Original Article

Effectiveness of "Discharge Guidance Programme" on Medication Compliance and Complications among Patients Undergone Heart Valve Replacement

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Abstract

Background: In India, rheumatic heart disease (RHD) affects approximately 5 to 7 out of every 1,000 children aged between 5 and 15 years, with an estimated 1 million individuals living with the condition, with many patients needing valve replacement surgery. While surgery is crucial, effective post-operative counseling and adherence to lifelong oral anticoagulant therapy (OAT) are vital to prevent complications such as thromboembolism or bleeding. Despite the clear need, there's a notable lack of formal research in India assessing how effective counseling truly impacts patient adherence and long-term outcomes after valve replacement.

Methods: A Quasi-experimental research study was conducted from December 2024 to Feb 2025, using a total enumeration method. A structured questionnaire was developed, validated, and administered to 54 patients.

Results: This comparative study involving 54 heart valve replacement patients (experimental group n=27, control group n=27) at KGMU, Lucknow, assessed the effectiveness of a Discharge Guidance Programme on medication adherence and post-operative complications. Baseline demographic and clinical characteristics were statistically comparable between the experimental and control groups, as indicated by non-significant p-values (all $p > 0.05$). The Kolmogorov-Smirnov test revealed that all outcome variables significantly deviated from a normal distribution (all $p < 0.05$); therefore, non-parametric statistical methods were employed for subsequent analyses.At baseline, medication adherence was similar between groups (Chi-square p=0.362; Mann-Whitney U p=0.517). However, the Discharge Guidance Programme significantly improved medication adherence in the experimental group. At 1st week post-discharge, 70.37% of the experimental group demonstrated high adherence compared to 18.51% in the control group (p=0.001), with a significantly higher mean adherence score (experimental: 8.00±0.00; control: 2.79±1.24; p=0.000). This improvement was sustained at 4th week post-discharge, with 88.88% high adherence in the experimental group vs. 51.85% in the control group (p=0.006), and significantly higher mean adherence (experimental: 8.00±0.00; control: 3.02±1.27; p=0.000). The program also significantly reduced post-operative

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complications. At 1st week post-discharge, the experimental group had a lower incidence of complications (7.40%) compared to the control group (44.4%), with a significantly lower mean complication score (experimental: 0.22±0.51; control: 1.00±1.24; p=0.01). By 4th week post-discharge, no patients in the experimental group reported complications (0%) compared to 29.6% in the control group, maintaining a significantly lower mean complication score (experimental: 0.00±0.00; control: 0.29±0.608; p=0.01). Significant positive correlations were found between 1st and 4th week scores for complications (r=0.377,p=0.005) and medication adherence (r=0.311,p=0.022).

Conclusion: The findings of this study demonstrate that the "Discharge Guidance Programme" is an effective intervention for improving medication adherence and reducing the incidence of post-operative complications among patients who have undergone heart valve replacement. The experimental group, which received the guidance programme, exhibited significantly better medication compliance and experienced fewer complications in the crucial 4-week period following discharge compared to the control group receiving standard care. This suggests that a structured discharge guidance programme can play a vital role in enhancing patient outcomes and potentially reducing the burden of post-surgical morbidity.

Keywords: Quasi experimental research study; Discharge Guidance Programme, medication compliance, complications, heart valve replacement.

Introduction

Heart valve surgery significantly effects a patient's quality of life. For individuals receiving mechanical heart valves, regardless of their specific design or material, lifelong chronic anticoagulation therapy is typically required. Managing these patients presents challenges, as attempts to control anticoagulation have sometimes led to unacceptable rates of valve clotting, embolic events, and bleeding complications. Patients undergoing anticoagulation are often advised to maintain consistent dietary habits, avoid alcohol, and manage physical activity levels, as these factors can influence the therapy's effectiveness. [1].

