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Comparison of Short Term Outcomes between Mitral Valve Repair & Replacement for Rheumatic Heart Disease in Bangladesh

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Abstract

Background and objective of the study: *Rheumatic mitral valve disease presents a surgical and medical challenge to surgeons in the developing and developed world. Mitral valve repair may be technically feasible in patients with suitable anatomy, but the appropriateness of repair for rheumatic disease remains controversial. We evaluated our short term outcomes after mitral repair and replacement for rheumatic disease. Methods: 62 patients with rheumatic heart disease were enrolled who underwent mitral valve surgery in National Heart Foundation Hospital & Research Institute according to inclusion and exclusion criteria. Sample size was divided into two groups. Group A had mitral valve repair (n=31) and group B had mitral valve replacement (n=31). Follow-up time was 3 months post-operatively.*

Results: *Follow-up echocardiography after 3 months revealed change of pre-operative and post-operative LVIDd and LVIDs between groups, but was not significant statistically. There was significant change regarding post-operative LVEF (p=0.049). There was no incidence of re-operation, post-operative myocardial infarction, neurological deficit, renal failure, post-operative IABP requirement in the two groups. New onset of post-operative atrial fibrillation found in 3 (9.7%) patient in group A and 2 (6.5%) in group B and difference was statistically not significant (p = xi 0.999). Incidence of low output syndrome was found in 18 (58.1%) patients in group A and 17 (54.8%) patients in Group-B. The difference between the two groups was statistically not significant (p = 0.798). Re-admission for heart failure was found in 1 (3.2%) patient in group A and in 6 (19.4%) in group B but the difference between the two groups was not statistically significant (p = 0.104).*

Conclusions: *In this study, based on short term outcomes, mitral valve repair is a safe operation and leads to better short term outcomes than valve replacement in case of rheumatic heart disease but requires more time. Mitral valve repair can be practiced safely in feasible cases of rheumatic mitral valve dysfunction.*

Keywords: *Mitral Valve Repair, Mitral Valve Replacement, Rheumatic Heart Disease.*

1. INTRODUCTION

Valvular heart disease (VHD) is one of the crucial among all cardiovascular diseases (CVD) which constitutes a major part of cardiovascular morbidity & mortality worldwide[1]. Among all VHD, rheumatic heart disease (RHD) is the worst in nature and a major medical and public health issue worldwide. In children and young people of developing countries, RHD is the most common acquired heart disease around the world[2].

In acute rheumatic fever (RF), the precursor to RHD, results from an abnormal autoimmune

response to group-A beta-hemolytic streptococcus infection in a genetically susceptible host. It affects the heart, joints, brain, subcutaneous tissue and skin; however, when affected, heart valves bear the brunt of RF[2,3]. Recently, for screening purpose when echocardiography (ECHO) is being used, surprisingly more & more sub-clinical cases of RHD are being diagnosed. So, the current prevalence of RHD may not be accurate and the true prevalence of RHD may be higher in Bangladesh than other countries of the world[2]. A large proportion of the patients with rheumatic mitral valve require surgical intervention. Traditionally, operative procedures in mitral valve surgery consisted mainly of valve replacement with mechanical valves or tissue bioprosthetic. Mitral valve replacement is associated with valve related complications including structural valve deterioration, thromboembolic and haemorrhagic events, endocarditis, perivalvular leaks and haemolysis[4] and also needs lifelong anti-coagulation with regular hospital visits for monitoring of coagulation status[5]. The benefits of mitral valve repair outweigh those of replacement in terms of a rapid left ventricular (LV) functional recovery due to preservation of left ventricular function, avoidance of long term anti-coagulation therapy, decreased thrombo-embolic complications, low risk of native valve endocarditis, and the patient's subsequent quality of life[6,7,8,9]. Furthermore, mitral valve repair favors somatic growth, active sports participation, and event-free pregnancy[5,10,11]. In mitral valve repair, the main drawbacks are that some diseased tissue may be left behind and despite good anatomic valve opening intra-operatively, some hemodynamic obstruction persists and may progress overtime and eventually will cause mitral stenosis[12]. In response to these challenges, overtime an approach is developed that involves aggressive excision of the diseased leaflet tissue and of the supporting fused sub-valvular apparatus to remove all valvular tissue that is affected by rheumatic heart disease[13,14,15,16].

