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Clinical characteristics and long-term outcome of patients with bioprosthetic mitral valve– Experience from a South Asian country

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ABSTRACT

Objectives: Due to rheumatic heart disease, young people are more likely to develop valvular heart disease in developing countries. In countries like Pakistan, surgeons implant more bioprosthetic mitral valves (MVs) in younger patients. However, bioprosthetic valves degenerate rapidly in younger people, leading to bioprosthetic MV dysfunction (BMVD). This study aims to evaluate the clinical characteristics and long-term outcomes of patients with bioprosthetic MV replacement (MVR) at a tertiary care hospital in a South Asian country.

Material and Methods: This is a retrospective observational study, conducted at a tertiary care hospital. We included a total of 502 patients who underwent bioprosthetic MVR from the year 2006 to 2020. Clinical and surgical characteristics along with transthoracic echocardiographic findings (pre-surgery and recent most follow-up studies) were noted. Follow-up data were also collected.

Results: Out of 502 patients, 322 (64%) were female, mean age at the time of surgery was 49.42 ± 14.56 years. Mitral regurgitation was more common, found in 279 (55.6%) patients followed by mitral stenosis in 188 (37.5%) patients. MVR was done as an elective procedure due to the New York Heart Association (NYHA) II to IV symptoms at the time of surgery in 446 (88.8%) patients. In the mean follow-up of 6.59 ± 2.99 years, BMVD was observed in 183 (36.5%) patients. However, re-do MV surgery was done in only 49 (9.8%) patients. Patients were divided into two groups based on normal functioning bioprosthetic MV and BMVD. Comparing the two groups, individuals with normal functioning bioprosthetic MV had a mean age of 51.6 ± 14.27 years, while those with BMVD had a mean age of 45.639 ± 14.33 years at the time of index surgery ($P = 0.000$). There were more long-term complications including heart failure ($n = 16$, 8.74%), atrial fibrillation ($n = 11$, 6.01%), and death ($n = 6$, 3.28%) in the BMVD group which were statistically significant.

Conclusion: This study is distinct because it demonstrates the outcomes of bioprosthetic valve replacement in a relatively younger South Asian population. Due to rapid degeneration of bioprosthetic valve in younger patients, significant number of patients developed BMVD along with poor long-term clinical outcomes, even at a short follow-up period of <10 years. These findings are similar to international data and signify that mechanical MVR may be a more reasonable alternative in younger patients.

Keywords: Mitral valve replacement, Bioprostheses, Echocardiography, Mitral valve insufficiency, Mitral valve stenosis

INTRODUCTION

The mitral valve (MV) apparatus modulates blood flow between the left atrium and left ventricle and structurally consists of an annulus, two leaflets, chordae tendineae, and two papillary

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muscles.^[1,2] MV pathologies can involve single or multiple levels of the apparatus, causing MV dysfunction leading to either stenosis or regurgitation or both, diagnosed mostly on echocardiography.^[3] These can be caused by rheumatic heart disease, congenital malformations, ischemic heart disease, infections, or collagen-vascular diseases, causing signs and symptoms of MV dysfunction with subsequent need for medical or surgical treatment.^[4,5]

In patients with severe or symptomatic MV disease, MV surgery (repair or replacement) is the usual strategy that reduces symptoms and improves survival, other treatment options include percutaneous interventions such as trans-mitral commissurotomy for mitral stenosis (MS) and transcatheter edge-to-edge repair for mitral regurgitation (MR).^[6-9] Surgical treatment includes repair or valve replacement, and the choice of the valve (mechanical or bio-prosthetic) is individualized based on many factors including age, the durability of the valve, need for anticoagulation, patient as well as the surgeon's preference, and many more.^[10,11] The latest guidelines for surgical treatment and prosthetic heart valve selection recommend repair as the preferred treatment. However, in patients with rheumatic or extensive mitral valvular damage/calcification, replacement is usually indicated, with either type of prosthetic valve for patients aged 60–70 years, mechanical prosthetic valve for patients younger than 60 years, and bioprosthetic valve for patients older than 70 years.^[6-9] Younger patients face a much higher lifetime risk of reoperation due to a higher rate of bioprosthetic structural valve degeneration, whereas reoperation rates are much lower with a mechanical valve, but there is an increased risk of thromboembolic/hemorrhagic complications and need for lifelong anticoagulation with a mechanical valve.^[6,7,12,13] Extensive international literature is available on the outcomes of bioprosthetic MV replacement (MVR), but there are limited local data in South Asian countries.

