Original Article

One-Year Follow-Up of Morbidity and Mortality in Mechanical Valve Replacement Patients at a Newly Established Cardiac Center in a Developing Country

Muhammad Tariq, Aamir Iqbal, Ubaid Ur Rahman, Asma Qudrat, Umama Qasim, Mohammad Waleed*

Peshawar Institute of Cardiology, KPK, Pakistan.

*Corresponding Author

Mohammad Waleed
Waleed1280@yahoo.com

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Abstract

Objective: To examine the morbidity and mortality rates associated with mechanical heart valve replacement in patients from a developing country at a 1-year follow-up.

Methodology: This retrospective observational study was conducted on the patients who presented with Aortic Valve Replacement (AVR), Mitral Valve Replacement (MVR) and Dual Valve Replacement (DVR), at the Cardiac Surgery Department of Peshawar Institute of Cardiology (PIC). The data of 258 patients who underwent these cardiac procedures was collected between a period of two years i.e., from Jan 2021 till Dec 2022 from the hospital records.

Results: Out of 258 patients, 37 (14.3%) were readmitted within one year of surgery due to complications such as pericardial effusion, pleural effusion, bleeding, endocarditis, hemorrhagic stroke, and stuck valve. The in-hospital mortality rate following the procedure was 2.7%, while the 1-year post-discharge mortality rate was 10.3%, with 14 cases (51.86%) attributed to warfarin-related complications. Within the first year after discharge, the average number of INR (International Normalized Ratio) tests conducted was 8.34 ± 8.268, and the average number of consultations for INR management was 2.53 ± 3.715.

Conclusion: Warfarin-related complications are a major contributor to mortality and morbidity in patients with mechanical heart valves in developing countries. To address this, newly established cardiac centers in the developing world should adopt innovative strategies, such as establishing dedicated warfarin clinics, promoting the use of self-testing devices, and developing remote cardiac care centers to reduce these complications.

Keywords: Cardiac valve replacement, Mitral valve replacement, Aortic valve replacement, Warfarin.

Introduction

The cardiac valve replacement has advanced significantly over the past 50 years and many changes have been made to the material and design of mechanical prosthesis to improve their thrombogenicity, hemodynamic profile and durability, but inspite of this, bleeding events continue to occur and account for 75% of all the complications.[1] Despite of the fact that bio-prosthesis do not require anticoagulant drugs after replacement, their short lifespan means that they are mainly suiTable for older population.[2] Over 100,000 valve replacements are done annually in the United States and 80-90% of these replacements use bio-prosthesis.[1] This strategy was implemented to reduce anticoagulation-related complications, particularly in the elderly population.[3] But rheumatic heart diseases is more common in underdeveloped countries therefore mechanical valve is a choice of prosthesis for younger patients having rheumatic desease.[4] This makes them more prone to develop warfarin related complication like bleeding and thromboembolism.[2]

The prevalence of rheumatic heart disease is 5.7 per 1000 in Pakistan which shows it is very common in developing world.[5] This condition places huge burden of aortic and mitral diseases in young population therefore forcing surgeons to choose mechanical valve rather than tissue valve. Mechanical valves are often chosen in low- and middle-income countries (LMICs) due to their durability, making them a suiTable option for younger patients needing long-term solutions.

Over time, they prove cost-effective by reducing the need for repeat procedures, which is particularly important in regions with limited medical facilities and surgical expertise. Although lifelong anticoagulation is required, warfarin remains widely available and affordable in LMICs.[3] A study reported overall 5-year and 10-year survival rates of 91.8 ± 1.4% and 84.5 ± 2.3%, respectively, in patients who underwent mechanical valve replacement, with freedom from bleeding and thromboembolic complications at 96.2 ± 1.0% and 91.5 ± 2.4% in an Asian population.[6]

Another study identified thromboembolic events and bleeding as the primary causes of mortality and morbidity.[7] Similar findings were observed in a comparable population, where survival rates following mechanical valve replacement were 95.5% at 30 days, 93.2% at 3 months, 87.5% at 1 year, and 82.9% at both 5 and 10 years.[8] There is limited data available on long term follow of these patients undergone mechanical valve replacement in developing world.[4] Our primary objective

was to find out mortality and morbidity rates associated with mechanical valve replacement within 1 year of the procedure, among patients in newly established cardiac center in Peshawar, Pakistan. The secondary objective was to explore different strategies to reduce complications associated with mechanical heart valves in patients from developing countries.

