Percutaneous Mitral Balloon Valvotomy; Single Center Experience: A Review of Outcome

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Abstract

Background-Percutaneous balloon mitral valvotomy (BMV) has been accepted as an alternative to surgical mitral commissurotomy in the treatment of patients with symptomatic rheumatic mitral stenosis. Despite the worldwide use of the BMV technique, no studies have been hitherto designed to assess the outcome of the patients undergoing BMV in Iran. The present study reports the outcome of 3138 BMV procedures at Shaheed Rajaei Cardiovascular, Medical and Research Center during a 15-year time period.

Methods- A total of 2531 patients underwent 3138 BMV procedures at Shaheed Rajaei Cardiovascular, Medical and Research Center between 1992 and 2006. Seventy-three percent (2278) of the cases were followed for 48±41 months.

Results- Recurrent stenosis in 802 (25.8%), mitral valve replacement (MVR) in 213 (6.9%), immediate good result in 3110 (99.1%), and successful outcome in 2000 (72.9%) cases were the outcome of the BMV procedures in the current study.

Conclusion- Concordant to the similar studies, we concluded that BMV produces a good clinical outcome in a high percentage of patients. The recent study demonstrated that the successful outcome of BMV was multi factorial and the selection of patients with rheumatic mitral stenosis is recommended to be based on both anatomic and clinical characteristics of the individuals. The procedure-related variables must also be considered in order to predict the outcome ***(Iranian Heart Journal 2011; 12 (2):16-22).***

Keywords: Percutaneous■ Balloon Mitral Valvotomy■ Outcome

Mitral stenosis is a common disease that causes substantial morbidity worldwide.

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The disease is most prevalent in developing countries, but is increasingly being identified in an atypical form in developed countries.

All treatments that increase the valve area improve morbidity. [1-5]
Percutaneous balloon mitral valvotomy (BMV), was first introduced by Inoue in 1984, as a balloon catheter which allowed mitral commissurotomy without thoracotomy.[6] In 1986, McKay and Palacios put BMV into practice in the United states [7-8]and in 1987 the Brazilian Peixoto et al. described the transseptal technique. [9-11]
As the long term results of the studies showed that BMV achieved comparable results to surgical commissurotomy both in the short and long terms,[2, 12-14] the method replaced traditional thoracotomy surgery, which has been reserved for the minority of patients concomitant with atrial thrombi or unfavorable mitral valve morphologic features such as heavy calcifications. [2, 15-16]
Despite the worldwide application of BMV, no study has been thus far designed to report the complications, results, and success rates of the mentioned procedure in Iran. The present study reports the outcome of 3138 BMV procedures at Shaheed Rajaei Cardiovascular, Medical and Research Center during a 15-year time period.

Methods

Patient Population

A total of 2531 patients underwent 3138 BMV procedures at Shaheed Rajaei Cardiovascular, Medical and Research Center between 1992 and 2006. There were 2472 women and 666 men; mean age was 38±11 (range, 11 to 77) years. Among the total number of the 3138 BMV procedures, 279 (8.9%) had their second and 17 (0.5%) had their third BMV procedures with 66±31 and 36±15 months' intervals from their previous operation, respectively. Seventy-three percent (2278) of the BMV cases were followed for 48±41 months.

Technique of BMV

BMV was performed in the fasting state under local anesthesia and mild sedation, using the transseptal antegrade technique. The Inoue single-balloon was used for all the patients. The balloon size was chosen considering the patients' height and body surface area.

All the patients underwent transesophageal echocardiography (TEE) before BMV. Mitral valve area (MVA), echocardiography score,[17] severity of mitral regurgitation (MR), left atrium diameter (LA), left ventricle end diastolic diameter (LVEDD), right ventricle end diastolic diameter (RVEDD), presence of clot in the LA and left atrium auricle (LAA), and the concomitant involvement of the other valves were assessed during the TEE.