Recently, it has been observed that surgeons in our population are implanting a larger number of bioprosthetic MV in younger patients, probably due to a greater prevalence of rheumatic heart disease with extensive valvular damage, risk of thrombosis with mechanical valve, and limited heart-valve clinics for decision-making and poor adherence to anticoagulation in less educated population. However, bioprosthetic valve degenerates rapidly in younger people.^[10,11] There is no such study that has evaluated the outcomes of patients with bioprosthetic MV in our population.

This study aims to evaluate the clinical characteristics and long-term outcomes of patients with bioprosthetic MVR at a tertiary care hospital in a South Asian country.

This article has been presented as an abstract in the Pakistan Cardiac Society's Cardiology conference and published in Pakistan Heart Journal on November 16, 2023.

MATERIAL AND METHODS

Study design

This was a retrospective observational study.

Study population

All the patients who underwent bioprosthetic MVR at a tertiary care hospital in Karachi, Pakistan from the year 2006 to 2020, had at least two complete echocardiograms: A pre-surgery echocardiogram and a follow-up echocardiogram which were done within the past 2 years (2021-2022) of our study were included in the study. Patients with incomplete clinical data, mechanical MVR, or MV repair were excluded from the study.

Ethical consideration

The study was started after getting approval from the Ethical Review Board (ERB) committee of our hospital. All the patients who fulfilled the inclusion criteria were included in the study. Data were collected on a predesigned data entry form, after reviewing the electronic medical records of all the patients. The study was conducted in compliance with the protocol and ethical board's regulatory requirements. Complete privacy was ensured. The patient's medical record number was the only identifiable information that was collected. Only ERB-approved study personnel had access to the data.

Statistics

Clinical and surgical characteristics along with transthoracic echocardiographic findings (pre-surgery and recent most follow-up studies) were noted. The etiology of MV dysfunction was divided into rheumatic, degenerative, and ischemic based on the transthoracic echocardiographic appearance of the MV and relevant past medical history.^[5] Bioprosthetic MV dysfunction (BMVD) was defined as a mean gradient of >5 mm Hg with restricted/reduced leaflet motion associated with/without valve degeneration, calcification, thrombus, pannus, vegetation, or patient-prosthesis mismatch, and/or newly developed MR on follow-up transthoracic echocardiography. The severity of bioprosthetic MR was evaluated solely through transthoracic echocardiography, adhering to the latest guidelines.^[11] Although transesophageal and 3D echocardiography are considered more reliable in cases where technical limitations exist with transthoracic echocardiography, we did not include patients undergoing these methods. Follow-up data were also collected after reviewing medical records and telephonic interviews of the patients after obtaining informed verbal consent from the patient or their first-degree relative if the patient was not available.

Data were analyzed using statistical software Statistical Package for the Social Sciences version 23. In the descriptive analysis, mean and standard deviation were calculated for continuous variables and percentages for categorical variables. The Chi-square test was applied to all the categorical variables and analysis of variance was applied to the continuous variables on a 95% confidence interval considering $P < 0.05$ as statistically significant.

RESULTS

A total of 502 patients with bioprosthetic MV implantation from 2006 to 2020, who fulfilled the inclusion criteria were included in the study. Out of 502 patients, 322 (64%) were female, the mean age of the patients at the time of surgery was 49.42 ± 14.56 years, and the most prevalent comorbid condition was hypertension in 281 (56%) patients followed by diabetes in 161 (32.1%) patients. The highest number of patients at the time of index surgery was in the age range of 49–58 years [Figure 1].

Baseline characteristics of patients at the time of surgery are shown in Table 1. Most patients ($n = 390$, 77.7%) showed no significant coronary artery disease (CAD), while 112 (22.3%) patients were diagnosed with moderate-to-severe CAD during pre-surgery assessment. MR was more common, found in 279 (55.6%) patients while MS was the underlying lesion in 188 (37.5%) patients, at the time of index surgery. Combined MS and regurgitation were present in only 35 (7%) patients. Concomitant aortic regurgitation was observed in 243 (48.4%) patients, while aortic stenosis was identified in 97 (19.3%) patients. In addition, tricuspid regurgitation was present in 378 (75.3%) patients. Left ventricular ejection fraction (LVEF) was normal in the majority of patients ($n = 399$, 79.5%) before surgery.

