ORIGINAL ARTICLE

EFFICACY AND IMMEDIATE OUTCOMES OF PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN SEVERE RHEUMATIC MITRAL STENOSIS

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Objectives: To assess the frequency of successful Percutaneous Balloon Mitral Valvuloplasty (PBMV) and immediate post-procedure outcomes in patients with severe rheumatic mitral stenosis (SRMS).

Methodology: This descriptive cross-sectional study was conducted at the Department of Cardiology at a tertiary care hospital, from 1st January 2018 to 31st December 2019. According to inclusion criteria, 200 patients with severe symptomatic mitral stenosis (SSMS) were recruited in the study, and written informed permission was acquired from patients or next of kin. Pre- and post-PBMV mitral valve area (MVA) and hemodynamics were recorded. Data were retrieved from the hospital chart record and collected on a pre-designed proforma.

Results: In 176 (88%, n=200) patients mean MVA following PBMV increased from 0.93±0.31 cm2 to 1.73±0.16 cm^2 ($p < 0.05$) and mean pulmonary artery systolic pressure (PASP) reduced from 56.62 mmHg ± 16.02 to 30.37±7.30 mmHg ($p<0.05$). Perioperative complications included severe mitral regurgitation (MR) in 2 (1%, n=200), moderate MR in 40 (20%, n=200), thromboembolic cerebrovascular accident in 1 (0.5%, n=200), pericardial effusion in 4 (2%, n=200), and new-onset atrial fibrillation in11 (5.5%, n=200), however, there was no mortality related to the procedure.

Conclusion: PBMV was effective with reasonable immediate post-procedure outcomes in 88% of patients. However, efficacy can be increased by selecting patients with favourable valve morphology for PBMV.

Keywords: percutaneous balloon mitral valvuloplasty, PTMC, severe rheumatic mitral stenosis, rheumatic heart disease, valvular heart disease, interventional cardiology

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INTRODUCTION

Acute rheumatic fever caused by group-A streptococcal (GAS) pharyngitis damages the mitral valve. 60 % of those afflicted go on to develop rheumatic heart disease (RHD), which is 1.5 to 2 times more frequent in females than in males.[1,2] Mitral stenosis (MS) affects around 40% of RHD patients. Although the global frequency of RHD has decreased, it continues to pose a considerable burden of add on cardiovascular disease, particularly in low and middle-income countries (LMICs).[3]

If left untreated, severe mitral stenosis can lead to pulmonary hypertension (PH), atrial fibrillation, right heart failure, and other complications. About 50% of the patients with RHD have developed complications at the time of presentation, most frequently PH and heart failure.[4] Severe mitral stenosis is defined when the mitral valve area (MVA) becomes lower than 1.5 cm^2 and patient becomes symptomatic at rest.[5] Pulmonary Hypertension is defined when there is sustained elevation of pulmonary artery systolic pressure (PASP) of 25 mm Hg or more at rest or 30 mm Hg or more with exercise.

In LMICs, the facilities of advanced surgical techniques and resources to treat severe valvularheart disease are sparse.[6] Percutaneous balloon mitral valvuloplasty (PBMV) has shown to be a useful alternative to surgical procedures in SSMS due to its greater efficacy and safety. The benefits of PBMV include effectiveness in both young and elderly patients, a shorter hospital stay, and a less intrusive procedure as compared to surgical repair or replacement.[7]

In pregnant patients with SSMS, PBMV may be a viable alternative with favorable maternal and foetal outcomes because of its shorter radiation period and lower frame count.[8]. PBMV improves left atrium (LA) and left atrial appendage (LAA) function, therefore,

providing hemodynamic stability and preventing thromboembolic events.[9] PBMV is preferred over surgical commissurotomy because of low periprocedural morbidity and mortality in young patients with favorable valve morphology, mainly those with low Wilkins score, with less than moderate MR and LA without thrombus.[10] PBMV with an Inoue balloon has been demonstrated to considerably lower PASP, transmitral valve gradient, and enhance MVA in both adults and children, and it is equally effective in both.[11] RV strain is significantly increased in post-PBMV patients and has been shown to have a prognostic value in such patients.[12]

The success of PBMV depends on the morphology, calcification and mobility sub valuvular fibrosis of the affected valve. PBMV is considered successful, if MVA increases more than 1.5cm^2, or 50% or more from the baseline. In addition, significant symptomatic improvement compared to the pre-PTMC status in also criteria to determine the success. The Worldwide success of PBMV has been reported to be around 80-95% in patients with MS and success rate in our institute falls in this range.[13,14]

Percutaneous commissurotomy is used to treat SSMS all over the world since it has a greater effectiveness and safety profile than open mitral commissurotomy and surgery.[15]

Given the high effectiveness and safety as compared to open mitral commissurotomy and surgical intervention, percutaneous commissurotomy is employed worldwide for the treatment of severe and symptomatic mitral stenosis.[16]

Because of the relatively high prevalence of severe rheumatic mitral stenosis (SRMS) in developing nations such as Pakistan, we need to expand our knowledge of percutaneous commissurotomy. Because data on PBMV is limited, this study was carried out to corroborate the conclusions of prior investigations. We also intend to gather data on the success of PBMV and its immediate results in Pakistan in order to make future suggestions.

