



ORIGINAL ARTICLE

## One-Year Outcomes of St. Jude Medical (SJM) Mechanical Valve Replacement: Mortality and morbidity analysis in a resource-constrained Cardiac Centre.

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**ABSTRACT... Objective:** To determine the mortality and morbidity rates at one year in patients with rheumatic heart disease undergone St. Jude Medical mechanical heart valves replacement. **Study Design:** Retrospective Cohort study. **Setting:** Peshawar Institute of Cardiology (PIC), a newly established cardiac centre located in Peshawar. **Period:** January 2021 to January 2023. **Methods:** Data were extracted from the hospital's Electronic Medical Records (EMR) and Health Management Information System (HMIS) of 208 adult patients ( $\geq 18$  years) who underwent mechanical valve replacement (aortic, mitral, or double valve) using St. Jude Medical Master series prostheses between 2021 and 2023 and analyzed with was SPSS version 26.0. **Results:** Mechanical valve replacement was performed on 208 patients with a median age of 41 years (IQR: 32–52) and a median BMI of 24.1 kg/m<sup>2</sup>. A total of 102 individuals (40.0%) had their mitral valves replaced. The most frequent reasons for readmission within a year were bleeding in 8 patients (3.8%) and pericardial effusion in 9 patients (4.3%). All cause mortality including operative mortality rate at one year was 9%. **Conclusion:** Although mechanical valve replacement is still a viable option for patients with rheumatic heart disease, it is linked to high rates of death and morbidity in settings with limited resources in developing nations.

**Key words:** St. Jude Medical, Mitral Valve, Aortic Valve.

### INTRODUCTION

Valvular heart disease is a rapidly increasing cause of cardiovascular death and morbidity and contributes to loss of function and quality of life. It has a varied epidemiology around the world with an increased prevalence of degenerative valve disease in high-income countries while a predominance of rheumatic heart disease (RHD) in middle and lower-middle income countries (LMICs).<sup>1</sup>

Rheumatic heart disease (RHD) remains the most common cause of valvular heart disease and an important concern of cardiovascular mortality around the world, especially in countries with less resources where it is associated with higher mortality and morbidity rates.<sup>2</sup> It is estimated that around 33 million people are affected by rheumatic heart disease (RHD) worldwide with an estimated

320,000 deaths annually.<sup>3</sup> South Asian countries face an increased risk of cardiovascular diseases particularly rheumatic heart diseases (RHD), the increasing burden of which is attributable to socioeconomic, genetic and environmental factors in the region.<sup>4</sup> However, there is still limited data on patients with chronic RHD and their postoperative follow-up from LMICs.<sup>5</sup> Valve replacement surgery is commonly performed to manage valvular heart disease with various types of valves available for use in patients with aortic or mitral valve disease.

St. Jude Medical (SJM) mechanical valve is one of the most used bileaflet valve around the world, since it was introduced in 1977. Due to its great durability and high performance, it is generally used in young patients with structural heart disease.<sup>6</sup>

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It is a pyrolytic carbon valve employed in both aortic and mitral valve replacements and ensured decreased transvalvular gradients and lower thromboembolic and mechanical issues in comparison with other mechanical valves when it was released.<sup>7</sup>

In this article, we present the 1-year outcomes of St. Jude Medical (SJM) mechanical valves in patients undergoing aortic and mitral valve replacements in a newly opened cardiac center from a resource-constrained region.

## METHODS

We conducted a retrospective cohort study at Peshawar Institute of Cardiology (PIC), a newly established cardiac centre located in Peshawar, Pakistan. This centre serves a population in a region affected by terrorism and ongoing conflict, presenting unique challenges in healthcare delivery and patient follow-up. The study included 208 adult patients ( $\geq 18$  years) who underwent mechanical valve replacement (aortic, mitral, or double valve) using St. Jude Medical Master series prostheses between 2021 and 2023. Patients who underwent concomitant procedures (e.g., coronary artery bypass grafting) were excluded from the study.

Data were extracted from the hospital's Electronic Medical Records (EMR) and Health Management Information System (HMIS). The following information was collected for each patient:

1. Demographic characteristics (age, gender, body mass index)
2. Preoperative clinical status (New York Heart Association functional classification)
3. Type of valve replacement (aortic, mitral, or double)
4. Comorbidities
5. Operative details
6. Postoperative complications
7. Readmission causes
8. Mortality data

One-year follow-up was conducted via telephone interviews with patients or their families. For patients lost to follow-up, we consulted local death registries where available.

Statistical analysis was performed using SPSS version 26.0. Categorical variables were presented as frequencies and percentages. Continuous variables were represented as median and interquartile ranges (IQR) after assessing data distribution using Shapiro-Wilk and skewness tests.

Associations between categorical variables were assessed using Chi-squared tests or Fisher's Exact tests for variables with frequencies  $< 5$ . Two-sample T-tests were used to compare continuous variables. Binary univariate logistic regression was employed to assess the association between valve-related mortality (dependent variable) and various independent variables, including gender, operation status, valve groups, comorbidities, and postoperative variables. Variables with  $p < 0.25$  in the univariate analysis and those of known clinical importance were included in a multivariable logistic regression model. Statistical significance for all tests was set at  $p < 0.05$ .

The study was approved by the Institutional Review Board of Peshawar Institute of Cardiology, Peshawar (Reference No: IRC/24/21). Given the retrospective nature of the study, the requirement for individual patient consent was waived. All patient data were de-identified to ensure confidentiality.

