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Balloon mitral valvuloplasty in low gradient severe rheumatic mitral stenosis: Immediate and short-term outcomes

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ABSTRACT

Background: Efficacy of balloon mitral valvuloplasty (BMV) in low gradient severe rheumatic mitral stenosis (MS) is not very well defined. This study was undertaken to evaluate the outcomes of BMV in low gradient severe rheumatic MS.

Methods: Severe MS was defined as mitral valve area < 1.5 cm^2. Low gradient was defined as mean diastolic *trans*-mitral gradient (MG) < 10 mmHg and low flow as stroke volume index < 35 ml/m^2 on echocardiography. Sixty patients were divided into normal-flow/low-gradient (NFLG) (40) and low-flow/low-gradient (LFLG) (20) groups. Post-BMV parameters were recorded after 72 h and at the end of one year.

Results: Mean age was 36.2 ± 6.6 years in NFLG group and 40.6 ± 2.6 years in LFLG group ($p < 0.01$) and females were 75 % ($n = 30$) in NFLG group as compared to 60 % ($n = 12$) in LFLG group. Patients in the LFLG group had higher Wilkins score ($p < 0.02$) and prevalence of atrial fibrillation ($n = 8$, 40 %) as compared to NFLG group ($n = 7$, 17.5 %; $p < 0.01$). A greater decrease in MG was observed in NFLG group ($p < 0.01$), whereas increase in MVA was comparable in both the groups ($p > 0.05$). Ninety percent ($n = 36$) patients improved in NFLG group in comparison to 70 % ($n = 14$) in LFLG group ($p < 0.01$). At the end of one-year, symptomatic improvement persisted in all patients who became asymptomatic post-BMV.

Conclusion: Symptomatic improvement following BMV was better seen in NFLG group because of greater decrease in MG in comparison to LFLG group. Results of BMV were suboptimal in LFLG group because of higher sub-valvular obstruction, increased age and higher prevalence of AF.

1. Introduction

Rheumatic Heart Disease (RHD) is a major public health problem in developing countries especially Asia and Africa.[1] Mitral stenosis (MS) is characterised by an elevation of left atrial (LA) pressure as a result of impairment in mitral valve opening and LA emptying. The normal area of the mitral valve orifice is about 4 to 6 cm^2. When the mitral valve area (MVA) goes below 2 cm^2, the valve causes an impediment to the flow of blood into the left ventricle, creating a pressure gradient across the mitral valve. [2,3].

Severe MS is defined by a MVA ≤ 1.5 cm^2. Trans-mitral mean gradient (MG) besides being decided by MVA can also vary considerably given their dependence on flow, stroke volume (SV) and heart rate. [4,5] Based on trans-mitral gradient, severe MS can be divided into low and high gradient MS. If the mean gradient is > 10 mmHg then it is high gradient MS and if the mean MG is ≤ 10 mm Hg it is low gradient. Low gradient (LG) MS is further divided into low flow and normal flow based on stroke volume index (SVI). If SVI > 35 ml/m^2 it is considered as normal flow (NFLG) whereas if SVI ≤ 35 ml/m^2 it is low flow (LFLG). [6,7].

Low gradient severe MS group is not very well studied till now and treatment of these patients is also not very clearly defined. Importantly, effectiveness of balloon mitral valvuloplasty (BMV) is also not well documented in these patients. Whether BMV outcomes will be similar to what is seen in high gradient MS needs to be studied. There is only one retrospective analysis of BMV in low gradient severe MS patients available till date and that too in older age western population with suboptimal results. Effectiveness of BMV in younger Asian patients of low gradient severe MS needs to be established and whether they will behave more appropriately in comparison to old age patients needs to be

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evaluated thoroughly. This study was undertaken to see the outcomes of BMV in low gradient severe rheumatic MS patients of Asian origin.

