

# Mitral valve replacement for mitral stenosis: A 15-year single center experience



Alqasem F. Al Mosa<sup>a</sup>, Aamir Omair<sup>b</sup>, Ahmed A. Arifi<sup>c</sup>, Hani K. Najm<sup>d,\*</sup>

<sup>a</sup> King Saud bin Abdulaziz University for Health Sciences, College of Medicine, Riyadh

<sup>b</sup> King Saud bin Abdulaziz University for Health Sciences, Medical Education, Riyadh

<sup>c</sup> Cardiac Clinical Research, Cardiac Surgery, Cardiac Sciences, King Abdulaziz Cardiac Center, Ministry of National Guard, Riyadh

<sup>d</sup> Heart and Vascular Institute, Cleveland Clinic, 9500 Euclid Ave/M41, Cleveland, Ohio, 44195

<sup>a,b,c</sup> Saudi Arabia

<sup>d</sup> USA

**Objectives:** Mitral valve replacement with either a bioprosthetic or a mechanical valve is the treatment of choice for severe mitral stenosis. However, choosing a valve implant type is still a subject of debate. This study aimed to evaluate and compare the early and late outcomes of mitral valve replacement [mechanical (MMV) vs. bioprosthetic (BMV)] for severe mitral stenosis.

**Methods:** A retrospective cohort study was performed on data involving mitral stenosis patients who have undergone mitral valve replacement with either BMV ( $n = 50$ ) or MMV ( $n = 145$ ) valves from 1999 to 2012. Data were collected from the patients' records and follow-up through telephone calls. Data were analyzed for early and late mortality, New York Heart Association (NYHA) functional classes, stroke, pre- and postoperative echocardiographic findings, early and late valve-related complications, and survival. Chi-square test, logistic regression, Kaplan–Meier curve, and dependent proportions tests were some of the tests employed in the analysis.

**Results:** A total of 195 patients were included in the study with a 30-day follow-up echocardiogram available for 190 patients (97.5%), while 103 (53%) were available for follow-up over the telephone. One patient died early postoperatively; twelve patients died late in the postoperative period, six in the bioprosthesis group and six in the mechanical group. The late mortality had a significant association with postoperative stroke ( $p < 0.001$ ) and postoperative NYHA Classes III and IV ( $p = 0.002$ ). Postoperative NYHA class was significantly associated with age ( $p = 0.003$ ), pulmonary disease ( $p = 0.02$ ), mitral valve implant type ( $p = 0.01$ ), and postoperative stroke ( $p = 0.02$ ); 14 patients had strokes in the mechanical (9) and in the bioprosthetic (5) groups. NYHA classes were significantly better after the replacement surgeries ( $p < 0.001$ ). BMV were significantly associated with worse survival ( $p = 0.03$ ), worse NYHA postoperatively ( $p = 0.01$ ), and more reoperations ( $p = 0.006$ ). Survival was significantly better with MMV ( $p = 0.03$ ). When the two groups were matched for age and mitral regurgitation, the analysis revealed that BMV were significantly associated with reoperations ( $p = 0.02$ ) but not significantly associated with worse survival ( $p = 0.4$ ) or worse NYHA ( $p = 0.4$ ).

**Conclusion:** MMV replacement in mitral stenosis patients is associated with a lower reoperation rate, but there was no difference in survival compared with BMV replacement.

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\* Corresponding author at: Heart and Vascular Institute, Cleveland Clinic, 9500 Euclid Ave/M41, Cleveland, Ohio, 44195, United States.  
E-mail address: [najmh@ccf.org](mailto:najmh@ccf.org) (H.K. Najm).



P.O. Box 2925 Riyadh – 11461KSA  
Tel: +966 1 2520088 ext 40151  
Fax: +966 1 2520718  
Email: [sha@sha.org.sa](mailto:sha@sha.org.sa)  
URL: [www.sha.org.sa](http://www.sha.org.sa)



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## Introduction

**M**itral stenosis (MS) is most commonly due to rheumatic fever resulting in rheumatic heart disease [1]. A surgical pathology series of 452 MS patients concluded that 99% of the patients had postinflammatory disease that was believed to be rheumatic in origin [2].

Symptomatic MS can be treated by percutaneous mitral balloon valvotomy, surgical valvotomy, or surgically replacing the dysfunctional valve with either a mechanical mitral valve (MMV) or a bioprosthetic mitral valve (BMV) [3]. Open valvotomy is a repair procedure that involves direct visualization of the valve and debridement of the valve structure and reconstruction of subvalvular apparatus. Mitral valve replacement is usually preserved for severe MS that is not fit for percutaneous mitral balloon valvotomy or valve repair [4].