Previous research has highlighted that thromboembolism and bleeding constitute a significant majority (75%) of complications following heart valve replacement, with these issues being more frequent within the initial six months post-operation. During this critical period, insufficient discharge education for both the patient and family can lead to difficulties in managing daily activities such as mobility, nutrition, elimination, respiration, sleep, and rest[4]

Research Approach: Quantitative Approach

Research Design: Quasi experimental research design

Table 1

GROUPS	PRETEST	INTERVENTION	POSTTEST 1 POST DISCHARGE AT 1st WEEK	POST TEST 2 POST DISCHARGE AT 4th WEEK
E	O1	X + R	O2	O3
C	O1	R	O2	O3

Study setting: This study was conducted within the Cardiothoracic and Vascular Surgery (CVTS) ward at King George's Medical University (KGMU) Hospitals, located in Lucknow, Uttar Pradesh, India.

Population and Sampling:

Target population: Patient undergone heart valve replacement available during data collection.

Accessible population: Patient undergone heart valve replacement admitted in cvts ward. The study's participants were patients with valvular heart disease who were admitted to KGMU Hospitals in Lucknow.

Sampling technique: Purposive sampling

- Allocation of subjects in experimental and control group will be done using UHID number the last 2 digit of UHID will be taken into consideration.

- The control group consisted of individuals whose UHID ended with an odd two-digit number.
- The experimental group consisted of individuals whose UHID ended with an even two-digit number.

Criteria for sample collection-

Inclusion Criteria:

- Patients undergone heart valve replacement (Double valve replacement, Mitral valve replacement, Aortic valve replacement.)
- Adults above 18 years old to 80 years old.
- Able to understand hindi.
- Agreed to participate after being informed

Exclusion Criteria:

- Patients with previous knowledge or who had received education on care following heart valve replacement.
- Patients unable to communicate effectively.
- Patients underwent valve repair surgery.

SAMPLE SIZE CALCULATION

$$\textbf{Sample Size: } n = \frac{(Z\alpha/2+Z\beta)^2 * 2 * SD^2}{\Delta^2}$$

- Zα/2 = critical value of the standard normal distribution for a two-tailed test at 95% confidence level (1.96 for α = 0.05)
- Zβ = critical value for 90% power (1.28)
- SD = standard deviation
- Δ(Delta) = minimum detectable difference or effect size (difference between the two means)
- n = sample size of each group

On applying in the above formula

$$n = \frac{(1.96+1.28)^2 * 2 * 1.7^2}{(1.5)^2} = 26.96 \sim 27$$

Zα/2 =1.96 Zβ = 1.28 Sigma = 1.7 Delta=1.5

Materials: The sample size for the study would be 27 subjects for each Group, hence overall 54 samples are required for the study

Estimated sample size is 54

Reference Article

Yaman, Yesim & Bulut, Hulya. (2010). Evaluation of discharge training given to patients who have undergone heart valve replacement. Turkish Journal of Thoracic and Cardiovascular Surgery. 18. 277-283.

Tool for data collection:

Section A: Demographic variables

It includes age, gender, education, income and occupation.

Section B: Baseline clinical data

It includes Previous Surgery, Endocarditis, Type of Sugery

Section C: Complication tool

It includes questions categories as Avoidable complications, Unavoidable complications, Situational complication, readmission was required due to complications.

Section D: Medication adherence tool

The Morisky Medication Adherence Scale (MMAS-8) is a structured, self-report measure used to assess medication adherence, developed from the 4-item Morisky Green and Levine scale, with the first 7 questions being yes/no, and the last using a 5-point Likert scale. The MMAS-8 aims to assess medication-taking behavior, including both unintentional (e.g., forgetfulness) and intentional (e.g., stopping medication due to side effects) reasons for non-adherence.

Development of the Questionnaire

A self-structured questionnaire designed to assess post-discharge complications was developed for this study. Its validity was also confirmed by experts from the CVTS department It includes questions categories as Avoidable complications, Unavoidable complications, Situational complication, readmission was required due to complications. Total 9 experts offered feedback on the tool's clarity and suitability.

Reliability of the Tool:

The reliability of the self-developed tool (the Post Discharge Complication Questionnaire) was evaluated using Cronbach's Alpha, which yielded a reliability coefficient of 0.81.

Intervention

The Discharge Guidance Programme intervention will be standardized and delivered by researcher in which.

