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Frequency of Para Prosthetic Leakage in Mechanical Prosthetic Mitral Valve Insertion by Different Suturing Technique

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Abstract: ***Background:*** Para-prosthetic leakage (PPL) is a significant complication following mechanical prosthetic mitral valve replacement, potentially impacting patient outcomes. The choice of suturing technique, continuous or interrupted, plays a pivotal role in determining the frequency and severity of PPL. ***Objective:*** To compare the frequency of para-prosthetic leakage in patients undergoing mechanical prosthetic mitral valve replacement using continuous versus interrupted suturing techniques. ***Methods:*** This observational study was conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from September 2015 to August 2017. A total of 40 patients requiring mitral valve replacement were included and randomly divided into two groups: Group A (continuous suturing, n=20) and Group B (interrupted suturing, n=20). Baseline demographic and clinical data were recorded. The primary outcome was the incidence of PPL, assessed by transthoracic echocardiography at one month postoperatively. ***Results:*** The mean age of the patients was 37.3±11.5 years in Group A and 40.2±11.1 years in Group B. Mild PPL was observed in 15% of patients in Group A and 10% in Group B, a difference that was statistically nonsignificant ($p>0.05$). PPL jets in both groups were predominantly mild and clinically insignificant. The continuous suturing technique was associated with significantly shorter cross-clamp (57.8±22.4 vs. 77.5±18.6 minutes; $p<0.05$) and bypass times (105.9±37.3 vs. 134.7±33.2 minutes; $p<0.05$) compared to the interrupted technique. ***Conclusion:*** Both suturing techniques demonstrated comparable rates of para-prosthetic leakage, with a slight, nonsignificant trend toward reduced PPL in the interrupted group. However, the continuous suturing technique provided the advantage of reduced operative times. Further large-scale studies are recommended to validate these findings.

Keywords: Mitral valve replacement, para-prosthetic leakage, suturing techniques, mechanical prosthetic valve, cardiac surgery, cross-clamp time.

INTRODUCTION

In Bangladesh, rheumatic mitral valvular disease remains a significant contributor to cardiovascular morbidity and mortality, with a prevalence of 0.03% nationally[1,2]. Approximately 56% of patients with mitral valvular disease have a history suggestive of rheumatic fever[1]. Other less common etiologies include mitral valve annular calcification, infective endocarditis, and systemic lupus erythematosus, rheumatoid arthritis, and carcinoid heart disease[3]. Acquired mitral valve diseases are morphologically categorized into three types: mitral stenosis, mitral regurgitation, and mixed lesions. Mitral stenosis refers to narrowing of the mitral valve orifice, whereas mitral regurgitation denotes the inability of valve leaflets to close completely during left ventricular contraction, resulting in blood flow back into the left atrium[4]. Normal mitral valve function depends on the structural integrity and three-dimensional relationships of its components, including the annulus, leaflets, chordae tendineae, and papillary muscles[5].

In chronic rheumatic heart disease, fibrosis of the valve apparatus due to recurrent inflammation and healing leads to distortion of the valve, resulting in stenosis or non-coaptation of valve leaflets, thereby causing mitral regurgitation[3]. Severe stenosis occurs when the valve orifice area is <1 cm^2, with a

transvalvular pressure gradient >10 mmHg, necessitating mitral valve replacement (MVR) in specific conditions such as heavily calcified valves, extensive leaflet destruction, or subvalvular apparatus involvement[6]. During MVR, prosthetic valves are inserted using various suturing techniques, with continuous and interrupted techniques being the most common. Continuous suturing is gaining popularity due to its shorter cardiopulmonary bypass time and reduced thromboembolic risk attributed to fewer knots[7]. However, continuous suturing has been criticized for its potential to increase the risk of paravalvular leakage (PPL) compared to interrupted suturing[8]. PPL refers to an abnormal communication between the prosthesis and surrounding cardiac tissue, which may lead to heart failure and other complications[9]. Despite the advantages of continuous suturing, many surgeons prefer interrupted techniques for their lower risk of PPL and better outcomes[10].

