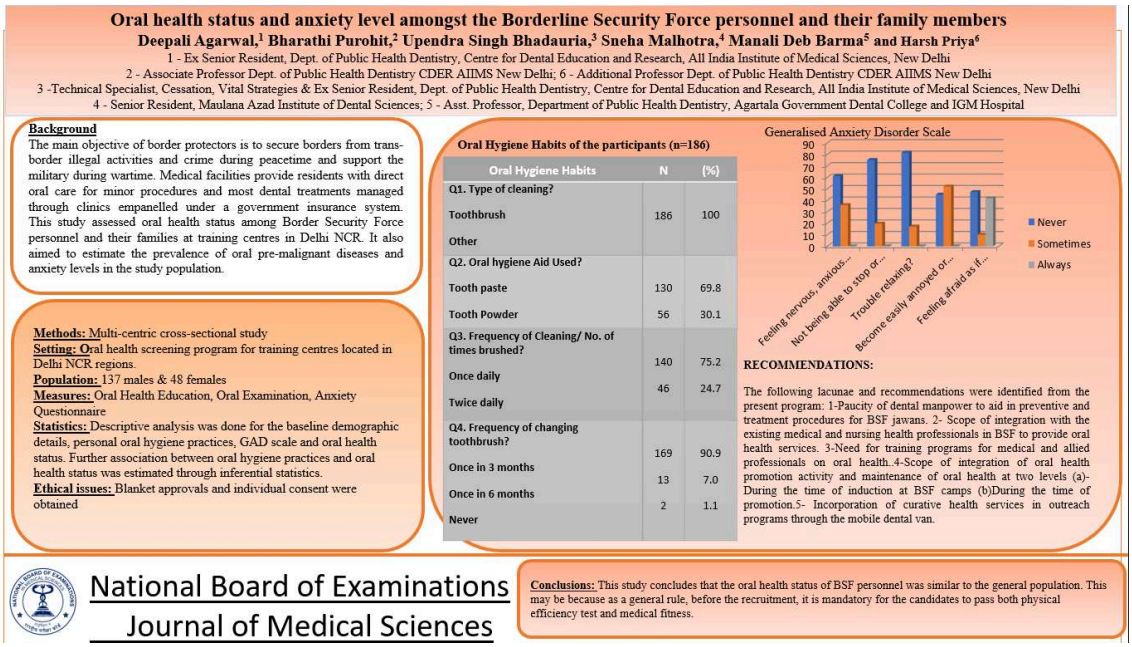
Graphical Abstract



Introduction

Borderline Security Force (BSF) in India is one of the segments of Central Armed Police Forces (CAPF) under Ministry of Home Affairs. Its headquarters is at New Delhi and is headed by Director General [1]. Its main objective is to secure the borders from any trans-border illegal activities and crime in regular time and to hold the grounds and guide the military force in the war times [1]. Borderline Security Force personnel are usually deployed at remote areas where the access to the basic health facilities is a challenge, let alone the oral diseases treatment [2].

Majority of the security forces are deprived of efficient oral health facilities due to an existing acute disparity between the burden of oral diseases and treatment facilities in India [3]. Common oral diseases like dental caries, gingivitis, periodontitis, recurrent ulcers and oro-dental trauma may compromise the working potential of any individual. It leads to loss of working hours [4]. A soldier is expected to stay ready and fit for any emergency situation and maintenance of oral health is essential part of overall fitness. The cost of conservative treatment of dental diseases increases with the progression of disease. Untreated oral diseases have untoward effects not only on their duties but also increases government financial burden by increasing the cost of treatment of progressive oral diseases [5]. The nature of soldiers work may create a constant environment of anxiety and pressure to perform well which may further lead to poor oral hygiene practices or poor diet aggravating the oral diseases [6,7]. Working under harsh conditions away from the families may plunge them to deleterious habits like that of tobacco use resulting in oral premalignant diseases [8]. Their stringent regimen on one hand may prove to be beneficial for oral health by restricting in

between snacking but at the same time it may be deleterious if not provided with a balanced or adequate diet.

BSF training centres

These training centres spread over huge land areas and harbour the BSF personnel along with their families estimating to around 5000 to 6000 people at each centre. Basic and emergency medical facilities are provided to all the residents. Direct oral health care delivery is provided for the minor procedure while majority of the dental treatments are catered through dental clinics near the vicinity of the campus empanelled under a closed panel insurance system by the government. However, there are a few limitations regarding the type of dental treatments available under this scheme. So, it becomes imperative to imbibe preventive oral care in their daily routine in order to avoid culmination of initial and less severe diseases to a more severe forms. Early diagnosis and prompt treatment could prove highly beneficial under such circumstances. So, the aim of this study was to assess the oral health status amongst the Borderline Security Force personnel and their family members at their training centres in Delhi NCR region. The other objectives were to estimate the prevalence of oral pre-malignant diseases and anxiety level amongst the study population.

Material and Methods

Study design and setting

A multi-centric cross sectional study was designed to assess the oral health status and treatment needs amongst the Borderline Security Force personnel and their family members. The headquarters of BSF was approached by the study investigators and consent was taken for the same. Permission was given for conducting oral health screening program for three BSF training centres located at Bhondsi, Chhawla and Tigri in Delhi NCR regions.

Participants

Participants included both BSF personnel and their families. There were no exclusion criteria for oral health examination. However, a separate counter was set up for the soldier's family members.

Oral Health Education and Oral Examination

Topics for oral health education included:

a) Oral cancer screening and early detection: Here participants were made aware of the prevalence of oral cancer in India. They were shown and taught about the oral pre malignant lesions and conditions so that they can identify them at the right time and seek treatment for the same. The risk factors for oral cancer were also highlighted along with a short self oral examination video to motivate the participants to stay vigilant about the oral health and not indulge in any harmful activities leading to oral cancer.

b) Oral health and oral diseases: Participants were given a general overview of healthy mouth and the most prevalent oral diseases in India. Pictorial presentations of diseases like gingivitis, dental caries, malocclusion and fluorosis helped the participants to co-relate and understand things.

c) Prevention of oral diseases and tobacco cessation: This section included preventive measures both at

the participant's and professional level to avoid oral diseases. A brief outline was also given about the basic dental procedures like pit and fissure sealants, dental caries restoration procedures and root canal treatment. People were motivated to quit tobacco use in all forms and a few tips were given to help them in tobacco cessation. This session was ended by a demonstration of correct brushing technique through a brushing model and measures of maintaining oral hygiene.

Following the sessions, an open discussion was encouraged where participants shared their experiences and problems which were addressed by the present doctors. Next oral screening was done for oral diseases and pre malignant lesions. Participants having any oral disease were explained about their condition with the help of corresponding models and then referred for the treatment of the same. Participants consuming tobacco in any form were counselled briefly and patient education material was provided to them on tobacco cessation.

Data Collection

A close ended questionnaire was pre designed for the data collection. It included questions on demographic details, personal tobacco history and oral hygiene practices, oral health status and anxiety. In oral health status; caries experience and periodontal status was assessed through Decayed, Missing and Filled index and Community Periodontal Index respectively. Level of anxiety was calibrated using modified Generalised Anxiety Disorder Questionnaire (GAD-7). Originally it is 7 point scale; however, it was modified to 5 pointer scale after a discussion by the expert committee. Questions which experts found irrelevant or repetitive were excluded. Further, emoji was added with each question to make the questions more explicit and enhance the understanding of the participants for the same. Oral examination was carried out with the help of a mouth mirror, explorer and CPI probe under a natural light.

Statistical analysis

Descriptive analysis was done for the baseline demographic details, personal oral hygiene practices, GAD scale and oral health status. Further association between oral hygiene practices and oral health status was estimated through inferential statistics. All statistical tests were performed at 5% significance level.

Results

A total of 137 males and 48 females were included in the study. The mean age of the population was 38.2 ± 13.0. Nearly 81% were BSF personnel and 70% were married. There were 50% participants who were either graduate or post graduate while other 50% had primary or secondary education. Only 19 participants had some history of some systemic illness. More than 80% of the participants had sleep between 7 hours to 10 hours (Table 1).

Table1. Demographic status of the participants

	N (186)	%
Gender		
Male	137	73.7
Female	48	25.8
Participants		
BSF personnel	152	81.7
BSF family members	34	18.3
Educational Qualification		
Primary/secondary	75	40.3
Graduation	57	30.6
Post-Graduation	54	29.0
Rank		
Constable	12	22.6
S.I.	100	53.8
R.M.	40	23.8
Marital Status		
Yes	130	69.9
No	56	30.9
Sleep Hours		
2 -6	35	18.8
7-10	151	81.1
Medical History		
Yes	19	10.2
No	151	81.2

It was reported that all the participants used toothbrush with 70% using tooth paste while others using toothpowder. Majority of the population brushed teeth once daily and changed the tooth brush once in three months. Khaini was most widely used tobacco product followed by bidi and cigarette (Figure 1). Mean GAD score was 7.4 ± 1.93 which indicated mild anxiety amongst the study participants (Figure 2).

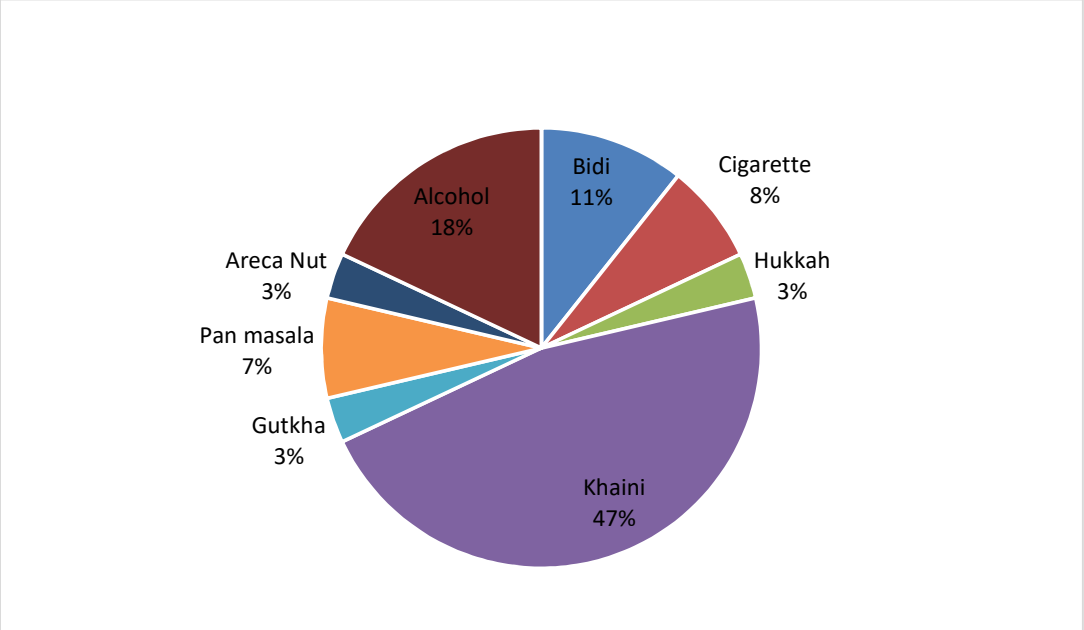


Figure 1. Forms of tobacco habits among those who consumed tobacco (n = 25)

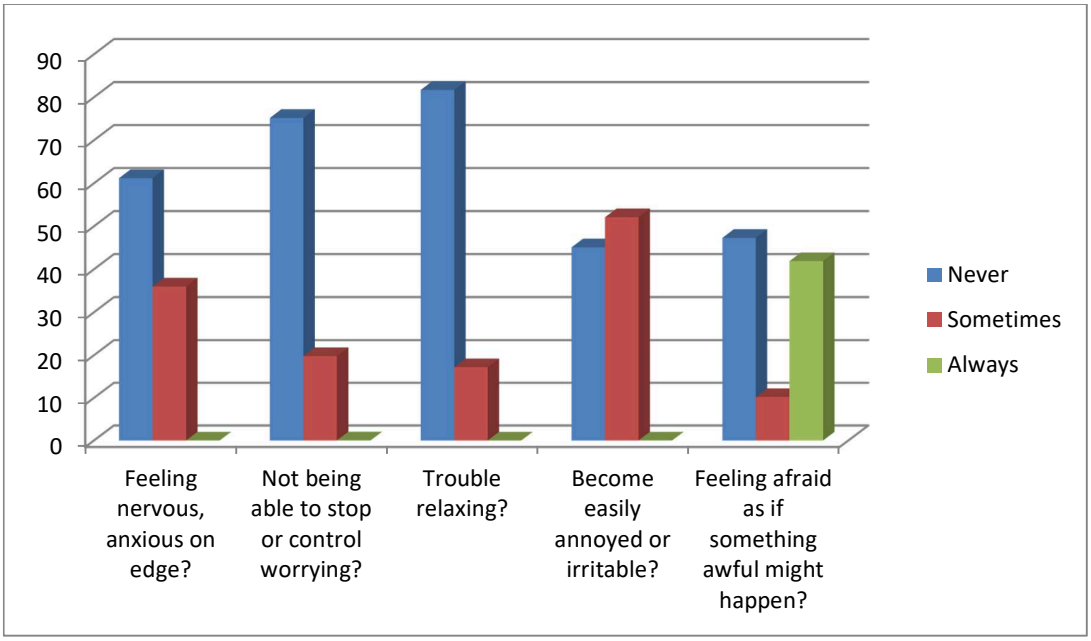


Figure 2. Generalised Anxiety Disorder Scale

Oral health status evaluation showed mean DMFT index to be 2.2 ± 3.2. Nearly 49% participants had healthy peridontium, 27.4% showed bleeding from gingiva, 18.8% had calculus and 4.8% had gingival pockets (Tables 2 and 3).

Table 2. Oral Hygiene Habits of the participants (n=186)

	N	(%)
Q1. Type of cleaning?		
Toothbrush	186	100
Other		
Q2. Oral hygiene Aid Used?		
Tooth paste	130	69.8
Tooth Powder	56	30.1
Q3. Frequency of Cleaning/ No. of times brushed?		
Once daily	140	75.2
Twice daily	46	24.7
Q4. Frequency of changing toothbrush?		
Once in 3 months	169	90.9
Once in 6 months	13	7.0
Never	2	1.1

Table 3. Oral health Status of the participants (n=186)

Variables	N(SD)
Mean decayed teeth	1.18(5.0)
Mean Missing teeth (MT)	0.65(1.4)
Mean Filled teeth (FT)	0.69(1.9)
Mean DMFT	2.2 (3.2)
Lesions	
TPK	1(0.5%)
Treated Case of Oral Cancer	1(0.5%)
Codes of CPI	
Healthy	91 (48.9)
Bleeding	51 (27.4)
Calculus	35 (18.8)
Pocket 4-5 mm	9 (4.8)

Discussion

This study concluded that the oral health status of BSF personnel was similar to the general population. This may be because, as a general rule, before the recruitment, the candidates must pass both physical efficiency test and medical fitness. This medical fitness includes oral health as well, because of which all the candidates get their oral health check-ups and treatment done if required before applying for the post of BSF personnel. In this study, about 37% were recruited and hence had fair oral health.

The current study showed that nearly 49% of participants had healthy peridontium which is in agreement to the findings by Jain et al. who assessed the oral health status amongst the BSF personnel in the Labana Cantonment, Jaipur, Rajasthan. However, the mean DMFT was higher in the current study when compared to that reported by Jain et al. probably owing to the inclusion of small number BSF family members in the current study. On the contrary the mean DMFT was reported to be 9.7 ± 5.3 and 8.15 ± 5.3 by Khalilazae et al. [9] and Jasmine et al. [10] amongst Iranian Armed Forces and Malaysian Territorial Army personnel which is much higher than observed in the current study population. Similarly, in these studies, the percentage of army personnel with significant calculus was higher compared to the current study population.

Oral hygiene practices like use of fluoridated toothpaste and frequency of brushing teeth were similar to that documented by Jasmin et al. [10] and Skec et al. [11] in Malaysian and Croatian Army respectively. However, use of tobacco products in any form was much less than usually found amongst the army personnel Sandhu et al. [8], Jasmin et al. [10] and Skec et al. [11]. Most commonly smokeless tobacco in the form of Khaini was used by the BSF personnel. Social desirability bias giving misleading information, BSF family members and new female recruits forming a significant part of the study population and further the study setting i.e. training centres where the people were not much stressed and fairly aware of the ill effects of tobacco use could be a the possibilities for this difference in tobacco usage pattern.

GAD scale depicted mild stress amongst the study population which is against to that documented by Sandhu et al.[8] where majority of the cadets visiting the dental care unit at Indo Tibetian Border Police Force Station showed significant occupational stress in all age groups.

Recommendations

The following lacunae and recommendations were identified from the present program:

1. Paucity of dental manpower to aid in preventive and treatment procedures for BSF jawans.
2. Scope of integration with the existing medical and nursing health professionals in BSF to provide oral health services.
3. Need for training programs for medical and allied professionals on oral health.
4. Scope of integration of oral health promotion activity and maintenance of oral health at two levels:
    a. During the time of induction at BSF camps
    b. During the time of promotion.
5. Incorporation of curative health services in outreach programs through the mobile dental van.

Statements and Declarations

Conflicts of interest

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

Funding

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ORIGINAL ARTICLE

Current Scenario of Rape Cases Reported in Healthcare Teaching Hospital in the North East India

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Abstract

Background: This study was done in Department of Forensic Medicine, RIMS, Imphal from July 2016 to June 2018. **Objectives:** To study trends of rape cases, identifying vulnerable survivors and common offenders and to identify injuries on survivors. **Methods:** Data were collected from cases of medicolegal examination of rape accused & survivor. Cases with no preceding or succeeding FIR, non-consenting cases were study were excluded. Demographic profile, month of the year, and victim-accused relations were noted. **Results:** In 352 cases, 185 were rape survivors & 167 were rape accused. 5.4% had a history of alcohol use by the accused and there is a positive co-relation between alcohol intake and injuries sustained by the survivor. Spermatozoa were detected in 18.56% on microscopic examination but were absent in 81.44%. Acid phosphatase present in 17.3% and absent in 82.7%. **Conclusion:** Sexual offence continues to be a prevalent but often overlooked menace to the society. Because of late reporting of sexual assault cases, medicolegal examination was done late. The reason behind late reporting is that the victim's family and the accused family usually tries to solve or come to a consensus for the issue using customary laws among various ethnic communities and the help of police and law is taken only after they cannot come to an agreement. General bodily and private parts injuries found were associated with alcohol use by the accused. Majority of the sexual assault survivors were students followed by self-employed workers.

Keywords: Rape, Alcohol, Students, Known Accused, Social Stigma

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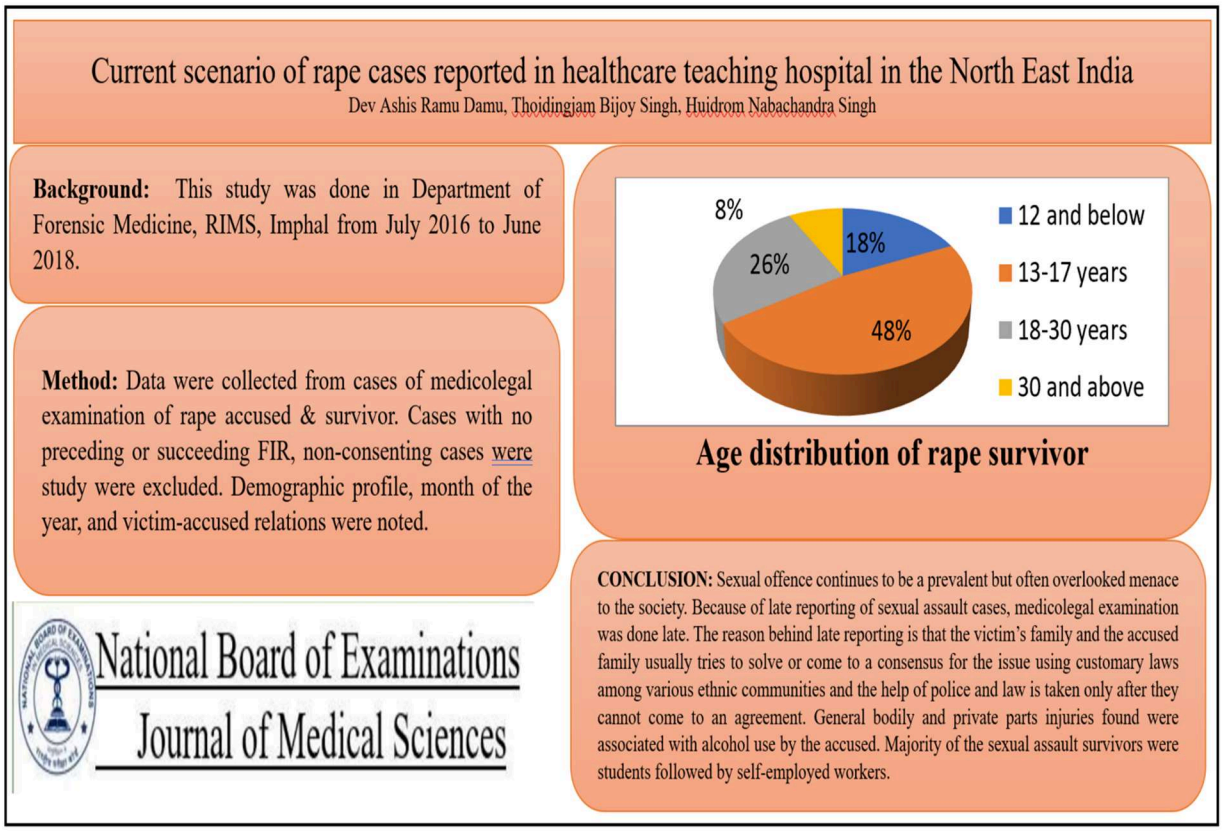
Graphical Abstract



Introduction

Sexual Assault is sexual violence in which a person is coerced, forced, or threatened to engage in involuntary sexual activity including sexual touching [1]. As per W.H.O "any sexual act regardless of relationship to the survivor, in any setting by any person is sexual violence [2]. Rape is derived from a Latin verb rapere having word which means to snatch, to grab, to carry off, to seize or take away by force, it implies hiding and attacking woman by man for the satisfaction of his sexual desire [3].

Rape not being a diagnosis in medical science but a definition in law. It is a charge made by the investigating officer, on FIR by the survivor [4]. Rape was defined in section 375 IPC5 [5,6,7] and the same is reenacted in section 63 of the Bharatiya Nyaya Sanhita (BNS) [8].

Materials and Methods

Materials were collected from the cases of alleged rape. All the survivors without preceding or succeeding police FIR, and all who do not give consent, and or do not want to participate in this study were excluded for this study. Study variables were: Age, occupation, ethnic groups, marital status, urban-rural distribution, socioeconomic status, season of the year, survivor-accused relation etc.

Outcome variables were: common survivors of rape as regards to age, socio-economic status, rural–urban distribution, caste, time and place of occurrence, common offenders of rape. Socio-economic condition

of accused and survivor was noted based on modified Prasad's classification of Per Capita Income [9]. The medicolegal examinations were done following request from investigating officer. A written informed consent was obtained. If the survivor was 12 yrs or less in age or has unsoundness of mind then her parent's consent was obtained in writing. Also, in case the survivor is a minor the consent of the survivor along with her parents were taken. The survivors were identified by the accompanying police personnel whose name, number and designation were recorded. The detail history from survivor and police were recorded separately. When the survivor is below 12 yrs or of unsoundness of mind then her parent's consent was taken. A written informed consent was obtained before beginning the examination. A female attendant was always be present during examination.

Extreme caution was taken up to keep the survivor's identity confidential keeping with the rule of professional secrecy. Approval of Institutional Ethics Committee was obtained with Ref No. A/206/REB-Comm (SP)/RIMS/2015/134/2/2016. Sample collection: The subject was asked to lie in lithotomy position. A female attendant was present to help the subject throughout the procedure. Under aseptic precautions and proper lighting, a sterile cotton tipped swab was introduced in the posterior fornix. A second vaginal swab was also taken using the same procedure. The first swab was immediately used for preparation of two thin smears at the spot-on clean glass slides while the second swab was air dried, stored in a screw capped tube, properly labelled for acid phosphatase analysis.

The smears for study of sperm morphology and the swab for acid phosphatase analysis were done in laboratory of Department of Forensic Medicine. Staining of smear using Haematoxylin and Eosin solutions and Quantitative analysis of Acid phosphatase test was done by using Brentamine Spot Test. The results obtained were recorded systematically.

Results

A total of 352 cases were examined, out of which 185 cases were survivors and 167 were accused. Out of 185 cases of survivors examined, 65.9% were less than 18 years of age and 34.1% were adult sexual assault cases. The age group distribution of the cases of rape survivor 47.6% belonged to 13 to 17 years, 25.9% belonged to 18-30 years, 18.4% belonged to 12 years and below, and 30 years and above age 8.1%. The Meitei ethnic group constituted the maximum number of cases totalling 77.2%, while Manipuri Muslim constituted 11.4%, Manipuri Tribal 9.2% and Non-Manipuri 2.2% were observed in this study. 76.2% hailed from urban population, 23.8% belonging to rural areas. 73.5% were students followed by self-employed workers 14.1%, 9.7% were Unemployed, professional/ government job holders being minimum at 2.7%. 44.3% belonged to lower middle-class family, upper middle class (41.1%), poor family (11.4%) and high class (3.2%). Most of the sexual assaults occurred during the daytime in between 6 a.m to 6 p.m (51.9%) and the rest of it (48.1%) occurred during night time. 51.4% occurred during winter season while 20% cases in autumn, 16.7 % in summer and least cases reported spring season with 11.9%.

29.2% examined were reported for medicolegal examination within 3-7 days, followed by 17.3% were reported after 30 days from the incidence of sexual assault. 16.2% were reported within 7 to 30 days. Only 9.2% were examined within 24 hours and 14.6 % within 48 to 72 hours. 13.5% were reported within 48 to 72 hours. In the present study, 1.6 % of sexual assaults were committed by strangers while 42.1% sexual assaults were committed by boyfriends, followed by neighbours 18.9%. 51.4% cases of sexual assault occurred at the house of the accused followed by 26.4% cases occurred at house of the relatives/ friends of the accused. 13% cases happened at the house of survivors.

Restaurants/Hotels/Isolated places constituted 6.5% and rented house constituted 2.7%. 44.9% were under-matric followed by 28.1% were matriculate. 14.6% were illiterate and 12.4% were graduate and above. 91.9% were unmarried followed by 7.6% were married and only one case of divorcee 0.5%. 9.2% sustained external injuries while 90.8% are without any external injuries. 5.4% had a history of alcohol used by the accused and there is a positive co-relation between the use of alcohol by the accused and external injuries sustained by the survivor (P-value <0.001).

