# **ORIGINAL ARTICLE**

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# Comparison of early and long-term follow-up results of percutaneous mitral balloon valvuloplasty and mitral valve replacement

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## **SUMMARY**

**BACKGROUND:** Percutaneous mitral balloon valvuloplasty and mitral valve replacement have been the treatment options for mitral stenosis for several years, however, studies that compare these two modalities are very rare in the literature.

**Objective:** In this article, we aim to investigate the comparison of clinical results of percutaneous mitral balloon valvuloplasty and mitral valve replacement. **Methods:** 527 patients with rheumatic mitral stenosis, treated with percutaneous mitral balloon valvuloplasty or mitral valve replacement (276 patients with percutaneous mitral balloon valvuloplasty and 251 patients with mitral valve replacement) from 1991 to 2012 were evaluated. The demographic characteristics, clinical, echocardiographic and catheterization data of patients were evaluated retrospectively. The results of early and late clinical follow-up of patients after percutaneous mitral balloon valvuloplasty group was 4.7 years and, for the mitral valve replacement-group, it was 5.45 years. The hospital stay of the percutaneous mitral balloon valvuloplasty group was shorter than that of the mitral valve replacement group (2.02 days vs 10.62 days, p<0.001). The hospital mortality rate of percutaneous mitral balloon valvuloplasty group, early postprocedural success rate was 92.1%. The event-free survival of percutaneous mitral balloon valvuloplasty-group (p<0.001), mortality rate was higher in mitral valve replacement-group (p<0.001).

**Conclusion:** Percutaneous mitral balloon valvuloplasty seems to be more advantageous than mitral valve replacement due to low mortality rates, easy application of the procedure and no need for general anesthesia.

KEYWORDS: Mitral Valve. Balloon Valvuloplasty. Outcome, Treatment. Follow-Up Studies.

## INTRODUCTION

The most common cause of mitral stenosis is rheumatic involvement. Acute Rheumatic Fever (ARF) is a multisystem, autoimmune disease caused by group-A beta-hemolytic streptococcal infections. It is still a serious health problem in many developing societies, and one of the leading causes of morbidity and mortality<sup>1-3</sup>. Carditis is the most important sequela of ARF that causes morbidity and mortality. It is observed in 40–60% of patients with rheumatic fever<sup>4</sup>. Carditis typically reveals itself as valvulitis. Mitral valve is the most frequent involvement site, while aortic and tricuspid valves are less frequently involved. Isolated mitral stenosis occurs in 25% of rheumatic valvular

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heart diseases, while mitral stenosis and mitral regurgitation exist concurrently in 40% of the patients. The primary symptoms of mitral stenosis are fatigue and exercise intolerance. Dyspnea in normal daily physical activities, orthopnea and pulmonary edema may occur as the disease progresses. Mitral valve area in normal healthy adults is 4–6 cm<sup>2</sup>. If it is below 2 cm<sup>2</sup>, that is called mild mitral stenosis. A valve area between 1 to 1.5 cm<sup>2</sup> is assessed as moderate stenosis, while one below 1 cm<sup>2</sup> is severe mitral stenosis<sup>5</sup>. Echocardiography is the most widely used and most useful method in the diagnosis and monitoring of mitral stenosis.

The treatment of mitral stenosis consists of three modalities; medical treatment, percutaneous mitral balloon valvuloplasty (PMBV) and surgery, particularly mitral valve replacement (MVR).

The early therapeutic approach for patients with severe mitral stenosis was only surgical. With the advent of technology, percutaneous commissurotomy techniques have developed significantly<sup>6</sup>. In 1982, Dr. Kanji Inoue described the Inoue technique, using a novel single balloon device for percutaneous mitral commissurotomy<sup>7</sup>. At first, PMBV was described as an alternative treatment option to surgical mitral commissurotomy for mitral stenosis<sup>6</sup>. Clinical trials comparing the long-term results of PMBV and surgery demonstrated that both modalities produce similar hemodynamic improvement<sup>7</sup>. Today, PMBV is accepted as the preferred treatment in selected patients due to shorter hospital stay, lack of general anesthesia and lower morbidity rates than any other surgical techniques<sup>7</sup>. MVR is performed for mitral insufficiency and patients with calcified mitral valve or left atrial thrombus.