The echocardiographic score was obtained by a relatively simple, semi-quantitative grading of leaflet thickening, mobility, calcification, and sub-valvular involvement on a scale of 0 to 4 and a total score of 16.[17]

The clinical evaluation was according to the New York Heart Association (NYHA) functional classification of congestive heart failure.

The severity of mitral regurgitation was considered as mild, moderate, and severe, using left ventriculography pre and post BMV in order to assess its presence and severity.

Complete right and left heart catheterization studies were performed before and after BMV to evaluate the changes in the hemodynamic produced by BMV.

The end points in order to terminate the BMV procedure were the opening of at least one commissure or a one-degree improvement in the mitral regurgitation state.

An immediate good result was considered as a significant reduction in the transmitral gradient, immediately post BMV.

The successful outcome was defined as the 24-48 hours post-op MVA≥1.5 cm^2 and lack of evidence of severe mitral regurgitation.

Statistical analysis was performed using SPSS® for Windows version 15.0. Quantitative variables were described as mean (±SD) and qualitative variables as frequency (relative frequency). Statistical significance was set as $p<0.05$. Means, standard deviations (SD) and standard error (SE) were calculated for each of the scale measurements.

Non-parametric tests were used in the statistical analyses wherever data were not normally distributed. To compare the mean of the demographic variables between the different groups, the One-Way ANOVA test was used.

Results

The baseline characteristics of the BMV cases and the hemodynamic changes before and after BMV are shown in Tables I and II.

Table I. Baseline characteristics of cases undergoing BMV procedure

Age, *y*	38±11
Sex (Female/Male), *n*	2472/666
Previous surgical Commissurotomy, *n(%)*	342 (10.9)
Echocardiography Score Female Male	 6.8±1.4 7.07±1.5
LVEF, *(%)*	53±6
Isolated MS, *n(%)*	701 (22.5)
MS + MR, *n(%)*	998 (32)
AI, *n(%)*	1350 (43.2)
AS, *n(%)*	69 (2.2)

TR, *n(%)*	1642 (52.6)
PS, *n(%)*	1 (0)
PI, *n(%)*	115 (3.7)

BMV indicates Balloon Mitral Valvotomy; LVEF, Left Ventricle Ejection Fraction; MS, Mitral Stenosis; MR, Mitral Regurgitation; AI, Aortic Insufficiency; AS, Aortic Stenosis; TR, Tricuspid Regurgitation; PS, Pulmonary Stenosis; and PI, Pulmonary Insufficiency

Table II. Hemodynamic changes of cases undergoing BMV procedure

	Pre-BMV	Post-BMV	P Value
MG, *mmHg*	16.5±6.2	2.3±1.4	< 0.05
MVA, cm^2	0.9±0.3	1.6±0.3	< 0.05
NYHA Class, *n(%)*			
I	82 (2.6)	3057 (97.7)	< 0.05
II	2442 (78)	65 (2.1)	
≥ III	606 (606)	7 (0.2)	
AF, *n*	802	803	0.4

BMV indicates Balloon Mitral Valvotomy; MG, Mitral Gradient; MVA, Mitral Valve Area; NYHA, New York Heart Association; and AF, Atrial Fibrillation.

BMV resulted in a significant decrease in mitral gradient (MG) and NYHA class of the patients. On the other hand, a significant increase in the mitral valve area was observed following BMV.

The pre-BMV pulmonary artery systolic pressure (PASP) was 41.7±14.8 mmHg, and the post-LV injection (pre-BMV) PASP was 55.6±17.4 mmHg. The pulmonary artery diastolic pressure (PADP) was also 19.3±8.3 mmHg pre-BMV and 27.5±9.6 mmHg post-LV injection (pre-BMV). The rise in both PASP and PADP post-LV injection before performing BMV was significant (P value < 0.05).

The outcome of BMV was as follows: mitral restenosis in 802 (25.8%), mitral valve replacement (MVR) in 213 (6.9%), immediate good result in 3110 (99.1%), and successful outcome in 2000 (72.9%) cases.

