Original Article

Mitral Regurgitation after Percutaneous Balloon Mitral Valvotomy in Patients with Rheumatic Mitral Stenosis: A Single-Center Study

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Abstract

Background: *Percutaneous balloon mitral valvotomy (BMV) is the gold standard treatment for rheumatic mitral stenosis (MS) in that it causes significant changes in mitral valve area (MVA) and improves leaflet mobility. Development of or increase in mitral regurgitation (MR) is common after BMV. This study evaluated MR severity and its changes after BMV in Iranian patients.*

Methods: *We prospectively evaluated consecutive patients with severe rheumatic MS undergoing BMV using the Inoue balloon technique between February 2010 and January 2013 in Madani Heart Center, Tabriz, Iran. New York Heart Association (NYHA) functional class and echocardiographic and catheterization data, including MVA, mitral valve mean and peak gradient (MVPG and MVMG), left atrial (LA) pressure, pulmonary artery systolic pressure (PAPs), and MR severity before and after BMV, were evaluated.*

Results: *Totally, 105 patients (80% female) at a mean age of 45.81 ± 13.37 years were enrolled. NYHA class was significantly improved after BMV: 55.2% of the patients were in NYHA functional class III before BMV compared to 36.2% after the procedure (p value < 0.001). MVA significantly increased (mean area = 0.64 ± 0.29 cm^2 before BMV vs. 1.90 ± 0.22 cm2 after BMV; p value < 0.001) and PAPs, LA pressure, MVPG, and MVMG significantly decreased. MR severity did not change in 82 (78.1%) patients, but it increased in 18 (17.1%) and decreased in 5 (4.8%) patients. Patients with increased MR had a significantly higher calcification score (2.03 ± 0.53 vs.1.50 ± 0.51; p value < 0.001) and lower MVA before BMV (0.81 ± 0.23 vs.0.94 ± 0.18; p value = 0.010). There were no major complications.*

Conclusion: *In our study, BMV had excellent immediate hemodynamic and clinical results inasmuch as MR severity increased only in some patients and, interestingly, decreased in a few. Our results, underscore BMV efficacy in severe MS. The echocardiographic calcification score was useful for identifying patients likely to have MR development or MR increase after BMV.*

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Introduction

First described in 1984 by Inoue, percutaneous balloon mitral valvotomy (BMV) has now become a recognized and common therapeutic approach[1] and is used as an alternative to surgical mitral commissurotomy in patients with symptomatic severe mitral stenosis (MS) and suitable valve anatomy.[2] BMV produces significant changes in mitral valve morphology and improvement in leaflet mobility.[3] With an increase in the use of BMV, the effectiveness of this procedure has become widely accepted despite its risks.[4, 5] Most patients with MS are female; and in comparison to the past, MS occurs more frequently in older people. Interventionists have also gained a great deal of experience, which has brought about a decrease in the incidence of severe mitral regurgitation (MR) necessitating surgery.

BMV has considerably high success rates and low complication rates in short-term and long-term follow-ups.[6] However, there are various reports describing the development of or increase in post-BMV MR,[2, 6-8] which remains a major procedure-related complication. This complication is usually mild and well tolerated but MR degree may increase in 25%-83% of cases after BMV.[9-11] The main concern is the development of severe MR following BMV requiring valve replacement in some patients. The incidence rate of severe MR after BMV in the literature varies between 1.4% and 7.5%.[12-14] In a previous study in our institute by Aslanabadi and colleagues[15] on 300 patients with moderate to severe MS, the incidence rate of severe MR after BMV was 2%. Whereas some patients may require emergency surgery, others do not need it. Moreover, MR severity is also reported to be decreased in a few patients.[5, 16-21]

We sought to evaluate BMV outcome with an emphasis on MR changes.

Methods

We prospectively studied 105 consecutive patients with rheumatic severe MS who were eligible for BMV using the Inoue balloon technique between February 2010 and January 2013 in Madani Heart Center, Tabriz, Iran. The study was approved by the institutional Review Board, and all the patients gave their informed consent for the procedure.

The inclusion criteria were symptomatic severe MS with New York Heart Association (NYHA) functional class (FC) II or more, mitral valve area (MVA) ≤ 1.5 cm^2, and mitral valve echocardiographic score ≤ 11, according to the scoring system described by Wilkins et al.[21, 22]

The presence of each of the following factors was considered an exclusion criterion: left atrial (LA) thrombus; MR severity higher than moderate; unfavorable mitral valve morphology; and need for cardiac surgery because of severe aortic, tricuspid, or coronary disease. The results of our previous study[15] showed that a high echocardiographic score is not a contraindication for BMV in rheumatic MS. The patients who met the exclusion criteria were referred for surgical treatment. The decision regarding BMV was mainly based on echocardiographic assessment, which was employed to measure MVA, valvular and subvalvular apparatus calcifications, and MR degree. The Wilkins score was used to determine the anatomic characteristics of the valve and subvalvular regions.[22] To avoid personal bias in assessing the anatomic scores and the mitral valves, these parameters were graded by at least two experienced echocardiologists and, in case of disparity, by a third one to ensure correct classification.

