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IMMEDIATE AND LONG TERM OUTCOMES OF BALLON MITRAL VALVOTOMY IN TERTIARY CARE HOSPITAL

Cardiology

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ABSTRACT

Balloon Mitral Valvotomy (BMV) is one the preferred modality of treatment for Rheumatic mitral stenosis. This is usually performed with onsite surgical backup to tackle the complications like cardiac tamponade needing surgical drainage and severe mitral regurgitation which requires emergency Mitral Valve Replacement. Our aim is to evaluate the pre and post procedural outcomes of the BMV. The immediate and one year clinical and echocardiographic results of 88 consecutive patients who underwent BMV for severe mitral stenosis between September 2016 to Jan 2018 from in our tertiary care hospital. All symptomatic patients (NYHA class II- IV) with their mitral valve area (MVA) <1.0cm2 were enrolled. Detail clinical evaluation and Echocardiography was done before and after the procedure. The procedure was performed under local anesthesia, using the step-wise Inoue balloon dilation with the ante grade transvenous approach. The successful procedure was 87 (98.7 %). The mean age was 35 ± 13 years, mean pre BMV MVA= 0.8 ± 0.18 cm2, mean Post BMV MVA =1.71 ± 0.24 cm2, by plannimetry ($p < 0.0001$). . The hemodynamic mean diastolic gradient decreased from 16.1 ± 5.3 mmHg to 3.8 ± 2.6 mmHg ($p < 0.0001$). The mean left atrial pressure was reduced from 23.42 ± 6.89 mmHg to 11.8 ± 4.1 mmHg ($p < 0.0001$). Minor complication like puncture site hematoma in 3 (3.44%) patients, vasovagal attack in 6 (6.89%) patients after intra atrial septal puncture, Ventricular arrhythmia in 1(1.4%) patients and supraventricular arrhythmia in 11 (12.64%) patients. Severe mitral regurgitation occurred in 5 (5.74%) patients out of which three patients managed medically and one patient required urgent MVR. Cardiac tamponade developed in 1(1.4%) patient, pericardiocentesis done. The one year follow up mean mitral valve area was 1.56 ± 0.19 cm2, restenosis rate was 21.83%; and 90% of patients were in class I - II. Balloon Mitral Valvotomy is safe and effective procedure for patient with severe and symptomatic patient with Rheumatic MS with lower complication rate and good clinical improvement.

KEYWORDS

Ballon mitral valvotomy, Mitral stenosis

INTRODUCTION

Rheumatic mitral valve disease continues to be the most prevalent organic valve disease encountered in clinical practice in India. For several decades surgical commissurotomy was being performed in patient with severe mitral stenosis.1 However, balloon mitral valvuloplasty (BMV) has been established as an effective method for treating mitral stenosis with result comparable to surgical commissurotomy(CMC).2,3 Since its introduction in the early 1980s, BMV have lead to its world wide adoption.4 Two BMV techniques have been extremely used; the Inoue balloon technique and the trans septal over the wire balloon technique. Studies to date have shown equal efficacy of the two BMV methods in terms of valve enlargement, although the inoue approach is simpler , faster and yielded similar benefit and is also associated with a lower risk of creating severe mitral regurgitation. Over the years, BMV has been performed with excellent short-term results in patients with symptomatic rheumatic mitral stenosis (M S). Long-term follow-up studies have shown a good outcome. We report our experience of BMV regarding its safety, efficacy and outcome in our setup .

METHODS

BMV was attempted in 88 patients with symptomatic severe M S (New York Heart Association [NYHA] functional class II to IV) at our center between September 2016 and Jan 2018. The procedure was completed in 87 patients while in one patient we could not cross the mitral valve and they underwent MVR. The study population included 87 patients and their baseline characteristics are listed in Table-1

Patients were accepted for BMV if they fulfilled the following clinical and echocardiographic criteria: (i) presence of severe M S (absolute mitral valve area [MVA] < 1.0 cm2); (ii) NYHA functional class II to IV; (iii) absence of more than mild mitral regurgitation; and (iv) absence of left atrial/left atrial appendage (LA/LAA) thrombus. Post BMV, the patients were followed up for one year with clinical and echocardiographic evaluation.