2. Materials & Methods

This is a non-randomized clinical trial done in National Heart Foundation Hospital& Research Institute,Mirpur, Dhaka, during the period of January 2017 to October 2018. The purpose of the study was to compare the short term outcomes following mitral valve repair with mitral valve replacement for RHD for a better understanding of the safety and effectiveness. Permission was taken from the academic and institutional Ethics Review Committee (ERC) of National Heart Foundation Hospital and Research Institute for conducting the study. Written informed consent was taken from the participants. A total 62 patients with rheumatic heart disease who underwent mitral valve surgery were enrolled in this study were prospectively allocated into two groups after assessment of mitral valve by operating surgeon. Group -A consisted of 31 patients undergoing mitral valve repair. Group-B consisted of 31 patients undergoing mitral valve replacement. Inclusion criteria's were patients, with rheumatic predominant mitral regurgitation undergoing elective mitral valve repair and replacement. Exclusion criteria's were concomitant CABG, concomitant others valve surgery, concomitant congenital heart diseases, re-do surgery, emergency surgery, patients with preoperative atrial fibrillation, patients with infective endocarditis, patient with thrombo-embolic event, ischemic mitral regurgitation, patient with left ventricular dysfunction (LVEF <35%), patients with acute or chronic pulmonary disease, associated severe mitral stenosis, failed mitral valve repair procedure. Main outcome Variables were mechanical ventilation time in hours, duration of ICU stay in days, post-operative length of hospital stay in days, reoperation for any reason, post-operative myocardial infarction, neurological deficit, renal failure, post-operative IABP requirement, low output syndrome (requirement of inotropes >24 hours), new onset of post-operative atrial fibrillation, re-admission for heart failure, LV performance, physical activity considering NYHA functional class and mortality. All demographic and clinical data were prospectively collected in a dedicated database. Echocardiographic evaluation was done pre-operatively to assess the mitral annulus, leaflet thickness and mobility, commissural and chordal fusion, calcification, regurgitation jets, thickness of the chordae tendineae, left atrial thrombus, sub-valvular changes and other valvular lesions. We also measured the LVIDd, LVIDs in millimeter and LVEF in percentage. Coronary angiogram was done in all patients >40 years in case of male, and >35 years in case of female. All patients received general anesthesia according to standard protocol for mitral valve surgery. Clinical monitoring was done routinely including: ECG, invasive arterial blood pressure, central venous pressure, SpO_2, urine output, core temperature and transesophageal echocardiography (TEE). Standard surgical

techniques were used for all patients. Three traction sutures was taken first, and then valve was assessed. Then the decision regarding valve replacement or repair was taken. If repair was feasible, a variety of repair techniques was applied. Commissurotomy first – if needed, peeling, assessment of the sub-valvular structure and then, if needed, chordal release, splitting, shortening, transfer of Neo Chord was done and then correction of any leaflet defect, cleft repair, elongation or resection, annuloplasty with appropriate ring selection. The competence of the mitral valve was tested by injecting saline through the mitral valve into the left ventricle under pressure from a 250 ml bulb syringe. In case of mitral valve replacement, mechanical valve was used. Post operatively patients were evaluated in the ICU. Standard protocol was used at ICU and if progress noted, then the patients were shifted to post ICU and then to post-operative ward whenever appropriate according to the ICU consultant's judgement. All patients were followed up for three months after operation. During follow-up, patients were contacted directly and requested individually to make an appointment with the primary surgeon and referring cardiologist to evaluate mitral valve status. All ECHO with color Doppler (3 months post-operatively) during follow-up visits were performed at the same institute. Echocardiographic findings were recorded into the computerized database of the hospital. Echocardiographic evaluation of the patients during the study period was performed using a Vivid® 8 pro (GE Healthcare; Wausheka, Wisc) ultrasonography system. Echocardiogram was interpreted by single observer in the department of cardiology in same hospital. Left ventricular performance was assessed by left ventricular ejection fraction (LVEF), left ventricular internal diameter end diastole (LVIDd), and left ventricular internal diameter end systole (LVIDs). Mean value of each measurement were derived from three consecutive beats in sinus rhythms and from 5 beats in those in atrial fibrillation. All patients continued anti-arrhythmic and anti-coagulant medication for 3 months even if they were in sinus rhythm. Data were collected using a preformed data collection sheet.