Spermatozoa were detected in 18.56% on microscopic examination but was absent in 81.44 %. Because of late reporting of sexual assault cases for medicolegal examination, spermatozoa detected under microscopic examination was 18.56% and absent in 81.44% (P-value <0.001). Acid phosphatase test for detection of semen was done and detected in 17.3 % and the acid phosphatase test was negative in 82.7% (p-value <0.001) (Figures 1 to 3).

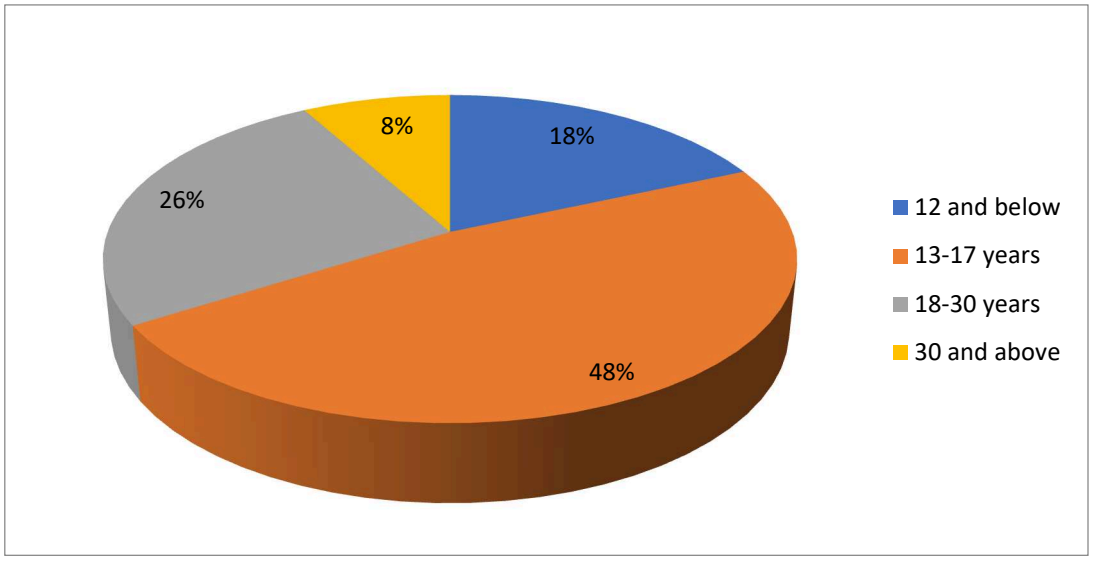


Figure 1. Age distribution of rape survivor

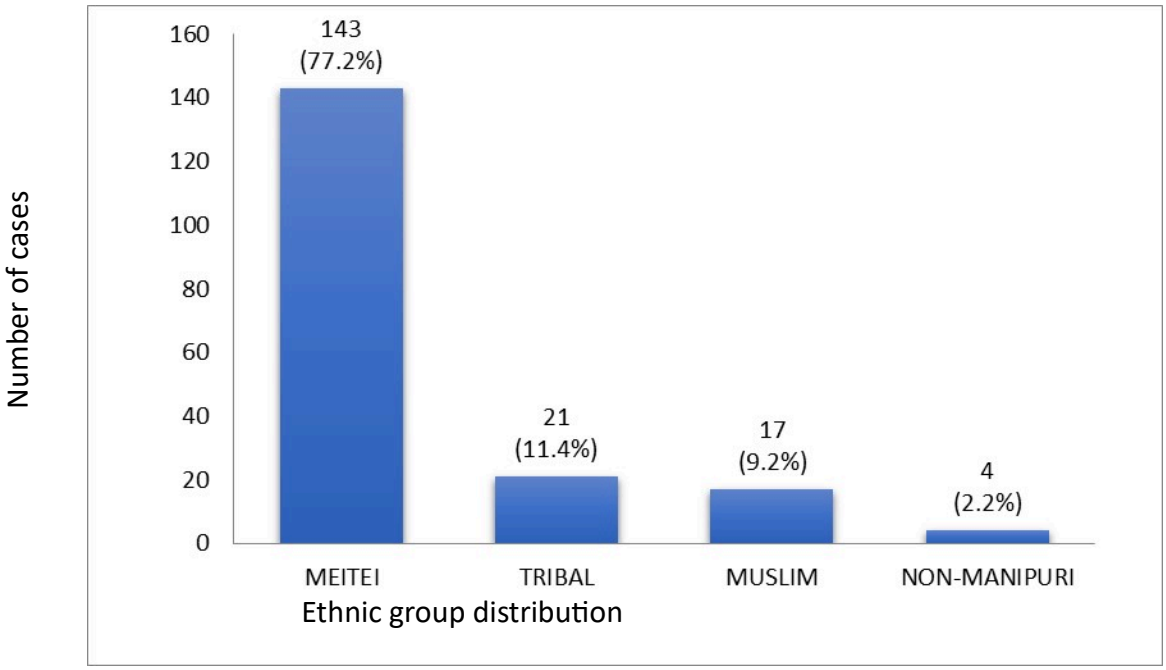


Figure 2. Bar chart showing ethnic group distribution rape survivor

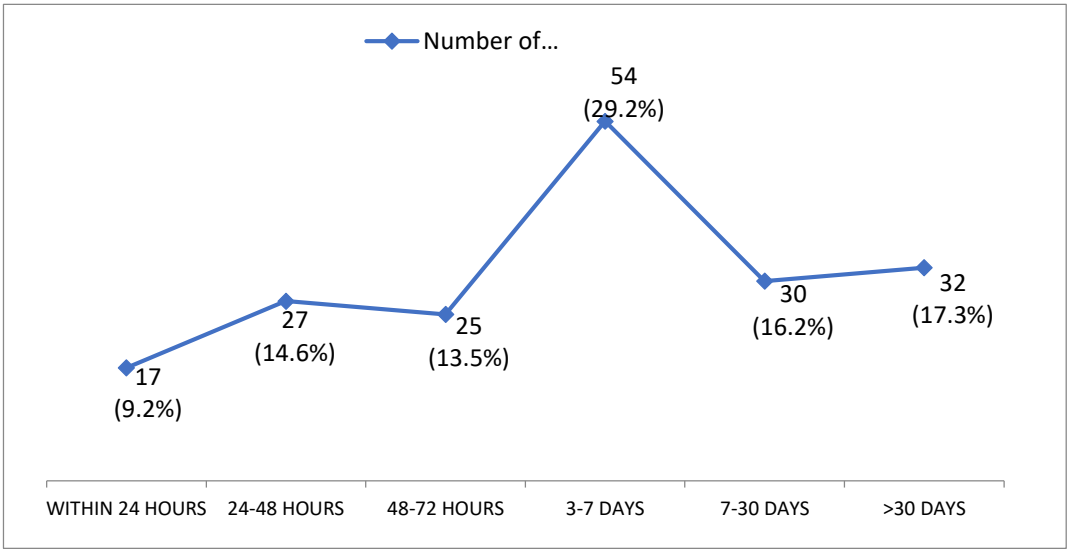


Figure 3. Time lapse between incidence and medicolegal examination

Discussion

Sexual offence continues to be a prevalent but often overlooked menace to the society. It is like the tip of iceberg, major part of which is hidden or under reported because of either lack of awareness, fear of social stigma or tiresome legal procedures. Most of the offences were committed against survivors who were less than 18 years of age. In a study of 182 female undergoing evaluation in 36 hours, half of cases were with injuries. The conclusion was physical evidence examination,

pelvic examination, sperm assays with acid phosphatase, should be advised for cases of sexual assault presenting in first 36 hrs following assault [10]. In a global prevalence study, child sexual assault cases comprised of 19.7% females and 7.9% males. Geographically, Africa accounts for the highest prevalence rate with 34.4% because of high South African rates. Lowest prevalence showed in Europe with rate at 9.2%. America and Asia at 10.1% and 23.9% respectively. Sexual assault in US occurs once in 6.4 mins with 1:6 female raped in lifetime and known person are 4 times likely assaulters, most cases go unreported [11].

Campus study on sexual assault in data from USDOJ shows 13.7% undergraduate women one complete sexual assault. On college entry, 4.7% survivors were forced physically. 7.8% of were stupefied following voluntarily consuming intoxicants and 0.6% assaulted were drugged without their knowledge [12]. Study from British Columbia done on women police service-reported sexual assault cases between 1993 & 1997, among 462 total cases, 151 charges filed and conviction was done in 51. Injury observed in 193 cases, and positive sperm or semen obtained in 100 out of 262 tested [13].

Another study in 418 sexual assaults in 1998 defines two groups, 1st group examined with 72 hrs after assault and 2nd group after 72 hrs. 86% were women with mean age 22.4 years. 76% in 2nd group were less than 15 years. Survivor's residence was the place of the assault with 35% in 1st group & 56% in 2nd group respectively. Stranger assailants were 51% in 1st group. In 2nd group, family member was 58% out of which the survivor's father was the assailant in 30% cases. Single assailant was involved in maximally in both groups. In 30.3% cases, spermatozoa were detected [14].

In a study, female were the most sexually assaulted sex from 78-89% in a study in which 14% age ranges from 0-5yrs, 20% in 6-11yrs & 33% in 12-17yrs age range. More cases were related to groups having low income associated with parental alcoholism, rejection with conflict in marriage. Juvenile committed a third number of cases children. In adult assailants, mostly were less than 30yrs. Family members and acquaintances commit most assaults up to 14 to 47%. Strangers were 7% to 25% [15]. A study from Athens, showed increase in drugs use to facilitate sexual assault across the world with drugs e.g., hypnotics, benzodiazepines, anaesthetics, sedatives, ethanol, etc, whose positive identification in body fluids is difficult due to its short acting nature and amnesia of the incident by the survivor and thereby late reporting incident [16].

One study suggests that sexual violence affects up to a third of women in her lifetime. Most cases go unreported and assailants are known to survivors in more than half of cases. Men and women both can be assaulted sexually but greatest risk is on the women. Vulnerable groups like adolescents, survivors of physical abuse or childhood sexual abuse, differently able individuals, substance and drug abusers, sex workers, persons in poverty or homelessness and prisonsers [17]. One study in Hanover, Germany between 2005 to 2007 in which 292 sexual assault survivors were studied of which 283 were females and 9 were males, and 88 alleged accused were examined. 41.8% survivors & 43.2% alleged accused were under alcohol intoxication and influence. Injuries found in 84.9% survivors and 39.8% suspects. 30 survivors have been strangled or

choked. Cytology done in 218 survivors and in 81 cases, sperm detected on vaginal swabs in up to 3 days after the incident. In 7 out of 37 anal swabs, sperm evidence was detected 24 hrs after assault. 22 oral samples came negative for spermatozoa. In 301 sexual assault cases, 171 were proven by forensic medical examination means. Alcohol abusers, differently able persons and persons having psychiatric disorders were vulnerable to sexual assaults [18].

A study with 136 sexual assault cases showed 5.9% false allegation, 44.9% did not get prosecuted, 35.3% were prosecuted, and 13.9% lacked sufficient findings. 8 cases were described false allegations in it 3 were admitted by plaintiff of report fabrication [19]. A study between 2003-2006, 176 alleged rape cases were studied in which 46 were rape opined and 130 were consensual sexual intercourse. It was found that rape survivor does not report to police due to consequent marital disharmony, police and relatives' harassment, humiliating cross examination in court. 130 cases were not opined rape case from victim's history about love affairs, secretly leaving home with their fiancés, living with them for many days, lack of physical signs of resistance prior to coitus, or directly admitting that consent was communicated and litigations were filed because parents could not accept the relationship. $1/4^{th}$ of cases were real rape cases. There were consensual sexual relations in other cases also. Many survivors were students from rural villages. Many were below the age for consent [20].

A study conducted in east Delhi, India in 4yrs from 2001 to 2005 with 50 case of sexual assaults shows 92% of survivors were unmarried female with 62% age ranging from 10 to 19 yrs. Survivors reported incidents were 10%. Acquaintances were 60% of the perpetrators, relatives were 6%. Sexual assault under threat with physical harm or death were noted in 4% cases. 60% filled complaint after 24hrs of incident with 14% had previous sexual assault done to them. 4% were intoxicated with stupefying substance added to food items before the assault. Examination done under anaesthesia were in 19 cases. Genital injury present in 28 in which 14 warranted surgeries. Other injuries were present in 5 cases out of which 1 in the eyes, 2 with limb fractures, and 2 suffered intra-abdominal injuries. 2 survivors suffered acute stress reaction and needed psychiatric intervention. 1 case resulted into death of the victim [21].

Another study on sexual assault conducted in south Delhi from 2001and 2002 shows 88.9% female & 11.1% male. Age ranged from 4yrs and 60 yrs with 68.9% were from 11 to 20 yrs, 12.2% belonged in 0 to10 yrs, and 5 males were form 6yrs to 10yrs. 2.2% survivor were more than 50 yrs age group. The female survivors maximum from 16yrs to 20yrs group and males from 6yrs to 10yrs group. 75.5% were Hindu. 81.1% of all cases were unmarried females. Most of the survivors were from poor socioeconomic conditions, and were less educationally qualified. The alleged accused mostly close friends and acquaintance, with 22% unknown individuals. 41.4% incident occurred in house of survivors, and 28.9% at the house of assailant. 5 showed positive sperm and 3 were positive of acid phosphatase out of 73 swabs tested [22]. A study on medico legal and social aspects of rape survivors conducted between 2005 and 2007 showed out of 80 studied cases 37.5% were form 16yrs to 20 yrs, 35% were form 10yrs to 15 yrs and 2.5% were above 30 yrs age group [23].

A study on 50 cases of alleged rape from 2007 to 2008 finds age is an important variable with younger age group being most vulnerable. Majority were 12 to 18 yrs of age. 90.40% were know accused to the survivors and 9.52% were strangers. 33.33% occurred at survivor's residence and 47.60% were unrelated, 9.53% accused person's residence and 9.52% in deserted open areas [24]. Another study in Delhi on 100 rape survivors, 34% were illiterate, and 37 % were educated up to 12th standard. Age range were 11 yrs to 30 yrs. 32% in age group of 11yrs to 15 yrs were maximally involved. Adolescents included 76.9% of the victims. 96% of total cases were unmarried. 48% cases had no biological parent or had one biological parent, parents living separately, orphan, or with step father or mother. As reported by the survivors, 25% parents had history substance abuse. 78% cases perpetrator knew the victim and 22% cases were total stranger. 32% were sexually assaulted by close family member and relatives, 19% assailant were neighbours and 9% were father, 12% whereas other known person e.g. masters, colleague, neighbour [25].

In a study on survivors of sexual assault, 71.6% belonged to 14yrs to 17yrs, mean age of 16yrs. 80.9% survivors from urban areas, 99% were educated. 48.9% were household workers and 23.4% students. 141 cases studied in which 57 were with the accused for few hours, 58 cases stayed for some days, and in 26 cases they lived together for many months and came back by themselves or were brought by police with complaint lodged by their parents.83.7% cases, sexual activity were consensual [26].

A study conducted on 230 female sexually assaulted survivors in Dhaka, Bangladesh in the year 2006 revealed that 57% were 11yrs to 20 yrs age and 11.30% were in 21yrs to 30 yrs age group. Over three-fourths 76.08% of rape survivors were Muslims, unmarried were 78.69%, 77.89 % belonged to poor socio-economic background, 32.18% were less educated. 43.91% knew the assailants, 30.43% cases were close friends. 36.95% incident occurred in victim's house which was maximum, 31.30% occurred in Boys' hostel [27]. A study on 53 survivors of sexual assault, 51 were female and 2 were males. 40% of which were from 21yrs to 30 yrs, and 36% were from 11yrs to 20years age group of which 64% were below 18 yrs age. Alleged accused were known in 47 cases to the rape survivors. As per history, 25 cases were consensual and 28 cases were forced, 3 cases were under intoxication at the time of incident. 34 were unmarried, 12 victims were married, 3 were divorced, and 2 were widow [28].

In a sexual violence and its relation to health study in female age group of 13yrs to 24 yrs shows 32% reported sexual violence before age 18 yrs. Most common (32.3%) first offenders were respondent's male neighbours, and 26.2% were boyfriends [29]. A casualty department of tertiary care study including 221 cases from year 2010 to 2013, showed that majority rape survivors were 20 yrs of age and above, 9% were less than 5 yrs in which youngest being 18months. Maximum cases were from poor socio-economic status, were uneducated, and unmarried. Restrain 51% of survivors were. Single incident sexual assault survivors were maximum except for 34% of them who were assaulted multiple times. One person accused were in 85% cases, and for 15% were gang raped. 2% cases had 5 or more than 5 accused. In 14% of cases the alleged accused and the rape survivor were relatives, 64% knew each other, 22% accused were unknown

assailants. 58% cases were reported within first 24hrs. 86% were peno-vaginal, 4% were peno-oral, 3% were peno-anal & 7% had no history of penetration. 6% were pregnant on examination. 13.5% suffered injuries [30]. A study done in Lahore, Pakistan between 2012 to 2013, total 19 cases with ages from 4yrs to 18 yrs there were 79% girls and 21% boys. Maximum cases of 57.89 % were from 12yrs to 15 yrs age group. 57.89 % were from 16yrs to 18yrsof age. All the cases were from lower socioeconomic condition and they were from urban location. 42.1% cases survivors knew the assailants. 26% were cases involving multiple perpetrators. Location of the incident were accused residence in 57.89%. Verbal threat were given in 21.05% cases, physical force used in 15.78% cases. Injuries on the body of survivor were seen in 10.52% cases [31].

A 2010 study in Guwahati on 382 rape survivors, 376 were female (98.43%) and 1 intersex. 61% were unmarried & 2% were widows. Most survivors were Hindus. Age group 11yrs to 20 yrs constituted 55.76%. Maximum cases were reported in month of October followed by November. Cases were maximum from low educational level up to high school. Most accused were boyfriend. The place of incidence was rented apartments. 19 cases were pregnant at examination [32].

Analytical 8yrs study on sexual assault in Manipur between 1990-1997, 40.7% were 13-20 years with next 30.2% from 21-30 years age group, 19.8% were children. Meitei Hindus 68.6%, Meitei Muslim 14%, 11.6% Christians. Victims were 79.1% literate students, 69.7% accused were acquaintance, and 25% were strangers. Associated general injuries seen with strangers [33]. Another sexual assault survivor study in Imphal and vicinity between 1998 to 2003, in total of 69 cases, rural areas include 44 and 25 were in urban areas. 41 were literate and illiterate were 28. 91.3% were unmarried, majority 82.6% were Meitei and 8.7% were Tribal, 7.2% were non-Manipuri and 1.5% Muslims. 50.75% age group 12-20 years, 29% child with youngest was of only 3yrs and oldest being 70yrs age. 76.8% assailants were from acquaintance (neighbours, boyfriends, admirers, relatives) and strangers were 18.8% [34].

A study on child rape in Manipur in 20 yrs period found that rape incidence in child was higher in 1996 and 2002 with each 11.54% and no cases in 1985, 1986, 1994, and least in 1987 with 1.90%. Hindus were 92.33% and next Christian 5.77% and Muslim victim 1.90%. Rural 67.30% and urban 32.70%. Summer months from May to July is highest with 36.53% and less in winter with 17.31%. Crime scene was accused person’s house in 36.53%, with next was victims' house in 21.15%. 86.54% accused were known to victim. Among-them some were close relatives and their friends and 13.46% were strangers. Age of alleged accused varies widely [35].

A study on 210 alleged sexual assault cases in Imphal, 8% were found to be date rape cases. 11. 6% and 13.4% date rapes were found in 2012 and 2013 respectively. Up until year 2009, no date rape cases were reported. 70.5% of the rape survivors belonged to Meitei community who were less than 20 yrs age. 82.3% were school or college students. Most assaults were seen in afternoon or in early evening. In 52.9% cases, location of incident were hotels or poorly lit restaurants and 17.6% were in a common friend’s residence. 52.9% were found with alcohol use, and in 23.5% cases suspected anaesthetic inhalant were used [36].

A sexual assault study in 144 cases in Manipur showed 51.4% were children and the cases increased from 6.5% in 2006 to 29.7% in 2011. 98.7% were females and maximum of 68.9% belonged to Meitei's community. 13.5% cases were non-Manipuri. The mean age of victims in the study was 12.4 yrs. 40.54% cases occurred assailant's or his friend residence. 16.22% children below 15yrs occurred in their primary residence. Very few cases occurred in the night. Maximum cases of 89.15% occurred in afternoon or early evening. 78.4% of assailants were known to children and 9.5% were total strangers [37]. A study from 2007-2011 on 224 cases, majority were rape victims and accused persons. Most were elopement cases. Disagreements among either party were seen and rape charges were filed against the accused following elopement (sec 137BNS [8] & sec 63BNS). When these cases were carefully examined with through history and personal interview with both the alleged accused and rape survivor, they were elopement cases. Only few were actual rape cases [38].

A study in Imphal, Manipur from 2005-2011, increasing trends were seen with maximum cases were in the year 2011. 51% of rape survivors were students. 34% cases occurred in summer months and 40% cases occurred in the afternoon as a preferred timing. In 83% cases, accused were known to the victim and the crime occurred in alleged accused residence [39].

Conclusion

Because of late reporting of sexual assault cases, medicolegal examination was done late. The reason behind late reporting is that the survivor's family and the accused family usually tries to solve or come to a consensus for the issue using customary laws among various ethnic communities and the help of police and law is taken only after they cannot come to an agreement. So, spreading awareness amongst the public for prompt medical examination of any suspected sexual assault, collection of swabs and preservation of evidence on the clothes and not to clean private parts before medicolegal examination are the need of the hour. The offenders were known to the rape survivors.

General bodily and private parts injuries found were associated with alcohol use by the accused. Majority of the sexual assault survivors were students followed by self-employed workers. To prevent such crime, stringent laws be passed by legislatures and properly enacted and enforced by law enforcement agencies. Education of women's rights & healthcare facilities is needed. Continuous efforts to raise awareness against rape is must.

Ethical Approval

Approval of Institutional Ethics Committee was obtained with Ref No. A/206/REB-Comm (SP)/RIMS/2015/ 134/2/2016

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Efficacy of Inhaled Steroid Over Systemic Steroid in Stabilizing Acute Asthma in Emergency Room

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Abstract

Background: Acute exacerbation of asthma is one of the most common illnesses presenting to Emergency Department. Glucocorticoids are good anti-inflammatory agents, effective at treating asthma and decreasing inflammation of the airways. Although systemic use of steroids is commonly being used, inhaled steroids could be also beneficial in acute asthma. AIM: To compare the efficacy of inhaled corticosteroid over systemic steroid in acute asthma. **Materials & Methods**: This was randomized, prospective, comparative study done on a total of 48patients in Emergency Department and ICU. All patients were assigned in random consecutive case fashion to one of the three groups such as Group I(inhaled steroid), Group II(intravenous steroid) and Group III(inhaled beta-2 agonist). The changes in respiratory rate, heart rate, oxygen saturation, peak expiratory flow and pulmonary score were recorded at 30minutes, 60minutes and 120minutes after treatment and were analysed. **Results**: Out of 48patients, highest number (n=13)(26.5%) of patients were of aged 30-39years and lowest being(n=2)(4.1%) aged 10-19years. There was female preponderance (n=21)(56.3%). Breathlessness grades were Grades 0 and 1(0%), Grade 2(n=13)(27.1%), Grade 3(n=26)(54.2%) and Grade 4(n=9)(18.7 %). Wheeze was present in 46(95.8%) patients. Accessory muscles of respiration were used in 34(70.8%) patients. There was no statistical difference ($p>0.05$) in decrease in respiratory rate, decrease in heart rate, increase in oxygen saturation, increase in peak flow and decrease in pulmonary score among all 3groups. **Conclusion**: The use of inhaled steroids is an effective treatment approach with faster clinical improvement compared to intravenous steroids in managing acute exacerbation of bronchial asthma in emergency room.

Keywords: Inhaled steroid, Systemic steroid, Asthma

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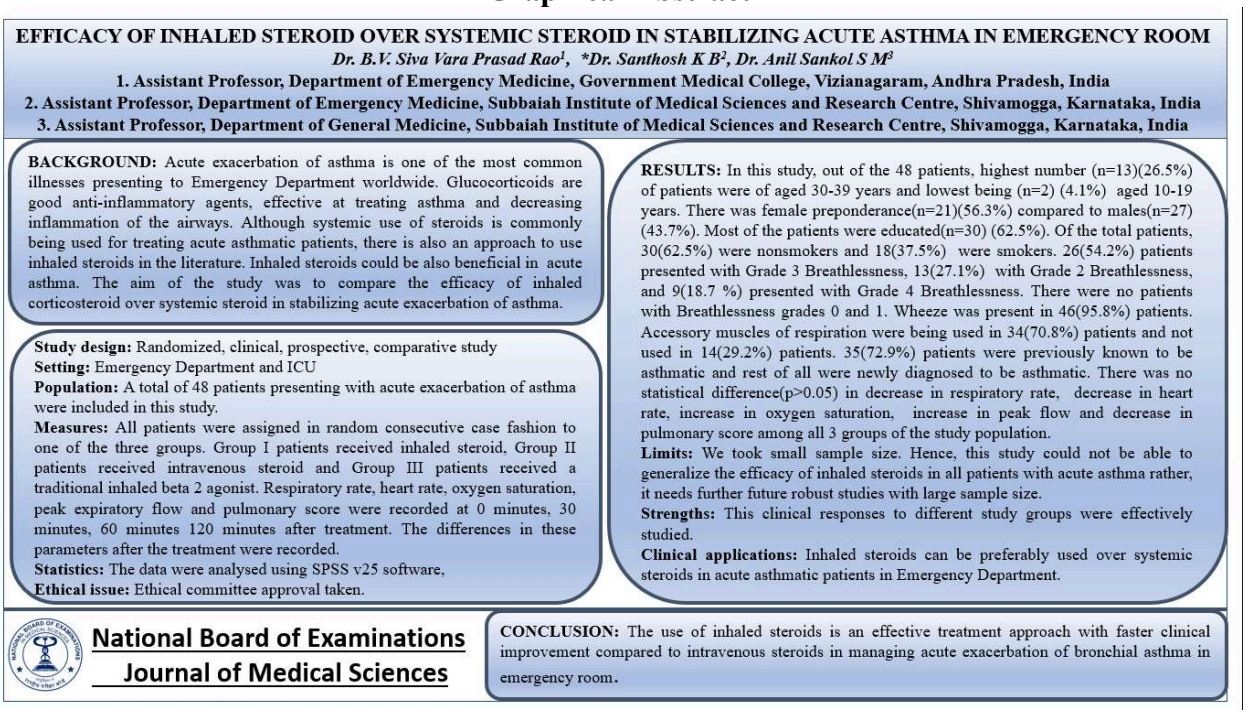
Graphical Abstract



Introduction

Asthma is traditionally defined as intermittent, reversible obstructive airway disease [1]. Acute exacerbation of bronchial asthma is one of the most common illnesses presenting to Emergency Departments worldwide. Appropriate, adequate and timely intervention is the cornerstone in the management of acute exacerbation of bronchial asthma.