The purpose of this study was to compare mitral valve replacement, with either a BMV or a MMV, in MS patients and evaluate their early survival and long-term outcome.

## Materials and methods

### Setting and patients

The study was conducted in a tertiary care cardiac center (King Abdulaziz Cardiac Center) in Riyadh, Saudi Arabia, and the study population included all consecutive adult mitral valve replacement (MVR) patients operated on for mitral valve stenosis from 1999 to 2012. All patients that fit the inclusion criteria were enrolled in the study regardless of their sex and nationality. All the available patients were included in the study.

### Study design

This study is a retrospective cohort of patient data collected from the center and the follow-up data gathered by contacting the patients through the telephone.

### Data collection

Eighty variables were collected. They were representing information related to demographics, preoperative underlying conditions, early and late valve related complications, and pre- and postoperative echocardiogram data. Patients' demographics, underlying conditions, preoperative echocardiograms, and early postoperative complications were obtained from the records of the

### Abbreviations

MS	Mitral Stenosis
BMV	Bioprosthetic Mitral Valve
MMV	Mechanical Mitral Valve
NYHA	New York Heart Association
DM	Diabetes Mellitus
HTN	Hypertension
CHF	Congestive Heart Failure
LV	left Ventricle
MR	Mitral Regurgitation
EF	Ejection Fraction
Op	operative
MVR	Mitral Valve Replacement
AVR	Aortic Valve Replacement
TV	Tricuspid Valve
AV	Aortic Valve

patients. Patients' records were provided as a soft copy in the form of Excel sheets (Microsoft Corporation, Redmond, WA, USA), which was then transferred into SPSS statistical package software version 20.0 (SPSS Inc., Chicago, IL, USA) for analysis. Postoperative echocardiogram data were collected using the Picture Archiving and Communication System to access the echo database. Late follow-up data (long-term) was acquired by calling the patients' phone numbers provided in their hospital records via the hospital telephone. The patients were called over a period of 1 month after the data were collected from the medical records. A total of three calls were made. The patients who did not respond to the first call were again contacted after 2 weeks and those remaining were contacted 1 week after the second phone call.

A standardized and Institutional Review Board, King Abdullah international Research Center, Riyadh approved consent form was used during telephone calls in gathering the long-term outcomes information (late follow-up) to collect the following: (1) late mortality; (2) New York Heart Association (NYHA) functional class; (3) late valve-related complications [bleeding (which required blood transfusion), stroke (embolic or hemorrhagic), abdominal embolism, and endocarditis]; and (4) reoperation.

### Data management

The patients who underwent MVR were divided into a BMV group and a MMV group. NYHA Classes I and II were grouped together as one group in the analysis, and the same was done for NYHA Classes III and IV. Ejection fraction (EF) groups are as follows: (1) normal EF ( $\geq 55\%$ ); (2) mild left ventricular dysfunction

Table 1. Baseline characteristics of patients.

		BMV (n = 50)	MMV (n = 145)	p
Age (y)		53.7 ± 16.4	46.1 ± 11.5	0.001
Female sex, n (%)		37 (74)	87 (60)	0.08
NYHA pre-op <sup>a</sup>	I & II	14 (31)	39 (33)	0.87
	III & IV	31 (69)	81 (68)	
Pre-op underlying conditions	Smoker	3 (6)	16 (11)	0.30
	Obesity	12 (24)	49 (34)	0.20
	Hyperlipidemia	17 (34)	39 (27)	0.34
	DM	12 (24)	25 (17)	0.29
	HTN	13 (26)	24 (17)	0.15
	Pulmonary disease	7 (14)	25 (17)	0.59
	CHF	19 (38)	36 (25)	0.07
EF <sup>b</sup> (pre-op)	Normal	34 (74)	109 (78)	0.32
	Mild LV dysfunction	5 (11)	20 (14)	
	Moderate to severe LV dysfunction	7 (15)	11 (8)	
MS (pre-op)	Mild	16 (32)	27 (19)	0.14
	Moderate	13 (26)	46 (32)	
	Severe	21 (42)	72 (50)	
MR (pre-op)	No regurgitation	4 (8)	28 (19)	0.005
	Mild	11 (22)	12 (8)	
	Moderate	10 (20)	50 (35)	
	Severe	25 (50)	55 (38)	

Data are presented as n (%) or mean ± standard deviation.