2. Methods

This was an observational prospective study conducted at our institute in New Delhi, India between December 2019 and July 2021. Study was undertaken after gaining clearance from the institutional ethics committee in accordance with the Declaration of Helsinki. Total 590 patients of severe rheumatic MS were screened in echocardiography room. Patients younger than 18 years, presence of prosthetic valves, greater than moderate mitral or aortic regurgitation, associated aortic stenosis, calcific MS and left ventricular ejection fraction (LVEF) < 45 % were excluded from study. After applying the exclusion criteria, 60 (10.1 %) patients turned out to be of low gradient severe MS and they were included in the study. The mean age of total patients screened for the study was 28.46 ± 3.14 years and females comprised of 74.5 % (440). Out of the selected cohort, mean age in LFLG group was 40.6 ± 2.6 years and that in NFLG group was 36.2 ± 6.6 years respectively. An informed consent was obtained from all patients and detailed clinical examination was done. Details of the history, examination and the investigations conducted were recorded on a pre-designed proforma. Indications for BMV were NYHA class II–IV, MVA ≤ 1.5 cm^2, mitral regurgitation (MR) ≤ 2+, suitable valve morphology and absence of concomitant cardiovascular disease requiring surgical intervention. The primary objective was to assess the effectiveness of BMV as a therapeutic option in low gradient severe MS patients of rheumatic origin. The primary outcome assessed was increase in MVA and decrease in MG across the mitral valve along-with symptomatic improvement of the patients.

Detailed two-dimensional (2D) and Doppler transthoracic echocardiography (TTE) parameters were recorded before BMV according to the American Society of Echocardiography guidelines. [8] All echocardiographic examinations were performed using the Philips echo machine (model UTAP20W Koninklijke, Philips NV) and 2.5–3.5 MHz transducers. LVEF was calculated according to the modified Simpson's method. Following echo parameters were measured: MVA, MG, SVI, left ventricular outflow tract (LVOT) area, systolic pulmonary artery pressure (SPAP), LVEF and LVOT velocity time integral (VTI). All patients were evaluated using 2D, M−mode, pulsed- and continuous-wave Doppler echocardiography. The MVA was calculated using pressure half time (PHT) and planimetry and severe MS was defined as MVA ≤ 1.5 cm^2. [4] The morphologic characteristics of the mitral valve were evaluated on echocardiography using the Wilkins score. It comprises of four echocardiographic characteristics of the mitral valve, including leaflet mobility, leaflet thickness, leaflet calcification, and subvalvular apparatus, each given a 1- to 4-point value. [9] The total echocardiographic score was obtained by adding the scores of each of these individual components. Valve was considered suitable for BMV with a score ≤ 10. [10] The maximum and mean pressure gradients were measured with continuous-wave Doppler from the apical four-chamber view. Patients were considered to have low gradient when their MG was ≤ 10 mmHg. SPAP was determined by calculating the right ventricular systolic pressure (using a simplified Bernoulli equation) from the apical four chamber view and adding the estimated right atrial pressure (determined as 5–15 mmHg according to left atrial diameter). In case of atrial fibrillation (AF), at least 5 cycles were averaged for all measurements.

SVI was calculated by the following formula:

SVI = Stroke volume/body surface area

SV = Cardiac output (CO)/Heart rate

CO = LVOT Area x LVOT VTI

SVI was considered to be low when it was < 35 ml/m^2. Transesophageal echocardiography (TEE) was done in all cases prior to BMV to rule out any left atrial or left atrial appendage clot. At the time of BMV, pre and post procedure LVEDP, mean LA pressure and mean SPAP were recorded. Data was collected prior to BMV and post procedure acutely at 72 h and short term at the end of one year. 6-minute walk test (6MWT) was done as per standard protocol. Decrease in atleast one NYHA class after valvuloplasty was taken as an improvement in symptoms.

No artificial intelligence (AI)– assisted technologies [such as Large Language Models (LLMs), chatbots, or image creators] were used in the production of submitted work.

2.1. Statistical analysis

Data were analyzed with statistical software SPSS version 25 (IBM, SPSS, Armonk, New York, USA). Continuous variables were presented as mean with standard deviation. Categorical variables were presented as percentages. Unpaired student *t*-test was applied to compare pre and post clinical echocardiography and catheterisation parameters between the two groups as well as to compare the change between the two groups. Homogeneity of variance assumption was performed using Leven's test. Welch test was performed in case of violation of homogeneity of variance. Paired student *t*-test was performed to compare within group pre and post BMV procedure parameters. Chi square/Fisher's exact test was performed to compare the proportion between the two groups. P-value < 0.05 was considered as significant.

3. Results

Out of 60 patients of low gradient severe rheumatic MS who were included in the study, 20 (33.33 %) were of LFLG (group 1) and 40 (66.66 %) of NFLG (group 2). For the whole study cohort, mean age was 37.3 ± 9.11 years. Age varied from 20 to 45 years. Overall, 70 % of patients were females and 25 % of patients had baseline AF. Clinical, echocardiographic and catheterization parameters of all patients are listed in Table 1. Patients in LFLG group had higher mean age (40.6 years vs 36.2 years, p < 0.004), lower percentage of females (60 % vs 75 %), and higher prevalence of AF (40 % vs 17.5 %, p < 0.001). Wilkins score was higher in LFLG group with higher prevalence of grade ≥ 2 subvalvular thickening (p < 0.03). Among drugs, beta-blockers were used more in LFLG group (p < 0.02).