Surgical details are shown in Table 2. In most of the patients ($n = 446$, 88.8%) MVR was done as an elective procedure due to NYHA II to IV symptoms at the time of index surgery. Among individuals diagnosed with CAD, 104 (20.7%) patients underwent both coronary artery bypass surgery and MVR. In addition, 5 (1%) patients had undergone

percutaneous coronary intervention before surgery, while 3 (0.6%) patients were medically managed due to inadequate surgical targets. Concomitant aortic valve replacement was done in 115 (23%) patients with moderate-to-severe aortic valve disease (isolated or mixed). The mean length of stay during index admission was $8.47 \text{ days} \pm 2.93$.

During the hospital stay, immediate post-surgical complications were observed, with unstable arrhythmia being the most common (11%), followed by stable arrhythmia (8.2%), pneumonia (1.8%), stroke (1.8%), and major bleeding/hemorrhage according to TIMI scoring (1.2%).^[14]

In the mean follow-up period of 6.59 ± 2.99 years, BMVD was observed in 183 (36.5%) patients, with valve degeneration as the most common pattern of structural deterioration ($n = 139$, 27.7%), as shown in Table 3. Nonetheless, redo MV surgery was performed in only 49 (9.8%) patients within our facility.

Table 1: Baseline characteristics.

Clinical characteristics	Number (n=502)	Percentage
Male	180	35.9
Female	322	64.1
Hypertension	281	56
Diabetes Mellitus	161	32.1
Coronary artery disease	112	22.3
Dyslipidemia	95	18.9
Chronic kidney disease	3	0.6
Echocardiographic features		
MR	279	55.6
MS	188	37.5
Both MS and MR	35	7
Etiology of mitral valve dysfunction		
Rheumatic	306	61
Degenerative (calcified/myxomatous)	183	36.4
Ischemic	13	2.6
Left ventricular ejection fraction before surgery		
Normal	399	79.5
Mildly reduced	40	8
Moderately reduced	31	6.2
Severely reduced	32	6.4
Concomitant aortic regurgitation		
Mild	113	22.5
Moderate	75	14.9
Severe	55	11
Concomitant aortic stenosis		
Mild	46	9.2
Moderate	15	3
Severe	36	7.2
Concomitant tricuspid regurgitation		
Mild	146	29.1
Moderate	109	21.7
Severe	123	24.5

MR: Mitral regurgitation, MS: Mitral stenosis

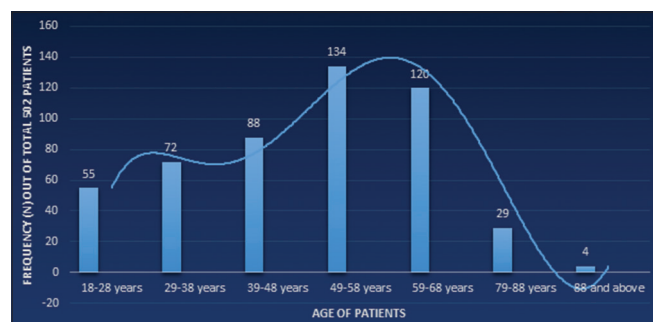


Figure 1: Age distribution at the time of index surgery.

Table 2: Surgical and post-surgical details.

	Number (n=502)	Percentage
Type of surgery		
Elective	446	88.8
Emergent or urgent	56	11.2
Reason for emergent or urgent surgery		
Heart failure	41	8.2
STEMI with papillary muscle rupture	3	0.6
Mitral valve abscess	5	1
NSTEMI	7	1.4
Concomitant other valve surgery		
Aortic valve replacement (mechanical AVR)	115	23
Tricuspid valve repair	140	27.9
Post-surgical complications (During hospital stay)		
Unstable arrhythmia	55	11
Major Hemorrhage (Thrombolysis in Myocardial Infarction criteria)	6	1.2
Pneumonia	9	1.8
Stable arrhythmia	41	8.2
Respiratory failure	6	1.2
Complete heart block	4	0.8
Stroke	9	1.8
Cardiac tamponade	2	0.4
Septic shock	5	1

STEMI: ST-segment elevation myocardial infarction,
NSTEMI: Non-ST-segment elevation myocardial infarction

All the patients were divided into two groups, based on normal functioning bioprosthetic MV or BMVD on follow-up. A comparison between the two groups is shown in Table 4.