METHODOLOGY

This descriptive cross-sectional study was conducted at a tertiary care center, from 1st January 2018 to 31st December 2019. The current study included 200 patients who were studied after receiving approval from the institutional ethics and research boards, (131/LRH/MTI/2018). All patients provided written informed consent for the procedure. The study comprised patients ranging in age from 15 to 45 years old, both male and female participants, and with a mitral valve area of 1.5cm^2 or less, as well as ≥NYHA II symptoms. All other patients who had MVA over 1.5cm^2, LA or LAA clot, severe mitral regurgitation (MR), aortic stenosis, congenital MS, primary pulmonary hypertension (PH), chronic obstructive pulmonary disease (COPD), other congenital heart diseases were excluded from the study.

A detailed history was obtained and physical examination was performed, followed by the transthoracic and transesophageal echocardiography to look for LA clot /LAA thrombus and other valvular pathologies. The right femoral route was used for PBMV. The Seldinger method was utilized to gain vascular access to the right femoral artery and venous systems. The trans-septal antegrade method was utilized. Transthoracic echocardiography was utilized to assess mean mitral valve area, PASP, and transmitral pressure gradients both before and after PBMV, as well as to search for any post-operation problems such as Mitral regurgitation and tamponade within 24 hours of the surgery. All of the necessary information, including demographic characteristics, was entered into a pre-designed proforma.

Data were analyzed in IBM Statistical Package for Social Sciences (SPSS) version 22.0. Mean and standard deviation was calculated for continuous variables like age, initial and final mean PASP, and duration of SRMS. Frequency and percentages were calculated for qualitative variables like gender, occupation, socioeconomic status, and efficacy. Statistical significance of hemodynamic values before and after PBMV was assessed using paired t-test and p-value ≤0 0.05 was taken significant. Efficacy was stratified for age, gender, and duration of symptoms of SRMS. Post-stratification chi-square test was applied in which P-value ≤0.05 was considered labelled significant. All the results are presented in the form of tables and charts.

RESULTS

Among 200 patients, 122 (61%) patients were in the 15-30 years age group, 78 (39%) patients were in the 31-45 years age group. The mean age was 30.86 ± 10.11 years. The majority of the patients were female 134 (67%) and the remaining 66 (33%) patients were male. 70% (n=140) patients had duration of symptoms > 6 months while 30% (n=60) patients had duration of symptoms ≤ 6 months. 42% (n=84) patients were employed and 58% (n=116) patients were unemployed. 50% (n=100) patients were poor with low socioeconomic status. Among the comorbidities, 10 (5%) patients had diabetes mellitus, 30 (15%) patients were smokers, and 15 (7.5%) patients had hypertension as given Table 1. Pre- and post-PBMV mean PASP were 56.62 ± 16.02 mmHg and

30.37±7.30mmHg (p<0.05) respectively. Mean MVA before PBMV was 0.93±0.31 cm^2 which increased to 1.73±0.16 cm^2 (p<0.05) as summarized in Table 2.

Table 1: Summarizes patient's demographic characteristics

	Frequency	Percentages
Age group		
15-30 years	122	61%
31-45 years	78	39%
Gender		
Male	66	33%
Female	134	67%
Marital status		
Married	90	45%
Unmarried	110	55%
Duration of Rheumatic Mitral Stenosis		
<6 months	60	30%
>6 months	140	70%
Socioeconomic status		
<20000 PKR	100	50%
20000 to 40000 PKR	72	36%
41000 to 60000 PKR	28	14%
Unemployed	116	58%
Employed	84	42%
Diabetes mellitus	10	5%
Smoking status	30	15%
Hypertension	15	7.50%

PBMV was effective in 88% (n=176) patients to optimally increase MVA to over 1.5cm^2 without inducing severe MR and reduced PASP optimally, and results were suboptimal in 12% (n=24) patients. PTMC was effective irrespective of the age and gender of patients (99 vs. 67; p>0.05 and 54 vs. 112; p>0.05 respectively). However, PBMV was more effective if performed earlier in the course of illness in symptomatic patients (59 vs. 107; p<0.05). Around 20% (n=4) of the patients were found to have sustained moderate MR, 1% (n=2) had severe MR, 0.5% (n=1) sustained CVA as a result of thromboembolism, 2% (n=4) suffered mild to moderate pericardial effusion, 5.5% (n=11) had new-onset atrial fibrillations and no patient was found to have died as a result of PBMV in this study shown in Table 3