BMV = bioprosthetic mitral valve; CHF = chronic heart failure; DM = diabetes mellitus; EF = ejection fraction; HTN = hypertension; LV = left ventricular; MMV = mechanical mitral valve; MR = mitral regurgitation; MS = mitral stenosis; NYHA = New York Heart Association; op = operation.

<sup>a</sup> New York Heart Association preoperation: BMV = 45, MMV = 120.

<sup>b</sup> EF: BMV = 46, MMV = 140.

(45–54%); and (3) moderate (30–44%) to severe (<30%) left ventricular dysfunction.

### Data analysis

Data were entered and analyzed using Microsoft Excel (Microsoft Corporation) and SPSS version 20 (SPSS Inc.). The categorical variables are presented as frequencies, percentages, and quantitative variables as mean ± standard deviation. Chi-square test and logistic regression were used to compare the categorical variables, and independent *t* test/analysis of variance to compare the numerical variables. Survival analysis using the Kaplan–Meier curve was employed. Dependent proportions test (McNemar test) was used to compare post- and preoperative categorical data. The primary outcomes were survival and NYHA functional classification. The secondary outcome was valve-related complications.

## Results

### Baseline characteristics

A total of 195 patients were enrolled in the study analysis (BMV = 50, MMV = 145). All of the patients enrolled in the study had their

postoperative data available up to 30 days postoperatively in the records. As for the postoperative echocardiogram before discharge of the patient, five patients' echo reports were not available (97.5% available). Regarding telephone calls, 103 (53%) of the 195 patients responded to the telephone calls.

The mean age of the patients at operation was 48 ± 13 years. There were 71 (36%) men [BMV (13) and MMV (58)] and 124 (64%) women [BMV (37) and MMV (87)]. The follow-up was complete in 190 patients (97.5%; five patients were lost to follow-up after discharge from the hospital). The follow-up period was a minimum of 1 month and a maximum of 15.5 years with an average of 5.6 ± 4 years of follow-up, a median of 5.2 years, and a total of 1055 patient years (Table 1). The patients in the BMV group were older (53.7 ± 16.4 years vs. 46.1 ± 11.5 years) and had a bigger proportion of severe MR (50% vs. 38%). Preoperatively, out of the 195 patients who had MS: 43 (22%) had mild MS, 59 (30%) had moderate MS, and 93 (48%) had severe MS.

### Mortality

Out of the 195 patients, one patient (0.5%) died early postoperatively (i.e., <30 days). He was in

the MMV group, and the cause of death was multiple organ failure. No further analysis in early mortality was carried out due to the small number of events. During follow-up, 12 patients died (6 in the BMV group and 6 in the MMV group). Post-operatively, both NYHA Classes III and IV ( $p = 0.002$ ) and occurrence of stroke ( $p < 0.001$ ) were found to be significantly associated with late mortality. NYHA postoperative Classes III and IV were related to late mortality ( $p = 0.002$ ). Postoperative stroke occurrence (embolic or hemorrhagic) was associated with late mortality ( $p < 0.001$ ; Table 2).

### Functional class

Postoperatively, 83 (81%) patients were in NYHA Classes I and II and 20 patients (19%) were in NYHA Classes III and IV. Postoperative NYHA class was significantly associated with mitral valve implant type ( $p = 0.01$ ) and postoperative stroke ( $p = 0.02$ ). BMV was associated with NYHA Classes III and IV ( $p = 0.01$ ; Fig. 1).

Logistic regression analysis was used for postoperative NYHA and preoperative underlying conditions and complications. It revealed that age ( $p = 0.003$ ) and pulmonary disease ( $p = 0.02$ ) were significantly associated with postoperative

Table 2. Factors associated with late mortality.<sup>a</sup>

Factors	<i>p</i>
NYHA post-op	0.002
Post-op stroke (MMV = 9 & BMV = 5)	<0.001
Mitral valve implant type	0.055
Post-op ventricular tachycardia	0.055

BMV = bioprosthetic mitral valve; MMV = mechanical mitral valve; op = operative.

<sup>a</sup> Chi-square test.

