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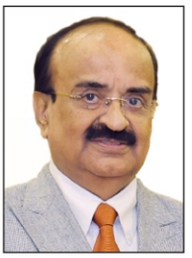

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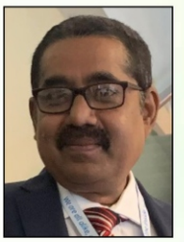

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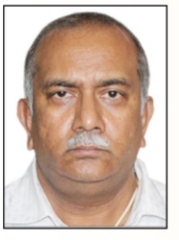

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Special Article

Haemovigilance Programme of India : Strengthening Blood Transfusion Safety

Akanksha Bisht[1]

The Haemovigilance Programme of India (HvPI), launched in December 2012, is implemented by the National Institute of Biologicals (NIB), NOIDA, under the Ministry of Health & Family Welfare. Serving as the National Coordinating Centre (NCC), HvPI aims to monitor, report, investigate, and analyze adverse reactions related to blood transfusion and donation across India.

To date, **1,728** blood centres have enrolled under HvPI, and over **80,000** adverse reaction reports have been submitted via the Haemovigilance software. Although reporting is currently voluntary, the data collected helps formulate expert-led guidelines and recommendations to improve transfusion safety nationwide which are freely available on NIB Website **nib.gov.in**

HvPI also focuses on capacity building. It has conducted 86 Continuing Medical Education (CME) Programmes, Workshops and Webinars, training over **16,400** healthcare professionals. The participants have predominantly been from blood centres, including medical officers, nurses, technical staff, as well as blood donors and motivators. Moving forward, we aim to enhance collaboration with our clinical colleagues, who play a critical role in recognizing bedside transfusion reactions and promptly reporting them to the blood centres. Strengthening this partnership is essential for improving patient safety and transfusion outcomes.

A **toll-free helpline (1800-180-2588)** is available to provide assistance and answer queries related to the programme.

Blood centres can enroll in HvPI free of cost by submitting the required enrolment form, available at https://nib.gov.in/media/Annexure7.pdf either by post to NIB, NOIDA or via email at haemovigilance@nib.gov.in.

HvPI has also developed a key reference document, **"Good Blood Transfusion Practices – Guidance for Rational Use of Blood",** available at https://nib.gov.in/media/Good%20Blood%20Transfusion%20Practices%20Guidance.pdf, to support rational and safe blood use.

Active clinician participation and increased reporting serves as a critical tool in ensuring patient safety and improving clinical outcomes in transfusion medicine. By actively reporting adverse transfusion reactions, clinicians contribute to a national database that enhances protocols, and reduces preventable risks. Participation in HvPI not only reinforces a culture of continuous learning but also empowers clinicians with data-driven insights to make safer, more informed decisions. Embracing this programme is a step toward advancing quality care and safeguarding the well-being of every patient receiving blood transfusion therapy.

Haemovigilance Programme of India (HvPI) looks forward to a collaborative partnership with the **prestigious Indian Medical Association (IMA)** to enhance the safety and quality of blood transfusion practices across the country.

Acknowledgment

(1) Dr Neelam Marwaha, Former Professor & Head, Department of Transfusion Medicine, PGIME&R, Chandigarh.

(2) Prof Ravneet Kaur, Head, Department of Transfusion Medicine, GMCH, Chandigarh.

(3) Dr Debasish Gupta, Former Professor & Head, Department of Transfusion Medicine, SCTIMST, Trivandrum, Kerala.

(4) HvPI acknowledges all the blood centres for their active participation in HvPI and reporting of adverse transfusion/donor reactions to the central database.

[1]S-I & Head Haemovigilance Programme of India, NIB Noida , MoHFW, GoI.

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Contents

Editorial

Psychological Impact of Present Middle East Crisis

The ongoing crisis in the Middle East—particularly the war involving United States and Iran the humanitarian catastrophe in Gaza Strip, and rising regional tensions involving Israel, Palestine, Lebanon, Iran, Iraq, Syria, Saudi Arabia, UAE and others - has had profound psychological effects both locally and globally. As tensions escalate across the Middle East in early 2026, including recent airstrikes and maritime conflict in the Persian Gulf, millions of Indians living in the region and their families back home are facing a significant psychological burden. Mental health experts are warning of a rise in 'transnational anxiety' - a state of persistent stress caused by worry over loved ones living in conflict zones[1].

The current tensions around Iran can trigger intense psychological distress for the Indian diaspora and their kin – the physical distance between families does not mitigate the emotional impact of conflict.

The psychological impact of war can be of different types as shown in Table 1.

Table 1 — *Different types of Psychological Impact of War*

(1) Acute Trauma and PTSD In Directly Affected Populations ■ Constant exposure to bombings, displacement, loss of loved ones. ■ Children exposed to violence show high rates of **Post-traumatic Stress Disorder (PTSD).** ■ Nightmares, hypervigilance, emotional numbing, regression in young children. ■ Survivors may experience "survivor's guilt."	**(2) Chronic Anxiety and Fear** Even for civilians not directly injured: ■ Persistent fear of attacks. ■ Uncertainty about safety, food, housing, and future stability. ■ Anticipatory anxiety (constantly expecting bad news).
(3) Intergenerational Trauma Long-standing conflict can lead to: ■ Trauma transmitted across generations. ■ Children internalizing narratives of fear, loss, and identity shaped by conflict. ■ Normalization of violence as part of daily life.	**(4) Grief, Collective Mourning, and Identity Trauma** Large-scale casualties create: ■ Collective grief. ■ Shared trauma narratives. ■ Heightened group identity and polarization.
(5) Moral Injury Among: ■ Civilians forced into impossible ethical situations. ■ Soldiers exposed to morally distressing events. ■ Healthcare workers overwhelmed by suffering. ■ Moral injury differs from PTSD; it involves deep guilt, shame, or loss of faith in one's moral framework.	**(6) Radicalization and Polarization** Prolonged exposure to conflict can: ■ Increase black-and-white thinking. ■ Reduce empathy for perceived opponents. ■ Fuel extremist narratives. ■ Spread misinformation-driven anger globally via social media.
(7) Global Psychological Impact Outside the region: ■ Diaspora communities experience secondary trauma. ■ Increased antisemitism and Islamophobia heighten fear and identity stress. ■ Continuous media exposure causes vicarious trauma. ■ Many people report "doom scrolling" and emotional exhaustion.	**(8) Humanitarian Workers and Journalists** Those covering or responding to the crisis often develop: ■ Compassion fatigue. ■ Burnout. Secondary traumatic stress.

In areas like the West Bank and southern Israel, these repeated episodes of violence generate compound trauma over a long period. In Israel, the frequent rocket alerts lead to heightened stress, anxiety, and depression amongst the at-risk population. In Gaza, due to unpredictability and restricted movement, the classic cognitive triad of depression - helplessness, hopelessness, and worthlessness - has been observed, as seen in long-term conflict zones worldwide. The collective trauma can strengthen in-group solidarity but deepen out-group hostility. The communities living far from the region also experience identity-based polarization[2].

This phenomenon, often termed "intergenerational trauma," arises from sustained exposure to violence and instability, leading to profound and lasting psychosocial impacts that permeate individual and collective identity. This inherited trauma can manifest through psychological effects and coping mechanisms that are transmitted across generations, impacting family dynamics and broader societal structures. The collective trauma influences social cognition, leading to processes of both social integration within in-groups and heightened differentiation from out-groups. Such dynamics are particularly salient in post-conflict societies where unresolved historical grievances and ongoing threats perpetuate a "victimhood psychology" that reinforces collective identity narratives and can impede reconciliation efforts. This psychological embedding of conflict, often discounted as an invisible barrier, necessitates a deeper understanding of its interplay with peacebuilding processes to enhance outcomes. Indeed, parental transmission of trauma, frequently through familial storytelling, can reproduce hostile attitudes towards perceived aggressors, thereby obstructing reconciliation efforts. This framework, crucial for understanding the enduring impact of mass violence, underscores how descendants can exhibit trauma symptoms even without direct exposure to the original traumatic events. This intergenerational transmission of trauma, observed in genocides and civil wars globally, often occurs through mechanisms such as parenting styles, parent-child attachment, and overall family functioning, demonstrating comparable patterns across diverse cultural contexts. This absorption of unresolved psychological burdens from those directly exposed to traumatic events can severely undermine social cohesion and stability within affected communities, perpetuating systemic inequalities[3].

The conflict between Iran and the United States (and allies) has created a serious economic and fuel crisis inside Iran and globally. The crisis is driven by sanctions, war damage, disruption of oil supply, and economic instability. The Iran–US conflict has intensified Iran's existing economic problems. Sanctions, war damage, and oil market disruptions have caused inflation, fuel shortages, poverty, and industrial shutdowns in Iran while also raising global oil prices and economic uncertainty worldwide. India imports about 85-90% of its crude oil, much of it from the Middle East. War disrupts supply and pushes global oil prices higher, increasing petrol, diesel, and LPG prices in India. Nearly 50% of India's crude imports pass through the Strait of Hormuz, which can be affected during the conflict. India imports **48.7% of crude oil, 68% LNG, and over 90% LPG from West Asia**. So the war creates **diplomatic challenges** for India in balancing these relationships. Nearly **10 million Indians work in Gulf countries**. If the war expands, it could affect jobs of Indian expatriates, reduce remittances sent to India and force evacuation of workers.

If the conflict persists, there are certain long-term risks. There could be higher rates of depression, substance abuse, domestic violence. The educational and developmental delays among children may be seen leading to reduced social trust and civic cohesion. However, there are optimism, protective factors, and resilience. Despite the trauma, research shows that during these periods of war crisis, there had been reports of strong family bonds buffering stress. Community solidarity can foster resilience. Access to mental health services significantly reduces long-term damage, and religious/spiritual coping can provide meaning during chaos. There are Many families experience the constant worry about their relatives, family members and friends waiting and living tin this conflict-affected region with apprehension, fear, sleep disturbances, heightened transnational anxiety, and emotional exhaustion. The repetitive checking the news, calling the family repetitively and enquiring their whereabouts and imagine worst-case situations, which increases anxiety more instead of reducing it.

References

1 Mawson AR, Croft AM — Gulf War Illness: Unifying Hypothesis for a Continuing Health Problem. *Int J Environ Res Public Health* 2019; **16(1):** 111. doi: 10.3390/ijerph16010111. PMID: 30609834; PMCID: PMC6339135.

2 Mantle D, Domingo JC, Golomb BA, Castro-Marrero J — Gulf War Illness, Fibromyalgia, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome and Long COVID Overlap in Common Symptoms and Underlying Biological Mechanisms: Implications for Future Therapeutic Strategies. *Int J Mol Sci* 2025; **26(18):** 9044. doi: 10.3390/ijms26189044. PMID: 41009608; PMCID: PMC12469932.

3 Rees SJ, Whitten T, Tay AK, Suomi A, Moussa B, Hassoun F, *et al* — The psychological impact of conflict in the Middle East from 2023 to 2025 on Australian communities: a prospective cohort study. *Lancet Reg Health West Pac* 2025; **61:** 101639. doi: 10.1016/j.lanwpc.2025.101639. PMID: 40740669; PMCID: PMC12304685.

4 Hinchey LM, Nashef R, Bazzi C, Gorski K, Javanbakht A — The longitudinal impact of war exposure on psychopathology in Syrian and Iraqi refugee youth. *Int J Soc Psychiatry* 2023; **69(7):** 1833-1836. doi: 10.1177/00207640231177829. Epub 2023 Jun 5. PMID: 37278010.

5 Pandi-Perumal SR, van de Put WACM, Maercker A, Hobfoll SE, Mohan Kumar V, Barbui C, *et al* — Harbingers of Hope: Scientists and the Pursuit of World Peace. *Clin Psychol Eur* 2023; **5(4):** e13197. doi: 10.32872/cpe.13197. PMID: 38357426; PMCID: PMC10863676.

Prof (Dr) Ranjan Bhattacharyya
MBBS (Cal), MD, DNB (Psychiatry)
Hony Editor, JIMA

Erratum : In the editorial of February 2026 issue please note that at present, only AIIMS Rishikesh & AIIMS Deoghar (not AIIMS Bhubaneswar) teaches MBBS Undergraduates Psychiatry separately as pointed out by Dr. Santanu Nath, MBBS; MD; DNB, Associate Professor & Faculty I/C, Department of Psychiatry, Nodal Officer, Addiction Treatment Facility (ATF), AIIMS, Deoghar, Jharkhand, India. ***— Hony Editor, JIMA***

Original Article

Socio-demographic Profile and Baseline CD4+ Count of Newly Diagnosed HIV Seropositive Patients Attending Linked ART Center at Dr RMLIMS Lucknow

Amit Kumar[1], Anupam Das[2], Manodeep Sen[3], Jyotsna Agarwal[4], Nikhil Gupta[5], Mamta Thacker[6]

Abstract

Background : HIV (Human Immunodeficiency Virus) is the most severe health problem in the World. The number of people infected with HIV has been increasing Worldwide.

Aims and Objective : To study the demographic characteristics and analyse the trend of baseline CD4+ count in newly diagnosed HIV seropositive patients.

Materials and Methods : This prospective cross-sectional hospital-based study was conducted at the ART Centre of Dr RMLIMS Lucknow from January, 2021 to July, 2022. A total of 402 newly diagnosed HIV patients enrolled. Demographic data were collected, and all patients™ blood samples were subjected to CD4+ count analysis using PIMA Analyzer.

Results : Out of a total of 402 newly diagnosed HIV patients, the majority were Male (73.4%, 295), Married (61.2%, 246), and 164 (40.8%) were between 18-29 years of age. Heterosexual transmission (47%, 189) was shown to be the most frequent method of HIV transmission. Most newly diagnosed patients presented late for HIV treatment care after their CD4+ cell levels had dropped below 350 cells/µl (59.7% 240).

Conclusion : In the research setting, late presentation for HIV care continues to be a significant barrier. Programs need to enhance early detection of HIV in healthcare setups to optimise the impact of the "test and treat" policy intended to reduce morbidity and death associated with HIV. For the most significant impact, this initiative should concentrate on early and rapid diagnosis of HIV patients.

Key words : HIV, AIDS, CD4+ count, Socio-demographic profile.

One of the most prevalent diseases Worldwide is HIV (Human Immunodeficiency Virus). The number of individuals diagnosed with HIV continues to rise Globally. In the past 30 years, over 60 million people have contracted the virus, resulting in more than 20 million deaths. The India HIV Estimation Report for 2021 states that the estimated national HIV prevalence among adults aged 15 to 49 was 0.21%[1]. The report also shows that the prevalence was slightly higher among males at 0.22% compared to females at 0.19%. According to estimates, the prevalence of HIV among adults in India has decreased from a peak of 0.54% between 2000 and 2010 to 0.21% in 2021[1]. India has an estimated 24.1 lakh HIV cases, ranking third Globally in prevalence. High-risk groups for HIV transmission include Female Sex Workers (FSWs) and their clients, truck drivers, homosexual men and Intravenous Drug Users (IVDUs). The HIV prevalence rate among IVDUs is significantly higher at 6.26% compared to other high-risk populations[1].

Editor's Comment :

- This study highlights that a substantial proportion of newly diagnosed HIV seropositive individuals present to ART Centre with low baseline CD4+ counts, reflecting delayed diagnosis and entry into care.
- Strengthening early detection programs and community-based interventions is essential to improve immune status at presentation, reduce morbidity and enhance long-term treatment outcomes.

An essential role in managing the HIV epidemic in India is played by the National AIDS Control Organization (NACO). Several ART centres in India have offered Anti-retroviral Therapy (ART) without charge since 2004[2]. Adopting the WHO 2010 recommendations, ART coverage increased from 3.57% in 2009 to 36% in 2015[3]. Between 2007 and 2011, more people had access to ART, which led to a 29% decrease in the number of people dying each year from AIDS-related causes.

Following WHO recommendations, India implemented "test and treat" in 2017, making anyone testing positive for HIV eligible for treatment regardless of their CD4+ count[4]. CD4+ counts are used to monitor HIV disease progression and ART effectiveness[5]. Point of Care (POC) CD4+ test devices have accelerated therapy initiation and

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improved linkage to care for ART programs[6]. CD4+ cell count is the most accurate assessment of a patient's immune condition. The risk of opportunistic infection significantly increases when it falls below 200 cells/µl[7]. The CD4+ cell count test remains critical in making diagnostic decisions, particularly for patients with advanced HIV disease[8].

Material and Methods

This prospective cross-sectional hospital-based study was conducted with the combined effort of the ICTC section of the Department of Microbiology and the ART Centre of the Department of Medicine of Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow. A total of 402 newly diagnosed HIV seropositive patients registered in the linked ART Centre from January, 2021 to July, 2022 were included who were ART-naïve. Patients under the age of 18, patients with prior ART experience, and registered patients referred from other facilities were all excluded from the analysis. All patients' blood samples were subjected to CD4+ count analysis using PIMA Analyzer. Demographic data were collected by questionnaire to patients on preformed patient proforma sheet. The questionnaire asked about sexual behaviours, potential modes of transmission, and Socio-demographic information (age, gender, level of education, occupation status, and place of residence) to calculate the risk variables. We define late presentation as patients presenting for HIV treatment with a baseline CD4+ count <350 cells/µl.

The data generated in this study were analysed by R-4.2.1 statistical software to interpret significant outcomes. Quantitative variables were evaluated using the One-Way ANOVA followed by a Post-hoc test, while qualitative data was analysed using the Chi-square test. Means or medians were reported, depending on the distribution of the continuous variable. The differences were statistically significant when the obtained p-value was less than 0.05.

Results

A total of 402 HIV seropositive patients were analysed during the study period. 164 (40.8%) patients were between aged 18 and 29. The study population had a mean age of 33.21±9.35 years, with the mean age of newly diagnosed male patients 33.29±9.27 years and for female patients 33.00±9.63 years. In our study, males contributed to 73.4% of patients. Regarding education, most patients had only completed Primary school (130; 32.3%). Most of the study subjects were Unemployed (23.1%). The Heterosexual route (189; 47%) was the most common route of HIV transmission. An overview of the Socio-demographic profile of the study population is presented in Table 1.

Table 1 — *Socio-demographic of the Study Population (N= 402)*

Variable	Category	Number of patients	Percentage (%)
Gender	Male	295	73.4
	Female	107	26.6
Age	18-29 years	164	40.8
	30-39 years	126	31.3
	40-49 years	83	20.6
	50-59 years	29	7.2
Residence	Rural	233	58.0
	Urban	169	42.0
Marital Status	Married	246	61.2
	Single	128	31.8
	Widowed	22	5.5
	Divorced	6	1.5
Education Status	Graduate	105	26.1
	Secondary Education	79	19.7
	Primary Education	130	32.3
	Illiterate	88	21.9
Mode of Transmission	Heterosexual	189	47.0
	Blood Transfusion	21	5.2
	MSM	24	6.0
	Injection Drug use	72	17.9
	Unsafe Injection	7	1.7
	Unknown	89	22.1
Occupation	Agriculture	18	4.5
	Business	72	17.9
	Laborer	68	16.9
	Service	86	21.4
	Student	43	10.7
	Unemployed	93	23.1
	Truck Driver	22	5.5

Baseline CD4+ counts of newly diagnosed HIV patients mainly were 0-200 cells/µl (141; 35.1%) followed by 200-349 cells/µl (99; 24.6%). Only 17.9% of patients have a baseline CD4+ count >500 cells/µl. Most Males (36.3%) and Females (31.8%) had a baseline CD4+ count of <200 cells/µl. There is no significant difference between absolute CD4+ count and gender among HIV patients. Table 2 outlines the distribution of baseline CD4+ count among HIV-positive patients.

Most newly diagnosed patients arrived for HIV treatment after their CD4+ levels had dropped below 350 cells/µl (59.7%). In our study, 183 (62.0%) Male patients and (57; 53.3%) Females had presented with CD4+ count <350 cells/µl. Eighty-four (51.2%) out of 164 HIV seropositive patients between 18 to 29 years of age were shown with CD4+ count <350 cells/µl. Rural areas provided most patients (143; 61.4%) with CD4+ counts below 350 cells/µl. The mean CD4+ count of the study group was 318.66±233.52 cells/µl. HIV-positive individuals between 18 and 29 had statistically significantly higher mean CD4+

Table 2 — *Baseline CD4+ count of HIV-positive patients. (N=402)*

	Male (n= 295) Number (%)	Female (n=107) Number (%)	Total (n=402) Number (%)
>500 cells/µl	52 (17.6)	20 (18.7)	72 (17.9)
350-499 cells/µl	60 (20.3)	30 (28.0)	90 (22.4)
200-349 cells/µl	76 (25.8)	23 (21.5)	99 (24.6)
0-200 cells/µl	107 (36.3)	34 (31.8)	141 (35.1)

counts than those between 50 and 59 (p=0.002). Females had higher mean CD4+ counts than Males (340.60±246.21 cells/µl versus 310.71±228.66 cells/µl). Married and Divorced patients had mean CD4+ counts of 246.96±213.41 cells/µl and 270.67±171.72 cells/µl respectively. Table 3 displays the correlation between Socio-demographic characteristics and CD4+ counts.

Discussion

This study's data analysis showed that Males contributed to 73.4% of our ART Centre. An observational study was done at PGIMER, Chandigarh, by Sehgal, *et al* among 622 HIV-infected patients, which showed Male predominance among the study subjects[9]. In contrast to a study conducted by Oo S, *et al* in South Africa, most newly diagnosed patients were Female[10]. In our study, the ratio of males to females was 2.7:1, higher than that found in the studies of Toshniwal, *et al* and Kumar, *et al*[11,12]. The population's impact may cause differences in the male-to-female HIV patient ratio in a given place. Overall, 59.7% of patients had a late presentation for HIV care; most were from Rural areas (61.4%). In Rural areas, more stigma may be associated with HIV infection, preventing people from disclosing risk factors and discouraging them from getting tested[13].

In this study, we analysed the CD4+ count and found that the baseline CD4+ count at registration in the ART Centre was 318.66±233.52 cells/µl. Our analysis also discovered that adult participants had lower mean CD4+ counts at ART initiation than younger participants. This finding is similar to the results of another study conducted by Shastri S, *et al*[14]. One explanation is that older people, even when they contract the infection at a younger age, experience a delayed diagnosis. Females had higher mean CD4+ counts than males. One possible explanation for Females' higher average CD4+ counts is that they tend to seek care and undergo HIV testing earlier. Expanded testing programs during pregnancy and partner testing programs initiated after a spouse test positive for HIV may contribute to this. Using a CD4+ count of 350 cells/µl as cut off for late presentation for HIV care, 59.7% of patients presented late for HIV treatment. In a study conducted by Shastri, *et al*, it was found that 65% of HIV-positive patients had a CD4+ count below 350 cells/µl[14]. This indicates that many HIV-positive individuals in India do not receive medical attention and treatment until the illness has progressed.

Late initiation of Anti-retroviral Therapy (ART) leads to worse outcomes and higher medical expenses. Furthermore, untreated patients may contribute to the spread of HIV for several years. Heterosexual contact is the most common method of transmission Worldwide, particularly in poorer nations. In this study, it was found that 47% of HIV transmissions occurred through heterosexual contact. This aligns with the national-level statistics provided by NACO[1]. Most studies have found a correlation between high levels of education and knowledge about HIV/AIDS, meaning that persons with greater levels of education also tend to be more knowledgeable of the disease's transmission, prevention of infection, and control. In our study, the educational status of newly diagnosed HIV patients showed that most

Table 3 — *Baseline CD4+ cell counts of the study population concerning Socio-demographic variables of patients*

		Number of patients with CD4+ cell count <350 cells/µl (%)	Number of Patients with CD4+ cell count >350 cells/µl (%)	Mean±SD CD4+ count	Median CD4+ count (IQR)
Gender	Male	183 (62.0)	112 (38.0)	310.71±228.66	275.00 (150.00 -421.00)
	Female	57 (53.3)	50 (46.7)	340.60±246.21	340.00 (139.00 -442.00)
Age	18-29 years	84 (51.2)	80 (48.8)	374.93±267.73	342.00 (184.00- 495.00)
	30-39 years	74 (58.7)	52 (41.3)	293.98±197.86	284.00 (135.00- 426.00)
	40-49 years	58 (69.9)	25 (30.1)	283.02±204.54	251.00 (150.00- 370.50)
	50-59 years	24 (82.8)	5 (17.2)	283.02±204.54	251.00 (150.00- 370.50)
Residence	Rural	143 (61.4)	90 (38.6)	319.98±240.35	284.00 (151.00- 434.00)
	Urban	97 (57.4)	72 (42.6)	319.98±240.35	284.00 (151.00- 434.00)
Marital status	Married	154 (62.6)	92 (37.4)	304.61±218.31	274.00 (136.00- 426.00)
	Single	68 (53.1)	60 (46.9)	352.11±256.80	318.00 (183.75- 465.00)
	Widowed	14 (63.6)	8 (36.4)	294.27±262.82	212.00 (77.00- 390.50)
	Divorced	4 (66.7)	2 (33.3)	270.67±171.72	230.50 (159.25- 334.00)
Education Status	Graduate	63 (60.0)	42 (40.0)	301.33±188.23	292.00 (151.00-397.00)
	Secondary Education	57 (72.2)	22 (27.8)	282.33±225.66	231.00 (128.00-359.50)
	Primary Education	75 (57.7)	55 (42.3)	331.28±228.47	302.00 (173.75-444.00)
	Illiterate	45 (51.1)	43 (48.9)	353.33±287.98	347.00 (150.50-498.00)
Occupation	Agriculture	15 (83.3)	3 (16.7)	212.83±129.38	199.00 (125.75-263.25)
	Business	47 (65.3)	25 (34.7)	299.04±195.50	262.50 (143.00-389.25)
	Laborer	37 (54.4)	31 (45.6)	360.18±262.90	296.00 (169.00-518.00)
	Service	63 (73.3)	23 (26.7)	242.50±175.02	219.50 (98.00-354.00)
	Student	20 (46.5)	23 (53.5)	395.07±256.59	395.00 (221.00-494.50)
	Unemployed	47 (50.5)	46 (49.5)	387.62±371.98	327.00 (197.50-448.50)
	Truck Driver	11 (50.0)	11 (50.0)	327.55±181.52	347.00 (179.00-453.25)

patients were reported to be educated till the Primary level (32.3%), and 21.9% were found to be illiterate. These findings are similar to the study conducted by Deshpande JD, *et al* and Jayaram, *et al*[15,16]. Lower education and lack of awareness about safe sex could contribute to higher prevalence in this group. However, Cauldbeck, *et al* observed no trends in education level concerning the seropositivity of HIV patients[17]. Housewives comprised 64.5 % (69/107) of newly diagnosed female HIV patients. A high percentage of Housewives was found in the study by Vyas N, *et al*[18]. A survey by Mehra, *et al* showed that Housewives rarely heard of HIV / AIDS (p= 0.002)[19]. These women are at a higher risk of behaviours associated with HIV infection if they are in a position of financial dependence on their Male counterparts.

Limitation :

The study's analysis of delayed ART's effect on HIV-positive patient outcomes was hindered due to the unavailability of follow-up data, which is one of its limitations.

Conclusion

Many patients came from Rural areas, with low literacy levels and working as labourers. Thus, awareness and literacy improvement are necessary. Most HIV-positive patients were Men, often married, serving as a link between the general public and high-risk groups. Husbands are more likely to spread an infection to their wives. The heterosexual route was the most common transmission mode; thus, focusing on barrier techniques and increasing Information, Education and Communication (IEC) was essential. Improving patient tracking and referrals between health facilities can reduce baseline CD4+ cell count testing wait times.

Ethical Consideration :

The Institutional Ethics Committee (IEC) of Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow, Uttar Pradesh, India, had approved undertaking the proposed research study under IEC no. 139/20 communicated vide letter no. 177/20/RMLMS/2021 dated January 14, 2021.

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References

1 Statistics | National AIDS Control Organization | MoHFW | GoI [Internet]. [cited 2022 Nov 8]. Available from: http://naco.gov.in/sites/default/files/Sankalak_Status_of_National_AIDS_Response_Third_Edition_2021.pdf

2 Narlawar UW, Lilare RR, Mirdude G — Socio demographic and clinical profile of people living with HIV/AIDS registered at ART centre of Government Medical College, Nagpur. *Int J Community Med Public Health* 2018; **5(5):** 1929-32.

3 HIV Basics | HIV/AIDS | CDC [Internet]. 2022 [cited 2022 Nov 8]. Available from: https://www.cdc.gov/hiv/basics/index.html

4 NACO Updates | National AIDS Control Organization | MoHFW | GoI [Internet]. [cited 2022 Nov 9]. Available from: http://www.naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Testing_21Apr2016.pdf

5 Bock P, James A, Nikuze A, Peton N, Sabapathy K, Mills E, *et al* — Baseline CD4 Count and Adherence to Antiretroviral Therapy: A Systematic Review and Meta-Analysis. *J Acquir Immune Defic Syndr* 1999; **73(5):** 514-21.

6 Vojnov L, Markby J, Boeke C, Harris L, Ford N, Peter T — POC CD4 Testing Improves Linkage to HIV Care and Timeliness of ART Initiation in a Public Health Approach: A Systematic Review and Meta-Analysis. *PLOS ONE* 2016; **11(5):** e0155256.

7 Bahemana E, Esber A, Dear N, Ganesan K, Parikh A, Reed D, *et al* — Impact of age on CD4 recovery and viral suppression over time among adults living with HIV who initiated antiretroviral therapy in the African Cohort Study. *AIDS Res Ther* 2020; **17(1):** 66.

8 Baker JV, Peng G, Rapkin J, Abrams DI, Silverberg MJ, MacArthur RD, *et al* — CD4+ count and risk of non-AIDS diseases following initial treatment for HIV infection. AIDS Lond Engl 2008; **22(7):** 841-8.

9 Sehgal S — HIV epidemic in Punjab, India: time trends over a decade. *Bull World Health Organ* 1998; **76(5):** 509-13.

10 Oo S, Dt G, Lc O, Bc I, Un N, Ai A, *et al* — Socio-demographic and clinical determinants of late presentation among patients newly diagnosed with HIV in the Eastern Cape, South Africa. Medicine (Baltimore) [Internet]. 2019 Feb [cited 2022 Nov 9];98(8). Available from: https://pubmed.ncbi.nlm.nih.gov/30813211/

11 Toshniwal H, Modi K, Talsania N, Shevkani M, Shah V, Sengal V, *et al* — Clinico-epidemiological and Socio-demographic Profile of HIV Positive Patients, Visiting Clinic in Ahmedabad, Gujarat, India. *Int J Health Sci* 2013; **(6):** 8.

12 Kumar S, Wanchu A, Abeygunasekera N, Sharma A, Singh S, Varma S — Profile of presentation of human immunodeficiency virus infection in north India, 2003-2007. *Indian J Community Med Off Publ Indian Assoc Prev Soc Med* 2012; **37(3):** 158-64.

13 Ohl M, Tate J, Duggal M, Skanderson M, Scotch M, Kaboli P, *et al* — Rural residence is associated with delayed care entry and increased mortality among veterans with human immunodeficiency virus infection. *Med Care* 2010; **48(12):** 1064-70.

14 Shastri S, Boregowda PH, Rewari BB, Tanwar S, Shet A, Kumar AMV — Scaling Up Antiretroviral Treatment Services in Karnataka, India: Impact on CD4 Counts of HIV-Infected People. *PLoS ONE* 2013; **8(8):** e72188.

15 Deshpande JD, Giri PA, Phalke DB — Clinico-epidemiological profile of HIV patients attending ART centre in rural Western Maharashtra, India. *South East Asia J Public Health* 2012; **2(2):** 16-21.

16 Jayarama S, Shenoy S, Unnikrishnan B, Ramapuram J, Rao M — Profiles of attendees in voluntary counseling and testing centers of a medical college hospital in coastal karnataka. *Indian J Community Med Off Publ Indian Assoc Prev Soc Med* 2008; **33(1):** 43-6.

17 Cauldbeck MB, O'Connor C, O'Connor MB, Saunders JA, Rao B, Mallesh VG, *et al* — Adherence to anti-retroviral therapy among HIV patients in Bangalore, India. *AIDS Res Ther* 2009; **6:** 7.

18 Vyas N, Hooja S, Sinha P, Mathur A, Singhal A, Vyas L — Prevalence of HIV/AIDS and Prediction of Future Trends in North-west Region of India: A six-year ICTC-based Study. *Indian J Community Med Off Publ Indian Assoc Prev Soc Med* 2009; **34(3):** 212-7.

19 Mehra B, Bhattar S, Bhalla P, Rawat D — HIV/AIDS awareness among VCT clients: a cross-sectional study from Delhi, India. *BioMed Res Int* 2014; **2014:** 269404.

Original Article

Comparison of Outcome of Accelerated Ponseti Technique with Standard Ponseti Technique in the Management of Idiopathic Congenital Talipes Equinovarus under Six Months of Age

Dhrubajyoti Deka[1], Sourav Dhar[2], Suvadeep Bose[3]

Abstract

Background : Congenital Talipes Equinovarus (CTEV) occurs in 1.2 per 1000 live births in Europe, but in some developing countries, the incidence is double[1]. The incidence of CTEV in India is 0.9 per 1000 live births[2]. In the past two decades, the minimally invasive Ponseti method has been proven and accepted as the worldwide gold standard for the treatment of idiopathic CTEV[3].

Aims and Objectives : To compare the outcome of Accelerated Ponseti Technique (ATP) with Standard Ponseti Technique (SPT) in the management of idiopathic congenital talipes equinovarus under six months of age.

Materials and Methods : In this prospective, randomised, controlled study, 36 patients aged less than 6 months with CTEV were randomly assigned to two interventional groups. Group A was treated by the Standard Ponseti Technique (SPT), ie, applying the Ponseti cast once a week, and Group B was treated by the ATP, ie, using the Ponseti cast twice a week. Pirani scoring for each group was done at the time of each casting, at the time of 3 weeks after Percutaneous Tendo Achilles Tenotomy (PCTAT) and after 1 month, 2 months and 3 months of Steen Beek brace (SB-brace) use by the two groups.

Results : The t-test showed that there were no significant differences in mean score of different parameters of Pirani score and total score of both right and left leg of the patients at the time of casting by two techniques till PCTAT, at the time of 3 weeks after PCTAT and after 1month,2months,3months of SB-brace use by the two groups. Though the mean number of plasters required for the patients of the STP Group was less than that of the patients of the ATP Group, the t-test showed that there was no significant difference in the mean number of plasters of the patients of the STP Group and that of the patients of the ATP Group ($t34=1.24$; $p=0.22$). However, the t-test showed that the mean number of days required for patients in the ATP Group was significantly less than that of patients in the SPT Group ($t34=8.39$, $p<0.001$).

Conclusions : Both techniques have significant effects on achieving correction and improvement of the Pirani score in CTEV of both groups. It appears that ATP requires a shorter number of days to accomplish the same result as SPT. Hence, ATP is less time-consuming and cost-effective than SPT. Moreover, by changing the cast twice in a week, ATP gives a chance to see the sore skin that may occur due to casting.

Key words : Congenital Talipes Equinovarus, Accelerated Ponseti Technique, Standard Ponseti Technique, Percutaneous Tendo Achilles Tenotomy, Steenbeek-brace.

Congenital Talipes Equinovarus (CTEV), also known as clubfoot, is a common congenital musculoskeletal deformity with an incidence of 1.2 per 1,000 live births in Europe and nearly double in developing countries[1]. In India, the incidence is approximately 0.9 per 1,000 live births[2]. Boys are more commonly affected than girls, and one-third of cases are bilateral[4]. The term talipes originates from Latin: talus (ankle), pes (foot), equinus (horse-like), and varus (inward deviation)[5]. If untreated, CTEV can result in significant physical disability and social hardship[6]. In 20 % of cases, clubfoot coexists with other congenital anomalies[7]. Idiopathic CTEV is defined by fixed adduction, supination, and varus positioning of the foot[8].

Editor's Comment :

- Both the Accelerated Ponseti Technique (ATP) and Standard Ponseti Technique (SPT) are effective in correcting idiopathic congenital talipes equinovarus (CTEV) in infants under six months.
- Both yield similar clinical outcomes, ATP significantly reduces the overall treatment duration, making it a faster and more cost-effective alternative.
- ATP enables more frequent assessment of complications, such as skin sores, thereby enhancing patient care.

Hippocrates first proposed a theory of its etiology[8]. Several hypotheses have since been suggested:

(1) Mechanical/positional Hypothesis[9] : Intrauterine constraint or oligohydramnios may restrict foot movement.

(2) Bone/joint Hypothesis[10] : Abnormal endochondral and perichondral ossification.

(3) Connective Tissue Hypothesis[11] : Excess fibrous tissue in ligaments and fascia.

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(4) Vascular Hypothesis[12] : Calf muscle atrophy from reduced anterior tibial artery perfusion.