1. Exclusive discharge guidance on Medicine compliance to the patient undergone heart vale replacement.

Medications: (5 minutes)

2. Provide Education concerning complication among patient undergone heart vale replacement.

Warning Signs and Complications: (5 minutes)

3 Managing Lifestyle Changes and Risk Factors: (5 minutes)

4. Follow-up Appointments: (5 minutes)

Statistical analysis

The collected data were coded and summarized using Microsoft Excel. Both descriptive and inferential statistics were performed. The Kolmogorov-Smirnov test was used to assess the normality of outcome variables, which indicated a non-normal distribution (all $p<0.05$). Consequently, non-parametric tests were employed for analysis.For comparisons between the experimental and control groups, the Mann-Whitney U test was utilized. The Chi-square test was also applied to assess baseline demographic and clinical comparability, as well as baseline medication adherence. Spearman's rank correlation was performed to examine relationships between variables.

Results

This study enrolled a total of 54 patients, with 27 in the experimental group receiving the Discharge Guidance Programme and 27 in the control group receiving standard care.

Section I: Demographic and Clinical Profile of Subjects Findings

Demographic Comparability: Both the experimental and control groups were found to be statistically comparable across all assessed demographic variables including age, gender, educational status, occupation, income status, marital status,family type, religion, language, and distance from healthcare setting. The p-values for all these variables were greater than 0.05, indicating no significant baseline differences.

Clinical Baseline Comparability: The baseline clinical characteristics of the two groups were also comparable. There were no statistically significant differences in the history of previous surgery ($p=1.00$) or the distribution of the types of valve replacement surgeries (MVR, AVR, DVR) performed ($p=0.152$). All participants in both groups were noted to be free from endocarditis at baseline.

Comparison of demographic profile variable of the experimental andcontrol group. N=54

No.	Demographic variables		f(%)		p-value
			Experimental Group n =27	Control Group n =27	
1	Age	< 20 years	1(3.70)	3(11.11)	0.556
		21-40	19(70.37)	14(51.85)	
		41-60	6(22.22)	9(33.33)	
		61 and above	1(3.70)	1(3.70)	
2	Gender	Male	12(44.44)	8(29.63)	0.398
		Female	15(55.56)	19(70.37)	

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3	Educational status	Professional	-	1(3.70)	0.259
		Graduate	-	-	
		Intermediate/Diploma	1(3.70)	3(3.70)	
		Higher School	-	1(3.70)	
		Middle School	5(18.52)	2(7.41)	
		Primary School	1(3.70)	4(14.81)	
		Illiterate	20(74.07)	16(59.26)	
4	Occupation	Professional	-	-	0.115
		Semiprofessional	-	-	
		Clerical/shop/farm	1(3.70)	-	
		Skilled worker	-	-	
		Semiskilled worker	6(22.22)	2(7.41)	
		Unskilled	2(7.41)	7(25.93)	
		Unemployed	18(66.67)	18(66.67)	
5	Income status	>123,322	-	-	0.300
		61,663-123,321	-	-	
		46129-61,662	1(3.70)	-	
		30,831-46,128	-	-	
		18,497-30,830	2(7.41)	2(7.41)	
		6,175-18,496	15(55.56)	10(37.04)	
		<6174	9(33.33)	15(55.56)	
6	Marital status	Married	23(85.19)	18(66.67)	0.203
		Unmarried	4(14.81)	9(33.33)	
		Widow	-	-	
7	Family type	Nuclear	33.3(33.3)	48.1(48.1)	0.406
		Joint	66.7(66.7)	51.9(51.9)	
		Extended	-	-	
8	Religion	Hindu	23(85.19)	23(85.19)	0.499
		Muslim	4(14.81)	4(14.81)	
		Sikh	-	-	
9	Language	Hindi	26(96.30)	27(100.00)	1.00
		English	1(3.70)	-	
10	Distance from health care setting	Approachable within an hour	9(33.33)	5(18.52)	0.283
			17(62.96)	21(77.78)	
		2-4 hours	1(3.70)	-	
		4-6 hours	-	1(3.70)	
		More than 6 hours	-	-	

Comparison of clinical variable of experimental and control group. **N = 54**

S No.	Clinical variables		f (%)		p-value
			Experimental Group n=27	Control Group n=27	
1	Previous surgery	Yes	3.70(3.70)	3.70(3.70)	1.00
		No	96.30(96.30)	96.30(96.30)	
2	Endocarditis	Yes	-	-	-
		No	27.00(100.00)	27.00(100.00)	
3	Type of surgery	MVR	15.00(55.56)	14.00(51.85)	0.152
		AVR	7.00(25.93)	12.00(44.44)	
		DVR	5.00(18.52)	1.00(3.70)	

Section II: Effectiveness of Discharge Guidance Programme Findings

Non-Normal Distribution of Outcome Data: The Kolmogorov-Smirnov test indicated that the data for both complication and medication scores at all time points (baseline, 1st week, and 4th week) significantly deviated from a normal distribution (all $p<0.05$), supporting the use of non-parametric statistical tests.