We found no significant difference on comparing the two subgroups on 6MWT and NYHA class at baseline (p > 0.05). After BMV, 6MWT test had shown significant improvement from 256.87 m to 305.3 m in NFLG group while in LFLG group it improved from 254 m to 274.8 m (p = 0.09). Both the groups improved significantly, but the improvement in NFLG group was more in comparison to LFLG group (p < 0.01). Similarly, in terms of improvement in NYHA class following BMV, 36 patients (90 %) improved after BMV in NFLG group in comparison to only 14 patients (70 %) in LFLG group (Fig. 1). Mean PAP was almost similar in both the groups. No incidence of stroke was reported in either group (Table 1).

3.1. Echocardiographic parameters

Following BMV, MVA increased in both groups equally. It increased to 1.66 ± 0.11 cm^2 in LFLG group while it increased to 1.8 ± 0.2 cm^2 in NFLG group (p > 0.07). MG in LFLG group was 9.5 ± 1.65 mmHg as compared to 9.12 ± 1.11 mmHg in NFLG group. Following BMV it decreased to 7.1 ± 1.8 mmHg in LFLG group in comparison to 5.73 ± 1.76 mmHg in NFLG group. Overall, there was a mean change of 1.8 ± 1.71 mmHg in LFLG group as compared to 3.53 ± 1.89 mmHg in NFLG group and this change was statistically significant (p < 0.01) (Fig. 2). SPAP reduced significantly in both the groups following BMV but this decrease was statistically non-significant comparing both the groups. Following BMV there was no difference in grade of MR between the two groups (15 % vs 10 %, p = 0.8). Both groups had normal LVEF. At the end of one-year, symptomatic improvement persisted in all the patients

Table 1
Clinical, echocardiographic and catheterization parameters of patients of LFLG and NFLG groups.

	LFLG (20)	NFLG (40)	p value
Age (years)	40.6 ± 2.6	36.2 ± 6.6	0.004
Females (%)	12 (60 %)	30 (75 %)	0.45
Height (cm)	158 ± 7.4	157 ± 7.0	0.35
Body Mass Index (kg/m^2)	21.2 + 4.2	21.4 + 3.9	0.7
Body Surface Area (m^2)	1.55 ± 0.18	1.54 ± 0.17	0.14
Atrial Fibrillation (%)	8 (40 %)	7 (17.5 %)	0.001
Heart Rate (bpm)	66 ± 12	78 ± 12	0.02
Beta blocker	16(80 %)	24(60 %)	0.02
Digoxin	8(40 %)	12(30 %)	0.18
Calcium Channel Blocker	2(10 %)	4 (10 %)	0.26
Diuretic	18 (90 %)	32 (80 %)	0.33
6MWT (m)	254 ± 38.14	256.87 ± 44.7	0.857
NYHA Class (I/II/III), %	0/20/80	0/40/60	0.2
Pre BMV echocardiographic and catheterization parameters			
Ejection Fraction (%)	60.2 ± 1.81	60.6 ± 1.93	0.30
LAVI (ml/m^2)	44.2 ± 4.83	43.73 ± 7.23	0.6
SVI (ml/m^2)	29.4 ± 4.43	42.27 ± 3.65	0.001
Wilkins score	9 ± 1	7 ± 2	0.03
Cardiac Output (L/min)	4.5 ± 1.0	4.7 ± 1.1	0.4
Cardiac index (L/min/m^2)	3.0 ± 0.8	3.3 ± 0.7	0.8
Mean Gradient (mmHg)	9.5 ± 1.65	9.12 ± 1.11	0.38
PHT (ms)	213.6 ± 22.06	206 ± 21.1	0.34
Mitral Valve Area (2D) (cm^2)	0.98 ± 0.29	1.01 ± 0.34	0.25
Mitral Valve Area (PHT) (cm^2)	1.02 ± 0.20	1.08 ± 0.21	0.14
Mean Arterial Pressure (mmHg)	104 ± 9	108 ± 10	0.2
Systolic PAP (mmHg)	44.2 ± 4.83	43.73 ± 7.23	0.82
Mean PAP (mmHg)	35 ± 7	32 ± 8.2	0.45
Mitral Regurgitation (Trivial/ Mild)	4 (20 %)	12 (30 %)	0.54
Left Atrial Pressure (mmHg)	16.2 ± 3.8	13,5 ± 4.2	0.04
LVEDP (mmHg)	3.6 ± 3.2	3.8 ± 2.4	0.4