The *Global Strategy for Asthma Management and Prevention* Guidelines define asthma as 'a chronic inflammatory disorder of the airways associated with increased airway hyper-responsiveness, recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. Airway inflammation produces airflow limitation through acute bronchoconstriction, chronic mucus plug formation and airway wall swelling or remodeling. It can occur at any age of which in half the cases the onset is before 10 years of age. Recent concept is that asthma as an inflammatory disease requires a change of conventional treatment strategy i.e., the need for anti-inflammatory medications [1]. Glucocorticoids are potent anti-inflammatory agents, reducing the inflammation of airways and thereby effective at treating asthma. Although the exact mechanism by which its molecule functions being unclear, important attempts have been made in understanding of its action [2,3]. During acute asthma crises, corticoids are generally administered systemically. But the use of systemic steroids can be associated with critical short and long-term adverse effects. As a result, it is now relatively common about the unpleasant systemic adverse effects that are associated with systemic corticosteroids therapy. Inhaled corticoids are effective for chronic asthma treatment and although some

recent studies have been done to assess the action of inhaled corticoids in acute respiratory diseases, their independent role in acute crises is still not yet been defined [4]. The use of inhaled corticosteroids can decrease the need for systemic corticosteroids and the side effects associated with these medications. The delivery of regionally active corticosteroids directly to the airways by inhalation has revolutionized the anti-inflammatory treatment of asthma. Comparisons of oral corticosteroids with inhaled corticosteroids has also demonstrated in few studies that both the routes are similar in terms of efficacy but, that repeat acute episodes are lesser when the medication is inhaled [5,6].

Aim

To compare the efficacy of inhalational and systemic steroid in stabilizing the patients presented with acute exacerbation of bronchial asthma.

Material and Methods

Study design: Randomized, clinical, prospective, comparative study.

Study area: Department of Emergency Medicine and ICU of Tirumala Hospitals, Vizianagaram, Andhra Pradesh.

Study population: Patients with acute exacerbation of asthma satisfying the following inclusion and exclusion criteria were taken for the present study.

Inclusion criteria: Patients between 15 years and 60 years of age of both sexes with acute asthma were included.

Exclusion criteria: The following exclusion criteria were considered.

- Age less than 15years and more than 60 years
- Cardiac illness on surgery or medications
- High grade fever
- Super added Pneumonia
- H/o foreign body aspiration
- Patients who received oral or parenteral corticosteroids within last 24 hours.
- Known case of renal or hepatic insufficiency
- Prior enrolment in the study
- known liver or kidney disease, of congenital heart disease
- Worsening clinical status during the evaluation period.
- Concurrent Stridor
- Pregnancy
- Patients with tracheostomy
- Already mechanically ventilated or intubated before arrival to ED

Sample size: To determine the sample size, the following formula was used and their values were considered based on based on previous similar study, conducted by Go J [11].

$$n = [Z_{a/2} + Z_b]^2 \times [(p_1(1-p_1)] + [p_2(1-p_2)] / [p_1 - p_2]^2$$

Where, n= desired sample size
Z=standard normal deviate, usually set at 1.96 (95% confidence interval)
a = alpha error
$Z_{a/2}$ based on level of significance (5%) =1.96
b = power=80%
Z_b = 0.84
P_1= proportion group 1 =0.65
P_2= proportion in group 2 =0.35

Minimum sample size needed according to above formula was ≈ 40.

Duration of the study

Ten months

Methodology

The study was approved by Institutional Ethics Committee. The written informed consent was taken by the patients after explaining about the study. Details of cases were recorded including history, clinical examination and investigations. mMRC (modified Medical Research Council) [13] dyspnea grade and the clinical severity score (Pulmonary score) were determined in all the patients. The average transcutaneous hemoglobin saturation (SpO2) was measured with a standard pulse oximeter. Then all the patients were allocated in random consecutive case fashion to one of the three groups as follows.

Group I (Inhalation group: Nebulized budesonide)

Group II (Intravenous group: Hydrocortisone)

Group III (Control group: Nebulization with salbutamol)

All three groups were treated with salbutamol by nebulization 2.5mg (2.5ml) in NaCl 0.9% solution q20 minutes in the initial first hour at ED. Nebulized bronchodilators were continued as per the patient's clinical status.

Group I patients received inhalation of budesonide 0.5mg (2ml) by nebulization within the first 30 minutes after admission.

Group II patients received intravenous injection of hydrocortisone 5mg per kg upto a maximum of 200mg within the first 30 minutes after admission.

Group III patients were treated by salbutamol nebulization.

All patients received oxygen supplementation at a rate of 5 L/min and was titrated to maintain the oxygen saturation of above 94%. Peak expiratory flow, oxygen saturation, heart rate, pulmonary score were recorded at 0 minutes, 30 minutes,60 minutes 120 minutes after treatment

Pulmonary Score

Pulmonary score, also called as Asthma clinical severity score designed by American Academy of Allergy Asthma and immunology is a useful indicator for clinical assessment of severity of acute exacerbation of bronchial asthma (Table 1).

Table 1. Pulmonary score

SCORE	***RESPIRATORY RATE (cycles per minute)***	***PRESENCE OF WHEEZE***	***USE OF ACCESSORY MUSCLES***
0	≤ 20	None	No apparent increase
1	21 – 35	Terminal expiration with stethoscope	Mild increase
2	36 – 50	Entire expiration with stethoscope	Increased
3	> 50	Inspiration & expiration without stethoscope	Maximal activity
Interpretation: Mild - Pulmonary score ≤ 3 Moderate - Pulmonary score 4-6 Severe- Pulmonary score >6			

Statistical methods

The descriptive and inferential statistical analysis of the collected data was carried out using software statistical package for social sciences (SPSS) 25.0. Descriptive analysis was used to describe the data and distribution of variables quantitatively. Univariate analysis was used to evaluate quantitative variable like heart rate, respiratory rate, Spo2, peak expiratory flow rate and pulmonary score to compare in different categorized groups. The p (probability) value of ≤0.05 was considered statistically significant.

Results

In this randomized, clinical, prospective, comparative study, 48 patients who presented with acute asthma satisfying the inclusion and exclusion criteria were studied. Out of the 48 patients, there were 2 (4.1%) (lowest) patients in 10-19 years group, 6(12.2%) patients in 20-29 years, 13(26.5%) (highest) patients in 30-39 years, 12(24.5%) patients in 40-49 years and 15 (30.6%) patients in 50- 60 years. This has been illustrated in Table 2. There was female preponderance (n=21) (56.3%) compared to males (n=27) (43.7%) (Table 3). Most of the patients were educated (n=30) (62.5%) (Table 4). Out of total patients included in the study, 30(62.5%) were nonsmokers and 18 (37.5%) were smokers (Table 5).

Table 2. Age distribution

AGE IN YEARS	NUMBER OF CASES (%)
10 – 19	2(4.1%)
20 – 29	6(12.2%)
30 – 39	13(26.5%)
40 – 49	12(24.5%)
50 – 59	12(24.5%)
60+	3(6.1%)
Total	48(100%)

Table 3. Gender distribution

GENDER	NUMBER OF CASES (%)
Male	21(43.7%)
Female	27(56.3%)
Total	48(100%)

Table 4. Education Status

EDUCATION	NUMBER OF CASES (%)
Educated	30(62.5%)
Uneducated	18(37.5%)
Total	48(100%)

Table 5. History of smoking

SMOKING	NUMBER OF CASES (%)
Yes	18(37.5%)
No	30(62.5%)
Total	48(100%)

Out of 48 patients, number of cases with mMRC breathlessness grade 2 were 13(27.1%), with grade 3 were 26(54.2%) and with grade 4 were 9(18.7%). We did not receive any patient with breathlessness grades 0 and 1. The same has been depicted in Table 6. As wheeze is a common finding in asthma, it was present in majority (n=46) (95.8%) patients in our study and absent in only 2(4.2%) patients (Table 7). Accessory muscles of respiration such as sternocleidomastoid, scalene, trapezius,

pectoralis and intercostal muscles were being used in 34(70.8%) patients and not used in 14(29.2%) patients (Table 8). Out of total patients included in the study, number of patients with new onset of asthma were 13(27.1%) and remaining 35(72.9%) patients were previously known to be asthmatic (Table 9). All the patients were allocated in random consecutive way to one of the three groups such as Group I (nebulized budesonide), Group II (intravenous hydrocortisone) and Group III (nebulization with salbutamol) with 16(≈33.3%) patients in each group (Table 10).

Table 6. mMRC Breathlessness grade

BREATHLESSNESS GRADE	NUMBER OF CASES (%)
2	13(27.1%)
3	26(54.2%)
4	9(18.7%)
Total	48(100%)

Table 7. Presence of Wheeze

WHEEZE	NUMBER OF CASES (%)
Present	46(95.8%)
Absent	2(4.2%)
Total	48(100%)

Table 8. Use of Accessory Muscles

USE OF ACCESSORY MUSCLES	NUMBER OF CASES (%)
Yes	34(70.8%)
No	14(29.2%)
Total	48(100%)

Table 9. Type of onset

ONSET	NUMBER OF CASES (%)
New	13(27.1%)
Old	35(72.9%)
Total	48(100%)

Table 10: Categorization into groups

GROUP	NUMBER OF CASES (%)
I - NEBULISATION WITH BUDESONIDE	16(≈33.3%)
II - INTRAVENOUS HYDROCORTISONE	16(≈33.3%)
III - NEBULISATION WITH SALBUTAMOL	16(≈33.3%)
Total	**48(≈100%)**

Decrease in Respiratory Rate

Decrease in mean respiratory rate (RR) at 30min of treatment in group I was 3.43 cycles per minute (cpm), in group II it was 3.43cpm and in group III it was 2.93cpm. (P=0.67) Decrease in mean respiratory rate (RR) at 60min of treatment in group I was 8.8 cpm, group II was 7.4cpm and group III was 7.25 cpm. (P=0.26) Decrease in mean respiratory rate (RR) at 120min of treatment in group I was11.56cpm, group II was 11.25cpm and group III was 10.37cpm. (P=0.71). All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 11.

Table 11. Decrease in respiratory rate (Mean±SD) (cycles per minute)

Time	Group I	Group II	Group III	P value
30mins	3.43±1.31	3.43±2.33	2.93±1.65	**0.67**
60mins	8.87±3.09	7.43±3.82	7.25±1.80	**0.26**
120mins	11.56±4.56	11.25±5.05	10.37±2.55	**0.71**

Decrease in Heart Rate

The mean decrease in heart rate (HR) at 30 minutes of the treatment in group I was 9.56 beats per minute(bpm), group II was 8.5bpm and in group III it was 7.87 bpm. (P=0.64) The mean decrease in heart rate (HR) at 60 minutes of the treatment in group I was 15.56 bpm, group II was 12.68 bpm and in group III it was 14.18 bpm. (P=0.42) The mean decrease in heart rate (HR) at 120 minutes of the treatment in group I was 21.12 bpm, group II was 16.56 bpm and in group III it was 19.3 bpm. (P=0.20) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 12.

Table 12: Decrease in heart rate (Mean±SD) (beats per minute)

Time	Group I	Group II	Group III	P value
30mins	9.56±5.79	8.50±5.29	7.87±3.98	**0.64**
60mins	15.56±5.86	12.68±6.75	14.18±5.67	**0.42**
120mins	21.12±7.70	16.56±7.53	19.31±6.21	**0.20**

Increase in SpO2 (Table 13)

Improvement of mean oxygen saturation after 30min in group I was 3.0%, group II was 2.9% and group III was 3.0%. (P=0.99) Improvement of mean oxygen saturation after 60min in group I was 4.9%, group II was 4.56% and group III was 4.5%. (P=0.79) Improvement of mean oxygen saturation after 120 min in group I was 6%, group II was 5.8% and group III was 5.06%. (P=0.47) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 13.

Table 13. Increase in SpO2 (Mean±SD) (%)

Time	Group I	Group II	Group III	P value
30mins	3.00±1.93	2.93±1.61	3.00±1.26	**0.99**
60mins	4.93±2.04	4.56±1.99	4.50±1.89	**0.79**
120mins	6.00±2.16	5.81±2.40	5.06±2.29	**0.47**

Increase in Peak Flow (Table 14)

At 30min, there was ~ 47mL increase in mean peak expiratory flow in group I, ~45mL in group II and ~40mL in group III (P=0.72). At 60min, there was ~78mL increase in mean peak expiratory flow in group I, ~86mL in group II and ~ 76mL in group III. (P=0.74) At 120min, there was ~103mL increase in mean peak expiratory flow in group I, ~122mL in group II and ~102mL in group III. (P=0.44) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 14.

Table 14. Increase in Peak expiratory flow (Mean±SD)(mL)

Time	Group I	Group II	Group III	P value
30mins	47.50±22.36	45.62±25.55	40.62±26.94	**0.72**
60mins	78.75±34.22	86.25±32.63	76.87±42.22	**0.74**
120mins	103.12±48.67	122.50±42.50	102.50±57.67	**0.44**

Decrease in Pulmonary Score (Table 15)

At 30min, mean decrease in pulmonary score in group I was 1.7, group II was 1.4 and group III was 1.3. (P=0.14) At 60min, mean decrease in pulmonary score in group I was 2.8, group II was 2.3 and group III was 2.4 (P=0.39). At 120min, mean decrease in pulmonary score in group I was 3.8, group II was 3.5 and group III was 3.3**.** (P=0.64) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 15.

Table 15. Decrease in Pulmonary score (Mean±SD)

Time	Group I	Group II	Group III	P value
30mins	1.75±0.68	1.43±0.72	1.31±0.47	**0.14**
60mins	2.81±1.16	2.37±0.80	2.43±0.89	**0.39**
120mins	3.81±1.75	3.50±1.46	3.31±1.30	**0.64**

Discussion

Glucocorticoids are good anti-inflammatory medications, effective in treating asthma by decreasing inflammation of the airways. Asthma management consensus recommends to use of oral corticoids for moderate acute episodes that do not respond or relapse after treating with inhaled β2-agonists. However, in severe crises the use of corticosteroids is highly essential [3]. It is conventional that, during acute asthma exacerbations, corticosteroids are commonly administered systemically. Although inhaled corticoids are effective in treating chronic asthma while their importance in acute crises has not yet been defined [4]. It is interesting to note that inhaled corticosteroids can be the preferred agents in the treatment of acute severe asthma owing to its direct action at the site of inflammation. Budesonide is one such drug, which is a non-halogenated corticosteroid which can be used as nebulization, in which it seems to have better efficacy during acute crises due to better binding with the intra-cellular lipophilic receptor than sprays. It could be an effective adjunct to intravenous steroid with acute asthma. This study was conducted to find the efficacy of inhaled steroids over intravenous steroids in acute asthmatic patients.

In this study, a total of 48 patients with acute asthma were included. The average age distribution shown in Table 2 coincides with prevalence rate of bronchial asthma in India. There was narrowing of prevalence at 15 to 29 years of age and widening beyond 29-years of age. This finding correlates with the results of a similar study by Prakash Kumar et.al. (2017) [7]. The gender distribution of the subjects studied in Table 3 shows 43.7% in males and 56.3% in females. This corroborates with the previous study by Prakash Kumar et.al. (2017) [7]. This is also in accordance with international prevalence of bronchial asthma. The Education status of the subjects studied in Table 4 shows 62.5% educated and 37.5% uneducated patients. Education

status was considered in this study possibly that could help us to make them understand better the hospital and home based treatment strategies and prevention of asthma exacerbations. The Smoking status of the subjects of this study shown in Table 5 shows 37.5% smokers and 62.5% non smokers.

In this study as shown in Table 6, majority (54.2%) patients presented with Breathlessness Grade 3, 27.1% presented with Breathlessness Grade 2, 18.7% presented with Breathlessness Grade 4. There were no patients with Breathlessness grades 0 and 1. Out of the 48 patients included in this study as shown in Table 7, 95.8% presented with Wheeze. Table 8 shows that 70.8% were using Accessory muscles and 29.2% were not using Accessory muscles. Majority (73%) of the patients had Old Onset Asthma and only 27% had New Onset Asthma. Table 10 shows the distribution of all the patients into three groups namely *GROUP I – NEBULISATION WITH BUDESONIDE, GROUP II – INTRAVENOUS HYDROCORTISONE and GROUP III – NEBULISATION WITH SALBUTAMOL.* All 48 patients were equally distributed among the three groups i.e. each group contains 16 patients.

In this study, as shown in Table 11, the decrease in mean respiratory rate at 30 minutes seemed to be similar both in nebulization with budesonide group and intravenous hydrocortisone group and the decrease was a little less in the nebulization with salbutamol group when compared with the other two groups. The decrease in mean respiratory rate at 60 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The decrease in mean respiratory rate at 120 minutes seemed to be almost similar both in nebulization with budesonide group and intravenous hydrocortisone group and the decrease was a little less in the nebulization with salbutamol group when compared with the other two groups. The decrease in respiratory rate at 30min, 60min and 120min had no statistical difference between all the three groups. These results were similar to the study by Edmonds et al. (2000) [8].

In this study, as shown in Table 12, the decrease in mean heart rate at 30 minutes in nebulization with budesonide group was more when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The decrease in mean heart rate at 60 minutes was more in nebulization with budesonide group when compared with the other two and less decrease in mean heart rate was observed in intravenous hydrocortisone group. The decrease in mean heart rate at 120 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group and less decrease in mean heart rate was observed in intravenous hydrocortisone group. Similar results were shown in the study by Rowe et al. (2012) [9].

In this study, as shown in Table 13, the increase in mean oxygen saturation at 30 minutes seemed to be similar both in nebulization with budesonide group and nebulization with salbutamol group and the

decrease was a little less in the intravenous hydrocortisone group when compared with the other two groups. The increase in mean oxygen saturation at 60 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The increase in mean oxygen saturation at 120 minutes seemed to be almost similar both in nebulization with budesonide group and intravenous hydrocortisone group and the increase was a little less in the nebulization with salbutamol group when compared with the other two groups. This corroborates with the previous similar study by Alangari et al. (2014) [10].

As shown in Table 14, the increase in mean peak expiratory flow at 30 minutes is more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. This corroborates with the previous study by Rodrigo (2009) [11]. The increase in mean peak expiratory flow at 60 minutes was more in intravenous hydrocortisone group when compared with nebulization with budesonide group and nebulization with salbutamol group. The increase in mean peak expiratory flow at 120 minutes was more in intravenous hydrocortisone group when compared with nebulization with budesonide group and nebulization with salbutamol group. This coincides with similar study in comparision of systemic and inhalational steroids by Alangari et al. (2014) [10].

In this study, as shown in Table 15, the decrease in mean pulmonary score at 30 minutes in nebulization with budesonide group was more when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The decrease in mean pulmonary score at 60 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group and less decrease in mean pulmonary score was observed in intravenous hydrocortisone group. The decrease in mean pulmonary score at 120 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. No significant adverse reactions were noticed in any of groups.

This study results support similar studies conducted in various places comparing nebulization vs. intravenous steroids. Study conducted in Federal university, Brazil on budesonide vs. intravenous steroid showed similar correlation and results. Study conducted by Rodrigo (2005) [12], showed the same results on inhaled vs systemic corticosteroids in acute asthma. An independent study conducted in University Medical School, Jerusalem, Israel, conducted on nebulized fluticasone vs. intravenous steroid also showed the same observations and similar results.

In our study mean values of decrease in respiratory rate, decrease in heart rate and decrease in pulmonary score seemed to be similar both in inhalation and intravenous groups. Improvement of oxygen saturation was observed in both inhalation and intravenous groups, with a statistically little margin. There was improvement of peak expiratory flowmetry in both groups after

the desired therapy. According to the results of our present study and previous reports of comparative studies on inhalation steroids, we are having the opinion that nebulized steroids may be used alone or be combined with systemic corticosteroids in treating acute attacks of asthma presenting to the emergency department. Our results highlight the effectiveness of inhaled steroids in the treatment of acute asthma and found to be beneficial in the management at par with intravenous steroids.

Conclusion

The use of inhaled steroids is an effective treatment approach with faster clinical improvement compared to intravenous steroids in managing acute exacerbation of bronchial asthma in emergency room.

Limitation

We took small sample size. Hence, this study could not be able to generalize the efficacy of inhaled steroids in all patients with acute asthma rather, it needs further future robust studies with large sample size.

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Statements and Declarations

Conflicts of interest

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

Funding

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Ethical Clearance

Institutional Ethical clearance approved.

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ORIGINAL ARTICLE

A Cross Sectional Study on Thrombocytopenia with Mean Platelet Volume and Platelet Distribution Width in Patient with Febrile Illness

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Abstract

Introduction: Thrombocytopenia is characterized by reduced platelet count, affecting men and women equally. It is usually associated with conditions such as febrile illnesses like dengue fever, malaria, and other infectious etiology. The causes of thrombocytopenia can be evaluated by studying the platelet parameters. **Aim:** Investigating the clinical and pathological characteristics of Acute Febrile Illness and Assessing Thrombocytopenia Using Mean Platelet Volume and Platelet Distribution Width. **Materials and Methods:** Study was conducted on 85 individuals, both male and female, aged between 18 and 65 years, who presented with thrombocytopenia and acute febrile infections. The cases of thrombocytopenia were classified as mild, moderate, or severe, and peripheral smears were performed on all 85 cases to rule out pseudo-thrombocytopenia. Several subgroups were also derived after evaluating the etiology of thrombocytopenia. **Results:** In all 85 individuals who presented with thrombocytopenia, MPV and PDW values were calculated. There was an increase in MPV and PDW values on day 1 compared to the values on day 2 and day 3. Thrombocytopenia severity was categorized as mild, moderate, or severe based on the MPV and PDW values. **Conclusion:** Platelet volume parameters such as mean platelet volume (MPV) and platelet distribution width (PDW) offer valuable insights into the mechanisms of thrombocytopenia. PDW, in particular, plays a critical role among these parameters. When assessed alongside other parameters, PDW can provide important information about the mechanisms behind platelet destruction.

Keywords: Thrombocytopenia, acute febrile illnesses, mean platelet volume and platelet distribution width

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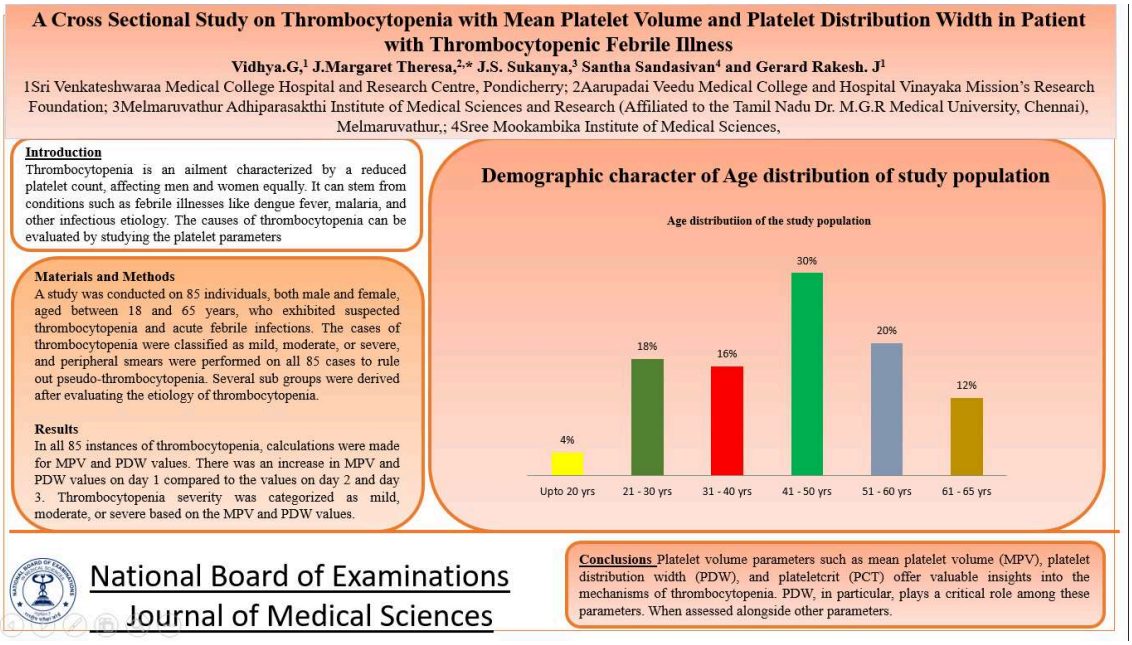
Graphical Abstract



Introduction

Thrombocytopenia is one of the most common problem among the clinicians in the routine clinical practice. Thrombocytopenia defined as platelet count decreased less than <1,50,000/µL [1].

Thrombocytopenia is considered to be a medical emergency which needs to be managed immediately. Thrombocytopenia can be graded as Grade I (75,000-<1,50,000/µL), Grade II (50,000-75,000/ µL), Grade III (25,000-50,000/ µL) and Grade IV (<25,000/ µL).

Most common cause for thrombocytopenia is acute febrile illness. Some of the infections associated with febrile thrombocytopenia are dengue, malaria, leptospirosis, chikungunya, enteric fever, rickettsia and Japanese encephalitis [2]. Patient with moderate and severe thrombocytopenia needs continuous monitoring, because they have a high propensity to bleed from mucous membrane, skin and various organs. Thrombocytopenia can be classified based on their aetiology like decreased production, increased destruction and pseudothrombocytopenia.

Pseudothrombocytopenia occurs due to Ethylenediamine tetraacetic acid (EDTA) anticoagulant used in the blood sample collection tube [3,4]. It is a in-vitro phenomenon caused by clumping of platelet, which give us false low value of platelet. Destruction of platelet can be mediated by immunological cause or non-immunological aetiology.

The mean platelet volume (MPV) reflects platelet size and the rate of platelet production in the bone marrow. Mean platelet volume used as indicator of platelet activation and severity of inflammation [5,6]. Platelet distribution width (PDW) represents the heterogenecity in platelet morphology due to the presence of large platelets along with normal-sized platelets. However, the mean platelet volume (MPV) and PDW are less often analysed and are poorly

understood. The main aim of the present study is to understand the role of mean platelet volume and platelet distribution width in patients presenting with thrombocytopenia associated with acute febrile illness.