Table 1 : Baseline characteristics of patients undergoing balloon mitral valvuloplasty (BMV).

Parameters	N=87	Parameters	N=87
Age(years)	35+13	AF	21(24.14%)
Male	27(31.03%)	Pre- BMV MVA(cm2)	0.8 +0.18
Female	60(68.96%)	Post BMV MVA	1.71+ 0.24
Re-do BMV	4(4.59%)	NYHA class I and II	66(75.87%)
OMV	01(1.14%)	NYHA class III	21(24.13%)
Pregnant	07(8%)	Pre BMV LApressure	23.42+6.89
MES (mean SD)	6.7 (1.6)	Post BMV LApressure	11.8+4.1

MES (mean[SD]) 6.8 (1.8)
MR Grade1 Pre-BMV 40 (45)
OMV = Open mitral valvotomy
AF = Atrial fibrillation
NYHA = New York Heart Association
MES = Mitral echocardiographic score
MR = Mitral regurgitation

Echocardiographic evaluation: Transthoracic echocardiography (TTE) was performed using standard techniques on 2D ECHO machines before and after BMV. The severity of M S and the morphology of the mitral valve were carefully assessed and transmitral gradients were measured. The MVA was derived from planimetry of the mitral valve orifice on short-axis 2-D echocardiography view in all patients. Pulmonary artery systolic pressure (PASP) was estimated using tricuspid regurgitation Doppler signal velocity. The mitral echocardiographic score (M E S) was evaluated by the method of Wilkins et al.5 Transesophageal echocardiogram (TEE) was done to rule out LA/LAA clot in all patients.

Cardiac catheterization and BMV: Informed consent was obtained from all the patients. A 6 F pigtail catheter was placed at the root of the aorta. Left ventriculography was done post procedure to assess mitral regurgitation (M R)severity and was graded 0 - 4+. BMV was performed using the conventional Inoue balloon technique.6 Transseptal puncture was done using Brockenbrough needle inserted via the right femoral vein. Heparin was administered (50 U/kg intravenously) after positioning the Inoue balloon in the left atrium.

The left atrial pressure and mitral valve mean diastolic gradients were recorded before and immediately after the valve dilatation. The stepwise dilatations were done till the transmitral diastolic gradient decreased to less than 5 mmHg, unless a prominent V wave suggesting significant mitral regurgitation appeared on the hemodynamic trace. The valve area and mitral regurgitation were assessed by TTE after the procedure. The procedure was considered successful if M V A increased by > 50% as compared to the baseline and final absolute mitral valve area of > 1.5 cm2 in the absence of significant mitral regurgitation.

Follow up: Clinical and TTE assessments were carried out at six months and one year after BMV. The primary end point of follow up was mitral restenosis, defined as loss of > 50% of the initial gain in M V A and M V A < 1.5 cm2. The combined secondary end point included:

(1) mitral restenosis (as defined above)
(2) redo BMV;
(3) mitral valve replacement (MVR);
(4) NYHA functional class
(5) cardiac death.

Statistical analysis: All data are expressed as mean ± SD. Comparison of data before and after BMV was performed using the t-test. A p value < 0.05 was considered significant.

RESULTS

Baseline characteristics of 87 patients are shown in Table 1. The patients were aged 35 ± 13 years (range 16 – 60 years) with 69% of them females. 24% of the patients were NYHA functional class III or IV; symptomatic despite treatment with diuretic therapy, digoxin and Beta-blockers. Five patients had mitral restenosis (4 of them had earlier BMV while One was post-open mitral valvotomy (OMV) patients). 21 patients were in atrial fibrillation with a controlled ventricular rate.

The mean M E S was 6.7 ± 1.6. The hemodynamic mean diastolic gradient pre and post procedure decreased from 16.1 ± 5.3 mmHg to 3.8 ± 2.6 mmHg ($p < 0.0001$). The mean left atrial pressure fell from 23.42 ± 6.89 mmHg to 11.8 ± 4.1 mmHg ($p < 0.0001$). The mean mitral valve area increased from 0.8 ± 0.18 cm2 to 1.71 ± 0.24cm2 ($p < 0.0001$). There was also significant drop in mitral mean pressure gradient as assessed by Doppler echocardiography.