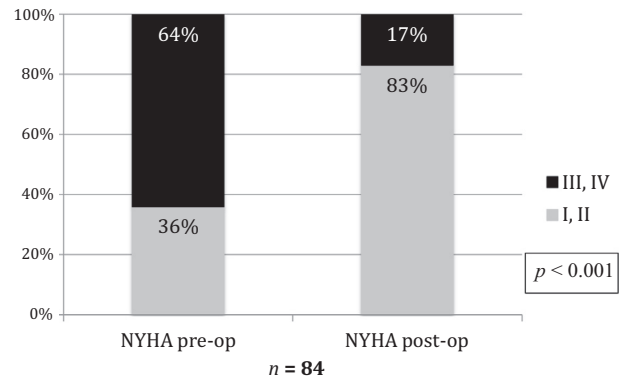


Figure 2. New York Heart Association (NYHA) preoperative and postoperative. op = operative.

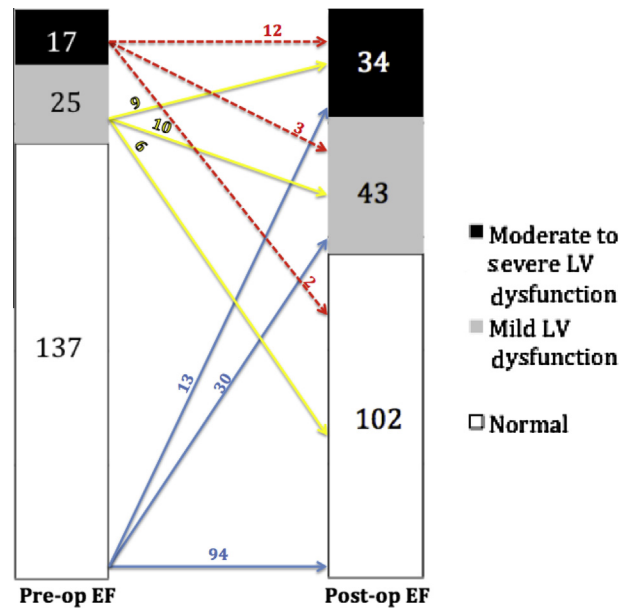


Figure 3. Preoperative (pre-op) and postoperative (post-op) ejection fraction (EF). LV = left ventricular.

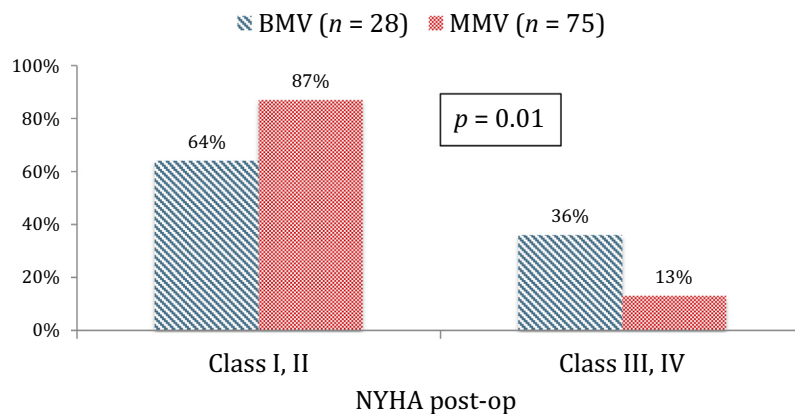


Figure 1. Mitral valve implant type and postoperative New York Heart Association (NYHA). BMV = bioprosthetic mitral valve; op = operative; MMV = mechanical mitral valve.