2.1. Statistical Analysis

Data were analyzed by software statistical program for social science (SPSS-24). Statistical tests were done using unpaired *t*-test between the groups and paired *t*- test within the group. C*hi-square* test and/or Fisher's exact tests were done for comparing categorized data. The Mann – Whitney U test used an alternative to a *t*- test when the data were not normally distributed. Continuous variables were shown as mean ± standard deviation (SD) and categorical variables were given as number (Percentage). A p-value of <0.05 was considered as significant.

3. Results & Observation

There was similarity in respect of demographic variables among groups. In group A 45.2% patients were male and 54.8% patients were female, and 32.3% patients were male with 67.7% female in group B. Mean age were (39.61 ± 11.10) yrs and (37.13 ± 10.02) yrs in group A & B respectively. Mean BMI were (22.25±3.92) (Kg/m^2) and (21.02±3.56) (Kg/m^2) in group A & B respectively.

Table 1. *Demographic data (N=62)*

	Operation Procedure		p value
	Group-A Mitral Valve Repair (n=31)	**Group –B Mitral Valve Replacement (n=31)**	
Age (Years) Mean ± SD	39.61 ± 11.10	37.13 ± 10.02	0.359a
Sex			
Male	14 (45.2%)	10 (32.3%)	0.297
Female	17 (54.8%)	21 (67.7)	
BMI (Kg/m^2) Mean±SD	22.25±3.92	21.02±3.56	0.204

Table 2. *Different baseline variables (N=62)*

Pre-operative baseline characteristics	Operation Procedure		p value
	Group-A Mitral Valve Repair (n=31)	**Group –B Mitral Valve Replacement (n=31)**	
Congestive heart failure	5 (16.1%)	3 (9.7%)	0.707
Previous CVA and TIA	0 (0.0)	0 (0.0)	
Renal impairment	0 (0.0)	0 (0.0)	
Diabetes mellitus	0 (0.0)	1 (3.2%)	0.999

In pre-operative assessment 16.1% of group A patient and 9.7% of group B patient had congestive heart failure, no patient had history of CVA or TIA, no patient had renal impairment one patient of group B had diabetes mellitus.

