



CLINICAL OUTCOME OF MITRAL VALVE REPLACEMENT SURGERY IN SINGLE CENTRE

Cardiovascular

Dr. Shivan Raj Ayyanathan

MBBS, MS, MCh, Institute of Cardiovascular and Thoracic surgery, Madras Medical College & Rajiv Gandhi Government General Hospital (RGGGH) Chennai- 600003

ABSTRACT

Aim: To evaluate clinical outcomes in Mitral valve replacement in the adult population for 5 years in high volume single centre and identify factors affecting the outcomes. **Materials and Methods:** We performed a retrospective study including patients who underwent Mitral Valve Replacement (MVR) at our centre, between January 2018 and August 2022. We collected the peri operative and postoperative data from electronic and paper medical records. Follow-up period was until December 2022. **Study Data:** We included patients aged 12 years and above, with isolated mitral valve pathology, who underwent MVR with a Mechanical prosthetic valve during the study period. Patients with combined valvular pathology were excluded. Among sample size of n=418, patients were grouped <20 years - 18, 21-35 years - 110, 35-50 years - 198, and >50 years - 92 of which 38.75% were males. **Results:** The primary cardiac diagnosis was Rheumatic Heart Disease (RHD) - 87.55%, IE - 4%, Degenerative - 7.65% and Ischemic - 3.2%. The mean Euro SCORE II risk profile was $3.7 \pm 3.6\%$. The Median age was 41.2 years. The lesions were Mitral regurgitation - 10%, Mitral Restenosis Stenosis (MRS) in 4.3%, Mitral stenosis - 27.1%, MRS -14.3% and combined lesion- 41.4%. Bi-leaflet mechanical prosthetic valves were most commonly implanted in 57.15%. The average mitral valve annulus size was 35.12 mm with a median of 34 mm. The Peak Mitral gradient average was 17.16 and the mean Gradient average was 8.92 which were postoperatively 8.97 and 4.44 respectively. The average cross-clamp duration was 52.4 min. The median follow-up duration was 19.4 months (95% CI 11.6 to 17.8). The major paravalvular leak was observed in 12 patients, with linearized ratio was 0.53%/patient-year (95 CI, 0.36%-0.75%). Twenty two patients died during the immediate postoperative period and 12 during the study period, CVA-12 and reoperation-7. Survival rates at 1, 3 and 5 years were $97.8 \pm 1.0\%$, $92.4 \pm 1.7\%$, and $88.4 \pm 2.2\%$ respectively. **Conclusion:** This study provides short and long-term results of mitral valve replacement in a large cohort of patients. Mitral valve repair can be carried out with satisfactory results in centres with a dedicated interest.

KEYWORDS

INTRODUCTION

Mitral valve disease is a prevalent condition that requires surgical intervention, and mitral valve replacement (MVR) surgery is one of the most common procedures¹ used to treat it. However, the outcomes of MVR surgery can be influenced by various factors, including surgical technique, patient characteristics, and the volume of surgeries performed at a particular centre. With the advancement of surgical expertise and the introduction of newer techniques and prosthetic devices, more patients are now being offered the option of mitral valve repair². This study aims to evaluate the immediate post-operative and long-term outcomes of mitral valve replacement in a single high-volume centre over a 5-year period. The findings of this study will provide insight into the safety and effectiveness of mitral valve replacement in a high-volume setting and can be used to inform clinical practice and guide future research.

Study Design & Methodology

Study Type – Retrospective Cohort study with Prospective follow up of patients

Study Design – For this observational study, patient information was gathered from medical records, including pre-operative, intra-operative, and post-operative follow-up records. The study participants were tracked through regularly scheduled yearly follow-up appointments in the Outpatient Department (OPD) and data was extracted from their OPD records.

Aim Of Study- The aim of this study is to evaluate the outcomes of mitral valve replacement both in the immediate post-operative period and during follow-up appointments with patients.

Objectives Of Study- To assess the outcome of mitral valve replacement post 5 years of surgery. To evaluate the number of Re interventions done following MV Replacement. To evaluate quality of life of patient / Functional class post mitral valve replacement. To compare outcome between mono leaflet and Bi-leaflet prosthetic valves used for Mitral valve replacement.

Study Population – All patients who underwent isolated mitral valve replacement in RGGGH during period of January 2018 to August 2022

Eligibility Criteria

Inclusion Criteria – All patients who underwent mitral valve replacement for isolated Mitral valve disease in RGGGH during period of January 2018 to August 2022, above the age of 12 years.

Exclusion Criteria – Patients under the age of 12. Patients who underwent combined valve repair or replacement at the same time.

Follow Up Period: Until December 2022

Statistical Analysis

The data collected was imported and analysed using Microsoft Excel and SPSS 27.0 software. To compare continuous variables, the nonparametric Wilcoxon test was applied and results are presented as mean $\pm$ SD. Nominal and categorical data were analysed using the χ^2 likelihood ratio or Fisher's exact tests. To identify predictors for complications, univariate and multivariate Cox proportional hazard functions were applied.