In patients with mitral restenosis, the mean age was 39.8±11.1 years and 636 (79.3%) were females. Compared to the patients without mitral restenosis, the mentioned group had a more frequent percent of previous closed mitral valve commissurotomy (115; 14.4% vs. 168; 7.3%; P value=0.001) and larger LA diameter (4.9±2.4 vs. 4.7±0.6 cm, P value=0.008). Except for the two mentioned factors, no other significant differences were observed in the baseline characteristics and the hemodynamic changes before and after BMV in patients with and without mitral valve restenosis.

Considering the outcome, the patients were categorized into two distinct groups of successful and unsuccessful outcomes. In the multivariate analysis, lower age of diagnosis and treatment onset, female gender, lower echocardiography score, atrial fibrillation (AF)-free cardiac rhythm pre-BMV, larger MVA, less MG, less LAA thrombosis frequency, less RVEDD, lower PASP and PADP, and less frequent concomitant valve involvement before the procedure were the factors which predicted a better prognosis and a more success rate for BMV (Table III).

Table III. Factors significantly related to the successful outcome

	Successful BMV	Unsuccessful BMV	P Value
Age, *y*	38±11	39±11	0.02
Female/Male, *(%)*	81.4/18.6	73.8/26.2	<0.001
AF Pre-BMV, *(%)*	23.4	32.4	<0.001
Echo Score Pre-	6.5±1.2	7.5±1.6	<0.001

BMV			
MVA Pre-BMV, cm^2	0.9±0.2	0.8±0.1	<0.001
MG Pre-BMV, *mmHg*	16.4±6	16.7±6	0.01
LAA Thrombosis, *(%)*	1.5	3.4	0.003
RVEDD, *cm*	2.7±0.6	2.9±0.7	0.002
PASP Pre-BMV, *mmHg*	41±14	44±16	<0.05
PADP Pre-BMV, *mmHg*	19±7	20±9	0.004
MR Presence Pre-BMV, *(%)*	30.4	35.2	0.01
TR Presence, *(%)*	51.8	58.5	< 0.001

BMV indicates Balloon Mitral Valvotomy; AF, Atrial Fibrillation; MVA, Mitral Valve Area; MG, Mitral Gradient; LAA, Left Atrium Auricle; RVEDD, Right Ventricle End Diastolic Diameter; PASP, Pulmonary Artery Systolic Pressure; PADP, Pulmonary Artery Diastolic Pressure; MR, Mitral Regurgitation; and TR, Tricuspid Regurgitation.

MVR was needed in 213 (6.9%) patients. Male gender, having the AF rhythm, lower MVA, higher echocardiographic score, larger LA, LVEDD and RVEDD, higher PASP and more frequent presence of concomitant valve disorders prior to BMV were all accompanied with more MVR occurrence (Table IV).

Complications occurred in 56 patients post BMV. Severe tamponade,[14] transient AF,[13] mild pericardial effusion,[9] atrioseptal defect,[9] peripheral emboli,[3] CNS emboli,[1] ventricular fibrillation,[1] acute tubular necrosis,[1] sepsis,[1] and endocarditis[1] were the complications being observed in the descending order.

Table IV- Factors significantly related to the need for MVR

	MVR Not Needed	**MVR Needed**	**P Value**
Female/Male, *(%)*	80.1/19.9	59.6/40.4	<0.001
AF Pre-BMV, *(%)*	24.9	39.9	<0.001
Echo Score Pre-BMV	6.8±1.4	7.2±1.6	< 0.001
MVA Pre-BMV, cm^2	0.9±0.2	0.8±0.2	<0.001
LA Diameter, *cm*	4.7±1.7	4.9±0.5	<0.001
LVEDD, *cm*	4.4±0.5	4.7±0.5	<0.001
RVEDD, *cm*	2.7±0.6	2.8±0.8	<0.001
PASP Pre-BMV, *mmHg*	58±17	62±20	0.02
AI Presence, *(%)*	42.9	50.5	0.02
TS Presence, *(%)*	1.3	3.8	0.003

MVR indicates Mitral Valve Replacement; AF, Atrial Fibrillation; BMV, Balloon Mitral Valvotomy; MVA, Mitral Valve Area; LA, Left Atrium; LVEDD, Left Ventricle End Diastolic Diameter; RVEDD, Right Ventricle End Diastolic Diameter; PASP, Pulmonary Artery Systolic Pressure; AI, Aortic Insufficiency; and TS, Tricuspid Stenosis.