We aimed to compare the echocardiographic parameters and the result of early and late clinical follow-up of patients after PMBV and MVR.

## **METHODS**

The study consisted of 527 patients with rheumatic mitral valve stenosis that were treated with PMBV or MVR (276 patients with PMBV and 251 patients with MVR) in our tertiary clinic between January 1991 and December 2012. All patients were followed up for at least 6 months with echocardiography and 12 months with clinical evaluations. The patients who undergone concomitant coronary artery bypass grafting, aortic valve replacement, tricuspid valve procedures or ablation procedures for atrial fibrillation were excluded. The treatment strategy for patients with mitral stenosis (MS), PMBV or MVR was determined by the attending cardiologist or cardiovascular surgeon and was based on echocardiographic and clinical findings. The demographic characteristics, clinical, echocardiographic and catheterization data of patients were evaluated retrospectively. Pretreatment clinical (functional capacity, medical history, concomitant disease), echocardiographic parameters and long-term follow-up of the patients were obtained.

The main end points included in hospital early follow-up and long-term follow-up were defined as death, need of early surgery, need of reintervention, pericardial tamponade, embolic stroke and serious hemorrhage. Early surgery was defined as need of MVR or re-MVR as a complication of the procedure at hospitalization. Need of reintervention was defined as re-PMBV and re-MVR on long-term follow-up. Serious hemorrhage was defined as bleeding leading to decrease in hemoglobin level of 5 g/dL or to the need of surgery for bleeding control (without dental/nasal/skin/hemorrhoids), as well as intravenous vasoactive agents.

#### Echocardiographic evaluation

2-dimensional and color Doppler echocardiographic evaluation was performed in all patients before and after the procedure. In addition to routine measurements, the mitral valve area was calculated by the planimetry of mitral valve orifice in parasternal short axis view and continuous wave Doppler technique was used to calculate the mitral gradient and the peak pressure gradient of tricuspid regurgitation for estimated systolic pulmonary arterial pressure (sPAP).

#### **Statistical analysis**

In this study, statistical analysis was made by SPSS (Statistical Package for Social Sciences) version 16.0.  $\chi^2$ , Fisher's exact  $\chi^2$  test were used for comparison of descriptive statistical methods (mean, standard deviation), as well as categorical variables, incidence and rate. Student's t-test was used for the comparison of variable mean of the two groups in parametric assumptions. Mann-Whitney U test was used in nonparametric assumptions. Wilcoxon signed-rank and marginal homogeneity tests also were used when needed. p<0.05 was considered for statistical significance.

## RESULTS

In our study, PMBV group's mean age was  $40.88\pm11.56$  and MVR group's mean age was  $51.49\pm11.51$  (p<0.05). In the PMBV group, 84.8% of patients were women; in the MVR group, 68.9% were women (p<0.05). Pre-procedure left atrium diameter was  $5.08\pm0.68$  cm in the PMBV group and  $5,49\pm0.87$  cm in the MVR group, which was statistically significant (p<0.05). In the PMBV group, pre-procedure rhythm was sinus in 71.4% of patients, whereas in the MVR group, pre-procedure rhythm was sinus in 41.4% patients (p<0.05).

Baseline clinical and echocardiographic characteristics for all patients are summarized in Table 1. After the intervention, the hospital stay of the PMBV group was significantly shorter than that of the MVR ( $2.02\pm1.75$  days;  $10.62\pm4.53$  days, p<0.001). The mean follow-up time of the PMBV group was 4.7 years, and, for the MVR group, it was 5.45 years (p=0.053).