(5) Neurological Hypothesis[13] : Association with conditions like spina bifida and cerebral palsy.

(6) Developmental Arrest Hypothesis[14] : Arrest of medial foot rotation during late fetal life.

Patho-anatomically, CTEV is characterised by smaller foot bones, an angled talus, medially rotated calcaneus and navicular bones, and shortening of posterior and medial soft tissue[15-17]. The posterior capsule of the ankle and subtalar joints is also shortened. A hallmark is a wavy collagen pattern (crimp), which facilitates gradual ligament stretching – a concept central to non-surgical correction[17].

Clinically, the foot appears in equinus, varus, adduction, and cavus deformity. The heel is small and tight, the calf muscles are wasted, and deep creases are present on the medial and posterior aspects. Diagnosis and monitoring are aided by the Pirani scoring system, which evaluates six clinical signs across the hindfoot[3] and midfoot[3] with a maximum (worst) score of[6,18,19].

Management Options Include :

(1) Non-operative – Repeated manipulation and casting with maintenance bracing[20,21].

(2) Operative – Posteromedial Soft Tissue Release (PMSTR)[22], tendon transfer, Dwyer's osteotomy[23], Dilwyn-Evans procedure[24], triple arthrodesis, and Ilizarov correction.

The Ponseti method, a minimally invasive approach, has become the Global standard. It involves weekly casting for 5-6 weeks, with final correction of equinus using percutaneous tendo-achilles tenotomy and bracing[25].

However, in resource-limited settings, weekly follow-ups pose logistical challenges for families. The Accelerated Ponseti Technique, which involves bi-weekly casting, may overcome these barriers by shortening treatment duration, improving compliance, and allowing closer monitoring for complications such as skin sores.

This study compares the outcomes of the Accelerated Ponseti Technique versus the Standard Ponseti Technique in managing idiopathic CTEV in children under six months of age.

Materials and Methods

Study Area : Outpatient Department, National Institute for Locomotor Disabilities (Divyangjan), Kolkata 700090.

Study Population : The patients visiting the Outpatient Department were listed according to the inclusion and exclusion criteria.

Sample Size : Total 36 newborn babies with idiopathic Congenital Talipes Equinovarus deformity of the foot.

Sample Size Rationale : Sample size has been calculated with the help of Epi Info (TM) 7.2.2.2. EPI INFO is a trademark of the Centres for Disease Control and Prevention (CDC). The same software was used for the statistical analysis of the data of this study.

According to the study by Harnett, *et al*[26] the tenotomy rates for the accelerated group and control group were 79% (n=19) and 52% (n=21), respectively.

This calculator uses the following formula for the sample size n:

$$n = (Z_{\alpha/2}+Z_{\beta})2 * [p_1(1-p_1)+p_2(1-p_2)] / (p_1-p_2)^2,$$

Where $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$ (eg, for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the essential value of the Normal distribution at β (eg, for a power of 80%, β is 0.2 and the critical value is 0.84) and p_1 and p_2 are the expected sample proportions of the two groups.

Thus, there was a need for 36 patients with 80% power at a 90% confidence level. The number of patients in each group was 1:1. Therefore, the required number of patients in each group was 18.

Thus, the sample size was 36

Study Design : A prospective, randomised, and comparative study.

Study Duration : December 2017 to April 2019 (16 months).

Data Collection / Study Tool : Pirani scoring system.

Study Technique : After obtaining approval from the Institute's Ethics Committee, the selected cases were initially screened according to the inclusion and exclusion criteria. The parents of the newborn who fulfilled the inclusion and exclusion criteria were approached with the proposal of the study. The aim of the research and procedure was explained, and written consent was taken from the parents of the newborn babies, who agreed to participate. A thorough history and physical examination were done as per the study protocol. Then the newborn babies were randomly assigned to two groups, ie, the Standard Ponseti Technique (group A) and the Accelerated Ponseti Technique (group B), for the management of idiopathic CTEV. Both groups received the same treatment, except that in the Accelerated Ponseti Technique, the cast was changed twice a week (every three days) instead of once, as in the standard Ponseti technique. Pirani scoring was done before applying each cast. After a serial casting of 4-8 settings (For standard Ponseti-3-6 weeks and accelerated Ponseti 3-4 weeks) when 60-70 degree abduction achieved percutaneous achellis tenotomy was done if 10-15 degree dorsiflexion

was not achieved and the feet were put in a final cast with 60-70degree abduction and 10-15 degree dorsiflexion for 3 weeks. After 3 weeks of final cast, the babies were given an HM Steenbeek brace[21] to be worn for 23 hours a day for 3 months. They were called for follow-up after 1 week of prescribing the Steenbeek brace to monitor the use of the brace. If the bracing was going well they were called after 3 months to reduce the time of brace wearing from 23 hours to 14-16 hours in a day ie, the child had to wear the brace for 12 hours at night time and 2-4 hours in the middle of the day till 3-4 years of their age[27]. For this study, each case was followed up for up to 3 months post-PCTAT, from the first day of casting, in both groups, to assess the outcome of the techniques.

Statistical Analysis : Statistical Analysis was performed using Epi Info (TM) 3.5.3, a trademark of the Centres for Disease Control and Prevention (CDC).

Using this software, basic cross-tabulation and frequency distributions were prepared. A test was used to assess the association between the different study variables under investigation. The corrected test was used in case any one of the cell frequencies was found to be less than 5 in the bivariate frequency distribution.

The test of proportions (Z-test) was used to test for a significant difference between two proportions. A t-test was used to determine the significance of the difference between the means. $p<0.05$ was considered statistically significant.

Inclusion Criteria :

- Age group from 0-6 months
- A self-reported idiopathic CTEV, clinically diagnosed
- Not treated previously

Exclusion Criteria :

- Age more than 6 months
- Atypical clubfoot or syndromic clubfoot
- Recurrent clubfoot/ relapsed
- Treated earlier

Result and Analysis

Descriptive statistical analyses were performed to calculate the means with corresponding Standard Deviations (SD). The test of proportions was used to find the Standard Normal Deviate (Z) to compare the differences in proportions, and the Chi-square test was performed to identify associations. In cases where one of the cell frequencies was less than 5, the corrected Chi-square (χ) was used to determine the association between variables. $p<0.05$ was taken to be statistically significant.

Discussion

In this comparative study between the effectiveness of the Standard Ponseti Technique and Accelerated Ponseti Technique in patients with Congenital Talipes Equinovarus under 6 months of age, out of a total of 36 patients enrolled, all 36 completed the whole period of casting and underwent PCTAT, followed by 3 months of follow-up with SB-bracing, 18 each in group A and group B (Table 1).

Table 2 shows that the Chi-square test revealed no significant association between the gender of patients in the two groups ($p = 0.46$). Thus, the patients in the two groups were matched for gender, with 69.4% male and 30.6% female. This is similar to the study done by Sana Ullah, *et al*[25], where 57% were male and 43% were female.

As depicted in Table 3, there were no significant differences in the mean scores of the different parameters of the Pirani Scoring System and the total score of both right and left legs of the patients at the time of the first cast using two techniques ($p = 0.99$).

As shown in Table 4, there was an improvement in Pirani scoring in both groups and there were no significant differences in the mean score of different parameters of the Pirani Scoring System and total score of both right and left legs of the patients at the different follow-up times by the two techniques ($p>0.05$).

Table 5 shows that the mean number of days required for patients in the ATP Group was significantly less than that for patients in the SPT Group ($t34 = 8.39$, $p < 0.001$). The mean number of days required to achieve full correction in SPT was 30.72±6.42, and that of ATP was 15.17±4.54. A similar result was observed by Barik, *et al*[28] in their study that the average number of days required for correction of feet was 54.38±8.01 and 33.88±9.03 ($p<0.01$), respectively, for standard and accelerated groups.

Table 1 — *Distribution of the types of treatment of the patients*

Type of treatment	Number	%
Accelerated Ponseti Technique (ATP)	18	50.0%
Standard Ponseti Technique (SPT)	18	50.0%
Total	36	100.0%

Table 2 — *Distribution of gender of the patients of the two groups*

Gender	SPT (n=18)	ATP (n=18)	TOTAL
Male	12	13	25
Row %	48.0	52.0	100.0
Col %	66.7	72.2	69.4
Female	6	5	11
Row %	54.5	45.5	100.0
Col %	33.3	27.8	30.6
TOTAL	18	18	36
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Table 3 — *Distribution of different parameters of the Pirani Scoring System and total score of both right and left legs of the patients at the time of first cast by two techniques*

Parameters of the Pirani Scoring System	SPT (n=18)			ATP (n=18)			t-test (t_{34})	p-value
	Mean±SD	Median	Range	Mean±SD	Median	Range		
Medical Crease								
Right leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Left leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Lateral Border Curvature								
Right leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Left leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
The lateral part of the head of the talus								
Right leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Left leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Posterior Crease								
Right leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Left leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Empty Heal								
Right leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Left leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Rigid Equinus								
Right leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Left leg	1.00±0.01	1	1 – 1	1.00±0.01	1	1 – 1	0.01	0.99 NS
Total Score								
Right leg	6.00±0.01	6	6 – 6	6.00±0.01	6	6 – 6	0.01	0.99 NS
Left leg	6.00±0.01	6	6 – 6	6.00±0.01	6	6 – 6	0.01	0.99 NS

Table 5 also showed that the mean number of plasters required for the patients of the STP Group was less than that of the patients of the APT Group, t-test showed that there was no significant difference in mean number of plasters of the patients of the STP Group and that of the patients of the APT Group (t_{34}=1.24; p=0.22). The mean number of casts for full correction was 4.94±0.87 for SPT and 5.39±1.24 for ATP, which is comparable to the result found by Elqohary HS, *et al*[29] in their study, that the mean number of casts for full correction was 4.88 ± 0.88 in the traditional group and 5.16 ± 0.72 in the accelerated group. Xu RJ_{34} also found in his study that there were no differences between the two groups in the average number of casts (P=0.61).

Hence, in our study, we found that both techniques play an effective role in correcting CTEV; however, ATP is less cost-effective and time-consuming than SPT. So we can recommend ATP for long-distance patients. Moreover, ATP gives us the opportunity to check for skin sores more frequently (twice a week) that may occur due to casting; hence, we can recommend ATP for babies with a higher

Table 4 — *Distribution of different parameters of the Pirani Scoring System and total score of both right and left legs of the patients at the time of the sixth cast by two techniques*

Parameters of the Pirani Scoring System	SPT (n=18)			ATP (n=18)			t-test (t_{34})	p-value
	Mean±SD	Median	Range	Mean±SD	Median	Range		
Medical Crease								
Right leg	0.010±0.01	0	0 – 0	0.010±0.01	0	0 - 0	0.01	0.999 NS
Left leg	0.010±0.01	0	0 – 0	0.010±0.01	0	0 - 0	0.01	0.999 NS
Lateral Border Curvature								
Right leg	0.063±0.18	0	0.0 - 0.5	0.143±0.24	0	0.0 - 0.5	0.721	0.486 NS
Left leg	0.063±0.18	0	0.0 - 0.5	0.010±0.01	0	0 - 0	1.272	0.351 NS
The lateral part of the head of the talus								
Right leg	0.010±0.01	0	0 – 0	0.010±0.01	0	0 - 0	0.01	0.999 NS
Left leg	0.010±0.01	0	0 – 0	0.010±0.01	0	0 - 0	0.01	0.999 NS
Posterior Crease								
Right leg	0.063±0.18	0	0.0 - 0.5	0.214±0.27	0	0.0 - 0.5	1.278	0.230 NS
Left leg	0.063±0.18	0	0.0 - 0.5	0.250±0.35	0.25	0.0 - 0.5	0.728	0.588 NS
Empty Heal								
Right leg	0.500±0.01	0.5	0.0 - 0.5	0.571±0.19	0.5	0.5 - 1.0	1.269	0.356 NS
Left leg	0.500±0.01	0.5	0.5 - 0.5	0.750±0.35	0.75	0.5 - 1.0	1.362	0.500 NS
Rigid Equinus								
Right leg	1.00±0.01	1	1 – 1	1.000±0.01	1	1 - 1	0.01	0.999 NS
Left leg	1.00±0.01	1	1 – 1	1.000±0.01	1	1 - 1	0.01	0.999 NS
Total Score								
Right leg	1.625±0.35	1.5	1.5 - 2.5	1.929±0.45	2	1.5 - 2.5	1.438	0.177 NS
Left leg	1.625±0.35	1.5	1.5 - 2.5	2.000±0.71	2	1.5 - 2.5	0.728	0.588 NS

Table 5 — *Comparison of the number of days and plaster required to achieve corrections for the patients of the two groups*

Number of days and Number of plasters	SPT (n=18)	ATP (n=18)
Mean ± SD	30.72±6.42 and 4.94±0.87	15.17±4.54 and 5.39±1.24
Median	35 and 5	14 and 5
Range	21-42 and 4-7	10-25 and 4-8

risk of skin break, such as low-birth-weight babies, preterm babies or babies with skin rashes. However, to obtain more conclusive results, studies with larger sample sizes and a longer follow-up period are recommended.

Conclusion

This study investigated the effectiveness of the Standard Ponseti Technique *versus* the Accelerated Ponseti Technique in managing congenital CTEV in patients under 6 months. The results indicated that both methods have a significant effect on improving the Pirani score. It seems that ATP is less cost-effective and time-consuming than SPT.

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References

1 Mkandawire NC, Kaunda E — Incidence and patterns of congenital talipes equinovarus (clubfoot) deformity at Queen Elizabeth Central Hospital, Banter, Malawi. *East Afr J Surg* 2004; **9:** 28-31.
2 Mittal R, Sekhon A, Singh G, Thakral H — The prevalence of congenital orthopaedic anomalies in a rural community. *Int Orthop* 1993; **17(1):** 11-2. doi: 10.1007/BF00195214.
3 Jowett CR, Morcuende JA, Ramachandran M — Management of congenital talipes equinovarus using the Ponseti method: a systematic review. *J Bone Joint Surg Br* 2011; **93:** 1160-4 [PMID: 21911524 DOI:10.1302/0301-620X.93B9.26947]
4 Bowyer G — The ankle and foot, Apley's System of Orthopaedics and Fractures, Ninth Edition, Chapter 21, page 591.
5 Africa Clubfoot Training Project. Chapter 2 Africa Clubfoot Training Basic & Advanced Clubfoot Treatment Provider Courses - Participant Manual. University of Oxford: Africa Clubfoot Training Project, 2017.
6 Olayinka O Adegbehingbe, Adeoye J Adetiloye, Ladipo Adewole, Dennis U Ajodo; Ponseti method treatment of neglected idiopathic clubfoot; Preliminary results of a multi-centre study in Nigeria. *World J Orthop* 2017; **8(8):** 624-30.
7 Siapkara A, Duncan R — Congenital talipes equinovarus: a review of current management. *J Bone Joint Surg [Br]* 2007; **89-B:** 995-1000.
8 Miedzybrodzka Z — Congenital talipes equinovarus (clubfoot): a disorder of the foot but not the hand. *J Anat* 2003; **202:** 39-40.
9 Hoffa A — Lehrbuch der Orthopadischen Chirurgie. Stuttgart: Ferdinand Enke; (1902).
10 Fritsch H, Eggers R — Ossification of the calcaneus in the Normal fetal foot and in clubfoot. *J Pediatr Orthop* 1999; **19:** 22-6.
11 Wynne-Davies R — Family studies and the cause of congenital club foot. *J Bone Joint Surg* 1964; **46B:** 445-63.
12 Atlas S, Menacho LCS, Ures S — Some new aspects in the Pathology of clubfoot. *Clin Orthop* 1980; **149:** 224-8.
13 Nadeem RD, Brown JK, Lawson G Macnicol MF — Somatosensory evoked potentials as a means of assessing neurological abnormality in congenital talipes equinovarus. *Dev Med Child Neurol* 2000; **42:** 525-30.
14 Bareiter D — Prenatal development of the foot and ankle. *J Am Podiatric Med Assocn* 1995; **85:** 753-64.
15 Dietz F — The genetics of idiopathic clubfoot. *Clinical Orthopaedics and Related Research* 2002; **401:** 39-48.
16 Adams JC, Hablen DL — Outline of Orthopaedics. London: Churchill Livingstone. 2001.
17 Staheli L — Clubfoot: Ponseti Management Third Edition. Seattle: Global Help. 2009.
18 Hussain FN — The role of the Pirani scoring system in the management of club foot by the Ponseti method. *J Bone Joint Surg Br* 2007; **89(4):** 561.
19 Ponseti IV, Zhivkov M, Davis N, Sinclair M, Dobbs MB, Morcuende JA — Treatment of the Complex Idiopathic Clubfoot. *Clin Orthop Relat Res* 2006; **451:** 171-6.
20 Maheshwari J — Congenital talipes equinovarus, Essential Orthopaedics, 3rd edition, Mehta publication, March 2009, 196-8.
21 Ponseti IV, Zhivkov M, Davis N, Sinclair M, Dobbs MB, Morcuende JA — Treatment of the Complex Idiopathic Clubfoot. *Clin Orthop Relat Res* 2006; **451:** 171-6.
22 Yamamoto H, Muneta T, Ishibashi T, Furuya K — Posteromedial release of congenital club foot in children over five years of age. *J Bone Joint Surg (Br)* 1994; **76-B:** 555-8.
23 Kumar PN, Laing PW, Klenerman L — Medial calcaneal osteotomy for relapsed equinovarus deformity. Long-term study of the results of Frederick Dwyer. *J Bone Joint Surg Br* 1993; **75(6):** 967-71.
24 Graham GP, Dent CM — Dilwyn Evans operation for relapsed club foot long-term results. *J Bone Joint Surg [Br]* 1992; **74-B:** 445-8.
25 Harnett P, Freeman R, Harrison WJ, Brown LC, Beckles V — An accelerated Ponseti versus the standard Ponseti method: a prospective randomised controlled trial. *The journal of bone and joint surgery* 2011; **93(3):** 404-8. DOI: 10.1302/0301-620X.93B3.24450.
26 Harnett P, Freeman R, Harrison WJ, Brown LC, Beckles V — An accelerated Ponseti versus the standard Ponseti method: a prospective randomised controlled trial. *The journal of bone and joint surgery* 2011; **93(3):** 404-8. DOI: 10.1302/0301-620X.93B3.24450.
27 Ponseti I, Morcuende JA, Pirani S — Clubfoot: Ponseti management, global help, third edition, page no 6.
28 Barik S, Nazeer M, Mani BT — Accelerated Ponseti technique: efficacy in the management of CTEV. *European Journal of Orthopaedic Surgery & Traumatology* 2019; **29(4):** 919-24.
29 Elgohary HS, Abulsaad M — Traditional and accelerated Ponseti technique: a comparative study. *European Journal of Orthopaedic Surgery & Traumatology* 2015; **25(5):** 949-53.

Original Article

Diabetic Otopathy : Have We Heard Enough? — A Regression Analysis to Identify High Risk Factors

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Abstract

Background : Diabetic Otopathy (DO), is one of the less studied complications of Type II Diabetes Mellitus (T2DM) with lack of detailed assessment of various parameters like Age, Gender, Body Mass Index (BMI), Addiction, Family History and Duration of T2DM etc. and their association with Sensorineural Hearing Loss (SNHL). It is important to identify the high-risk factors associated with SNHL in T2DM to propose the potential screening strategy.

Aims and Objectives : To identify and evaluate the predictive value of the most common parameters leading to SNHL in T2DM.

Materials and Methods : A prospective, cross-sectional study was conducted on patients with T2DM (25- 85 years). A spectrum of parameters including Age, Gender, BMI, Addiction, Duration and Family history of T2DM, Glycemic control, PPI use, Presence/ absence of other Microvascular complications were analyzed to establish an association using Chi Square and regression analysis.

Results : A high prevalence of SNHL (73.30 %) was noticed among diabetics. After detailed statistical analysis of multiple parameters, on multivariate logistic regression, BMI (Adjusted Odds Ratio or AOR = 26.217, p = 0.001), Family history (AOR = 24.865, p = 0.006), Duration of T2DM (AOR =15.530, p = 0.037) and Glycemic control (AOR = 12.583, p = 0.018) were found to be significant predictors of SNHL.

Conclusion : In the present study, multiple parameters analyzed among adults with T2DM, positive Family history, Duration more than 10 years, BMI in overweight/obesity range, and poor Glycemic control were found to be significant and independent predictor factors for SNHL.

Key words : Diabetic Otopathy, Sensorineural Hearing Loss, Type II Diabetes Mellitus, Diabetes Mellitus.

It would not be an exaggeration to say that Diabetes Mellitus (T2DM) has reached a state of an epidemic Worldwide. According to the International Diabetes Federation (IDF), approximately 537 million people in the World and 90 million people in the South East Asia region have T2DM, whereas its prevalence in India is estimated to be more than 8.3% of the adult population[1].

It affects almost all organ systems of the body and as a consequence has many complications including Retinopathy, Nephropathy, Peripheral Neuropathy and atherosclerosis. Diabetic Otopathy (DO), ie, involvement of audio-vestibular system, is one of the less studied complications of T2DM, leading to significant deterioration of Quality of Life of those affected[2].

According to World Health Organization (WHO), SNHL, which is one of the significant non-vascular complications of T2DM, has been reported in approximately 466 million people (6.1% of the Global population)[3].

Editor's Comment :

- A diabetic patient with a positive family history, having a prolonged duration of T2DM more than 10 years with above normal BMI and poor glycemic control is at higher risk of developing SNHL.
- It is imperative to identify and screen such individuals for early detection of diabetic otopathy and prompt intervention.

Although the prevalence of measured hearing impairment in T2DM is approximately twice when compared to general population, it's magnitude and pathophysiology are not yet clearly defined and often underestimated[4].

The well-established complications like retinopathy, peripheral neuropathy and nephropathy, have prompted the American Diabetes Association to produce clear clinical recommendations suggesting a screening protocol. However, the epidemiological relationship between T2DM and Hearing Loss (HL) remained ambiguous[5].

There are many studies demonstrating an association between T2DM and SNHL but there is a lack of detailed assessment of various parameters like Age, Gender, BMI, Addiction, Family history and Duration of T2DM, Glycemic control, Microvascular complications, PPI use and their association with SNHL. Establishment of predictor variables for SNHL in T2DM might lead to identification

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of at-risk/high risk patients and effective screening protocols.

Hence, this study was conducted to identify and evaluate the predictive value of the most common parameters leading to SNHL in T2DM.

Materials and Methods

A single centered, hospital based, prospective, observational, cross-sectional study was conducted in a Tertiary Care Medical College & Hospital for fifteen months starting from December, 2023 to March, 2024 (after obtaining Institutional Ethics Committee approval). Consecutive patients with T2DM between 25 to 85 years of age were included, while, patient unwilling to be included in the study, suffering from congenital hearing loss, noise induced hearing loss, Meniere's disease, history of exposure to ototoxic drugs, middle ear surgeries or diseases and conductive hearing loss, history of systemic illness like Meningitis, Renal failure and others like Autoimmune disease, Hypertension and Thyroid dysfunction and history of Head or Ear trauma were excluded.

The informed consent and the demographic profile of the patients were recorded which included Age, Gender, BMI, Addiction, Duration and Family history of T2DM, Glycemic control, PPI use, Presence / absence of other Microvascular complications (Retinopathy, Nephropathy and Neuropathy). BMI was calculated and classified[6]. These parameters were finalized and selected from recent literature including a systematic review[7,8].

Otoscopic examination was done in all patients. Results of Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS) and glycosylated Hemoglobin (HbA1c) were noted. Assessment of HL was then done using Pure Tone and Speech Audiometry. The testing was performed using Auditivo Audiometer and TECMO MT- 30 Headphones. Pure Tone Audiometry was performed on both ears, one at a time, at frequencies of 0.125, 0.250, 0.5, 0.750, 1, 1.5, 2, 3, 4, 6, and 8 kHz. Before the test, the patient was asked to identify his or her better ear. From the Audiogram, hearing impairment for conversational speech was calculated as the Pure Tone Average (PTA) for the better ear as an average of four frequencies (0.5, 1 & 2 KHz) and was classified as per American Speech Language and Hearing Association[9,10]. All the included patients were also assessed using Speech Audiometry. The patients' Speech Discrimination Score (SDS) was measured with the help of listed monosyllable words (intensity $\geq$ 40 dB). Speech Reception Threshold (SRT) analysis was done using listed bisyllable words[11].

The relevant operational definitions are presented in Table 1.

Table 1 — *Operational Definitions*[12]

Test	Pre-diabetes	Diabetes	Comments
Fasting Plasma Glucose	Impaired Glucose Tolerance $\geq$100 <126 mg/dl	>126mg/dl	No caloric intake for at least 8 hours
2-hour Plasma Glucose (during an oral glucose tolerance test)	Impaired Glucose Tolerance $\geq$140 <200mg/dl	$\geq$200 mg/dl	Using glucose load of 75g anhydrous glucose dissolved in water
HbA1c	Increased diabetes risk HbA1c 5.7-6.4%	$\geq$6.5 %	

Sensorineural Hearing Loss (SNHL) - The most commonly used definition of SNHL, as endorsed by the American Academy of Otolaryngology-Head and Neck Surgery (AAOHNS) and the National Institute of Deafness and Other Communication Disorders (NIDCD), is hearing loss of at least 30 dB (dB) in three sequential frequencies in the standard pure tone audiogram[13,14].

Study parameters were entered in Microsoft Excel Worksheet and data was analyzed using Statistical Package of Social Sciences (SPSS) version 20.0. Significant threshold established prior to beginning the study considering p as 0.05. Association of study parameters with presence or absence of SNHL was tested with Chi square test. Variables (parameters) which were found to have significant association with SNHL were subjected to uni-variate and multivariate logistic regression model to assess independent predictive value of each variable (while adjusting for the covariates).

Sample size of 86 was calculated using Cochrane's formula where expected population proportion (expected prevalence in population under study obtained from comparable studies) as 66%[15].

Results

In this study, most participants were in the age group of 46-55 years (33.7%). Male to Female ratio was 1.5:1 and males were found to be more afflicted by SNHL. Prevalence of SNHL among 86 diabetics was found to be 73.30%. Among the study subjects 32.6% were Overweight and 40.7% were Obese. All Obese and 75% of Overweight diabetics had SNHL. A positive family history of T2DM was seen in 41.9% of the participants out of which 88 % had SNHL. History of long duration of T2DM (>10 years) was seen in 51.2% patients. SNHL was found in 38.3%, 66.7%, 90.9% patients suffering with T2DM for less than 5 years, 5-10 years, more than 10 years respectively. In the present study 65.1% of the patients had poor glycemic control status. Among the patients with poor glycemic control, 83.9% were found to be suffering from SNHL. HL was noted in 14% of the Smokers and 15.1% of those addicted to Alcohol. It was found that 90% of the diabetics with microvascular complications had SNHL. Amongst PPI users 77.2% had SNHL.

PTA test revealed SNHL to be almost bilaterally symmetrical, more so in the higher frequencies, ranging from 4-8 kHz (Table 2). Similarly, most of the patients had hearing loss in both Right and Left ears as per the results of SRT. However, SDS did not show significant hearing loss in the patients (Table 2).

Analysis of individual parameters using chi square test was done. BMI, Duration of disease, Family history, Glycemic control were significantly associated with SNHL, while no significant association was seen with Age & Gender, Addiction, PPI and Presence/absence of other Microvascular complications. A summary of the results obtained in this study are shown in Table 3.

On univariate logistic regression, Body mass index (OR = 18.296, p <0.001), Family history (OR = 24.865, p = 0.006), Duration of T2DM >10 years (OR=15.714, p = 0.000) and Poor Glycemic control (OR = 4.569, p = 0.003) were found to be risk factors for developing SNHL.

On multivariate logistic regression, Body Mass Index (AOR = 26.217, p = 0.001), family history (AOR = 24.865, p = 0.006), Duration of T2DM (AOR = 15.530, p = 0.037) and Glycemic control (AOR = 12.583, p = 0.018) were found to be significant predictors of SNHL (Table 4). The model fitting statistics was good. It had significant Omnibus test value (p <0.001) and insignificant Hosmer Lemeshow (p = 0.747).

Discussion

The most important finding of the current study is that out of the multiple parameters analyzed, positive family history of T2DM, duration more than 10 years, BMI in overweight / obesity range and poor glycemic control were found to be significant and independent predictor factors for SNHL in T2DM.

Family history of T2DM was found to be significantly associated with SNHL similar to results of Bhavita, *et al* and Gadag RP, *et al*[16,17]. The reason could be attributed to maternally inherited Diabetes linked to mitochondrial DNA mutations, a known cause of hearing loss. Moteki, *et al* also mentioned 3243 A>G (mitochondrial) and P2X2 gene mutations to be associated with T2DM and SNHL, respectively[18].

A strong correlation between the duration of Diabetes and SNHL is noted in our study similar to the findings of studies by Srinivas C V, *et al* and Gadag RP, *et al* but contradictory to the findings of a study by Axelsson A, *et al*. The increase in hearing threshold may be attributed to the microvascular angiopathy in the capillaries of stria vascularis[15,17,19]. An association between duration of Diabetes Mellitus and SNHL was made in a study by Jyothi, *et al* showing that patients with more than 10 years of T2DM had a maximum prevalence of hearing loss when compared to fewer years of duration[20]. Thimmasettaiah, *et al* in their study done in Bengaluru, stated that Diabetes of more than 5 years duration was found to have more hearing impairment (79%) as compared to freshly detected diabetics (42%)[21]. The proposed mechanism may be due either microangiopathy or neuropathy. These changes may be

Table 2 — *Prevalence of Hearing Loss in T2DM Patients based on PTA, SDS* and SRT tests

PTA (dBHL)	Right Ear	Left Ear
<25	44(51.2%)	44(51.2%)
25-40	24 (28%)	25(29.1%)
41-55	11(13%)	10(12%)
56-70	6(7%)	5(6%)
71-90	1(1.2%)	2(2.3%)
>90	0	0
Hearing loss level	SDS, SRT (PERCENTAGE (%)	
	Right Ear	Left Ear
Hearing Loss +	3.2%, 69%	7.6%, 80%
Hearing Loss -	97.8%, 30%	94.2%, 27%

PTA - Pure Tone Audiometry, SDS - Speech Discrimination Score, SRT - Speech Reception Threshold, dBHL - Decibel Hearing Loss

Table 3 — *Frequency of Sensorineural Hearing Loss in various parameters and Chi Square test*

Variables	Hearing loss		Chi-square value	p value
	Absent [n (%)]	Present [n (%)]		
Age :				
25-35	0 (0.00)	1(1.1)	3.506	0.061
36-45	5 (5.8)	7 (8.3)		
46-55	9 (10.4)	20 (23.3)		
56-65	5 (5.8)	21 (24.4)		
66-75	4 (4.7)	12 (13.9)		
76-85	0 (0.00)	2 (2.3)		
Gender :				
Male	14 (16.28)	38 (44.19)	0.002	0.963
Female	9 (10.46)	25 (29.07)		
BMI :				
Underweight	0 (0.0)	0 (0.0)	34.347	0.000
Normal	16 (18.7)	7 (8.1)		
Overweight	7 (8.1)	21 (24.4)		
Obese	0 (0.0)	35 (40.7)		
Smoking :				
Absent	14 (16.3)	41(47.7)	2.181	0.1397
Present	9 (10.5)	12 (14)		
Addiction to Alcohol :				
Absent	16 (18.6)	50(58.1)	0.906	0.3412
Present	7 (8.1)	13 (15.1)		
Family h/o of T2DM :				
Absent	19 (22.1)	31 (36.0)	7.724	0.005
Present	4 (4.6)	32 (37.3)		
Duration of T2DM :				
< 5 years	11 (12.8)	7 (8.1)	18.382	0.000
5-10 years	8 (9.3)	16 (18.6)		
>10 years	4 (4.7)	40 (46.5)		
Glycaemic control :				
Good (<6.5)	14 (89.1)	16 (10.9)	9.333	0.002
Poor (>6.5)	9 (16)	47 (84)		
Microvascular complications :				
Absent	22(26)	54 (63)	1.619	0.2032
Present	1 (1.2)	9(10.4)		
PPI use				
Absent	10(11.6)	19 (22.1)	1.337	0.2476
Present	13 (15.1)	44 (51.1)		

Table 4 — *Univariate and Multivariate Regression Analysis*

Variables	Odds Ratio/OR	p value	Adjusted Odds Ratio (AOR)	95% Confidence Interval (CI)		p value
				Lower	Higher	
BMI :						
Normal (n = 23)	ref	-	-			-
Overweight and Obese (n = 63)	18.286	<0.001	26.217	3.737	183.909	0.001
Family history of T2DM :						
Absent (n = 50)	ref	-	-			-
Present (n = 36)	24.865	0.006	24.865	2.552	242.229	0.006
Duration of T2DM :						
< 5 years (n = 18)	ref	-	-			-
5- 10 years (n = 24)	3.143	0.078	4.433	0.517	37.971	0.174
> 10 years (n = 44)	15.714	0.000	15.530	1.180	204.301	0.037
Glycaemic control :						
Good (< 6.5) (n = 30)	ref	-	-			-
Poor (> 6.5) (n = 56)	4.569	0.003	12.583	1.540	102.785	0.018

evident from the autopsy of T2DM patients which showed internal auditory artery thickening, spiral ganglion atrophy or cranial nerve degeneration, especially VIII cranial nerve[17].

Majority of the Overweight and all Obese diabetics had SNHL and a significant association between BMI and SNHL was noted. The reason for significant association could be attributed to the excess body fat. Moreover, diabetic patients have lipid metabolism dysfunction which may be a cause for inner ear malfunction on a biochemical basis. There is very limited literature exploring this association. However, study findings by Huang, *et al* showed an inconclusive association[22].

We found significant association between Glycemic control and SNHL where Diabetics with HbA1c more than 6.5% were found to be more affected (55%). The relation between the Random Blood Sugar levels and Hearing Threshold in a study by Srinivas C V, *et al* was inconclusive, as Random Blood Sugar gives an idea of Present Blood Sugar level, but it does not signify about long-term sugar control. In our study, HbA1c was taken into consideration as it directly gives an idea about the Blood Sugar control of the patient in the recent past 3 months. Srinivas, *et al* found that patients with poor control (HbA1c>8 %) of their Glycemic status had raised Auditory Thresholds[15]. In a study by Jyothi, *et al* diabetic patients with poor control of disease had increased prevalence of SNHL[20]. Huang, *et al* didn't find any association between hearing impairment and HbA1c in diabetic patients[22]. Poor Glycemic control can lead to SNHL because it damages the tiny blood vessels in the inner ear, which are crucial for supplying Oxygen and nutrients to the delicate hair cells responsible for hearing, ultimately leading to their dysfunction and hearing loss. It reflects that poor glycemic control contributes to more pronounced Cochlear hair cell damage, primarily attributed to increased oxidative stress and inflammation.

This study shows Hearing Thresholds are affected more in higher frequencies similar to the study by Rajendran, *et al*[23]. Tay, *et al* stated that the HL was seen in mid and low frequencies and same was the finding of Taylor and Irwin, *et al*[24,25]. Fangchao et al. found HL in diabetics only in 500Hz frequency[26]. Axelsson, *et al* has showed no significant relation between the two[19]. It is hypothesized that high frequency sounds are affected more due to accelerated atherosclerosis, thickening of basement membrane, which decreases blood flow to cochlea, mainly to the basal and middle turn leading to cell degeneration and loss of high frequency hearing sounds[27] .

In the opinion of the authors, the most important clinical utility of the current study is in identification of high-risk individuals. Diabetics with high BMI, duration of T2DM>10 years, with Family History and poor Glycemic control may be at the highest risk for developing SNHL. Efforts must be directed towards developing a targeted screening methodology in such high-risk individuals so as to allow for timely intervention and development of management strategies to minimize further HL.

Limitations :

There are some limitations of the present study. Patients are between 25-85 years of age and thus presbycusis comes into the picture. T2DM is known to cause bilateral progressive SNHL. With aging, both HL as well as risk of Diabetes increases. So, the HL seen in patients with T2DM would be similar to that of presbycusis but with more severe losses and early onset than expected by aging alone. As a result, it is difficult to distinguish whether HL in T2DM is due to aging or due to biochemical and vascular abnormalities associated with T2DM. Presbycusis, by definition, is a diagnosis of exclusion and hence, in this study, SNHL can be attributed to T2DM[28].

This study may be subjected to referral bias. Being a Tertiary Care Referral Center, it is possible that the prevalence of Otopathy may be higher in our included sample than in the community.

Failure to use objective HL assessment methods may be considered as another limitation of the study. However,

pure tone Audiometry is the most commonly employed screening tool (owing to its availability and cost effectiveness) at all level of Health Care Centers. In the authors' opinion, the targeted screening of high-risk individuals should also include PTA before going for higher objective assessment methods.

Conclusion

Among the various parameters analyzed in adults with T2DM, a positive family history, disease duration exceeding 10 years, Overweight / Obese BMI, and poor Glycemic control emerged as significant and independent predictive factors for SNHL.