Baseline Medication Adherence: Prior to the intervention, both the experimental and control groups demonstrated similar levels of medication adherence, predominantly in the low to medium categories. The Chi-square test (p=0.362) and the Mann-Whitney U test for mean scores (p=0.517) confirmed no significant difference in medication adherence between the groups at baseline.

Improved Medication Adherence Post-Intervention: The Discharge Guidance Programme significantly improved medication adherence in the experimental group compared to the control group.

At the 1st week post-discharge, a significantly higher percentage of the experimental group showed high adherence (70.37%) compared to the control group (18.51%) (p=0.001). The mean medication adherence score was also significantly higher in the experimental group (8.00±0.00) than the control group (2.79±1.24) (p=0.000). This improvement was sustained and even increased by the 4th week post-discharge, with 88.88% of the experimental group demonstrating high adherence compared to 51.85% in the control group (p=0.006). The mean medication adherence score remained significantly higher in the experimental group (8.00±0.00) than the control group (3.02±1.27) (p=0.000).

Reduced Complications Post-Intervention: The Discharge Guidance Programme was effective in reducing the incidence of post-operative complications.nAt the 1st week post-discharge, significantly fewer patients in the experimental group reported experiencing complications (7.40%) compared to the control group (44.4%). The mean complication score was significantly lower in the experimental group (0.22±0.51) compared to the control group (1±1.24) (p=0.01).By the 4th week post-discharge, none of the patients in the experimental group reported complications (0%), while 29.6% of the control group still experienced complications. The mean complication score remained significantly lower in the experimental group (0.00±0.00) than the control group (0.29±0.608) (p=0.01). Specific avoidable complications were notably less frequent or absent in the experimental group at both the 1st and 4th weeks compared to the control group.

Correlations Between Scores: Significant positive correlations were observed between complication scores at the 1st and 4th weeks post-discharge (r=0.377, p=0.005) and between medication scores at the 1st and 4th weeks post-discharge (r=0.311,p=0.022). This suggests a degree of consistency in the trends of complications and medication adherence over the post-discharge period. Baseline scores were not significantly correlated with later scores.

Comparison of pretest score of medication adherence among experimental group and control group N=54

S No.	Medication timeline		f(%)		p-value
			Experimental Group n =27	Control Group n =27	
1	At baseline	Low adherence	18	21	0.362
2		Medium adherence	9	6	
3		High adherence	0	0	

**p-value<0.05 -Chi-square value*

Comparison of Post-test score for medication adherence between experimental and control group at 1st week and 4th week post discharge. N=54

S No.	Medication timeline		f (%)		p-value
			Experimental Group n =27	Control Group n =27	
1	At 1st week	Low adherence	6(22.22)	9(33.33)	(0.001)
2		Medium adherence	2(7.40)	13(48.18)	
3		High adherence	19(70.37)	5((18.51)	
1	At 4th week	Low adherence	-	6(22.22)	(0.01)
2		Medium adherence	3(11.11)	7(25.92)	
3		High adherence	24(88.88)	14(51.85)	

Comparison of mean between the experimental and control group.

Timeline		Group		
		Experimental	Control	p- value
		Mean±.Standard Deviation	Mean±.Standard Deviation	
Medication	At baseline	3.37±0.97	3.23±0.97	0.517
	At 1st week	8.00±0.00	2.79±1.24	0.000
	At 4th week	8.00±0.00	3.02±1.27	0.000

Comparison of pretest score of Surgery complication among experimental and control group N=54

Complication (54)		At baseline			
	Experimental group		Control group		
		Yes n (%)	No n (%)	Yes n (%)	No n (%)
Q1. Do you experience any complications in at the time of Discharge , Last 1st / 4th weeks post discharge?		27 (100)	-	27 (100)	-