Materials and Methods

This cross-sectional study was conducted in the Department of Pathology over a period of two years. Sample size was calculated using the formula $4pq/d^2$, with analysis of a total of 85 samples. The study included adult males and females aged between 18-65 years with suspected thrombocytopenia, as well as patients with a platelet count < 1.5 lakh/mm^3 (with or without clinical bleeding). Patients on anticoagulant therapy, those with malignancy and patients on chemotherapy were excluded from the study. Informed consent was obtained from all participating patients, and the study was approved by the Institutional Ethics Committee.

A structured survey was created to gather personal and medical details from the study group, including age, gender, medical history, existing conditions, and medication usage. 5ml of blood was aseptically extracted from the superficial vein in the anticubital fossa of the study population. The complete blood count (CBC) was studied using the Sysmex Automated Hematology Analyzer, and peripheral smears were prepared, examined and recorded. The gathered data was documented into a Microsoft Excel spreadsheet. Analysis was performed using SPSS software, with a P-value of <0.05 being deemed statistically significant.

Results and Observations

The study involved 85 samples of individuals with low platelet counts associated with acute febrile illness received in the hematology laboratory.

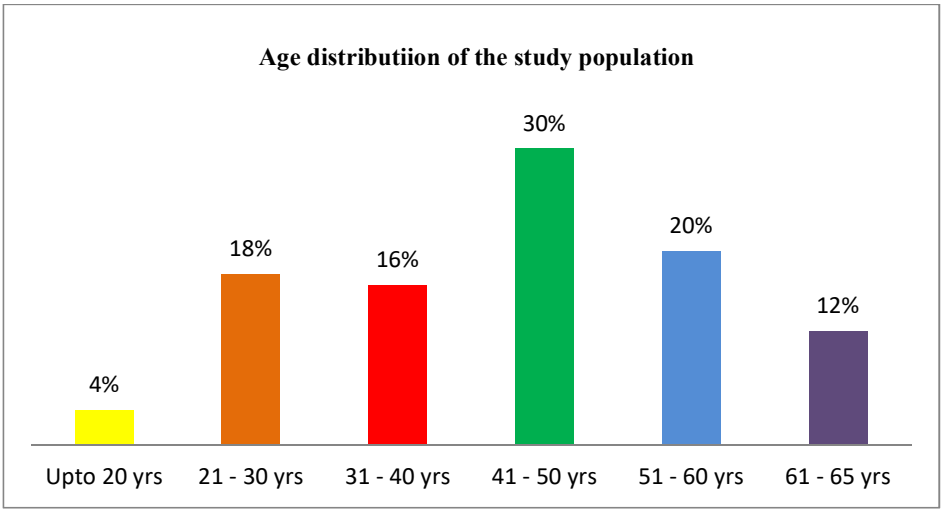


Figure 1. Demographic character of Age distribution of study population

In this study, we analyzed the demographic features of patients presenting with thrombocytopenia and acute febrile illness. The highest incidence of thrombocytopenia was observed in the age group of 41-50 years (30%) (Figure1).

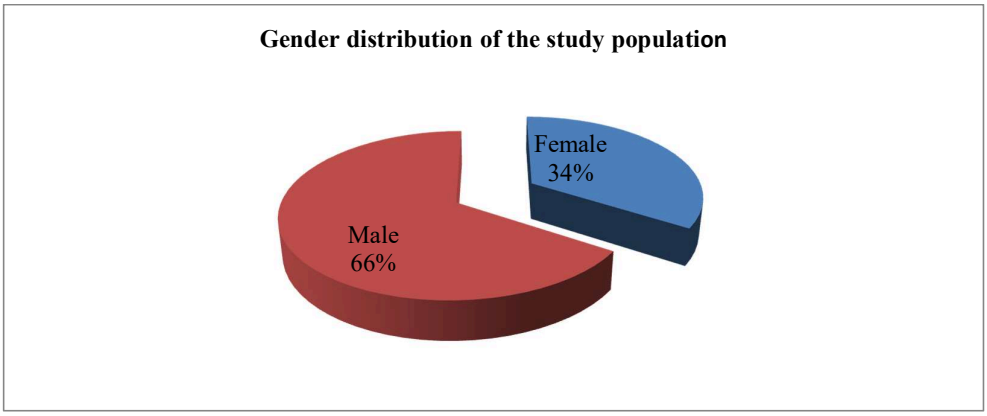


Figure 2. Gender distribution of the study population

In this study, among 85 cases, male patients (66%) showed high incidence of thrombocytopenia with acute febrile illness when compared to the female population (34%) (Figure 2).

Table 1. Distribution of various infectious diseases among the study population

S.No	Disease	Frequency	Percentage
1	Dengue	22	25.88
2	Malaria	6	7.06
3	Leptospira	5	5.88
4	Fever of unknown origin	52	61.18

In this study, out of 85 cases of thrombocytopenia with acute febrile illness, 22 cases were due to dengue, 6 cases were due to malaria, and 52 cases were attributed to fever of unknown origin (Table 1).

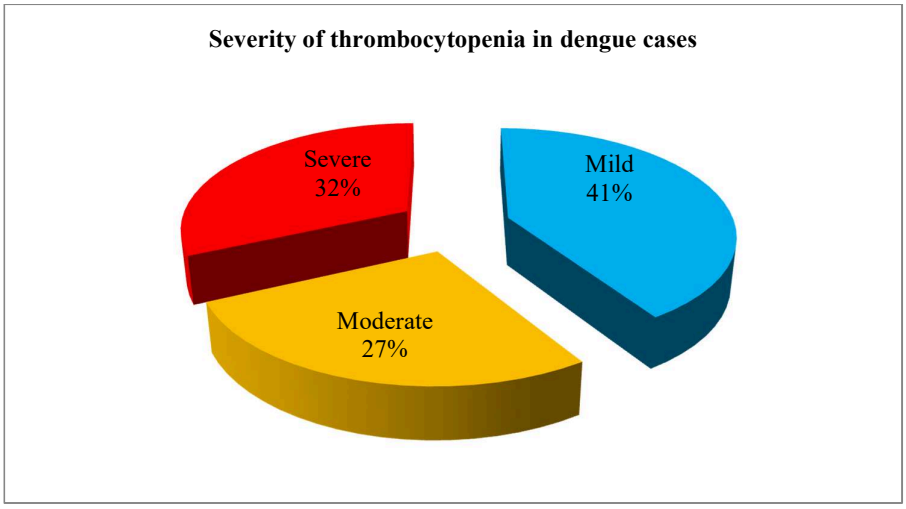


Figure 3. Severity of thrombocytopenia in dengue cases

Figure 3, Out of 22 Dengue cases of thrombocytopenia with acute febrile illness, 7 cases had severe thrombocytopenia, 6 cases had moderate thrombocytopenia and 9 cases had mild thrombocytopenia.

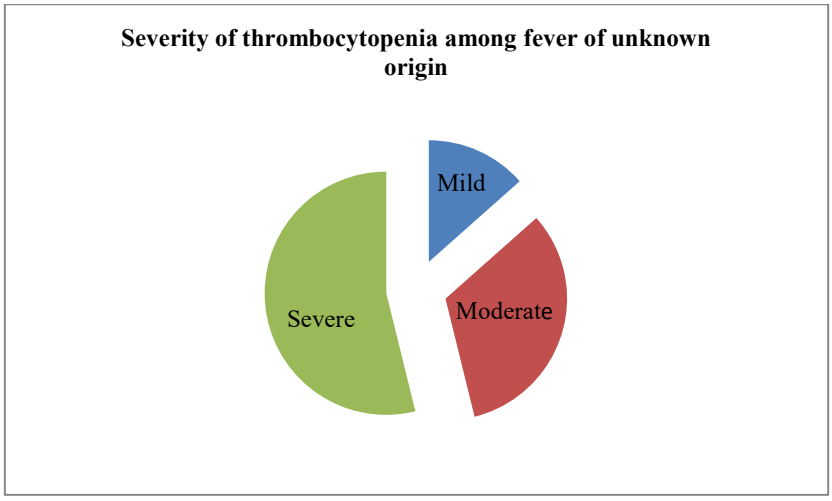


Figure 4. Severity of thrombocytopenia in fever of unknown origin

Figure 4, In a group of 52 fever of unknown origin cases, 26 cases had severe thrombocytopenia, 18cases had moderate thrombocytopenia, and 8 cases had mild thrombocytopenia.

Table 2. Severity of thrombocytopenia in leptospirosis cases

S.No	Leptospirosis	No of Cases
1	Mild	2
2	Moderate	1
3	Severe	2

Out of 5 cases of leptospirosis, 2 cases had severe thrombocytopenia, 1 case had moderate thrombocytopenia and 2 cases had mild thrombocytopenia (Table 2).

Table 3. Comparison of MPV by repeated measure of ANOVA

Days	Mean	SD	N	F-Value	p- Value
Day 1	8.62	1.33	85	11.062	0.0005**
Day 2	8.44	1.03	85		
Day 3	7.98	1.15	85		

** Highly Significant at P < 0.01 level

A comparison of mean platelet volume (MPV) values on day 1, day 2, and day 3 revealed statistical significance (p = 0.0005). The standard deviations (SD) of MPV were 1.33 on day 1 with a mean value of 8.62, 1.03 on day 2 with a mean value of 8.44, and 1.15 on day 3 with a mean value of 7.98. MPV value was higher on day 1 compared to day 2 and day 3 (Table 3).

Table 4: Comparison of PDW by repeated measure of ANOVA

Days	Mean	SD	N	F-Value	p- Value
Day 1	16.68	2.16	85	5.172	0.007**
Day 2	15.84	2.35	85		
Day 3	16.19	2.56	85		

** Highly Significant at P < 0.01 level

A comparison of platelet distribution width (PDW) from day 1 to day 3 also showed statistical significance ($p < 0.01$). PDW value was higher on day 1 compared to day 2 and day 3 (Table 4).

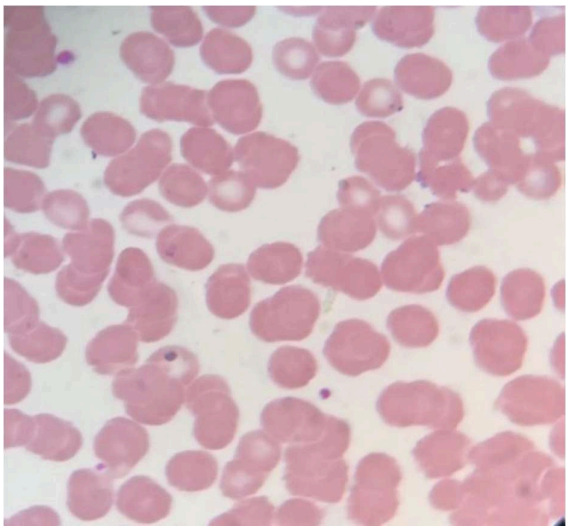


Figure 5. Peripheral Smear

Figure 5 Peripheral smear picture show features of thrombocytopenia win a patient suffering from acute febrile illness.

Discussion

In the present study, it was found that, prevalence of thrombocytopenia was notably high between the age group of 41 and 50, affecting around 30.5% of individuals. Research study conducted by Manoj Kumar Choudhary et al. [7] observed thrombocytopenia was commonly observed between age group of 21 and 40 associated with acute febrile

illness. Study conducted by Chris I. Jones et al. [8] observed decrease in the occurrence of thrombocytopenia with increasing age. In the present study, out of 85 cases, prevalence of thrombocytopenia in males (66%) were observed more, than in females (34%). Suresh et al [9] studied on evaluation of the cause of fever with thrombocytopenia cases, also observed male preponderance (54%) than females (46%) which is concordant with the present study.

In the current study, most fever-associated thrombocytopenia patients do not exhibit any bleeding manifestation. Only a small number of patients presented with minor bleeding manifestations like petechiae, purpura, and minor mucosal bleeding. Bichile et al. [10] also observed, fever-related thrombocytopenia patients occasionally experienced features of bleeding. The present study witnessed, both hereditary and acquired causes of thrombocytopenia, with acquired causes being more prevalent. The majority of acquired cases were due to infections such as dengue (22 cases, 25.88%), malaria (6 cases, 7.06%), leptospirosis (5 cases, 5.88%), and viral infections

Sekhon et al. [11] studied the thrombocytopenia in adults and a practical approach to evaluation and management of thrombocytopenia. He categorized platelet counts into Grade I, II, III, and IV. Platelet count of 75,000 to < 1, 50,000/μL as grade I thrombocytopenia, 50,000 to<75,000/μL as grade II, 25,000 to <50,000/μL as grade III thrombocytopenia and below 25,000 as grade IV thrombocytopenia. In the present study also grading was done and observed 18 cases of grade I, 34 cases of grade II and 24 cases of grade III and 9 cases of grade IV.

In the present study Platelet distribution width (PDW) was analyzed on day 1 to day 3. PDW values was increased on day 1 but day 2 and day 3 had no significant change in PDW values. Study conducted by Xiude Fan et al [12] also studied the PDW on day 1, day 2 and day 3 and observed PDW value on first day of hospitalization is a valuable parameter for evaluating the severity of Hemorrhagic fever. In the present study MPV was also studied along with PDW on day 1 to day 3 and observed, these parameters were highly sensitive and specific indicator to detect and understand the mechanism of thrombocytopenia. Kaito et al. [13] study also stated, the role of MPV and PDW play a significant role in detecting the thrombocytopenia in patient presenting with acute febrile illness. The present study also revealed, individual with thrombocytopenia tend to have elevated mean platelet volume (MPV) and platelet distribution width (PDW), which were studied as parameters to determine the cause of thrombocytopenia.

Conclusion

The leading cause of thrombocytopenia is infectious disease caused by various organisms. Among these, Dengue fever was found to be the primary cause of thrombocytopenia in patients with acute febrile illness, followed by malaria and leptospirosis. Platelet volume parameters like Mean Platelet Volume (MPV), Platelet Distribution Width (PDW) play a vital role in understanding the mechanism behind thrombocytopenia. Platelet Distribution Width and Mean Platelet volume also offer important insights into platelet destruction. An increased PDW indicates higher levels of platelet destruction and splenic pooling,

while Platelet Distribution Width varies in an inverse relationship with platelet count. Meanwhile, Mean Platelet Width serves as a useful screening test for distinguishing the cause of thrombocytopenia through the assessment of patient blood samples. Both MPV and PDW have the potential to detect the thrombocytopenia effectively with continuous assessment of blood samples of the patients.

Statements and Declarations

Conflicts of interest

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

Funding

No funding was received for conducting this study.

Informed Consent

Informed consent was obtained from all participating patients, and the study was approved by the institutional Ethics Committee

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ORIGINAL ARTICLE

A Study on Diagnostic Accuracy of Dipsi Method Over Traditional Oral Glucose Tolerance Test Among Antenatal Women

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Abstract

Introduction: Gestational diabetes mellitus (GDM) is a condition of glucose intolerance during pregnancy, with potential adverse effects on both maternal and neonatal outcomes. Detecting and treating GDM early is crucial to prevent complications. Various diagnostic criteria and methods, such as the Diabetes in Pregnancy Study Group of India (DIPSI) criteria, IADPSG (International Association of the Diabetes and Pregnancy Study Groups) have been debated for GDM screening. This study is aimed to compare the DIPSI and IADSP criteria which is widely used in India with the World Health Organization (WHO) criteria and assess their diagnostic accuracy. **Methods:** A cross-sectional study involving 100 antenatal mothers was conducted in a tertiary care hospital. Sociodemographic data, risk assessments, gestational age, and clinical measurements (height, weight) were collected. Participants underwent both OGTT (using WHO criteria) and DIPSI tests. The blood sugar values were classified, and diagnostic accuracy was measured using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The correlation between the two methods was also examined. **Results:** The study demonstrated a lower sensitivity, and a high specificity compared to OGTT (WHO criteria). A new cutoff of 120 mg/dl for DIPSI was obtained by ROC curve analysis for our study which had a specificity and sensitivity of 78.02% and 77.78% respectively. The correlation between OGTT fasting/postprandial and DIPSI measurements was weak. **Conclusion:** The study assessed the diagnostic accuracy of the DIPSI method compared to the OGTT, particularly in resource-constrained settings like India. Given the DIPSI method's observed low sensitivity, relying solely on it for GDM diagnosis is ill-advised. Failure to identify true positive cases could have significant clinical implications, impacting maternal and neonatal outcomes and overburdening healthcare systems. Further research with larger and diverse populations is needed to establish more accurate diagnostic thresholds for GDM using the DIPSI method or alternative criteria.

Keywords: Gestational Diabetes Mellitus, Diagnostic Accuracy, DIPSI method, Fasting and Postprandial Blood sugar

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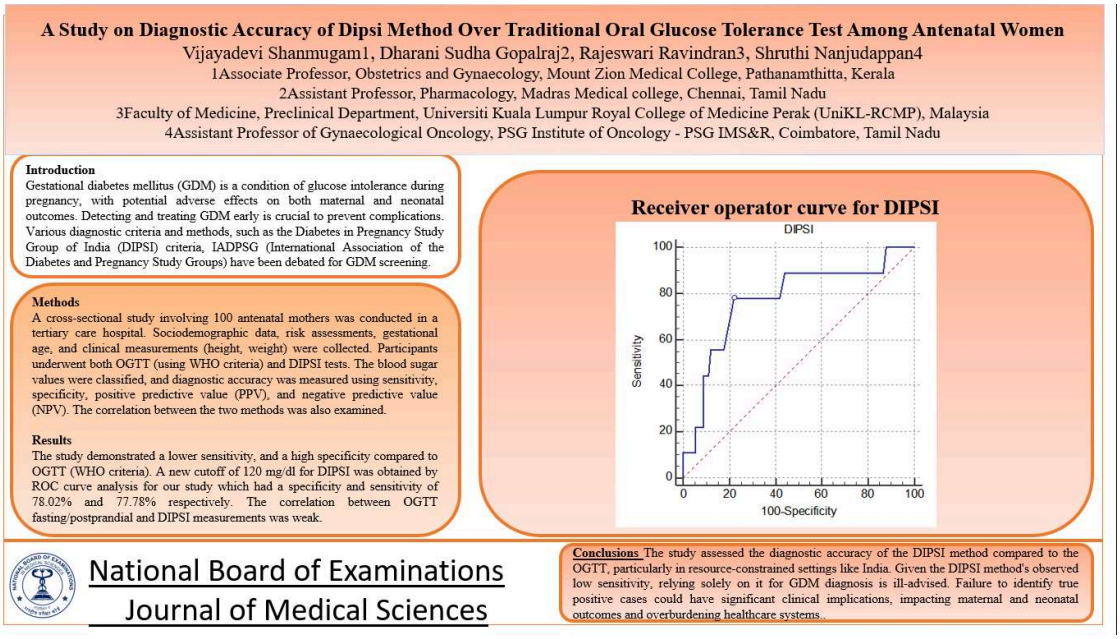
Graphical Abstract



Introduction

Gestational diabetes mellitus (GDM) is a general term for any degree of glucose intolerance that manifests or first noticed during pregnancy. Women with a history of GDM are more likely to experience unfavourable maternal and neonatal outcomes. They are also more likely to develop future Type II diabetes, which includes their children, putting two generations at risk [1,2]. The unfavourable maternal complications include hydramnios, preeclampsia, hypertension, urinary tract infection, increased surgical intervention, and future diabetes. It is linked to macrosomia, congenital malformations, metabolic abnormalities, respiratory distress syndrome, etc. in foetuses and newborns, as well as to later childhood and adolescent obesity [2]. Therefore, in order to avoid complications, it is crucial to detect early and treat this condition quickly. When it comes to screening and diagnosis of GDM, the precise glucose level to pick up glucose intolerance that characterises GDM is highly on debate.

Asian women are more likely to acquire GDM and associated complications due to the high incidence of familial DM and genetic vulnerability to metabolic syndrome, notably in Indian women [1]. In India, GDM affects 5 to 8 million women annually, accounting for one-third to two-thirds of births [3]. In India, it ranges from 6 to 9% in rural areas and 12 to 21% in urban areas, and it affects 7% of all pregnancies worldwide [4]. The high rate suggests that Indians are more likely to have GDM and have a higher incidence of diabetes and impaired glucose tolerance. Diagnoses are made at 16.3% within the first 16 weeks of gestation, 22.4% between 17 and 23 weeks, and 61.3% beyond 23 weeks [2]. The diagnostic criteria for diabetes outside of pregnancy have changed over time and are now broadly agreed by the world's leading diabetic organisations. However, there is still debate related to the screening and diagnosis of gestational diabetes mellitus (GDM). Despite years of research and numerous international conferences devoted to GDM, there is still no agreement among international organisations on a standard global strategy for GDM screening and diagnosis. There are different screening and diagnosis standards for GDM in different nations and among the world's main societies [4].

In India, where the prevalence of GDM is as high as 16.55% and the risk of developing the disease is 11 times higher for Indians than for Caucasians, more sensitive tests are needed to diagnose GDM. As a result, the test to be used depends on the ethnic group being researched.(5) Therefore, a universal, affordable screening and diagnostic procedure is required. The HAPO study shows that maternal hyperglycaemia, even at a level below that indicative of DM, is linked to macrosomia and higher birth weight. This continues to be a risk factor for having DM in the future and directly affects the foetal pancreas as it develops [2]. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria are based on the results of the large-scale hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study and are therefore well-known throughout the world. However, it is argued that this has the disadvantage of producing a high number of false-positive cases because the fasting cutoffs are too low, increasing the burden of GDM [6]. Additionally, the 2-hour cutoff is higher at 153 mg/dl, and it is debatable whether the blood glucose levels between 140 and 153 mg/dl can be left untreated without risk [5]. Additionally, the HAPO study's lack of Indian representativeness in its findings, diagnosing the Indian population by means of overseas studies can be inconclusive [6]. While WHO (1999) advises a fasting OGTT 126 mg/dl and/or after 75g of glucose with a cut-off plasma glucose of 140 mg/dl after 2-hours, DIPSI recommends non-fasting oral glucose tolerance testing (OGTT) with 75g of glucose with a cut- off of 140 mg/dl after 2-hours [7].

The Government of India guidelines propose using the Diabetes in Pregnancy Study Group of India (DIPSI) criteria, which is a variation of the previous WHO criteria, and it is utilized in epidemiological research all over India [7]. However, the test has also been shown to have a low positive predictive value and inadequate sensitivity. The WHO 1999 criteria of 2-h plasma glucose of 140 mg/dl was proved to be sufficient to diagnose GDM based on a sizable retrospective analysis comparing the IADPSG and WHO criteria. It was intended to compare the diagnostic accuracies of DIPSI criteria to WHO and IADPSG criteria for the diagnosis of GDM as both of these tests are widely used and acknowledged on a global scale [6].

Patients must visit the antenatal clinic in a fasted state and must then submit to several blood samplings for testing, as recommended by the ADA, WHO, and IADPSG. In contrast, the DIPSI proposes a two-hour plasma glucose measurement following the administration of a 75 g glucose load in a non-fasting state, regardless of the time since the last meal, as a straightforward, affordable, and practical single-step approach for the diagnosis of GDM. According to the DIPSI's recommendations, GDM is identified if the venous plasma glucose level is more than 140 mg/dl. It is extensively utilized since it is undoubtedly a simpler test, more patient-friendly, and it minimizes the discomfort for pregnant women. It is believed that this test can be used for both screening and diagnosis. In order to validate the use of a 75 g glucose load in a non-fasting state as a single step in the diagnosis of GDM, we decided to undertake this study [8]. With this background our study was undertaken to assess diagnostic utility of DIPSI compared to WHO criteria. Also secondarily the diagnostic utility of IADPSG classification was also assessed.

Materials and Methods

This cross-sectional study was commenced among 100 antenatal mothers who attended Obstetrics OPD in a tertiary care hospital, after IHEC approval. All antenatal women who attended the OPD were explained about the rationale and objective of the study, rights of the participants and other ethical issues concerned. The participant information sheet was given to them, and ample time

was given to the participant to understand the contents and make an informed decision. Written informed consent was obtained once they have consented to participate in the study. Those on steroids for auto immune disorders, obstructive lung disease, overt diabetes mellitus, Type 1 Diabetes mellitus were excluded from the study. A structured questionnaire was used to measure the socio demographic variables, basic risk assessment, gestational age, and clinical measurements (height, weight).

All those who accepted to participate were subjected to DIPSI test. The test was redone after few hours on the same day or was requested to come next day if the participant has vomited after glucose ingestion. If the patient has vomited the second time also, then she may be excluded from the study. After ingestion of the glucose, the participant was requested not to have meals for two hours. Two hours later, two ml of venous blood was drawn into sterile vials containing lithium heparin. For the OGTT, the individual was instructed to arrive after an 8 to 14-hour fast. All these samples were centrifuged before being processed in 1 hour on an automated Randox Daytonal clinical chemistry analyser utilising the Glucose Oxidase Peroxidase (GOD-POD) method to analyse for glucose. The internal quality control samples were tested following standardisation. The participant was asked to come for the OGTT within a week. After an overnight fast of 8 to 14-hours, a standard OGTT was conducted using 75g of anhydrous glucose in 250–300ml of water. It was determined that pregnant women who met the requirements for diabetes mellitus (DM) or impaired glucose tolerance (IGT) had gestational diabetes mellitus (GDM) after fasting and two hours.(9) DIPSI was a one-step process regardless of the most recent meal. In order to determine plasma glucose levels, pregnant women who were present at the prenatal OPD were given 75g of anhydrous glucose in 250–300ml of water [10]. The diagnosis cut offs of various guidelines are provided in Table 1.

Table 1. Diagnostic Criteria of various guidelines for GDM

Guideline	Fasting (mg/dl)	2 hour PPBS
WHO 1999	≥126	≥140
ACOG	≥95	≥155
Canadian Diabetes Association	≥95	≥160
IADPSG	≥92	≥153
DIPSI	NA	≥140

The results observed were entered in Microsoft Excel and analysed using SPSS software 20. The basic descriptive variables were expressed as frequency and percentages. The blood sugar values were classified according to the criteria mentioned and was expressed as frequency and percentages. The agreement between IADPSG criteria classification of GDM and DIPSI criteria was measured using kappa statistics.. Diagnostic accuracy specificity, sensitivity, Positive Predictive value (PPV) and Negative Predictive Value (NPV) were calculated for DIPSI and IADPSG classification considering WHO criteria as gold standard. Pearson correlation was done to measure the correlation between OGTT measurement and DIPSI measurements. $P<0.05$ was considered statistically significant.

Results

The prevalence of GDM with WHO criteria, IADPSG criteria and DIPSI method was 9%, 17% and 6% respectively. (Table 2). There was a poor agreement

between DIPSI and IADPSG Criteria (Table 3). The specificity and sensitivity of IADPSG Criteria was better compared to DIPSI classification (Table 4). There was a poor correlation between OGTT and DIPSI (Figure 1). Receiver operator characteristics Curve (ROC Curve) was drawn for GDM cutoff for Indian standards (Figure 2). The area under the curve was 0.773 with a significant P Value of 0.0037 for a DIPSI cut off of 120mg/dl at which the specificity was 78% and sensitivity was 77.78%. The specificity and sensitivity for various cut off is given in Table 5. At the usual cutoff of 140, though the specificity is more than 94.5%, the sensitivity is compromised to 11.1%.