Table 2: Pre and post-percutaneous balloon mitral valvuloplasty mitral valve area and right ventricular systolic pressure

	Pre-PBMV	Post-PBMV	p-value
Mean MAV	0.93±0.31 cm^2	1.73±0.16cm^2	<0.05
PASP	56.62 ± 16.02 mmHg	30.37±7.30mm Hg	<0.05
TPPG	27.54 ± 6.53mmHg	12.62±3.40 mmHg	<0.05

PBMV= percutaneous balloon mitral valvuloplasty, MVA=mitral valve area, PASP= pulmonary artery systolic pressure, TPPG= Transpulmonary pressure gradient

Table 3: Immediate outcomes of percutaneous balloon mitral valvuloplasty

	Frequency	Percentages
Successful PBMV	176	88%
Suboptimal PBMV	24	12%
Moderate MR	40	20%
Severe MR	1	0.50%
CVA	2	1%
Pericardial effusion	4	2%
New onset AF	11	5.50%
In-hospital death	0	0%

PBMV= Percutaneous Balloon Mitral Valvuloplasty, MR=mitral regurgitation, CVA=cerebrovascular accident, AF=atrial fibrillation

DISCUSSION

Pulmonary hypertension is a common complication that occurs with mitral stenosis and, Balloon Valvotomy can reduce a previously raised pulmonary artery pressure.[17] In symptomatic Severe symptomatic mitral stenosis, prompt therapy is critical for improving prognosis and long-term results. In such individuals, PBMV is a successful therapeutic method with favorable anatomical and clinical aspects. The current study looked at the incidence of effective PBMV and immediate procedural results in SSMS patients.

In our study mean age of the patients was 30.86 ± 10.11years, mean PASP before PTMC was 56.62 ± 16.02 mm Hg and mean PASP after PBMV was 30.37± 7.30mmHg (p<0.05). Mean MVA before PBMV was 0.93±0.31 cm2, which increased to 1.73±0.16cm^2 after PBMV (p<0.05). PBMV was effective in 88% of the patients, while in 12% of the patients it had suboptimal results. Similar findings have been documented in other studies. The effectiveness rate of PBMV in optimally treating Severe mitral stenosis symptoms ranged from 82 % to 88 %. Female patients made up the majority of the study population, which was comparable to our study.[18]

PBMV performed using Inoue balloon was found to be equally effective in children and adults in reducing PASP and increasing MVA to more than 1.5cm^2 while reducing the gradient across the MV.[19]

In our study, we noted that around 1% (n=2) patients suffered severe MR which was tolerated well with conservative treatment and patients survived, similarly 0.5% (n=1) patients suffered CVA as a result of thromboembolism, 2% (n=4) patients developed mild to moderate pericardial effusion, no patient was found to have died as a result of PBMV in our study and 11 patients developed new-onset AF immediately post-procedure which was reverted successfully.

Vahanian et al noted the frequency of post-PBMV MR to be around 3-5%.[20]

Comparable results were reported by another study with severe MR occurring in 5% patients, failure of PMC was reported to be 7%, in-hospital procedure-related death in 0.87%, cardiac tamponade in 0.17%, and thromboembolism was reported in 0.53% patients

It is a useful alternative against surgical commissurotomy with low periprocedural morbidity and mortality.[21]

A meta-analysis of over 900 references from the database indicated that PBMV is a safe and effective symptomatic improvement that also improves echocardiographic measures. After a successful PBMV, the stated 10-year event-free period is between 70 % and 90%.[22]

Study limitations: The current study has a skewed population, which included 67 % females, but the SRMS can affect both genders equally and requires larger randomized controlled trials for more accurate representations. Because the research population did not include MS patients with sub valvular disease, the findings cannot be extended to such individuals. This study did not take into account patient outcomes in relation to operator experience, thus the difference in procedural complications cannot be generalized. Lastly, this study is has limited sample size and single-center data; thus, similar studies should be undertaken in multicenter settings with operator experience throughout Pakistan in the future

CONCLUSION

PBMV was shown to be efficacious in 88 percent of the patients in this study with a statistically significant increase in MVA and alleviation of PH, as well as reduced acute morbidity and mortality. As a result, in patients with favorable anatomy, PBMV should be used as a first-line therapeutic option.

AUTHORS' CONTRIBUTION

AI, JA, and SG: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. YK, ZH, MUJ, and UK: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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