The hospital mortality rates of PMBV and MVR were 0% and 2%, respectively. In the PMBV group, early postprocedural success rate was 92.1%, whereas 7.9% of patients needed surgical intervention during hospital stay. Comparison of early results of the PMBV and MVR groups are summarized in Table 2.

The mortality rates of the PMBV group and the MVR group were 0% and 4%, respectively (p<0.001). The reintervention rate of the PMBV group was 16.3%, and this rate was 2.4% for the MVR group (p<0.001). The rate of event-free survival of PMBV after the follow-up was 81% and, in the MVR group, it was 88% (p=0.107). The comparison of long-term follow-up results of the PMBV and MVR groups is summarized in Table 3.

	PMBV (n=276)	MVR (n=251)		р	
	mean±std	mean±std			
Age	40.88±11.56	51.49±11.51	-10.54	0.001**	
Pre-procedural MVA (cm <sup>2</sup> )	1.00±0.22	1.04±0.21	-2.178	0.029*	
Pre-procedural mean gradient (mmHg)	13.68±5.55	13.00±4.10	-0.474	0.633	
Pre-procedural LA diameter (cm)	5.08±0.68	5.49±0.87	-6.23	0.001**	
Pre-procedural sPAP (mmHg)	51.87±14.01	53.02±13.23	-1.383	0.167	
	n (%)	n (%)	χ²	р	
Sex (female)	84.8	68.9	17.908	0.001**	
Pre-procedural rhythm SR	71.4	41.4	1.007	0.001**	
AF	33.3	58.6	1.807		
Previous procedure	11.6	23.1	0.010	0.001**	
Pre-procedural MR None	51.8	23.1		0.001**	
+1	37.7	51.2			
+2	8.0	21.5	63.608		
+3	2.6	12.0			
+4	0.0	0.0			
Pre-procedural FC NYHA 1–2	46	50.2	0.025	0.850	
NYHA 3–4	54	49.8	0.035		

Table 1. Baseline clinical and echocardiographic characteristics.

\*p<0.05; PMBV: percutaneous mitral balloon valvuloplasty; MVR: mitral valve replacement; MVA: mitral valve area; LA: left atrial; sPAP: systolic pulmonary arterial pressure; SR: sinus rhythm; AF: atrial fibrillation; MR: mitral regurgitation; FC: functional class; NYHA: New York Heart Association.

Table 2.	Comparison o	of early resu	lts of percu	itaneous mitral	balloon valvulo	plasty and	d mitral valve	e replacement qu	roups.

		PMBV (n=276) mean±std	MVR (n=251) mean±std	z	р
Hospital Stay (day)		2.02±1.75 (2)	10.62±4.53 (10)	-19.40	0.001*
		n (%)	n (%)	χ²	р
Death	No	276 (100)	246 (98)		0.024*
	Yes	0 (0)	5 (2)	5.551	0.024**
Urgent Surgery	No	257 (93.1)	251 (100)	15.00	0.001**
	Yes	19 (6.9)	0 (0)	15.99	0.001^^

\*p<0.05; PMBV: percutaneous mitral balloon valvuloplasty; MVR: mitral valve replacement.

## DISCUSSION

In our retrospective clinical study, we demonstrated that the hospital mortality rate of PMBV was significantly lower than MVR. The event-free survival of PMBV and MVR was found to be similar. The need of reintervention was higher in the PMBV group than in the MVR group, which was statistically significant, however, the mortality rate of MVR was higher than PMBV's.

Almost all of the rheumatic mitral stenosis patients need intervention<sup>7</sup>. In the patients with inappropriate anatomic and clinical conditions for percutaneous approach, MVR and other surgical procedures can be performed. There are several studies that compare PMBV and other surgical procedures, such as open or closed mitral commissurotomy. Nevertheless, there are very few studies that compare early and long-term complications of PMBV and MVR. Although success rates of these modalities have been proven, complications can be seen in follow-up duration.