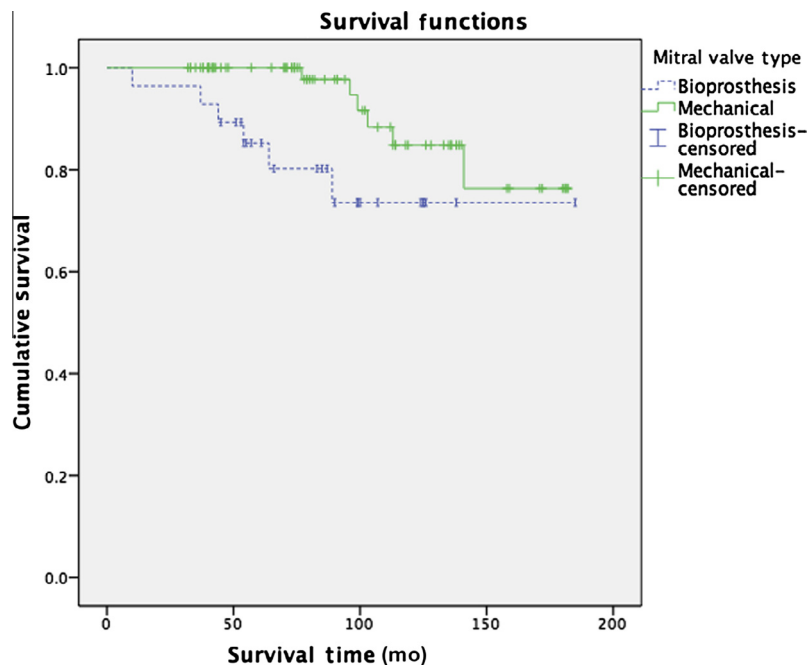


Figure 4. Kaplan–Meier survival curve of mitral valve replacement comparing mechanical mitral valves with bioprosthetic mitral valves;  $p = 0.03$  (Mantel–Cox).

NYHA Classes III and IV. Moreover, it showed that postoperative stroke was the only significant complication ( $p = 0.04$ ) associated with NYHA Classes III and IV and mortality.

Analysis of NYHA classes showed significant difference in proportions ( $p < 0.001$ ). Most of the patients who were in NYHA Classes III and IV preoperatively shifted to Classes I and II postoperatively (Fig. 2). However, there was a significant drop in EF before and after the surgery ( $p < 0.001$ ; Fig. 3). Before the surgery 137 (77%) patients had normal EF, and after the surgery 102 (57%) had normal EF. These findings might be attributed to the fact that 84 (43%) patients had MVR, 51 (26%) patients had MVR-tricuspid valve (TV) repair, 42 (22%) patients had MVR-aortic valve (AV) replacement, 13 (7%) patients had MVR-A replacement-TV repair, three (2%) patients had MVR-TV replacement, one (0.5%) patient had MVR-AV repair-TV repair, and one (0.5%) patient had MVR-TV valvectomy. The reduction of the EF could also be attributed to the fact that most of our patients had partial subvalvular apparatus preservation.

### Complications

Regarding the early complications for the patients enrolled in the study ( $n = 195$ ), atrial fibrillation or flutter, bleeding, and ventricular tachycardia were the most common early

complications. The frequencies are as follows ( $n = 104$ ): 19 (18%) patients had bleeding that required blood transfusion (13 in the MMV group and 6 in the BMV group), 14 (14%) patients had strokes (9 in the MMV group and 5 in the BMV group), 12 (12%) patients died, seven (7%) patients had reoperations (5 in the BMV group and 2 in the MMV group), one (1%) patient in the BMV group had an abdominal embolism, and one (1%) patient in the MMV group had endocarditis.

### BMV versus MMV

MMV had significantly better survival than BMV (Fig. 4). In the analysis, the following were significant: MMV was associated with NYHA postoperative Classes I and II and BMV associated with NYHA Classes III and IV (Fig. 1); BMV was associated with reoperations ( $p = 0.006$ ). BMV was also associated more with late mortality with  $p = 0.055$ .

When the two groups (BMV and MMV) were matched for age and mitral regurgitation, the analysis revealed that BMVs were significantly associated with reoperations ( $p = 0.02$ ) but not significantly associated with worse survival ( $p = 0.4$ ) or worse NYHA ( $p = 0.4$ ).

### Survival

Twelve patients died (6 from BMV and 6 from MMV). Log rank (Mantel–Cox) test showed that

there was a significant difference in survival between BMV and MMV with  $p = 0.03$ . The mean survival time of BMV is  $150.6 \pm 12$  months (12.5 years), while MMV had a mean survival of  $166 \pm 6$  months (13.8 years). The mean survival time of both BMV and MMV is  $162 \pm 6$  months (13.5 years; Fig. 4). The analysis was carried out on the two groups (BMV and MMV) that were case matched for age and mitral regurgitation. There was no significant difference in survival ( $p = 0.4$ ) between the case-matched groups.

## Discussion

There have been a number of studies comparing MMVs to BMVs along with recommendations from the American Heart Association for the management of patients with valvular heart disease that mentioned the advantages and disadvantages for each of those valve implant types. This study results matches with the results of previous studies that were performed to compare BMVs to MMVs.