All the patients underwent BMV using the transvenous trans-septal antegrade technique from the right femoral vein.[1] The initial balloon size was chosen according to the patient's height. The balloon size was chosen to obtain an effective balloon dilation area/ body surface area of approximately 4cm^2/m^2. The balloon size was stepwise increased by 0.5 mm consecutive dilations until an MVA > 1.5cm^2 was reached or MR significantly increased.

Right and left heart pressures, including simultaneous LA and left ventricular (LV) end diastolic pressure (trans-mitral gradient), were measured before and after BMV. The BMV procedure was terminated once the gradient was ≤ 4 mmHg, there was no diastolic rumble, or in case MR occurred or increased.

Standard transthoracic echocardiography (TTE) was performed almost one week before and 24 hours after BMV with a GE Vivid 7 scanner, equipped with an M3S multi-frequency phased array transducer and tissue Doppler imaging facility. Data were acquired with the subjects at rest, lying in the lateral supine position. Grey-scale images were obtained using second-harmonic imaging (1.7/3.4 MHz). Two-dimensional (2D) electrocardiography (ECG) was superimposed on the images, and end-diastole was considered at the peak R-wave of the ECG. Left ventricular ejection fraction (LVEF) was determined using the Simpson biplane method by measuring the end-diastolic and end-systolic volumes in 2D images. All the measurements, including MVA, mitral valve peak gradient (MVPG), mitral valve mean gradient (MVMG), MR severity, LA pressure, and pulmonary artery systolic pressure (PAPs), were obtained in accordance with the American Society of Echocardiography (ASE) recommendations.

Transesophageal echocardiography (TEE) was performed on the same day or on the day before intervention for the exclusion of LA thrombi, better evaluation of mitral valve structure, Wilkins score, and MR severity (grades 1-4), interatrial septal thickening measurement, and reassessment of TTE data.[23-25]

The MV score was judged according to the Wilkins score system, obtained by adding the score of each of these individual morphological features: leaflet mobility; thickness;

calcification; and subvalvular thickening.[21] A score of 0-4 was assigned to each component in accordance with the Wilkins echocardiographic scoring system. Adding the individual scores generally resulted in a total echocardiographic score, which varied from 0 to 16 for the MV, with higher values representing increased morphological abnormality.[21] In this study, the final total echocardiographic scores ranged from 5 to 12.

After BMV, color Doppler echocardiography was used to screen left-to-right atrial shunts. LV gram was performed in all the patients before and after BMV to assess MR severity.

The data are presented as mean ± standard deviation (SD). The variables were compared before and after the procedure using the paired samples t-test (continuous variables) or the chi-squared test (categorical variables). The continuous variables were compared between the patients with and without an increase in MR severity and between the patients with and without a decrease in MR severity using the independent samples t-test. Multivariate logistic regression analysis was used to define the predictors of an increase in MR severity after BMV. A p value was considered significant when it was ≤ 0.05. Data were collected and analyzed using SPSS statistical package version 16.0 (SPSS Inc. Chicago, IL, USA).

Results

Complete pre-and post-BMV evaluation was performed in 105 patients (84 [80%] females) at a mean age of 45.81 ± 13.37 (range = 20 to 76) years. Mean LVEF was 52.16% ± 4.40% (range = 35% to 60%). Sixteen (15.24%) patients had atrial fibrillation and 89 (84.76%) had sinus rhythm. The echocardiographic score ranged from 5 to 12 (8.50 ± 1.38). Three (2.85%) patients had a history of previous cerebrovascular accident (CVA).

Three (2.85%) female patients aged 22, 25, and 31 years were pregnant and underwent BMV at 23, 21, and 28 weeks of pregnancy, respectively. BMV was successful in all the three patients, and there were no maternal or fetal complications after BMV.

NYHA FC was significantly improved after BMV (p value < 0.001). Following BMV, the patients had mainly FC I and FCII, as opposed to a higher FC III before BMV (Figure 1).