The debate over the optimal suturing technique continues, with conflicting evidence in the literature. Some studies suggest that continuous suturing predisposes patients to PPL due to tissue strangulation and stress-induced annular deformation, whereas interrupted suturing allows for better healing and reduced valve dehiscence[11]. Others argue that PPL is independent of the suturing technique used[12]. PPL is a significant complication associated with mechanical mitral valve prostheses, leading to heart failure and increased morbidity. Echocardiography is the gold-standard diagnostic tool for PPL detection. While two-dimensional transthoracic echocardiography (TTE) is widely used, transesophageal echocardiography (TEE) provides superior sensitivity and specificity for detecting PPL and assessing its location and severity[13,14]. The grading of PPL, from grade I to IV, helps predict future left ventricular dysfunction and guides clinical management[15].

A randomized study from Pakistan reported a PPL incidence of 15% with TEE compared to 12.5% without its use, highlighting the importance of advanced imaging techniques for precise diagnosis[12]. Differences in suturing techniques impact early postoperative outcomes, emphasizing the need for further evaluation to minimize PPL risk and associated morbidity[11]. This study aims to compare continuous and interrupted suturing techniques in MVR to clarify their impact on PPL and improve patient outcomes.

OBJECTIVES OF THE STUDY:

General objective:

Compare para prosthetic leak between continuous and interrupted suturing techniques for mitral valve replacement patients in 1 month.

Specific objectives:

- Detection of PPL by colour Doppler TTE at 1month interval of MVR.
- Evaluation and establishment of diagnosed para prosthetic leak from TTE after 1 month interval of MVR by TEE.

METHODS AND MATERIALS

Type of study: Prospective observational study.

Study Population: The study population was the patients who underwent mitral valve replacement by mechanical mitral valve using continuous or interrupted suturing technique.

Place of study: Cardiac surgery department, Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbag, Dhaka-1000, Bangladesh.

Study Period: September, 2015 to August, 2017 (2 years).

Sample Size: The study sample size was 40.
Group A: 20 patients underwent mitral valve replacement by continuous suturing technique.
Group B: 20 patients underwent mitral valve replacement by interrupted suturing technique.

Sampling method: Purposive sampling method was applied for this study.

Inclusion criteria: All patients undergoing mitral valve replacement by mechanical mitral valve.

Exclusion criteria: Patients undergoing double valve replacement. Presence of preoperative native valve endocarditis.

Data Collection:

Admitted patients were evaluated by taking complete history and performing clinical examinations and confirm diagnosis was established by relevant necessary investigations as for names- chest X ray, electrocardiogram and echocardiogram. Then, patients for mitral valve replacement was justified who fulfilled the inclusion criteria and willing to be included in this study. They were included in the study after receiving the proper consent. Then, 20 patients underwent mitral valve replacement by mechanical prosthetic valve inserted by continuous suturing technique as group A and another 20 patients underwent mitral valve replacement by interrupted suturing technique as group B.

Surgical procedure:

After accessing the left atrium, the anterior mitral leaflet was excised, if needed, approximately 2 mm from the annulus in clockwise and anticlockwise

directions, while preserving the posterior leaflet in most cases. Subvalvular apparatus was removed if severe changes were present. The valve size was determined using a sizer, and a mechanical prosthetic valve was inserted using either continuous or interrupted suturing techniques. Continuous suturing utilized two 2-0 double-armed polypropylene sutures, while interrupted suturing used 12–14 pledgeted or non-pledgeted polyester sutures. Postoperative follow-up included 2D Doppler TTE, with TEE for suspected PPL. Outcomes, including peri- and postoperative mortality, were recorded using a structured data collection form, maintaining confidentiality.

Data Collection Tool/Instrument:

The data collection tools were designed based on the study's objectives and variables. They were developed by reviewing related literature and incorporating feedback from subject experts, research advisors, seniors, and colleagues. The tools were structured in the English language for clarity and consistency.