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Avoidable complications	Q2a) 1-Redness, swelling or fluid flowing from the stitch site?	27 (100)	-	27 (100)	-
	Q2a) 2-Do you have swelling in your legs?	1 (3.70)	26 (96.3)	1 (3.7)	26 (96.3)
	Q2a) 3-Do you ever suddenly have trouble in breathing?	-	27 (100)	-	27 (100)
	Q2a) 4-Do you ever feel irregularities in your heartbeat?	-	27 (100)	-	27 (100)
	Q2a) 5-Does your wound ever bleed for a long time?	5 (18.51)	22 (81.48)	3 (11.11)	24 (88.88)
	Q2a) 6-Do you found blood in your stool or urine?	-	27 (100)	-	27 (100)
	Q2a) 7-Do you have unbearable chest pain?	10 (37.03)	17 (62.96)	12 (44.4)	15 (55.6)
	Q2a) 8-Do you ever get itching or rashes?	1 (3.70)	26 (96.3)	-	27 (100)
	Q2a) 9-Do you have fever?	4 (14.81)	23 (85.18)	7 (25.92)	20 (74.1)
	Q2a) 10-Do you have difficulty resuming normal activities?	18 (66.66)	9 (33.33)	16 (59.26)	11 (40.74)
Unavoidable complications	Q2b) 1-Recurrence of the heart valve problem	-	27 (100)	-	27 (100)
	Q2b) 2-Valve leakage	-	27 (100)	-	27 (100)
	Q2b) 3-Valve stenosis	-	27 (100)	-	27 (100)
	Q2b) 4-Arrhythmias	-	27 (100)	-	27 (100)
	Q2b) 5-Stroke	-	27 (100)	-	27 (100)
Situational complication	Q2 - Situational complication	-	27 (100)	-	27 (100)
Q3-Whether readmission was required due to complications?		-	27 (100)	-	27 (100)
Q4-Readmission was done in the treating hospital (KGMU)		-	27 (100)	-	27 (100)

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Q5 -What was the length of stay?	-	27 (100)	-	27 (100)
Q6-Whether any procedure/Surgery was performed?	-	27 (100)	-	27 (100)

Mean Comparison of Complication and Medication Scores Between Experimental and Control Groups

N=54

Timeline		**Group**		
		Experimental	**Control**	**p- value**
		Mean±.Standard Deviation	**Mean±.Standard Deviation**	
Complication	At baseline	3.4±.891	3.4±1.121	0.847
	At 1st week	0.22±.51	1±1.24	0.01
	At 4th week	0.00±0.00	.29±.608	0.01

Noted: Mann-Whitney U test**p-value<0.05*

Normality test of complication and medication scores

Timeline		**Kolmogorov-Smirnov test.**		
		Statistic	**df**	**p – value**
Complication	At baseline	0.245	54	0.000
	At 1st week	0.393	54	0.000
	At 4th week	0.517	54	0.000
Medication	At baseline	0.453	54	0.011
	At 1st week	0.284	54	0.000
	At 4th week	0.427	54	0.000

*Noted: *p-value<0.05*

Spearman's Rank Correlation Between Complication and Medication Scores at 1st and 4th Weeks **N=54**

Timeline			**At 1st week**	**At 4th week**
Complication	At baseline	Correlation value	0.177*	0.090*
		p – value	0.201	0.520
	At 1st week	Correlation value		0.377*
		p – value		0.005
Medication	At baseline	Correlation value	0.195*	-0.010
		p – value	0.157	0.941
	At 1st week	Correlation value		0.311
		p – value		0.022

*Noted: *p-value<0.05*

Discussion

The present study unequivocally demonstrates the effectiveness of the "Discharge Guidance Programme" in significantly enhancing medication adherence and reducing the incidence of post-operative complications among patients who have undergone heart valve replacement surgery. At baseline, both the experimental and control groups