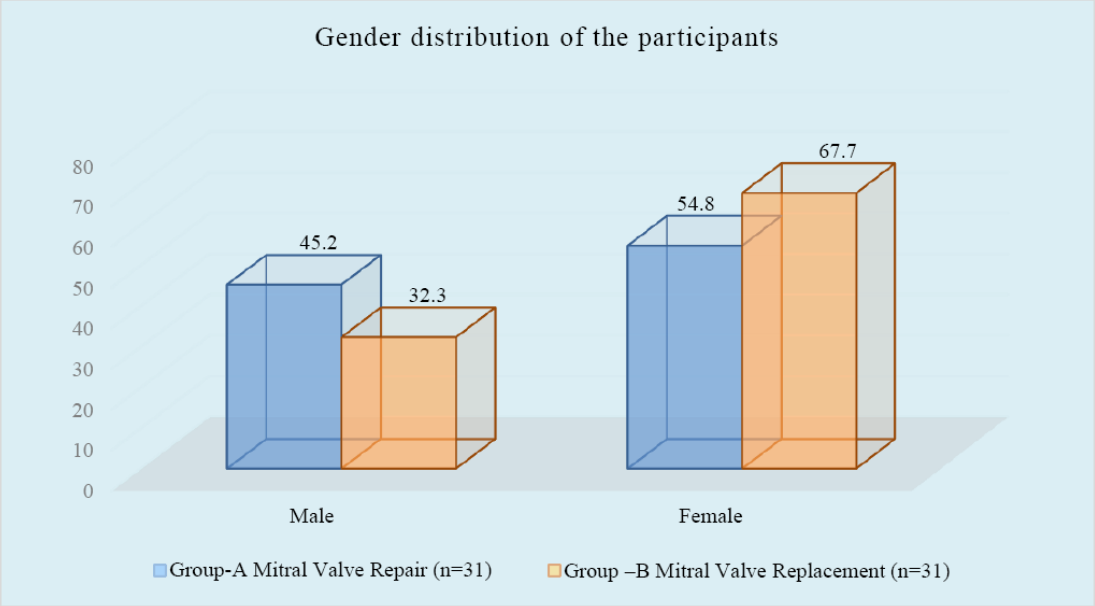

Figure I. *Column chart showed gender wise participants distribution (N=62)*

Table 3. *Different preoperative and post-operative variable (N=62)*

Operation Procedure			
Intraoperative variables	Group-A Mitral Valve Repair (n=31)	Group-B Mitral Valve Replacement (n=31)	p value
CPB time	153.48 ± 20.49	129.94 ± 31.01	0.001a
Aortic cross clamp time	104.39 ± 13.75	87.81 ± 23.04	0.001a
Mechanical Ventilation Time			
Normal (<24hr)	29 (93.5)	31 (100.0)	0.269a
Prolonged (>24hr)	2 (6.5)	0 (0.0)	
Mean ± SD	10.42 ± 4.82	10.13 ± 5.09	
Mean Rank	33.98	29.02	
ICU stay			
Normal (<3days)	26 (83.9)	29 (93.5)	0.063a
Prolonged (>3days)	5 (16.1)	2 (6.5)	
Mean ± SD	2.87 ± 1.82	2.26 ± 1.37	
Mean Rank	35.56	27.44	
Hospital Stay			
Normal (<14days)	28 (90.3)	31 (100.0)	0.685a
Prolonged (>14days)	3 (9.7)	0 (0.0)	
Mean ± SD	8.71 ± 3.18	8.10 ± 1.83	
Mean Rank	32.34	30.66	
Complications			
Reoperation for any reason	0 (0.0)	0 (0.0)	0.999a
Neurological deficit	0 (0.0)	0 (0.0)	
Post-operative myocardial infarction	0 (0.0)	0 (0.0)	
Renal failure	0 (0.0)	0 (0.0)	
New onset of post-operative atrial fibrillation	3 (9.7)	2 (6.5)	
Post-operative IABP requirement	0 (0.0)	0 (0.0)	
Re-admission for heart failure	1 (3.2)	6 (19.4)	0.104a

Required cardio-pulmonary bypass time was 153.48 ± 20.49 minutes for group A and 129.94 ± 31.01 minutes for group B, aortic cross clamp (XCL) time for group A was 104.39 ± 13.75 and 87.81 ± 23.04 minutes for group B. there was significant difference regarding these two parameters among groups (Table 3). Longer period of ICU & hospital stay was observed in

group A compared to group B though the difference was not statistically significant(p>0.05) (Table 3). The extent of complications we studied here were similar between groups.