Females were in the majority in both groups with almost similar percentages, the mean age of patients at the time of index surgery was 51.6 ± 14.27 years in the normal functioning bioprosthetic MV group while it was 45.6 ± 14.33 years in the BMVD group. There were more patients with younger ages in the BMVD group, with a statistically significant difference ($P = 0.000$).

There was no significant difference in the echocardiographic findings at the time of index surgery among the two groups, except that the LVEF was lower in the normal functioning bioprosthetic MV group.

DISCUSSION

This study is the first of its kind which has assessed the outcomes of bioprosthetic MVR in a relatively young Pakistani population, as opposed to earlier studies where bioprosthetic MVR was done in middle-aged to elderly patients.

Similar to earlier studies,^[4,5,15] this study also showed that MV disease requiring surgical MVR is more common in young

Table 3: Follow-up details.

	Number (n=502)/ Mean±SD	Percentage
Echocardiographic features		
Left ventricular ejection fraction on follow-up compared to the pre-surgery		
No change	442	88
Mildly reduced	10	2
Moderately reduced	4	0.8
Severely reduced	46	9.2
Condition of bioprosthetic mitral valve		
Bioprosthetic mitral valve dysfunction (BMVD)	183	36.5
Degenerative valve	139	
Valve calcification	18	
Pannus formation	8	
Vegetation	8	
Patient prosthesis mismatch	4	
Malalignment/dislocation	4	
Thrombus formation	2	
Severity of mitral regurgitation (valvular/paravalvular)		
Mild mitral regurgitation	18	
Moderate mitral regurgitation	94	
Severe mitral regurgitation	71	
Pressure half time in BMVD	100.137±32.969	
Mean gradient in BMVD	13.989±4.202	
Peak gradient in BMVD	27.524±5.788	
Doppler velocity index (DVI) in BMVD	2.785±0.435	
Re-do mitral valve surgery	49	9.8
Type of valve used in re-do surgery		
Bioprosthetic	22	4.4
Mechanical	27	5.4
Follow-up complications		
Congestive heart failure	16	3.2
Infective endocarditis	8	1.6
Atrial fibrillation	12	2.4
Death	6	1.2
Cause of death		
Infective endocarditis	1	0.2
Major bleeding	1	0.2
Multiple organ dysfunction	2	0.4
Cardiac arrest	2	0.4

SD: Standard deviation, BMVD: Bioprosthetic mitral valve dysfunction

females, likely due to rheumatic heart disease involvement at a younger age.

In contemporary clinical practice, there is considerable disagreement about which type of valve to use for patients aged 50–70 who require MVR,^[16] and a mutual (doctor-patient) decision-making is considered appropriate to decide about the type of valve, keeping in view the age of the patient, life expectancy, reoperation risk, anticoagulation related adverse events, and the patient preference. On the other hand, the

Table 4: Comparison between normal functioning bioprosthetic mitral valve and BMVD.

	Normal functioning bio-prosthetic mitral valve n=319 (%)	BMVD n=183 (%)	P-value ^a
Gender			
Male	119 (37.3)	61 (33.3)	0.372
Female	200 (62.7)	122 (66.7)	
Mean ^b Age (in years)	51.6±14.27	45.639±14.33	0.000
Age categories at the time of MVR (in years)			
18–28	25 (7.83)	30 (16.3)	0.000
29–38	38 (12)	34 (18.6)	
39–48	60 (19.1)	28 (15.3)	
49–58	84 (26.3)	50 (27.3)	
59–68	82 (25.7)	38 (20.8)	
69–78	26 (8.1)	3 (1.63)	
79–88	4 (1.25)	0	
Comorbidities			
Hypertension	195 (61.11)	86 (46.99)	0.002
Diabetes mellitus	114 (35.7)	47 (25.7)	0.020
History of coronary artery disease	80 (25.0)	32 (17.48)	0.049
Type of admission at the time of surgery			
Elective	278 (87.1)	168 (91.8)	0.111
Emergent/urgent	41 (12.85)	15 (8.2)	
Presurgery echocardiography			
Mitral regurgitation	180 (56.4)	99 (54.1)	0.161
Mitral stenosis	122 (38.24)	66 (36.0)	
Dual mitral valve pathology	17 (5.3)	18 (45.35)	
Concomitant significant (moderate or severe) aortic regurgitation	79 (24.76)	51 (27.86)	0.784
Concomitant significant (moderate or severe) aortic stenosis	28 (8.8)	23 (12.56)	0.335
Concomitant significant (moderate or severe) tricuspid regurgitation	153 (47.96)	79 (43.16)	0.177
Left ventricular ejection fraction			
Normal	240 (75.2)	159 (86.9)	0.018
Mildly reduced	30 (9.4)	10 (5.46)	
Moderately reduced	23 (7.2)	8 (4.4)	
Severely reduced	26 (8.15)	6 (3.3)	
Concomitant aortic valve replacement	72 (22.6)	43 (23.5)	0.812
Concomitant tricuspid valve repair	96 (30.1)	43 (23.5)	0.097
Long-term complications			
Heart failure	0	16 (8.74)	0.000
Atrial fibrillation	1 (0.31)	11 (6.01)	
Infective endocarditis	0	8 (4.4)	
Death after follow-up echo	0	6 (3.28)	