Early randomized, controlled studies showed similar clinical outcomes for both PMBV and MVR<sup>8,9</sup>. The limitation of previous clinical studies was the heterogeneity for both patient groups; moreover, open mitral commissurotomy was included in both studies. In our study in the PMBV group, the mean age was 40.88, and 84.8% of patients were women, which are both statistically significant factors in comparison to the MVR group. In the PMBV group, pre-procedure rhythm was sinus rhythm in 71.4% of patients, whereas, in the MVR group, pre-procedure rhythm was atrial fibrillation in 58.6% of patients. These baseline characteristics were similar to previous studies<sup>9</sup>.

Immediate procedural success for both of these modalities has been shown in some randomized clinical trials<sup>8-14</sup>. Early procedural success for PMBV is defined as MVA>1.5 cm<sup>2</sup> without significant mitral regurgitation (MR)<sup>8-9,11</sup>. In the PMBV group, early postprocedural success rate was 92.1% in our study, which was relatively higher when compared to previous studies.

MR is the most common complication of PMBV. According to previous studies, severe MR after PMBV was observed in between 7.5–18.5%<sup>15-18</sup> of patients. In our study, severe MR occurred in 3.6% of patients, which was relatively low compared to other studies. Mild to moderate MR is one of the most important determinant factors to patient selection for PMBV or MVR. Due to the aforementioned reason, the MVR

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		PMBV (n=276) mean±std	MVR (n=251) mean±std	z	р
Clinical follow-up (year)		4.70±4.16 (3)	5.45±4.54 (4)	-1.936	0.053
Echocardiographic follow-up (year)	Echocardiographic follow-up (year)		4.93±4.64 (3)	-0.397	0.001**
Postprocedural LA diameter (cm)		4.88±0.71 (5)	5.44±3.82 (5)	-5.236	0.001**
Postprocedural sPAP (mmHg)		38.23±11.92 (37)	40.63±10.26 (38)	-3.399	0.001**
		n (%)	n (%)	χ²	р
Death	No	276 (100)	241 (96)	11 200	0.001**
Death	Yes	0 (0)	10 (4)	11.209	
Deinterrentier	No	231 (83.7)	245 (97.6)		0.001**
Reintervention	Yes	45 (16.3)	6 (2.4)	27.545	
	NYHA 1-2	261 (94.5)	239 (95.2)	0.012	0.910
Postprocedural functional capacity	NYHA 3-4	15 (5.5)	16 (4.8)	0.012	
Event-free survival		206 (81.1)	222 (87.9)	2.596	0.107
	No	271 (98.2)	246 (98.0)	0.022	1.000
Embolic stroke	Yes	5 (1.8)	5 (2.0)	0.023	
E de la constituía	No	275 (99.6)	) 249 (99.2)		0.007
Endocarditis	Yes	1 (0.4)	2 (0.8)	0.438	0.607
	SR	184 (66.7)	119 (47.4)	10.100	0.001**
Postprocedural rnythm	AF	92 (33.3)	132 (52.6)	19.166	

Table 3. Comparison of long-term follow-up results of the percutaneous mitral balloon valvuloplasty and mitral valve replacement groups.

\*\*p<0.01; PMBV: percutaneous mitral balloon valvuloplasty; MVR: mitral valve replacement; LA: left atrial; AF: atrial fibrillation; sPAP: systolic pulmonary arterial pressure; NYHA: New York Heart Association; SR: sinus rhythm.

group had higher MR incidence in our study, corroborating previous studies. In the MVR group, Dhasmana et al.<sup>19</sup> found a rate of 5.7% perivalvular leakage; in our study, this rate was 6.4%. Additionally, like similar studies, we found 2 days hospital stay in the PMBV group, whereas, in the MVR group, hospital stay was 10 days, which is statistically significant.

Cardiac tamponade is one of the serious complications of both PMBV and MVR. In an analysis of 23.000 patients with percutaneous cardiac interventions, cardiac tamponade ratio is highest in PMBV patients<sup>20</sup>. In our study, 4 patients (1.4%) had a cardiac tamponade due to PMBV, but no deaths were observed in the follow-up.