Table 4. *Echo findings comparing preoperative and post-operative status in same group (N=62)*

LV performance	Group-A (Mitral Valve repair)		p value
	Pre-operative	**Post-operative**	
LVIDd	55.03 ± 4.32	48.10 ± 3.54	<0.001a
LVIDs	37.03 ± 3.75	33.84 ± 3.80	<0.001a
LVEF (%)	59.42 ± 4.82	60.39 ± 5.02	0.243a
	Group-B (Mitral Valve replacement)		
	Pre-operative	Post-operative	
LVIDd	54.87 ± 7.70	48.00 ± 5.76	<0.001a
LVIDs	37.52 ± 6.71	34.10 ± 5.77	0.001a
LVEF (%)	58.84 ± 5.39	57.59 ± 5.75	0.323a

Change of LV performance within group A, mean pre-operative LVIDd was 55.03 ± 4.32 and post-operative LVIDd was 48.10 ± 3.54(follow up on 3 months). The difference was statistically significant (p<0.001). Mean LVIDs pre-operatively 37.03 ± 3.75 and mean LVIDs post-operatively (follow up on 3 months) 33.84 ± 3.80. The difference was statistically significant (p<0.001). Mean LVEF pre-operatively 59.42 ± 4.82 and mean LVEF post-operatively (follow up on 3 months) 60.39 ± 5.02. The difference was not statistically significant (p=0.243). In case of group B pre-operative mean LVIDd was 54.87 ± 7.70 and post-operative 48.00 ± 5.76. The difference was statistically significant (p<0.001). Mean pre-operative LVIDs was 37.52 ± 6.71 and post-operatively 34.10 ± 5.77. The difference was statistically significant (p=0.001). Mean LVEF pre-operatively 58.84 ± 5.39 and mean LVEF post-operatively (follow up on 3 months) 57.59 ± 5.75. The difference was not statistically significant (p=0.323). (all are follow up on 3 months).

Table 5. *Echo findings comparing post-operative parameters among groups*

Operation Procedure			
ECHO findings	Group-A Mitral Valve Repair (n=31)	Group-B Mitral Valve Replacement (n=30)	p value
Pre-operative LVIDd	55.03 ± 4.32	54.87 ± 7.70	0.919a
Post-operative LVIDd	48.10 ± 3.54	48.00 ± 5.76	0.938a
Pre-operative LVIDs	37.03 ± 3.75	37.52 ± 6.71	0.728a
Post-operative LVIDs	33.84 ± 3.80	34.10 ± 5.77	0.836a
Pre-operative LVEF	59.42 ± 4.82	58.84 ± 5.39	0.656a
Post-operative LVEF	60.39 ± 5.02	57.59 ± 5.75	0.049a

4. DISCUSSION

Rheumatic heart disease (RHD) is the leading cause of mitral valve (MV) disease and representing almost one-third of all acquired left-sided valve pathologies[17]. Rheumatic mitral valve disease often has fibrosis or calcification of the leaflet free margin with fused chordae, as well as occasional fibrosis and calcification of the papillary muscle of the commissural region[18,19]. Mechanical MV replacement has its attendant complications[20].

MV repair avoids these complications, permits growth and preserves left ventricular geometry and function. MV repair in RHD is technically demanding[21]. This study is comparable to those of others. To compare the short term outcome between mitral valve replacement and repair we compared different variables among groups like cardio-pulmonary bypass time, Aortic cross clamp (XCL) time, Mechanical ventilation time & duration of ICU stays and post-operative length of hospital, post-operative myocardial infarction, neurological deficit, renal failure, post-operative IABP requirement, post-operative complications consisting of re-exploration of bleeding, myocardial infarction, cerebrovascular accident, acute renal failure requiring dialysis, mediastinitis, Re-admission for heart failure, physical activity considering NYHA functional