6MWT: 6-minute walk test; BMV: balloon mitral valvuloplasty; LAVI: left atrial volume index; LFLG: low flow low gradient; LVEDP: left ventricular end diastolic pressure; NFLG: normal flow low gradient; PAP: pulmonary artery pressure; PHT: pressure half time; SVI: stroke volume index.

who initially responded to BMV.

3.2. Catheterization parameters

LVEDP was equal in both groups and in normal range. Both groups had almost similar MG of around 9 ± 2 mm Hg. Mean LA pressure was lower in NFLG group and it was statistically significant in comparison to LFLG group (13.5 ± 4.2 mmHg vs 16.2 ± 3.8 mmHg; $p < 0.04$). Following BMV, there was a significant fall in LA pressure in NFLG group in comparison to LFLG group (7.2 ± 2.3 mmHg vs 9.8 ± 2.5 mmHg; $p < 0.02$). Mean PAP was similar between the two groups which decreased significantly following BMV whereas LVEDP increased marginally in both the groups (Table 2).

4. Discussion

Severe rheumatic MS patients usually have high gradient and BMV is the treatment of choice for these patients with suitable valve morphology. Previous studies on severe MS have already established successful outcome following BMV in terms of improvement in echocardiographic and clinical parameters. [11,12,13] Long term results of BMV have also shown that event-free survival rate at 10 years ranges from 70 to 90 %.[14] In some specific subgroups of patients, response to BMV is sub-optimal as seen in older age, presence of AF, calcific MS, severe subvalvular disease and associated other valvular lesions. Similarly, role of BMV in cases of low gradient severe MS is also not very well defined. Despite being symptomatic and having suitable valve morphology, these patients are frequently denied BMV due to lack of evidence. In our prospective study, incidence of low gradient severe MS is around 10.1 % which is not negligible, hence this sub-group of patients needs to be addressed for their proper and definite management. Rayburn et al [15] in their retrospective study have also shown an incidence of around 17 % and mean age of patients was on higher side (55 ± 9 years).

El Sabbagh et al [16] in 2019 studied the impact of BMV on low gradient severe MS patients, but it was a retrospective study and older (mean age > 65 years) patient population of western origin with decreased LV compliance and they concluded that the presence of low gradient in patients with severe MS was associated with lesser symptomatic benefit. In our study which is a prospective analysis, patients were younger (mean age ≈ 37 years), of Indian origin having more suitable valve morphology for BMV. Higher mean age in El Sabbagh [16] study was one of the reasons for higher prevalence of AF (70 %) as also shown by Rayburn et al (56%). [15] In our study, patients in LFLG group (mean age 40.6 years) were comparatively older than NFLG group (mean age 36.2 years). Higher age suggests longer duration of disease which in turn leads to LA dilatation causing electrical heterogeneity and non-uniform conduction velocities predisposing to AF as shown by previous studies. [16,17,18] Hence, prevalence of AF is also seen more in LFLG (40 %) group in comparison to NFLG group (17.5 %). Presence of AF leads to loss of atrial kick and reduced SV and irregular cycle length ultimately affecting the preload and CO as well leading to the worsening of symptoms. [19,20] Success rate of BMV and long-term outcomes in presence of AF are not encouraging as shown in various studies with higher event rates and increase mortality. [14,16].