Table 2. Distribution of study population according to diabetic status in each category

Method	**Normal**		**GDM**	
	F	**%**	**F**	**%**
WHO criteria	91	91.0	9	9.0
IADSP	83	83	17	17
DIPSI method	94	94.0	6	6.0

Table 3. Agreement between OGTT fasting, OGTT post prandial, Combine Fasting postprandial (WHO Criteria) with IADSP

Parameter	**Classification**	**IADSP**				**Agreement (Kappa)**	**P VALUE**
		NORMAL		**GDM**			
		F	**%**	**F**	**%**		
DIPSI	NORMAL	**79**		**15**		0.094	0.272
	GDM	**4**		**2**			

Table 4. Diagnostic accuracy of DIPSI/IADSP method over WHO OGTT classification

Criteria	**TP**	**TN**	**FP**	**FN**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
DIPSI	**1**	**86**	**5**	**8**	**11.1**	**94.5**	**16.7**	**91.5**
IADSP	**7**	**81**	**10**	**2**	**77.8**	**89**	**41.2**	**97.6**

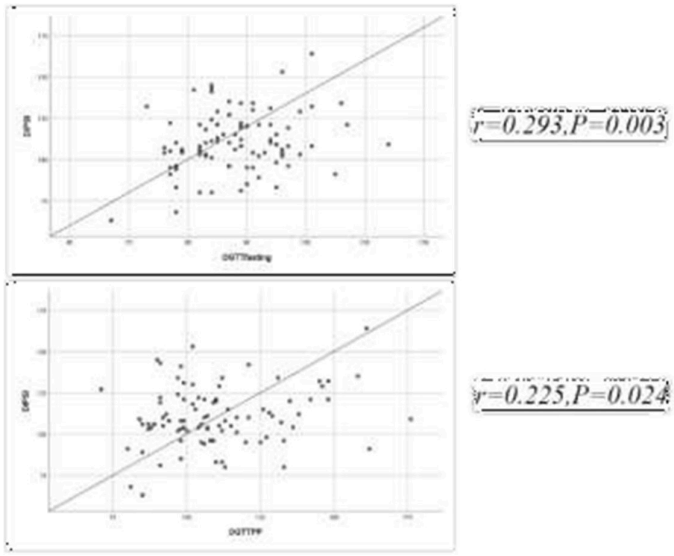
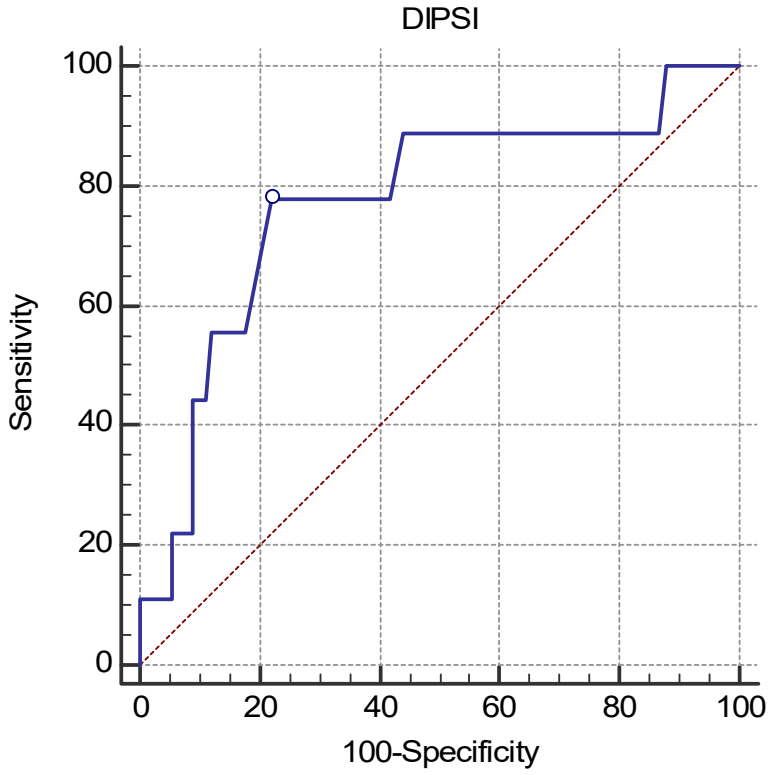


Figure 1. Correlation between OGTT and DIPSI



Area under the ROC curve (AUC)	0.773
Standard Error[a]	0.0939
95% Confidence interval[b]	0.678 to 0.851
z statistic	2.906
Significance level P (Area=0.5)	0.0037

Figure 2. Receiver operator curve for DIPSI

Table 5. Specificity and sensitivity for various DIPSI cutoff

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	95% CI	-LR	95% CI
≥63	100.00	66.4 - 100.0	0.00	0.0 - 4.0	1.00	1.0 - 1.0		
>89	100.00	66.4 - 100.0	12.09	6.2 - 20.6	1.14	1.1 - 1.2	0.00	
>91	88.89	51.8 - 99.7	13.19	7.0 - 21.9	1.02	0.8 - 1.3	0.84	0.1 - 5.8
>108	88.89	51.8 - 99.7	56.04	45.2 - 66.4	2.02	1.5 - 2.8	0.20	0.03 - 1.3
>109	77.78	40.0 - 97.2	58.24	47.4 - 68.5	1.86	1.2 - 2.8	0.38	0.1 - 1.3
>120	77.78	40.0 - 97.2	78.02	68.1 - 86.0	3.54	2.1 - 6.0	0.28	0.08 - 1.0
>121	55.56	21.2 - 86.3	82.42	73.0 - 89.6	3.16	1.5 - 6.6	0.54	0.3 - 1.1
>127	55.56	21.2 - 86.3	87.91	79.4 - 93.8	4.60	2.1 - 10.3	0.51	0.2 - 1.1
>129	44.44	13.7 - 78.8	89.01	80.7 - 94.6	4.04	1.6 - 10.3	0.62	0.3 - 1.1
>131	44.44	13.7 - 78.8	91.21	83.4 - 96.1	5.06	1.9 - 13.5	0.61	0.3 - 1.1
>132	22.22	2.8 - 60.0	91.21	83.4 - 96.1	2.53	0.6 - 10.1	0.85	0.6 - 1.2
>134	22.22	2.8 - 60.0	94.51	87.6 - 98.2	4.04	0.9 - 17.9	0.82	0.6 - 1.2
>135	11.11	0.3 - 48.2	94.51	87.6 - 98.2	2.02	0.3 - 15.5	0.94	0.7 - 1.2
>153	11.11	0.3 - 48.2	100.00	96.0 - 100.0			0.89	0.7 - 1.1
>164	0.00	0.0 - 33.6	100.00	96.0 - 100.0			1.00	1.0 - 1.0

Discussion

This cross-sectional analytical study was done to understand the diagnostic accuracy of DIPSI method over traditional OGTT method. Our result revealed that DIPSI is specific but not sensitive. Similar results were observed by other authors [1,8,11-16]. Many of the women who are mistakenly classified as normal have deranged fasting sugar readings, which may influence obstetrical outcomes [8].

Anjalakshi et al. [17] investigation on a population of South Indians revealed that the 75 g, two-hour non-fasting DIPSI test has 100% sensitivity and 100% specificity when compared to the WHO-recommended 75g OGTT for the diagnosis of GDM. They concluded that there was no discernible difference between the two tests for detecting GDM in women. Similar findings from another study on the Indian population were obtained [18]. The DIPSI test had been endorsed for widespread usage in India by Magon et al. [19]. Even though it involved fewer participants, a different study (20) found that 22.36 percent of instances of GDM were not identified using the DIPSI criteria. GCT with a two-hour cut-off value of less than 140 mg/dl is not sensitive enough to identify GDM recognised by GTT, according to a study done on Sri Lankan women. The main cause of the increased false positives is the DIPSI single cut off [22,23]. The 75 g, two-hour non-fasting DIPSI test's low positive predictive value (PPV) when compared to different OGTT types further emphasises the issue with accuracy. Low PPV suggests that many of the women diagnosed with GDM using this approach are unlikely to have the condition. Given that the test has a very high negative predictive value, a woman is not likely to have GDM if her values do not fall within the acceptable range.

A significant flaw in the DIPSI test is the substantial percentage of false positives and the very low number of false negatives. It is impossible to ignore the effects of clinical procedures brought on by

a false diagnosis of GDM. We attempted to determine if there was a likely cutoff with the highest level of specificity and sensitivity that could be utilised or advised in a South Indian scenario. The cutoff point that we were able to achieve with a balanced specificity (55%) and sensitivity (76%) was 107 mg/dl. The specificity and sensitivity were insufficient for the DIPSI Method to be employed as a diagnostic or screening method, as the estimated cutoff is extremely low. The present study is not without limitations.

In our study, the optimal cutoff for the DIPSI method was identified as **120 mg/dL** using ROC curve analysis, which showed better diagnostic performance compared to the standard DIPSI cutoff of **140 mg/dL**. This lower threshold demonstrated higher sensitivity and specificity, making it more suitable for our population. Similar findings have been reported in studies conducted in Indian and Asian subpopulations, where metabolic and glucose tolerance variations justify the need for region-specific cutoffs [10,24]. Adopting a cutoff of 120 mg/dL could facilitate earlier detection and timely management of gestational diabetes, potentially reducing adverse maternal and neonatal outcomes. However, further large-scale studies are needed to validate this threshold across diverse populations.

Conclusion

The primary objective of this study was to assess the diagnostic precision of the DIPSI method in comparison to the OGTT. In a developing nation like India, where expectant mothers continue to work until their anticipated delivery date, and where transportation options are limited, resulting in significant travel distances to prenatal appointments, often leading to inconvenience. Consequently, the non-fasting oral glucose tolerance test (OGTT) has garnered considerable attention in less developed countries. Given the observed low sensitivity of the DIPSI criteria in the current evaluation, it is unwise to rely solely on it for the diagnosis of gestational diabetes mellitus (GDM). It is crucial to recognize that failing to detect genuine positive cases could have significant clinical ramifications, potentially adversely affecting both maternal and neonatal outcomes, and further straining our healthcare system. Further research employing the DIPSI method or alternative criteria with larger sample sizes across diverse populations is warranted to establish more precise diagnostic thresholds for GDM.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Drug Adherence in Patients Attending Non-Communicable Disease Clinic: A Cross-Sectional Study

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Abstract

Introduction: Non communicable diseases are leading causes of Morbidity, Mortality and disability in worldwide. Non adherence to the medication plays a vital role for the inadequate control of NCDs. **Objectives:** To assess the drug adherence among patients attending the NCD clinic and the factors associated with compliance to the medications. **Methods:** A Cross-sectional study was done among 296 NCD patient attending NCD clinic at Govt Villupuram Medical college and the field practice community areas of Govt Villupuram Medical college and Hospital. WHO'S Morisky Medication Adherence Scale (MMAS)-8 was used to assess low medication adherence. **Results:** Among the 296 patients, 57% males and 43% females. The study found that 81.3% people have poor drug adherence, 10% have medium adherence and 9% have high Adherence. There was a statistical significance found between Age, Educational status occupation and Physical activity. **Conclusion:** Nearly two third of the patients have poor drug adherence in the study. The importance of Drug adherence to be sensitised and periodically health education sessions to be organized at NCD clinic to create awareness about drug adherence for the control and prevention of complications of NCDS.

Key words: Drug adherence, NCD Patient, Morbidity, Mortality, MMAS-8 SCORE

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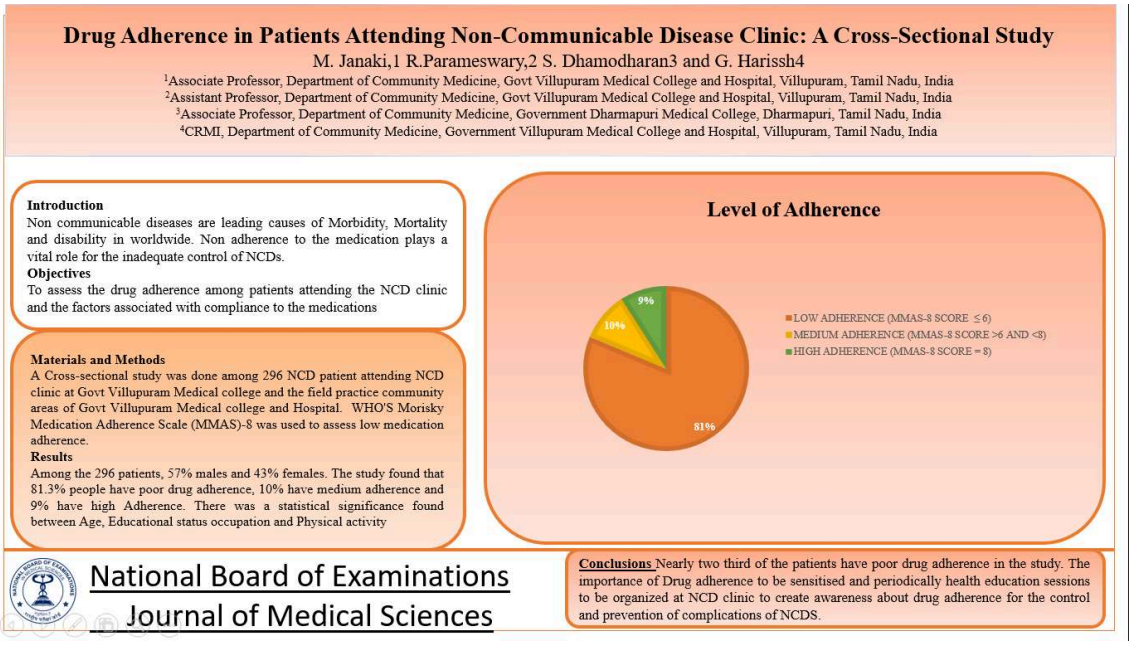
Graphical Abstract



Introduction

Globally, noncommunicable diseases (NCDs), particularly diabetes mellitus and cardiovascular disorders, have been identified as the primary cause of death [1]. Major NCDs are responsible for 47% of the world's illness burden and about 60% of all deaths in terms of morbidity, mortality, and disability [2]. Low- and middle-income nations like China and India account for the bulk of deaths [3]. In India, NCDs are responsible for 53% of all fatalities.

The main cause of the rising burden of illness and mortality from NCDs is patients' inadequate control status [4]. A number of variables, such as inadequate adherence to self-care guidelines, medication compliance, and a lack of integrated treatment at the health system level, contribute to individuals with NCDs having poor control status [5]. Of them, one of the most prevalent and possibly changeable reasons for insufficient NCD control is pharmaceutical nonadherence. Medication adherence is the "degree to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen," according to the International Society for Pharmacoeconomics and Outcomes Research [6].

It has been claimed that 50% of people worldwide fully comply with their chronic illness therapy, and this percentage is even lower in underdeveloped nations like India [7]. Research conducted throughout India has revealed that the prevalence of nonadherence among NCD patients varies [8–10]. Due to outpatient care, emergency room visits, and hospitalization for the treatment of problems brought on by an uncontrolled condition, poor drug adherence raises out-of-pocket expenses. Therefore, this study will be crucial in providing a precise picture of treatment adherence in NCD patients.

This research aimed to study the drug adherence in patients attending the NCD clinic which was achieved by assessing the adherence pattern in patients

with non-communicable diseases and finding out the factors associated with the compliance to medication in patients with non-communicable disease. The majority of patients with NCD in our nation receive healthcare services from primary care and family physicians, who must ensure that patients with NCD comply to their drug regimens in order to improve their control status. Knowing the prevalence of low drug adherence to NCD will help us understand the factors that lead to it. Thereby, First corrective actions can be taken at the patient level by encouraging and teaching them about the significance of drug use, followed by family and community level actions including community awareness campaigns and clinic health education sessions. To attain a high degree of adherence among all NCD patients, all of these interventions can be coordinated at the health system level.

Methodology

This was a cross-sectional survey done among patients with NCD attending NCD outpatient department in Government Villupuram Medical College and Hospital (GVMCH) and Rural Health training centres in Villupuram district namely Kandamandi Primary Health Centre, Kedar Primary Health Centre, Thogaipadi Primary Health Centre, Urban Primary Health Centre, Keezhperubakkam Primary Health Centre, to ascertain the nonadherence prevalence. The population served by each primary health center ranges from 30,000 to 50,000. With assistance from nursing personnel and public health nurses, medical officers and undergraduate intern trainees stationed from the GVMCH Department of Community Medicine offered health services. This research was carried out in February 2023. The GVMCH Institutional Ethics Committee gave their approval to the project.

The study included every adult patient who visited the NCD clinic. The sample size was estimated to be 296 with a 5% absolute precision and a 95% confidence interval (CI) based on the prevalence of low adherence among patients with chronic conditions, which was determined to be 74% based on a previous study [8]. Nevertheless, all patients who satisfied the inclusion requirements were included in the study. Since the study included all patients who visited the NCD clinic during the study period, no sampling technique was employed.

The three medical interns assigned to the rural health centre were chosen to collect the data. They received training on how to present the questionnaire to the participants as well as sensitization on the study's goals, information confidentiality, participant rights, and informed consent. Before administering the questionnaire, the participants were informed about the study's objectives and the procedure involved. Also, individuals received assurances about the privacy of the data, and data collection only began after receiving fully informed consent. The interview was divided into three sections: sociodemographic data were covered in the first section; behavioural data, such as current tobacco and alcohol use and adequate physical activity, were covered in the second section (Figures 1 and 2).

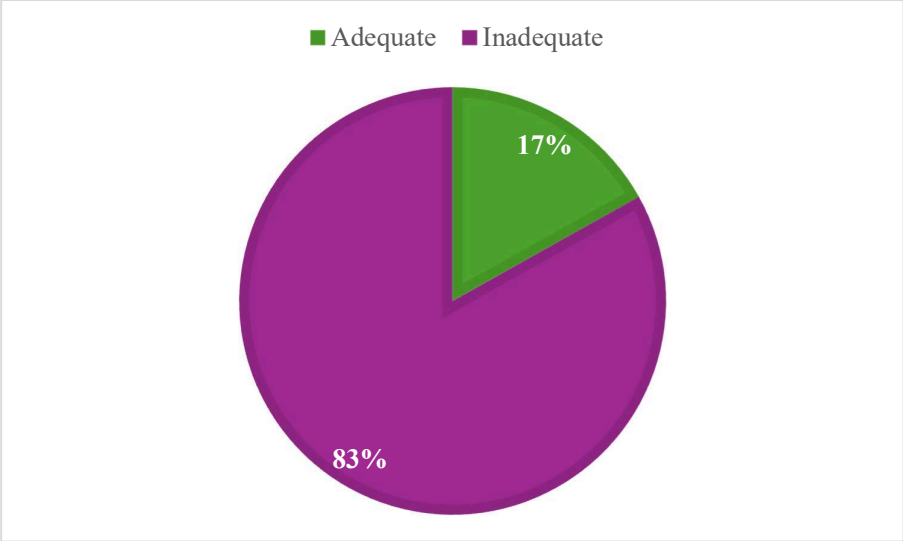


Figure 1. Physical Activity

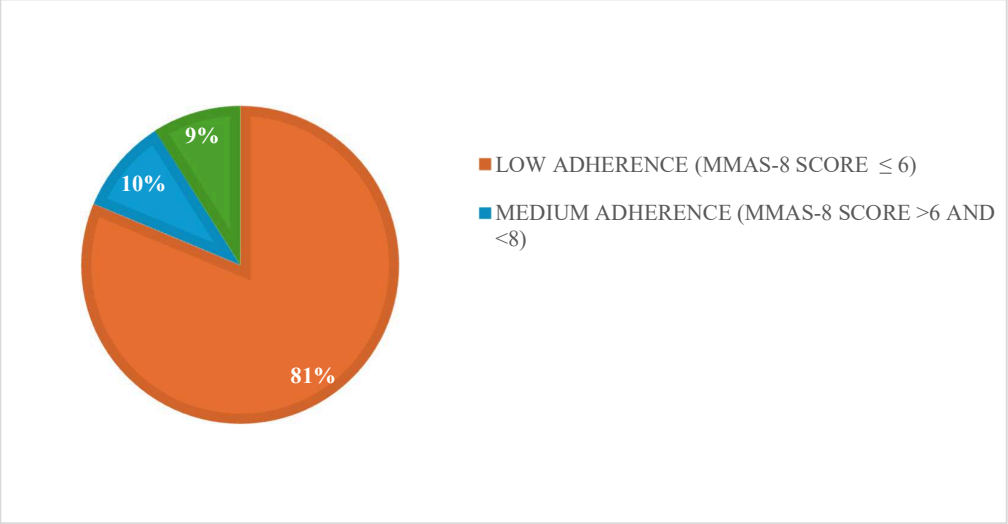


Figure 2. Level of Adherence

Those who used tobacco products regularly or infrequently during the month before the study period were considered current tobacco users; those who drank alcohol during the previous 12 months were considered current alcohol users. According to the World Health Organization's (WHO) international guidelines for physical exercise for health, it was considered sufficient to perform 150 minutes of moderate-level physical activity or 75 minutes of intense-intensity physical activity per week. The Morisky Medication Adherence Scale (MMAS)-8 was used to evaluate the study participants' poor medication adherence. An easy-to-use, eight-item scale for evaluating specific medication-taking behavior is the MMAS-8. Each question is assigned a score of either 0 or 1, depending on whether the answer is positive or negative. Cronbach's alpha reliability for the questionnaire was 0.83. [11] Pretesting, cognitive interviewing, forward translation, expert panel back translation, and final version preparation all helped to standardize MMAS for our study. The results showed that those with a score of less than six were considered to have low adherence.

Microsoft Excel 2016 was used to enter the data, while SPSS 24.0 was used for analysis. Continuous variables were summarized using mean values and standard deviation. The prevalence of low adherence was displayed as a percentage with a 95% confidence interval. Bivariate analysis (chi-square test/Fisher's exact test) was used to determine the relationship between sociodemographic traits and medication adherence. Using multivariate logistic regression analysis, factors impacting low medication adherence (independent effects) were identified. The dependent variable was medication adherence, and the explanatory variables were gender, age category, education, and occupation. The 95% CI for the adjusted prevalence ratio (PR) was calculated. Statistical significance was defined as a P value of 0.05 or less (Tables 1 to 6).

Results

Table 1. Sociodemographic Characteristics (N=296)

Sociodemographic parameters	**frequency**	
	n	**%**
Age (in years)		
20-29	3	1
30-39	44	15
40-49	77	26
50-59	79	27
60-69	62	21
70-80	31	10
Gender		
Male	170	57
Female	126	43
Educational Status		
Uneducated	233	79

Informally educated	51	17
Formally educated	12	4
Occupational Status		
Unemployed	93	31
Employed	203	69
Family Type		
Nuclear	157	53
Joint-family	40	14
Three-generation	101	34

Table 2. Behavioural Characteristics

Behavioural Characteristics	**Frequency**	
	n	**%**
Current Tobacco user (in past 1 month)		
Yes	51	17
No	245	83
Current Alcohol user (in past 1 year)		
Yes	78	26
No	218	74
Physical Activity		
Adequate	50	17
Inadequate	246	83

Table 3. MMAS-8 Score Obtained by Participants

SCORE	**FREQUENCY**	
	n	**%**
0	51	17.2
1	12	11.4
2	24	8
3	25	8.4
4	24	8
5	42	14
6	62	21
7	29	10
8	27	9

Table 4. Sociodemograghic Factors Influencing MMAS-8 Score

AGE (in years)	**n**	**LOW ADHERENCE**		**MEDIUM ADHERENCE**		**HIGH ADHERENCE**		**P VALUE**	**R VALUE**
		n	**%**	**n**	**%**	**n**	**%**		
20-29	3	3	100	0	0	0	0	0.00	0.01
30-39	44	32	73	11	25	1	2	0.00	0.01
40-49	77	62	81	6	8	9	12	0.00	0.01
50-59	79	66	84	7	9	6	8	0.00	0.01
60-69	62	52	84	5	8	5	8	0.00	0.01
70-80	31	25	81	0	0	6	19	0.00	0.01
GENDER									
MALE	170	141	83	18	11	11	6	0.23	0.70
FEMALE	126	100	79	11	9	16	13	0.23	0.70
EDUCATIONAL STATUS									
UNEDUCATED	233	184	79	23	9	26	50	0.00	0.05
INFORMALLY EDUCATED	51	44	86	6	11	1	1	0.00	0.05
FORMALLY EDUCATED	12	12	100	0	0	0	0	0.00	0.05
OCCUPATIONAL STATUS									
UNEMPLOYED	93	73	78	13	14	7	8	0.00	0.01

EMPLOYED	203	167	82	16	8	20	10	0.00	0.01
FAMILY TYPE									
NUCLEAR	157	121	77	19	12	17	11	0.00	0.49
JOINT FAMILY	40	33	83	7	18	0	0	0.00	0.49
THREE GENERATION	101	88	87	3	3	10	10	0.00	0.49

Table 5. Behaviourial Characteristic Factors Influencing MMAS-8 Score

CURRENT TOBACCO USER (IN PAST ONE MONTH)	**n**	**LOW ADHERENCE**		**MEDIUM ADHERENCE**		**HIGH ADHERENCE**		**P VALUE**	**R VALUE**
		n	**%**	**n**	**%**	**n**	**%**		
YES	51	39	76	6	11	6	11	0.9	0.33
NO	245	201	82	23	9	21	8	0.9	0.33
CURRENT ALCOHOL USER (IN PAST ONE YEAR)									
YES	78	66	85	7	8	5	6	0.00	0.525
NO	218	174	80	22	10	22	10	0.00	0.525
PHYSICAL ACTIVITY									
ADEQUATE	50	31	62	6	12	13	26	0.00	0.00
INADEQUATE	246	209	85	23	9	14	5	0.00	0.00

Table 6. Response to Each Question and Its Influence on MMAS-8 Score

QUESTIONS	n	LOW ADHERENCE		MEDIUM ADHERENCE		HIGH ADHERENCE		P VALUE	R VALUE
		n	%	n	%	n	%		
Have you ever forgotten take your medication?									
YES	171	119	70	25	15	27	16	0.00	0.00
NO	125	121	97	4	3	0	0	0.00	0.00
In the past 2 weeks, have you forgotten to take your medications?									
YES	146	90	62	29	20	27	18	0.00	0.00
NO	150	150	100	0	0	0	0	0.00	0.00
When you feel that the condition is aggravated or changed, do you adjust the dose without telling your doctor?									
YES	146	90	62	25	17	27	18	0.00	0.00
NO	150	146	97	4	3	0	0	0.00	0.00
When you travel or leave home for a long time, have you ever forgotten to bring medications?									
YES	135	83	61	25	17	27	20	0.00	0.00
NO	161	157	98	4	2	0	0	0.00	0.00
Did you take medications Yesterday?									
YES	167	160	72	20	12	27	16	0.00	0.00
NO	129	120	93	9	6	0	0	0.00	0.00
When you feel that your condition is under control, do you stop taking your medication without consulting your doctor?									
YES	145	93	64	25	17	27	19	0.00	0.00
NO	151	147	97	4	2	0	0	0.00	0.00
Do you ever find it difficult to adhere to your medication?									
YES	151	122	81	29	19	27	18	0.00	0.00
NO	145	145	100	0	0	0	0	0.00	0.00
Do you find it difficult to remember to take your daily dose of medicine on time?									
YES	167	115	69	25	15	27	16	0.00	0.00
NO	129	125	97	4	4	0	0	0.00	0.00

Discussion

In the Villupuram district, this community-based cross-sectional study was done among NCD patients who visited primary health care centres. The primary objective of this study was to identify the prevalence of low adherence and the contributing factors. 81.3% of people were found to have poor drug adherence. After possible confounding factors were taken into account, it was discovered that older and female participants had a higher likelihood of not taking their drugs as indicated.