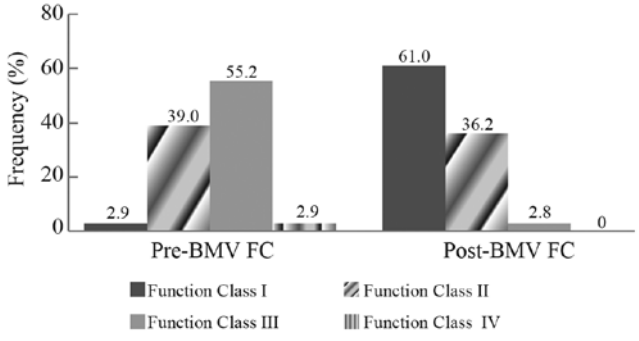

Figure 1. Comparison of NYHA functional class pre and post BMV
FC, Function class; BMV, Balloon mitral valvotomy; NHYA, New York Heart Association

Table 1.Comparison of baseline and echocardiographic characteristics in patients with and without increased MR after BMV*

	Increased MR Severity (n=18)	MR Severity without Change (n=82)	P value
Age (y)	41.38±12.61	47.19±13.47	0.097
Gender (female)	17 (94.4)	63 (76.8)	0.112
Ejection fraction (%)	53.50±3.97	51.87±4.54	0.165
Mean Wilkins echocardiographic score	8.00±0.97	8.64±1.36	0.060
Favorable valve anatomy (Wilkins Score ≤ 8)	6 (33.3)	38 (46.3)	0.192
Unfavorable valve anatomy (Wilkins Score > 8)	12 (66.7)	44 (53.7)	0.341
Wilkins score components			
Mobility	2.11±0.47	2.04±0.41	0.573
Calcification	2.03±0.53	1.50±0.51	< 0.001
Thickness	2.05±0.41	2.07±0.51	0.893
Subvalvular	2.27±0.46	2.45±0.54	0.215
Mitral valve area (cm^2)	0.81±0.23	0.94±0.18	0.011
Pulmonary artery peak systolic pressure (mmHg)	44.00±9.91	47.06±10.18	0.249
Left atrial pressure (mmHg)	26.55±4.91	26.15±4.27	0.729
MV peak gradient (mmHg)	21.44±4.24	21.20±4.82	0.848
MV mean gradient (mmHg)	12.33±3.72	12.56±3.80	0.818

*Data are presented as mean±SD or n (%)
MR, Mitral regurgitation; BMV, Balloon mitral valvotomy; MV, Mitral valve

Table 2. Hemodynamic and echocardiographic characteristics before and after BMV*

	Before BMV	After BMV	P value
Mitral valve area (cm^2)	0.64±0.29	1.90±0.22	< 0.001
Pulmonary artery peak systolic pressure (mmHg)	46.07±10.22	36.90±6.23	< 0.001
Left atrial pressure (mmHg)	26.21±4.62	16.26±4.18	< 0.001
Mitral valve peak gradient (mmHg)	21.34±4.75	9.62±2.78	< 0.001
Mitral valve mean gradient (mmHg)	12.60±3.76	5.89±2.32	< 0.001
MR severity			0.913
No MR	70 (66.7)	68 (64.8)	
MR 1+	20 (19.0)	18 (17.1)	
MR 2+	15 (14.3)	18 (17.1)	
MR 3+	0	1 (0.9)	

*Data are presented as mean±SD or n (%)
BMV, Balloon mitral valvotomy; MR, Mitral regurgitation

MR severity did not change in 82 (78.1%) patients. Interestingly, MR severity decreased in 5 (4.8%) and increased in 18 (17.1%) patients. The cases of reduction included a one-grade reduction in 4 patients and a 2-grade reduction in one patient. The increased cases comprised a one-grade increase in 10 patients, a 2-grade increase in 6 patients, and a 3-grade increase in one patient. The reduction cases included one male and 4 female patients with Wilkins scores of 5, 6, 9, 9, and 11.

After BMV, small atrial septal defect (ASD) was reported in 26 (25%) patients by color Doppler with a calculated pulmonary-to-systemic flow ratio (Qp/Qs) < 1.2.

There were no major complications such as mortality, CVA, severe MR necessitating surgery, and tamponade during and after BMV.

The low incidence rate of MR reduction precluded a comparison between the patients with a decrease in MR and those with no MR change. The patients were divided into two groups according to MR degree after BMV: Group A with no increase in MR severity and Group B with increased MR severity. Table 1 shows the pre-BMV baseline and echocardiographic findings in the groups. The patients with an increased MR degree after BMV had a significantly higher calcification score and a lower MVA before BMV. Our multivariate logistic regression analysis demonstrated that only the calcification score could predict a rise in MR severity after BMV (OR = 6.38, 95%CI: 2.098-19.433; p value = 0.001). Indeed, MR increased in tandem with an increase in the calcification score. Most cases with increased MR post BMV had commissural MR in the anterior commissure and were more likely to have commissural rupture. The hemodynamic and echocardiographic changes are shown in Table 2. After BMV, MVA significantly increased, whereas PAPs, LA pressure, MVPG and MVMG were significantly reduced.