The Veterans Affairs trial randomized 575 patients to either a MVs or BMVs between 1977 and 1982. After 15 years of follow-up, the study found that the mortality was similar between the two groups, primary valve failure was more common with the BMV group in patients younger than 65 years, reoperations were more common in BMVs, and there was a similar rate of valve-related complication incidences between the two groups, except for bleeding which was more common in MMVs [5]. Our study had similar results except for bleeding which was not significantly different between the two valve implant types.

In a 2003, a randomized prospective trial performed by Oxenham et al. [6] that involved 261 mitral valve replacements with either a MMV or a BMV, the survival between the two groups was similar. The reoperation rate was also higher in the BMV group. As for the other valve-related complications, only major bleeding was more prevalent in the MMV group. But there was no significant difference in endocarditis or major embolic events between the two groups. Our study showed that bleeding was not significantly different between the two valve types.

Comparable results were found in an observational study by Ruel et al. [7] that was published in 2007 that examined the long-term survival outcomes of heart valve replacement with either a BMV or a MMV in 567 adults who were younger than 60 years. They concluded that the survival in mitral valve replacement is similar between the two groups, but the reoperation rate was significantly higher in the BMV group.

With regards to perioperative mortality, our study shows a much lower incidence of early mortality compared with other studies. In our study, one patient died perioperatively (0.5%) compared with 4.3% [7], 7.7% [5], and 8.6% [6] in other studies. These results show us that in this new era, specialized centers with proper indication for surgeries can produce extremely good outcomes with low perioperative mortality, even in the setup of double and triple valve surgery.

In our study, some results were similar to what has been found in the literature. The late mortality was associated more with BMVs. Like the previous studies, the reoperation rates were also more common with the BMV group. Moreover, the other late valve-related complications (abdominal thromboembolism, stroke, severe bleeding, and endocarditis) were not significantly different between the two groups (MMV and BMV), similar to what has been demonstrated in some of the previous studies. Postoperative NYHA functional class analysis showed that the MMV group had significant association with Classes I and II. To adjust for the differences in terms of age and mitral regurgitation between the two groups, case matching was carried out. Case matching analysis revealed that BMVs were only significantly associated with reoperation rates, but not with worse survival or worse NYHA classes.

There was a significant drop in EF after the surgery. This drop is most likely attributed to two factors. Firstly, 84 (43%) of our patients had MVR while the remaining 111 (57%) patients had MVR plus another valve operation. Secondly, this drop might be due to the fact that most of our patients had partial subvalvular apparatus preservation which has been shown to be associated with lower EF in comparison to total subvalvular apparatus preservation in a number of studies. In a prospective study published in 2010 conducted by Zakai et al. [8] that included a total of 122 patients, it was noted that the EF improved in MVR in the preservation groups compared with the complete resection group which showed a decline in EF at follow-up. At the 6th month of follow-up, the mean EF of Group 1 (complete excision of the subvalvular apparatus) was 52.8%, Group 2 (preservation of the posterior leaflet) had a mean EF of 54.8%, and Group 3 (total chordal preservation) mean EF was 63.4%. In another retrospective study published in 2013 conducted by Ghavidel et al. [9] that included 151 patients, it was concluded that preserving the mitral annulus and the papillary muscle continuity may enhance cardiac performance and lower mortality and morbidity rates after MVR. A study published in

1999 by Yun et al. [10] that included 50 patients compared partial versus complete chordal preservation methods of MVR. The study concluded that complete retention of the subvalvular apparatus during MVR in comparison to posterior chordal preservation resulted in improved ejection performance. Many other studies have demonstrated that subvalvular apparatus preservation is superior to complete excision in MVR [11–14].

Most of the studies in the literature are comparing MMV and BMV in the setting of both mitral and TV or mitral regurgitation and MS. Our study was focused on a specific subgroup of pathology, which is MS. Furthermore, we were not able to find a similar study in our region to display what the data are in relation to the population residing in this part of the world.

### Study limitations

The study design is a retrospective cohort conducted in a single center. Long-term functional outcome information collection and late complication data gathering was done using telephone calls, and 53% of the patients responded at the time of writing the manuscript.

### Conclusion

This retrospective cohort study involved 195 patients with MS who underwent MVR with either BMV or MMV. Late mortality had a significant association with postoperative stroke and postoperative NYHA Classes III and IV. Postoperative NYHA class was significantly associated with: age, pulmonary disease, and postoperative stroke. MMV was significantly better in terms of reoperation rate compared with BMV. Partial preservation of the subvalvular apparatus in MVR as opposed to total preservation might lead to a decrease in the postoperative EF.

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