A total of 40 % patients had no symptomatic benefit from BMV in El Sabbagh et al series [16] in comparison to 20 % in our study. Patients in NFLG group had shown better improvement in NYHA class and 6MWT. Following BMV, there was a significant increase in MVA in both the groups which was statistically non-significant. On the contrary, there was a significant decrease in MG in NFLG group ($\Delta MG = 3.53$ mmHg) in comparison to LFLG group ($\Delta MG = 1.8$ mmHg) which was statistically significant ($p < 0.01$). Hence, symptomatic improvement in NFLG group was more due to greater decrease in MG rather than increase in MVA. Lesser symptomatic improvement in LFLG group was also due to more sub-valvular obstruction. All patients in Rayburn et al series [15] had undergone mitral valve replacement with sub-valvular correction with excellent long term results showing majority of patients in NYHA class 1 after 10 years follow-up. Patients in LFLG group had higher prevalence of AF which also leads to lesser decrease in MG following BMV. Similarly, patients of low gradient severe MS had lower baseline LA pressure and this could be one of the reasons for sub-optimal response to BMV. El Sabbagh et al [16] have also discussed arterial stiffness, ventricular-vascular uncoupling and decreased LV compliance as additional reasons for failure of BMV in their study. Similarly, Rayburn et al [15] have also stressed on the diminished functional LV compliance caused by extensive disease of the sub-valvular apparatus as the major pathophysiologic characteristic in their retrospective series. These reasons are justifiable in their study because of higher age group of patients. Though some earlier studies have identified LV myocardial abnormalities due to chronic inflammation, and an increased afterload in a subset of patients with MS, their role in younger patients does not seem to affect the outcomes of BMV as myocardial compliance and vascular stiffness gets compromised with increasing age. Hence, presence of AF, older age and increased sub-valvular obstruction were the main reasons for poor outcome in patients with LFLG group in our study. Higher prevalence of AF may be the target for intervention with cardioversion or rhythm control to improve the preload and increasing the exercise capacity, thus decreasing the symptoms in this subgroup of patients. As transmitral MG is the main determinant of outcome of BMV in these groups of patients, they can be subjected to exercise testing for functional capacity evaluation and assessment of MG before subjecting them for BMV.

One year follow up has shown similar echocardiographic and clinical

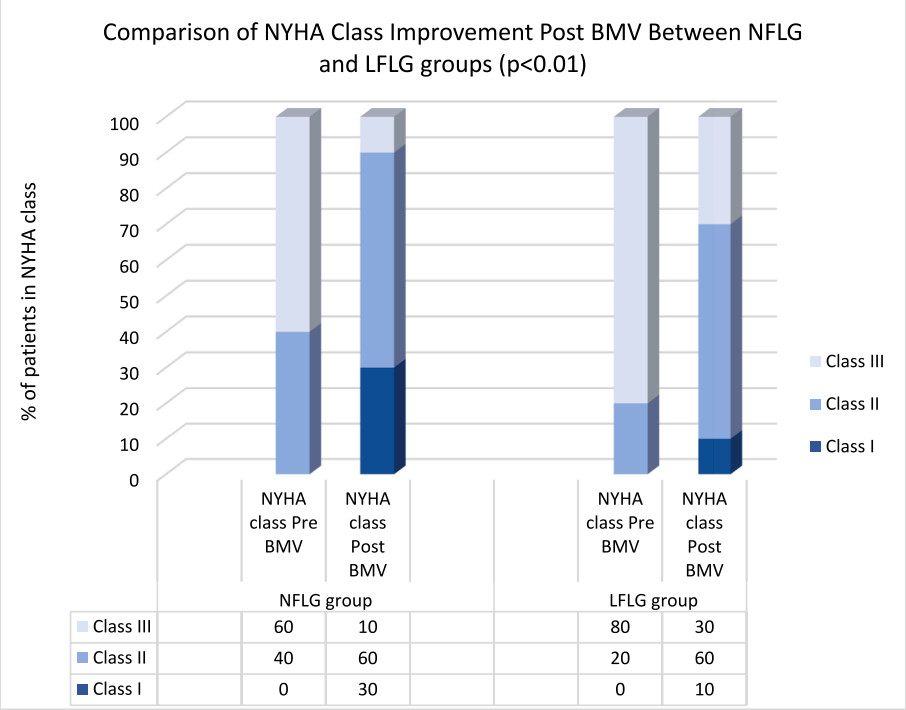

Fig. 1. Post BMV improvement in NYHA class in NFLG and LFLG groups. BMV: balloon mitral valvuloplasty; LFLG: low flow low gradient; NFLG: normal flow low gradient.