## RESULTS

The study cohort consisted of 208 patients with a median age of 41 years (IQR: 32-52) and a median BMI of  $24.1 \text{ kg/m}^2$  (IQR: 21.3-27.2). The gender distribution was nearly equal, with 101 (48.6%) males and 107 (51.4%) females. Preoperative NYHA classifications were distributed as follows: Class I (1, 0.5%), Class II (80, 38.5%), Class III (118, 56.7%), and Class IV (9, 4.3%).

Mitral valve replacement was the most common procedure, performed in 102 patients (49.0%), followed by aortic valve replacement in 65 patients (31.3%), and double valve replacement in 41 patients (19.7%).

The most frequent complications within the first year were:

Complication	No of Patients (%)
Pericardial effusion	9 (4.3%)
Bleeding	8 (3.8%)
Haemorrhagic stroke	3 (1.4%)
Prosthetic valve thrombosis	3 (1.4%)
Surgical site infection	2 (1.0%)
Endocarditis	1 (0.5%)
Pleural effusion	1 (0.5%)

**Table-I: Complications of Mechanical Valve Replacement.**

All cause mortality including operative mortality rate at one year was 9% (19 patients).

The univariate analysis of readmission causes revealed significant associations with valve-related mortality. Other factors such as age, gender, body-mass index (BMI), valve-surgery type, hypertension, diabetes and were included in the univariate analysis, but these associations were not significant.

## DISCUSSION

Around the world more than 33 million people have been symptomatically affected by rheumatic heart disease. The total global burden of disease in terms of mortality is 345000 in the year 2010, but it is reported to be a decreasing trend. There are also approximately 47 million people who have asymptomatic damage to their heart that have not yet been symptomatic.<sup>8</sup> Given the burden of disease the World Health Federation has launched criteria that use echocardiography and clinical history to make the diagnosis for RHD. Mitral and Aortic valve repair is recommended for degenerative etiology based on their superior outcomes<sup>9</sup> but few recommend repair in RHD.<sup>10,11</sup>

The aim of our study was to present one year follow up of patients undergone mechanical valve with SJM prosthesis in relatively young population of median age (41 years). This reflects the demographic profile of valvular heart disease in many LMICs, where rheumatic heart disease remains a significant contributor to valve pathology.<sup>12</sup> This underscores the importance of early intervention and the potential for long-term

benefits from successful valve replacement in this population.

Variable	Univariable	
	Odds Ratio (95% CI)	P-Value
Age		
>41 (ref)		
<41	1.065 (0.384-2.952)	0.904
Gender		
Male		
Female (ref)	1.065 (0.384-2.952)	0.904
Body Mass Index (BMI)		
>24		
<24 (ref)	0.436 (0.146-1.302)	0.137
Valve Surgery Type		
DVR (ref)		0.719
AVR	1.195 (0.395-3.616)	0.753
MVR	1.983 (0.381-10.332)	0.416
Hypertension		
Yes		
No (ref)	0.333 (0.043-2.614)	0.296
Diabetes Mellitus		
Yes		
No (ref)	0.00 (0.00)	0.999
NYHA Class		
I/II (ref)		
III/IV	1.24(0.443-3.473)	0.682
Readmission Causes		
No Readmissions (ref)		
Hemorrhagic Emergency	23.067 (4.914-108.27)	<0.001
Pericardial Effusion	0.800 (0.141-4.534)	0.801
Others	2.333 (0.310-17.545)	0.410

Note:  
OR odds ratio  
CI confidence interval  
HTN Hypertension  
DM Diabetes Mellitus

**Table-II. Logistic regression all cause mortality associated with patient factors**

Pericardial effusion and bleeding emerged as the most common causes for readmission, highlighting areas for potential improvement in postoperative care and anticoagulation management.<sup>3</sup> (1.4%) patients presented with Prosthetic valve thrombosis in emergency department.

There is limited long term follow-up data available in south Asian population with rheumatic disease undergone mechanical valve replacement. Study done in Indian population showing 1 year all cause mortality after mitral valve replacement

with mechanical valve was 8.25%.<sup>13</sup> Another study conducted in sub Saharan country in population with rheumatic heart disease undergone aortic valve replacement showing all cause mortality at one year was 6.5%.<sup>14</sup> In our study all cause mortality including operative mortality was 9%. This high mortality can be due difficulty in access to medical facilities to check on INR, Low literacy level in our region affected by terrorism. 49% of our patients undergone mitral valve replacement which is also reported to be a risk factor for mortality.<sup>15</sup> Mechanical valve are usually used in under-developed countries because of younger population having RHD using bio-prosthesis in these population is associated with high rates of degeneration and low cost.<sup>16</sup>

### LIMITATION

Our study has several limitations. The single-centre design may limit the generalizability of our findings to other resource-constrained settings. The retrospective nature of the study introduces potential for bias and missing data. Additionally, the one-year follow-up period may not capture long-term complications or prosthetic valve durability.

### CONCLUSION

This study demonstrates the feasibility and relative safety of mechanical valve replacement surgeries using St. Jude Medical prostheses in a resource-constrained, conflict-affected setting. The mortality and morbidity rates observed are encouraging and highlight the crucial role of experienced surgical teams and standardized perioperative protocols in achieving favourable outcomes. Future research should focus on long-term outcomes, strategies to reduce readmissions, and interventions to improve postoperative care in similar challenging healthcare environments.

### CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	<b>Yasir Bilal:</b> Writing of the manuscript.
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5	<b>Musa Salar:</b> Data collection.
6	<b>Abdul Nasir:</b> Idea, data collection, writing of the manuscript.