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References

1 Kumar A, Gangwar R, Zargar AA, Kumar R, Sharma A — Prevalence of Diabetes in India: A Review of IDF Diabetes Atlas 10th Edition. *Curr Diabetes Rev* 2024; **20(1):** e130423215752. doi: 10.2174/1573399819666230413094200. PMID: 37069712.

2 Dabrowski M — Diabetes and hearing dysfunction: Under- recognized complication of diabetes? *North Am J Med Sci* 2013; **5:** 66-7.

3 Addressing the rising prevalence of hearing loss. Geneva: World Health Organization; 2018. Available from: http://www.who.int/pbd/deafness/estimates/en/

4 Bainbridge KE, Hoffman HJ, Cowie CC — Diabetes and hearing impairment in the United States: Audiometric evidence from the National Health and Nutrition Examination Survey, 1999 to 2004. *Ann Intern Med* 2008; **149:** 1-10. doi: 10.7326/0003-4819-149-1-200807010-00231

5 Sekaran G, Selvan T, Kala S, Kumar JS, Venkataraman P, Selvarajan G, *et al* — High-Frequency Hearing Sensitivity Level among Young Adults with Insulin-Dependent and Non-Insulin-Dependent Diabetes Mellitus. *International Journal of Nutrition, Pharmacology, Neurological Diseases* 2023; **13(3):** 133-9. DOI: 10.4103/ijnpnd.ijnpnd_57_22

6 WHO Expert Consultation. Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies. *Lancet* 2004; **363(9403):** 157-63. doi: 10.1016/S0140-6736(03)15268-3. Erratum in: Lancet. 2004 Mar 13;363(9412):902. PMID: 14726171.

7 Deng Y, Chen S, Hu J — Diabetes mellitus and hearing loss. *Mol Med* 2023; **29(1):** 141. doi: 10.1186/s10020-023-00737-z. PMID: 37875793; PMCID: PMC10599066.

8 Mane SD, Mane R, Patil BC, Lakshmi J, Bedwal D — Deafness and Diabetes Mellitus: A Systematic Literature Review. *BJOHNS* [Internet]. 2022Mar.18 [cited 2025May20]; **29(3):** 217-23. https://bjohns.in/journal3/index.php/bjohns/article/view/554

9 Majumder J, Patel RC, Kotadiya S, Shah P — Hearing Threshold Status and Risk Estimate of Hearing Impairment among Administrative Workforce. *Indian J Occup Environ Med* 2018; **22(1):** 11-6. doi: 10.4103/ijoem.IJOEM_22_18. PMID: 29743779; PMCID: PMC5932904.

10 John C — Uses and abuses of hearing loss classification. *ASHA* 1981; **23:** 493-500.

11 Behrbohm H, Kaschke O, Nawka T, Swift A — Ear, Nose and Throat Diseases. Thieme. 2019.

12 Hirsch GE, Heck TG — Inflammation, oxidative stress and altered heat shock response in type 2 diabetes: the basis for new pharmacological and non-pharmacological interventions. *Archives of Physiology and Biochemistry* 2019; 1-15. doi: 10.1080/13813455.2019.1687522.

13 Stachler RJ, Chandrasekhar SS, Archer SM, Rosenfeld RM, Schwartz SR, Barrs DM, *et al* — American Academy of Otolaryngology-Head and Neck Surgery. Clinical practice guideline: sudden hearing loss. *Otolaryngol Head Neck Surg* 2012; **146(3 Suppl):** S1-35. doi: 10.1177/0194599812436449. PMID: 22383545.

14 Chandrasekhar SS, Tsai Do BS, Schwartz SR, Bontempo LJ, Faucett EA, Finestone SA, *et al* — Clinical Practice Guideline: Sudden Hearing Loss (Update). *Otolaryngol Head Neck Surg* 2019 Aug; **161(1_suppl):** S1-S45. doi: 10.1177/0194599819859885. PMID: 31369359.

15 Srinivas CV, Shyamala V, Shiva Kumar BR — Clinical Study to Evaluate the Association Between Sensorineural Hearing Loss and Diabetes Mellitus in Poorly Controlled Patients Whose HbA1c >8. *Indian J Otolaryngol Head Neck Surg* 2016; **68(2):** 191-5. doi: 10.1007/s12070-016-0973-5. Epub 2016 Mar 15. PMID: 27340635; PMCID: PMC4899376.

16 Bhavitha R, Simha V — Clinical Evaluation of Sensoneural Hearing Loss in Pateints with Diabetes Mellitus. *Scholars Journal of Applied Medical Sciences* 2018; **6:** 2950-4.

17 Gadag RP, Nayak PS, J T — Clinical Assessment of Sensorineural Hearing Loss among Diabetes Mellitus Patients. BJOHNS [Internet]. 2020Aug.31 [cited 2024Aug.7]; **28(2):** 112-9. Available from: https://bjohns.in/journal3/index.php/bjohns/article/view/297

18 Moteki H, Azaiez H, Booth KT, Hattori M, Sato A, Sato Y, *et al* — Hearing loss caused by a P2RX2 mutation identified in a MELAS family with a coexisting mitochondrial 3243AG mutation. *Ann Otol Rhinol Laryngol* 2015; **124 Suppl 1(1 0):** 177S-83S. doi: 10.1177/0003489415575045. Epub 2015 Mar 18. PMID: 25788561; PMCID: PMC4441871.

19 Axelsson A, Sigroth K, Vertes D — Hearing in diabetics. *Acta Otolaryngol Suppl* 1978; **356:** 1-23. PMID: 279215.

20 Jyothi AC, Malli MNA — Prevalence of sensorineural hearing loss in type 2 diabetes mellitus. *Int J Otorhinolaryngol Head Neck Surg* 2019; **5:** 1227-33. https://www.ijorl.com/index.php/ijorl/article/view/1527/916

21 Thimmasettaiah NB, Shankar R, Ravi GC, Reddy S — A one year prospective study of hearing loss in diabetes in general population. *Translational Biomedicine* 2012. 3. doi: 10.3823/433

22 Huang YM, Pan CY, Gu R, Cai XH, Yu LM, Qiu CY — Hearing impairment in diabetics. *Chin Med J* 1992; **105(1):** 44-8.

23 Rajendran S, Anandhalakshmi, Mythili B, Viswanatha Rao — Evaluation of the incidence of sensorineural hearing loss in patients with type 2 diabetes mellitus. *Int J Biol Med Res* 2011; **2(4):** 982-7. https://www.biomedscidirect.com/

24 Tay HL, Ray N, Ohri R — Diabetes mellitus and hearing loss. *Clinical Otolaryngol* 1995; **20:** 130-4.

25 Taylor IG, Irwin J — Some audiological aspects of diabetes mellitus. *J Laryngol Otol* 1978; **92:** 99-113.

26 Fangchao MA — Diabetes and Hearing Impairment in Mexican American Adults:a population-based study. *J Laryngol Otol* 1998; **112:** 835-9.

27 Krishnappa S, Naseeruddin K — A clinical study of age related hearing loss among diabetes patients. *Indian J Otol* 2014; **20:** 160-5.

28 Scott Brown's Otorhinolaryngology, Head and Neck Surgery, Volume – 2, Edition - 8, CRC PRESS, UK, 2018.

Original Article

Prevalence of Peripheral Retinal Degenerations in LASIK Patients : A Prospective Observational Study

Rajendra V Pathakjee[1], Jaini Shah[2], Garima Ray[2], Nikhil Gore[2], Stuti Golchha[3]

Abstract

Background : Laser-assisted in Situ Keratomileusis (LASIK) is widely performed for refractive error correction. However, concerns exist regarding potential retinal complications, particularly in myopic patients who may have pre-existing Peripheral Retinal Degenerations (PRD).

Aims and Objective : To assess the prevalence of Peripheral Retinal Degenerations in patients undergoing LASIK surgery and evaluate the association between myopia severity.

Materials and Methods : This prospective observational study was conducted at the Department of Ophthalmology, Dhiraj Hospital, Vadodara, from June, 2023 to January, 2025. A total of 110 patients (220 eyes) undergoing LASIK surgery were included. Comprehensive ophthalmic evaluation including dilated fundus examination was performed preoperatively and at days 7, 30, 90 and 180 postoperatively. Patients were categorized based on myopia severity: Low (<-3.0D), Moderate (-3.0 to -6.0D) and High (>-6.0D). Statistical analysis was performed using Chi-square test for categorical variables and unpaired t-test for continuous variables.

Results : The mean age was 24.5±3.9 years with 54.5% females. High myopia was present in 76.4% (84/110), Moderate in 22.7% (25/110) and Low in 0.9% (1/110) patients. Peripheral Retinal Degenerations were found in 17.3% (19/110) patients. The prevalence of PRD varied significantly across myopia groups: Moderate myopia 48.0% (12/25), High myopia 7.1% (6/84) and Low myopia 100% (1/1) ($p<0.001$). Types of PRD included lattice degeneration (n=11), pigmentary alterations (n=3), white without pressure (n=4), peripheral retinal breaks (n=1), snail track degeneration and retinoschisis. All patients achieved 6/6 visual acuity postoperatively with no progression of PRD during 180-day follow-up.

Conclusion : The prevalence of Peripheral Retinal Degenerations in LASIK candidates was 17.3%, with Moderate myopia patients showing the highest prevalence at 48.0%. Preoperative detailed peripheral fundus evaluation is crucial across all myopia severities to identify and prophylactically treat PRD before LASIK.

Key words : High Myopia, LASIK, Peripheral Retinal Degeneration, Refractive Surgery.

Laser-assisted in Situ Keratomileusis (LASIK) has become the most popular refractive surgical procedure Worldwide for correcting myopia, hyperopia, and astigmatism[1]. LASIK is particularly indicated in patients with Low to Moderate myopia (-0.5D to -9.0D) due to higher probability of achieving emmetropia[2]. While LASIK demonstrates excellent safety and efficacy profiles, concerns remain regarding potential vitreoretinal complications, especially in myopic patients[3].

Peripheral Retinal Degeneration encompasses various lesions including lattice degeneration, snail-track degeneration, atrophic retinal holes, peripheral retinal tears, and retinoschisis[4]. Although most PRDs are clinically benign, certain types can predispose to rhegmatogenous retinal detachment, particularly in the presence of posterior vitreous detachment[5]. The mechanical stress during LASIK, including intraocular pressure elevation >65 mmHg during microkeratome suction and rapid decompression, may theoretically affect vitreoretinal structures[6].

Previous studies have reported varying incidences of vitreoretinal complications after LASIK, ranging from 0.06% to 0.45%[7,8]. However, limited data exists on follow

Editor's Comment :

- The prevalence of Peripheral Retinal Degenerations (PRD) in LASIK candidates was 17.3%, highlighting that retinal screening is essential before refractive surgery.
- Moderate myopia (-3 to -6 D) showed the highest prevalence of PRD (48%), an unexpected but clinically significant finding—screening should not be limited only to high myopes.
- Lattice degeneration was the most common peripheral retinal lesion identified.
- Careful preoperative dilated peripheral fundus examination is mandatory in all myopia severities.
- Prophylactic laser treatment, when indicated, allows safe progression to LASIK.
- No progression of PRD or new retinal lesions were observed over 6 months follow-up, and all patients achieved 6/6 visual acuity, supporting the safety of LASIK in properly screened patients.
- LASIK-related mechanical stress does not appear to worsen stable peripheral retinal lesions in the short term.
- Long-term follow-up remains important, especially in patients with identified peripheral retinal changes.

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up of prevalant pre-existing peripheral retinal degenerations in LASIK candidates and their clinical significance. This study aimed to assess the prevalence of Peripheral Retinal Degenerations in patients undergoing LASIK and evaluate its association with myopia severity and 6 month follow up of PRDs.

Materials and Methods

This prospective observational study was conducted at the Department of Ophthalmology, Dhiraj Hospital, Sumandeep Vidyapeeth University, Vadodara, Gujarat, from June, 2023 to January, 2025, after obtaining Institutional Ethics Committee approval (SVIEC/2023/06/15).

Inclusion Criteria :

The study included patients aged 21 years and older with stable myopia who demonstrated normal corneal topography and had no ocular pathology or lid abnormalities. Participants were required to have no history of previous ocular surgery. Patients with lattice degeneration and peripheral retinal breaks were included in the study following prophylactic laser barrage treatment.

Exclusion Criteria :

Patients were excluded from the study if they had inconsistent followup patterns, corneal pathology such as keratoconus or corneal ulcers, active ocular infections, or any history of previous ocular surgery.

Sample size was calculated using the formula: $n = (Z^2 \times P \times (1-P))/e^2$, where Z=1.96 for 95% confidence level, P=0.20 (expected prevalence 20%) and e=0.05 (precision 5%), yielding a minimum sample of 246 eyes. We enrolled 110 patients (220 eyes) during the study period.

Preoperative Evaluation : All patients underwent comprehensive ophthalmic examination including : • Uncorrected and best-corrected visual acuity (Snellen chart) • Autorefractometry • Slit-lamp biomicroscopy • Goldmann applanation tonometry • Corneal topography (Carl Zeiss Atlas Model 9000) • Pentacam analysis (Oculus Pentacam®) • Dilated fundus examination with 20D lens and slit-lamp biomicroscopy with 90D lens • Schirmer test and contrast sensitivity assessment.

Surgical Procedure :

LASIK was performed using Moria M2 Evolution microkeratome creating superior-hinged flaps (8.5-9mm diameter, 90-130µm thickness). Stromal ablation was performed using Carl Zeiss MEL 80 excimer laser (193nm wavelength, 0.7mm spot size). Optical zone ranged from 6-6.5mm with treatment zone >2.2mm larger than optical zone.

Postoperative Management :

Patients received moxifloxacin 0.5% QID, moxifloxacindexamethasone combination QID (tapered weekly) and carboxymethylcellulose 0.5% every 2 hours for 3 months. Follow-up examinations were conducted on days 1, 1 week, 1 month, 3 months and 6 months.

Statistical Analysis :

Data was analyzed using SPSS version 25.0. Continuous variables were expressed as Mean±Standard Deviation and categorical variables as frequencies and percentages. Chi-square test was used for comparing categorical variables and unpaired t-test for continuous variables. P-value <0.05 was considered statistically significant.

Results

The study flow shows excellent retention with all 110 enrolled patients completing the 180 day follow-up period (Fig 1).

The study population comprised predominantly young adults with mean age 24.5±3.9 years, slight female predominance (54.5%) and majority having high myopia (76.4%) (Table 1).

Peripheral Retinal Degenerations were identified in 19 patients (17.3%), with lattice degeneration being the most common finding (11 patients). PRD occurred across all myopia severity groups (Table 2).

A highly statistically significant association was found between myopia severity and presence of Peripheral Retinal degenerations (p<0.001), with Moderate myopia

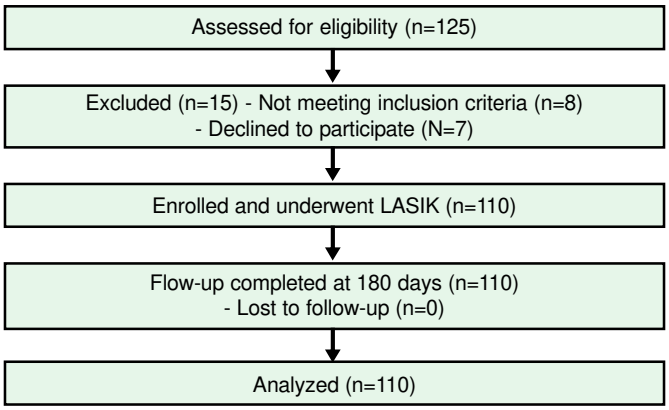

Fig 1 — Consort Flow Diagram

Table 1 — *Demographic characteristics and myopia distribution*

Parameter		Value	n (%)
Age (years)		24.5 ± 3.9	-
Sex	Male	-	47 (42.7)
	Female	-	60 (54.5)
Myopia Severity	Low (<-3.0D)	-	1 (0.9)
	Moderate (-3.0 to -6.0D)	-	25 (22.7)
	High (>-6.0D)	-	84 (76.4)

Table 2 — *Peripheral retinal findings distribution*

Finding Type	Number of Patients	Myopia Distribution
Lattice degeneration	11	Low: 1, Moderate: 7, High: 3
Pigmentary alterations	3	Moderate: 2, High: 1
White Without Pressure (WWOP)	4	Moderate: 3, High: 1
Peripheral retinal breaks	1	High: 1
Snail track degeneration	0	
Retinoschisis	0	
Total	19 (17.3%)	All severities

patients showing the highest prevalence at 48.0% (Table 3).

All patients achieved excellent visual outcomes with 6/6 vision postoperatively. No progression of existing Peripheral Retinal Degenerations or development of new lesions was observed during the 180-day follow-up period (Table 4).

All patients with Peripheral Retinal Degenerations were young adults (age range 22-26 years) distributed across all myopia severity groups, with Moderate myopia showing the highest frequency (Table 5).

Discussion

The present study found a 17.3% prevalence of Peripheral Retinal Degenerations in LASIK candidates, with a surprising finding that Moderate myopia patients showed the highest prevalence at 48.0%, compared to 7.1% in High myopia and 100% in the single Low myopia patient. This finding challenges conventional understanding and emphasizes the importance of thorough preoperative peripheral fundus evaluation across all myopia severities.

Our overall prevalence rate of 17.3% is higher than previously reported rates of 10-15% in general myopic populations[9,10]. This difference may be attributed to our comprehensive examination protocol and inclusion of various PRD types including white without pressure and pigmentary alterations, which are often overlooked in routine examinations. The unexpected pattern of moderate myopia showing higher PRD prevalence than

Table 3 — *Association between myopia severity and peripheral retinal degenerations*

Myopia Severity	Total Patients	Patients with PRD	Prevalence (%)	p-value
Low	1	1	100.0	
Moderate	25	12	48.0	<0.001[S]
High	84	6	7.1	
Total	110	19	17.3	

Table 4 — *Visual outcomes and PRD status at follow-up*

Time Point	Visual Acuity 6/6 n(%)	PRD Progression	New PRD
Day 7	110 (100%)	None	None
Day 30	110 (100%)	None	None
Day 90	110 (100%)	None	None
Day 180	110 (100%)	None	None

Table 5 — *Clinical characteristics of patients with peripheral retinal degenerations*

Age/Sex	Myopia	PRD Type	Location
22/F	Low	Lattice degeneration	Superotemporal
25/M	Moderate	Lattice degeneration	Superiorly at 12-o clock
23/F	Moderate	Lattice degeneration	Superotemporal
26/M	Moderate	Lattice degeneration	Superonasal
24/F	Moderate	Lattice degeneration	Inferiorly at 7-o clock
25/M	Moderate	Lattice degeneration	Inferonasal
23/F	Moderate	Lattice degeneration	Superotemporal
22/M	Moderate	Lattice degeneration	Superiorly at 11-o clock
24/F	High	Lattice degeneration	Inferotemporal
25/M	High	Lattice degeneration	Inferiorly at 5-o clock
23/F	High	Lattice degeneration	Superotemporal
26/M	Moderate	Pigmentary alterations	Inferiorly at 7-o clock
24/F	Moderate	Pigmentary alterations	Superiorly at 1-o clock
25/M	High	Pigmentary alterations	Inferotemporal
23/F	Moderate	WWOP	From 6-11-o clock
22/M	Moderate	WWOP	From 5-12-o clock
24/F	Moderate	WWOP	From 12-3 o clock
25/M	High	WWOP	From 6-8 o clock
26/F	High	Peripheral retinal breaks	Inferiorly at 7-o clock

High myopia warrants further investigation and may represent a unique characteristic of refractive surgery candidates.

The predominance of lattice degeneration (11/19 patients, 57.9%) aligns with established literature identifying it as the most common Peripheral Retinal Degeneration[11]. However, the distribution pattern across myopia severities, with 7 of 11 lattice degeneration cases occurring in Moderate myopia, represents a novel finding that may have important clinical implications for pre-LASIK screening protocols.

Mirshahi, *et al* reported a 9.5% incidence of partial posterior vitreous detachment following LASIK in myopic patients[12]. While we did not specifically evaluate PVD, the absence of new retinal lesions or progression during follow-up suggests that LASIK-induced mechanical stress did not adversely affect pre-existing peripheral retinal pathology in our cohort, regardless of myopia severity. This corroborates findings by Arevalo, *et al*, who reported a 0.06% incidence of vitreoretinal complications after LASIK[13].

The inclusion of White Without Pressure (WWP) as a significant finding in 4 patients adds to our understanding of peripheral retinal changes in LASIK candidates. WWP, while generally considered benign, may represent early vitreoretinal interface changes that warrant monitoring in the post-LASIK period[14]. The single case of peripheral retinal breaks in our high myopia group emphasizes the continued importance of thorough screening in this population.

All patients achieved excellent visual outcomes (6/6 vision) without PRD-related complications during the 180-day follow-up. This suggests that LASIK can be safely performed in patients with stable Peripheral Retinal

Degenerations when appropriately evaluated and managed preoperatively, regardless of myopia severity. However, the high prevalence in Moderate myopia patients suggests that screening protocols should be equally rigorous across all myopia groups[15].

The mechanical stress during LASIK, including IOP elevation during suction ring application and rapid decompression, theoretically poses risk to the vitreoretinal interface[16]. Our findings suggest these forces do not significantly impact stable peripheral retinal lesions in the immediate postoperative period. However, continued vigilance and regular fundus examinations remain important, particularly given the unexpectedly high PRD prevalence in moderate myopia patients.

Limitations :

The study limitations include a relatively short follow-up period (180 days), which may not capture late-onset complications. The small sample size in the low myopia group (n=1) limits statistical interpretation. Additionally, we did not perform optical coherence tomography or ultrawide-field imaging, which might have identified additional peripheral pathology.

Conclusion

The prevalence of Peripheral Retinal Degenerations in LASIK candidates was 17.3%, with Moderate myopia patients unexpectedly showing the highest prevalence at 48.0%. A thorough examination of the peripheral retina before LASIK is important for all levels of myopia so that any Peripheral Retinal Degenerations can be found and managed appropriately. This may help ensure a safe procedure. When stable peripheral lesions are present and appropriately managed, LASIK can be safely performed with excellent visual outcomes across all myopia groups. Long-term follow-up remains important, and clinicians should maintain heightened vigilance for peripheral retinal pathology in all myopia severities when considering LASIK surgery.

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Conflict of Interest : None.

References

1 Sugar A, Rapuano CJ, Culbertson WW, Huang D, Varley GA, Agapitos PJ, *et al* — Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy. *Ophthalmology* 2020; **109(1):** 175-87.
2 Shortt AJ, Allan BD, Evans JR — Laser-assisted in-situ keratomileusis (LASIK) versus photorefractive keratectomy (PRK) for myopia. *Cochrane Database Syst Rev* 2021; **(1):** CD005135.
3 Ruiz-Moreno JM, Alió JL, Pérez-Santonja JJ, de la Hoz F — Retinal detachment in myopic eyes after laser in situ keratomileusis. *J Cataract Refract Surg* 2019; **25(12):** 1776-86.
4 Wilkinson CP — Evidence-based analysis of prophylactic treatment of asymptomatic retinal breaks and lattice degeneration. *Ophthalmology* 2020; **107(1):** 12-5.
5 Byer NE — Long-term natural history of lattice degeneration of the retina. *Ophthalmology* 2019; **96(9):** 1396-401.
6 Flaxel CJ, Choi YH, Sheety M, Oeinck SC, Lee JY, McDonnell JM — Proposed mechanism for retinal tears after LASIK. *Arch Ophthalmol* 2020; **122(11):** 1232-3.
7 Arevalo JF, Ramirez E, Suarez E, Morales-Stopello J, Cortez R, Antzoulatos G, *et al* — Incidence of vitreoretinal pathologic conditions within 24 months after laser in situ keratomileusis. *Ophthalmology* 2020; **107(2):** 258-62.
8 Stulting RD, Carr JD, Thompson KP, Waring GO, Wiley WM, Walker JG — Complications of laser in situ keratomileusis for the correction of myopia. *Ophthalmology* 2019; **106(1):** 1320.
9 Lewis H — Peripheral retinal degenerations and the risk of retinal detachment. *Am J Ophthalmol* 2023; **136(1):** 155-60.
10 Celorio JM, Pruett RC — Prevalence of lattice degeneration and its relation to axial length in severe myopia. *Am J Ophthalmol* 2021; **111(1):** 20-3.
11 Saw SM, Gazzard G, Shih-Yen EC, Chua WH — Myopia and associated pathological complications. *Ophthalmic Physiol Opt* 2022; **25(5):** 381-91.
12 Mirshahi A, Schopfer D, Gerhardt D, Terzi E, Kasper T, Kohnen T — Incidence of posterior vitreous detachment after laser in situ keratomileusis. *Graefes Arch Clin Exp Ophthalmol* 2019; **244(2):** 149-53.
13 Arevalo JF, Lasave AF, Torres F, Suarez E — Rhegmatogenous retinal detachment after LASIK for myopia: frequency, characteristics, and mechanism. *Retina* 2021; **21(3):** 109-13.
14 Byer NE — Clinical study of retinal breaks. *Trans Am Acad Ophthalmol Otolaryngol* 2019; **71:** 461-73.
15 Nassaralla JJ, dos Santos RC, Nassaralla BA — Retinal peripheral changes after LASIK. *J Refract Surg* 2020; **36(4):** 246-52.
16 Krueger RR, Seiler T, Gruchman T, Mrochen M, Berlin MS — Stress wave amplitudes during laser surgery of the cornea. *Ophthalmology* 2019; **108(6):** 1070-74.

Original Article

The Role of High Sensitivity C-reactive Protein and Lipoprotein (a) in Chronic Obstructive Pulmonary Disease Cases as Severity and Early Atherogenic Markers

Thivyah Prabha AG[1], Synthia A[2], Rasheed Khan M[3], Gokul Kumar[4]

Abstract

Background : Chronic Obstructive Pulmonary Disease (COPD) is considered as a risk factor for atherosclerosis and a leading cause of mortality due to cardiovascular disease. The progression of atherogenic events in chronic obstructive disease patients is not due to the smoking and other cardio vascular risk factors. Lipoprotein (a) measures the hypercoagulable status.

Aims and Objectives : To evaluate the levels of High Sensitivity C-reactive Protein (hs-CRP) and Lipoprotein (a) in chronic Obstructive Pulmonary Disease patients and to find the role of them in the atherogenesis of COPD patients.

Materials and Methods : This Case control study was conducted in the Chennai Medical College hospital and research centre during January, 2014 - December, 2014. Eighty cases of COPD diagnosed by spirometry were included in the study and classified by GOLD staging. After informed consent, blood samples were collected and analysed for hsCRP and Lipoprotein (a) levels.

Results : There was a statistically significant elevation of hsCRP among cases and a positive correlation was observed among the severity of disease, obese individuals and smokers. In COPD patients Lipoprotein [a] levels were increased.

Conclusion : In COPD patients , hsCRP may be used as a marker for the disease severity and prognosis. Lipoprotein [a] may be used as an auxiliary marker for the prediction of risk of atherosclerosis among COPD patients for early intervention.

Key words : Lipoprotein (a), Chronic Obstructive Pulmonary Disease, High Sensitive C-reactive Protein, Atherogenetic Markers.

Chronic Obstructive Pulmonary Disease (COPD) is a Chronic Respiratory Disease characterized by progressive airflow limitation which is poorly reversible and often associated with systemic manifestations. Although COPD is a complex, heterogenous condition, it can be prevented as well as treated if identified earlier. Accounting for more than 3 million deaths worldwide in 2019, it is one of the leading causes of mortality as well as morbidity especially in low- and middle-income countries in patients under 70 years of age[1,2]. COPD patients have a significant systemic inflammation which can be identified by the elevated levels of a potential biomarker called high sensitivity C-reactive Protein (hs-CRP). With the recent advances in the methods used for measuring the elevated biomarkers in COPD patients we will be able to identify even low levels of hs-CRP. Systemic inflammation occurring in COPD patients leads to a hypercoagulable state with increased risk of atherogenesis even after the exclusion of smoking and other cardiovascular risk factors from the affected patients. This hypercoagulable state and atherogenesis in COPD patients can be identified using the marker Lipoprotein(a).

Editor's Comment :

- High-sensitivity C-reactive protein (hs-CRP) reflects systemic inflammation in Chronic Obstructive Pulmonary Disease (COPD) and correlates with disease severity, frequent exacerbations and declining lung function.
- Elevated Lipoprotein(a) [Lp(a)] acts as an independent early atherogenic marker, contributing to increased cardiovascular risk in COPD patients.
- Together, hs-CRP and Lp(a) serve as valuable biomarkers to identify high-risk COPD individuals who may benefit from early cardiovascular risk assessment and targeted preventive strategies.

Aims and Objectives

- To estimate the levels of bio markers [hs-CRP and Lipoprotein(a)] in COPD patients.
- To assess the correlation of hs-CRP with the severity of the disease and Lipoprotein(a) with the risk of atherosclerotic disease in COPD patients.
- To find out the association between the biomarkers and Socio-demographic variables

such as Age, Sex, BMI and smoking habits in COPD patients.

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Materials and Methods

This was a case-control study conducted by the Department of Biochemistry, Chennai Medical College Hospital and Research Centre for a duration of one year from January, 2014 to December, 2014. The study included 80 COPD patients and out of those 80 patients, 50 were Cases and remaining 30 are Controls. We used GOLD criteria to diagnose the COPD patients by Spirometry. Those patients having other co-morbidities like acute infections, bronchial asthma, inflammatory diseases, connective tissue disorders, disorders of thyroid, malignancy, renal failure (acute and chronic), stroke and diabetic ketoacidosis were not included in the study. After obtaining the necessary approval from the Institutional Ethical Committee, all the study participants were explained the purpose of the study, procedures involved and assured regarding the confidentiality of their results. Written informed consent was obtained from all the patients included in the study. About 5ml of venous blood was collected from each patient and centrifuged at 3500 rpm for a duration of 10 minutes at -20ºC, serum samples were stored and used for analysis. Immuno-turbidimetry was used for analysing the serum samples for both high sensitivity C-reactive protein and Lipoprotein(a). Serum total cholesterol estimation was carried out using Enzymatic cholesterolesterase method, Colorimetric Enzymatic method GPO was used for serum triglycerides and Phosphotungtistic acid method was used for estimation of serum High density Lipoprotein. Statistical analysis of data was done by calculating mean, Standard Deviation, p-value by applying student 't' test, ANOVA and Bonferroni.

Observation and Results

The mean age of the patients was around 60 years and in the Control group it was around 45 years and this difference was found to be statistically significant ($p<0.05$). Males and females were equally distributed between the Case and Control groups. Among the Cases, patients were equally distributed in all four stages of the Spirometry. About 54% of the cases have of BMI within the normal range and the remaining 44% were either Overweight or Obese. We used ANOVA test to identify the difference in the mean BMI levels of four groups according to the Spirometry staging. Among the cases, 80% of them had COPD for more than 10 years and 16% have COPD for more than 20 years. The duration of addiction was more than ten years among the smokers in Cases group. The mean pack years was used as a measure for estimation of the magnitude of smoking. The mean smoking pack years was significantly increased in stage 4 and vice versa and was correlating with the disease severity. The mean hsCRP levels in Cases was 12.66 mg/L and in Controls was 3.5 mg/L and it was statistically significant. ANOVA test was used to study the statistical significance in the mean hsCRP between the four groups. There was a statistically significant ($p<0.005$) difference in mean hsCRP levels in different stages of COPD as per the Bonferroni test. The mean hsCRP levels change with the severity of the disease. The mean Lipoprotein (a) levels were 211mg/dl in Cases group and 143 mg/dl in Control group. There was statistical significance among the Lipoprotein (a) value of cases and controls. There was no statistical significance in the Lipoprotein (a) value of different stages, as the data was analysed by ANOVA test. Lipid parameters were high in Cases as compared to the Controls and the difference in the mean levels of Lipid parameters were significant except Low Density Lipoprotein (LDL) and Total cholesterol levels. The increase in hs CRP levels in serum were correlating with the BMI levels and the increase was in the same direction. The correlation between High Density Lipoprotein (HDL) and Body Mass Index (BMI) was in opposite direction and negative correlation was seen. Statistically no significance was observed between the disease duration, hs-CRP, Lp(a) and lipid profile. The Odd ratio was statistically significant and the risk of COPD increased by 14% as the age increases by one unit and the correction of other variables have been done in the model. For each unit increase of hs-CRP in the serum, the COPD risk will increase by 25% after adjusting the other variables. For each unit increase of Lp (a) in the serum, the COPD risk will increase by 7% after adjusting the other variables. Odds ratio was not statistically significant for the females in the Cases group as compared to the Control group even though the females were having high risk. In 62.5% of variability was explained by the Nagelkerke's pseudo-R square in the possibility of occurrence of COPD. Statistically significant correlation in positive direction was present between the serum Lipoprotein (a) levels and Total cholesterol levels in serum (Tables 1-3).

Discussion

Chronic Obstructive Pulmonary Disease is the leading cause of morbidity and mortality among the major public health problems. To understand and control the disease progression, biomarkers implicating severity and atherogenesis are needed. The biomarker of low grade systemic inflammation is hs-CRP[3]. The levels of hs-CRP

Table 1 — *Distribution of the cases according to Spirometry staging and smoking as continuous variable (in pack-years) (n=50)*

Spirometry staging	N	Mean smoking pack-years	STD Deviation	95% Confidence Interval for Mean	
				Lower Bound	Upper Bound
Stage I	13	11.81	9.2478	6.219	17.396
Stage II	14	12.11	12.6691	4.792	19.422
Stage III	13	15.42	15.1215	6.285	24.561
Stage IV	10	29.95	11.2779	21.882	38.018
Total	50	16.46	13.8372	12.528	20.392

Table 2 — *Correlation matrix between BMI, serum markers and Lipid parameters among cases (n=50)*

	BMI	hs-CRPmg/L	Lp(a)mg/L	Total Cholesterol mg/dl	Triglycerides mg/dl	HDL-Cmg/dl	LDL-Cmg/dl	VLDL-Cmg/dl
BMI	1	0.640**	-0.40	-0.191	-0.224	-0.311*	-0.068	-0.224

Table 3 — *Correlation matrix between disease duration, serum markers and Lipid parameters among cases (n=50)*

	Disease duration	hs-CRPmg/L	Lp(a)mg/L	Total Cholesterol mg/dl	Triglycerides mg/dl	HDL-Cmg/dl	LDL-Cmg/dl	VLDL-Cmg/dl
Disease duration	1	0.099	0.098	0.073	0.013	0.0111	0.047	0.013

among the cases were (12.66 ± 3.92) and its significantly higher than the control group (3.5 ± 1.57) and the p=0.001. Similar observations were found in a study by Lisatileman, Lena Ginder, *et al*[4] and Sanjamarevic, *et al*[5]. The correlation between the levels of hs CRP and disease severity and stages of the disease (as gold criteria) was shown by Tahia H Saleem, *et al*[3] and SA Alavi, *et al*[6] In our study the levels of hs CRP were significantly elevated among the smokers and it was even correlating with the packyears and the same was observed in a study by SA Alavi, *et al*[6] Yannick MTA, *et al*[7] and Rehuaarwal, *et al*[8]. Studies by SA Alavi, *et al*[6], Breyer MK, *et al*[9] and PO Bridevaux, *et al*[10] have shown there is significant correlation between the increase of hs-CRP levels and BMI levels and the same was observed in our study also. But no correlation was observed between the hs-CRP levels and disease duration, in a study done by Daianatolz, *et al*[11] among 100 patients for a period of >1 year. Significant negative correlation was observed between HDL and hs-CRP in this present study. In developed countries Cardiovascular diseases are the potent killers among the COPD patients. The cardiovascular risk is high in COPD cases as there is basic underlying chronic inflammation of lung with systemic features also. Moreover Cardiovascular diseases are causing more deaths among the COPD patients[12]. Lipoprotein (a) is the important and sensitive risk factor for Coronary Artery Diseases in COPD patients[10]. The mortality and morbidity is increased due to the changes in the Lipoprotein metabolism and hence the increased Cardiovascular risk[13]. Thus the Lipid parameter abnormalities are highly important. The 20 year follow-up study of ARIC cohort among the African Americans and Caucasians have found that Lp (a) are associated with similar degree of cardiovascular risk[14]. The role of Lipoprotein (a) as an independent risk factor for Coronary Heart Disease has been shown in the meta-analysis by the Emerging Risk factors collaboration evaluation with 126,634 subjects of 36 prospective studies. In contrast to previous studies that suggested Lp(a) was only relevant as a risk factor when levels were extremely elevated, the meta-analysis demonstrated that risk and that Lp(a) levels are continuously associated with CHD risk[15].

Conclusion

hs-CRP is a biomarker for indicating the progression and severity of disease in COPD patients and for initiating the preventive and therapeutic strategies for the patients. Lipoprotein (a) is an auxillary marker to predict the risk of atherosclerosis in COPD patients.