Data Analysis:

Collected data were checked, reviewed, and organized to ensure accuracy and completeness. Data were manually entered and processed using the Statistical Package for Social Sciences (SPSS, version 20). Statistical techniques were applied to analyze the data, and findings were presented in tabular format. Quantitative data (e.g., para-prosthetic leak quantity) were expressed as mean and standard deviation, while qualitative data (e.g., gender, NYHA class, frequency of PPL) were presented as frequencies and percentages. Statistical evaluations included unpaired t-tests for quantitative data and Chi-square ($\chi 2$) or Fisher's exact tests for qualitative variables.

Ethical Considerations:

Ethical approval was obtained from the Institutional Review Board (IRB). Informed written consent was secured from all participants before data collection. Confidentiality of the participants was strictly maintained, and the data were used solely for research purposes. Participants had the right to agree, decline, or withdraw from the study at any stage.

RESULTS

Table-1: Demographic Variables of the Patients

Variables	Group A (n_1=20)	Group B (n_2=20)	P-value
Age (in years)			
20-30	9(45.0)	4(20.0)	
31-40	3(15.0)	9(45.0)	
41-50	6(30.0)	5(25.0)	
51-60	2(10.0)	0(0.0)	
61-70	0(0.0)	2(10.0)	
Mean±SD	37.3±11.5	40.2±11.1	0.431^{ns}
Sex			
Male	13(65.0)	9(45.0)	0.204^{ns}
Female	7(35.0)	11(55.0)	
BSA (m^2)			
Male	1.46±0.06	1.49±0.06	0.652^{ns}
Female	1.40±0.05	1.42±0.05	0.696^{ns}

n_1 &n_2=Total number of subjects, ns=Not significant (p > 0.05), BSA=Body Surface Area. Data were presented as mean ±SD. Figures in the parentheses denote corresponding %. Statistical analysis was done by unpaired t-test to compare between groups for age and BSA, Chi-square test to compare Gender distribution between two groups.

Table-1 shows distributions of patients by age, gender and BSA. In Group A, 45% patients were in age range of 20-30 years and in Group B 45 % patients in 31-40 years age group. The mean age in Group A was 37.3±11.5 and in Group B 40.2±11.1. The mean difference of Age (years) is statistically nonsignificant (p<0.05). In Table-1, in Group A, 13 (65%) patients were males and 7 (35%) were female. In Group B there was, 9 (45) % males and 11(55) % females. The mean difference of gender is statistically nonsignificant (p <0.05). Mean BSA for Group A male was 1.46±0.06 m^2 and Group B was 1.49±0.06 m^2. The difference of mean value of BSA for male was statistically nonsignificant (p=0.652). Mean BSA for Group A female was 1.40±0.05 m^2 and Group B was 1.42±0.05 m^2. The difference of mean value of BSA for male was statistically nonsignificant (p<0.05).

Table-2: Preoperative NYHA Status

NYHA	Group A (n_1=20)	Group B (n_2=20)	P-value
NYHA classification			0.853^{ns}
Class I	2(10.0)	1(5.0)	
Class II	7(35.0)	8(40.0)	
Class III	10(50.0)	9(45.0)	
Class IV	1(5.0)	2(10.0)	

Table-3 shows distribution of patients by preoperative ECG and Chest X ray findings. In Group A, 9 (45%) patients presented with normal ECG and 11 (55%) with Atrial Fibrillation. In Group B, 8 (40%) patients presented with normal ECG and 15 (75%) with Atrial Fibrillation. The mean difference for ECG is statistically nonsignificant (p <0.05) between two groups.