exhibited comparable and generally suboptimal levels of medication adherence, evidenced by non-significant differences (p=0.362 and p=0.517). This finding underscores the widespread challenge of adherence in this patient population prior to targeted interventions. The introduction of the Discharge Guidance Programme led to a profound and statistically significant improvement in adherence within the experimental group. By the first week post-discharge, a remarkable 70.37% of experimental patients achieved high adherence, a stark contrast to only 18.51% in the control group (p=0.001). Crucially, this improvement was sustained and increased by the fourth week post-discharge, reaching 88.88% high adherence in the experimental group (compared to 51.85% in the control group, p=0.006). These results strongly align with existing literature emphasizing the critical role of patient education and support for essential therapies like anticoagulation. The structured nature of the guidance program appears to effectively bridge knowledge gaps and facilitate adherence. Beyond adherence, the DGP also proved instrumental in reducing post-operative complications. The experimental group exhibited a significantly lower mean complication score at both the first week (0.22±0.51 vs. 1±1.24,p=0.01) and the fourth week (0.00±0.00 vs. 0.29±0.608,p=0.01). By the fourth week, no patients in the experimental group reported complications (0%), while 29.6% of the control group still experienced issues. The observed reduction in specific preventable complications further underscores the program's efficacy. Given the well-documented risks of complications like thromboembolism and bleeding in patients with mechanical valves, this significant reduction strongly suggests that improved anticoagulant adherence, facilitated by the guidance program, played a pivotal role in mitigating these risks.

Limitation of the study

- The study's relatively small sample size (n=54) drawn from a single center (KGMU, Lucknow) may significantly limit the extent to which the findings can be generalized to patients in other geographical areas or different healthcare settings. The reliance on a specific patient population within one specialized ward affects external validity.
- The four-week post-discharge follow-up period is relatively short. A longer follow-up (e.g., three to six months or more) is necessary to provide a more robust understanding of the sustained long-term impact of the intervention on critical clinical outcomes such as readmission rates, quality of life, and mortality.
- The primary assessment of complications relied on a self-structured, self-report questionnaire. While the tool's validity and reliability were established by experts, integrating objective measures (e.g., verifying complications and readmissions with medical records or clinical data) would have provided superior validation and strengthened the rigor of the findings.
- The study evaluated the overall "Discharge Guidance Programme". However, it did not explore the individual effectiveness of its specific components (e.g., education on medications, warning signs, lifestyle changes, or follow-up). Future research should investigate this to identify which specific elements are most impactful and resource-efficient.
- The allocation method based on the UHID number's last two digits is transparent but may introduce an unintended selection bias if the digit sequence is not truly random or if the researcher was aware of the sequence during patient enrollment. Full disclosure on blinding and allocation concealment would improve the perceived rigor.
- The results lack specific findings related to the frequency of individual complications assessed, such as thromboembolism, bleeding complications, wound infections, or others within the self-developed categories (Avoidable, Unavoidable, Situational). Furthermore, **s**pecific data on complications leading to readmission were not detailed, which limits the clinical understanding of the program's targeted effect on preventing life-threatening post-surgical issues.

Practical Implications of the study

Nursing Practice: Nurses must view discharge guidance as a critical intervention, utilizing standardized protocols for heart valve replacement

patients covering medication, complications, activity, diet, and follow-up. Active education on medication adherence, especially anticoagulants, is crucial, explaining purpose, dosage, and side effects. Patients and families need clear instructions on identifying and reporting post-operative complications.

Nursing Education: Programs should dedicate resources to effective discharge planning for complex cardiac patients, focusing on assessing health literacy, tailoring content, and using diverse teaching methods.

Nursing Research: Future research should involve extended follow-up periods to assess long-term effects on outcomes like readmissions and quality of life.

Nursing Administration: Administrators must allocate sufficient staff, time, and educational materials for comprehensive discharge planning.

Conclusion

The findings of this study demonstrate that the "Discharge Guidance Programme" is an effective intervention for improving medication adherence and reducing the incidence of post-operative complications among patients who have undergone heart valve replacement. The experimental group, which received the guidance programme, exhibited significantly better medication compliance and experienced fewer complications in the crucial 4-week period following discharge compared to the control group receiving standard care. This suggests that a structured discharge guidance programme can play a vital role in enhancing patient outcomes and potentially reducing the burden of post-surgical morbidity.

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Ethical approval and consent to participate: The institutional ethical committee of KGMU provided ethical clearance. The study was conducted in Lucknow, with reference letter no. 3141/Ethics/2025.

Availability of data and materials: The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Competing interest: Not Applicable

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