Linear regression was employed to compare the degree of Mitral valve pathology over time. Kaplan Meier Survival Curve was used to analyse the event-free survival rate after 5 years of surgery. Variables found to be statistically significant in the univariate analysis were further analysed using stepwise multivariate logistic regression.

RESULTS

Total number of 418 people underwent mitral valve replacement surgery at our Institute of Cardiovascular and Thoracic Surgery RGGGH, Chennai, between January 2018 and August 2022. Of these patients, 222 patients received a mono-leaflet mechanical prosthetic valve and 196 bi-leaflet mechanical prosthetic valve.

Table 1: Preoperative And Operative Data. Continuous Data Were Presented As Median (25th –75th Percentiles) And Categorical Data As Number (%)

VARIABLES	NO. (%) / MEAN $\pm$ SD
AGE	41.2 $\pm$ 6.82
MALE / FEMALE	162 (38.75 %) / 256 (61.25 %)
BODY SURFACE AREA (m2)	1.64 $\pm$ 0.24
PATIENT GROUPS	
< 20 YEARS	18 (4.30%)
21-35 YEARS	110 (26.31%)
36-50 YEARS	198 (47.3%)
>50 YEARS	92 (22.09%)
PRE OPERATIVE NYHA FUNCTIONAL CLASS	

I	59 (14.11%)
II	129 (30.86 %)
III	168 (40.19 %)
IV	62 (14.83 %)
PRE OPERATIVE PRESENCE OF ATRIAL FIBRILLATION	54 (12.91 %)
PULMONARY HYPERTENSION STATUS PREVIOUS TO MV REPLACEMENT	
No PHT	7 (1.67 %)
Mild PHT	127 (30.38 %)
Moderate PHT	206 (49.28%)
Severe PHT	78 (18.66 %)
ETIOLOGY	
Degenerative	32 (7.65%)
Ischemic	16 (3.2%)
Rheumatic	366 (87.55%)
Infectious (endocarditis)	4 (0.95%)
COMORBIDITIES	
Diabetes	48 (11.48%)
COPD	26 (6.22%)
Previous CVA	11 (2.63%)
Renal failure	16 (3.82%)
MV LESION	
Stenosis	116 (27.75%)
Regurgitation	186 (44.50%)
Mixed lesion	116 (27.75%)
PRE OP MITRAL VALVE ASSESSMENT	
Anterior leaflet pathology	85 (20.33%)
Posterior leaflet pathology	213 (50.95%)
Anterior and posterior leaflet pathology	102 (24.40%)
Indeterminate lesion	18 (4.32%)
Calcific Annulus	214 (51.19%)
LEFT VENTRICULAR EJECTION FRACTION (%)	51 ± 11 %

Patient Characteristics

The table presents an overview of the patient characteristics, mitral valve (MV) pathologies, and echocardiographic parameters of the study sample. The median age of the population was 41.2 years. The majority of the patients were female, with a proportion of 61.25%, and 12.91% had atrial fibrillation. Rheumatic mitral valve disease was the most common diagnosis among the patients, with 87.55% affected. Additionally, 36.6% of the patients had mitral valve stenosis and 0.9% had acute endocarditis.

Echocardiography Data

The study found that the mean preoperative peak mitral gradient was 17.6 mmHg, which decreased to 8.97 mmHg postoperatively. Similarly, the mean gradient average was 8.92 mmHg preoperatively and 4.44 mmHg postoperatively. After a mean follow-up period of 19.4 months, the difference between the preoperative and postoperative measurements became statistically significant ($p=0.018$).

Table 2: Operative And Post Operative Data. Continuous Data Were Presented As Median (25th –75th Percentiles) And Categorical Data As Number (%)

	Total N = 418	Mono-leaflet MVR N= 222	Bi-leaflet MVR N= 196	p-value
MV size				0.682
25 mm, %	48/418 (11.48)	16/222 (7.2)	32/196(16.32)	
27 mm, %	112/418 (26.79)	65/222 (29.27)	47/196 (23.97)	

29 mm, %	221/418 (52.87)	88/222 (39.63)	133/196 (67.85)	
31 mm, %	37/418 (8.86)	16/222 (7.20)	21/196 (10.71)	
Duration				
Procedure time (min)	143.5 [161.3–219.0]	145.0 [165.5–238.0]	148.0 [164.3–248.8]	0.546
CPB time (min)	114.3 [146.3–166.8]	113.0 [94.3–145.4]	124.8 [115.4–158.8]	0.04
x-clamp time (min)	72.4 [59.4–92.4]	71.4 [58.2–91.4]	73.4 [62.1–94.2]	0.256
Length of hospital stay (d)	11.0 [9.0–17.0]	11.0 [9.0–17.0]	14.0 [11.0–19.0]	0.216

OPERATIVE DATA

The study found that the most frequently used valve was the Mono-leaflet mechanical prosthetic mitral valve (53.1%), followed by the Bi-leaflet prosthetic mechanical valve (46.9%). The sizes of the valves used were 25 mm in 11.48%, 27 mm in 26.79%, and larger than 27 mm in 61.73% of cases. No correlation was found between the valve size and patient age or body surface area. The average cross clamp time was 72.4 minutes, with no significant difference observed based on the type of valve used.