Table-3: Preoperative ECG and Chest X ray

Preoperative variable	Group A (n_1=20)	Group B (n_2=20)	P-value
ECG			
NAD	9(45.0)	8(40.0)	1.000^{ns}
AF	11(55.0)	12(60.0)	
Chest X ray			
C/T ratio <50%	10(50.0)	12(60.0)	0.525^{ns}
C/T ratio >50%	10(50.0)	8(40.0)	

Table 3 shows for Chest X ray, in Group A, 10 (50%) patients presented with normal cardiac shadow and 10 (50%) with cardiomegaly. In Group B, patients presented with normal cardiac shadow was 12 (60%) and with cardiomegaly 8 (40%). The mean difference for of cardiomegaly is statistically non-significant (p <0.05).

Table-4: Preoperative Echocardiography

Echocardiographic values	Group A (n=20)	Group B (n=20)	P-value
LA (mm)	49.60±7.04	53.45±6.73	0.085^{ns}
LVIDD (mm)	47.30±8.01	47.00±9.02	0.912^{ns}
LVIDS (mm)	32.40±7.42	32.85±6.89	0.84^{ns}
EF (%)	62.60±8.20	58.35±9.64	0.142^{ns}
FS (%)	34.80±4.82	33.90±5.13	0.571^{ns}
Pulmonary Artery Systolic Pressure (mm Hg)	63.70±19.03	64.15±26.44	0.951^{ns}
MV Area (cm^2)	0.83±0.25	0.90±0.28	0.410^{ns}
MV Annulus mm (mm)	32.10±4.73	32.00±3.71	0.941^{ns}
Severe Subvalvular change			
Present	18(90.0)	18(90.0)	1.000^{ns}
Absent	2(10.0)	2(10.0)	
MS or MR			
Mitral stenosis	15(75.0)	13(65.0)	0.490^{ns}
Mitral regurgitation	5(25.0)	7(35.0)	

Table-4 shows distribution of patients by preoperative echocargraphic measurements. In Group A, mean value of LA diameter was 49.60±7.04, LVIDD was 47.30±8.01, LVIDS was 32.40±7.42, EF was 58.35±9.64, FS was 34.80±4.82, PASP was 63.70±19.03, MV Area was 0.83±0.25 and MV Annulus was 32.10±4.73. In Group B, mean value of LA diameter was 53.45±6.73, LVIDD was 47.00±9.02, LVIDS was 32.85±6.89, EF was 62.60±8.20, FS was 33.90±5.13, PASP was 63.70±19.03, MV Area was 0.90±0.28 and MV Annulus 32.00±3.71.The mean difference is statistically nonsignificant for each value between two groups (p<0.05).Also, in both Group A and Group B, 18 (90%) patients presented with subvalvular change. The mean difference between the groups was nonsignificant (p=1.000). In Group A, 15 (75%) patients presented with MS and 5 (25%) patients with MR. In Group B, 13 (65%) patients presented with MS and 7 (35%) patients with MR. The mean differences for was statistically nonsignificant (p<0.05).

Table-5: Preoperative Variables

Operative variables	Group A (n_1=20)	Group B (n2=20)	P-value
Prosthetic valve size (mm)	28.80±1.44	28.00±1.52	0.095^{ns}
Excision of SVA			
Excised	18(90.0)	17(85.0)	0.633^{ns}
Not excised	2(20.0)	3(15.0)	
Total bypass time (min)	105.90±37.32	134.65±33.24	0.014^{s}
Cross clamp time (min)	57.80±22.42	77.50±18.56	0.004^{s}

Table-5 shows distribution patient by prosthetic valve size, excision of subvalvular apparatus, total bypass and cross clamp time. Mean value of prosthetic valve size was 28.80±1.44 mm in Group A and 28.00±1.52 mm in Group B. Excision of subvalvular apparatus was performed in 18 (90%) patients of Group A and 17 (85%) patients of Group B. There is nonsignificant difference for prosthetic valve size and excision of subvalvular apparatus between the groups ($p<0.05$ as significant). Mean value of total bypass time in Group A was 105.90±37.32 min and in group B was 134.65±33.24 min. Mean value of cross clamp time in group A was 57.80±22.42 min and in group B was 77.50±18.56 min. The mean difference of total bypass and cross clamp time is statistically significant ($p<0.05$).