Methodology

This retrospective observational study was conducted from Jan 2021 to Dec 2022. Ethical approval was obtained from the Institutional Review Board (IRB) of Peshawar Institute of Cardiology (PIC) (IRC/24/81). The patients presented for Aortic Valve Replacement (AVR), Mitral Valve Replacement (MVR) and Double Valve Replacement (DVR=AVR+MVR) at the Cardiac Surgery Department of Peshawar Institute of Cardiology (PIC). In addition to that, follow up was conducted on the patients who completed their 1-year follow-up. The inclusion criteria for patients were those who underwent valvular heart surgeries, including AVR, MVR, and DVR, at the same center (PIC) over a two-year period. Patients aged 18 years and above who completed a 1-year follow-up were included.

The exclusion criteria were patients who underwent additional cardiac surgeries alongside valve surgery. The data was collected from Electronic Medical Records (EMR) and Health Management Information System (HMIS). The phone numbers of patients were extracted from the electronic medical records (EMR). Data analysis was performed using Statistical Package of Social Sciences (SPSS) version 23.

Mean ± standard deviation was calculated for variables including age, BMI, Valve size, INR at discharge, number of INR (International normalized ratio) done after discharge in one year, number of INR done after discharge in one year, number consultation for INR management in one year and INR during re-admission.

The overall percentages of male and female patients, operation status, types of valve surgeries and the comorbidities including hypertension, diabetes mellitus, smoking, previous stroke history, chronic renal insufficiency, chronic lung diseases, congestive heart failure and atrial fibrillation was calculated. The occurrence of The New York Heart Association (NYHA) classes was also assessed.

The percentage of the readmitted patients was calculated. Additionally, frequency of different causes of readmission was also analyzed. Similarly, the percentages of the valve related mortalities were also evaluated. Furthermore, the frequency of different valve types used in this study was also determined. To analyze the association of risk factors with post-operative complications, Chi Square test was applied and considered significant at $p<0.05$.

Follow up patients

Further analysis was focused on the follow up patients in which the percentage of mortality was determined. The reasons behind valve related mortality were then further analyzed focusing on the different valve procedures i.e., AVR, DVR and MVR.

Results

258 patients underwent valve replacement during the study duration. All the patients were included in the final analysis. Out of 258 patients, 50.8% were female and 49.2% were male. The Table 1 showed the baseline and clinical characteristics of mechanical valve replacement patients. The mean age of patients was 40.50 years with ±14.137 (Table 1).

Of these patients, 8.9% were operated on emergency bases while 91.1% were operated electively. The surgical procedures performed during the time period were AVR 32.5%, DVR 20.9% and MVR 46.5%. Hypertension was 15.1%, diabetes mellitus and atrial fibrillation were 3.5%, and smoking 3.1% as shown in Table 1. The New York Heart Association (NYHA) class II was reported in 40.7% and class III was in 54.7% patients respectively (Table 1).

Out of these, 37 patients (14.3%) were re-admitted due to various reasons i.e., Pericardial effusion, Pleural effusion, Bleeding, Endocarditis, Hemorrhagic stroke, Stuck valve and Pseudoaneurysm as shown in Figure 1. Using the chi-square test, we checked for the association of risk factors with patients' re-admission and valve related mortality (VRM). Chronic renal insufficiency showed significant association ($P<0.05$) with valve related mortality. Other risk factors, like, hypertension, diabetes mellitus, previous stroke, chronic lung disease, congestive heart failure, atrial fibrillation, peripheral artery disease, chronic liver disease and smoking did not show any strong association with valve related mortality and re-admission.

During this study, SJM mechanical heart valves were implanted in 208 patients, Carbomedics in 36, Medtronic in 11 patients respectively.

Follow up

One-year telephonic follow-up was conducted. Patients were asked about their number of INR done after discharge in one year and number of consultations for the INR management in one year as shown in Table 3. During this one year follow up period, the mortality rate was 10.3% (Table 4). The causes of mortality were bleeding in 7 (2.71%), stuck valve in 2 (0.77%), hemorrhagic strokes in 5 (1.93%), pseudoaneurysm in 2 (0.77%) and unknown reason of deaths were occurred in 11 (4.26%) patients (Table 3).