According to this survey, over two-third (81.3%) of the patients were not taking their drugs as prescribed. Similarly, research conducted in Kerala revealed a prevalence of nonadherence of 74%.[8] Although roughly one-third of the participants in previous south Indian studies in Andhra and Karnataka reported nonadherence to medicine, they also found results that were contrast to those of this study [9,10]. Use of a validated scale to measure drug adherence was one of the study's key strengths. As the technique used to measure adherence includes questions linked to forgetfulness or carelessness and the attitude of the patients towards drug consumption, we were unable to obtain the precise number of pills skipped. The study is strengthened by its higher response rate (100%) and examination of nonadherence obstacles for several NCDs.

The study, however, had certain drawbacks. Apart from the links that were explicitly indicated by the participants, this study was conducted as a single cross-sectional interview, hence no causal relationship between nonadherence and factors related could be established. Although the majority of the responses were based on memory, bias can still exist. For patients with NCDs to experience improved control status, good medication adherence is crucial. The majority of patients in our nation with NCDs receive their medical care from family doctors and primary care doctors, who must make sure this is the case.

Conclusion

According to this study, over two thirds of the patients did not take their drugs as prescribed. Corrective actions must begin at the patient level by inspiring and educating them about the significance of drug consumption, and family level and community level actions can be carried out, such as health education workshops at the clinic and awareness campaigns in the community. To obtain high adherence levels among all NCD patients, all of these interventions must be coordinated at the level of the health system.

Statements and Declarations

Conflicts of interest

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

Funding

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ORIGINAL ARTICLE

A Study of Hypothyroidism in Chronic Kidney Disease (CKD) Patients

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Abstract

Introduction: Chronic kidney disease (CKD) is a progressive condition affecting over 800 million people worldwide, primarily attributed to diabetes, hypertension, and other risk factors. The progression of CKD leads to significant complications, including cardiovascular disease, anemia, and metabolic bone disorders. Hypothyroidism, a condition marked by deficient thyroid hormone levels, is known to affect patients with CKD through impacts on thyroid metabolism. **Materials and Methods:** A hospital-based cross-sectional study was conducted over three months in a tertiary care center in South India. The study involved 237 CKD patients who provided informed consent and met inclusion criteria. Patients with medication histories that could influence thyroid function or those with acute kidney injury were excluded. Detailed clinical assessments and laboratory analyses of renal and thyroid functions were performed. **Results:** The study population had a mean age of 50.6 years, with 61.2% females. Hypothyroidism was observed in 27.4% of the patients, predominantly subclinical (22.36%) rather than overt hypothyroidism (5.06%). CKD severity correlated significantly with hypothyroidism prevalence, with increased hypothyroidism rates in advanced CKD stages ($p < 0.001$). Correlation analysis revealed a negative association between estimated glomerular filtration rate (eGFR) and TSH ($r = -0.147$, $p = 0.023$), suggesting declining kidney function aligns with thyroid dysfunction. **Conclusion:** This study highlights a notable correlation between CKD progression and the occurrence of hypothyroidism, particularly subclinical hypothyroidism. Findings suggest a need for routine thyroid evaluation in CKD patients to facilitate early detection and management of thyroid-related complications, improving patient outcomes.

Keywords: Chronic kidney disease, hypothyroidism, thyroid dysfunction, CKD stages, subclinical hypothyroidism

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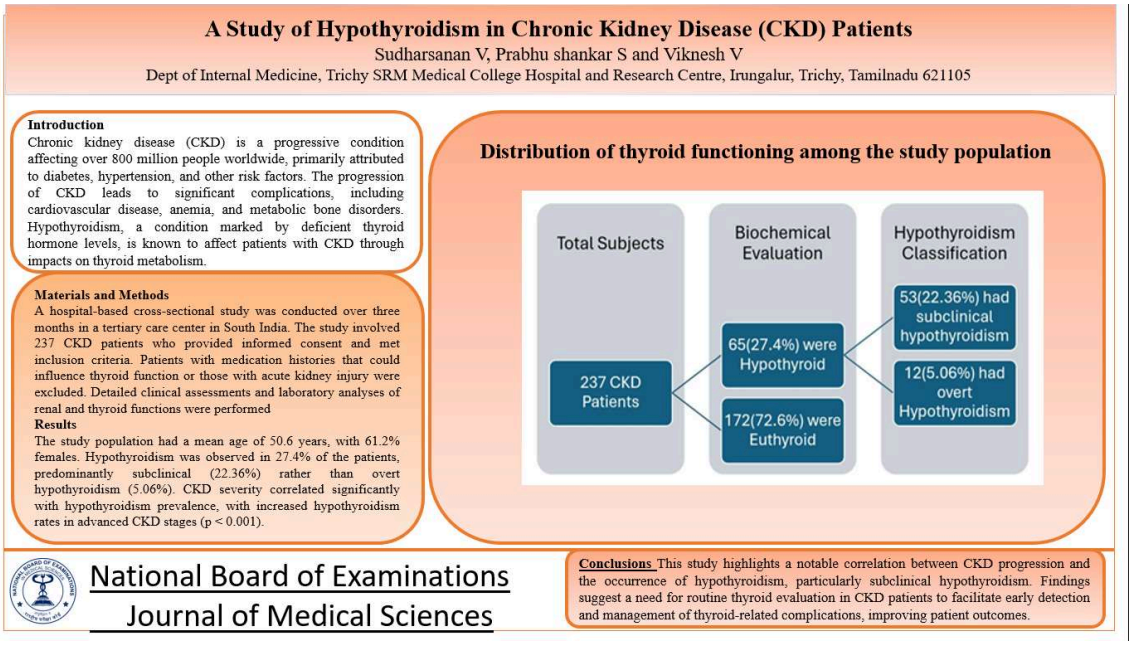
Graphical Abstract



Introduction

Chronic kidney disease (CKD), a progressive condition impacting more than 10% of the global population, exceeds 800 million individuals worldwide [1]. The primary causes of CKD in the majority of adults are typically diabetes and high blood pressure. Additional risk factors comprise heart disease, obesity, familial predisposition to CKD, inherited kidney disorders, prior kidney damage and advancing age [2]. The advancement of CKD is linked to several significant complications, such as a heightened risk of cardiovascular disease, hyperlipidemia, anaemia, and metabolic bone disease [3].

CKD diagnosis in adults involves identifying patients with a Glomerular Filtration Rate (GFR) persistently below 60 ml/min/1.73 m^2 for three months or more [4]. The 2012 KDIGO CKD classification provides guidelines regarding the etiology of chronic kidney disease (CKD) and categorizes it into six groups based on the glomerular filtration rate (G1 to G5, with G3 further divided into 3a and 3b). Additionally, it includes staging based on three levels of albuminuria (A1, A2, and A3). Each CKD stage is further subclassified according to the urinary albumin-creatinine ratio, measured in either milligrams per gram (mg/g) or milligrams per millimole (mg/mmol), using an early morning "spot" urine sample [5].

Hypothyroidism is a widespread pathological condition characterized by deficiency of thyroid hormones. Without proper treatment, it can cause significant adverse health outcomes eventually leading to death. Overt or clinical primary hypothyroidism is identified by thyroid-stimulating hormone (TSH) concentrations surpassing the reference range and free thyroxine concentrations falling below the reference range. Mild or subclinical hypothyroidism, often considered an early indication of thyroid dysfunction, is characterized by TSH concentrations exceeding the reference range while free

thyroxine concentrations remain within normal limits [6].

CKD had been known to influence the pituitary-thyroid axis as well as the peripheral metabolism of thyroid hormones. Low T3 levels are the most common laboratory finding followed by subclinical hypothyroidism in CKD patients [7]. The kidney typically plays a vital role in the metabolism, breakdown, and elimination of thyroid hormones. In CKD, the hypothalamus-pituitary-thyroid axis is impacted, leading to various effects on thyroid function such as decreased circulating hormone levels, modified peripheral hormone metabolism, inadequate binding to carrier proteins, diminished tissue thyroid hormone content and altered iodine storage in the thyroid gland. Consequently, CKD impairs thyroid hormone metabolism [8]. This study endeavours to discern hypothyroidism in individuals with chronic kidney disease (CKD) to enable early intervention and mitigate the risk of complications.

Methodology

A hospital-based cross-sectional study was conducted in a tertiary care center in South India, involving patients of both sexes admitted with chronic kidney disease under the Department of General Medicine. The study was carried out over a period of three months, from November 2023 to January 2024. Based on a literature review, it was determined that approximately 30.4% of individuals with chronic kidney disease (CKD) also had hypothyroidism. Using a relative precision of twenty in the sample size formula with an attrition rate of 95%, the minimum required sample size for the study was calculated as 237 patients. This study received approval from the Institutional Human Ethics Committee (IHEC), and all ethical procedures were strictly followed, ensuring adherence to guidelines for patient safety and confidentiality.

Eligible participants were individuals aged 18 years or older who were willing to undergo an examination after providing informed consent. Patients with a history of medication intake known to affect thyroid function, such as lithium, amiodarone, iodine, methimazole, or propylthiouracil, were excluded. Additionally, individuals with acute kidney injury were excluded to maintain the study's focus on chronic manifestations of kidney disease. These inclusion and exclusion criteria were carefully defined to ensure homogeneity in the study population and to reduce potential confounding factors that could influence the examination of the relationship between hypothyroidism and CKD.

After informed consent was obtained from each participant, a detailed history and clinical examination were performed. Blood and urine samples were collected under aseptic conditions and processed for thyroid profile and renal function tests in the central laboratory of the Trichy SRM Medical College. Following the collection of creatinine values, the respective estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. The stages of CKD were defined according to the Kidney Disease Improving Global Outcomes (KDIGO) guidelines. CKD stages were classified as follows: stage 1 with 24-hour proteinuria > 0.15 g and eGFR ≥ 90 mL/min/1.73 m^2, stage 2 with 24-hour proteinuria > 0.15 g and 60 mL/min/1.73 m^2 ≤ eGFR < 90 mL/min/1.73 m^2, stage 3 with 30

mL/min/1.73 m² ≤ eGFR < 60 mL/min/1.73 m², stage 4 with 15 mL/min/1.73 m² ≤ eGFR < 30 mL/min/1.73 m², and stage 5 with eGFR < 15 mL/min/1.73 m².

Thyroid-stimulating hormone (TSH) levels between 0.35 mIU/mL and 4.50 mIU/mL were considered indicative of euthyroid status, while mildly elevated TSH levels (4.6–8.0 mIU/mL) in the presence of normal free T4 were considered subclinical hypothyroidism. The study variables were carefully measured to assess the prevalence of hypothyroidism in relation to CKD severity.

Data was entered into Microsoft Excel 2021 and analyzed using JASP R 4.2.1 software. The prevalence of hypothyroidism among the study population was determined and compared with the severity of CKD. The results were presented as numbers and percentages for categorical variables, and as mean (SD) or median (IQR) for numerical variables. The Chi-square test or Fisher's exact test was used to assess associations between categorical variables. For continuous variables, One-way ANOVA, and Pearson rank correlation were applied to determine the association between CKD and hypothyroidism. A p-value of less than 0.05 was considered statistically significant.

Results

Descriptives

Socio-demographic profile

Around 237 patients were enrolled in the study as per selection criteria and after obtaining detailed history, clinical and biochemical evaluation were done. The mean ± SD of age the study population was 50.6 ± 9.8 years, among which 92 (38.8%) were males and 145 (61.2%) were females respectively. The mean ± SD of height, weight, and BMI of the study population were 162.2 ± 9.6 cm, 69.5 ± 11.2 cm, and 26.5 ± 4 kg/m^2 respectively.

Figure 1 explains the thyroid function evaluation among 237 patients with chronic kidney disease (CKD). After conducting biochemical assessments, 65 patients (27.4%) were found to have hypothyroidism, while the majority, 172 patients (72.6%), were euthyroid. Among those diagnosed with hypothyroidism, 53 patients (22.36%) were classified as having subclinical hypothyroidism, and 12 patients (5.06%) were identified as having overt hypothyroidism. This distribution indicates that subclinical hypothyroidism is more prevalent than overt hypothyroidism in the CKD population studied.

Figure 2 shows the distribution of patients across different stages of chronic kidney disease. The majority of patients are in **Grade-5 (32.07%)** and **Grade-3 (31.65%)**, indicating that a significant proportion of the study population is in the advanced stages of CKD. **Grade-4** accounts for **23.21%** of patients, while **Grade-2**, representing the earlier stages of CKD, includes only **13.08%** of patients. This distribution suggests that the patient population is skewed towards more severe stages of CKD, with a notable majority in Grade-3 to Grade-5 stages, reflecting the progressive nature of the disease.

Table 1 highlights the relationship between chronic kidney disease (CKD) staging and thyroid status, indicating that hypothyroidism becomes more prevalent as CKD severity increases. Among Grade-2 CKD patients, 90.32% were euthyroid and 9.68% were hypothyroid, while in

Grade-3 CKD, 89.33% were euthyroid and 10.67% were hypothyroid. The prevalence of hypothyroidism rises significantly in Grade-4 CKD, where 38.18% of patients were hypothyroid and 61.82% were euthyroid. In the most severe stage, Grade-5 CKD, 44.74% of patients were hypothyroid, with 55.26% remaining euthyroid. The chi-square test revealed a significant association between CKD staging and thyroid status (p-value < 0.001), confirming that hypothyroidism becomes increasingly common as CKD progresses.

Table 2 Depicts the clinical parameters across the different stages of chronic kidney disease (CKD) reveal several key insights. The mean height and weight of patients show minimal variation across CKD stages, with no statistically significant differences (Height: $p = 0.67$, Weight: $p = 0.66$), indicating that these variables do not change significantly as CKD progresses. Similarly, body mass index (BMI) remains relatively consistent across the stages ($p = 0.97$). However, estimated glomerular filtration rate (eGFR), thyroid-stimulating hormone (TSH), proteinuria, serum creatinine, and urea levels show significant differences between the stages (all $p < 0.001$), reflecting the worsening kidney function and thyroid dysfunction as CKD severity increases. For instance, eGFR decreases progressively from Grade-2 to Grade-5 (75.79 mL/min/1.73m² in Grade-2 to 9.01 mL/min/1.73m² in Grade-5), while TSH increases significantly (8.92 mIU/L in Grade-2 to 19.39 mIU/L in Grade-5), highlighting the association between CKD progression and declining renal function alongside increased thyroid dysfunction. Proteinuria, serum creatinine, and urea also exhibit marked increases, indicating the progressive nature of CKD and its impact on kidney function and metabolic waste regulation.

Table 3 shows the correlation analysis demonstrates significant associations between kidney function and thyroid parameters in patients with chronic kidney disease (CKD). A negative correlation between eGFR and TSH ($r = -0.147$, $p = 0.023$) suggests that as kidney function declines, TSH levels increase, indicating worsening thyroid function. eGFR also shows a positive correlation with free T4 (fT4) ($r = 0.203$, $p = 0.002$), meaning better kidney function is associated with higher fT4 levels. A strong negative correlation is observed between eGFR and urea ($r = -0.980$, $p < 0.001$), as well as between eGFR and creatinine ($r = -0.816$, $p < 0.001$), indicating that as kidney function worsens, urea and creatinine levels significantly rise. Furthermore, TSH is negatively correlated with fT4 ($r = -0.578$, $p < 0.001$), showing the expected inverse relationship between thyroid hormones, while it is positively correlated with urea ($r = 0.172$, $p = 0.008$) and creatinine ($r = 0.129$, $p = 0.047$), linking higher TSH levels with markers of declining kidney function. The negative correlations between fT4 and both urea ($r = -0.195$, $p = 0.003$) and creatinine ($r = -0.148$, $p = 0.022$) further highlight the connection between improved thyroid function and reduced kidney dysfunction. Overall, the findings emphasize a clear relationship between worsening CKD and increasing thyroid dysfunction, particularly hypothyroidism.

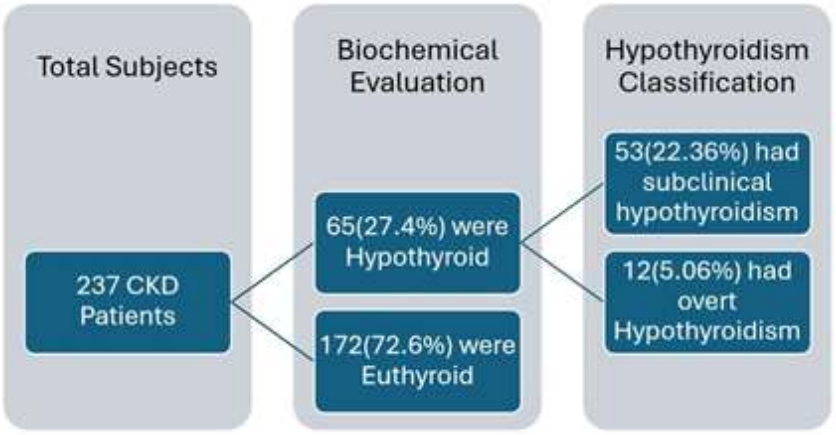


Figure 1. Distribution of thyroid functioning among the study population

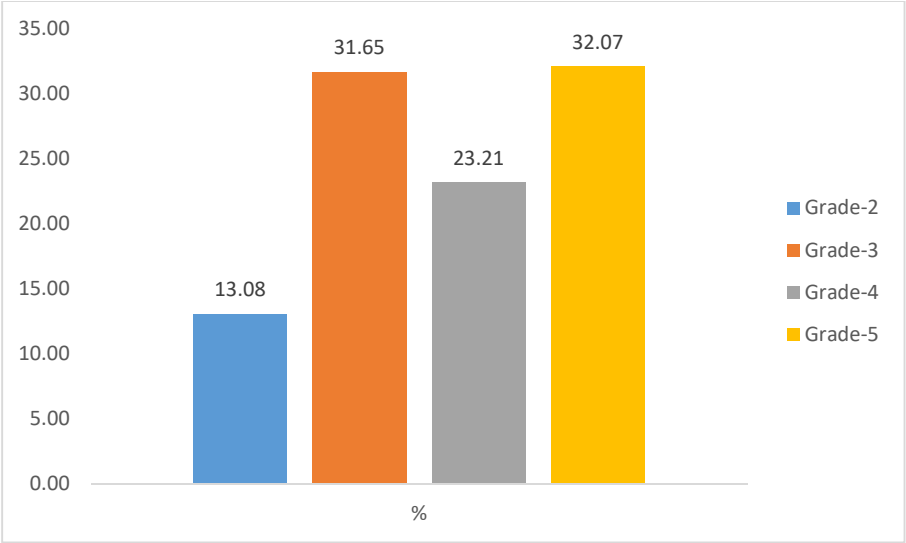


Figure 2. The grade wise distribution of CKD

Table 1. Association between Chronic Kidney disease and Hypothyroidism

Chronic Kidney Disease	Thyroid status				Total	CSV	p-value
	Euthyroid		Hypothyroid				
	N	%	N	%	N (%)		
Grade-2	28	90.32	3	9.68	31(13.08)	**28.95**	**<0.001**
Grade-3	67	89.33	8	10.67	75(31.65)		
Grade-4	34	61.82	21	38.18	55(23.21)		
Grade-5	42	55.26	33	44.74	76(32.07)		

*Chi-square test was performed

Table 2. The biochemical parameters of the patients

Variable	CKD grading	N	Mean	SD	F Value	P Value
Height (in cm)	Grade-2	31	161.28	9.532	0.517	0.67
	Grade-3	75	161.51	10.206		
	Grade-4	55	162.83	9.302		
	Grade-5	76	163.15	9.375		
Weight (in Kg)	Grade-2	31	68.83	9.625	0.5928	0.66
	Grade-3	75	68.59	11.814		
	Grade-4	55	70.51	11.688		
	Grade-5	76	70.53	10.720		
BMI (Kg/m^2)	Grade-2	31	26.66	4.491	0.0626	0.97
	Grade-3	75	26.37	4.538		
	Grade-4	55	26.68	4.576		
	Grade-5	76	26.56	4.060		
eGFR ($mL/min/1.73m^2$)	Grade-2	31	75.79	7.862	1152.06	<0.001
	Grade-3	75	43.61	7.175		
	Grade-4	55	21.57	4.374		
	Grade-5	76	9.01	3.173		
TSH (mIU/L)	Grade-2	31	8.92	1.34	**622.93**	**<0.001**
	Grade-3	75	10.47	1.21		
	Grade-4	55	14.18	1.38		
	Grade-5	76	19.39	1.68		
Free_T4 (ng/dl)	Grade-2	31	1.12	0.483	0.3042	0.82
	Grade-3	75	1.16	0.502		
	Grade-4	55	1.21	0.492		
	Grade-5	76	1.14	0.441		
Proteinuria (mg/dl) Gradually increasing	Grade-2	31	109.23	8.23	1899.30	<0.001
	Grade-3	75	121.19	9.51		
	Grade-4	55	183.27	8.97		
	Grade-5	76	219.65	9.06		
Sr. Creatinine	Grade-2	31	0.786	0.059	44.79	<0.001

(mg/dl)	Grade-3	75	1.114	0.057		
	Grade-4	55	2.212	0.214		
	Grade-5	76	4.396	3.37		
Urea (mg/dl)	Grade-2	31	55.1	2.74	862.05	<0.001
	Grade-3	75	65.7	2.94		
	Grade-4	55	73.6	2.46		
	Grade-5	76	88.02	4.47		

Table 3. Correlation between renal and Thyroid parameters

Variable	**eGFR** r (p-value)	**TSH (mIU/L)** r (p-value)	**fT4** r (p-value)	**Urea** r (p-value)	**Creatinine** r (p-value)
eGFR	1				
TSH (mIU/L)	-0.147* (0.023)	1			
fT4	0.203** (0.002)	-0.578*** (<0.001)	1		
Urea	-0.980*** (<0.001)	0.172** (0.008)	-0.195* 0.003	1	
Creatinine	-0.816*** (<0.001)	0.129* (0.047)	-0.148* (0.022)	0.816*** (<0.001)	1

Pearson co-relation was applied
* p < .05, ** p < .01, *** p < .001

Discussion

In this study, the thyroid profile of 237 chronic kidney disease patients was evaluated, and findings revealed that more than one-fourth (27.4%, n=65) of the study population exhibited hypothyroidism. These findings align with previous research by Lo et al. [14], who reported a similar prevalence of hypothyroidism where they have found the prevalence of hypothyroidism among CKD patients with an eGFR of less than 30 ml/min/1.73m^2.

Hypothyroidism and chronic kidney disease (CKD) may be coupled via a range of multifaceted and insufficiently comprehended mechanisms. The impact of CKD on thyroid hormone metabolism is one such explanation. Low circulating thyroid hormone levels, altered peripheral hormone metabolism, inadequate binding to carrier proteins, reduced tissue thyroid hormone content, and altered iodine storage in the thyroid gland are all consequences of chronic kidney disease (CKD), which additionally impacts the hypothalamus-pituitary-thyroid axis [15].

Further, our study revealed that among those hypothyroid cases, around 17.3% were Subclinical, which was supported by the similar findings reported

by Shreewastav et al. [16], where it has been found that a higher prevalence of subclinical hypothyroidism of about 27.2% among the CKD patients. It is also estimated that through previous studies the occurrence of primary hypothyroidism among the elderly was between 7%-26% [17].

Association between subclinical hypothyroidism and CKD may worsen kidney function by through direct and indirect effects, which were due to reduced cardiac output, raised systemic vascular resistance, intrarenal vasoconstriction, and impairment of glomerular anatomy. Also, studies have demonstrated that thyroid hormone replacement therapy among CKD patients with subclinical hypothyroidism has been led to attenuate the rate of eGFR decline [18].

Also, previous studies have found an increased prevalence of thyroid dysfunction among individuals with end-stage renal disease [19,20], which may be attributed to the underlying chronic inflammation [19]. Other contributing factors through which chronic renal failure may influence the thyroid parameters were low circulating thyroid hormone concentration, altered peripheral hormone metabolism, disturbed binding to carrier proteins, possible reduction in tissue thyroid hormone content, and increased iodine stored in thyroid glands [20].

In our study, we detected that low T4 levels which was in positive correlation with eGFR values, further supporting the evidence of hypothyroidism among CKD patients, and also through various studies, it has been demonstrated that free T4 levels vary from being low to normal among patients with chronic renal diseases [21]. Such heterogeneity might be due to several underlying factors, which include the severity of CKD, the presence of co-morbidities, and variations in levels of thyroid hormone-binding proteins.

Our findings on levels of free thyroxine align with previous research by Srivastava et al. [22], which observed a similar inverse correlation was found between the free T4 levels and renal function markers in a population with CKD, who were not requiring dialysis. The current study strengthens the existing evidence by reestablishing a comparable association in our patient population

Further, prior studies have demonstrated that CKD results in reduced iodide excretion, leading to a rise in serum inorganic iodide level & thyroid iodine content and consequently resulting in thyroid gland swelling, and finally ending up with goiter thyroid nodules and thyroid carcinoma [23].

Conclusion

It has been noted that there is a significant correlation between the severity of hypothyroidism with stages of chronic kidney disease. Additionally, there is a substantial association between CKD patients and prevalence of subclinical hypothyroidism. Our research suggests a comprehensive evaluation of the patient's medical history, encompassing information regarding the beginning and development of thyroid function as well as kidney health. Further the importance of Thyroid function test in all CKD patients for early diagnosis and treatment of hypothyroidism.