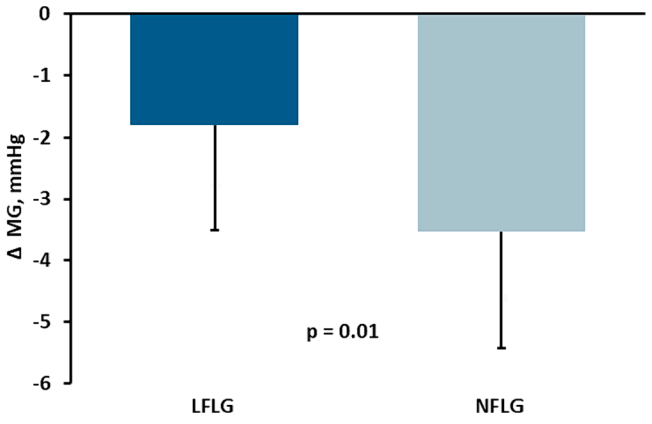

Fig. 2. Post BMV change in mean gradient in NFLG and LFLG groups. ΔMG: change in mean gradient across mitral valve; BMV: balloon mitral valvuloplasty; LFLG: low flow low gradient; NFLG: normal flow low gradient.

parameters with symptomatic improvement persisting in all the patients. This was because our patients were younger and had more suitable valve morphology as compared to patients in El Sabbagh study. [16] Further longer follow up will establish the efficacy of BMV in this group of patients. Ours is the first prospective study in world literature which has clearly demonstrated the suitability of BMV in younger patients of low gradient severe MS of South Asian origin.

5. Conclusion

There was symptomatic improvement in both the groups of LFLG and NFLG of severe rheumatic MS following BMV. Symptomatic improvement following BMV was better seen in NFLG group because of greater decrease in transmitral mean gradient rather than increase in mitral valve area. BMV can be considered as a suitable treatment strategy in low gradient severe MS younger patients. Future studies with exercise testing may be needed to determine which patients will respond better to valvular interventions.

Table 2
Post BMV echocardiographic and catheterization parameters of patients of LFLG and NFLG groups.

Post BMV echocardiographic and catheterization parameters			
	LFLG (20)	**NFLG (40)**	**p value**
6MWT (m)	274.8 ± 40.07	305.33 ± 50.85	0.09
NYHA Class (I/II/III) (%)	10/60/30	30/60/10	0.06
Mean Gradient (mmHg)	7.1 ± 1.8	5.73 ± 1.76	0.04
Mitral Valve Area (2D) (cm^2)	1.66 ± 0.11	1.8 ± 0.2	0.06
Systolic PAP (mmHg)	33 ± 12.39	26.4 ± 11.77	0.14
Mean PAP (mmHg)	26 ± 8.2	23 ± 7.1	0.3
Left Atrial Pressure (mmHg)	9.8 ± 2.5	7.2 ± 2.3	0.02
LVEDP (mmHg)	4.4 ± 2.2	4.9 ± 1.3	0.18
Change (Δ) in parameters			
6MWT (m)	20.8 ± 15.59	48.46 ± 18.41	0.01
Cardiac index (L/m^2)	0.1 ± 0.3	0.2 ± 0.3	0.3
SVI (ml/m^2)	+3.2 ± 7.0	+3.1 ± 6.9	0.4
No symptom improvement (%)	30	10	0.04
Mean Gradient (mmHg)	−1.8 ± 1.71	−3.53 ± 1.89	0.01
Mitral Valve Area (2D) (cm^2)	+0.68 ± 0.08	+0.79 ± 0.16	0.06
Systolic PAP (mmHg)	−14.42 ± 9.47	−17.33 ± 11.17	0.16
Mean PAP (mmHg)	−8 ± 2.5	−11 ± 3.1	0.2
Left Atrial Pressure (mmHg)	−4.2 ± 1.9	−8.33 ± 2.47	0.001
LVEDP (mmHg)	+1.2 ± 1.2	+1.4 ± 2.1	0.17

6MWT: 6-minute walk test; BMV: balloon mitral valvuloplasty; LFLG: low flow low gradient; LVEDP: left ventricular end diastolic pressure; NFLG: normal flow low gradient; PAP: pulmonary artery pressure; SVI: stroke volume index.

6. Limitations

Main limitation of our study was small sample size and lack of long-term follow-up data. Echocardiographic and catheterization data evaluation was not done simultaneously but since both the studies were

performed without any active diuresis or medication changes, it is unlikely to have altered our results. This study included mainly younger patients of rheumatic MS, hence whether same haemodynamics will be applicable for calcific degenerative MS needs to be evaluated.

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CRediT authorship contribution statement

Jamal Yusuf: Conceptualization, Formal analysis, Funding acquisition, Investigation, Project administration, Writing – original draft, Writing – review & editing. **Manny Kumar Chaudhary:** Investigation, Formal analysis, Data curation. **Ghazi Muheeb:** Writing – review & editing, Writing – original draft, Data curation. **Vimal Mehta:** Visualization, Supervision. **Saibal Mukhopadhyay:** Visualization, Validation, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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