class and re-operation for wound infection. We used echocardiographic findings to compare morphological changes and functional status among groups. In this study we found that Group A required significantly higher CPB time and aortic cross clamp time than Group B (P=0.001). Although higher time required for mitral valve repair than replacement, this extra period was well tolerated without any residual effect by the advancement of improved myocardial protection. This result was consistent with the study of Silaschi, et al. (2016)[22]. Mechanical ventilation time & duration of ICU stays and post-operative length of hospital stay were other indicators of recovery. Here we found the difference of these parameters between groups were not statistically significant (Table 3). Bakir, et al. (2013)[23] found the mean mechanical ventilation time was 10.2 ± 5.9 hours (median, 8 hr) and the lengths of stay in the intensive care unit and hospital were 3 ± 7.6 days (median, 1 d) and 11 ± 7.7 days (median, 8 d), respectively in repair group which was similar to our study. There was no incidence of re-operation, post-operative myocardial infarction, neurological deficit, renal failure, post-operative IABP requirement in the two groups. In the study by Oumeiri et al. (2009), 20.5% had post-operative complications consisting of re-exploration of bleeding (n=3), myocardial infarction (n=1), cerebrovascular accident (n=1), acute renal failure requiring dialysis (n=2), mediastinitis (n=1), and re-operation for wound infection (n=2)[18]. Yau et al. (2000) found there was no statistically significant difference between groups in the prevalence of myocardial infarction or perioperative stroke[24]. These results were similar to our study. New onset of post-operative atrial fibrillation found in 3 (9.7%) patient in group A and 2 (6.5%) in group B. The difference between groups was statistically not significant (p = 0.999). In Bakir, et al. (2013), new-onset AF developed in only 2 of 28 patients (7.1%) who had presented with sinus rhythm preoperatively in repair group[23]. Our results were similar to those studies. Re-admission for heart failure was found in 1 (3.2%) patient in group A and in 6 (19.4%) in group B. The difference was not statistically significant (p = 0.104). Pomerantzeff and Brandao (2000) found re-admission for heart failure was found 6.6% in repair group and 11.9% in replacement group which was also not significant[25]. When we compared physical activity considering NYHA functional class (follow up in 3 months) between two groups, NYHA functional class I occupied 25 (80.6%) in group-A and 19 (65.5%) in group-B. NYHA functional class II occupied 5 (16.1%) in group-A and 8 (27.6%) in group-B. NYHA functional class III occupied 1 (3.2%) in group-A and 2 (6.9%) in group-B. The difference between the two groups was not statistically significant (p = 0.411). Oumeiri, et al. (2009) found the same results[18]. Pre-operative to post-operative change of LVIDd & LVIDs within group were significant in case of group A (p<0.001). The difference was not statistically significant in respect of LVEF change (p=0.243) (follow up on 3 months). In group-B, the difference between pre-operative and post-operative mean LVIDd & LVIDs were statistically significant (p<0.001). The difference was not statistically significant in respect of LVEF change (p=0.243) (follow up on 3 months). No statistically significant difference of pre-operative LVIDd, LVIDs, and LVEF was found between two groups. No statistically significant difference of post-operative LVIDd, LVIDs was found between two groups but in case of post-operative LVEF difference was significant (p=0.049) between two groups. This was supported by the study of Bakir, et al. (2013)[23] and Pomerantzeff and Brandao (2000)[24]. Left ventricular ejection fraction is currently accepted as one of the most important tool of measuring LV function in practice[26]. The change of post-operative left ventricular ejection fraction pre-operatively and post-operatively (follow up on 3 months) was not significant within groups but significant between groups. So, left ventricular status was better in repair group. One patients (3.2%) of Group-B expired during three months follow up period. On the contrary, no patients of group-A died in three months follow up period. The difference was non-significant statistically (p=0.999).

5. Conclusion

In this study, based on short term outcomes, mitral valve repair is a safe operation and leads to better short term outcomes than valve replacement in case of rheumatic heart disease but requires more time. Mitral valve repair can be practiced safely in feasible cases of rheumatic mitral valve dysfunction.

6. Limitations

This was a single center study. Follow up period was only 3 months. Sample size was small. The study had time limitation.

7. Recommendation

In feasible cases mitral valve repair would be attempted but further study needed to determine

the long term outcomes. Multi-center study should be performed.

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