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Conflict of Interest : None.

References

1 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. [Updated 2016]. Available from: https://goldcoped.org/.
2 WHO Fact sheet: the top 10 causes of death dated 24 May 2018. Available from: https://www.who.int/news-room/fact-sheets/detail/thetop-10-causes-of-death. Accessed May 14, 2019.
3 Saleem TH, Manal AM, Mandour — High Sensitivity C- Reactive Protein as a biomarker for Chronic Obstructive Pulmonary Disease. *AAMJ* 2011; **9:** 36-46.
4 LisaT, LenaGindner, Franz M — Differences in Local And Systemic Inflammatory Markers in patients with Obstructive Airway Disease. *Prim Care Respir J* 2011; **20(4):** 407-13.
5 Marevic S, Vrkic N, Sanja P, Ivana C — TNF Alpha, CXCL8 And Hs CRP In COPD Patients. *Croatica Chemical ACTA CCACAA* 2008; **81(1):** 211-7.
6 Alavi SA, Soati F, Amani H, Forghanparast K — Hs CRP in patients with Acute Exacerbation Of COPD. *Iranian Red Crescent Medical Journal* 2011; **13(10):** 713-18.
7 Yannick M, VanDurme T, Guy G, Bruslee, Bruno HC, Stricker — CRP Levels Haplotypes And The Risk Of Incident COPD. *Am J Respir Crit Care Med* 2009; 375-82.
8 Agarwal R, ShoaibZaheer M — The Relationship between C-Reactive Protein and prognostic factors in Chronic Obstructive Pulmonary Disease. *Multidisciplinary Respiratory Medicine* 2013; **(8):** 63.1-5.
9 Breyer MK, Spruit MA, Celis AP — Highly Elevated CRP Levels In Obese Patients With COPD. *Clin Nutr* 2009; **28:** 642-7.
10 Bridevaux PO, Wgerbase M, Cschindler — Sex specific effect of body Weight Gain On Systemic Inflammation in subjects with COPD: Results from the SAPALDIA Cohort Study 2. *European Respiratory Journal* 2009; **34:** 332-9.
11 Stolz D, Christ M, Crain, Joachim SBM, Michael T — Copeptin, CRP, Procalcitonin as Prognostic Biomarkers in Acute Exacerbation Of COPD. *Chest* 2007; **131:** 1058-67.
12 Maclay JD, MacNee W — Cardiovascular Disease in COPD. *CHEST* 2013; **143(3):** 798-807.
13 Begum K, Begum MK, Sarker ZH, Dewan MRK — Lipid Profile Status of Chronic Obstructive Pulmonary Disease in Hospitalized Patients. *Bangladesh J Med Biochem* 2010; **3(2):** 42-5.
14 Virani SS, Brautbar A, Davis BC, Nambi V, Hoogeveen RC, Sharrett AR, *et al* — Associations between lipoprotein(a) levels and cardiovascular outcomes in black and white subjects: the Atherosclerosis Risk in Communities (ARIC) Study. *Circulation* 2012; **125:** 241-9.
15 Erqou S, Kaptoge S, Perry PL, Di Angelantonio E, Thompson A, White IR, *et al* — Lipoprotein(a) concentration and the risk of coronary heart disease, stroke, and nonvascular mortality. *JAMA* 2009; 302: 412-23.

Original Article

HPV Vaccine Hesitancy among Medical Students in Goa : A Cross-sectional Study

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Abstract

Background : Human Papillomavirus (HPV) causes cervical, oropharyngeal and anogenital cancers, with types 16 and 18 being the most oncogenic. Cervical cancer is the second most common cancer among Indian women aged 15-44 years. Despite effective vaccines, HPV vaccine hesitancy remains prevalent. This study examines hesitancy among medical students in Goa using the WHO three Cs model (Confidence, Complacency and Convenience).

Materials and Methods : A cross-sectional study conducted at Goa Medical College from February, 2024 to November, 2024 surveyed 400 MBBS students using a self-administered questionnaire. Participants were selected via convenience sampling, and statistical analyses included percentages and significance tests.

Results : Only 22.5% (90 students) had received the vaccine, while 77.5% expressed hesitancy. Convenience was the leading factor (57.1%), primarily due to lack of awareness about vaccine availability, cost, and access. Complacency (18.8%) reflected perceived low risk, while confidence issues (11.8%) included safety and efficacy concerns. Despite 70.25% of students being aware of the vaccine, most had not taken it. Hospitals and schools were the primary sources of vaccine information (73.2%). Hypothetically, 75% would take the vaccine if included in the national immunization schedule and 69% if offered at college.

Conclusion : This study highlights that vaccine hesitancy is primarily driven by Convenience, followed by Complacency and Confidence.

Key words : Vaccine Hesitancy, Medical Students, WHO three Cs Model, HPV Vaccine, Cervical Cancer.

Human Papillomavirus (HPV), with over 200 types, causes cervical, oropharyngeal and anogenital cancers[1,2]. Cervical cancer, primarily due to types 16 and 18, ranks as the 4th most common cancer in women globally[2,3] and the 2nd most frequent among Indian women aged 15-44[4]. Despite bivalent, quadrivalent, and nine-valent vaccines, HPV vaccine hesitancy - defined as delayed acceptance or refusal despite availability[5] persists. This study evaluates vaccine hesitancy among Goa's medical students using the WHO 3Cs model[6,7], acknowledging their critical role as future healthcare advocates and influencers. The safety of HPV vaccines is strongly supported by the World Health Organization, the Centres for Disease Control and Prevention, the National Advisory Committee on Immunization, and other international health bodies[2,8].

Materials and Methods

Sample size : As per review of literature, considering the prevalence of the study "HPV Vaccine Hesitancy among medical students in China: a multicentre survey." [6] The sample size was calculated as follows :

$N = z^2pq/L^2$

Where,

N = sample size
z = confidence level
p = proportion of variable of interest (%)
q = complement of p, [1-p] (%)
L = allowable error on either side of the estimated 'p'[2]
and a Sample size of 400 was obtained.

Study Design : A cross-sectional study was planned to attain the objectives.

Study Period : February, 2024 to November, 2024.

Study Duration : Nine months.

Study Population : Medical Students.

Inclusion Criteria :

Consenting MBBS students enrolled in Goa Medical College who are under 26 years of age.

Exclusion Criteria :

Study participants who did not have a WhatsApp number.

Editor's Comment :

- Convenience barriers such as cost, access and unawareness are the primary causes of HPV vaccine hesitancy among medical students.
- Addressing these barriers through inclusion in immunization schedules, improved accessibility and targeted education can enhance vaccine uptake.
- Empowering medical students as public health advocates is crucial for bridging the gap between awareness and action.

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Students who did not respond after three reminders.

Data Collection : Upon the approval of the Institutional Ethics Committee a formal online survey was conducted amongst the students of Goa Medical College (GMC) (the only Medical college in the state of Goa). The survey was based on three C model approved by WHO for vaccine hesitancy.

Study Tool : Upon literature review, a self-administered questionnaire was designed based on the WHO three Cs model (Confidence, Complacency, and Convenience) to identify barriers to HPV vaccination. This model not only categorizes reasons for vaccine hesitancy but also provides a framework that can be integrated into medical education to teach students about vaccine-related behavioural dynamics and public health strategies.

The WHO approved three Cs model offers a structured approach to understanding hesitancy, which is critical for medical students as future healthcare providers and public health advocates. Questions were tailored to the target population for relevance. The participants were provided information on the purpose and details of the study and they could proceed to the questionnaire upon consenting.

Convenience sampling method was used and the link was disseminated in coordination with the class representatives and kept active until required number of responses were received. The questions were framed in an easy-to-understand manner for quick completion time however all the questions in the form were made mandatory to obtain complete information.

The questionnaire included four sections namely Informed consent & Participant Information Sheet, Demographic details, Participant's knowledge and Reasons for hesitancy which included the 11 options and provided space to mention any other reason for hesitancy. These included reasons based on

Confidence:

(1) Heard or read negative news/ Have Less knowledge on its safety.

(2) Had a bad experience with previous vaccinations due to health clinics/vaccinators.

(3) Health Care Workers' unreliable attitudes towards the HPV vaccine.

(4) Parents are not comfortable about the vaccine.

(5) Religious Reasons.

Complacency :

Vaccination was not considered as important.

Convenience :

(1) Don't know where to get vaccinated

(2) Don't know when to get vaccinated.

(3) The vaccination site is far away and requires a long journey.

(4) Don't know where to get reliable information from.

Statistical Analysis : The responses obtained were compiled in Excel format and percentages were calculated. Wherever relevant, tests of significance were applied.

Results

Batches consisted of 180 medical students each. We received 5(27.7%), 99(55%), 66(36.6%), 107(59.4%) and 123(68.3%) responses from Batch 2020, 2021, 2022, 2023 and 2024 respectively.

Of the total number of 400 study participants, 234 (58.5%) were females and the 166 (41.5%) were males (Table 1).

Vaccine Hesitancy & related factors: Though 307 (76.6%) of the participants agreed that the vaccine should be received by everyone irrespective of the sex, the vaccine uptake in our study was noted to be 22.5% (90 out of 400).

Of the 310 (77.5%) who did not receive the vaccine, 129 (77.7%) were males and 181 (77.3%) females. Hesitancy rates were 75.7% (122) in Rural and 78.9% (188) in Urban areas. The rate of hesitancy among different religions was 79.2% (42 out of 53), 77.2% (254 out of 329), 78.5% (11 out of 14) among Christians, Hindus and Muslims respectively showing no significant relation between religion and hesitancy.

Upon batch wise analysis, the hesitancy was found to be 100%, 90.90% (90), 84.8% (56), 63.55% (68), 73.9% (91) for batch 2020, 2021, 2022, 2023 and 2024 respectively. There was a significant variation in hesitancy among different batches with maximum hesitancy in 2021 batch and minimum hesitancy in batch 2023. There was a

Table 1 – *Distribution of study participants as per Socio-demographic details. (original)*

Details		Number	Percentage (%)
Age :	16-20	292	73%
	21-25	108	27%
Sex :	Male	166	41.5%
	Female	234	58.5%
Batch Year :	2020	5	1.25%
	2021	99	24.75%
	2022	66	16.5%
	2023	107	26.75%
	2024	123	30.75%
Residence :	Urban	239	59.75%
	Rural	161	40.25%
Religion :	Hindu	329	82.25%
	Muslim	14	3.5%
	Christian	53	13.25%
	Others	4	1%

decline in rate of hesitancy from batch 2020 to 2023, showing a decrease in hesitancy in the newer batches. (Table 2).

Source of Information : 73.2% (270) people got the information about the vaccine from hospitals/schools making it the biggest source of information. Other sources were doctor consultation (21.1%), family or friends (19%), radio/TV (10.8%), newspaper/magazine (14.1%), internet (16.5%).

Vaccine Availability : If the vaccine was added in the national immunization schedule, 300 (75%) people agreed to take the vaccine, 85 (21.3 %) were not sure and 15 (3.7%) refused to take the vaccine. If the vaccine is made available in the college itself, 276 (69%) people agreed to take the vaccine, 106 (26.5 %) were not sure and 18 (4.5%) refused to take the vaccine.

Among those aware of the vaccine, only 88 (22%) received it, while 281 (70.25%) did not, reflecting high hesitancy (Table 3).

Using the three Cs model, (Confidence, Complacency, Convenience)

From a total of 287, Hesitancy due to Confidence was found in 34 (11.8%) of people, due to Convenience in 164 (57.14%) and due to complacency in 54 (18.8%). Additionally, 4 (1.39%) of people were hesitant due to all three causes, 11(3.8%) were hesitant due to both Confidence and Convenience, 18 (6.27%) due to both Convenience and Complacency, and 2 (0.06%) due to both Confidence and Complacency.

Table 2 — *Distribution of study participants as per HPV vaccine uptake & various parameters (original)*

Parameters	HPV Vaccine Uptake		
	Yes (%)	No (%)	
Sex :			
Female	22.7	77.3	*Chi Square = 0.0072; df=1;*
Male	22.3	77.7	*P=0.93 (Significance at <0.05; Not Significant)*
Residence :			
Urban	21.1	78.9	*Chi Square = 0.45; df=1;*
Rural	24.3	75.7	*P=0.49 (Significance at <0.05; Not Significant)*
Religion :			
Hindu	22.8	77.2	*Chi Square = 3.032; df=3;*
Christian	20.8	79.2	*P=0.387 (Significance at <0.05; Not Significant)*
Muslim	21.5	78.5	
Others	0	100	
Batch Year :			
2020	0	100	*Chi Square = 26.51; df=4;*
2021	9.1	90.9	*P=0.000025 (Significance at <0.05; Highly Significant)*
2022	15.2	84.8	
2023	36.45	63.55	
2024	26.1	73.9	*df = degree of freedom*

Table 3 — *Pattern of Vaccine uptake with regards to knowledge of the vaccine (original)*

Knowledge about the HPV vaccine	HPV Vaccine Uptake		
	Yes (%)	No. (%)	
Present	88 (22 %)	281(70.25%)	*Chi Square = 4.95 df=1, P=0.02 (Highly Significant) df = degree of freedom*
Absent	2(0.5%)	29 (7.25%)	

Discussion

Hesitancy and the three Cs : Vaccination hesitancy refers to the reluctance or refusal to be vaccinated despite the availability of the vaccines. There can be various factors associated with vaccine hesitancy such as lack of information, misinformation, fear about its side effects, doubts on its effectiveness, mistrust in healthcare staff, etc. Experts have divided these reasons majorly into 3 categories : Convenience, Complacency and Confidence. Through the use of the three Cs model, medical students can better understand how factors like misinformation (confidence), perceived risk (complacency) and accessibility (convenience) influence public health outcomes. This fosters critical thinking and equips them with the knowledge to counteract vaccine hesitancy in their future practice.

From the study we conducted, we found that the major reason for hesitancy among students is convenience, ie, they did not know where to get the vaccine, its availability was low, or high-cost was the reason. Other reasons for the hesitancy are confidence (12% of the students did not have confidence in the vaccine because they had learnt about side effects or in effectiveness of the vaccine). Complacency contributed as a reason for 18%. Some students think they are not at risk and hence are reluctant to take it. Hence, the youth need to be convinced about the benefits. Rest of the students had more than one factor for their hesitancy. Convenience being the major reason for hesitancy across the population makes it easy for healthcare providers to reach out and provide vaccination by making it easily available and cutting down the cost of the vaccine. Thus, including it as a vaccine in the vaccination schedule by the Government may be helpful in reaching out to the general public. For the remaining hesitant population (lacking confidence or complacency), targeted efforts are required. For them, healthcare providers need to be more sensitive towards the excellence of the vaccine. Extensive health education, social media outreach, and parental counselling are urgently needed.

To address vaccine confidence, workshops, lectures, and symposiums during college hours can effectively dispel myths and increase awareness. Convenience can be improved through Government initiatives, including making vaccines more accessible. Role-playing exercises and case studies in public health courses can help students handle vaccine hesitancy. Including the HPV vaccine in routine immunization schedules can broaden

coverage and increase uptake. Medical students must be educated on their key role in public health education and the benefits of vaccination to reduce complacency.

Knowledge and Attitude of Health Care Providers :

"Knowledge on the part of healthcare providers is also critical to vaccine uptake. Multiple studies have shown that the knowledge and attitudes of healthcare providers toward vaccination are reflected in parental attitudes toward vaccination"[9-11].

We found that people trust their Healthcare Professionals (HCPs) and the information they provide. This element is crucial when we consider that HCPs can promote vaccination by sharing accurate information and offering counselling to parents to facilitate decision-making. Nonetheless, previous studies have found that the percentage of HCPs who speak with parents about HPV vaccines for their children is very low[12,13].

Myths and Hesitancy :

When we asked students whether only sexually active individuals should receive the HPV vaccine or if everyone should, 14.5% believed that sexually inactive individuals are not at risk of contracting the virus and therefore do not need to be vaccinated. However, since the vaccine protects against multiple strains of the virus, it is important to encourage vaccination even for those who are not sexually active.

This misconception could be one of the reasons why many adolescents are not vaccinated at the recommended age. Parents may assume that their children are not sexually active and therefore do not need the vaccine. Such beliefs can persist across generations, emphasizing the importance of targeting parents of adolescents with accurate information about the vaccine's benefits.

Parents play an important role in perpetuating such myths among the young population. There are some studies where hesitancy among parents is shown in the above context. It is seen from some studies in the USA, Italy, etc. that parents' hesitancy towards the vaccine has a major role in the percentage of adolescents being vaccinated at the right time. Thus, it is important to target the parents and educate them about the benefits of the vaccine for their children.

The study found that most students cited schools, hospitals, and public lectures as their primary sources of information, highlighting the importance of health education in shaping their beliefs. Another study revealed that the media had the greatest influence on perspectives, followed by consultations with doctors. However, families and friends could negatively affect perceptions by sharing adverse personal experiences[14,15].

A study which focussed on vaccine related perspectives in adolescents highlighted the importance of providing complete information related to the vaccines and involving the adolescents, the major stakeholders, in the decision process[16].

A report on focus group discussions in Mysore, India (a city where 76% of the population is Hindu, 19% is Muslim, and 4% is Christian, Jain, Buddhist, or other religions) observed that many parents were accepting of the HPV vaccine, especially since it would prevent Cervical cancer. Although most of these parents felt strongly that young girls were unlikely to become sexually active before marriage, several did recognize that young people may engage in premarital sex, leading most to conclude that adolescent girls should be vaccinated between 15 and 18 years of age[9,17].

Several studies have reported that parents and caregivers may associate the vaccine with fears of compromising fertility[12,18] or giving children the permission to become sexually active[12,19].

Limitations :

This study has some limitations. Our study only targeted a specific subset of medical students, which limits the generalizability of our findings. Batch 2020 had limited participation due to exam schedules. Limited religious diversity in Goa restricts generalizability of inter-religious comparisons. Furthermore, our study did not include parents or younger students, whose perspectives would have been valuable in understanding the underlying reasons for hesitancy.

Conclusion

This study highlights that vaccine hesitancy is primarily driven by Convenience, followed by Complacency and Confidence. These barriers can be addressed by improving vaccine availability, affordability and accessibility. Making vaccines cheaper, including them in immunization schedules, and educating students on their effectiveness are key steps. Collaborative efforts from policy makers, healthcare providers, and educators will further increase vaccine uptake across diverse populations.

Confidentiality : All the entries were anonymous to maintain the privacy of the participants.

Conflict of Interest & Funding : None.

References

1 Burd EM. Human papillomavirus and cervical cancer. *Clinical Microbiology Reviews* 2003; **16(1):** 1-17. DOI: 10.1128/CMR.16.1.1-17.2003. PMID: 12525422; PMCID: PMC145302.

2 World Health Organization. Cervical cancer. World Health Organization. Available from: https://www.who.int/health-topics/cervical-cancer#tab=tab_1. Accessed December 24, 2024.

3 Pimple S, Mishra G — Cancer cervix: Epidemiology and disease burden. *Cytojournal* 2022; **19:** 21. DOI: 10.25259/CMAS_03_02_2021. PMID: 35510109; PMCID: PMC9063649.

4 Taneja N, Chawla B, Awasthi AA, Shrivastav KD, Jaggi VK, Janardhanan R — Knowledge, Attitude, and Practice on Cervical Cancer and Screening Among Women in India: A Review. *Cancer Control* 2021; **28:** 10732748211010799. DOI: 10.1177/10732748211010799. PMID: 33926235; PMCID: PMC8204637.

5 Azimi M, Yadgari MY, Atiq MA — Acceptance and Hesitancy Toward the Covid-19 Vaccine Among Medical Students in Kabul, Afghanistan. *Infection and Drug Resistance* 2023; **16:** 457-61. DOI: 10.2147/IDR.S389582. PMID: 36721628; PMCID: PMC9884452.

6 Zhou L, Wang J, Cheng P, Li Y, Liu G, Zhang X — HPV Vaccine Hesitancy Among Medical Students in China: A Multicenter Survey. *Front Public Health* 2022; **10:** 774767. DOI: 10.3389/fpubh.2022.774767. PMID: 35265570; PMCID: PMC8900914.

7 Hardin B, Graboyes M, Kosty D, Cioffi C — Vaccine decision making among people who inject drugs: Improving on the WHO's three C model of vaccine hesitancy. *Preventive Medicine Reports* 2023; **33:** 102341. Available from: https://doi.org/10.1016/j.pmedr.2023.102341

8 Smith LM, Harman K, Pielak K, Tang K, McNeil S, Rafferty E, *et al* — Safety of the human papillomavirus vaccine: a population-based cohort study of adolescent girls in Ontario, Canada. *Canadian Medical Association Journal Open* 2022; **10(2):** E370-7. DOI: 10.9778/cmajo.2022001

9 Patel PR, Berenson AB — Sources of HPV vaccine hesitancy in parents. *Human Vaccine Immunotherapy* 2013; **9(12):** 2649-53. DOI: 10.4161/hv.26224. Epub 2013 Aug 27. PMID: 23982270; PMCID: PMC4162068.

10 Connors CM, Miller NC, Krause VL — Universal hepatitis B vaccination: hospital factors influencing first-dose uptake for neonates in Darwin. *Australian and New Zealand Journal of Public Health* 1998; **22:** 143-5. DOI: 10.1111/j.1467- 842X.1998.tb01159.x. [DOI] [PubMed] [Google Scholar]

11 Freed GL, Freeman VA, Clark SJ, Konrad TR, Pathman DE — Pediatrician and family physician agreement with and adoption of universal hepatitis B immunization. *Journal of Family Practice* 1996; **42:** 587-92. [PubMed] [Google Scholar]

12 Cordoba-Sanchez V, Lemos M, Tamayo-Lopera DA, Sheinfeld Gorin S — HPV-Vaccine Hesitancy in Colombia: A Mixed-Methods Study. *Vaccines* 2022; **10(8):** 1187.DOI: 10.3390/vaccines10081187

13 Hendaus MA, Hassan M, Alsulaiti M, Mohamed T, Mohamed R, Yasrab D, *et al* — Parents attitudes toward the human papilloma virus (HPV) vaccine: A new concept in the State of Qatar. *Journal of Family Medicine and Primary Care* 2021; **10:** 2488. DOI: 10.4103/jfmpc.jfmpc_1122_20

14 Rosen BL, Shew ML, Zimet GD, Ding L, Mullins TLK, Kahn JA — Human Papillomavirus Vaccine Sources of Information and Adolescents' Knowledge and Perceptions. *Global Pediatric Health* 2017; **4:** 2333794X17743405. DOI: 10.1177/2333794X17743405.

15 Hamlish T, Clarke L, Alexander KA — Barriers to HPV immunizationfor African American adolescent females. *Vaccine* 2012; **30(45):** 6472-6. DOI: 10.1016/j.*vaccine*.2012.07.085. Epub 2012 Aug 18. PMID: 22910288.

16 Herman R, McNutt LA, Mehta M, Salmon DA, Bednarczyk RA, Shaw J — Vaccination perspectives among adolescents and their desired role in the decision-making process. *Human Vaccine Immunotherapy* 2019; **15(7-8):** 1752-9. DOI: 10.1080/21645515.2019.1571891.

17 Madhivanan P, Krupp K, Yashodha MN, Marlow L, Klausner JD, Reingold AL — Attitudes toward HPV vaccination among parents of adolescent girls in Mysore, India. *Vaccine* 2009; **27:** 5203-8. doi:10.1016/j.vaccine.2009.06.073.[DOI][PubMed] [Google Scholar

18 Friedman AL, Oruko KO, Habel MA, Ford J, Kinsey J, Odhiambo F, *et al* — Preparing for human papillomavirus vaccine introduction in Kenya: Implications from focus- group and interview discussions with caregivers and opinion leaders in Western Kenya. *BMC Public Health* 2014; **14:** 855. DOI: 10.1186/1471-2458-14-855. [Google Scholar] [CrossRef] [Green Version]

19 Morales-Campos DY, Snipes SA, Villarreal EK, Crocker LC, Guerrero A, Fernandez ME — Cervical cancer, Human papillomavirus (HPV) and HPV vaccination: Exploring gendered perspectives, knowledge, attitudes, and cultural taboos among Mexican American adults. *Ethnicity and Health* 2021; **26:** 206-24. DOI: 10.1080/13557858.2018.1494821. [Google Scholar] [CrossRef]

Original Article

A Cross Sectional Study about the Perception and Practice of Health Information Technology (HIT) Interventions amongst the Healthcare Professionals Working in Intensive Care Units (ICU) of Multispeciality Hospitals in Kolkata

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Abstract

Background : Patient safety in the Intensive Care Unit (ICU) is a critical aspect of healthcare where the integration of advanced technology has revolutionized patient care; particularly in ICUs. From Electronic Health Records (EHRs) and smart monitoring systems to predictive analytics and telemedicine platforms, each tool offers unique advantages in enhancing diagnostic accuracy, treatment efficacy, and overall patient outcomes.

Aims and Objectives : To assess the Knowledge (K), Attitude (A), Practice (P) of ICU professionals about usage of Healthcare Information Technology (HIT) tools to augment Patient safety.

Results : A cross sectional pilot study was conducted in 7 hospitals of Kolkata, India through a validated structured questionnaire among ICU professionals to assess their acceptance of HIT tools. from April, 2024 to June, 2024. A total of 727 responses were obtained where 78.5% use HIT in work, 74% agreed that using HIT reduces medication errors, 79.1% agreed that it is an important patient safety tool, 77.2% agreed it improves adherence, medication ordering and vaccination process, 79.9% agreed it improves handover process, 77.3% agreed it reduces charting time, 70.7% agreed it helps achieve higher compliance.

Conclusion : The study's results clearly demonstrate a high level of agreement among healthcare professionals regarding the positive impact of HIT on reducing medication errors, improving process adherence, and enhancing clinical outcomes in a developing country like India.

Key words : Patient Safety, Health Information Technology, Intensive Care Unit.

In the fast-evolving landscape of healthcare, the integration of advanced technology has revolutionized patient care; particularly in Intensive Care Units (ICUs).[1] These critical settings demand precision, efficiency, and constant vigilance to ensure patient safety amidst complex medical conditions. Healthcare technology tools tailored for ICUs play a pivotal role in this endeavor, yet the extent to which Healthcare Professionals perceive and utilize these tools varies widely. Patient safety in the Intensive Care Unit (ICU) is a critical aspect of healthcare, where the complexity of cases and the severity of illnesses require highly coordinated and effective medical care. In recent years, healthcare technology tools have emerged as crucial allies in improving patient outcomes and ensuring safety.[2]

Editor's Comment :

- Healthcare Information Technology interventions to be integrated in ICUs for more accurate, efficient and safe patient care.
- These tools help in clinical decision making and improved workforce efficacy.

Healthcare Technology Tools in the ICU[2] includes Electronic Health Records (EHRs) which are digital versions of patients' paper charts and provide comprehensive, real-time patient data. They facilitate better coordination among healthcare providers and improve the accuracy of diagnoses and treatments.

Tele-ICU involves remote monitoring of ICU patients through video conferencing and real-time data transmission. It enables specialists to provide expert guidance and support to on-site clinicians, especially in resource-limited settings. Along with this the Automated Medication Dispensing Systems, help in reducing medication errors by ensuring accurate dispensing and administration of drugs. They are integrated with EHRs to provide alerts for potential drug interactions and allergies.

Healthcare Technology also involves Wearable Monitoring Devices to monitor vital signs continuously and transmit data to healthcare providers. They help in early detection of clinical deterioration, allowing timely interventions.

From Electronic Health Records (EHRs) and smart monitoring systems to predictive analytics and

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telemedicine platforms, each tool offers unique advantages in enhancing diagnostic accuracy, treatment efficacy and overall patient outcomes. However, the gap between technological advancement and practical implementation can present hurdles, influencing how these tools are perceived and utilized in real-world clinical scenarios.

Understanding the perspectives of Healthcare Professionals - ranging from nurses, doctors and intensivists - regarding healthcare technology tools in the ICU is crucial. Their insights not only highlight the current state of adoption and awareness but also provide invaluable feedback on efficacy and potential areas for improvement. Studies conducted Globally indicate varying levels of awareness and acceptance of healthcare technology tools among Healthcare Professionals. Factors influencing these variations include education, training, availability of resources, and institutional support[3-5].

This study delves into the intricate relationship between ICU patient safety and the technology that supports it, exploring both the challenges and opportunities faced by frontline healthcare providers. By examining the knowledge base, attitudes, and training needs of Healthcare Professionals, we can uncover critical insights into optimizing the integration of healthcare technology in ICUs. Moreover, addressing these insights can pave the way for more streamlined workflows, improved decision-making processes, and ultimately, enhanced patient safety.

Limited research work is available on the perception of Healthcare Workers in Indian ICUs about the utility of healthcare technology tools for enhancing patient safety. Hence, this capstone project was conducted in seven ICUs of multispecialty Hospitals in the City of Kolkata.

Aims and Objectives

To assess the Knowledge, Attitude and Practice of using Healthcare technology interventions among the Healthcare Professionals working in ICUs of 7 Hospitals in Kolkata through a validated structured objective questionnaire based survey.

Materials and Methods

It is a cross sectional study on the perception and practice of Health Information Technology among Healthcare Professionals working in ICUs. The study was conducted in 7 hospitals of Kolkata from April, 2024 to June, 2024. The participating Hospitals were Peerless Hospital, Manipal Hospital, Dhakuria, Manipal Hospital, Mukundapur, Desun Hospital, Joint and Bone Care Hospital, Saltlake, Joint and Bone Care Hospital, Sodepur & Institute of Child Health, Kolkata. The sample size was calculated to be 727 with a confidence interval of 95%.

All Doctors, Nurses and Healthcare Professionals working in the Intensive Care Units of the hospitals mentioned above and those who were willing to give informed consent were included in the study.

An online questionnaire through Google form were sent to all Physicians, Nurses, Healthcare Technicians through whatsapp and their email ids.

The validation of the questionnaire was done before distribution among 10 doctors and 20 Nurses working in Peerless Hospital, Kolkata and Manipal Hospital, Dhakuria, Kolkata. Two reminders were given to all the participants to complete the online. Proper written informed consent was taken before sharing of the questionnaire.

The study was initiated after Ethics Committee Approval (PHH& RCLCREC/4312/2024)

The data from participants were collected and descriptive analysis was done by using SPSS 31 software.

Percentage distribution, frequency distribution and educational pursuance were looked into. Categorical data was analysed using Chi square test. A p-value less than 0.05 was considered as statistically significant.

Results

This study was carried out in 7 ICUs of Multispecialty Hospitals in Kolkata.

Out of them, most number of responses ie, 342 responses (47.3%) came from the age group of 20-29 years and least ie, 29 responses (3,7%) came from the age group of 60-69 years (Table 1). Among them 204 were Male (29.1%) and 523 were Female (71.9%).

Out of 727 responses, 571 persons (78.5%) have used HIT in their workplace whereas 156 persons (21.5%) have never used any form of HIT (Table 2). In 36.3% of responses (264) were from Doctors, 57.8% (420) from Nurses and the rest were from Technicians.

Majority (74%) of the people agreed to the fact that HIT reduces medication error in ICU whereas 13.7% disagreed on the same.

Almost 77% responded positively to the fact that HIT brings in improvement in the process adherence, medication ordering, vaccination lab ordering and clinical outcomes whereas 1.8% strongly disagreed.

Out of the 727 responses analysed, 343 (47.2%) strongly agreed that HIT improves handover process and there are fewer omissions of critical patient information. A minor section (2.3%) strongly disagreed and 40 (5.5%) disagreed regarding the same.

37.7% strongly agreed that EMR can help to plan the care pathway and follow the trend of the physical condition of the patient while 3.2% strongly disagreed on the same.

A sizable population (32.9%) strongly agreed and (32%) agreed that HIT helps in reduction in smart pump programming errors whereas 5% strongly disagreed on this question.

Majority (40.6%) strongly agreed and agreed (36.7%) on the fact that HIT helps in reduction of charting time and increases the time spent on direct patient care, reducing the occurrence of error.

Out of the 727 responses analyzed, 255 participants strongly agreed that HIT helps in reduction in the rate of retained surgical items while the rest disagreed on this fact.

35.8% strongly agreed that HIT helps in achieving higher compliance to preventive medical services. 3.2% strongly disagreed and 7.4% disagreed on this question.

41.3% of the participants were of the opinion that HIT is an important tool of patient safety but 4% disagreed regarding the same (Table 3).

Discussion

Our findings align with existing literature, particularly regarding the positive perceptions of Healthcare Information Technology (HIT) interventions in Intensive Care Units (ICUs) concerning patient safety. A significant portion of the participants (78.5%)reported using healthcare technology interventions in the ICU, indicating widespread adoption and integration of these technologies. This is consistent with studies by Zhou, *et al* in 2019[6] and Carayon, *et al* in 2015[7], which highlight the increasing adoption of HIT in critical care settings due to its potential to enhance patient safety and care outcomes.

The study's results also demonstrate a high level of agreement among Healthcare Professionals regarding the positive impact of HIT on reducing medication errors, improving process adherence and enhancing clinical outcomes. A similar study was done by Bates, *et al* in 1998[8], who also observed a significant reduction in medication errors with the implementation of electronic prescribing and medication administration systems. Even Black, *et al* in 2011[9] reported similar benefits in clinical settings.

The results also revealed that 72.2% of the respondents believe that Electronic Medical Records (EMR) help in planning care pathways and monitoring patient conditions. This finding is consistent with the study by Jamoom, *et al* in 2014[10], which demonstrated that EMRs contribute to better care coordination and patient monitoring, ultimately leading to improved clinical outcomes. Additionally, the reduction in charting time, which allows more time for direct patient care , supports the findings of Jones, *et al* in 2014[11], who identified similar efficiencies resulting from HIT implementation.

Franklin, *et al* in 2011[12] found that HIT significantly improved handover processes in clinical settings which is similar to our findings in this study depicting the usefulness of HIT tools.

The perception of HIT as a tool for enhancing transparency and communication between healthcare providers and patients' families is another point of convergence with previous studies. A research done by Banger, *et al* in 2015[13] emphasized that HIT, particularly EMRs, facilitates better communication and engagement with patients and their families, leading to improved satisfaction and care outcomes.

Despite the overall positive perception of HIT, there are areas where this study's findings diverge from previous research. While majority of participants agreed in our study that HIT reduces the rate of retained surgical items, other studies have reported mixed or inconclusive results. A study by Greenberg, *et al* in 2016[14] noted that while technology can aid in reducing such incidents, the effectiveness often depends on factors such as staff training and the integration of technology into existing workflows. The relatively lower agreement in this area compared to other aspects of HIT might reflect ongoing challenges in fully integrating these technologies to achieve the desired outcomes.

Another point of divergence is related to the reduction in smart pump programming errors. While a vast majority of respondents agreed to this fact, studies by Vanderveen, *et al* in 2018[15] and Ruppel, *et al* in 2018[16] have reported varied success with smart pumps, highlighting that while they can reduce errors, their effectiveness is often compromised by user-related issues and the complexity of the devices. This discrepancy suggests that while the potential of smart pumps is recognized, there may still be significant barriers to their optimal use.

Table 1 — *Distribution of responses according to age group (n=727)*

Age	Frequency	Percentage
20-29	342	47.3
30-39	187	25.9
40-49	85	11.6
50-59	84	11.5
60-69	29	3.7
Total	727	100.0

Table 2 — *Shows the result of healthcare technology intervention in ICU*

		Profession			Total	p Value	Significance
		Doctor	Nurse	Technicians			
Have you used any Healthcare technology intervention in ICU?	NO	26(9.85)	119(28.33)	11(25.58)	156(21.46)	<0.001	Significant
	YES	238(90.15)	301(71.67)	32(74.42)	571(78.54)		
Total		264(100)	420(100)	43(100)	727(100)		

Table 3 — *Perception of HIT as tools for patient safety*

		Profession			Total	p Value	Significance
		Doctor	Nurse	Technicians			
Please rate your overall perception of HIT as tools to patient safety	Strongly Disagree	7(2.65)	8(1.9)	0(0)	15(2.06)	0.021	Significant
	Disagree	12(4.55)	17(4.05)	0(0)	29(3.99)		
	Neutral	49(18.56)	52(12.38)	7(16.28)	108(14.86)		
	Agree	109(41.29)	146(34.76)	20(46.51)	275(37.83)		
	Strongly Agree	87(32.95)	197(46.9)	16(37.21)	300(41.27)		
Total		264(100)	420(100)	43(100)	727(100)		

Strengths of the our Project :

One of the main strengths of this study is the large and diverse sample size. This broad representation across different professions (Doctors, Nurses and Technicians) provides a comprehensive view of the perceptions and practices related to HIT in ICUs. The study's focus on a specific and critical setting, the ICU, adds to its relevance, as this is an area where patient safety is of utmost importance, and where HIT interventions can have a significant impact.