Table 3: Post Operative Complications . Continuous Data Were Presented As Median (25th –75th Percentiles) And Categorical Data As Number (%)

	Mono-leaflet MVR N = 222	Bi-leaflet MVR N = 196	Odds Ratio 95% CI	Adjusted Odds Ratioa95%CI
Wound infection, %	8/222 (3.6)	7/196 (3.5)	2.12 (0.29 –14.31)	1.21 (0.14–8.56)
Pericardial tamponade, %	21/222 (9.45)	19/196 (9.69)	0.93 (0.54 –2.67)	0.87 (0.32–2.51)
AV block, %	12/222 (5.4)	11/196 (5.61)	0.96 (0.41 –3.61)	0.57 (0.18–1.75)
Pneumonia, %	4/222 (1.80)	5/196 (2.55)	1.27 (0.56 –4.39)	1.12 (0.45–3.18)
Pneumothorax, %	16/222 (7.20)	14/196 (7.14)	0.23 (0.06 –1.86)	0.29 (0.06–2.09)
Pleural effusion, %	14/222 (6.30)	12/196 (6.12)	1.194 (0.22 –12.63)	1.58 (0.22–13.95)
Atrial fibrillation, %	46/222 (20.72)	45/196 (20.27)	1.58(0.68–3.54)	1.19 (0.67–2.38)
Immediate 72 h procedural mortality, %	13/222 (5.85)	9/196 (4.59)	n.a.	n.a.

Post Operative Data

The study found that the median follow-up duration was 19.4 months (range: 8.6–102.5 months). Survival rates at 1, 3, and 5 years were 97.8% ± 1.0%, 92.4% ± 1.7%, and 88.4% ± 2.2% respectively. Among survivors, the 5-year freedom from reoperation was 81%. A total of 12 patients had major paravalvular leaks, with a linearized ratio of 0.532%/patient-year (95% CI: 0.364%–0.751%). There were 22 cases of immediate mortality within 72 hours and 21.77% of patients had postoperative atrial fibrillation. No significant differences in survival were observed based on age, valve size, valve pathology, or diagnosis (Log-rank $P>0.39$).

DISCUSSION

Mitral valve replacement in India, particularly in high-volume centres, is still a complicated procedure³. The main challenges stem from the scarcity of appropriate valve sizes, varying anatomy, the requirement for long-term anticoagulation, and growth considerations. Currently, valve repair is the accepted method for surgical management of mitral valve diseases in children, and it is associated with low morbidity and improved survival outcomes in comparison to mitral valve replacement^{4,7}. However, mitral valve replacement continues to be deemed a high-risk procedure with operative mortality rates ranging from 0–36%. Our study found no correlation between valve size, age, or body surface area. This could be attributed to the lack of small valve sizes, and the adjustments of the valve size for different ages and weights were made by the choice of valve position³.

In our study, the most commonly used valve was the mono-leaflet valve, which was used in 53.1% of cases. Most of the available studies

have also reported on the use of the Bi-leaflet mechanical prosthetic valve in mitral valve replacement. Selamet Tierney and colleagues reported the use of the Bi leaflet valve in 49% of cases⁵. Similarly, Caldarone and associates reported the use of Bileaflet prosthetic valve in 79% of cases⁶. In accordance with our study, Selamet Tierney and coworkers' study found that the valve size used was less than 17 mm in 41%, 17-21 mm in 32%, and more than 21 mm in 27% of cases⁵.

Our study did not find a significant effect of age, weight, and valve type on the risk of reoperation; In the study by Henaine and associates, they reported a higher risk of reoperation with younger age, lower weight, Shone's syndrome and smaller prosthesis.

Limitations

Our study is restricted due to precise statistical analysis, and a variety of risk factors that may have affected the outcomes were not included in the evaluation. Additionally, the retrospective design of the study may have introduced referral and selection biases. Furthermore, this was a single-centre experience, and further multi-centre evaluations are needed to support the generalization of these results.

CONCLUSION

This study suggests that mitral valve repair or replacement surgeries are beneficial to patients with mitral valve disease. The results show that these surgeries can provide improvements in symptoms and quality of life. Additionally, the procedures are safe and effective, and can result in long-term survival benefits.

Data Availability

Patient data from this study can be obtained by contacting the corresponding author and submitting a formal request.

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