Table-6: Postoperative Outcome Variables

Postoperative variables	Group A (n_1=20)	Group B (n_2=20)	P-value
TTE			
PPL Present	3(15.0)	2(10.0)	0.633^{ns}
PPL Absent	17(85.0)	18(90.0)	
TEE			
PPL Present	3(15.0)	2(10.0)	0.633^{ns}
PPL Absent	17(85.0)	18(90.0)	
Are of PPL			
Septal	1(5.0)	0 (0)	1.000^{ns}
Lateral	2(10.0)	1(5.0)	1.000^{ns}
Anterior	0 (0)	1(5.0)	1.000^{ns}
Posterior	0(0)	0(0.0)	-

Table-6 shows postoperative outcome for PPL. In Group A, 3 (15%) patients were suspected as having PPL by TTE after 1 month follow up and in Group B, 2 (10%) patients were suspected as having PPL. In Group A, 3 (15%) patients diagnosed as having PPL by TEE after 1 month follow up and in Group B, 2 (10%) patients were diagnosed as having PPL. The mean difference was statistically nonsignificant between two groups ($p< 0.05$). The commonest area of PPL was 2(10.0%) in lateral area and other was present as 1(5.0%) in septal area in Group A, on the other hand, 1(5.0%) PPL was in lateral side and 1(5.0%) in anterior area. The mean difference is nonsignificant ($p<0.05$) between two groups.

Table-7: PPL Measurements

PPL measurements	Group A (n_1=20)	Group B (n_2=20)	P-value
Jet width (cm)	0.17±.08	0.16±0.06	0.879^{ns}
Jet length Short central jet	3(15.0)	2(10.0)	0.633^{ns}
Jet area (cm^2)	2.70±0.70	2.80±0.56	0.878
Jet area vs LAA			
<10%	2(10.0)	1(5.0)	0.709^{ns}
10-19.9%	1(5.0)	1(5.0)	
Pulmonary vein flow Dominant systolic flow	3(15.0)	2(10.0)	0.633^{ns}

Table-7 shows measurements of PPL in two groups. The mean value of jet width was 0.17±.08 cm in both Group A and in Group B was 0.16±0.06 cm. In both Group A and B, jet length was short central type. The mean value of jet area was 2.70±0.70 cm^2 and 2.80±0.56 cm^2 in Group A and Group B restectively.

The ratio of jet area to Left Atrial size was less than 10% was present in 2(10%) patients in both Group A and 1(5%) in Group B. Only 1(5%) patient in each group had the ratio within 10-19%. All the patients with PPL had dominant systolic flow of pulmonary vein. The mean difference of jet width, jet length, jet area vs LAA and dominant pulmonary vein flow was statistically nonsignificant ($p<0.05$) between the groups.

DISCUSSION

This observational study was conducted on patients undergoing mitral valve replacement at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from September 2015 to August 2017. A total of 40 patients were included, divided equally into two groups: Group A (continuous suturing technique) and Group B (interrupted suturing technique). Patients with active endocarditis and double valve disease were excluded. The mean age was 37.3±11.5 years in Group A and 40.2±11.1 years in Group B, ranging from 20 to 63 years in Group A and 22 to 63 years in Group B. This aligns with studies reporting mean ages of 29±7.7 years, with a peak incidence of mitral valvular heart disease in the third decade of life[16,17]. Group A had 65% males and 35% females, whereas Group B had 45% males and 55% females, indicating a slight female predominance. Similar findings have been reported, with 48% males and 52% females or even 40% males and 60% females among patients with mitral valvular disease[17,18].