Another strength is the detailed analysis of different types of HIT interventions, such as smart pumps, EMRs, and telemedicine tools. By examining various technologies, the study offers a nuanced understanding of how different tools are perceived and their impact on patient safety.

Limitations of our Project :

Despite its strengths, this project has several limitations. One of the primary limitations is its reliance on self-reported data, which may be subject to response bias. Participants might overestimate the positive impact of HIT due to social desirability bias or might underreport negative experiences due to fear of repercussions. The cross-sectional nature of the study also limits the ability to draw causal inferences; the study captures perceptions at a single point in time, which may not fully reflect the dynamic and evolving nature of HIT implementation and its impact on patient safety.

Another limitation is the project's geographical focus on Kolkata, which may limit the generalizability of the findings to other regions or countries with different healthcare systems, technological infrastructures, or cultural attitudes towards technology. The specific context of multispecialty hospitals may also limit the applicability of the findings to other healthcare settings, such as primary care or single-specialty hospitals.

Furthermore, the study did not explore the specific barriers and facilitators to HIT adoption and effective use, which could have provided deeper insights into the reasons behind the varied perceptions and outcomes associated with different HIT tools. Additionally, the study did not assess the actual outcomes of HIT implementation, such as changes in patient safety metrics or clinical outcomes, relying instead on Healthcare Professionals' perceptions, which may not always align with objective measures of impact.

Conclusion

Overall, the study underscores the critical role of HIT in modern ICU settings, particularly in enhancing medication safety, communication, and care coordination. Continued investment in training, infrastructure and system integration is recommended to fully realize the potential benefits of HIT and ensure consistent, evidence-based improvements in patient outcomes across all areas of critical care.

Future research should explore the specific barriers and facilitators to HIT adoption and effective use, including factors such as staff training, technological infrastructure, and organizational culture, to identify strategies for optimizing HIT implementation.

Conflict of Interest : None

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References

1 Bourne RS, Jeffries M, Phipps DL, Jennings JK, Boxall E, Wilson F, *et al* — Understanding medication safety involving patient transfer from intensive care to hospital ward: a qualitative sociotechnical factor study. *BMJ Open* 2023; **13(5):** e066757. doi: 10.1136/bmjopen-2022-066757. PMID: 37130684; PMCID: PMC10163459.
2 Guinemer C, Boeker M, Fürstenau D, Poncette AS, Weiss B, Mörgeli R, *et al* — Telemedicine in Intensive Care Units: Scoping Review. *J Med Internet Res* 2021; **23(11):** e32264. doi: 10.2196/32264. PMID: 34730547; PMCID: PMC8600441.
3 Holden RJ, Karsh BT — The technology acceptance model: its past and its future in health care. *J Biomed Inform* 2010; **43(1):** 159-72. doi: 10.1016/j.jbi.2009.07.002. Epub 2009 Jul 15. PMID: 19615467; PMCID: PMC2814963.
4 Brasaite I, Kaunonen M, Martinkenas A — Health care professionals' attitudes regarding patient safety: cross-sectional survey. *BMC Res Notes* 2016; **9**: 177.
5 Li L, Cotton A — A Systematic Review of Nurses' Perspectives Toward the Telemedicine Intensive Care Unit: A Basis for Supporting Its Future Implementation in China? *Telemed J E Health* 2019; **25(5):** 343-50. doi: 10.1089/tmj.2018.0006. Epub 2018 Jul 23. PMID: 30036155.
6 Zhou L, Soran CS, Jenter CA, Volk LA, Orav EJ, Bates DW, *et al* — The impact of health information technology on the quality of medical and health care: a systematic review. *Health Informatics J* 2019; **25(1):** 186-97.
7 Carayon P, SchoofsHundt A, Karsh BT, Gurses AP, Alvarado CJ, Smith M, *et al* — Work system design for patient safety: the SEIPS model. QualSaf Health Care. 2006; 15 Suppl 1.
8 Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, *et al* — Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. JAMA 1998; **280(15):** 1311-6.
9 Black AD, Car J, Pagliari C, Anandan C, Cresswell K, Bokun T, *et al* — The impact of eHealth on the quality and safety of health care: a systematic overview. *PLoS Med* 2011; **8(1).**
10 Jamoom EW, Patel V, Furukawa MF, King J — EHR adopters vs. non-adopters: Impacts of, barriers to, and federal initiatives for EHR adoption. *Healthc (Amst)* 2014; **2(1):** 33-9. doi: 10.1016/j.hjdsi.2013.12.004. Epub 2014 Mar 18. PMID: 26250087; PMCID: PMC4878018.
11 Jones SS, Rudin RS, Perry T — Health information technology: an updated systematic review with a focus on meaningful use. *Ann Intern Med* 2014; **160(1):** 48-54.
12 Franklin BD, O'Grady K, Donyai P — The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors, and staff time: a before-and-after study. *Qual Saf Health Care* 2011; **16(4):** 279
13 Banger A, Graber ML — Recent evidence that health IT improves patient safety. *BMJ Qual Saf* 2015; **24(6):** 1-4.
14 Greenberg CC, Diaz-Flores R, Lipsitz SR — Bar-coding surgical sponges to improve safety: a randomized controlled trial. *Ann Surg* 2016; **264(4):** 602-7.
15 Van der Veen W, van den Bemt PMLA, Wouters H — Association between workarounds and medication administration errors in bar-code-assisted medication administration in hospitals. *J Am Med Inform Assoc* 2018; **25(4):** 385-92.
16 Alamer F, Alanazi AT — The Impact of Smart Pump Technology in the Healthcare System: A Scope Review. *Cureus* 2023; **15(3):** e36007. doi: 10.7759/cureus.36007. PMID: 37051011; PMCID: PMC10085524.

Original Article

Evaluation of Serum Magnesium Level and its Significance in Critically ill Patients

Linda P Johnson[1], C Arul Murugan[2], R Prabu[3]

Abstract

Background : Critically ill patients are especially prone to Magnesium deficiency, a condition often overlooked that can worsen their chances of recovery.

Aims and Objectives : This study aimed to assess Serum Magnesium levels in critically ill patients and correlate them with patient outcomes in terms of the duration of ICU stay, need and duration of mechanical ventilation and mortality.

Materials and Methods : This observational study was conducted on 104 patients aged between 18 and 85 years who were admitted to the ICU with an APACHE II score >10 in the Department of General Medicine, VMKV Medical College Hospital, Salem, over a study period of 1 year. Serum Magnesium levels were measured within the first 24 hours of admission for patients fulfilling the inclusion and exclusion criteria. Patients were followed-up until discharge, and the outcomes were noted and statistically analysed to determine the correlation.

Results : Of the 104 patients, 72 (69.2%) had normal Serum Magnesium levels (1.6 to 2.6), while 32 (30.8%) had Hypomagnesaemia (<1.6). Mechanical ventilation was required in 44 of the 104 patients (42.3%). Of the 32 patients in the Hypomagnesaemia group, 19 (59.4%) required mechanical ventilation, 23 (71.9%) were discharged, and nine (28.1%) died. A significant association was observed between Hypomagnesaemia and the requirement for mechanical ventilation ($p = 0.019$) and mortality ($p = 0.016$). ICU stay duration and duration of ventilatory support did not correlate significantly with Magnesium levels.

Conclusion : The study revealed a significant association between Hypomagnesaemia and the need for mechanical ventilation and increased mortality.

Key words : Serum Magnesium, Critically ill Patients, Mechanical Ventilation, APACHE II Score, Mortality.

Minerals play a crucial role in various physiological processes within the human body. Among these, Magnesium (Mg) stands out due to its involvement in over 300 enzyme systems, including those regulating Sodium-potassium ATPase-mediated transport. Magnesium is vital for maintaining Calcium homeostasis, nerve conduction, skeletal muscle activity and the overall balance of electrolytes like Calcium and Potassium[1]. Recently, Serum Magnesium levels have garnered increased attention from the medical community due to mounting evidence linking its deficiency to various health issues.

Several factors contribute to a higher prevalence of magnesium deficiency in elderly patients, including inadequate dietary intake, increased urinary excretion due to medications like diuretics and digitalis, and reduced intestinal absorption[2]. Disorders of Magnesium metabolism, though frequently unrecognised, are among the most common electrolyte disturbances in patients admitted to hospitals, especially in critically ill elderly patients. Hypomagnesemia, defined by low Serum Magnesium levels, exhibits a wide prevalence range of 11% to 61% in this population. The impact of Magnesium on patient outcomes, however, remains a topic of debate, with considerable controversy regarding its influence on morbidity and mortality[3]. For ensuring optimal neuromuscular excitability and cardiac function, maintenance of a specific Magnesium concentration is crucial to ensure optimal neuromuscular excitability and cardiac function. Deviations from normal levels, whether increase or decrease, often result in significant abnormalities with serious consequences. Hypomagnesemia in critically ill individuals carries numerous potential implications and emerges as a notable factor impeding their recovery[4].

Editor's Comment :

- Hypomagnesemia is a common often overlooked electrolyte disturbance in critical care which is found to be associated with patient outcomes like increased mortality and need for mechanical ventilation.
- Management of Hypomagnesemia could potentially improve patient outcomes.

The incidence of Hypomagnesemia is reported to be 50-60% in Intensive Care Unit (ICU) patients, 30-80% in persons with alcoholism, 10-20% in hospitalised patients, 25% in Outpatients with Diabetes Mellitus, and 2% in the

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general population. Clinical manifestations of Hypomagnesemia are Tetany, Vertigo, Reversible Psychiatric Aberrations, Asthma, Seizures, Hypertension, Cardiac Arrhythmias, Muscular Weakness and Acute Cerebral Ischemia[5].

Hypomagnesemia, a deficiency in magnesium levels, arises from various factors. These include gastrointestinal disorders, metabolic acidosis, increased renal excretion due to medications or underlying disease, and other contributors. Critically ill patients are particularly susceptible to Magnesium dysregulation. Studies have shown a concerning association between Hypomagnesemia in this population and poorer outcomes, including increased and prolonged use of mechanical ventilation, extended ICU stays, difficulty weaning from ventilation, and even higher mortality rates[6].

Hypomagnesemia often coexists with other electrolyte imbalances such as hypokalaemia, wherein patients show relative resistance to Potassium Supplementation until Magnesium deficiency is addressed. Similarly, Hypocalcemia frequently accompanies Hypomagnesemia, presenting a challenge in correction, unless Magnesium deficits are addressed first. These electrolyte disturbances compound the morbidity and mortality rates in critically ill patients[7].

Hypomagnesemia has been identified as a significant indicator of mortality risk in critically ill patients. Many studies corroborate that individuals with Hypomagnesemia upon admission exhibit elevated mortality probabilities[8]. The current investigation sought to examine the factors mentioned earlier and evaluate serum Magnesium levels in critically ill patients admitted to an Intensive Care Unit (ICU) within a Tertiary Care Facility.

Aims and Objectives

This study investigated Serum Magnesium levels in critically ill ICU patients, examining correlations with ICU stay length, need for mechanical ventilatory support, ventilator use duration and mortality.

Materials and Methods

This observational study included 104 patients aged between 18 and 85 years who were admitted to the ICU, Department of General Medicine, Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, between October, 2022 and October, 2023.

Inclusion Criteria :

Patients aged between 18 and 85 years and critically ill patients admitted to the ICU with an APACHE II score of >10 were included in the study.

Exclusion Criteria :

Patients who received Magnesium Supplements, Calcium Infusions, Diuretics, Proton Pump Inhibitors, Aminoglycosides, or Blood Transfusions before ICU admission, chronic alcoholics and pregnant women with eclamptic seizures were excluded from the study.

All patients were informed of the study at the time of enrolment, and informed consent regarding their willingness to participate was obtained. Ethical Committee Approval was obtained before proceeding with this study.

A detailed history was obtained and a clinical examination of the patients who met the inclusion and exclusion criteria was performed. Serum Magnesium samples of the patients were taken within 24 hours of admission to the ICU. The serum Magnesium levels were evaluated using the methylene blue Spectrophotometric method. The normal reference range for serum Magnesium is between 1.6 and 2.6 mg/dL. Value less than 1.6 mg/dL was considered as Hypomagnesemia and more than 2.6 mg/dL as Hypermagnesemia. Other routine blood investigations, including RBS, CBC, RFT, Serum electrolytes, LFT, serology, urine routine, chest radiography, and ECG, were also performed. Patient outcomes in terms of mortality, need, duration of ventilator support, and duration of ICU stay were noted.

Statistical Analysis :

Data were collected, entered into Microsoft Excel, and analysed using SPSS software (version 22). Categorical data were presented as frequencies and percentages. The p-value was calculated using the Chi-square test, and a p-value <0.05 was considered significant.

Results

Of the 104 patients, 55 (52.9%) were Males and 49 (47.1%) were Females. When stratified based on age, 8 patients (7.7%) were aged ≤40 years, 29 patients (27.9%) were aged between 41 and 50 years, 27 (26%) were aged 51-60 years, 23 (22.1%) were aged 61-70 years, and 17 (16.3%) were aged >70 years. Based on Sr-Mg levels, 72 patients (69.2%) had a value range of 1.6 to 2.6, and 32 (30.8%) had <1.6 (Hypomagnesemia). None of the patients had serum Magnesium values >2.6 (Hypermagnesemia).

Sixty patients (57.7%) did not require mechanical ventilation and 44 (42.3%) required mechanical ventilation. 37 patients (84.1%) had a duration of ≤5 days of mechanical ventilation and seven (15.9%) had a duration of >5 days. Based on the duration of ICU stay, 63 patients (60.6%) had a duration of ≤5 days, 37 (35.6%) had a duration of 6-10 days and 4 (3.8%) had a duration of >10 days. Based on the outcomes, 88 (84.6%) patients were discharged and the remaining 16 patients (15.4%) died (Table 1).

Table 1 — *Demographic details of the study population*

		Number of patients	Percentage
Age group	≤40	8	7.7
	41 to 50	29	27.9
	51 to 60	27	26
	61 to 70	23	22.1
	>70	17	16.3
Gender	Female	49	47.1
	Male	55	52.9
Sr Magnesium	<1.6	32	30.8
	1.6 to 2.6	72	69.2
Need for mechanical ventilation	No	60	57.7
	Yes	44	42.3
Duration of mechanical ventilation	≤5	37	84.1
	≥6	7	15.9
Duration of ICU stay	≤5	63	60.6
	6 to 10	37	35.6
	>10	4	3.8
Outcome	Discharged	88	84.6
	Expired	16	15.4

There was no significant correlation between Serum Magnesium levels and duration of ICU stay (Table 2).

Among patients with Sr Magnesium values <1.6, 19 (59.4%) required mechanical ventilation and among those with Sr Magnesium levels between 1.6 and 2.6, 25 (35.7%) required mechanical ventilation. There was a statistically significant correlation between the need for mechanical ventilation and low Mg levels (p = 0.019). The outcome status was that in patients with Sr Magnesium values <1.6, 9 (28.1%) died. Seven patients (9%) died in the group with Sr-Mg values from 1.6 and 2.6. There was a statistically significant correlation between low serum magnesium level and mortality (p = 0.016) (Table 3).

In patients with hypomagnesaemia (Sr Mg <1.6), 14 (73.7%) required mechanical ventilation for ≤5 days, whereas 5 (26.3%) required ventilatory support for >5 days.

Table 2 — *Correlation of Sr Magnesium with APACHE II Score and Duration of ICU Stay*

		APACHE II Score	Duration of ICU stay
Sr Magnesium	Pearson correlation	-0.16	-0.147
	P value	0.105	0.138

Table 3 — *Comparison of Sr Magnesium with the need for mechanical ventilation and Outcome*

		Sr Magnesium		P value
		<1.6	1.6 to 2.6	
Need for mechanical ventilation	No	13 (40.6%)	47 (65.3%)	0.019
	Yes	19 (59.4%)	25 (35.7%)	
Outcome	Discharged	23 (71.9%)	65 (90.3%)	0.016
	Expired	9 (28.1%)	7 (9%)	

Table 4 — *Comparison of Sr Magnesium with the duration of Mechanical Ventilation*

		Sr Magnesium		P value
		<1.6	1.6 to 2.6	
Duration of Ventilatory support	≤5 days	14 (73.7%)	23 (92%)	0.100
	>5 days	5 (26.3%)	2 (8%)	

In patients with Serum Magnesium levels between 1.6 and 2.6, 23 (92%) required ventilatory support for ≤5 days and 2 (8%) required ventilatory support for >5 days. However, the correlation between Serum Magnesium levels and duration of ventilatory support was found to be statistically insignificant, with a p-value of 0.100 (Table 4).

Discussion

Magnesium is predominantly found in the bones and cells. Magnesium deficiency in critical conditions is associated with morbidity and mortality[9]. In studies conducted on critically ill patients Globally, the typical occurrence rate of Hypomagnesemia ranges from 14% to 70%.

In our study, 30.8% of the patients had Sr-Mg levels <1.6. Among patients with Hypomagnesaemia, 59.4% required mechanical ventilation and 40.6% did not require mechanical ventilation. Of the patients, 69.2% had Sr-Mg values in the range of 1.6 and 2.6, 65.3% did not require mechanical ventilation and 35.7% required mechanical ventilation. There was a statistically significant correlation between Hypomagnesaemia and requirement for mechanical ventilation. A study done by Safavi, *et al* also found that the cases of low Serum Magnesium needed more and longer mechanical ventilation compared with other patients[10].

In our study, the majority of patients (84.1%) had a mechanical ventilation duration of ≤5 days, and the remaining 15.9% of patients had a duration of >5 days. In the Hypomagnesaemia group, 14 (73.7%) patients required ventilatory support for ≤5 days, whereas 5 (26.3%) required for >5 days. However, the p-value is insignificant. 60.6% of patients had a duration of ≤5 days of ICU stay, 35.6% had ICU stay from 6 to 10 days and the remaining 3.8% had >10 days of ICU stay. The p-value for the duration of ICU stay was not statistically significant. However, this result differed from the study done by Jahangirifard, *et al* as the admitted patients in ICU with Low Serum Mg levels, not only had significantly higher rates of mortality but also needed more mechanical ventilation, besides having longer hospital stays[11].

In our study, 84.6% of the patients were discharged; among them, 73.86% of patients had Sr-Mg levels ranging from 1.6 to 2.6 (which makes 62.5% of the total participants in the study), and 26.13% had Sr-Mg levels <1.6 (which makes up 22.11% of the total participants). The remaining 15.4% of patients died; among them, 56.25% had a Sr Magnesium level of <1.6 (which made up 8.6% of the total participants), and 43.75% had a Sr Magnesium level between 1.6 and 2.6 (which makes 6.7% of the total participants). Mortality and Hypomagnesaemia were significantly correlated. However, the correlation between the APACHE II Score of the study population and Serum Magnesium level was considered statistically

insignificant. This differs from the results of the study done by Gonuguntla, *et al* as they reported that the mean APACHE II and SOFA scores were significantly higher in patients with hypomagnesemia followed by those with Normomagnesemia and Hypermagnesemia[12].

The results of the study by Laddhad, *et al* also differed from those of our study. They reported that most participants scored APACHE II below 10, indicating less to nil severity, yet the results were not statistically significant[13].

Limitations :

In this study, we studied Serum Magnesium values only on the day of admission, and any changes in the Serum Magnesium values during the ICU stay and their relationship with outcome were not assessed. Confounding factors such as other electrolyte imbalances including serum Potassium, Sodium, Calcium and Phosphorus were not taken into account which could have affected patient outcomes as well. Further studies with a trial of Magnesium Supplementation in critically ill patients would help develop guidelines regarding the treatment of hypomagnesaemia in Intensive Care.

Conclusion

Serum Magnesium levels <1.6 mg/dL were significantly associated with increased requirements for mechanical ventilation and higher mortality rates. Notably, no significant correlation was observed among Magnesium levels, ICU stay duration, and ventilatory support duration. These findings advocate the assessment and management of Magnesium homeostasis in critical care settings to potentially improve patient outcomes.

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References

1 Pelczyñska M, Moszak M, Bogdañski P — The role of magnesium in the pathogenesis of metabolic disorders. *Nutrients* 2022; **14:** 1714. https://doi.org/10.3390/nu14091714.
2 Guerrera MP, Volpe SL, Mao JJ — Therapeutic uses of magnesium. *Am Fam Physician* 2009; **80:** 157-62. https://pubmed.ncbi.nlm.nih.gov/19621856/
3 Zafar MSH, Wani JI, Karim R, Mir MM, Koul PA — Significance of serum magnesium levels in critically ill-patients. *Int J Appl Basic Med Res* 2014; **4:** 34-7. https://doi.org/10.4103/2229-516X.125690.
4 Limaye CS, Londhey VA, Nadkart MY, Borges NE — Hypomagnesemia in critically ill medical patients. *J Assoc Physicians India* 2011; **59:** 19-22. https://pubmed.ncbi.nlm.nih.gov/21751660/
5 Humphrey S, Kirby R, Rudloff E — Magnesium physiology and clinical therapy in veterinary critical care: Magnesium physiology in veterinary critical care. *J Vet Emerg Crit Care (San Antonio)* 2015; **25:** 210-25. https://doi.org/10.1111/vec.12253.
6 Chen M, Sun R, Hu B — The influence of serum magnesium level on the prognosis of critically ill patients. *Zhonghua Wei Zhong Bing Ji Jiu Yi Xue* 2015; **27:** 213-7. https://doi.org/10.3760/cma.j.issn.2095-4352.2015.03.011.
7 Schafer AL, Shoback DM, Feingold KR, Anawalt B, Blackman MR, Boyce A — Hypocalcemia: Diagnosis and Treatment. *Diagnosis and Treatment Endotext South Dartmouth (MA)* 2000. https://doi.org/10.4103/ijciis.ijciis_11_23.
8 Kumar S, Honmode A, Jain S, Bhagat V — Does magnesium matter in patients of Medical Intensive Care Unit: A study in rural Central India. *Indian J Crit Care Med* 2015; **19:** 379-83. https://doi.org/10.4103/0972-5229.160272.
9 Herroeder S, Schönherr ME, Hert D, Hollmann SG — Magnesium - Essentials for anesthesiologists. *Anesthesiology* 2011; **114:** 971–93. https://doi.org/10.4103/2229-516X.125690.
10 Safavi M, Honarmand A — Admission hypomagnesemia—impact on mortality or morbidity in critically ill patients. *Middle East J Anesthesiol* 2007; **19:** 645-60. https://europepmc.org/article/med/18044292.
11 Jahangirifard A, Safarzaei M, Eraghi MG, Mahjoubifard M — Effects of magnesium on clinical outcome of critical care traumatic patients. *Journal of Cellular & Molecular Anesthesia* 2017; **2:** 9-14. https://doi.org/10.22037/jcma.v2i1.13579.
12 Gonuguntla V, Talwar V, Krishna B, Srinivasan G — Correlation of Serum Magnesium Levels with Clinical Outcome: A Prospective Observational Study in Critically Ill Patients Admitted to a Tertiary Care ICU in India. *Indian J Crit Care Med* 2023; **27:** 342-7. https://doi.org/10.5005/jp-journals-10071-24451.
13 Tong GM, Rude RK — Magnesium Deficiency in Critical Illness. *Journal of Intensive Care Medicine* 2005; **20(1):** 3-17. https://doi.org/10.1177/0885066604271539

Original Article

Comparing the Outcome of Conventional Suture Ligation Technique *versus* Sutureless Technique Using Bipolar Diathermy in Thyroidectomy — a Randomized Controlled Trial

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Abstract

Background : Thyroidectomy is among the most commonly performed surgical procedures Worldwide for managing thyroid disorders. The Conventional Suture Ligation (CSL) technique, while effective, is associated with prolonged operative time, increased intraoperative blood loss, and a higher risk of complications such as knot slippage and foreign body reactions. The introduction of advanced electrosurgical devices has paved the way for sutureless techniques using bipolar diathermy, which offer precise vessel sealing with reduced thermal spread and minimal tissue trauma. This study aimed to compare the safety and effectiveness of a sutureless technique using bipolar diathermy versus the Conventional Suture Ligation technique in thyroidectomy.

Materials and Methods : An open-label randomized controlled trial was conducted at the Department of General Surgery, Aarupadai Veedu Medical College and Hospital, Puducherry, over an 18-month period. A total of 82 patients, aged 18-60 years and diagnosed with thyroid disorders, were randomly allocated into two equal groups (n = 41). Group 1 underwent thyroidectomy with the sutureless technique using bipolar diathermy, while Group 2 underwent the Conventional Suture Ligation technique. Baseline demographic and clinical parameters - including Age, Gender, BMI, and preoperative laboratory values - were comparable between the groups. Primary outcomes measured were intraoperative blood loss, operative time and postoperative haemoglobin levels, with secondary outcomes including drain volume, recurrent laryngeal nerve injury, hypocalcemia and duration of hospital stay.

Results : Despite similar baseline characteristics, Group 1 exhibited a significantly higher mean postoperative haemoglobin level (12.8 ± 0.9 g/dL) compared to Group 2 (11.7 ± 1.3 g/dL; $p<0.05$). Additionally, the duration of hospital stay was significantly shorter in Group 1 (3.0 days) than in Group 2 (3.6 days; $p<0.05$).

Conclusion : The sutureless technique using bipolar diathermy is a safe and efficient alternative to Conventional Suture Ligation in thyroidectomy, offering improved intraoperative hemostasis and reduced hospital stay.

Key words : Thyroidectomy, Bipolar Diathermy, Sutureless Technique, Suture Ligation, Intraoperative Blood Loss, Hospital Stay.

Thyroidectomy is one of the most commonly performed surgical procedures Worldwide for managing thyroid disorders[1]. Thyroidectomy has undergone substantial advancements over the years, with refined surgical techniques leading to lower morbidity and better patient outcomes. The adoption of safer practices, including intracapsular vessel ligation and careful identification of the recurrent laryngeal nerve before ligating blood vessels, has greatly minimized the risk of complications, as evidenced by the work of pioneering surgeons[2,3].

Historically, thyroidectomy has been performed using the Conventional Suture Ligation (CSL) technique, which continues to be a commonly used and effective approach. However, CSL has several drawbacks, such as extended operative time, greater intraoperative blood loss, an increased risk of knot slippage, slower wound healing, a higher chance of postoperative infections, potential damage to surrounding structures, and foreign body reactions. These limitations have driven the search for alternative techniques to enhance surgical efficiency and improve patient safety[4,5].

Editor's Comment :

- Sutureless techniques in thyroidectomy can provide outcomes comparable to conventional suture ligation with potential advantages such as reduced operative time and improved surgical efficiency. These techniques may be considered a safe and effective alternative in thyroid surgery when performed with appropriate expertise.

The introduction of advanced electrosurgical devices has transformed Thyroid Surgery by enabling suture-free vessel sealing techniques that shorten operative time, reduce blood loss, and minimize tissue trauma and postoperative complications. Among these innovations, bipolar diathermy has emerged as a reliable tool in thyroidectomy due to its precision and safety. Unlike monopolar cautery, which poses a greater risk of lateral thermal spread and unintended tissue injury, bipolar cautery ensures focused hemostasis with minimal collateral damage. It functions through a straightforward electrosurgical unit controlled by a foot pedal, making it both widely available and cost-effective[6]. Additionally, the power required for bipolar cautery is significantly lower -

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approximately 5% of that used in monopolar electrocautery - reducing the risk of excessive thermal injury[7,8]. Bipolar cautery operates by transmitting electrical energy between two closely positioned electrodes, allowing for precise coagulation of blood vessels while maintaining controlled thermal spread. During the process, negatively charged erythrocytes move toward the anode tip, promoting tissue adherence. This targeted mechanism enhances surgical accuracy, reduces excessive tissue charring, and optimizes intraoperative hemostasis[9].

The primary objective of this study is to evaluate the effectiveness of bipolar cautery in Thyroid Surgery compared to the Conventional Suture Ligation technique. The study aims to assess key intraoperative and postoperative parameters, including operative time (measured in minutes), intraoperative blood loss (quantified by the number of gauze pieces soaked), and postoperative complications. By comparing these outcomes, we seek to determine whether bipolar diathermy offers a safer, faster and more efficient alternative to the traditional suture ligation method in thyroidectomy. The aim of this study is to compare the safeness and effectiveness of sutureless technique using bipolar diathermy with Conventional Suture Ligation technique in thyroidectomy

Materials and Methods

This open-label, randomized controlled trial was conducted in the Department of General Surgery at Aarupadai Veedu Medical College and Hospital, Puducherry, over 18 months. The study included patients presenting with thyroid diseases who were scheduled for thyroidectomy, aged between 18 and 60 years, and willing to provide informed consent. Patients with toxic nodular goiter, those undergoing re-surgery, and those who declined participation were excluded to ensure homogeneity. A total of 82 patients were enrolled and randomly assigned to two groups using a computer-generated sequence: Group A (41 patients) underwent a sutureless thyroidectomy using bipolar diathermy, while Group B (41 patients) underwent a Conventional Suture Ligation technique. Convenience sampling was used for patient selection.

All participants underwent a standardized preoperative evaluation, including blood tests, thyroid profile, fine-needle aspiration cytology, Ultrasound and indirect laryngoscopy, along with anesthetic fitness clearance. The surgical procedure was performed under General Anesthesia with endotracheal intubation. The operative site was prepared with aseptic precautions, and the thyroidectomy was performed following established techniques for each group. Group A employed bipolar diathermy for hemostasis, while Group B utilized Conventional Suture Ligation for vascular control. Postoperative care included broad-spectrum antibiotics for two days, with most patients being discharged on the third postoperative day.

Patients were followed up at 10 days, 6 weeks, and 12 weeks post-surgery to assess complications such as recurrent laryngeal nerve injury, hypocalcemia, hematoma formation, and changes in voice. Blood loss was measured using a standardized method, calculating intraoperative blood loss through gauze weight differences. Hypocalcemia was assessed clinically and confirmed through serum calcium tests when necessary. Hematoma formation and voice changes were monitored throughout the follow-up period.

The study analyzed multiple variables, including patient demographics, pre- and postoperative haemoglobin levels, intraoperative blood loss, operative duration, drain volume, and postoperative complications. Data were entered into an Excel sheet and analyzed using SPSS v26.0. Continuous variables were compared using an unpaired t-test, while categorical variables were analyzed using the chi-square test. A p-value of <0.05 was considered statistically significant.

Result

Present study included total of 82 cases with 41 in each group as group 1 and group 2. Group 1 underwent sutureless technique using bipolar diathermy and group 2 underwent Conventional Suture Ligation technique (Table 1).

The mean age between the group were comparable with mean age of 44.3 in group 1 and 43.1 years in group 2 patients. The physical parameters such as Height, Weight and BMI between the group were comparable with no significant difference. There is no significant difference in mean level of pre-hemoglobin, TLC and PCV between the groups. The mean postoperative calcium level were comparable between the groups. The mean duration of hospital stay was significantly lower in group 1(3.0 days) compared to group 2 patients (3.6days)($p<0.05$). The

Table 1 — *Showing mean parameters of patients between the groups*

	Group 1		Group 2		p-value
	Mean	SD	Mean	SD	
Age	44.3	9.1	43.1	9.1	0.65
Height in cm	155.7	7.1	161.9	7.5	0.34
Weight in kg	53.6	11.1	58.3	8.6	0.55
BMI	21.95	3.25	22.09	1.56	0.21
Pre- Hemoglobin mg/dl	13.2	1.0	12.6	1.4	0.31
TLC 10 µL	6.94	1.80	6.41	1.69	0.22
PCV	38.8	1.7	38.8	2.0	0.28
Post-op Haemoglobin mg/dl	12.8	.9	11.7	1.3	0.01*
RBS mg/dl	112.4	12.3	110.8	13.5	0.21
Post-op calcium level	9.0	.8	8.9	.8	0.32
Duration of hospital stay	3.0	.2	3.6	.7	0.05*

mean Postoperative hemoglobin was significantly higher in group 1 (12.8±0.9) compared to group 2 patients (11.7±1.3)(p<0.05). The RBS was found to be similar between the group with no significant difference (Table 2).

Gender distribution between the groups were comparable, with female pre-ponderance in both the group in study. The type of thyroid disorder were comparable between both the groups, with majority of single nodular goiter in both the groups.

Table 2 — *Comparison of distribution between the groups*

	Group 1		Group 2		Chi-square (p-value)
	Count	N %	Count	N %	
Gender :					
Female	35	85.4%	27	65.9%	2.32 (0.32)
Male	6	14.6%	14	34.1%	
Thyroid Disorder Type :					
MNG	17	41.5%	16	39.0%	0.05 (0.92)
SNG	24	58.5%	25	61.0%	

Discussion

Present study included total of 82 cases with 41 in each group as group 1 and group 2. Group 1 underwent sutureless technique using bipolar diathermy and group 2 underwent Conventional Suture Ligation technique. The mean age between the group were comparable with mean age of 44.3 in group 1 and 43.1 years in group 2 patients. Gender distribution between the groups were comparable, with female pre-ponderance in both the group in study. The physical parameters such as Height, Weight and BMI between the group were comparable with no significant difference. In concordance to present study Aljuraibi W, *et al*, documented with no significant differences between the two groups in terms of Age, Sex, Body Mass Index, or Operative Mortality[10]. Another study by Kumar R, *et al*, among the 116 patients, 52 cases were diagnosed with solitary thyroid nodule, 30 cases were diagnosed with multinodular goitre, 17 cases were diagnosed with carcinoma thyroid and17 cases were diagnosed with Grave's disease[11]. Vasuki R, *et al*, documented majority of patients were aged 30-40 years, followed by those aged 40-50 years, with a male-to-female ratio of 1:25[12].

Another study by Abdulmageed MU, *et al*, the mean age was comparable between groups, with 40.0±9.7 years in the conventional suture ligation group and 40.5±11.7 years in the harmonic scalpel group[13]. Another study by Parveen K, *et al*, the mean age and BMI were similar between both groups, with Group I having a mean age of 35.34±6.55 years and BMI of 25.15±7.21 kg/m², while Group II had a mean age of 36.23±4.31 years and BMI of 25.15±8.15 kg/m². The gender distribution was comparable, with a majority being female in both groups. Multinodular goiter was the most common condition, affecting 80% in Group I and 75% in Group II[14].

The mean Post Operative haemoglobin was significantly higher in group 1 (12.8±0.9) compared to group 2 patients (11.7±1.3).(p<0.05) The RBS was found to be similar between the group with no significant difference. The mean duration of hospital stay was significantly lower in group 1(3.0 days) compared to group 2 patients (3.6 days)(p<0.05). Similarly, Aljuraibi W et al. reported that the Ligasure technique significantly outperformed the suture-ligation method in total thyroidectomy. Patients in the Ligasure group experienced a notably shorter surgery duration (115.54 ± 15.35 minutes) compared to those undergoing suture ligation (127.1 ± 7.95 minutes). Additionally, intraoperative blood loss was substantially lower with Ligasure (62.06 ± 7.34 ml) than with suture ligation (75.84 ± 9.21 ml). Postoperative fluid drainage also showed a marked reduction in the Ligasure group (54.16 ± 9.21 ml) compared to the suture-ligation group (66.28 ± 8.99 ml). The study ultimately affirmed that the Ligasure sealing system offers a safe and efficient alternative for total thyroidectomy, minimizing surgical time, blood loss, and postoperative drainage while ensuring the preservation of laryngeal nerve and parathyroid function[10]. Another study by Prakash O, *et al*, found the average procedure time for suture ligation was significantly longer at 131.6±17.7 minutes, whereas bipolar cautery required only 97±7.5 minutes. Additionally, hospital stays were prolonged in the suture ligation group (6±0.8 days) compared to the bipolar cautery group (4.9±1.3 days). This study concludes that bipolar cauterization offers a significant advantage over conventional suture ligation by reducing surgery time, hospital stay and postoperative complications such as seroma, hoarseness of voice, and hypocalcemia, making it a more efficient and safer technique[15].

The sutureless technique resulted in significantly lower intraoperative and postoperative blood loss, drain volume, transient hypocalcemia, general postoperative complications, and hospital stay in study by Amer I, *et al*[16]. Hegab AM, *et al*, group A (knot-tying) had a mean operative time of 124.7±5.2 minutes and an estimated blood loss of 101±15.9 ml, while group B (bipolar) showed a significantly lower mean operative time of 103.9±7.8 minutes and blood loss of 80±16.2 ml. Postoperative pain was significantly lower in the bipolar group, but there was no significant difference in operative and postoperative complications between the two groups. The study concluded that bipolar electro-cautery is a simple and effective technique for thyroidectomy, offering reduced operative time and blood loss without increasing the risk of complications[17]. Prathap R, *et al*, concluded that using a bipolar thermal device is a cost-effective method for achieving hemostasis in thyroid surgery, offering reduced operative time and lowering perioperative and postoperative morbidity and mortality, making it a promising alternative to standard ligature techniques[18].