BMVD: Bioprosthetic mitral valves dysfunction, ^aChi square's test, ^bANOVA test, MVR: Mitral valve replacement

latest guidelines recommend that younger patients (age <50 years) should undergo mechanical valve replacement due to its longer durability as compared to bioprosthetic valves.^[6,7]

Similarly, Goldstone *et al.*^[13] showed that mechanical valve replacement was associated with a long-term mortality benefit, as compared to a bioprosthesis, especially in younger patients undergoing surgical MVR. Another retrospective study from Taiwan showed that the all-cause mortality and re-do operation rates in the bioprosthetic valve group were comparatively higher than those in the mechanical valve group, while no group difference was observed in major adverse cardiovascular events.^[17]

In our study population, bioprosthetic valves are still used in younger patients despite the recommendation against bioprosthetic valves in younger populations. Bioprosthetic valves degenerate rapidly in younger people.^[10,11] However, probably due to the risk of thrombosis with mechanical valves, limited medical facilities, and poor adherence to anticoagulation in less educated populations, surgeons still preferring bioprosthetic valves even in younger populations. In the case of younger females, reproductive age might be another factor when considering the choice of prosthetic MV.

One of the studies conducted in South Korea^[18] demonstrated that the risk factors associated with BMVD and poor clinical outcomes include young age at operation, chronic kidney disease, and increased pressure gradients across the bioprosthetic MV early after surgery. Studies by Kulik *et al.* and Ruel *et al.*^[19,20] demonstrated that middle-aged patients with bioprosthetic valves were associated with more major adverse prosthesis-related events as well as a rise in the need for reoperation.

Despite the short follow-up period (6.59 ± 2.99 years) of our study, we also observed that many patients ($n = 183$, 36.5%) developed BMVD with degeneration and calcification being the most frequent structural deteriorations. This is likely due to using bioprosthetic MVs at a younger age, as previously demonstrated in various studies.^[18-21]

In our study, patients who developed BMVD were younger compared to the group with normal functioning bioprosthetic MV, with a statistically significant difference. However, redo surgery was done in only 9.8% of our patients. The small number of redo surgeries may be due to the short follow-up, we have done or due to reluctance to redo surgery by either the patient or the surgeon.

With the increased use of bioprosthetic MVs, the clinical outcomes of patients using bioprostheses require more attention. We observed that patients with BMVD developed significantly more long-term complications compared to those with normal functioning bioprosthetic MVs. Among various complications, heart failure (8.74%) and atrial fibrillation (6.01%) were the most frequent ones, which can be attributed to increased gradients and left atrial dilatation in BMVD group. Six patients died in the BMVD group with multi-organ dysfunction and cardiac arrest as the main causes of death.

However, our study has some limitations as it was a single-center retrospective observational study, so we did not evaluate surgical techniques or the type of bioprosthetic valves, which may have an impact on the results. In addition, multivariate analysis was not done due to a relatively smaller number of patients with bioprosthetic MV abnormalities.

CONCLUSION

To the best of our knowledge, this is the first study in the existing literature that has been conducted to assess the outcomes of bioprosthetic MVR in a relatively younger South Asian population. We conclude by saying that in our population, younger patients (patients younger than 50 years of age) are undergoing bioprosthetic MVR at a higher rate, resulting in an earlier onset of BMVD and poor long-term outcome.

Ethical approval

The research/study approved by the Institutional Review Board at Aga Khan University Hospital, number 6082-17258., dated April 20, 2021.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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