Pregnant patients had their abdomen wrapped from just below the diaphragm down to the pubic symphysis by lead shields > 0.5 mm thickness. All pregnant patients underwent successful BMV with no complications, there were no maternal or fetal deaths and all patients delivered at full term by vaginal delivery. Mean MVA before and after BMV were similar as in other patients. Seven patients were pregnant with mean of 24 +/-4.1 weeks gestation. All pregnant patients were in NYHA class III-IV.

The procedure was considered successful in 87 (98.86%) patients. Procedural complications are shown in table 2. Post BMV MR was absent in 44 patients, recorded as grade I in 35 patients, grade II in 3 patients, grade III in 4 patient and grade IV in 1 patients. Overall five patients (5.74%) developed moderate to severe mitral regurgitation. Two patients had a tear of the anterior mitral leaflet, others had excessive commissural MR. One patient required urgent MVR. Two patients developed atrial septal defect (ASD) < 1.5:1 shunt.

Table 2: Complications

Parameters	N=87	Parameters	N =87
Severe MR	5(5.74%)	Pseudoaneurysm	1(1.14%)
Minor stroke	2(2.29%)	Vasovagal attack	6(6.89%)
Cardiac tamponade	1(1.14%)	Non fatal VT	1(1.14%)
Need for MVR	1(1.14%)	Supra ventricular arrhythmias	11(12.64%)
Death	0	Restenosis	19 (22%)
Puncture site hematoma	3(3.44%)	ASD	2 (2.29%)

Follow up and Restenosis

One patient (1.14%) developed cardiac tamponade after septal puncture and was managed by pericardiocentesis and BMV procedure was completed. Minor stroke was developed in two (2.29%) patients. No death reported after the procedure. Puncture site hematoma occurs in 3 patients (3.44%) out of which one patient developed Psudoaneurysm which was managed medically. Non fatal Ventricular arrhythmias in 1(1.14%) and supraventricular arrhythmias in 11(12.64%) were noted during procedure.

87 patients were followed up for one year. The one year follow up mean mitral valve area was 1.56 ± 0.19 cm2. Restenosis was encountered in 19 patients (21.8%). Majority of the patients followed up showed an improvement in the functional class by at least I grade. At one year after the procedure, 57 patients were in NYHA functional class I (65.5%), 23 patients were in class II (26.4%) and 7 patients were in class III-IV (8%). Among the patients with restenosis, 7 patients with class III-IV symptoms required reintervention (3 patients underwent MVR electively and 4 required redo-BMV), the remaining 12 patients (63%) were in NYHA class I-II and were being managed medically. There were no late deaths. There was significant reduction in pulmonary artery systolic pressure and left atrial diameter on follow up .