Conclusion

The findings underscore the potential benefits of employing bipolar diathermy in Thyroid Surgery, as it not only enhances surgical efficiency but also improves patient recovery without compromising safety. Overall, the results of this study support the adoption of the sutureless technique using bipolar diathermy as a viable alternative to traditional suture ligation in thyroidectomy, while also highlighting the need for further research with larger sample sizes and extended follow-up periods to validate these outcomes and assess long-term efficacy.

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Conflict of Interest : Nil

References

1 Hu J, Zhao N, Kong R, Wang D, Sun B, Wu L — Total thyroidectomy as primary surgical management for thyroid disease: surgical therapy experience from 5559 thyroidectomies in a less-developed region. *World J Surg Oncol* 2016; **14(1):** 20.

2 Ludwig B, Ludwig M, Dziekiewicz A, Mikula A, Cisek J, Biernat S, *et al* — Modern Surgical Techniques of Thyroidectomy and Advances in the Prevention and Treatment of Perioperative Complications. *Cancers (Basel)* 2023; **15(11).**

3 SK R, Panduranga Rao SU — Total thyroidectomy using intracapsular dissection: the technique, complications, and surgical outcomes. *Egypt J Otolaryngol* 2022; **38(1):** 72.

4 Al-Dhahiry JKS, Hameed HM — Total thyroidectomy: Conventional Suture Ligation technique versus sutureless techniques using Harmonic Scalpel or Maxium. *Ann Med Surg* 2016; **5:** 29-34.

5 Thayalan Dias SJ, Gobishangar S, Priyatharsan K, Praramanathan S — Outcome Analysis of Total Thyroidectomy: Conventional Suture Ligation Technique vs Sutureless Technique. *Cureus* 2023; **15(10):** e48005.

6 Manouras A, Markogiannakis HE, Kekis PB, Lagoudianakis EE, Fleming B — Novel hemostatic devices in thyroid surgery: electrothermal bipolar vessel sealing system and harmonic scalpel. *Expert Rev Med Devices* 2008; **5(4):** 447-66.

7 Alkatout I, Schollmeyer T, Hawaldar NA, Sharma N, Mettler L — Principles and safety measures of electrosurgery in laparoscopy. *J Soc Laparoendosc Surg* 2012; **16(1):** 130-9.

8 Sharma S, Haji AG, Vijaykumar DK, Shaji AK — Irrigation-coupled bipolar cautery unit: A practical, economical, and simple version. *Indian J Plast Surg Off Publ Assoc Plast Surg India* 2008; **41(2):** 162-6.

9 Spivak H, Richardson WS, Hunter JG — The use of bipolar cautery, laparosonic coagulating shears, and vascular clips for hemostasis of small and medium-sized vessels. *Surg Endosc* 1998; **12(2):** 183-5.

10 AlJuraibi W, Ahmed MR, Saber A — Use of ligasure sealing versus conventional suture-ligation in total thyroidectomy. *J Surg* 2016; **4(3-1):** 34-8.

11 Ravi KH, Sunil KSR, Gosavi S — Sutureless thyroidectomy with bipolar diathermy. *J Evol Med Dent Sci* 2016; **5(42):** 2574-8.

12 Vasuki R, Thanmaran NB, Malathi V, Kujur L — A study of use of bipolar cautery in thyroidectomy. *Int Surg J* 2017; **4(3):** 1059-64.

13 Abdulmageed MU, Katoof FM, Abdullah AA — Comparison study between the usage of harmonic scalpel versus classical suture method for thyroidectomy in Iraqi patients. *J Pak Med Assoc* 2021; **71(Suppl 8(12):** S40-4.

14 Parveen K, Kokab S, Akhtar Z — Comparison Between Conventional and Sutureless Thyroidectomy. *Pakistan J Med Heal Sci* 2022; **16(05):** 1090.

15 Prakash O, Chandrashekar S, Mattews J, George R, Suprej K, Mattew J, *et al* — Bipolar cautery versus conventional suture ligation of vascular pedicles in thyroidectomy: a comparative clinical study. *Int Surg J* 2021; **8(4):** 1181-4.

16 Amer I, Elraheem A, Abd Allaha O — Total thyroidectomy: Conventional suture ligation technique versus sutureless techniques, Sohag experince. *Egypt J Ear, Nose, Throat Allied Sci* 2021; **22(22):** 1-11.

17 Hegab AM — Comparative study between bipolar electro-cautery and knot-tying technique in total thyroidectomy. *Al-Azhar Int Med J* 2021; **2(10):** 7-11.

18 Prathap R, Asim PA, Vivekanand A, Krishna S — A Prospective Study on Safety of Bipolar Diathermy in Thyroid Surgery. *Kerala J ENT Head Neck Surg* 2024; **3(1):** 3-8.

Original Article

Comparative Analysis of Escitalopram, Sertraline and Amitriptyline in Patients with Major Depressive Disorder in India : A Real-World Study

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Abstract

Background and Objective : Major Depressive Disorder (MDD) is one of the leading causes of non-fatal disease burden in India. Researchers have been trying to find the best therapy for Depression for many years. Limited data on antidepressants in clinical practice highlights the need for more real-world evidence. This study aimed to compare the efficacy and safety of Escitalopram, Sertraline and Amitriptyline in patients with MDD.

Materials and Methods : This was a real-world, observational, prospective study conducted in India between May, 2021 and April, 2023.

Results : Overall, 268 patients were enrolled in the study (Escitalopram [n=101]; Sertraline [n=87]; Amitriptyline [n=80]). While a reduction in Hamilton Depression Rating Scale-17 (HAM-D 17) scores was reported over time in each cohort, the change in HAM-D 17 scores from baseline for Escitalopram was significantly higher than Sertraline ($p<0.005$) and Amitriptyline ($p<0.005$), with no significant difference between Sertraline and Amitriptyline. At Week 8, Clinical Global Impression, European Quality of Life Five Dimension Five Level-health states, and visual analogue scale values in the Escitalopram cohort were significantly lower than Sertraline ($p<0.005$ each) and Amitriptyline cohorts ($p<0.005$ each). Columbia-Suicide Severity Rating Scale scores were also significantly lower in the Escitalopram cohort compared to Sertraline ($p=0.01$) and Amitriptyline ($p=0.002$). Adverse events were reported by 245 (91.4%) patients during the study. Insomnia (42.6%), Nausea (31.0%) and Constipation (81.3%) were most frequent in Escitalopram, Sertraline and Amitriptyline cohorts, respectively.

Conclusion : Escitalopram elicited better responses and significantly improved Quality of Life compared to Sertraline and Amitriptyline. No new safety concerns were observed.

Key words : Amitriptyline, Antidepressants, Escitalopram, India, Real-world, Sertraline.

Mental health issues are a significant cause of non-fatal disease burden in India, with their proportional contribution nearly doubling since 1990. Major Depressive Disorder (MDD), characterized by persistent low mood, loss of interest in pleasurable activities, guilt, lack of energy, concentration difficulties, appetite changes, sleep disturbances and suicidal thoughts, is a prevalent condition. In 2019, the prevalence of MDD in the Indian population was 2.68%, with higher prevalence in the 40-59 years age group[1].

MDD can be managed with various treatment modalities. Per Indian Psychiatric Society (IPS) guidelines, treatment begins with thorough patient assessment and typically involves medication and/or psychotherapy. While some antidepressants show higher response rates in clinical trials, ongoing debate surrounds their efficacy and safety. Many patients experience only partial relief or relapse within weeks of treatment[2]. However, data on inadequate response and relapse rates in the Indian population is limited. In India, selective serotonin reuptake inhibitors (SSRIs) are the most commonly prescribed medicines for Depression[3], followed by Tricyclic Antidepressants (TCAs)[4]. Despite their known Adverse Events (AEs), antidepressants are frequently prescribed. Escitalopram, despite causing more AEs and sexual disturbances compared to other antidepressants[5], is the preferred monotherapy in >65% of patients[6]. Similarly, other commonly prescribed antidepressants like Sertraline and Fluoxetine also elicit multiple AEs[7]. Some antidepressants, like Escitalopram and Sertraline, have also been reported to induce suicidal ideation[8], although conclusive data on this topic is limited[9].

Antidepressant use is considerable, especially in the Western World, and increasing in several countries[10].

Editor's Comment :

- Escitalopram was found to elicit a significant reduction in HAM-D 17, CGI-S, and CGI-I scores, help achieve response in higher number of patients (97% *versus* 67.8% *versus* 73.8%), and significantly improve the QoL compared to Sertraline ($p<0.005$) and Amitriptyline ($p<0.005$) at Week 8 in this real-world study.
- All three antidepressants reduced suicidal tendency (C-SSRS scores), with significantly better results observed in the Escitalopram cohort ($p=0.004$).
- The adverse events observed during the study were consistent with the known safety profile of the drugs; 95%, 82.8%, and 96.2% of patients had AEs in the Escitalopram, Sertraline, and Amitriptyline cohorts, respectively.

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Globally, both Psychotherapy and Pharmacotherapy have demonstrated efficacy in alleviating patients' symptoms and Quality of Life (QoL)[11]. However, in India, the prescription patterns for antidepressants have known to deviate from the World Health Organization (WHO) recommendations[12], with reported off-label use, high dropout rate from clinical trials, and poor adherence to medications[12]. The limited research on the overall efficacy and safety of antidepressants in India[13] indicates the need for more real-world evidence.

This real-world study aimed to compare the efficacy and safety of three antidepressants, Escitalopram, Sertraline, and Amitriptyline, in patients with MDD in India. It also assessed their impact on the QoL and suicidal risk.

Materials and Methods

Study Design :

This real-world, observational, comparative, prospective study was conducted at the Department of Psychiatry, Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai, Maharashtra, India, between May, 2021 and April, 2023. Patients were followed-up for 8 weeks. The study protocol was approved by the Institutional Ethics Committee of Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai (Registration number: ECR/ 266/ Lokmanya/ Inst/ MH/ 2013RR 16; Study approval number: IEC/40/21). The study was conducted in accordance with Good Clinical Practice and the ethical principles outlined in the Declaration of Helsinki 2008. Informed consent was obtained from patients or parents/ legal guardians for children under the age of 18.

Study Population :

Patients of all age groups were eligible to be enrolled into the study if they presented episode(s) of MDD (diagnosed by psychiatrist), had Hamilton Depression Rating Scale-17 (HAM-D 17) total score of $\geq$15 or a Clinical Global Impression-Severity of illness (CGI-S) score of $\geq$3, and were prescribed either of the three study drugs by the treating Psychiatrist (based on age, disease severity, comorbid conditions etc). Patients with current or a history of seizure disorder, bipolar disorder, schizophrenia, or brain injury were excluded from the study.

Study Therapy :

The three study drugs Escitalopram, Sertraline, and Amitriptyline were prescribed by the Psychiatrist per standard practice. Although the typical starting dose for Escitalopram, Sertraline, and Amitriptyline is 10 mg[14], 50 mg[15], and 25 mg[16] per day, respectively, the dose for this study was determined by the treating psychiatrist based on the disease severity, age, comorbidities, etc. Dose adjustments were allowed at any time during the study. Patients were allowed to continue medication for general illnesses such as Diabetes or Hypertension. All assessments were performed every 2 weeks until Week 8.

Data Collection :

Baseline demographic and clinical details were collected at Visit 1. Subsequent data were collected during the routine patient visits at Week 2, Week 4, Week 6 and Week 8. Data were collected by the psychiatrists on a predefined case report form (CRF). Patients were divided into three groups based on the prescribed antidepressant.

Efficacy Assessment :

Scores from the various assessment tools (Total HAM-D 17, HAM-D 17 subscores, CGI-S, CGI Scale-Global Improvement [CGI-I], European Quality of Life Five Dimension Five Level [EQ-5D-5L], and Columbia-Suicide Severity Rating Scale [C-SSRS]) were recorded on the CRF at each visit. The primary endpoint of the study was the change in HAM-D 17 scores from baseline up to Week 8 between and within therapies. Secondary endpoints included response and remission rates, change in HAM-D 17 subscale scores, change in CGI-S and CGI-I scores, and QoL scores over time. Response was defined as a decrease in HAM-D 17 total score at Week 8 relative to baseline by $\geq$50%. Remission was defined as HAM-D 17 total score of $\leq$7 at Week 8. The QoL was assessed by the EQ-5D-5L scale.

Safety Assessment :

AEs (including grade/severity) and C-SSRS scores for suicidal ideation/behaviour were monitored during each visit.

Statistical Analysis :

Statistical Package for the Social Sciences (SPSS) version 26.0 was used for analyses. The data were analyzed using non-parametric tests as the data did not follow a normal distribution. Kolmogorov-Smirnov tests were performed on the actual data ($p<0.05$ for each cohort), percent change from baseline data ($p<0.05$ for each cohort), and log-transformed data ($p<0.05$ for each cohort). However, it did not satisfy the assumptions of normality. The Kruskal-Wallis test was used for overall comparison between the three cohorts, and the Wilcoxon signed-rank test for pairwise comparisons. All the tests were two-tailed, with a significance level (α) of 0.05.

Results

Among 268 patients included in the analyses, 101 patients received Escitalopram, 87 received Sertraline, and 80 received Amitriptyline. There were 54.5%, 57.5% and 61.3% of men, and the mean (SD) age of patients was 41.8 (13.8) years, 35.5 (13.1) years, and 39.3 (11.8) years, in the three cohorts, respectively. At baseline, the mean doses of the antidepressants were 9.6 (±4.1) mg, 33.5

(±12.1) mg, and 30.3 (±11.5) mg, respectively. There were no significant differences between the HAM-D 17, CGI-S, total EQ-5D-5L health state values, VAS, or C-SSRS scores in the three cohorts at baseline (Table 1).

Efficacy Evaluation :

Hamilton Depression Rating Scale-17 (HAM-D 17)

The change in HAM-D 17 scores from baseline to each time point was compared among the three cohorts. A significant difference was observed between the three cohorts at each timepoint (Table 2, Fig 1A). The change in HAM-D 17 scores from baseline for the Escitalopram cohort was significantly higher than the Sertraline ($p<0.005$) and Amitriptyline cohorts ($p<0.005$), with no significant difference observed between the latter two.

Each cohort was also analyzed separately. A significant reduction ($p<0.005$) in HAM-D 17 scores was reported at Week 2, Week 4, Week 6, and Week 8 compared to baseline for each cohort (Table 2).

Response and Remission Rates

Overall, response was achieved by <20% of patients at Week 2 and increased gradually. In all three cohorts, >60% of patients achieved response at Week 8. The response rate was higher in the Escitalopram than the Sertraline and Amitriptyline cohorts at all the study time points (Fig 1B)

Remission was achieved by <10% of patients at Week 2 across all three cohorts and increased gradually thereafter. However, >50% of patients on Escitalopram achieved remission at Week 4, and >72.3% at Week 8, while the rate of remission stayed <40% at Week 8 for Sertraline and Amitriptyline cohorts (Fig 1C).

Table 1 — *Baseline demographic and clinical characteristics of patients*

	Escitalopram (n=101)	Sertraline (n=87)	Amitriptyline (n=80)	*p*-value
Age (years), mean (SD)	41.8 (13.8)	35.5 (13.1)	39.3 (11.8)	0.002
Sex				0.656
Male, n (%)	55 (54.5)	50 (57.5)	49 (61.3)	NA
Female, n (%)	46 (45.5)	37 (42.5)	31 (38.8)	NA
Concomitant medication, n (%)	20 (19.8)	16 (18.4)	22 (27.5)	0.308
Dose (mg), mean (SD)	9.6 (4.1)	33.5 (12.1)	30.3 (11.5)	NA
HAM-D 17 score, mean (SD)	24.8 (8.4)	25.9 (6.5)	24.0 (6.5)	0.531
CGI-S score, mean (SD)	5.2 (1.1)	4.7 (1.2)	4.3 (0.9)	0.066
EQ-5D-5L health state value score, mean (SD)	14.4 (3.5)	14.4 (4.0)	13.1 (3.1)	0.824
Mobility	1.7 (0.9)	2.4 (1.0)	2.2 (0.9)	NA
Self-care	2.2 (1.1)	2.7 (1.0)	2.1 (0.9)	NA
Pain	2.9 (1.2)	2.7 (1.2)	3.1 (0.9)	NA
Anxiety/depression	4.1 (0.9)	3.4 (1.0)	3.2 (0.6)	NA
Usual activities	3.4 (1.0)	3.2 (0.9)	2.6 (0.8)	NA
EQ-5D-5L visual analogue score, mean (SD)	74.2 (16.3)	67.2 (18.4)	59.0 (16.1)	0.069
C-SSRS score, mean (SD)	2.1 (2.5)	1.7 (2.3)	1.8 (2.8)	0.239
Patients with suicidal tendency/ideation, n (%)	59 (58.4)	49 (56.3)	45 (56.3)	0.944

CGI-S:Clinical Global Impression-Severity of illness, C-SSRS:Columbia-Suicide Severity Rating Scale, EQ-5D-5L:European Quality of Life Five Dimension Five Level, HAM-D 17:Hamilton Depression Rating Scale-17, SD:Standard Deviation.

HAM-D 17 Subscale Scores

To better understand the efficacy of antidepressants, few components of HAM-D 17 were compared between the groups at Week 8 (Table 2). The scores for Escitalopram cohort were significantly lower than Sertraline ($p<0.005$) and Amitriptyline ($p<0.005$) on most subscales (depressed mood, sleep disorder, work and activities, anxiety, somatic symptoms, hypochondriasis, and insight). For the retardation subscale, both Escitalopram ($p<0.005$) and Amitriptyline cohort ($p=0.006$) had significantly lower scores than Sertraline. For hypochondriasis, the scores for Sertraline were significantly lower than Amitriptyline cohort ($p=0.023$).

Clinical Global Impression (CGI)

The CGI-S values for all three cohorts reduced over time. A significant difference was observed between CGI-S scores of the three cohorts at Week 2 ($p=0.001$), Week 6 ($p=0.002$), and Week 8 ($p<0.005$). At Week 8, patients in the Escitalopram cohort had significantly lower scores ($p<0.005$) than the other two cohorts, while the scores of Sertraline and Amitriptyline cohorts were not statistically different from each other (Fig 2A).

The CGI-I values for all three cohorts reduced over time. The CGI-I values in the Escitalopram cohort were significantly lower at Week 6 and Week 8 compared to the Sertraline ($p<0.005$) and Amitriptyline cohorts ($p<0.005$) (Fig 2B).

EQ-5D-5L Health State Values and Visual Analogue Scale (VAS)

At Week 8, the total EQ-5D-5L values and individual values for all 5 dimensions in the Escitalopram cohort were significantly lower than Sertraline ($p<0.005$) and Amitriptyline cohorts ($p<0.005$) (Table 2). At Week 8, total EQ-5D-5L values for Sertraline and Amitriptyline cohorts were not statistically different from each other, and for the dimensions of mobility, anxiety, and usual activities. For the dimension of self-care, Amitriptyline cohort reported significantly lower values than Sertraline ($p=0.022$), and for pain, Sertraline cohort had significantly lower values ($p=0.013$) compared to Amitriptyline (data not shown).

The VAS scores for all 3 cohorts reduced over time (Fig 2C). A significant difference was observed between the three cohorts at Week 2 ($p<0.005$), Week 4 ($p=0.027$), Week 6 ($p=0.003$), and Week 8 ($p<0.005$). While patients in the Amitriptyline cohort had significantly lower VAS scores compared to the other two cohorts ($p<0.005$) at Week 2, patients in the Escitalopram cohort reported significantly lower values ($p<0.005$) at Week 8. Sertraline and Amitriptyline cohorts did not report statistically different values at Week 8.

Table 2 — *Comparison of change in HAM-D 17 scores between and within cohorts at each time point, and summary of HAM-D 17 subscale scores, EQ-5D-5L health state values, and C-SSRS scores*

Change in HAM-D 17 scores between cohorts

	Escitalopram (n=101)	Sertraline (n=87)	Amitriptyline (n=80)			Escitalopram vs Sertraline	Escitalopram vs Amitriptyline	Sertraline vs Amitriptyline
	Change in HAM-D 17 score			H*	p-value	p-value (pair-wise comparisons)		
Change from Baseline to Week 2	7 (4-10)	3 (3-5)	3 (2-4)	55.6	<0.005	<0.005	<0.005	0.691
Change from Baseline to Week 4	13 (9-20)	7 (6-11)	7 (6-9)	54.2	<0.005	<0.005	<0.005	0.200
Change from Baseline to Week 6	16 (13-23)	11 (9-14.5)	11 (8-13.25)	48.1	<0.005	<0.005	<0.005	0.223
Change from Baseline to Week 8	18 (15-25)	15 (12-18)	15 (11.75-17)	36.7	<0.005	<0.005	<0.005	0.236

Change in HAM-D 17 scores within cohorts

	Escitalopram (n=101)		Sertraline (n=87)		Amitriptyline (n=80)	
	HAM-D 17 score	p-value	HAM-D 17 score	p-value	HAM-D 17 score	p-value
Baseline	26 (18-30)	NA	24 (22-28)	NA	25 (18-28)	NA
Week 2	17 (12-24)	<0.005	21 (18-24)	<0.005	22 (15-24.25)	<0.005
Week 4	7 (5-16)	<0.005	17 (12-20)	<0.005	17.5 (11-20)	<0.005
Week 6	4 (2-12)	<0.005	14 (7-16.5)	<0.005	14 (6-17)	<0.005
Week 8	1 (0-8)	<0.005	11 (4-13)	<0.005	10 (3.75-14)	<0.005

HAM-D 17 subscale scores at Week 8

	Escitalopram (n=101)	Sertraline (n=87)	Amitriptyline (n=80)		Escitalopram vs Sertraline	Escitalopram vs Amitriptyline	Sertraline vs Amitriptyline
	Subscale score			p-value	p-value (pair-wise comparisons)		
HAM-D 17 depressed mood subscale	0 (0-1)	1 (1-1)	1 (1-1.25)	<0.005	<0.005	<0.005	0.365
HAM-D 17 sleep disorder subscale	0 (0-0)	0 (0-1)	0 (0-1)	<0.005	<0.005	<0.005	0.756
HAM-D 17 work and activities subscale	0 (0-0)	1 (0-1)	0 (0-2)	<0.005	<0.005	<0.005	0.712
HAM-D 17 retardation subscale	0 (0-0)	0 (0-1)	0 (0-0)	0.001	<0.005	0.430	0.006
HAM-D 17 anxiety somatic symptoms subscale	0 (0-0)	1 (0-1)	1 (0-1)	<0.005	<0.005	<0.005	0.550
HAM-D 17 hypochondriasis subscale	0 (0-0)	0 (0-0)	0 (0-1)	<0.005	0.005	<0.005	0.023
HAM-D 17 insight subscale	0 (0-0)	0 (0-1)	0 (0-1)	0.001	0.021	<0.005	0.201

EQ-5D-5L health state values

	Escitalopram (n=101)	Sertraline (n=87)	Amitriptyline (n=80)		Escitalopram vs Sertraline	Escitalopram vs Amitriptyline	Sertraline vs Amitriptyline
	Health state value score (Total score)			p-value	p-value (pair-wise comparisons)		
Baseline	14 (11-16)	13 (12-16)	14 (12-16)	0.824	NA	NA	NA
Week 2	11 (10-13)	11 (9-14)	11(9-13)	0.428	NA	NA	NA
Week 4	8 (7-10)	9 (8-11)	10 (8-11)	<0.005	<0.005	<0.005	0.733
Week 6	6 (6-7)	8 (7-9)	8 (6-10)	<0.005	<0.005	<0.005	0.715
Week 8	5 (5-6)	7 (6-8)	7(6-8)	<0.005	<0.005	<0.005	0.642

C-SSRS scores

	Escitalopram (n=101)	Sertraline (n=87)	Amitriptyline (n=80)		Escitalopram vs Sertraline	Escitalopram vs Amitriptyline	Sertraline vs Amitriptyline
	CSSRS score			p-value	p-value (pair-wise comparisons)		
Baseline	2 (0-3)	1 (0-2)	1 (0-2)	0.240	NA	NA	NA
Week 2	0 (0-2)	0 (0-2)	0 (0-1)	0.216	NA	NA	NA
Week 4	0 (0-0)	0 (0-0)	0 (0-0)	0.710	NA	NA	NA
Week 6	0 (0-0)	0 (0-0)	0 (0-0)	0.005	0.004	0.008	0.875
Week 8	0 (0-0)	0 (0-0)	0 (0-0)	0.004	0.010	0.002	0.614

*The test statistic is adjusted for ties. All values are presented as median and interquartile range. C-SSRS, Columbia-Suicide Severity Rating Scale; EQ-5D-5L, European Quality of Life Five Dimension Five Level; H, Kruskal Wallis H statistic; HAM-D 17, Hamilton Depression Rating Scale-17.

Safety Evaluation :

Columbia-Suicide Severity Rating Scale (C-SSRS)

The C-SSRS scores were not significantly different between the three cohorts at baseline, Week 2 and Week 4, but reduced over time (Table 2). At Week 6 and Week 8, the scores were significantly lower in Escitalopram compared to Sertraline (p=0.004; p=0.01) and Amitriptyline cohorts (p=0.008; p=0.002).

Similarly, there was a reduction in the number of patients with suicidal ideation/behaviour over time in all three cohorts (Fig 3).

Adverse Events (AEs)

During the study, AEs were reported by 245 (91.4%) patients: Escitalopram: 96 (95%), Sertraline: 72 (82.8%), and Amitriptyline: 77 (96.2%). The most frequently reported AEs were insomnia (42.6%) and nausea (35.6%) with Escitalopram, nausea (31.0%) and anorexia (29.9%) with Sertraline, and constipation (81.3%) and dry mouth (61.3%) with Amitriptyline. Most were Grade 1 or Grade 2 in intensity. Table 3 summarizes the AEs reported during the study. In addition to the solicited AEs listed in the CRF, two unsolicited AEs of irritability (n=1) and erectile dysfunction (n=2) were reported.

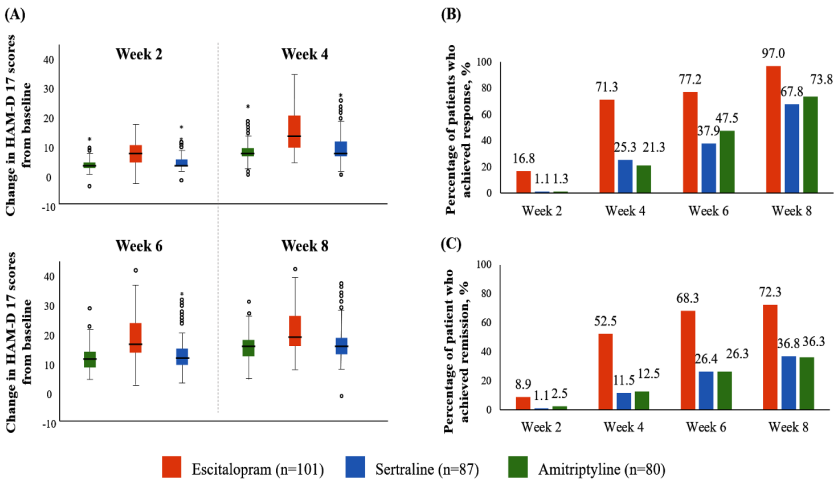

Fig 1 — (A) Comparison of change in HAM-D 17 scores between cohorts at each time point, (B) Response rates from baseline to Week 8, and (C) Remission rates from baseline to Week 8

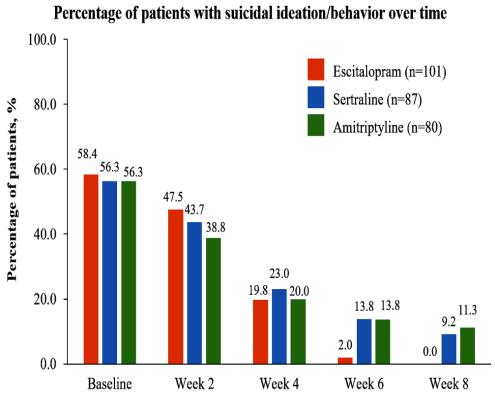

Fig 3 — Percentage of patients with suicidal ideation/ behavior over time

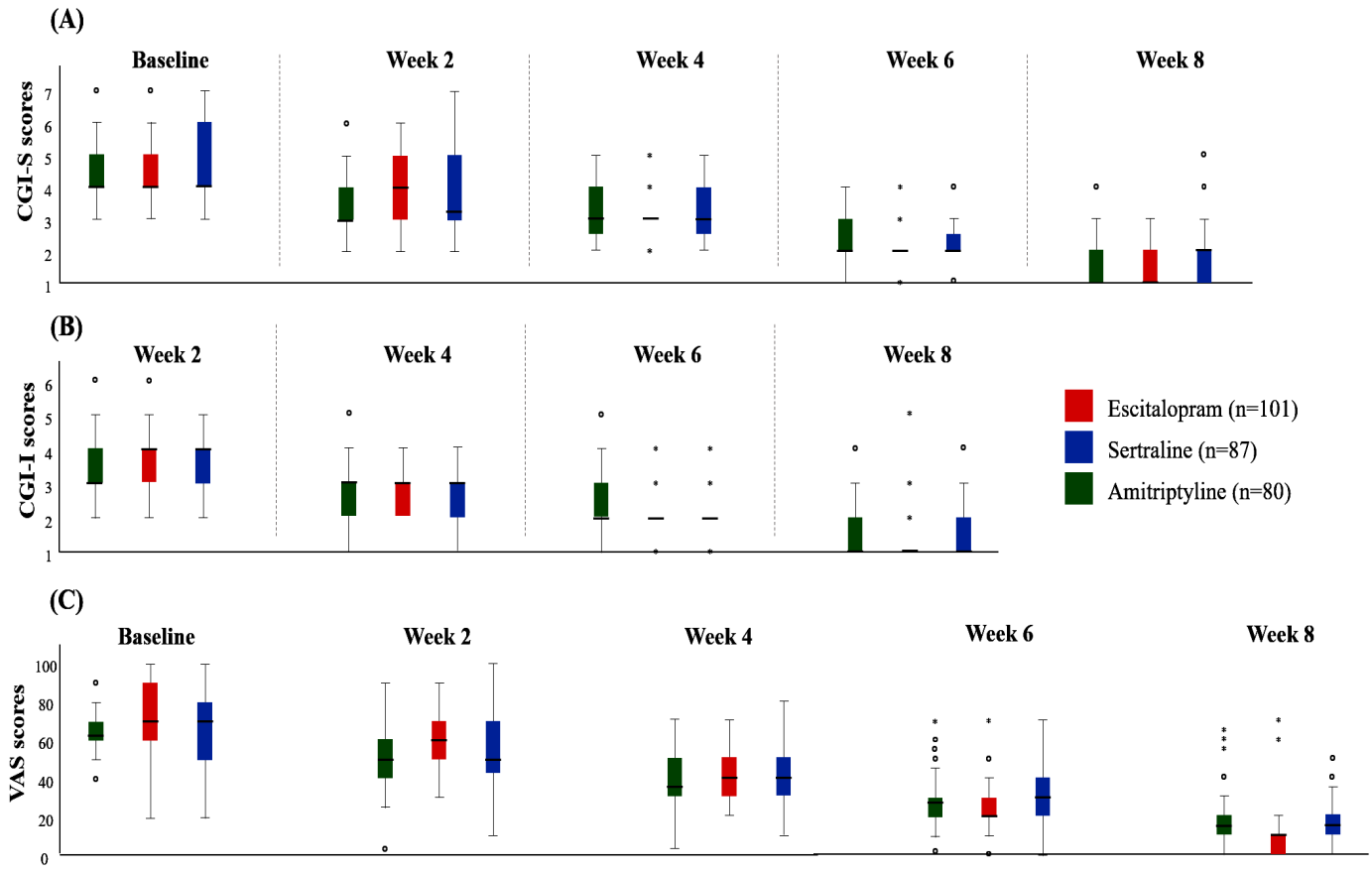

Fig 2 — (A) Comparison of CGI-S, (B) CGI-I, and (C) EQ-5D-5L-VAS scores between cohorts at each time point

Discussion

To the best of our knowledge, this is the first study comparing the efficacy and safety of three commonly prescribed antidepressants, Escitalopram, Sertraline, and Amitriptyline, in the real-world in the Indian population. The HAM-D 17 is widely recognised for its reliability in measuring depression[17]. Depression is associated with substantial disability[18], underscoring the importance of investigating the potential impact of antidepressants on QoL. Data of the first 50 patients has been previously published[2].

Previously, global and Indian studies have demonstrated improvement with Escitalopram[19] and Sertraline[7]. By Week 2, all three antidepressants led to a significant decrease in HAM-D 17 scores, consistent with existing literature indicating early onset of action compared to placebo[7,20]. Escitalopram was found to be better than Sertraline and Amitriptyline, exhibiting significantly lower HAM-D 17, CGI-S, and CGI-I scores. Escitalopram has previously demonstrated comparable efficacy to Agomelatine, Desvenlafaxine[21] and Duloxetine in the Indian population, with early onset[22] and statistically better efficacy than Desvenlafaxine[23]. In this study, Escitalopram continued to show significantly higher overall efficacy and superiority in addressing insomnia, work and activities, anxiety, and insight by Week 8, indicating that Escitalopram may be considered over other anti-depressants for patients with these comorbidities. Additionally, a previous randomized study reported that Escitalopram improved psychomotor functions while Amitriptyline deteriorated them[20]. Response and remission rates were also significantly better in the Escitalopram cohort.

Quality of Life is a vital outcome measure for psychiatric interventions, offering valuable insights into the burden of depressive disorders and informing intervention strategies[24]. Habits, physical changes, or medical conditions that develop during depression do not necessarily reverse when depression remits[18]. Unlike some studies suggesting no effect of second-generation antidepressants like Escitalopram and Sertraline on QoL[25], the current study demonstrated improvements in QoL with all three antidepressants by the end of the study. While Escitalopram consistently yielded better outcomes across domains, variations were noted in self-care and pain domains. Despite belonging to the same class of antidepressants, our findings underscore significant differences between Escitalopram and Sertraline in both efficacy and QoL. Suicidal ideation is more prevalent in psychiatric patients, particularly in those with depressive disorders[18,26]. Some studies have linked antidepressant use to an increase in suicidal tendency[8], especially in young individuals, potentially uncovering bipolar disorder or inducing mixed states[27]. Conversely, this study suggested a reduction in suicidal tendency among patients on antidepressants for all three cohorts. By the end of the study, no patients had suicidal ideation/behaviour in the Escitalopram cohort.

Most patients (>90% from Escitalopram and Amitriptyline cohorts; >80% from the Sertraline cohort) reported AEs.

Table 3 — *Number of patients with adverse events reported during the study in each cohort*

	Escitalopram (n=101)					Sertraline (n=87)					Amitriptyline (n=80)				
	Patients with AEs, n (%)														
	Total	G1	G2	G3	G4	Total	G1	G2	G3	G4	Total	G1	G2	G3	G4
Anxiety	13 (12.9)	2	8	3	0	17 (19.5)	0	5	12	0	1.0 (1.3)	1	0	0	0
Anorexia	23 (22.8)	14	7	1	1	26 (29.9)	4	15	7	0	5 (6.3)	2	1	2	0
Asthenia	8 (7.9)	4	3	1	0	3 (3.4)	1	2	0	0	4 (5.0)	2	1	1	0
Constipation	5 (5.0)	2	1	1	1	3 (3.4)	2	1	0	0	65 (81.3)	28	23	13	1
Decreased libido	6 (5.9)	3	2	0	1	6 (6.9)	4	1	0	0	3 (3.8)	2	0	1	0
Diarrhea	11 (10.9)	8	3	0	0	15 (17.2)	6	7	2	0	0	0	0	0	0
Dizziness	10 (9.9)	5	2	3	0	2 (2.3)	0	2	0	0	15 (18.8)	3	7	4	1
Dry mouth	12 (11.9)	6	4	1	1	8 (9.2)	2	3	3	0	49 (61.3)	22	14	13	0
Dyspepsia	19 (18.8)	7	6	3	3	21 (24.1)	3	11	7	0	6 (7.5)	3	2	1	0
Fatigue	13 (12.9)	5	5	1	2	5 (5.7)	1	4	0	0	1 (1.3)	0	1	0	0
Headache	22 (21.8)	7	6	9	0	9 (10.3)	0	6	3	0	0	0	0	0	0
Insomnia	43 (42.6)	13	17	9	4	14 (16.1)	2	4	8	0	1 (1.3)	0	1	0	0
Nausea	36 (35.6)	17	15	4	0	27 (31.0)	10	10	7	0	9 (11.3)	4	4	1	0
Somnolence	4 (4.0)	2	2	0	0	3 (3.4)	2	1	0	0	31 (38.8)	10	17	4	0
Upper abdominal pain	6 (5.9)	2	3	1	0	13 (14.9)	2	5	6	0	3 (3.8)	1	2	0	0
Vomiting	11 (10.9)	8	2	1	0	5 (5.7)	2	2	1	0	0	0	0	0	0
Giddiness	1 (1.0)	0	1	0	0	0	0	0	0	0	1 (1.3)	1	0	0	0
Irritability	1 (1.0)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Erectile dysfunction	2 (2.0)	1	1	0	0	0	0	0	0	0	0	0	0	0	0

AE:Adverse Event, G:Grade

SSRIs commonly cause nausea and anorgasmia[18]. Previously, Escitalopram and Sertraline have induced higher AEs than other antidepressants, with Insomnia, Weight gain, and anxiety being the most common. In the current study, the most frequently reported AEs for Escitalopram were Insomnia (42.6%) and Nausea (35.6%), along with Headache, Anxiety, Fatigue and Gastrointestinal disturbances such as Anorexia, Diarrhea, Dry mouth, Vomiting and Dyspepsia (>10%). These findings align with Escitalopram's known profile, including higher incidence of headache, pruritus, memory impairment, decreased concentration, and dizziness compared to Sertraline and Fluoxetine[5], with weight gain, gastrointestinal intolerance, and sexual disturbances leading to discontinuation[28]. Although there have been case reports of akathisia[8], hyponatremia[29], mastalgia, and galactorrhea[30] induced by Escitalopram, no such cases were reported in this study. The high rate of insomnia needs to be interpreted with caution, as insomnia is also a symptom of the disease itself. Sertraline has previously demonstrated a significant reduction in appetite compared to Escitalopram[5]. Similar findings were observed in the current study with a high incidence of anorexia (>25%). Tricyclic antidepressants are associated with dry mouth and constipation[18]. As anticipated, Amitriptyline demonstrated a high incidence (>80%) of constipation and dry mouth (>60%). Most of the AEs reported during the study were Grade 1 or 2 in intensity. Unlike many studies that have reported high rates of sexual dysfunction associated with SSRIs, especially Escitalopram[28] and Sertraline[31], the rates of decreased libido were low (<10%) in the current study. Comparison of the three cohorts revealed that the rate of AEs was highest in the Amitriptyline cohort and similar between the other two.