On the other hand, 297 patients experienced an increase in their MR severity: 165 had a one-degree increase, 118 had a two-degree increase, and 14 had a three-degree increase in the severity of their MR status.

The mortality rate was 0.001% and mostly (80%) occurred in hospital or immediately after discharge. Of the total 5 deaths, one case died in the operating room during the emergency MVR, one died 24 hours post-BMV with sudden death, and two died because of tamponade after BMV. The last mortality occurred one month after the procedure; the cause of death was massive pulmonary emboli.

The MVR-free 5-year survival was 94.9%. The 10 and 15 years' MVR-free survival rates were 68.5% and 60.7% respectively.

Discussion

In our study, the mean age of the patients was 38±11 years old and in accordance with the literature, there were more females in the study group. [18-20]

The previous studies showed that, compared with Western countries, the BMV candidates from non-Western countries are younger, with more severe valve stenosis. [21] The immediate increase in PASP and PADP post-LV injection before performing BMV emphasized the severity of mitral stenosis in our patients.

The immediate good result in 3110 (99.1%) and successful outcome in 2000 (72.9%) cases demonstrate that BMV confers a good immediate hemodynamic and clinical improvement in the majority of patients with mitral stenosis.

Dr. Iung et al. reported a 90% immediate good result in their study performed on 1514 patients. [22]Dr. Hernandez and Dr. Palacios also revealed a 78% and 71.7% successful outcome rates after BMV. [23-24] In another study performed in a Cardiology Clinic in Turkey, the analysis of 311 patients revealed that acute post-procedural success, which was defined as MVA $\geq$1.5 cm^2 without severe mitral regurgitation, was 94% and was only associated with larger pre-procedural MVA (p=0.008).[25]

The present study demonstrated that the successful outcome of BMV was multi factorial and more evident in younger women with the first attempt at BMV. The recurrent restenosis significantly lowered the success rate. Pre-BMV conditions such as larger MVA, less MG, and less PA pressures (PASP and PADP) were also accompanied by a higher success rate. Overall, the less-complicated patients had a better outcome, as was expected. Less frequent concomitant valve involvement was also the other factor which seems to be influential in the BMV outcome.

In a study performed by Borges et al., the factors that predicted long-term deaths were a pre-procedural echocardiographic score > 8 and the presence of severe valvular mitral regurgitation during the procedure. The events that predicted combined events were a previous history of mitral valvular commissurotomy, AF, and the presence of severe mitral valvular regurgitation during the procedure, and post-procedure mitral valve area of less than 1.5 cm^2.[2, 20, 26]

In assessing the risk factors for MVR, men with AF rhythm, lower MVA, higher echocardiographic score, larger cardiac indices, and higher PASP prior to BMV were more prone to the mitral valve replacement surgical therapy. The presence of concomitant valve disorders also increased the risk of MVR.

The echocardiography score played an important role in both the success rate of the BMV procedure and the MV replacement necessity. A higher echocardiography score was accompanied by more MVR and a lower score was accompanied by better success rates.

The mortality rate was about 0.001% in our center, which was significantly lower than that in the similar studies, which showed a 0.4-0.6 % mortality rate.(6-7) The lower rate may be due to the lower age group of the patients in our study.

Conclusion

Chiming in with similar studies,[27] we concluded that BMV produces a good clinical outcome in a high percentage of patients. The current study demonstrated that the successful outcome of BMV was multi factorial and the selection of patients with rheumatic mitral stenosis is recommended to be based on both anatomic and clinical characteristics of the individuals. The procedure-related variables must also be considered in order to predict the outcome.

Conflict of interest

No conflicts of interest have been claimed by the authors.

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