Mechanical heart valve replacement remains a crucial intervention for patients in developing countries; however, it is associated with significant morbidity and mortality, particularly within the first year. In this study, 14.3% of patients were readmitted due to complications such as pericardial effusion, pleural effusion, bleeding, endocarditis, hemorrhagic stroke, and stuck valves.

The in-hospital mortality rate was 2.7%, while the 1-year post-discharge mortality rate reached 10.3%, with over half of these deaths linked to warfarin-related complications. Limited monitoring, reflected by an average of 8.34 INR tests and 2.53 consultations for INR management within a year, highlights the challenges in anticoagulation management. These findings emphasize the need for innovative approaches, including dedicated warfarin clinics, self-testing devices, and remote cardiac care, to improve outcomes in resource-limited settings.

Table 1: Baseline Characteristics of Patients (n=258)

Characteristics	Mean ± SD	N (%)
Age	40.58 ± 14.137	
BMI	24.1840 ± 5.07281	
Valve size	31.24 ± 10.827	
INR at discharge	1.941 ± 0.9731	
Gender		
Male		127 (49.2)
Female		131 (50.8)
Operation status		
Elective		235 (91.1)
Emergency		23 (8.9)
Valve surgery		
AVR		84 (32.5)
DVR (AVR+MVR)		54 (20.9)
MVR		120 (46.5)
Comorbidities		
Hypertension		39 (15.1)
Diabetes mellitus		9 (3.5)
Previous stroke		5 (1.9)
Chronic renal insufficiency		1 (0.4)
Chronic lung diseases		1 (0.4)
Congestive heart failure		2 (0.8)
Atrial fibrillation		9 (3.5)
Smoking		8 (3.1)
NYHA class		
Class-I		1 (0.4)
Class-II		105 (40.7)
Class-III		141 (54.7)
Class-IV		11 (4.3)

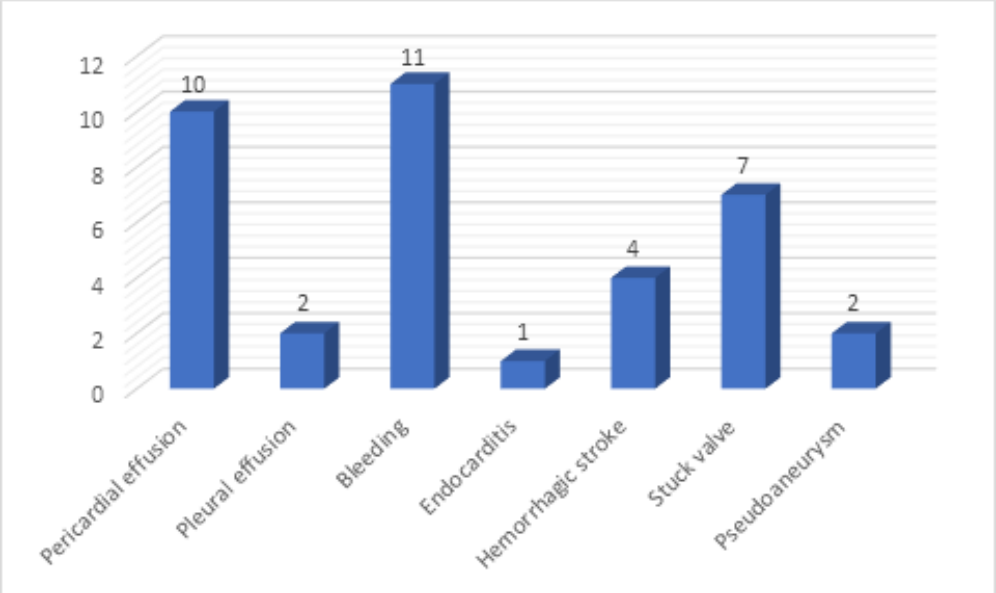

Figure 1: Shows the number of causes of re-admission.

Table 2: Association of risk factors with Readmission and valve related mortality (n=258).