This study had some limitations. As the discrete data for the study was collected in the real world, it was not normally distributed and did not follow normality assumptions despite being converted into logarithmic scale or percentage change. Non-parametric tests were thereby applied to the discrete data for hypothesis testing. Other limitations of the study included a small sample size and limited data on HAM-D 17 subscale scores. Additionally, the impact of confounders such as exercise or physiotherapy was not measured in the current study.

With the emergence of newer classes of antidepressants, it is necessary to continue to compare the efficacy and safety profiles of frequently prescribed drugs, especially in the real-world, which will help regulatory authorities in making sound decisions on the need for continuity or change in the treatment recommendations for depression in India.

Conclusion

Our findings indicate that all three drugs showed improvement starting at Week 2, with significant progress observed by Week 8. However, Escitalopram demonstrated higher efficacy than Sertraline and Amitriptyline, notably improving QoL and suitability for patients with anxiety and work-related disturbances. Each drug reduced suicidal tendencies with Escitalopram showing the best results. Safety profiles were consistent with known literature, with the Amitriptyline cohort reporting higher incidence of AEs.

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References

1 Arvind BA, Gururaj G, Loganathan S, Amudhan S, Varghese M, Benegal V, *et al* — Prevalence and socioeconomic impact of depressive disorders in India: multisite population-based cross-sectional study. *BMJ open* 2019; **9(6):** e027250.

2 Dharadhar S, Sharma A. Real-world observational study of escitalopram for newly diagnosed versus relapsed patients with major depressive disorder in India. *Natl J Physiol Pharm Pharmacol* 2022; **12(9):** 1399-407.

3 Newale S, Patel K, Fegade T — A cross-sectional, multi-centric, non-interventional study to understand the management practices of major depressive disorder in India (DMI: Depression Management in India) Sanket Newale, Patel K, Fegade T. *The Indian Practitioner* 2019; **68(8):** 31-8.

4 Beg MA — A Comparative drug utilization study of depression patients between tertiary care teaching hospital and private practitioners of Dehradun city, Uttarakhand. *Journal of Drug Delivery and Therapeutics* 2013; **5(2):** 45-9.

5 Anagha K, Shihabudheen P, Uvais NA — Side Effect Profiles of Selective Serotonin Reuptake Inhibitors: A Cross-Sectional Study in a Naturalistic Setting. *The primary care companion for CNS disorders* 2021; **23(4)**.

6 Newale S, Bachani DS — Detection, Management Approach of Depression and Antidepressant Utilization in Adult Patients: Results of a Cross-Sectional Survey. *The Journal of the Association of Physicians of India* 2016; **64(10):** 52-7.

7 Wagner KD, Ambrosini P, Rynn M, Wohlberg C, Yang R, Greenbaum MS, *et al* — Efficacy of sertraline in the treatment of children and adolescents with major depressive disorder: two randomized controlled trials. *JAMA* 2003; **290(8):** 1033-41.

8 Pratap A, Akhtar S, Sinha P, Bakhla AK — Escitalopram-induced severe akathisia leading to suicide attempt. Industrial psychiatry Journal 2019; **28(2):** 315-7.

9 Rajgadhi H, Gupta S, Malhotra SD, Thakor A, Patel P — Antidepressants triggering suicidal ideation: An area of concern. *Indian journal of pharmacology* 2016; **48(6):** 733-5.

10 Jakobsen JC, Gluud C, Kirsch I — Should antidepressants be used for major depressive disorder? *BMJ evidence-based medicine* 2020; **25(4):** 130.

11 Almohammed OA, Alsalem AA, Almangour AA, Alotaibi LH, Al Yami MS, Lai L — Antidepressants and health-related quality of life (HRQoL) for patients with depression: Analysis of the medical expenditure panel survey from the United States. *PloS one* 2022; **17(4):** e0265928.

12 Pillai A, Keyes KM, Susser E — Antidepressant prescriptions and adherence in primary care in India: Insights from a cluster randomized control trial. *PloS one* 2021; **16(3):** e0248641.

13 Mandal T, Bairy LK, Sharma PSVN, Valaparla VL — Impact of gender, depression severity and type of depressive episode on efficacy and safety of escitalopram: an observational study on major depressive disorder patients in southern India. *The Egyptian Journal of Neurology, Psychiatry and Neurosurgery* 2021; **57(1):** 47.

14 Wade AG, Crawford GM, Yellowlees A — Efficacy, safety and tolerability of escitalopram in doses up to 50 mg in Major Depressive Disorder (MDD): an open-label, pilot study. *BMC psychiatry* 2011; **11:** 42.

15 Preskorn SH, Lane RM — Sertraline 50 mg daily: the optimal dose in the treatment of depression. International clinical psychopharmacology 1995; **10(3):** 129-41.

16 Thour A, RM Amitriptyline. [Updated 2023 Feb 16]. In: StatPearls [Internet]: StatPearls Publishing; Feb 2023. p. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537225/.

17 Olden M, Rosenfeld B, Pessin H, Breitbart W — Measuring depression at the end of life: is the Hamilton Depression Rating Scale a valid instrument? Assessment 2009; **16(1):** 43-54.

18 Andrade C — A Primer on How to Critically Read an Observational Study on Adverse Medical Outcomes Associated With Long-Term Antidepressant Drug Use. *The Journal of clinical psychiatry* 2022; **83(6)**.

19 Andrade C, De Sousa A, Shah N — Efficacy outcomes in the MDD-1 India study: First episode major depressive disorder outcomes in antidepressant-treated real-world patients in India. *Journal of psychopharmacology (Oxford, England)* 2020; **34(10):** 1098-104.

20 Modi A, Desai M, Shah S, Parikh M — A randomized open label study to evaluate the effects of escitalopram and mirtazapine on psychomotor functions and memory in patients with depression. *Journal of Pharmacology and Pharmacotherapeutics* 2018; **9(4):** 174-9.

21 Maity N, Ghosal MK, Gupta A, Sil A, Chakraborty S, Chatterjee S — Clinical effectiveness and safety of escitalopram and desvenlafaxine in patients of depression with anxiety: a randomized, open-label controlled trial. *Indian journal of pharmacology* 2014; **46(4):** 433-7.

22 Urade CS, Mahakalkar SM, Tiple PG — A comparative study of the clinical efficacy and safety of agomelatine with escitalopram in major depressive disorder patients: A randomized, parallel-group, phase IV study. *Journal of pharmacology & pharmacotherapeutics* 2015; 6(4): 198-203.

23 Mahajan SS, Tandon VR, Arora M, Mahajan A, Kotwal S — Comparative Efficacy and Safety of Escitalopram versus Desvenlafaxine in Postmenopausal Women with Depression and Anxiety: A Randomized, Open-Label, Comparative Trial. *Journal of mid-life health* 2019; **10(3):** 141-6.

24 Ara SK — Analysis of the prescribing pattern of antidepressants and the side effects in depression patients. *Journal of family medicine and primary care* 2022; **11(11):** 6640-5.

25 Teng T, Zhang Z, Yin B, Guo T, Wang X, Hu J, *et al* — Effect of antidepressants on functioning and quality of life outcomes in children and adolescents with major depressive disorder: a systematic review and meta-analysis. *Translational psychiatry* 2022; **12(1):** 183.

26 Belsiyal CX, Rentala S, Das A — Frequency of suicide ideation and attempts and its correlates among inpatients with depressive disorders at a tertiary care center in North India. *Journal of family medicine and primary care* 2022; **11(6):** 2537-44.

27 Brent DA — Antidepressants and Suicidality. *The Psychiatric clinics of North America* 2016; **39(3):** 503-12.

28 Mansharamani D, Awana S, Jagannath G, Ali J, Shah N, Swami O — Escitalopram Usage Pattern in India: A Knowledge, Attitude and Practice Survey among Indian Psychiatrists. *British Journal of Medicine and Medical Research* 2016; **16:** 1-13.

29 Rawal G, Kumar R, Yadav S — Severe hyponatremia associated with escitalopram. *Journal of family medicine and primary care* 2017; **6(2):** 453-4.

30 Pathania M, Goel B, Dhamija P, Kant R, Dhar M, Mittal S — A rare adverse drug reaction to escitalopram. *Journal of family medicine and primary care* 2018; **7(2):** 466-7.

31 Bathla M, Anjum S — A 12-week prospective randomized controlled comparative trial of vilazodone and sertraline in Indian patients with depression. *Indian journal of pharmacology* 2020; **52(1):** 10-5.

Review Article

Recent Supreme Court Judgements bring Urgency to a Sociolegal Review of the Inclusion of Medical Profession in the Consumer Act

Supratik Sanatani[1], Paromita Sanatani[2]

Abstract

Background : A three judge bench of the Supreme Court in Bar Association of Indian Lawyers *versus* DK Gandhi has allowed the inclusion of Medical Profession in the Consumer Protection Act (CPA) while keeping lawyers out of its purview. It was first included in the CPA by the judgement in Indian Medical Association *versus* VP Shanta by interpreting the word "any" before "service" and by classifying medical treatment as a "contract for service" and not "contract of service "which is excluded. Medical Profession neither figures in the legislative intent leading to the act nor in the United Nations Resolution on Consumer Protection which inspired it. CPA does not regulate the Medical Profession by acts such as the National Medical Commission Act 2019 which registers doctors. CPA neither gives any specific direction to the medical profession as by acts like the Medical Termination of Pregnancy Act 1971 nor does it have any reference to the Medical Profession as in General Acts such as the Bharatiya Nyaya Sanhita 2023. Yet the largest number of medical complaints are adjudicated by the Consumer Courts where in 70 % of cases no expert opinion is taken to favor a summary trial. However, this intent is defeated since a medicolegal complaint on an average takes 8.04 years to resolve. Consumer Court judgements, however, influence contemporary medical treatment protocols in diverse areas from consent taking, investigations in common cases like Acute Appendicitis to the interpretation of the specialist qualification of an Anaesthetist. CPA has spurred the rise of defensive practice which is detrimental to the Health Care Delivery System of the country. It violates fundamental rights of the citizens and the doctors. A review of the inclusion of medical treatment in CPA as pointed out in the SC judgement, is the need of the hour.

Key words : Supreme Court, Consumer Protection Act, Defensive Medical Practice.

A three-judge bench of the Supreme Court (SC) reconfirmed the inclusion of medical profession in the Consumer Protection Act (CPA) as earlier decided in Indian Medical Association *versus* VP Shanta[1]. It, however, left other factors to be considered in a future trial. Earlier a two-judge bench of the SC in Bar of Indian Lawyers *versus* D K Gandhi[2] had questioned its inclusion. This review examines some of the fall outs of the continuation of medical profession in the CPA which lends urgency to a sociolegal examination.

Editor's Comment :

- A new court case based on socio legal facts is needed to examine the fallouts of the inclusion of Medical Profession in the Consumer Protection Act since it is leading to defensive medical practice and increasing the cost of treatment.

History of the Inclusion of Medical Profession in CPA

Consumer Protection Act 1986 was the first act in India to curb unfair trade practices and strengthen consumer rights[3]. It was enacted in response to the United Nations General Assembly declaration number 39/248 (1985) on consumer rights which urged Governments to implement consumer protection policies[4]. CPA set up consumer courts in the districts, states and at the national level for speedy disposal of consumer grievances. Medical profession, however, was neither mentioned in the United Nations Declaration nor in the CPA 1986 which followed. There was no legislative intent to include Medical Profession in CPA as evident from the parliamentary debate which preceded the enactment of the act. Indian Medical Association *versus* VP Shanta, SC (1995) first included medical profession under the CPA when it interpreted the preposition "any" before the word "services"[5]. The CPA offered the consumer an opportunity for a summary trial. Consumer Courts, therefore, became the first forum for grievance related to medical treatment.

The CPA 1986 was repealed by the CPA 2019 which changed the pecuniary powers of the various Consumer Courts and also introduced mediation[6]. Even though the Minister of Consumer Affairs Late Mr Ram Vilas Paswan mentioned in the parliamentary debate introducing the bill that medical profession would be outside the purview of the act, the final draft accepted by the Parliament still contained the word "any" qualifying services even though "medical" was not specifically mentioned[7]. Services offered free of charge and those under a "personal contract" were excluded. A public interest litigation against this act, citing the views of the Minister in the Parliamentary debate was rejected by the Bombay High Court in Medicos legal Action Group *versus* Union of India (2019).

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Analysis of Laws regulating medical profession and the Consumer Protection Act

The CPA 2019 or its predecessor CPA 1986 do not have any directions remotely related to the conduct of a Medical Professional. This in contrast to the regulatory laws which ensure that the citizens receive safe and effective medical treatment. These include the acts for registering qualified and trained Medical Professionals (Table 1), laws which regulate specific clinical areas of a medical professional eg abortion, organ donation and surrogacy (Table 2) and some general acts and regulations which have specific non clinical directions for the medical professionals such as criminal liability, clinical waste disposal and professional ethics and conduct (Table 3).

Yet the consumer courts are the first forum for medical grievance. In 70% cases they try medical complaints without an expert opinion which often lead to a disconnect between popular perception and professional practice. V Kishan Rao *versus* Nikhil Super Specialty Hospital & Anr felt that the confusion of diagnosis between typhoid and malaria was a simple issue not meriting an expert opinion, in the process overlooking a diagnostic dilemma which continues to be highlighted in academic journals as a clinical challenge[8,9].

Effect of the Inclusion of Medical Treatment in CPA

Consumer Court judgements create sensational headline in the lay press by causing knee jerk reactions in management protocol which is not always in the patient's best interest. A few of such instances are highlighted.

Table 1 — Acts registering medical professionals

(1)	National Medical Commission Act 2019
(2)	National Commission for Indian System of Medicine Act 2020
(3)	National Dental Commission Act 2020
(4)	National Commission of Homeopathy Act 2020
(5)	National Nursing and Midwifery Commission Act 2023
(6)	The Pharmacy Act 1948
(7)	The National Commission for Allied and Healthcare Professions (NCAHP) Act, 2021

Table 2 — *Acts providing directions for medical professionals in specific clinical conditions*

(1)	Mental Health Act 2017
(2)	HIV & AIDS (prevention & control act) 2017
(3)	Medical Termination of Pregnancy Act 1971
(4)	Pre Conception & Pre Natal-Diagnostics Techniques Act 1994
(5)	Transplantation of Human Organs & Tissue Act 1994
(6)	Assisted Reproductive Technology (regulation) Act 2021
(7)	Surrogacy (Regulation) Act 2021

Table 3 — *Acts with miscellaneous direction for medical professionals*

(1)	Bharatiya Nyaya Sanhita 2023
(2)	Epidemic Disease Act 1897
(3)	Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
(4)	Biomedical Waste Management Rules 2016
(5)	Indian Medical Council (Professional Conduct & Ethics Regulation) 2002
(6)	Drugs and Cosmetic Control Act 1940

Consent :

In Samira Kohli *versus* Dr Prabha Manchanda a consent for diagnostic laparoscopy was obtained from an unmarried lady who subsequently needed a total Hysterectomy because of extensive endometriosis discovered in laparoscopy[10]. The consent for Hysterectomy was taken from the mother because then the patient was under anesthesia. The court thought that consent taking was not proper and that the indication of Emergency Hysterectomy was not urgent. It awarded compensation for medical negligence. Since then, doctors' professional organizations have been circulating consent forms of various types without clear uniformity[11]. Some of them mention the probability of cardiac arrest which appears in the product insert of the commonly used local anaesthetic lignocaine injection[12]. This is a source of considerable anxiety to the patient. When Vinod Khanna *versus* RG Stone Urology & Laparoscopy Center ruled that preprinted consent forms are improper, many clinical establishments changed to videography of consent, causing logistic difficulty, adding to the cost without contributing to the success of treatment[13]. In Dr Soumitra Kumar *versus* Debashish Goswami, the doctor was held guilty of taking improper consent because amniotic fluid embolism as a cause of death was not mentioned in the consent form of caesarian section , overlooking the extreme rarity of this condition which occurs in 1: 40,000 to 1 in 50,000 deliveries[14,15].

Computerized Tomography (CT) in Acute Appendicitis:

A Cochrane review found the incidence of Negative Appendicectomy Rate (NAR), where no inflamed appendix was found following Appendicectomy, dropping from 23% to 3% when the use of pre-operative CT scan went up from 10% to 90%[16]. In 2014, 90% of American surgeons used CT for acute appendicitis while 13% of UK doctors used it in 2012. However, CT caused a delay in treatment which exposed the patient to the risk of abscess or perforation. This places the Indian doctor in a piquant situation where he risks a charge of medical negligence if he doesn't inform the risks and benefits of a pre-operative CT to a clinically diagnosed patient of acute appendicitis even when it isn't readily available and affordable. Such a counselling often unsettles the patient and cause a dangerous delay in treatment. The doctor continues to face the risk of a charge of medical negligence since even in a positive CT scan 3% patient will have NAR.

Anesthetists Without Recognized MCI Qualification :

The Government of India recognized in 2002 that the shortage of Anesthetists with Medical Council of India (MCI) recognized qualification threatened its emergency obstetrics and neonatal services. Consequently, the

maternal mortality rate and infant mortality rates, that are key indicators of public health were negatively affected. It, therefore, has a programme to train doctors with MBBS degree to administer anesthesia after three months of training[17]. However, in HM Alkute *versus* Grant Medical Foundation Ruby Hall Clinic (2016) the Consumer Court in Pune held the Anesthetist guilty of medical negligence because he did not possess an MCI recognized degree[18]. This overlooked the judgement of the Kerala High Court in Dr Balachandran *versus* the State of Kerala which had accepted that a six months experience in anesthesia is sufficient for a doctor to be able to work as an Anesthetist[19]. Poor awareness of the rules, regulations, acts and judgements, therefore, continue to threaten a charge of medical negligence to the surgeon for taking the services of an anesthetist without MCI recognized qualification.

Violation of Fundamental Rights of Citizens by the CPA :

The CPA is an impediment to the fundamental rights of the citizens. The violation of right to life under article 21 of the Constitution highlighted in Paschim Banga Khet Mazoor Samity *versus* the State of West Bengal stands to be amplified. In this case one Hashim Sheikh had to run from pillar to the post for getting a state hospital bed to treat his head injury sustained from a train accident[21]. He finally had to be treated in a private hospital for which he was awarded compensation by the court. An enquiry committee of the West Bengal Government had then recommended that the patient should have been treated in a trolly when there was no vacant hospital bed available. However, today such a situation of strained resources does not spare the treating Physician from the charge of medical negligence before a Consumer Court. Compelling a Physician to treat under such compromised situation is a violation of his fundamental right to profession under article 19(1)(g) especially when CPA does not have the power under article 19(6) to override this right[22].

Conclusion

The inclusion of medical profession under the CPA is today in a dire need of review. The initial idea of a speedy trial has been defeated when a review shows that a medicolegal complaint in India takes average 8.04 years to resolve[23]. Its socio-legal fallouts , such as encouraging defensive medical practice, are serious and challenges the nation's health care resources.

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References

1 U Anand, "SC reaffirms doctors' accountability under Consumer Protection Act" Hindustan Times, New Delhi, 8th November 2024
2 Bar of Indian lawyers vs D K Gandhi SC CA 2646/2009 14th May 2024
3 Consumer Protection Act 1986 preamble
4 United Nations General Assembly resolution 39/248 of 9th April 1985
5 Indian Medical Association vs V P Shanta 1995 SCC (6) 651
6 Consumer Protection Act 2019 preamble
7 Lok Sabha, Synopsis of debates 30 July 2019 Parliament of India Lok Sabha Digital Diary
8 V. Kishan Rao vs Nikhil Super Speciality Hospital & Anr SC CA2641/2010 8th Mar 2010
9 Cunha, Burke A.: Malaria or typhoid fever: A diagnostic dilemma? The American Journal of Medicine, Volume 118, Issue 12, 1442 – 1443
10 Samira Kohli vs Dr Prabha Manchanda 2008 (2) SCC 1
11 Kumar A, Mullick P, Prakash S, Bharadwaj A. Consent and the Indian medical practitioner. Indian J Anaesth. 2015 Nov;59(11):695-700..
12 Product insert of Lidocaine HCL US FDA 721566-04 451175A/ Revised February 2010 https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/006488s074lbl.pdf last accessed 22/10/2024
13 Vinod Khanna vs RG Stone Urology and Laparoscopy Center NCDRC CC 428 /2018 6th July 2020
14 Dr Soumitra Kumar vs Debashish Goswami, NCDRC FA 1686/2018 10th February 2025
15 F Gary Cunningham ed, Williams Obstetrics 25 ed Mc Graw Hill 2018 p 785,
16 Rud B, Vejborg TS, Rappeport ED, Reitsma JB, Wille-Jørgensen P. Computed tomography for diagnosis of acute appendicitis in adults. Cochrane Database of Systematic Reviews 2019, Issue 11. Art. No.: CD009977. DOI: 10.1002/14651858.CD009977.pub2
17 Operational Guidelines: Life Saving Anaesthesia Skills (LSAS) & Comprehensive Emergency Obstetric & New Born Care (CEmONC). Ministry of Health & Family Welfare, Govt India , 21st February 2020
18 H.M Alkute & Anr vs Grant Medical Foundation Ruby Hall Clinic & Anr, Maharashtra SCDRC Consumer Case CC/12/32 26th September 2016
19 Dr Balachandran vs the State of Kerala , Kerala High CrA 22/2014 2014 2nd February 2023
20 Constitution of India article 21
21 Paschim Banga Khet Mazoor Samity vs the State of West Bengal 1996 SCC (4) 37
22 Constitution of India article 19(1)(g)
23 Gaurav Aggarwal, Sharad Kumar Agarwal, Poonam Khatri, "Court Judgements on Expert Opinion in Medical Negligence Cases — Systematic Review' J Indian Med Assoc 2023; 121(12): 59-63

Case Series

Modified Electroconvulsive Therapy in Manic Phase of Bipolar Disorder — a Case Series

Aritra Chakraborty[1], Ranjan Bhattacharyya[2], Shatabdi Saha[3], Saswati Nath[4], Uday Sankar Mandal[5]

Abstract

Background : Modified ECT (mECT) is an important non-pharmacological treatment found very effective in severe depressive episodes with or without suicidal thoughts, catatonia, Neuroleptic Malignant Syndrome (NMS), acute psychosis, schizophrenia, depression in pregnancy, severe postpartum depression and psychosis, obsessive compulsive disorder, bipolar disorder in depressive and mixed phases.This is a case series of five cases are who received mECT in manic phase of Bipolar disorder, who didn't respond well to conventional pharmacological and psychological treatment. All the cases symptomatically as well as statistically (using objective YMRS score) found to be improved and no worsening of manic symptom was noticed.

Key words : mECT, Bipolar Disorder, Manic Phase, YMRS Score.

Electroconvulsive Therapy (ECT) is an important non-pharmacological intervention that is particularly effective treatment for patients suffering from certain severe psychiatric disorders. If patients do not respond adequately to pharmacological treatment, develop adverse effects that make medications intolerable or are suffering from severe symptoms that need urgent intervention and rapid response, then we can consider ECT as a useful, safe and sometimes a lifesaving intervention[1].

Editor's Comment :

- Modified Electroconvulsive Therapy (mECT) is an important nonpharmacological intervention for patients suffering from certain severe psychiatric disorders.
- Electroconvulsive Therapy is a safe, useful and sometimes a lifesaving intervention in Manic phase of Bipolar affective disorder.

Case Presentation

We have discussed 5 cases of bipolar affective disorder, current episode manic with psychotic symptoms (ICD-10 diagnosis)[2]. In all the cases, Routine blood investigations, ECG, Chest X-ray, CT scan of the Brain [non-contrast] were done, and they were all within normal limits. Fundus examination was done in every case to rule out raised intracranial tension. They had no other co-morbid physical illnesses. After getting fitness from the Anaesthesia Department and getting proper consent from family members, bitemporal modified Electroconvulsive Therapy (mECT) was given using the RMS PC ECTRON machine at a twice-weekly frequency. Propofol was used as an anesthetic agent and succinylcholine was used as a muscle relaxant. Physiological monitoring was done using pulse oximetry and an electrocardiogram throughout the procedure. Hamilton's cuff method was used to measure seizure duration. Patients were ventilated with 100% Oxygen until spontaneous respiration started. MMSE scoring was done before initiating ECT and at regular intervals to rule out any cognitive impairment[3]. Young Mania Rating Scale (YMRS). Scoring was done at regular intervals to monitor disease severity in all cases[4]. The number of sessions was determined by the treatment response, and it was between 6 and 12 sessions in all cases.

Case Vignettes

Case 1 :

Md SH, a 25-year-old Muslim male from a lower middle-class Urban background, presented demanding and aggressive behavior, impulsive buying, hypersexuality, big talk, suspiciousness towards neighbors, poor sleep. He has had multiple similar kinds of episodes in the last 6 years, along with episodes of low mood, suicidality, anhedonia, poor sleep. He had a provisional diagnosis of Bipolar affective disorder, a current episode of manic episode with psychotic symptoms. He was treated with multiple typical and atypical antipsychotics and mood stabilizers without any long-lasting improvement. After admission to the hospital, he was given up to 300 mg of clozapine for a period of one month. Still, there was no improvement. Routine blood investigations were all within normal limits. So, a modified ECT (mECT) was planned. Dosage of clozapine and mood stabilizers was reduced. Before starting ECT, he was on quetiapine (300 mg), clozapine (50 mg), and clonazepam (1 mg). After gaining fitness from the pre-anaesthetic check-up, he was given 12 sessions of modified ECT. At the beginning of ECT

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treatment, his YMRS score was 40. After the third session, his YMRS score was 32. After the 6th session, YMRS score was 28. After the 12th session, YMRS score was 5. He was discharged in a stable condition (Table 1)

Case 2 :

Mr SM, a 22-year-old male, came to the Psychiatry OPD with chief complaints of aggressive behavior, physical and verbal abusiveness, big talk, suspiciousness and decreased sleep for the last 2 months. His symptoms started 4 years back with a similar kind of presentation and, after a period of 3 years, he totally discontinued medications on his own. He had a past suicide attempt by hanging 3 years back. He also had a history of cannabis and alcohol abuse. He was admitted to the Psychiatry Ward with a provisional diagnosis of 'Bipolar Affective Disorder, Current Episode Manic with Psychotic Symptoms'. He was treated with sodium valproate, lithium carbonate, risperidone, clozapine. In spite of giving high dosages of the above-mentioned medications for adequate duration, there was no significant improvement. His Routine blood investigation reports were all within normal limits. So, after getting consent from family members and the patient and proper pre-aesthetic check-up, he was given 8 sessions of modified ECT. Medications continued during the ECT sessions were clozapine (50 mg), haloperidol (7.5 mg), sodium valproate (600 mg), lorazepam (1 mg), trihexyphenidyl (4 mg). His YMRS score was 42 before starting ECT. After the third session, YMRS score was 30. After the 6th session, YMRS score was 22. After 8 sessions, YMRS score was 6 (Table 2).

Case 3 :

Mr A G, a 37-year-old Hindu male from a lower Socio-economic status, from a Rural background, was presented with an episode of violent behavior, restlessness, tall talks, decreased sleep, refusal to take food for the last 3 weeks. He has had multiple such episodes, along with episodes of low mood, suicidal attempts, staying away from work, poor self-care, in the last 10 years. He had a diagnosed case of Bipolar disorder. Treatment compliance was poor and there was a history of frequent relapses. After getting consent from family members and getting clearance from the Anesthesiologist, he was given 10 sessions of modified ECT. Before ECT, his medications were decreased, and he was on sodium valproate (800mg), olanzapine (5 mg), clozapine (150 mg), trihexyphenidyl (4 mg), propranolol (40 mg). His YMRS score was 38 before starting ECT. After the third session, his YMRS score was 28. After the 6th session, his YMRS score was 24. After the 10th session, his YMRS score was 8 (Table 3).

Table 1 — *Parameters of modified ECT (mECT) of Case 1*

Md SH	Frequency (Hz)	Pulse Width (mSec)	Duration (Sec)	Current (Amp)	Seizure Duration(Sec)
Session-1	90	1.0	1.2	750	73
Session -2	80	1	1	750	58
Session-3	80	1	1	750	46
Session-4	80	1	1	750	52
Session-5	80	1	1	700	50
Session-6	80	1.2	1.4	800	55
Session-7	90	1.4	1.5	800	39
Session-8	90	1.4	1.5	800	29
Session-9	90	1.5	1.6	800	27
Session-10	100	1.5	1.8	800	40
Session-11	110	1.5	2	800	30
Session-12	110	1.5	2.2	800	33

Table 2 — *Parameters of modified ECT (mECT) of Case 2*

Mr SM	Frequency (Hz)	Pulse Width (mSec)	Duration (Sec)	Current (Amp)	Seizure Duration(Sec)
Session-1	90	1.0	1.2	750	40
Session-2	90	1.0	1.2	750	43
Session-3	90	1.0	1.4	800	28
Session-4	90	1.0	1.4	800	26
Session-5	100	1.2	1.5	800	26
Session-6	100	1.2	1.5	800	28
Session-7	110	1.4	1.6	800	37
Session-8	110	1.4	1.6	800	31

Case 4 :

Mr HM, a 25-year-old Hindu male from a Rural background, came to Psychiatry Outdoors with an elevated mood, big talks, aggressive behavior towards family members and others. He was not taking food and was not sleeping properly. He was admitted to Psychiatry Indoors with a provisional diagnosis of Bipolar disorder and, after being given haloperidol and promethazine injections -each 1 ampule twice daily dosage-for 3 days, he was shifted to oral antipsychotics and mood stabilizers. Oral medications were not effective in treating his symptoms even after 6 weeks of treatment. On the other hand, after giving injectable [to control his violence as needed], he developed extrapyramidal symptoms and delirium. His blood investigations, CT Brain, ECG, EEG were all within normal limits. So, he was given modified ECT after getting fitness from anesthesia and obtaining proper consent. Medications continued during ECT were amisulpride (200 mg), divalproex sodium (1000 mg), lorazepam (2 mg), trihexyphenidyl [6 mg]. Just after the first ECT session, he experienced a dramatic improvement. His YMRS score was 42 before starting ECT. After the third session, his YMRS score was 18.

Table 3 — *Parameters of modified ECT (mECT) of Case 3*

Mr AG	Frequency (Hz)	Pulse Width (mSec)	Duration (Sec)	Current (Amp)	Seizure Duration(Sec)
Session-1	90	1.2	1.4	800	26
Session-2	100	1.5	1.8	800	25
Session-3	110	1.5	2	800	30
Session-4	110	1.6	2.4	800	36
Session-5	120	1.6	2.6	800	30
Session-6	120	1.8	2.8	800	30
Session-7	120	1.8	3.0	800	29
Session-8	130	2.0	3.4	800	25
Session-9	140	2.0	3.8	800	28
Session-10	140	2.0	4.1	800	26

After the sixth session, his YMRS score was 5. As there was significant improvement after 6 sessions, ECT was discontinued and the patient was discharged in a stable condition (Table 4).

Case 5 :

Mrs RG, a 25-year-old Hindu female from a Rural background, came to Psychiatry Outdoors with an elevated mood, tall grandiosity, and violent behavior towards neighbors. She was not taking food properly. She has had 3 such episodes in the last 8 years and multiple depressive episodes. She was admitted to Psychiatry Indoors with a provisional diagnosis of Bipolar disorder and, after being given haloperidol and promethazine injections -each 1 ampule twice daily dosage-for 3 days, she was shifted to oral antipsychotics and mood stabilizers. But she was not taking oral medications and refused to take any oral medications in spite of regular counselling. Her blood investigations, CT Brain, ECG, EEG were all within normal limits. So, she was given modified ECT after getting fitness from anaesthesia and obtaining the proper consent. Medications continued during ECT were olanzapine (10 mg), clozapine (25 mg), divalproex sodium (500 mg), clonazepam (0.5 mg). Her YMRS score was 40 before starting ECT. After the third session, her YMRS score was 28. After the sixth session, his YMRS score was 16. After the eighth session, her YMRS score was 8. As there was significant improvement after 8 sessions, ECT was discontinued and the patient was discharged in a stable condition (Table 5).

The age group of these five cases ranges from (22 to 37 years), 4 cases were male and only 1 case was female (Case 5). Number of ECT sessions were 6-12. The YMRS scores in each cases (baseline, midway and at the end were given in Table 6.

Paired 't' test was performed between YMRS score at the beginning and end of applying mECT. The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant. Confidence interval : The mean of YMRS beginning minus YMRS end equals 33.80, 95% confidence interval of this difference: From 30.47 to 37.13 (Table 7).

Table 4 — *Parameters of modified ECT (mECT) of Case 4.*

Mr HM	Frequency (Hz)	Pulse Width (mSec)	Duration (Sec)	Current (Amp)	Seizure Duration(Sec)
Session-1	90	1.0	1.2	750	26
Session-2	100	1.2	1.7	800	25
Session-3	110	1.4	2.0	800	28
Session-4	120	1.5	2.2	800	28
Session-5	130	1.6	2.5	800	32
Session-6	140	1.6	2.8	800	34

Table 5 — *Parameters of modified ECT (mECT) of Case 5.*

Mrs RG	Frequency (Hz)	Pulse Width (mSec)	Duration (Sec)	Current (Amp)	Seizure Duration(Sec)
Session-1	90	1.0	1.2	750	25
Session-2	100	1.2	1.4	800	34
Session-3	110	1.4	1.6	800	34
Session-4	120	1.6	2,0	800	25
Session-5	120	1.8	2.2	800	28
Session-6	120	2.0	2.6	800	28
Session-7	130	2.0	2.8	800	29
Session-8	140	2.0	3.4	800	26

Table 6 — *Key Summary of five cases of Bipolar disorder received modified ECT (mECT).*

Variables	Case-1 [Md SH]	Case-2 [Mr SM]	Case-3 [Mr AG]	Case-4 [Mr HM]	Case-5 [Mrs RG]
Age	25 years	22 years	37 years	25 years	24 years
Sex	Male	Male	Male	Male	Female
Co-prescribed medications	quetiapine [300 mg], clozapine [50 mg], clonazepam [1 mg].	clozapine [50 mg], haloperidol [7.5 mg], sodium valproate [600 mg], lorazepam [1 mg], trihexyphenidyl [4 mg]	sodium valproate [800mg], olanzapine [5 mg], clozapine [150 mg], trihexyphenidyl [4 mg], propranolol [40 mg].	amisulpride [200 mg], divalproex sodium [1000 mg], lorazepam [2 mg], trihexyphenidyl [6 mg]	olanzapine[10 mg], clozapine [25 mg], divalproex sodium [500 mg], clonazepam [0.5 mg]
Modified ECT sessions given	12	8	10	6	8
YMRS Scores	Baseline [40], after 3rd ECT [32], after 6th ECT [28], after 12th ECT [5]	Baseline [42], after 3rd ECT [30], after 6th ECT [22], after 8th ECT [6]	Baseline [38], after 3rd ECT [28], after 6thECT [24], after 10th ECT [8]	Baseline [42], after 3rd ECT [18], after 6th ECT [5]	Baseline [40], after 3rd ECT [28], after 6thECT [16], after 8 th ECT [8]

Table 7 — *Two tailed paired 't' test of YMRS score at base line and at the end of mECT sessions*

Case number	YMRS score (Baseline)	YMRS score (End)	CI (Confidence interval (95%)	DF(Degree of freedom)	't' value	Standard level of difference	Two tailed p-value
Case 1	40	5	30.47-37.13	4	28.1667	1.200	0,0001**
Case 2	42	6					
Case 3	38	8					
Case 4	42	6					
Case 5	40	8					

Discussion

'Bipolar disorders' refers to a group of affective disorders in which patients experience episodes of Depression and episodes of either mania, or hypomania[2,5].