Statements and Declarations

Conflicts of interest

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

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No funding was received for conducting this study.

Human and animal rights

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

Informed consent

Informed consent obtained from all patients

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PERSPECTIVE ARTICLE

The Morgue: Aesthetics of the Space and Thanato-Aesthetics of the Bodies

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Mortuaries are often associated with dark, mysterious, ominous spaces, akin to dungeons, and evoke strong negative emotions in common people. The mere mention of a morgue or the sight of a dead body can trigger feelings of fear, aversion, and disgust, prompting a deep-seated instinct to recoil. This reaction is common across cultures, reflecting a universal discomfort with death and the spaces where the deceased are kept. In fact, discussing the idea of writing an article on this subject with peers and friends from different backgrounds has been a challenging experience for me. I have encountered significant resistance and scepticism, which has often made these conversations difficult.

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In the Indian context, as forensic pathologists, our primary focus may not usually be on the aesthetics of the morgue or how bodies are presented for viewing. The design of a morgue typically falls under the expertise of architects, while the presentation of deceased bodies lies within the realm of thanato-aesthetics, often handled by funeral directors or funeral service providers (Such services are professionally organized in Western countries, whereas in our country, they exist in an informal or unorganized manner). However, as the custodians of facilities where public services are provided during times of grief and crisis, we play a essential role in maintaining an environment that respects both the deceased and their families. In many cases, relatives spend long hours in morgues, waiting for the release of the mortal remains of their departed family members. Nonetheless, we are responsible for ensuring that even dismembered or mutilated bodies are cosmetically presented with dignity.

The design and aesthetics of the morgue are important not only to prevent burnout and vicarious traumatization among those of us who work there but also to provide a space that supports the bereaved in reflecting on their memories and coping with their loss. In this context, attention to aesthetic details in morgue design and body presentation becomes a matter of importance for both the service providers and the grieving families.

Although there is some information available on the functional design of morgues [1], there is scant to no discourse on the aesthetics of morgue premises. A modern morgue typically includes a reception and intake area, body storage area, autopsy suite, virtual autopsy suite, toxicology and histopathology labs, viewing room, decontamination room, central reception and waiting area etc. While most areas in a morgue are seamlessly connected, access to certain spaces is restricted for the public. Staff often have designated areas, and there are sometimes separate entry and exit points for deceased bodies and relatives. [2]

Thanato-aesthetics is not merely about the beauty of the morgue or the proper presentation of the deceased for viewing; it is primarily about helping families confront the reality of their loss and fostering a sense of harmony amidst the ongoing crisis.

The aesthetics of space is about the design elements that make a physical environment visually appealing and comfortable to experience. It involves the way a space looks and feels, including the arrangement of furniture, choice of colours, lighting, textures, and materials, all of which drive together to create a certain atmosphere or mood. In the context of a morgue, the aesthetics of space are essential not only for functionality but also for creating a respectful and calming environment for both staff and visitors.

To begin with, incorporating natural light wherever possible helps create a soothing and less oppressive environment. In places such as viewing rooms or waiting rooms, windows or skylights can lighten the mood of the next of kin (Despite handling large crowds and heavy caseloads at every center, this scenario can be organized more efficiently.) In areas where natural light is not possible, the use of warm, yellowish, or amber-hued adjustable lighting can make the space feel more inviting and less clinical. Similarly, all body-viewing spaces should feel open and impeccably connected to the larger environment. They should never be enclosing or isolating. In fact, the experience of viewing a dead body in a closed space intensifies emotions and may make the experience more overwhelming than it could be. The design needs to allow for openness and flow, creating a calm and less confining space that offers a better balance without intimidation for those coming to pay their respects.

Colours such as greens, peach, soft blues, and neutral tones tend to facilitate a relaxed and quiet environment [3]. These colours prove particularly effective in areas where families stay, such as while waiting or viewing. For functional areas, like the autopsy suite, light and clean tints such as white or pale grey are used often to emphasize cleanliness and ambience appeal.

A morgue should make use of heavy-duty but compelling materials that are easy to clean and maintain, such as stainless steel and ceramic tiles. Modern alternatives for morgues include epoxy resin flooring for seamless, durable surfaces; antimicrobial-coated stainless

steel for enhanced hygiene; and advanced composite panels for walls, combining ease of cleaning with durability and resistance to stains or chemicals. However, in non-clinical areas, textures like wood or fabric can create a warm and comforting atmosphere. Also, smooth, non-porous surfaces would not only be hygienic but also assure an orderly and neat appearance that is important in both functional and aesthetic terms.

Seating comfortably in the waiting areas and viewing rooms helps minimize the stress levels of the mourners. The design needs to provide for privacy and/or intimacy when needed, yet it should allow for an easy movement/navigation in order not to confuse and cause stressful situations for both staff and visitors. In addition, soundproofing is a common concern in morgues as the cascading effect of wailing heightens distressful moments. This quiet and peaceful ambiance is achieved through the use of sound-absorbing materials in the design, especially for family areas. A good acoustic design will also maintain privacy; thus, conversations in consultation rooms remain confidential and private.

A calm atmosphere can be created using art that reflects peace, nature, or abstract forms, especially in waiting areas and viewing rooms. Minimal decoration helps maintain a respectful and serene environment, avoiding clutter or distractions. Clear, logical pathways and proper zoning ensure the clinical and functional areas are distinct from spaces designed for visitors, preserving an appropriate atmosphere in each. The morgue's aesthetics should balance functionality with a calming environment that supports both staff and visiting families.

The *thanato-aesthetics* of the corpse refers to how the dead body has been treated, preserved, and presented, with a focus on both its appearance and its symbolic meaning. Embalming is one form of a thanatoaesthetic that is well known to all of us, yet there are many more advanced restorative techniques, such as tissue fillers, wax reconstruction, and airbrushing, enabling a *living* appearance to the *liminal* corpse. Thanatopraxy and postmortem cosmetology have evolved themselves as new branches in the field of death industry which are more concerned about presenting the corpse for viewing purposes while embalming is classically something associated with preservation [4].

Although the corpse has sometimes been viewed with abjection in various cultures and throughout history, it has never been regarded as something that does not deserve attention, especially in civilized societies [5]. Historically speaking, from ancient Egypt, where elaborate mummification processes were developed to preserve the body for the afterlife, to early embalming practices in other cultures, the way we treat the deceased has always been tied to beliefs about life, death, and the soul. These practices were not just about keeping the body intact, but also about making it look dignified or serene, reflecting the cultural importance placed on the body even after death.

In modern times, embalming has evolved with advanced techniques that aim to maintain a natural and peaceful appearance, markedly in funeral practices. The appearance of the body at a funeral can offer solace to the grieving, providing a sense of closure or a final moment of connection with the deceased. Thus, the corpse serves as the *aesthetic therapeutic* [4].

In conclusion, the aesthetics of morgue spaces and the bodies within them serve profound purposes. A thoughtful design of a mortuary fosters a calming environment, mitigating if not totally alleviating the trauma for both visitors and staff. Meanwhile, respectful and dignified body presentation honours the deceased and aids families in actualising their loss. These elements are not merely functional but deeply symbolic, bridging the gap between the practicalities of postmortem care and the emotional needs of the living. By embracing these principles, morgues in India can transform into spaces that uphold dignity, support grieving processes, and reflect the cultural importance of death and remembrance.

Statements and Declarations

Conflicts of interest

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

Funding

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CASE REPORT

Fatal Haemorrhagic Stroke Due to Concomitant Abuse of Sildenafil and Alcohol: A Case Report

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Abstract

Sildenafil is increasingly being abused recreationally for improving sexual endurance. The combined use of sildenafil with alcohol increases the risk of cerebrovascular accidents. We present the case of a 39-year-old male with no significant medical history who suffered a fatal stroke after consuming high doses of sildenafil while intoxicated with alcohol. Notable findings at autopsy include left ventricular hypertrophy, left capsuloganglioninc bleed and atherosclerotic changes in the coronary arteries. This case report highlights the risks of recreational sildenafil use, especially when combined with alcohol, and underscores the need for pharmacovigilance and public awareness.

Keywords: Sildenafil, Erectile Dysfunction, Recreational Abuse, Stroke, Dangerous Sexual Practices, Death

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Introduction

Sex is a fundamental aspect of human existence not just intended for reproduction but a way of self-expression and intimacy. Like many aspects of human behaviour, it has evolved over time, shaped by biology, culture, social norms, and more recently, technology. What someone may find as a *weird sexual fantasy* could often be normal for others in the vast diverse spectrum of human sexuality. Nowadays, many aspects of sexual adventures are shaped by exposure to explicit content and curiosity to personalise those experiences. The global porn industry, with its exploration of various fantasies, mirrors the growing human desire to experiment with different forms and expressions of sex [1].

Deaths occurring during or shortly after sexual activity have been documented in literature. For instance, in a 12-year multi-centric study although the overall incidence of deaths was low, middle-aged men during heterosexual intercourse are the largely affected group. Most of the fatalities are cardiac in origin, classically linked to undiagnosed ischemic heart disease. The abuse of cocaine and erectile dysfunction medications like sildenafil are common contributory factors in them, along with a higher prevalence of obesity and engagement in unusual sexual practices [2].

Sildenafil is the first globally approved drug for erectile dysfunction. It was initially developed as a treatment for pulmonary hypertension and angina pectoris. However, during the clinical trials researchers unexpectedly observed marked penile erections among the volunteers, prompting the pharma company to repurpose this drug for erectile dysfunction. As a phosphodiesterase type 5 (PDE5) inhibitor, sildenafil works by selectively inhibiting PDE5, which increases the levels of cyclic guanosine monophosphate (cGMP) in the corpus cavernosum, leading to smooth muscle relaxation and vasodilation, thereby improving erectile function [3].

Currently, sildenafil is primarily indicated for the treatment of erectile dysfunction and pulmonary arterial hypertension. However, it is contraindicated in individuals with hypersensitivity to sildenafil, those undergoing concurrent nitrate therapy, and those with severe cardiovascular disease. Common adverse effects include headache, flushing, dyspepsia, nasal congestion, impaired vision, and indigestion.

Sildenafil is often recreationally abused worldwide, driven by myths of enhanced duration of intercourse and the pursuit of greater sexual satisfaction. However, combining sildenafil with alcohol, cocaine, or other drugs of abuse to enhance sexual endurance can pose serious health risks. While sildenafil is an effective treatment for erectile dysfunction when used as prescribed, misuse can cause serious complications including death. This combination can disrupt blood pressure regulation and cardiovascular function, increasing the risk of stroke and other severe effects [4,5].

Case presentation

A 39-year-old male, who was on vacation with his friend without any significant history of medication or recreational drug abuse, developed acute right-sided hemiparesis the next morning after consuming 3-4 tablets of 50 mg sildenafil in an intoxicated state with alcohol. On examination in the emergency department, the patient was diagnosed with left capsulo-ganglionic hemorrhage. The etiology of the hemorrhage was suspected

to be induced by the synergistic effects of sildenafil and alcohol. The patient was initially stabilized and managed in the hospital for five days, after which he was transferred to a tertiary care facility in another city for ongoing management. On day 10, following stabilization, the patient was discharged with a recommendation for physiotherapy to aid in neurological rehabilitation. However, the day after discharge, while undergoing physiotherapy, the patient suffered a seizure, followed by a loss of consciousness. Despite resuscitation efforts, he was subsequently pronounced dead at another hospital. Since the patient was brought dead and the case fell under the category of suspicious deaths, it was subjected to a medico-legal autopsy.

At autopsy, the deceased was found to be obese, and the heart had left ventricular hypertrophy (20-25 mm) (Figure 1), and the brain revealed a left capsulo-ganglionic hemorrhage with intraventricular extension, showing both a dark brownish red color old clot and a bright red fresh hemorrhage (Figure 2). Chemical analysis of stomach contents and viscera detected no poisonous substances or sildenafil. Histopathological examination showed hemorrhage within the left lateral ventricle and white matter of the brain, accompanied by reactive gliosis, extravasated red blood cells, hemosiderin-laden macrophages, and edematous changes. The heart revealed left ventricular wall thickening, and the left coronary artery exhibited irregular thickening with a lipid core and scattered foamy histiocytes in the tunica media. The liver displayed fat accumulation and congestion, while the kidneys demonstrated glomerular congestion, acute tubular necrosis, luminal hemorrhage in the collecting ducts, and interstitial hemorrhage with edema in the medulla (Figure 3).

The initial cause of death was opined as a cerebrovascular accident due to unknown substance poisoning. However, upon reviewing the scene of the offence report, inquest findings, autopsy report, chemical analysis of viscera, and histopathology, the cause of death was determined to be a cerebrovascular accident temporally associated with the abuse of sildenafil and alcohol. Negative findings included the absence of signs of trauma, infection, or other systemic abnormalities. These autopsy findings are consistent with the complications of sildenafil (drug) and alcohol abuse.

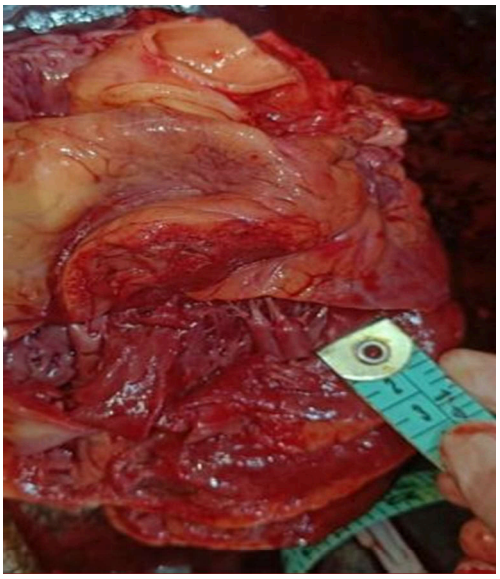

Figure 1. Left ventricle transverse cut section: hypertrophy of heart.

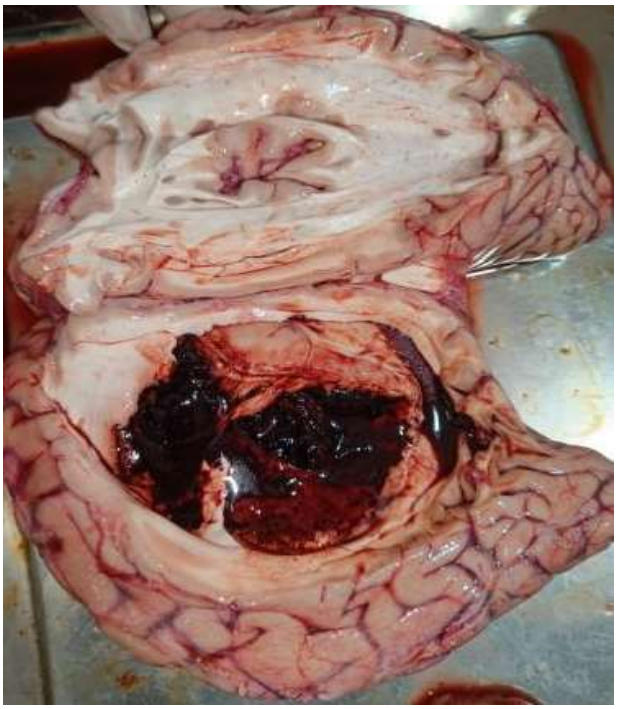

Figure 2. Resolving and fresh left capsulo-ganglionic bleed with ventricular extension on sagittal section.

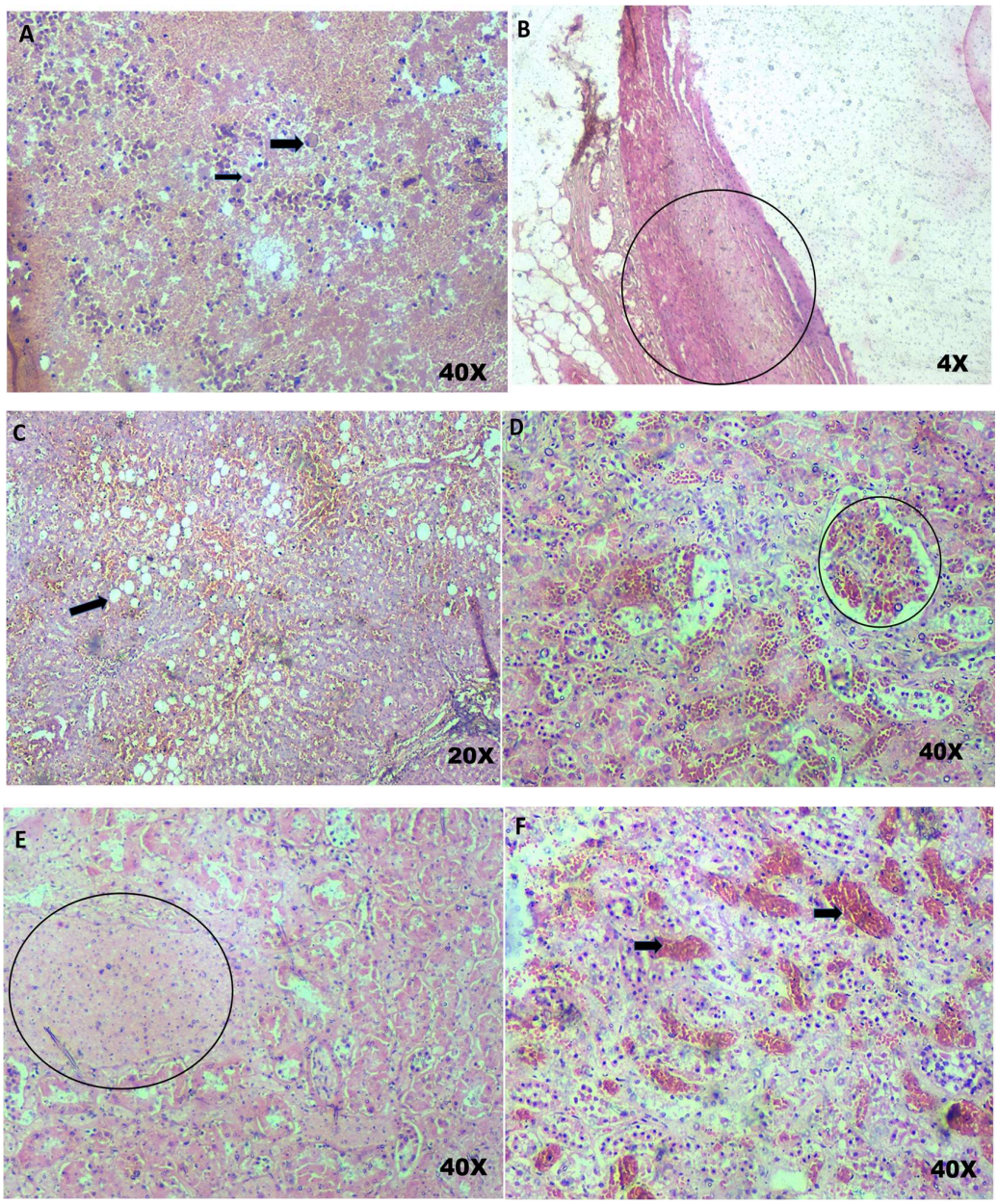

Figure 3. Photomicrographs, haematoxylin and eosin staining. **A** Extravasated RBCs and haemosiderin laden macrophages in brain (arrow) associated with reactive gliosis; **B** Irregular thickening of left coronary artery in heart (circled); **C** Fat cells and congestion in liver (arrow); **D** Glomerular congestion in kidney (circled); **E** Tubular Necrosis (circled); **F** Interstitial haemorrhage (arrow)

Discussion

The recommended dose of sildenafil is 50 mg, and the maximum dose is 100 mg within 24 hours [6]. Though sildenafil could not be detected qualitatively or quantitatively from the chemical analysis of viscera due to a lapse of approximately 10 days since consumption, it was inferred from the discovery of an empty blister pack at the scene and subsequent investigation that the deceased had consumed at least 200 mg of sildenafil which is an abnormally high dose.

The concomitant use of sildenafil and alcohol can induce substantial vasomotor effects, leading to blood pressure fluctuations that may directly or indirectly trigger cerebrovascular accidents, as reported in the literature [3,6]. The exact pathophysiology of stroke in such scenarios remains unclear. Sildenafil influences cerebral circulation through the nitric oxide (NO)-cGMP pathway, leading to vasodilation and increased cerebral blood flow. This heightened blood flow can raise the risk of intracranial haemorrhage, particularly in individuals with underlying conditions such as latent atherosclerosis or undiagnosed hypertension, as seen in this case. Additionally, sildenafil's effects on enzymes like PDE-1 and PDE-2 in the brain may further alter cerebral hemodynamics, exacerbating the risk of vascular complications.

The misuse of sildenafil, markedly among young populations without underlying erectile dysfunction, has grown, often as a countermeasure to the erectile dysfunction caused by other recreational drugs. High-dose sildenafil is sometimes combined with substances like MDMA (ecstasy), stimulants, or opiates in dangerous mixes referred to as "sextasy" or "trail mix." The concurrent use of sildenafil with amyl nitrite or alcohol is potentially fatal and can cause haemorrhagic stroke.

The risk of rebleeding is a critical consideration in this case, as the patient developed a secondary haemorrhage over a resolving haemorrhagic stroke that occurred 10 days prior. Rebleeding in cases of cerebrovascular accidents (CVA) of the haemorrhagic type can occur at variable intervals, ranging from days to years, depending on several factors. [7] These include the use of anticoagulants, persistent vascular injury, and uncontrolled hypertension, all of which contribute to vascular instability. However, one of the major limitations of this case report is absent data from the medical records and the previous medical history or drug history of the decedent [7].

Alcohol is known to cause cerebral vasodilation by several mechanisms including modulation of the biogenic amine and NO pathways. Alcohol potentiates the effects of sildenafil on the brain by increasing the production of nitric oxide (NO) from the endothelial cells, which promotes vasodilation and lowers vascular smooth muscle tone. This enhanced NO production can lead to further cerebral vasodilation, increasing the risk of adverse cerebrovascular events like stroke or transient ischemic attacks (TIA), particularly in individuals with pre-existing cardiovascular risk factors. It is also known that sildenafil redistribution in the arterial flow because of vasodilatory effect reduce the perfusion and cause myocardial circulatory insufficiency leading to ischemia [6].

The misuse of sildenafil and similar drugs by younger individuals is increasingly associated with psychological dependence, potentially masking underlying issues related to sexual function.

Furthermore, combining these drugs with alcohol or other substances can impair cognitive function, leading to reduced inhibitions which can lead to engaging in unsafe sexual practices, thereby elevating the risk of contracting sexually transmitted infections (STIs) due to unprotected sex [5].

Conclusion

The crux of the present discussion is to bring to limelight the adverse effects of unprescribed use of sildenafil, which has become a matter of concern. In the present case, the contributory role of key factors, such as the potentiating effect of alcohol and the presence of underlying comorbidities like hypertension and atherosclerotic heart disease in precipitating a cerebrovascular accident cannot be overlooked. Sildenafil is commonly used by both younger and older adults, and its over-the-counter availability has led to misuse without prescription. Public awareness campaigns are crucial to educate high risk groups like young adults on the dangers of non-prescribed sildenafil use.

The expectations surrounding sexual performance have become distorted, often driven by unrealistic ideals and external pressures. This leads some to misuse drugs like sildenafil, not out of medical indication, but to fit an imagined standard of performance. It's important to recognize that sexual experiences vary intra-individually and inter-individually, influenced by factors such as stress, fatigue, underlying health conditions and the emotional dynamics between the partners. These variations often don't require any medical attention as generally perceived. To foster better understanding, these topics should be discussed openly, without stigma, through anonymous platforms where young adults, and healthcare professionals, including andrologists, can engage in meaningful dialogue**.**

Statements and Declarations

Conflicts of interest

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

Funding

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CASE REPORT

From Benign Beginning to Malignant Giant: The Journey of Recurrent Cystosarcoma Phyllodes

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Abstract

A 42-year-old lady presented with a recurrent left breast mass, initially diagnosed as a benign phyllodes tumor. Despite wide local excision, the tumor recurred thrice over three years, each recurrence demonstrating increasing stromal cellularity and atypia. Imaging revealed a giant heterogeneous mass, and core biopsy confirmed a borderline phyllodes tumor. Surgical management included a wide local excision of the mass and chest wall with immediate reconstruction. Histopathology showed malignant transformation with negative margins. Postoperative recovery was uneventful. This case highlights the aggressive potential of recurrent phyllodes tumor and emphasizes the importance of close monitoring, timely surgical intervention, and consideration of adjuvant therapy.

Keywords: Fibro-epithelial neoplasm, Benign phyllodes; borderline phyllodes; malignant phyllodes; recurrence; margins

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Case Report

A 42-year-old woman, previously operated thrice for cystosarcoma phyllodes (histologically benign), presented with a massive 30 cm × 28 cm recurrent tumor in the left breast, causing breathlessness, restricted daily activities, and significant cosmetic concerns (Figure 1). MRI was unfeasible due to the tumor size, and CT revealed chest wall involvement with axillary lymphadenopathy. A trucut biopsy indicated a borderline tumor.

With no significant family or medical history, she underwent a wide local excision with a 1 cm margin, axillary dissection, and chest wall resection from 4th to 6th intercostal spaces. Chest wall reconstruction was achieved using dual mesh and a bi-lobed latissimus dorsi flap (Figure 2). The excised postoperative specimen weighed 6 kg (Figure 1). Postoperative recovery was uneventful (Figure 1), and she was discharged on the 10th day. Histopathology confirmed malignant phyllodes with clear margins and reactive lymph nodes. The patient was referred to oncology division for adjuvant therapy.