In our study, mortality rates of PMBV and MVR were 0% and 4% respectively, which was statistically significant. Korkmaz et al.<sup>11</sup> found a 0.7% death rate on long-term follow-up. Zhang et al.<sup>21</sup> found that the death rate after MVR was 2–10% in the early period. In our study, the death rate was 2% in early stage and 2% in long-term follow-up. The reason for death was hemorrhagic cerebrovascular disease in three patients, gastrointestinal bleeding in one patient, and unknown in one patient.

The reintervention rate of the PMBV group was 16.3%, and this rate was 2.4% for the MVR group (p<0.001). According to previous studies<sup>10,22</sup>, MVR rate after PMBV is 15–27%; in our study, we found it to be 13.8% (7.9% on early stage, 5.9% on long-term follow-up). Karp et al.<sup>23</sup> found 5% re-MVR after 5 year follow-up; in our study, 2.4% of patients needed re-PMBV.

Although PMBV and MVR are accepted gold standard therapy for mitral stenosis, both of them have some important complications. Babic et al.<sup>24</sup> found a 2% rate of embolic stroke after PMBV; similarly, in our study, five patients (1.8%) had embolic stroke. Four of them had embolic stroke on long-term follow-up. On the other hand, Cohen et al.<sup>8</sup> found 2% cerebrovascular stroke rate after MVR; similarly, in this study, the cerebrovascular stroke rate was 2% (five patients) in the MVR group. Infective endocarditis due to mechanical valve is one of the serious complications after MVR, and Katircioglu et al.<sup>25</sup> have seen it in 2% of patients on long-term follow-up; in our study, the ratio was 0.8% on long-term follow-up. Cohen et al.<sup>8</sup> presents a rate of 13% of atrial septal defect due to PMBV; in our study, this rate was 3.3%.

Event-free survival rate of the PMBV group after the follow-up was 81%, and, in the MVR group, it was 88% (p=0.107).

Song et al.<sup>9</sup>, after 8 years follow-up, found an event-free survival rate of 82% on PMBV and 86% on MVR patients. In our study, the 81% ratio on PMBV and 88% ratio on MVR patients' event-free survival could explain the increased rate of PMBV treatment for mitral stenosis worldwide, with noninferiority of PMBV to MVR. Our study showed that, although event-free survival of both the PMBV and the MVR groups were similar, the need of reintervention was higher in the PMBV group; contrarily, mortality rate in the MVR group was higher than in the PMBV group.

#### **Study limitations**

The most important limitation of this study was that it was a retrospective study. The other limitation of this study was lack of echocardiographic mitral valve score of patients.

### CONCLUSION

In our study, the event-free survival rates of PMBV and MVR were found to be similar. The need of reintervention was higher in the PMBV group; however, the mortality rate of MVR was higher than PMBV. In conclusion, despite the fact that both modalities are used in the treatment of mitral stenosis, PMBV seems to be more advantageous in selected patients, considering the low mortality rates, easy application of the procedure and no need for general anesthesia.

## AUTHORS' CONTRIBUTIONS

EU: Conceptualization, Data Curation, Formal Analysis, Validation, Writing – Original Draft, Writing – Review & Editing. RE: Conceptualization, Data Curation, Formal Analysis, Validation. SG: Writing – Original Draft, Writing – Review & Editing, Validation. AD: Conceptualization, Data Curation, Formal Analysis, Writing – Original Draft, Writing – Review & Editing. ME: Conceptualization, Data Curation, Formal Analysis. SK: Conceptualization, Data Curation, Formal Analysis. SK: Conceptualization, Data Curation, Formal Analysis. Vilidation, Writing – Original Draft, Writing – Review & Editing. MB: Conceptualization, Data Curation, Formal Analysis. NY: Conceptualization, Data Curation, Formal Analysis, Validation, Writing – Original Draft, Writing – Review & Editing.

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