Variables	Hypertension	Diabetes mellitus	Previous stroke	Chronic renal insufficiency	Chronic lung disease	Congestive heart disease	Atrial fibrillation	Smoking
Re-admission	0.430	0.211	0.356	0.682	0.682	0.561	0.778	0.382
Valve related mortality	0.272	0.852	0.649	0.010	0.695	0.580	0.069	0.263

INR checking and number of consultations done at 1 year	
Characteristic	Mean ±SD
No. of INR done after discharge in one year	8.34±8.268
No. of consultation for INR management in one year	2.53±3.715
In-hospital and one-year follow-up mortality	
Mortality	n (%)
In-hospital	7 (2.7)
One year follow up	27 (10.3)

Table 3: Post-operative one year mortality causes and type of surgical procedure.

Mortality Causes	Total mortality, n (%)	AVR only	DVR (AVR+MVR)	MVR only	Warfarin related mortality N (%)
Bleeding	7 (2.71)	3	1	3	
Stuck valve	2 (0.77)	0	1	1	14 (51.86)
Hemorrhagic stroke	5 (1.93)	1	2	2	
Pseudoaneurysm	2 (0.77)	1	0	1	
Unknown reason	11 (4.26)	4	3	4	

Discussion

In last decade there is good advancements in improving quality of mechanical valves in terms of hemodynamic performance and thrombogenicity. But still because of lack of anticoagulation management facilities and poor socioeconomic conditions makes the use of mechanical valve in these population controversial.[9] The selection of mechanical valve prostheses in our study was influenced by several factors, with the primary one being the relatively young age of our population. Younger patients typically need valve that offers long-term durability, and mechanical valves are preferred in this case due to their extended lifespan, which reduces the need for future replacements or surgeries. Second, decision to use mechanical valves may be justified by the limited financial resources as the cost associated with Redo operation after bio-prosthesis would been unaffordable. In developing world valvular diseases are mainly in rheumatic origin showing higher incidence among young patients.[10] In older patients or those requiring long-term valve replacement, bioprosthetic valves and conservative procedures often face early structural deterioration and repair failure over time.[11,12] Consequently, many cardiac surgeons view mechanical valve replacement as a preferable alternative, despite the potential risk of complications, due to its durability and long-term benefits.

As a result, many cardiac surgeons consider mechanical valve replacement a favorable option for many patients, even with the risk of potential complications. Our in-hospital mortality rate, which was 2.7%,(Table 1), was comparable to those from the EACTS and STS databases, which showed that the ranges for AVR and MVR were 4.3% and 6% and 2.9% and 3.7%, respectively.[13,14]. There are limited studies on the long-term follow-up of patients in similar populations; however, one study reported an operative mortality rate of 3.7% in patients who underwent MVR.[15] After a year of follow-up, the mortality rate was 10.3%, which was comparable to many impoverished nations.[16] Among these fatalities, 51.86% were linked to complications associated with warfarin, including bleeding, hemorrhagic stroke, and stuck valve.

In our study, the yearly average number of INR tests was 8.34 ± 8.268, while the average number of consultations conducted per year was 2.53 ± 3.715 (Table 2). The lower

number of consultations compared to the frequency of INR testing may potentially contribute to the higher incidence of warfarin complications. Our group experienced a 14.3% readmission rate, primarily attributed to complications such as pericardial effusion, pleural effusion, bleeding, hemorrhagic stroke, and stuck valve. We believe that these complications can be attributed to the intensity of anticoagulation, inadequate compliance with INR testing, and improper hospital follow-up.

Our data highlight the need to reassess the management strategies for patients on warfarin following mechanical valve replacement in the developing world.[17,18] Introducing changes such as establishing a warfarin clinic with easy phone access, particularly for patients unable to visit from remote areas,[19] introducing safe and effective INR self-testing devices, setting up remote satellite cardiac clinics, and conducting screening campaigns can significantly reduce complications associated with warfarin use.[20,21]

Limitations

Our study has several limitations, including its retrospective design. Additionally, conclusions regarding long-term outcomes, which are essential for this patient population, cannot be drawn due to the small sample size and short follow-up period.

Conclusion

According to our findings, warfarin-related complications significantly contribute to mortality and morbidity among patients with mechanical valves in developing countries. Given this, it's important for new cardiac centers in these regions to adopt more innovative strategies. This may include establishing specialized warfarin clinics, providing INR self-testing devices to patients, implementing remote cardiac clinics, and launching screening campaigns. These initiatives could greatly improve patient outcomes and reduce the burden of warfarin-related complications in this vulnerable population

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