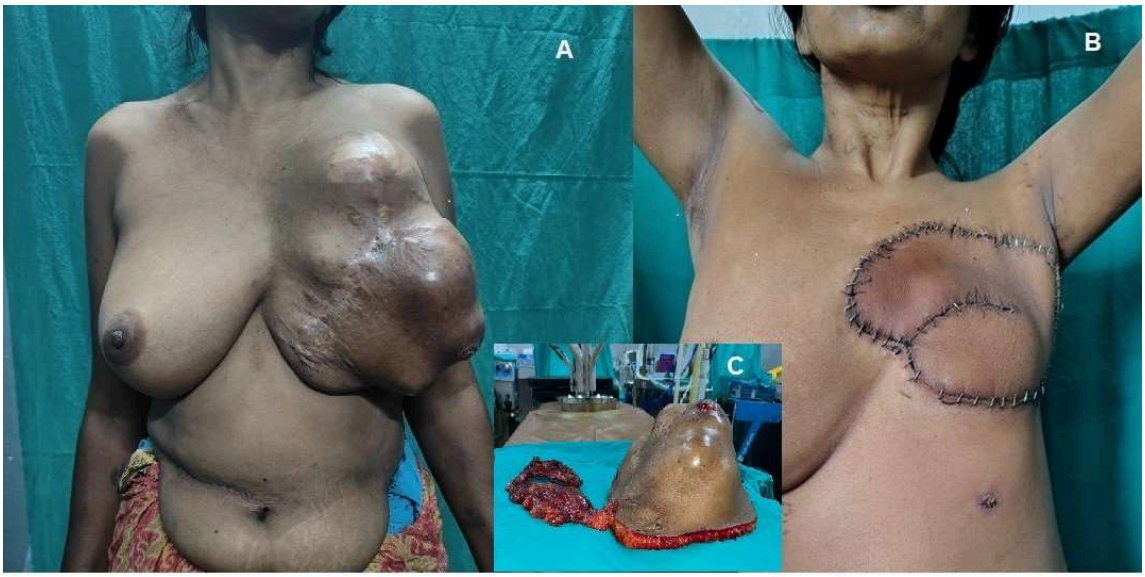

Figure 1. **A.** Preoperative picture of recurrent Phyllodes, **B**. Postoperative picture after reconstruction, **C.** Specimen.

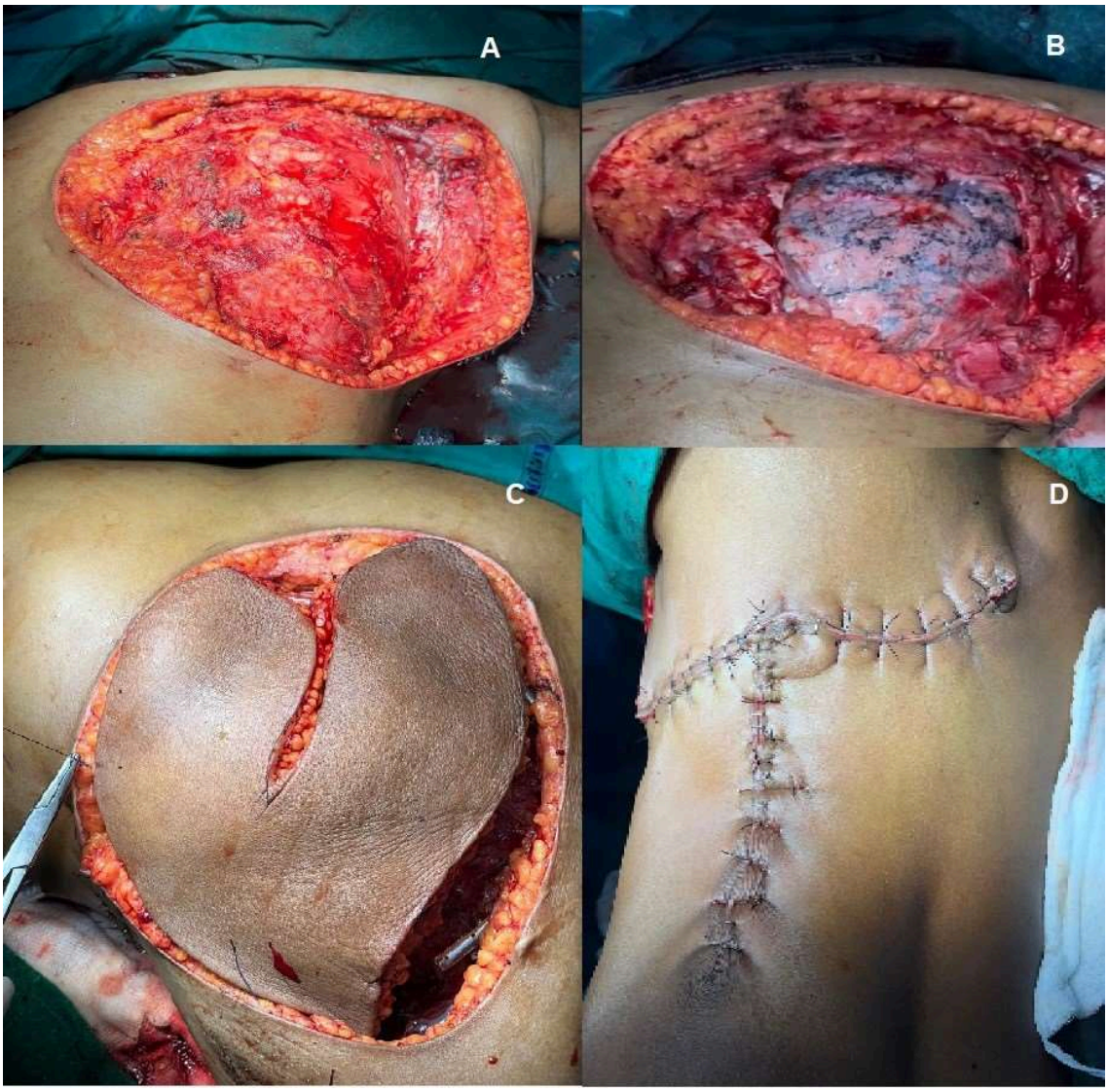

Figure 2. **A.** After wide excision, **B.** Chest wall excision, **C.** Coverage with bi-lobed myo-cutaneoous Latissimus Dorsi Flap, **D.** Primary closure of doner site.

Discussion

Phyllodes tumours are rare fibroepithelial lesions, accounting for 0.3% to 0.5% of all breast neoplasms [1]. They primarily affect women aged 45 to 49 years and are histologically classified into benign, borderline, and malignant subtypes [2]. Benign tumours constitute 35% to 64% of cases, while the remainder are borderline or malignant [2]. These tumours arise from the stromal components of the breast and involve monoclonal proliferation, often triggered by somatic mutations, endothelin-1 stimulation, or growth factor pathways [3]. Typically, they occur in the upper outer quadrant of the breast and can grow significantly, with giant phyllodes tumours exceeding 10 cm and reaching up to 40 cm [1,2]. Clinically, they may present with dilated subcutaneous veins, skin or pectoral fixation, while ulceration is rare. Axillary lymphadenopathy is seen in 10% to 15% of cases, but less than 1% show

pathological involvement [4]. Radiological investigations such as ultrasonography and mammography are the mainstay for diagnosis, while MRI is reserved for complex cases. Cytologically, fine-needle aspiration cytology (FNAC) can be helpful, but a core needle biopsy using Paddington's criteria is more reliable for diagnosis [5]. The treatment of choice is a wide local excision with at least a 1 cm margin for smaller tumours. For tumours larger than 10 cm, mastectomy is often required, though axillary dissection is typically unnecessary. Adjuvant treatment remains controversial due to the low incidence of metastatic spread [1-5]. Despite appropriate management, recurrence is common, necessitating close follow-up.

Conclusion

Recurrent phyllodes tumors require vigilant follow-up and timely surgical intervention due to their potential for aggressive behavior and malignant transformation

Authors Contribution

Study conception and design –UD, DK, SR, SD; Material preparation – SR, DK, SD; Data collection - SR, DK; Drafting and final approval – UD, DK, SR, SD

Data Availability

All the data pertaining to the patient is available with the corresponding author and would be made available if necessary.

Conflict of Interest

The authors declare no competing interests.

Patient consent

With the corresponding author would be made available if necessary.

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CASE REPORT

Ruptured Suprasellar Dermoid Cyst presenting with Chemical Meningitis and Blindness

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Abstract

Background: Intracranial dermoid cysts (ICDC) are rare benign lesions. They typically originate from the ectoderm and contain dermal elements like hair follicles, sweat glands, sebaceous glands, and sometimes teeth. Ruptured suprasellar dermoid cysts with intracranial dissemination are extremely rare. **Case presentation:** We report one such patient who presented with headache and blindness, imaging suggestive of ruptured intracranial dermoid cyst. We performed a pterional craniotomy and excised the tumor and the diagnosis was consistent with dermoid cyst on histopathology. **Conclusion:** Rare cases should be reported for further scientific advancements and a better understanding of physicians in the future if they encounter.

Keywords: dermoid cyst, chemical meningitis, blindness, suprasellar

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Introduction

Dermoid cysts, also called mature cystic teratoma, are congenital benign tumors arising from embryonic ectodermal cells and contain dermal elements like retained hair follicles, sweat glands, sebaceous glands, and sometimes teeth. The incidence of ICDC is less than 1% of all intracranial tumours [1]. ICDC are typically seen in the suprasellar region, Sylvian fissure, and posterior fossa including cerebellopontine angle or within the fourth ventricle. Extracranial dermoid cysts are seen in the orbit and spine. Malignant transformation to squamous cell carcinoma is extremely rare [2]. ICDC usually presents with headache, seizures, visual loss, cerebral ischemia with neurodeficit, meningitis when ruptured, obstructive hydrocephalus, and lower cranial nerve palsy, as per their locations [3]. Craniotomy and excision of the lesion with a capsule is the treatment of choice [4]. We report a case of a middle-aged gentleman with ruptured suprasellar dermoid cyst presenting with headache, blindness, and aseptic meningitis.

Case Report

A 49-year-old male patient presented with headache for one month and progressive drowsiness and disorientation for one week before his presentation, without any history of seizures or vomiting. He had impaired vision in his left eye since childhood. On examination, there was no focal motor or sensory deficit. He was confused but obeying commands, pupils were equal and reacting to light and accommodation. Fundus examination showed primary optic atrophy in his left eye. NCCT scan of the patient showed an extra-axial fat density lesion in the suprasellar and right frontal region (Figure 1) with fat attenuation in the subarachnoid spaces and areas of calcification around the lesion. The lesion measured 65 mm x 52 mm x 45 mm (AP x TR x CC).

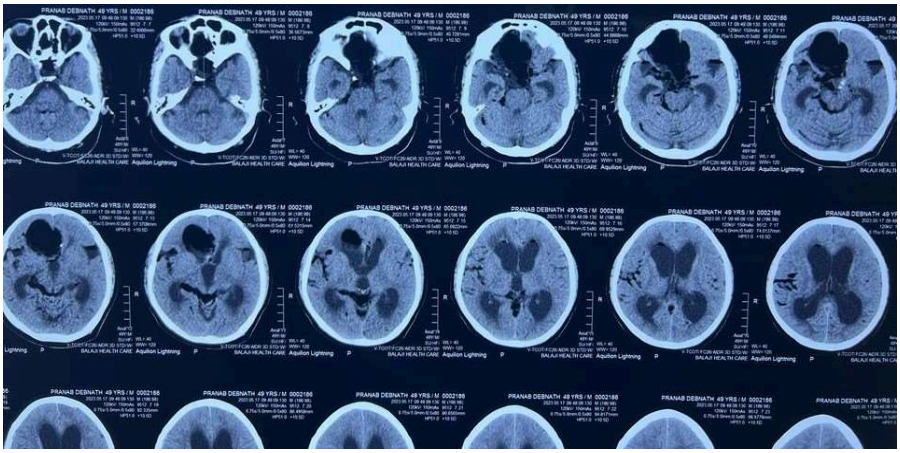
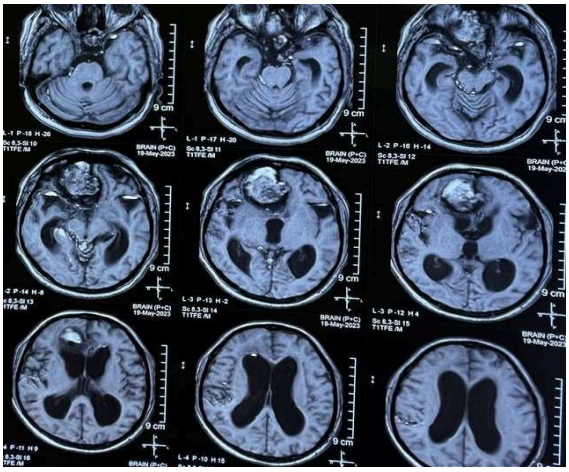
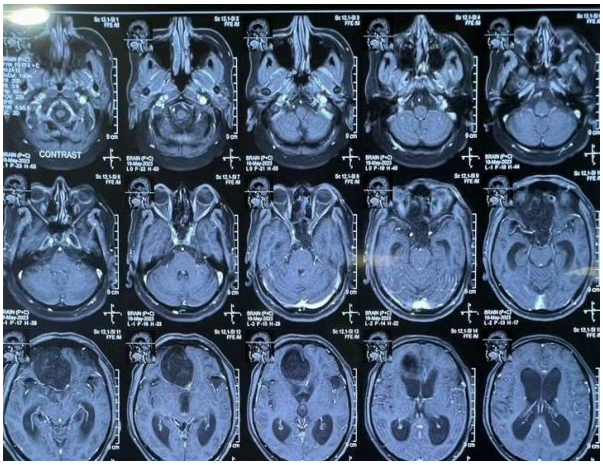


Figure 1. NCCT of brain showing extra-axial fat density in the suprasellar and right frontal region with fat attenuation in the subarachnoid spaces, areas of calcification around the lesion, and obstructive hydrocephalus.

MRI Brain with contrast (Figures 2 and 3) revealed a fairly marginated lesion in T1 sequence & T2W hyperintense lesion, in midline suprasellar and right basi-frontal region, with patchy restricted diffusion, minimal post-contrast enhancement.





Figures 2 and 3. MRI showing a fairly marginated T1 hyperintense lesion, in midline suprasellar and right basi-frontal region, minimal post-contrast enhancement.

Multiple T1 & T2W hyperintensities were seen in both lateral ventricles, quadrigeminal cistern, Sylvian cisterns, and basal cisterns which showed blooming on gradient echo. Radiologically it favoured the diagnosis of a ruptured intracranial dermoid cyst (Figure 4).

After obtaining proper written consent from the patient, we performed a right pterional craniotomy, with EVD inserted through Paine's point. After wide splitting of Sylvian fissure and basal cistern, a large dermoid cyst was removed from the subarachnoid space. The tumor capsule was adherent to branches of the middle cerebral artery, right optic nerve, and optic chiasm. Post-operative recovery was uneventful. Histopathology confirmed a Dermoid cyst. His vision improved significantly at the 3-month follow-up-up (Figures 5 and 6).

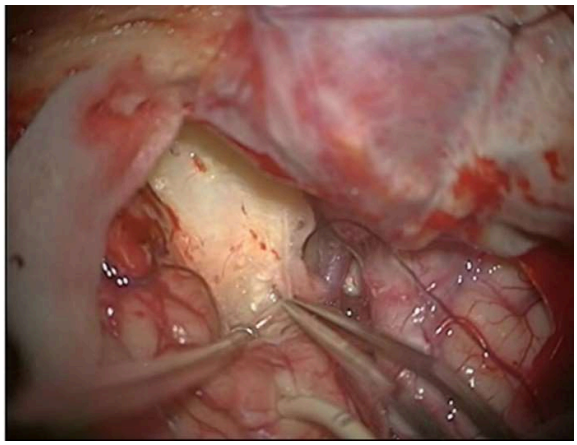


Figure 4. Intraop image showing under microscope after right pterional craniotomy and sylvian fissure dissection, lesion can be seen (yellowish).

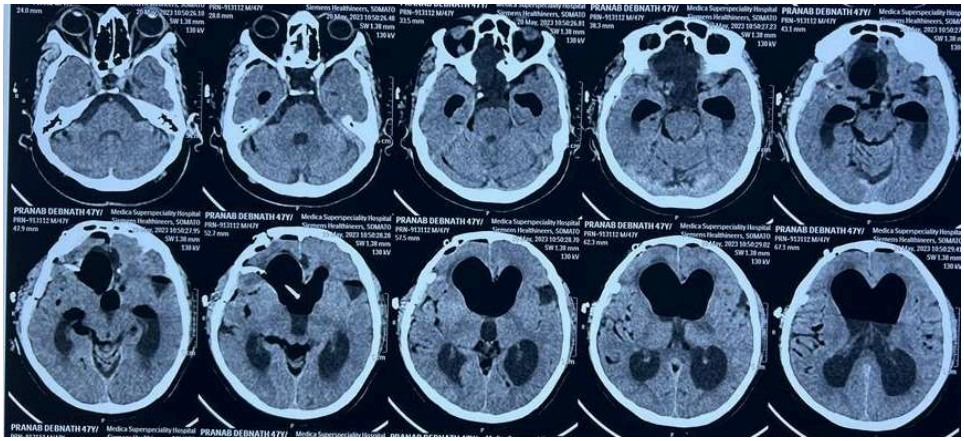


Figure 5. NCCT brain showing post op changes with pneumocephalus, EVD tip in situ.

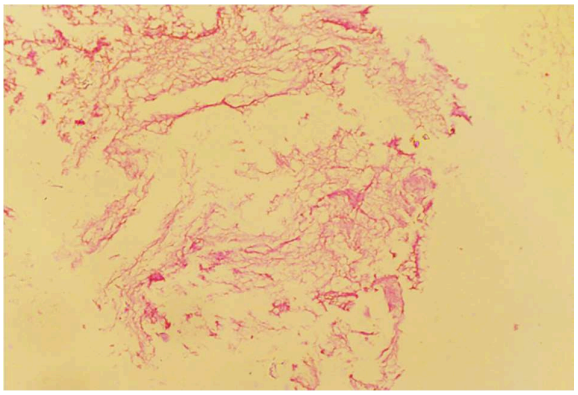


Figure 6. Microscopy (10X magnification) on H&E staining section showing keratinous debris with no lining squamous epithelium

Discussion

Dermoid cysts are congenital benign tumors arising from ectodermal cells during 3rd to 5th week of embryogenesis at the time of neural tube closure5. They contain apocrine glands, sweat glands, sebaceous glands, squamous epithelium, hair follicles, and sometimes teeth6. Epidermoid cysts, different from dermoid cysts, have only squamous epithelial lining. ICDC are more commonly infratentorial in location, in the midline, in the vermis, or inside the 4th ventricle. The supratentorial location of dermoid cysts is less common. Other rare sites are suprasellar and pineal regions.

ICDC accounts for 0.04% to 0.25% of all intracranial tumors4. The duration of presentation of ICDC is months to years. Suprasellar dermoid cysts present early because of the mass effect on the optic apparatus. Usual presentations of unruptured ICDC are due to mass effect on neurovascular structures mainly optic apparatus, presenting late due to their slow-growing nature. Ruptured ICDC presents with headache, seizures, cerebral ischemia with focal deficits, hydrocephalus,

vasospasm resulting in infarcts, fat embolism, visual deficits, aseptic meningitis, increased intracranial pressure (ICP), chronic granulomatous arachnoiditis and can be fatal. Headache is the most common symptom (32.6%) [7]. Rupture occurs spontaneously in the majority of cases but head trauma can also be a cause. Intraventricular fat can cause motion-dependent intermittent raised ICP by blocking the CSF pathways, resulting in acute hydrocephalus8.

Radiological features of ICDC are very characteristic. Non-contrast CT scan of the brain shows mixed density of ICDCs with hyperdense areas of calcification and hypodense areas of fat density (negative Hounsfield units). They do not enhance post-contrast CT. T1W MRI typically shows high signal intensity within the lesion (and in the subarachnoid space in case of ruptured ICDC). FLAIR shows subtle sulcal hyperintensity. T2WI, GRE, and SWI show sulcal "bloom". In T1 Post Gadolinium MRI, lesions commonly do not enhance but can show leptomeningeal reaction and contrast enhancement, if complicated by chemical meningitis [9].

Close differentials of ICDCs are epidermoid cysts, cystic craniopharyngiomas, and arachnoid cysts.

Surgical excision with copious lavage of subarachnoid space is the mainstay of treatment. In many cases, total removal is not possible when the capsule is densely adherent to neurovascular structures, in which case subtotal resection is performed to avoid neurovascular complications. There are instances when ruptured ICDCs have been treated with a lumbar drain for prevention of post-operative hydrocephalus [10].

The recurrence following the excision of ICDCs is rare, in contrast to epidermoids that frequently recur.

The prognosis is relatively good if the tumor is completely excised. However, ruptured ICDC can result in many complications and can turn fatal.

Conclusion

Dermoid cysts are congenital benign tumors arising from embryonic ectodermal cells and dermal elements. ICDCs are rare brain tumors and suprasellar/supratentorial are extremely rare locations for ICDC. It usually presents with mass effect on neurovascular structures and compression of optic apparatus. Radiological diagnosis is straightforward and is diagnosed pre-operatively in most of cases, more so if it is ruptured. Treatment is craniotomy and micro-neurosurgical excision with copious irrigation and lavage. We recently encountered one such case.

List of Abbreviations

ICDC – Intracranial dermoid cysts
NCCT – Non contrast Computed Tomography
AP x TR x CC – Anteroposterior x Transverse x Craniocaudal
MRI – Magnetic Resonance Imaging
ICP – Intracranial pressure
CSF – Cerebrospinal fluid
FLAIR – Fluid Attenuated Inversion Recovery sequence

Statements and Declarations

Conflicts of interest

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

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POINT OF VIEW

How Paediatric Key-hole and Endoscopic Surgery has Transformed Paediatric Surgical Care in India

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"Don't forget. To be a successful surgeon, you must have the eyes of a hawk, the heart of a lion, and the hands of a lady."
- Sir Lancelot Spratt

Minimally invasive surgery was introduced in the year 1901 by Georg Kelling from Germany when he performed the first laparoscopic procedure in dogs but it was not up to 1910 when Hans Christian Jacobaeus of Sweden performed the first laparoscopic operation in humans. There were challenges, complications and initial apprehension but since then, the introduction of Paediatric Key hole and endoscopic surgery gave the kids suffering from various surgical ailments to undergo surgery with minimal pain, quick recovery, minimal scar with minimal days of hospital stay. At present, it's a real surgical wonder and marvel for the paediatric patients undergoing 'maximally' complicated surgical procedure through 'minimally' invasive procedure [1].

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Once upon a time, people used to be afraid of paediatric surgery. Already, the thought of having surgery done on a child is a harrowing one, but what if the surgery also leaves an ugly scar behind? What, then? Well, some parents would even have that listed as one of the reasons not to get surgery for their child.

But what alternatives do they have? Especially in cases like appendicitis and hernias where surgery is the only way to cure. This is where Paediatric Keyhole and endoscopic surgeries made a mark and brought new hope and success through the minimally invasive route. But before we discuss how this class of surgery has revolutionised the field of paediatric surgery, we need to know what it means in the first place [2].

In 1927, William Edwards Ladd, Surgeon-in-Chief at Boston Children's Hospital, established the first paediatric surgical training program and he knew that surgery in this age group of patients would be very challenging and risky. Paediatric surgery itself is a young speciality, only

around 45 years old in India. The Indian Association of Paediatric Surgeons (IAPS) established in 1965, as a section of Association of Surgeons of India (ASI) which separated from its parent body and became an independent Association in 1994. Minimally invasive paediatric surgery has developed rapidly in the last 20-30 years extending from fetuses to 17-year-old adolescents [3].

Paediatric keyhole surgery is a term used for laparoscopic surgery done on a child. In conventional open surgeries, the body wall is incised using instruments to allow surgeons direct access to the body cavity. However, in laparoscopic surgeries, the surgeon makes precise small 'keyhole' incisions through your abdominal wall and uses a camera, called a laparoscope and specialized instruments to guide the surgery and finish the procedure without ever entering the abdominal cavity. Funnily enough, the first laparoscopic surgery was done by a gynecologist!

With the advent of electronic videoscopes, small instruments and insufflators feasible for children, Minimally Invasive Surgery was also gaining ground in paediatric surgery. In 1976 Rodgers reported thoracoscopy for diagnostic reasons in children. But the main era of innovation was the 1990s which marked many firsts such as the first laparoscopic congenital diaphragmatic hernia repair in 1995, and the first MIS oesophageal atresia repair among others. There was a new dawn on the world of pediatric surgery and the field had been changed forever.

But was it all rainbows and sunshine? How effective was it practically? Would parents trust the doctors who could not directly see what he was operating on, instead of using a camera?

Well, the reality is that pediatric keyhole surgeries hold many advantages over conventional open procedures. This included reduced pain and discomfort, smaller incisions which lead to less scarring, a faster recovery time, and reduced exposure to the external environment which automatically reduces the risk of infection. It also grants an improved visualisation of the surgical site, which allows for more precise surgery which in turn, leads to reduced hospital stay, reduced blood loss and lesser post-operation complications.

It can also be used for a range of common pediatric procedures such as hernia repairs, appendectomies, pull-through surgery to treat Hirschsprung disease, orchidopexy to treat undescended testis and cholecystectomies.

But such a high level of care brings its costs and disadvantages. A smaller body to operate on means a larger margin for error, which makes surgery more difficult. It also means the treating team has to be highly specialised and skilled to be able to perform said surgery. Laparoscopic surgeries have a steeper learning curve and it has been accentuated even more in the case of paediatric surgeries.

Paediatric laparoscopic procedures are likely to cause an increase in pulmonary and systemic vascular resistance, sudden bradycardia during pneumoperitoneum because of raised intraabdominal pressure, the chances being much more than adults. Children have a high level of vagal tone and occasionally peritoneal stimulation by a blast of insufflated gas or penetration by trocars and laparoscopes can provoke bradycardia or asystole. There can also be ventilation perfusion mismatch. Hypercapnia, high systemic vascular resistance and head low position combine

to elevate intracranial pressure. The insufflated gas leads to increased intraabdominal pressure which in turn, increases the risk of regurgitation. Intraoperatively, there is very little space for the surgeon to work on in a paediatric patient during laparoscopy so there are chances of causing iatrogenic complications like trocar related injuries.

However, these complications are rare and most often occur in children with some other preexisting condition or co-morbidity. Hence this should not serve as a point to disregard keyhole surgeries, but perhaps to take a more nuanced approach. Since this is still a procedure in its infancy and there's a way to go, many of the complications I've mentioned now may not even be relevant in the future.

All of these significantly improved the standard of patient care and satisfaction. Especially in India where the socioeconomic status of the patients plays a major role in their future. Socioeconomically, any ugly looking scar on a girl child's body may be the reason her suitor refusing to wed her or demand a high dowry when she grows up as an adult or the girl thinking of taking up a modelling career as a profession in future, Key hole surgery is the right choice [4].

The advent of Robotic surgery adds another dimension to keyhole surgeries as now we can have instruments which work with pinpoint accuracy and opens the field to even more specialities such as oncology in paediatric patients.

Conclusion

"*Minimal Access Surgery is the marriage of modern technology and Surgical innovation*"

The world is moving at a very fast pace and so is the world of paediatric surgery. Unlike in the past, the innovation in the paediatric anesthesia as well as refinement of the paediatric laparoscopic instruments and gadgets along with advance training of the surgeons in treating complex surgical procedures, paediatric Keyhole surgery is now the accepted and recommended method in our country and they are here to say as compared to the conventional open method. Being a surgeon is a gift of excellence and perhaps laparoscopic surgeries are the way we can express our gift.

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