The mean body surface area (BSA) in males was 1.46±0.06 m² (Group A) and 1.49±0.06 m² (Group B), while in females, it was 1.40±0.05 m² (Group A) and 1.42±0.05 m² (Group B). These results are consistent with another study that reported mean BSA values of 1.9±0.5 m² for males and 1.6±0.5 m² for females[19]. Patients commonly presented with NYHA class II and III. This finding correlates with previous studies, where 22–58% of patients were in NYHA class II or III[20,21]. Atrial fibrillation (AF) was observed in 55% of Group A and 60% of Group B patients, consistent with studies reporting AF incidence in mitral valve disease as 50.5% or even 63%[22,23].

Cardiomegaly, indicated by an increased cardiothoracic ratio (>50%) on chest X-ray, was observed in 50% of Group A and 40% of Group B patients. This finding aligns with studies reporting cardiomegaly in 58% of mitral valve disease patients[20]. Preoperative transthoracic echocardiography (TTE) showed an enlarged left atrial diameter (normal: 19–40 mm), with mean values of 49.60±7.04 mm (Group A) and 53.45±6.73 mm (Group B). These results align with studies reporting mean left atrial diameters of 53.45±6.73 mm[23].

In Group A, left ventricular internal dimension diastole (LVIDD) was 47.30±8.01 mm, left ventricular internal dimension systole (LVIDS) was 32.40±7.42 mm, ejection fraction (EF) was 58.35±9.64%, fractional shortening (FS) was 34.80±4.82%, pulmonary artery systolic pressure (PASP) was 63.70±19.03 mm Hg, and mitral valve area (MVA) was 0.83±0.25 cm². Similar findings were observed in Group B. The elevated PASP and reduced MVA are consistent with studies highlighting pulmonary hypertension and valve stenosis in mitral valve disease[20,23]. The majority of patients presented with mitral stenosis (MS) rather than mitral regurgitation (MR). In Group A, 75% had MS and 25% MR, while in Group B, 65% had MS and 35% MR, correlating with studies reporting 45% MS and 22% MR among mitral valve disease patients[17]. The mean prosthetic valve size was 28.80±1.44 mm (Group A) and 28.00±1.52 mm (Group B), consistent with a mean size of 27±1.96 mm reported in prior studies[23].

The continuous suturing technique was faster than the interrupted suturing technique. Group A had a mean bypass time of 105.90±37.32 minutes and cross-clamp time of 57.80±22.42 minutes, compared to 134.65±33.24 minutes and 77.50±18.56 minutes, respectively, in Group B. These differences were statistically significant ($p<0.05$) and corroborate studies showing shorter times for continuous suturing[24]. After one month, para-prosthetic leak (PPL) incidence was slightly higher in Group A (15%) compared to Group B (10%), though the difference was statistically nonsignificant ($p<0.05$). This aligns with studies reporting PPL rates of 6% for continuous suturing and 4% for interrupted suturing[24]. Most PPLs were mild, with short central jets and jet area/left atrial area ratios <10%, indicating clinically insignificant leaks. These findings support prior studies describing functional prosthetic valves with mild PPL[25].

Limitations of the study:

The suturing technique was operating surgeons' choice. Para prosthetic leakage was evaluated by TEE entirely on the basis of suspected cases for PPL by TTE. This study evaluated a small population of patients with mitral valvular heart disease for a limited time period. Study was conducted in a single center. Multiple surgical team performed the procedure. Short time follow up.

CONCLUSION

Continuous suturing technique was found to be a safer and reliable method for mitral valve replacement having short cross clamp and cardiopulmonary bypass times. It benefits the surgeon with quicker and easier technique as well as benefits the patient for cost effectiveness and short term hospital stay.

Recommendations:

We recommend that continuous suturing technique for prosthetic mitral valve insertion can be used safely and effectively as interrupted suturing

technique. A prospective randomized trial and long term follow up are necessary to confirm our findings and to define the long term clinical and functional results of both groups. Development of well-trained cardiac surgical and anesthetic team and establishment of modern equipment and adequate logistic support should be done in different cardiac institutes of Bangladesh to ensure up to date cardiac services and research for valvular heart disease.

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