Manic episode usually responds well to treatment with mood stabilizers and antipsychotic medications. So, they are the first-line treatments for the disorder. ECT can be considered as an effective therapeutic alternative for patients who do not respond to medications, who cannot tolerate medications due to side effects or patients presenting with severe symptoms, extreme agitation, delirium or exhaustion[6].

In our cases, first 3 cases were not responding well to medications. So, we had to start ECT. In the 4th case the patient could not tolerate medications due to side effects and so he was treated with ECT. The 5th patient was not taking oral medications and so she was given ECT. Response to ECT treatment was very good and without any significant side effect.

We cannot use modified ECT in Outdoor or even in spite of having Indoor admission due to Anaesthetist availability, fitness issues related to giving Anaesthesia. For common people ECT is a cruel, painful treatment as depicted in serials and cinemas. So, getting consent for ECT is also a challenge.

But like many other studies, our study also showed ECT to be an effective, safe and lifesaving treatment option[7-10].

Two tailed paired 'T' test of YMRS score at base line and at the end of mECT sessions shows significant reduction of YMRS scores with p value <0.0001 in the five cases who had been diagnosed to suffer from Manic episode, not responsive to conventional pharmacotherapy.

Conclusion

Though unmodified electroconvulsive therapy was very popular treatment option among Psychiatrists, modified electroconvulsive therapy is not used much by the Psychiatrists probably due to unavailability of Anaesthetist and legal issues. Electroconvulsive therapy can be a very good treatment option in Manic phase of Bipolar disorder and even can be used as a first line of treatment.

Conflicts of Interest : Nil

Funding and Financial Support : Nil

Ethical Approval : Written informed consent had been taken from the cases.

References

1 Salik I, Marwaha R — Electroconvulsive Therapy. [Updated 2022 Sep 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from:https://www.ncbi.nlm.nih.gov/books/NBK538266/

2 World Health Organization. ICD-10 classification of mental and behavioural disorders: Clinical disorders: Clinical description and diagnostic guidelines. Geneva: Oxford University Press; 1992.

3 Folstein MF, Folstein SE, McHugh PR — Mini-mental state. A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975; **12(3):** 189-98. https://doi. org/10.1016/0022-3956(75)90026-6

4 Young RC, Biggs JT, Ziegler VE, Meyer DA — A rating scale for mania: reliability, validity and sensitivity. *Br J Psychiatry* 1978; **133:** 429-35. https://doi.org/10.1192/bjp.133.5.429

5 Phillips ML, Kupfer DJ — Bipolar disorder diagnosis: challenges and future directions. *Lancet* 2013; **381(9878):** 1663-71. doi: 10.1016/S0140-6736(13)60989-7. PMID: 23663952; PMCID: PMC585893

6 Yatham LN, Kennedy SH, Parikh SV, Schaffer A, Bond DJ, FreyBN, *et al* — Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for BipolarDisorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. *Bipolar Disord* 2018; **20:** 97-170.

7 Perugi G, Medda P, Toni C, Mariani MG, Socci C, Mauri M — The role of Electroconvulsive Therapy (ECT) in Bipolar Disorder:effectiveness in 522 patients with bipolar depression, mixedstate,mania and catatonic features. *Curr Neuropharmacol* 2017; **15:** 359-71.

8 Patel RS, Jain SB, Youssef NA — Electroconvulsive treatment utilization for the inpatient management of severe manic episodes of bipolar disorder. *J ECT* 2019; **35:** 195-200.

9 Macedo-Soares MB, Moreno RA, Rigonatti SP, Lafer B — Efficacy of electroconvulsive therapy in treatment-resistant bipolar disorder: a case series. *J ECT* 2005; **21:** 31-4.

10 Beale MD, Kellner CH — ECT in treatment algorithms: no need to save the best for last. *J ECT* 2000; **16(1):** 1-2. https://doi.org/10.1097/00124509-200003000-00001

Case Report

Multifocal Pyoderma Gangrenosum Complicated by Multiple Organ Dysfunction

Asharbh Raman[1], Devi Sriveni Bolisetti[2], Rohan Manoj[3], Banyameen Iqbal[4], Aayush Gupta[5]

Abstract

Background : A 21-year-old male with cardiomyopathy presented to our clinic with symptoms consistent with Dermatitis Herpetiformis. Despite a favourable clinical response, dapsone initiated for treating dermatitis herpetiformis had to be discontinued following the development of hepatic dysfunction. The lesions ulcerated following treatment cessation, exhibiting characteristics consistent with Pyoderma Gangrenosum as defined by the Delphi diagnostic criteria. Since traditional first-line treatments could not be used for pyoderma gangrenosum due to the underlying cardiac dysfunction, the patient was started on oral cyclophosphamide. However, a rapid decline in renal function ensued, forcing us to withdraw cyclophosphamide. Eventually, the patient was started on low-dose prednisolone. This led to clinical improvement; however, cardiac failure eventually occurred, leaving us searching for alternatives. The patient was counselled about administering biologicals, but he succumbed to cardiac arrest before a decision was made. The lack of proper guidelines for immunosuppressive therapy in multiorgan dysfunction made managing this case extremely challenging.

Key words : Pyoderma Gangrenosum, Multiple Organ Dysfunction, Cardiomyopathy.

Pyoderma Gangrenosum (PG), an acute necrotising neutrophilic dermatosis, is characterised by painful ulcers with raised, undermined, violaceous borders and surrounding erythema. Most ulcers are preceded by nodules, plaques, or pustules and eventually resolve with cribriform scarring[1]. The absence of any discernible infection is a hallmark of this disease, suggesting that autoinflammatory processes may be involved. Autoactivation of key Interleukins (IL) and cytokines, such as IL-1, IL-17, IL-18, IL-33 and IL-36, propel the inflammatory pathway. This stems from an autonomous inflammasome activity, which cleaves inactive cytokine precursors into their active forms[1]. Another interesting caveat of this disease is the presence of the pathergy phenomenon, wherein minor trauma can further propagate the disease mechanisms and lead to extensive ulcers. Hence, surgical debridement and suturing are not viable therapeutic options in PG.

Case Presentation

A 21-year-old man of Uzbek descent, with an underlying non-ischaemic dilated cardiomyopathy and left ventricular systolic dysfunction was awaiting cardiac transplantation. He presented to the clinic with complaints of multiple bilaterally symmetrical, erythematous, pruritic papules and pustules over the face, arms, back, buttocks, and knees which had appeared over the past 10 days. A provisional clinical diagnosis of Dermatitis Herpetiformis (DH) was made, for which the patient was started on tablet dapsone 100 mg and advised a gluten-free diet. There was immediate improvement, but three days later, serum bilirubin levels were found to be significantly elevated, preventing further use of dapsone. The patient was maintained on mid-potent topical steroids and mupirocin[2-4].

Editor's Comment :

- Pyoderma gangrenosum is a recalcitrant autoinflammatory ulcerating dermatosis, which often requires months of immunosuppressive therapy. When complicated by multiple organ dysfunction, especially in a patient with non-ischaemic dilated cardiomyopathy, low dose prednisolone and secukinumab may be the only medication with a favourable adverse effect profile that can manage the disease without precipitating cardiovascular decompensation.

However, the lesions progressed and eventually ulcerated, becoming painful, purulent, and punched out with violaceous margins and surrounding erythema (Fig 1). Infection was ruled out after a negative pus culture report, and the diagnosis was revised to Pyoderma Gangrenosum (PG) based on the morphology as well as the histopathology of the new lesions (Table 1). Systemic corticosteroids and cyclosporine were deemed unsuitable as treatment options by the Cardiologist. Tablet cyclophosphamide, 50 mg OD, along with topical tacrolimus 0.1% ointment, was thus started[5]. However, five days later, there was a significant elevation of serum Creatinine, necessitating the stoppage of cyclophosphamide and worsening his symptoms again. As the ulcers progressed to increase in size and become more painful, it was imperative that systemic steroids in low doses be started to improve his Quality of Life[5-7]. The patient was started on prednisolone, with the dosage limited to 20 mg OD to prevent cardiac decompensation. The symptoms improved, and the patient was discharged. Unfortunately, the patient returned a month later with severe shortness of breath and signs of cardiac failure, forcing us to withhold prednisolone. This improved his cardiac symptoms but worsened the skin lesions. As a last resort, the patient was counselled for secukinumab administration; however, before he could make up his mind, he passed away due to cardiac arrest[8].

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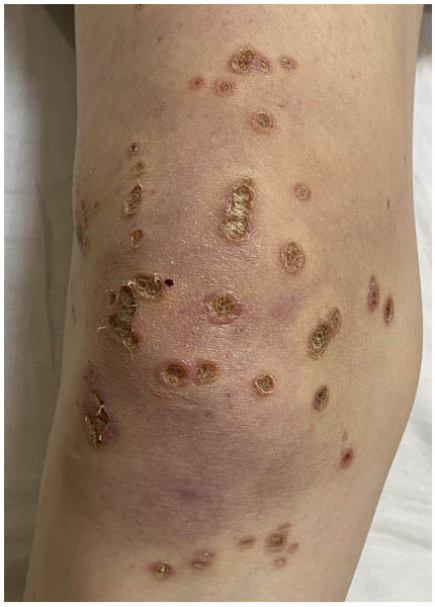

Fig 1 — Multiple well-defined punched-out ulcers with violaceous margins, yellow crusts on the floor and surrounding erythema over the right knee.

Discussion

PG remains a major diagnostic and therapeutic dilemma, especially in the early stages of the lesions. Although the Delphi diagnostic criteria aids in confirming the diagnosis, most of the essential components of this criteria can only be fulfilled after the lesions completely ulcerate. Furthermore, PG ulcers have often been confused with ulcers of infective aetiology which prompts most doctors to debride these lesions before receiving the culture and sensitivity reports[7]. This error can lead to a worse prognosis due to the pathergy phenomenon. While the precise aetiology of PG remains unknown, several cytokines, such as tumour necrosis factor-alpha and IL-1β, have been suggested to play a role in its pathogenesis. Hence, immunosuppressants, such as oral corticosteroids and cyclosporine, remain the cornerstone of treatment[5]. However, both drugs were ruled out due to their tendency to worsen heart failure. Further, dapsone and cyclophosphamide had to be discontinued due to an increase in bilirubin and creatinine levels, respectively[5,6]. Biologics like Infliximab could not be infused due to the risk of volume overload, whereas Adalimumab was contraindicated due to its risk of precipitating new-onset cardiac failure. Finally, after exhausting all other treatment options, the administration of low-dose prednisolone led to some clinical improvement but eventually exacerbated the Heart failure and had to be discontinued, sending us back to square one[5,6]. Thus, we were left searching for alternative therapeutic options for managing this case of cardiac failure, complicated by drug-induced hepatic and renal dysfunction.

Conclusion

The unique challenges faced during our patient's treatment prompted us to scour the literature in search of immunosuppressants with superior adverse effect profiles to effectively control the disease and improve the patient's Quality of Life. We believe secukinumab is particularly safe in the background of cardiac dysfunction as there are no reported cases of this drug precipitating cardiac events[8,9]. More research and guidelines on immuno-suppressive treatment ladders for individuals with multiorgan dysfunction would help guide clinicians in managing similar cases more efficiently.

Table 1 — *A summary of the essential laboratory reports*

y parameters	Day 01	Day 04	Day 09	Day 42
Haemoglobin	11.90	11.90	10.20	11
Total Leukocyte Count	11,000	10,000	8,500	10,200
Platelets	5,67,000	5,40,000	3,49,000	3,21,000
Urea	83	75	89	104
Creatinine	1.17	1.21	1.66	1.58
Total Bilirubin	3.65	6.01	5.57	2.34
AST/ALT/ ALP	27/19/136	23/18/167	23/16/145	28/18/159

Histopathology Report : The sections show epidermis with ulceration and inflammatory infiltrate at the base composed predominately of neutrophils. Vessel wall shows endothelial cell thickening nut fibrinoid degeneration and nuclear dust is not seen. Papillary microabcess, eosinophils, frank vasculitis, thrombus formation, granulomas or dysplasia are not evident in this section. In appropriate clinical settings, the histological findings raise the possibility of Pyoderma Gangrenosum.
Anti-TTG antibody : Negative.
Swab from the ulcer floor sent for culture and sensitivity : No organisms detected
AST - Aspartate Transaminase; ALT - Alanine Transferase; ALP - Alkaline Phosphatase; Anti-TTG antibody – Anti-tissue Transglutaminase antibody.

Funding : None.

Conflict of Interest : None.

References

1 Maverakis E, Marzano AV, Le ST, Callen JP, Brüggen MC, Guenova E, *et al* — Pyoderma gangrenosum. *Nature Reviews Disease Primers* 2020; **6(1):** 81.
2 Ahronowitz I, Harp J, Shinkai K — Etiology and management of pyoderma gangrenosum: a comprehensive review. *Am J Clin Dermatol* 2012; **13(3):** 191-211. doi: 10.2165/11595240-000000000-00000. PMID: 22356259.
3 Ruocco E, Sangiuliano S, Gravina AG, Miranda A, Nicoletti G — Pyoderma gangrenosum: an updated review. *J Eur Acad Dermatol Venereol* 2009; **23(9):** 1008-17. doi: 10.1111/j.1468-3083.2009.03199.x. Epub 2009 Mar 11. PMID: 19470075.
4 Maverakis E, Ma C, Shinkai K —. Diagnostic Criteria of Ulcerative Pyoderma Gangrenosum: A Delphi Consensus of International Experts. *JAMA Dermatol* 2018; **154(4):** 461-6. doi:10.1001/jamadermatol.2017.5980
5 Maronese CA, Pimentel MA, Li MM — Pyoderma Gangrenosum: An Updated Literature Review on Established and Emerging Pharmacological Treatments. *Am J Clin Dermatol* 2022; **23:** 615-34. https://doi.org/10.1007/s40257-022-00699-8
6 Fletcher J, Alhusayen R, Alavi A — Recent advances in managing and understanding pyoderma gangrenosum. *F1000Res* 2019; **8:** F1000 Faculty Rev-2092. doi: 10.12688/f1000research.19909.1. PMID: 31885859; PMCID: PMC6913206.
7 Allen JT, Toro D, Lough M, Griswold L — Pyoderma gangrenosum following gynaecological surgery. *BMJ Case Reports* 2023; **16(12).**
8 Froehlich F, Dreßler M, Staeger R, French LE, Meier-Schiesser B — Successful long-term treatment of pyoderma gangrenosum with secukinumab. *JEADV Clinical Practice* 2023; **2(2):** 316-9.
9 Gottlieb AB, Deodhar A, Mcinnes IB, Baraliakos X, Reich K, Schreiber S, *et al* — Long-term safety of secukinumab over five years in patients with moderate-to-severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis: update on integrated pooled clinical trial and post-marketing surveillance data. *Acta dermato-venereologica* 2022; 102.

Case Report

A Case of HbQ India Heterozygous in a Patient of Bengali Origin

Anannya Ghosh[1], Neepa Chowdhury[2], Suparba Chakrabarti[3]

Abstract

Background : HbQ India (HbA1:c. 193 G>C), is relatively an uncommon alpha 1 -chain structural Hemoglobin variant, due to mutation at codon 64 of the alpha1-globin gene causing an amino acid substitution of histidine for aspartic acid. With an overall incidence of 0.4% HbQ India is predominantly found amongst the Sindhi population, mostly in individuals from western and Northern India. We reported a case of HbQ India Heterozygous by HPLC in a 33-year-old female of Bengali origin in Eastern part of India.

Key words : HbQ India, Alpha Chain Variant, Mutation.

India is a land of plenty of Hemoglobin variants. HbQ India has a prevalence of 0.4% in the Indian subcontinent. HbQ India (HbA1:c. 193 G>C), is relatively an uncommon alpha 1 -chain structural hemoglobin variant, due to mutation at codon 64 of the alpha1-globin gene causing an amino acid substitution of histidine for aspartic acid[1]. HbQ was first described by Vella, *et al*, in association with alpha Thalassaemia in a Chinese patient[2]. There are three variations that have been described namely India (alpha 64 Asp to His), Thailand (alpha 74 Asp to His) and Iran (alpha 75 Asp to His)[3]. This rare disorder has been detected in the Homozygous and heterozygous states mostly in association with alpha and beta Thalassemia. HbQ-India is clinically silent normally. The replacement of aspartic acid with histidine, which is on the surface of the protein structure, does not affect the protein interchain contacts and electrical charges of the molecule; therefore, it does not cause any changes in hematologic parameters and indices[4]. It becomes symptomatic when it is present in association with other conditions like beta-thalassemia, alpha-thalassemia, HbE, HbH and nutritional Anemia. HbQ India is pre -dominantly found amongst the Sindhi population, mostly in individuals from Western and Northern India[5]. However, our case is of Bengali origin from West Bengal, Eastern India (Fig 1 & Table 1).

We recently encountered a case of HbQ India Heterozygous in a 33-year-old female patient who came to us for Hemoglobin typing by HPLC for pre-marital screening for Thalassemia trait.

Her HPLC (using D10 Hemoglobin Testing System (Bio-Rad) revealed normal HbF <0.8%, HbA0 76.6%, HbA2 1.6% and an unknown peak in the retention window of 4.48 mintutes, the percentage of area was 10.35%. HbQ India is an alpha chain variant and does not cause any clinical manifestation which is obvious from the hematological parameters. There is no anemia or reticulocytosis, MCV & MCH are normal. Adult Hemoglobin though reduced yet HbA2 being <3% rules out association of beta Thalassemia trait. The unknown peak at 4.48 minutes show the area percentage to be in the range of

Editor's Comment :

- HbQ India is a rare, clinically silent alpha globin chain variant which may be an incidental finding for routine hemoglobinopathy screening by HPLC. Although heterozygous cases typically show normal hematological parameters, accurate identification and differentiation from other hemoglobin variants are essential, especially in premarital or antenatal screening settings.
- Confirmation can be done by molecular testing and familial studies to ensure appropriate genetic counseling and ruling out co-inheritance with clinically significant hemoglobinopathies.

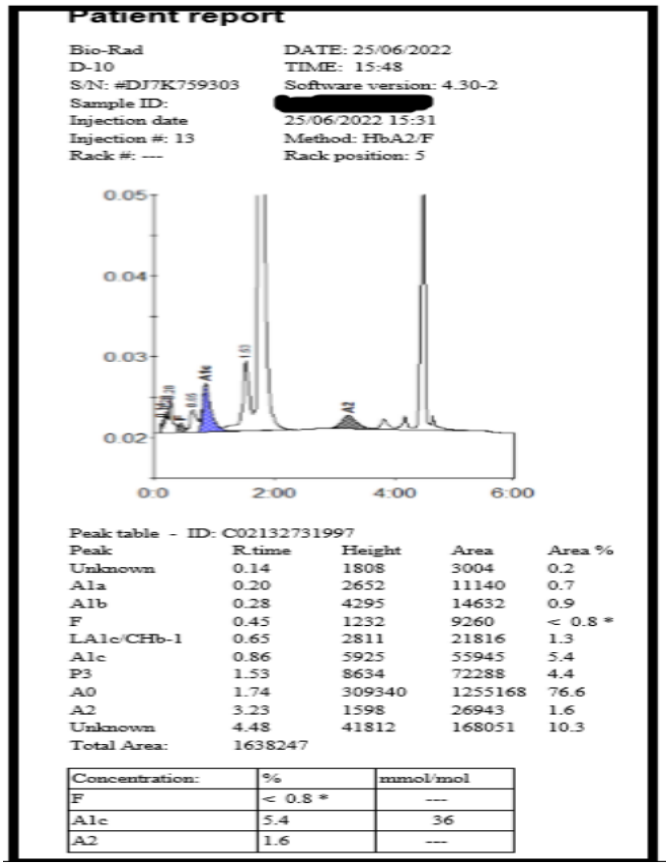

Fig 1 — Showing Patient Report

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Table 1 — *Hematological Parameters of the Patient*

Parameters	Values	Ref int
Hemoglobin	14.0 gm/dl	13-17 gm/dl
RBC	5.06*10^6/µl	4.5-5.5*10^6/µl
Hematocrit	43.9%	40-50%
MCV	86.9 fl	83-101 fl
MCH	27.6 pg	27-32pg
RDW	14.7%	11.6-14%

10-20% which differentiates it from Homozygous condition where the presence of HbQ is >35%[6]. The patient's family members (parents and siblings) were requested to undergo Hemoglobin typing (HPLC) to find out the inheritance history, however it was denied by the party. In presence of abnormal Hemoglobin the use of a single test to establish presumptive identification is inappropriate and second or even third line testing procedures should be in place. The patient was suggested to undergo a parental screening and DNA analysis for the same

Conclusion

India Is a land of huge prevalence of different Hemoglobinopathies which are yet to be identified. Now-a-days various procedures like HPLC, IEF, ARMS–PCR, DNA sequencing are available for diagnosis of the abnormal Hemoglobin.

Moreover, consanguineous marriage being common in India , screening and genetic counseling are essential to prevent the occurrence of Homozygous Hemoglobinopathies .

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Conflict of Interest : The authors declare no conflict of interest.

References

1 Harrison A, Mashon RS, Kakkar N, Das S — Clinico-Hematological Profile of Hb Q India: An Uncommon Hemoglobin Variant. *Indian J Hematol Blood Transfus* 2018; **34(2):** 299-303. doi:10.1007/s12288-017-0864-2.
2 Vella F, Wells RHC, Ager JAM, Lehmann H — A hemoglobinopathy involving hemoglobin H disease and new Q disease. *Br Med J* 1958; **1:** 725-7.
3 Wiwanitkit V — Phylogenetic Tree Of Hemoglobin Q Disorders. *The Internet Journal of Hematology* 2004; **2(1):**
4 Lorkin PA, Charlesworth D, Lehmann H, Rahbar S, Tuchinda S, Eng LI — Two haemoglobins Q, alpha alpha-73(EF3) and alpha-75 (EF4) aspartic acid to histidine. *Br J Haematol* 1970; **19:** 117-25.
5 Dhawle M, Methwani A, Tangde A, Bindu R — HBQ-India: an uncommon hemoglobin variant. *Int J Res Med Sci* 2018; **6:** 168790.
6 Phanasgaonkar, Colah S R, Ghosh K, Mohanty D, Gupte S — Hb Q-India and its interaction with ßthalassaemia: a study of 64 cases from India. *Brit J Biomed Sci* 2007; **64(4):** 160-3.

Short Communication

The Role of Private Medical Practitioners in Medical Literature : Benefits, Challenges and a Roadmap

Imran Ahmed Khan[1]

Abstract

At first look, switching from the field of clinical medicine practice to that of medical literature publishing may appear like an attribute unrelated to a doctor's core responsibility. However, the true impact of their experiences can be augmented by publishing and disseminating their keen observations. By translating these experiences into the written word, practitioners not only contribute to the collective understanding of diseases and treatments but also provide a platform for fellow professionals to learn from real-world scenarios. It promotes professional growth and patient trust by sharing medical knowledge and adds to medical advancements. Medical journals, online platforms, and social media provide diverse channels for Private Medical Practitioners to contribute. The dispersion of information allows practitioners to become authors, sharing their stories, wisdom, and insights with a Global audience.

Key words : Ethics, Journal, Research, Private Medical Practitioner, Publication.

Becoming an expert in their field is not the only important aspect of one's professional development. In reality to become a world-class expert today, one must also be able to disseminate his/her knowledge through the publishing process with skill and speed, as well as writing with clarity and accuracy. At first look, switching from the field of clinical medicine practice to that of medical literature publishing may appear like an attribute unrelated to a doctor's core responsibility[1]. However, the true impact of these experiences can be augmented by publishing and disseminating one's keen observations[2]. This paper aims to shed light on the significance of this transition and the profound benefits it shows to both practitioners and the medical community at large.

Importance of Publication :

Private Medical Practitioners, having years of clinical experience, encounter a multitude of cases with a wide spectrum of medical conditions. Some cases are often imbued with nuances that textbooks fail to capture, and it is these intricacies that form the basis of invaluable insights. By translating these experiences into the written word, practitioners not only contribute to the collective understanding of diseases and treatments but also provide a platform for fellow professionals to learn from real-world scenarios. It promotes professional growth and patient trust by sharing medical knowledge and adds to medical advancements[3]. The influence of medical publications isn't limited to the immediate circle of practitioners. The ripple effect is far-reaching, extending to institutions, researchers, and healthcare systems Worldwide. This collects evidence regarding the current understanding of a health problem. A meticulously documented case study might offer insights that inform medical guidelines, shaping treatment protocols across borders[4,5]. A well-drafted review article introduces a novel perspective on previous research[6]. In essence, sharing one's experiences through literature has the capacity to go beyond the individual and benefit the entire medical sector.

Editor's Comment :

- Private medical practitioners possess a wealth of real-world clinical experience that can significantly enrich medical literature when systematically documented and shared. Their active participation in academic publishing can enhance professional growth, strengthen evidence-based practice, and ultimately improve patient care. Encouraging collaboration, ethical research practices, and scientific writing can help practitioners translate clinical experience into meaningful contributions to medical knowledge and ultimately patient-centered care.

Opportunities and Hurdles for a Private Practitioner :

The path of a Private Medical Practitioner is both difficult and lucrative in the constantly changing field of modern medicine. Daily interactions with diverse groups of patients, challenging diagnoses, and intricate treatment plans impart rich shades of experiences. These experiences carry far-reaching potential beyond the confines of the hospital and clinics. They possess the power to shape the extent of medical knowledge and practice on a broader scale through the journey of academic publications[7]. From challenging diagnostic dilemmas to innovative treatment approaches, the stories from the practice hold the potential to revolutionize conventional thinking. As we navigate the digital age, the avenues for sharing experiences have expanded significantly. Medical journals, online platforms, and social

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media provide diverse channels for Private Medical Practitioners to contribute[8]. The dissemination of information allows practitioners to become authors, sharing their stories, wisdom, and insights with a Global audience. This dispersion, in turn, fosters diversity in thought, enriching the pool of medical knowledge and improving patient care on a Global scale.

There are some unique set of challenges that Private Medical Practitioners may face when trying to do research and publish their findings, such as time constraints, financial constraints, ethical and regulatory hurdles, limited access to research resources, data collection challenges, or lack of writing skills[9]. They may have a large dataset but have little knowledge to make it presentable and draw meaningful inferences. Maintaining a balance between clinical responsibilities and research activities can be difficult at times. They have to manage their time effectively and prioritize their roles.

Once you have crossed the hurdles and decided to indulge in research and medical publishing, you need to be well-versed with some rules of this specialized process.

Ethical Considerations :

To safeguard participants' rights the research process needs to be scrutinized beforehand. You have to make a research protocol according to guidelines and produce it to the Ethical Committee for approval[10]. Ethical Committee members will scrutinize your proposal and give approval or advice on some corrections in the research protocol considering the safeguard of participants and weighing different aspects of the research process. Ethical clearance can be obtained from the Hospital Ethical Committee in existence. In the absence of such an establishment, ethical clearance can also be obtained from a nearby institute having such a committee. For example, freelance private practitioners may apply to a nearby Medical College or a big institute for ethical clearance. One should ensure obtaining ethical clearance before the recruitment of the first participant in the study. It should be followed in all studies be it observational or interventional.

Patient Consent and Privacy :

You have to ensure maintaining patient confidentiality, obtain informed consent for data collection, and seek permission to use their data in publications. A participant can't be forced to participate in a study and any data or picture should be used only after their written informed consent.

Conflict of Interest and Financial Disclosure :

This is also a very important aspect of research and publication. Authors have to declare a conflict of interest if any and also financial support obtained in the conduct of research.

Relevance to the Practitioner's Specialty :

The topic chosen should be relevant to the practitioners. They can collaborate with another specialty as per requirement.

Collaborations and Networking :

The benefits of collaborating with other practitioners and researchers are many. You get opportunities for multi-center studies, enhancing your knowledge, publication quality, and impact on scientific society[11].

Types of Publications :

Research articles may be of different types. It may be an original research work addressing a particular research question. It may be a description of some rare case report or a collection of some peculiar cases called case series. It may be a review article which is actually a compilation of findings of several studies to answer a particular research question.

Journal Selection :

Once you are done with your research process you have to pen it down as an academic draft. This draft or manuscript preparation needs various factors to consider. You have to choose the target audience, journal scope, and other specifications. Journal indexing and Impact factors are among the top criteria. It is advised to avoid predatory journals.

Writing and Submission Process :

Writing : Emphasize clear, concise, and evidence-based writing. Outline the structure of a scientific paper (Abstract, Introduction, Methods, Results, Discussion, and Conclusion).

Submission: Go through the process of submitting a manuscript to a journal. There are standard international guidelines, but some journals may have a few peculiar requirements.

Peer-review process: Once you submit your manuscript to a journal for publication consideration, they have a system of reviewing the manuscript for suitability for publication[12]. Some journals have a policy to have a primary editor's check once they get a submission. At this stage, they may reject it or send it for peer review. According to the feedback provided by reviewers, a further decision is taken about accepting, revising, or rejecting the manuscript. Now the corresponding author is informed about the decision and further step is completed accordingly. Satisfactory revision and required corrections in the manuscript pass it to the publication process.

Promoting Publications :

Once published, you should produce it to a large target audience. The use of social media and professional platforms in sharing publications is very helpful.

Communicate your findings to both medical and non-medical audiences.

Benefits and Rewards :

There are a number of benefits to oneself and to society. They include but are not limited to enhanced professional reputation, contribution to the medical community, opportunities for speaking engagements and collaborations, career advancement, continual learning, financial benefits, improving patient care and personal satisfaction. etc.

Conclusion

In conclusion, the journey from medical practice to literature is not a departure from the core essence of a Private Medical Practitioner. Instead, it is an expansion—an extension of the commitment to patient care and the pursuit of excellence. By documenting experiences, translating insights, and participating in the discourse of medical literature, practitioners can truly amplify their impact. While there are many benefits to academic publication for Private Medical Practitioners, it's essential to recognize that it can be time-consuming and challenging. Balancing clinical responsibilities with research and writing can be demanding. The stories from the clinic have the potential to shape the narrative of medicine, leading us into a future where knowledge flows seamlessly from practice to literature and back again, enriching the lives of patients and practitioners alike. Medical publishing is a skill that should be learnt under the guidance of an expert to produce scientific and accurate evidence.

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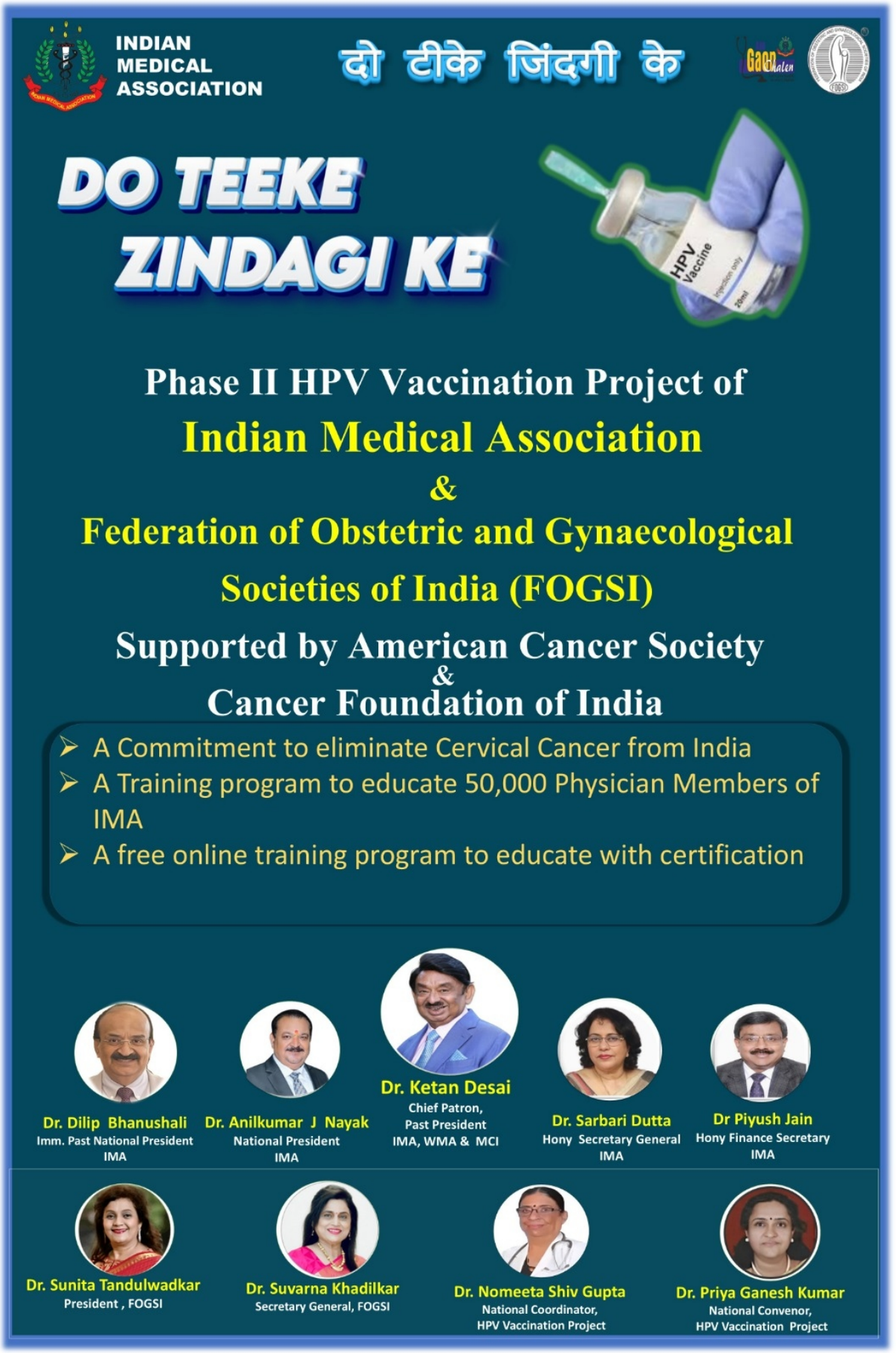
References

1 Wright SM, Kern DE, Kolodner K, Howard DM, Brancati FL — Attributes of excellent attending-physician role models. *New England Journal of Medicine* 1998; **339(27):** 1986-93.
2 Bearman S, Beard SB, Hunt L, Crosby FJ — New directions in mentoring. The Blackwell handbook of mentoring: A multiple perspectives approach 2007; **10:** 373-95.
3 Ventola CL — Social media and health care professionals: benefits, risks, and best practices. *Pharmacy and therapeutics* 2014; **39(7):** 491.
4 Fambirai T, Chimbari MJ, Ndarukwa P — Global Cross-Border Malaria Control Collaborative Initiatives: A Scoping Review. *International Journal of Environmental Research and Public Health* 2022; **19(19):** 12216.
5 Venturo-Conerly KE, Wasil AR, Osborn TL, Puffer ES, Weisz JR, Wasanga CM — Designing culturally and contextually sensitive protocols for suicide risk in global mental health: lessons from research with adolescents in Kenya. *Journal of the American Academy of Child and Adolescent Psychiatry* 2022; **61(9):** 1074-7.
6 Post C, Sarala R, Gatrell C, Prescott JE — Advancing theory with review articles. *Journal of Management Studies* 2020; **57(2):** 351-76.
7 Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC — Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science* 2009; **4(1):** 1-5.
8 Chen J, Wang Y — Social media use for health purposes: systematic review. *Journal of medical Internet research* 2021; **23(5):** e17917.
9 Phothongsunan S — Thai University academics' challenges of writing for publication in English. *Theory and Practice in Language Studies* 2016; **6(4):** 681.
10 Brown C, Spiro J, Quinton S — The role of research ethics committees: Friend or foe in educational research? An exploratory study. *British Educational Research Journal* 2020; **46(4):** 747-69.
11 Wen J, Wang W, Kozak M, Liu X, Hou H — Many brains are better than one: The importance of interdisciplinary studies on COVID-19 in and beyond tourism. *Tourism Recreation Research* 2021; **46(2):** 310-3.
12 Tennant JP, Ross-Hellauer T — The limitations to our understanding of peer review. *Research integrity and peer review* 2020; **5(1):** 6.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