DISCUSSION

Balloon mitral valvuloplasty (BMV) as an alternative to surgery was first performed in 1982 by Kanji Inoue6,7 in Japan. In patients with pliable valves, randomized trials8 have shown that balloon mitral valvuloplasty gives an excellent result and is equal to that obtained with open or closed surgical valvotomy and benefit is sustained during long term follow up9 This study demonstrates that BMV results in a good immediate hemodynamic and clinical improvement in the majority of patients with mitral stenosis which is similar to other studies10,11,12. The in-hospital complications were low. Restenosis after BMV has been evaluated in a number of studies, with an incidence ranging from 6.5% to 40% 10,12,13,14,15. Chen et al,10 reported an 11 year incidence of 8%. Zaki et al12, from Egypt reported 5 year restenosis rate of 6.5%. Fawzy et al13, from Saudi Arabia have reported 5 year restenosis incidence of 14.3% and 16.1% in patients less than and more than 20 years respectively. They have again reported 31% restenosis rate in 531 patients with mean followup of 8.5 years14. Hernandez et al15, from Spain have reported a restenosis rate of 39% at 7 years. Wang et al16, reported 40% restenosis rate at 6 years follow up and this was predicted by higher echocardiographic score. The restenosis incidence in our study was 23% at one year even though majority of patients were having an echocardiographic score of < 8 implying that valve morphology was not the main determinant of restenosis. It has been hypothesized that younger patients (majority in our study) may be more prone to developing restenosis because of the increased likelihood of smouldering rheumatic activity or recurrence of rheumatic fever in this age group. Majority of our patients are followed up in regional hospitals and are not on regular penicillin prophylaxis. Also there may be an ongoing immunologic response with progressive valve injury. G. Packirisamy, P. Arun Prasath, K. Geofi George, E et al17 retrospectively studied a total of 1374 patients who underwent BMV in the period between October 2000 and October 2011. The complications observed were mitral regurgitation of varying grades, pericardial effusion, cardiac tamponade, atrial fibrillation, transient ischemic attack, cerebrovascular accident, seizures, detached coil wire and on table death. Mitral regurgitation was observed in 53 patients(3.85%). But acute severe mitral regurgitation requiring mitral valve replacement was noticed in 17 (1.23%) patients. Moderate mitral regurgitation occurred in 7 patients. These patients were followed up on medical treatment . Mild mitral regurgitation of hemodynamic insignificance was noticed in 29 patients. Cardiac tamponade occurred in 17 patients (1.23%) . Emergency pericardiocentesis and subsequent balloon dilatation was done in 14 patients and the remaining 3 patients were transferred for surgery. Mild pericardial effusion was seen in 7 patients and BMV was deferred in the three of these patients. Atrial fibrillation was encountered in 14 patients (1.018%). Of the 14 patients, six required DC cardioversion, there was spontaneous termination in seven patients and only one patient had persistent atrial fibrillation following procedure. Two patients developed cerebrovascular accident following balloon dilatation which recovered gradually and one patient had a transient ischemic attack. One patient had seizures and required mechanical ventilation during the procedure but recovered later. Coiled wire got detached in the left atrium in one patient and it was removed using a snare. One patient died on table and the reason for death was not made out.

Similarly, various cardiac catheterization laboratores19-23 reported

the complications of BMV as follows. Failure rate ranges from 1-15%. Procedural mortality ranges from 0.5-3.0%. Incidence of hemopericardium varies from 0.5- 12%. Embolism is encountered in0.5 -5% of cases. Severe MR, which occurs in 2-10% cases is a result of non commissural leaflet tearing. Urgent surgery is seldom needed for complication (<1%). Cardiac tamponade and acute severe mitral regurgitation are the most important complications following balloon mitral valvotomy which might need immediate cardiac surgery in the form of repair of the punctured side and mitral valve replacement. Our study showed the incidence of severe MR in 5 (5.74%) patient which is similar to above mentioned large studies. Among 4 patients, two patients had poor valve morphology (Echo score= 10-11) , severe heart failure(NYHA III-IV) and they refused cardiac surgery. Threel were managed medically and improved symptomatically and one patient underwent urgent MVR surgery. Regarding other complications like hemopericardium, minor stroke , supraventricular and ventricular arrhythmias, incidence is lower in our study as compared to above studies.

Restenosis and clinical outcome: Even though the restenosis rate was high in our patients, clinically they were either asymptomatic or mildly symptomatic and were managed on medical treatment. Our study demonstrated that restenosis defined by 2-D echocardiographic measurement of MVA was not related to late clinical outcome. Although MVA continues to decline during follow-up, they were relatively asymptomatic (NYHA class I-II 60%) demonstrating the disparity between the gradual process of restenosis and clinical outcome. The excellent acute procedural results of BMV may be the predominant predictors of later symptoms rather then MVA itself. This has been seen in the study done by Wang et al. Wherein, when adjusted for baseline factors and post procedural results, restenosis was no longer predictive of either major events or poorer functional status16, and they noted that the disparity between restenosis and clinical outcome suggests that the hemodynamic benefits of successful BMV persisted beyond the point of restenosis as defined by their study. A greater reduction in MVA or duration of time may be necessary before recurrent symptoms develop. After BMV, LA stiffness has been shown to decline significantly18, and this improvement in compliance may confer symptomatic benefit despite a reduction in MVA. In support of this hemodynamic change after BMV, our analysis found that in majority of patients LA pressure after successful BMV was significantly reduced. Longer clinical follow-up of our patients who experience restenosis may reveal a stronger association between restenosis and adverse clinical events and poor functional status.

CONCLUSION

The results of this study show that BMV is a safe and effective procedure for symptomatic mitral stenosis with lower complication rates and good clinical improvement.

Conflict of interest : None

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