Discussion

BMV, thanks to its considerable efficacy, high success rates, and low complication rates, has become one of the preferred treatments for severe MS since 1984.[2, 26, 27] However, the development of or increase in MR is still a concern after BMV.

In this study, we prospectively evaluated BMV outcome and MR changes after BMV in MS patients. We observed a significant improvement in hemodynamic indices and no major complications. NYHA FC also significantly improved following BMV, from class III to class I and II in most of the patients. BMV yielded excellent immediate hemodynamic and clinical results insofar as MR severity increased only in some patients and, interestingly, decreased in a few. There were also no major complications. These findings further highlight the efficacy of BMV in severe MS.

There has been a considerable improvement in patients' outcome over the past few years. While the reported complication rate during the first 10 years after BMV introduction varied between 8% and 19%,[5, 18] it has been reduced considerably in recent studies with reported rates of only 0-2%.[28, 29] Moreover, there has been a significant reduction in severe MR development in need of emergent surgery. Accordingly, a significant improvement in hemodynamic indices after BMV has also been observed.[2, 3]

It has been previously demonstrated that an MVA ≥ 2 cm^2 can be achieved irrespective of the technique used in most patients.[29, 30] In our study, there was a significant improvement in hemodynamic variables, including MVA, PAPs, LA pressure, MVPG, and MVMG after BMV. The increase in MVA was ≤ 2 cm^2 in most of the patients. It is believed that a higher increase in MVA can be achieved only at the expense of more frequent complications.[31] However, in our study, a higher than twofold increase in MVA with no complications shows the efficacy of BMV.

Although the incidence of MR has slightly decreased in the past few years,[2, 6-8, 19] MR development or MR increase is still the major concern after BMV. Approximately half of the patients undergoing BMV have a small increase in MR.[32, 33] Interestingly, in this study we observed MR increase or development in 17.1%, MR decrease in 4.8%, and no MR change in 78.1% of the patients. To the best of our knowledge, the increase rate in our study is probably the lowest reported in the literature. The increase in MR (18 patients) was small in 10 cases. The majority of the cases with increased MR following BMV had commissural MR from the anterior commissure, most probably due to commissural rupture.

There are few reports describing a decrease in MR after BMV,[5, 16-21] with the highest incidence rate being 17 of 20 patients in the Palacios and colleagues[5] study. Most investigators have reported a one-grade decrease in MR. We observed a one-grade reduction in 4 patients and a 2-grade reduction in one patient.

Palacios and colleagues[5] described three possible mechanisms responsible for the decrease in MR: 1) reversible mitral valve "stretching" by BMV; 2) fibrosis and healing of the end of the commissures, which may diminish MR due to the excessive splitting of the commissures; and 3) improvement in transient papillary muscle dysfunction caused by balloon trauma at the time of BMV. We also believe that in our cases, this decrease could be due to improvement in excessive commissural zone damage and relative structural improvement.

Most studies have evaluated the effect of hemodynamic and echocardiographic variables on the BMV outcome. Aslanabadi and colleagues[34] evaluated repeated BMV and mitral valve replacement in patients (even with a Wilkins score > 11) who had restenosis after primary balloon valvotomy and achieved acceptable results. Similarly, other studies have shown that a high Wilkins mitral score is not a very robust predictor of poor outcomes after BMV.[35, 36]

In our study, BMV was successful in all the patients. We evaluated the factors that could influence MR severity or MR development. A higher calcification score and a lower MVA before BMV predicted a rise in MR, but the total Wilkins score could not predict its occurrence. In contrast, Abascal and colleagues[37] reported that an increase in MR could not be predicted by any features of the valve or the subvalvular apparatus, clinical characteristics of the patient, or technical aspects of the procedure. Also worthy of note is that Pan et al.[38] found no predictors for the development of significant MR after BMV.

Overall, the calcification score is the most important component of the Wilkins classification in that it can predict MR development or MR increase because the probability of MR development increases with a rise in the calcification score. Indeed, in our previous study,[15] MR incidence was increased in cases with higher calcification scores.

Conclusion

In our study, BMV conferred excellent immediate hemodynamic and clinical results inasmuch as MR severity increased only in some patients and, interestingly, decreased in a few. What is more, there were no major complications. Our results, therefore, give emphasis to the efficacy of BMV in the treatment of patients with severe MS. The echocardiographic calcification score was useful for identifying patients likely to have MR development or MR increase following BMV.

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