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PREDICTORS OF MITRAL REGURGITATION IN PATIENTS UNDERGOING BALLOON MITRAL VALVOTOMY

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ABSTRACT

Introduction: Successful use of a balloon catheter for opening a stenotic mitral valve was introduced by Inoue in 1982. PTMC has been performed using a variety of balloons, including single balloons, double balloons, and metal commissurotomies. This study was undertaken in patients with severe mitral stenosis who had undergone PTMC by JOMIVA balloon catheter with a modified technique.

Aim and Objective: To predict mitral regurgitation in patients undergoing Balloon Mitral Valvotomy.

Methods: In our study, the right femoral artery and vein are cannulated for line insertion using 6Fr and 7Fr sheaths, respectively. In order to pierce the septum, a 6Fr pigtail catheter is inserted into the aortic root with its tip in the non-coronary aortic sinus. The balloon catheter was also utilised to monitor systemic pressure. Septal puncture procedure and echocardiographic assessment were also done to reach at the goal.

Results: Individuals of Group-I had either the advancement of pre-existing mild to trivial MR. One patient with severe MR had emergency MVR, while the other patients were given conservative care. Group-II patients were still alive but did not experience a rise in MR as a result of BMV. The echocardiographic parameters of MV annulus size, leaflet exertion, leaflet thickness, papillary muscle length, and chordal length did not significantly differ between the two groups.

Conclusion: The current investigation shows that none of the clinical, hemodynamic, or echocardiographic markers can accurately predict whether MR would develop as a side effect of BMV.

Keywords: Valvotomy, mitral regurgitation, mitral stenosis, commissurotomy, valvuloplasty

BACKGROUND

Inoue first described the technique of percutaneous dilatation of mitral valve in 1982[24] since then PTMC has gained rapid acceptance among cardiologists. Most cardiologists use the antegrade approach, however few like Stefandis et al[l3] and Bahal et al[l4] have used retrograde techniques to dilate the mitral valve with good results. However, at present this technique is used in patients where antegrade approach is difficult i.e., those with patch closure of ASD or those where there is difficulty in septal puncture due to its abnormal orientation. The Inoue balloon is most commonly used worldwide and also in India. Because of its many advantages which include its low profile, short length, its capability of slenderisation by a metal cannula. It does not slip from valve during inflation, it allows sequential step wise dilatation and short procedure / fluoroscopy time[15].

Joseph balloon which functions as an over the wire system is a cheap, tough, durable balloon with a low crossing profile. As it passes over the backup wire, there is less change of MR also. This balloon and its technique were used by Joseph et al initially[24]. But this technique has not been accepted widely because many a times the balloon fails to cross IAS, and fear of cardiac tamponade due to use of stiff LV wire. There are not much studies with large number of patients and long follow up database with this technique and the incidence severity of MR following this technique. Many studies have been done to assess the incidence and mechanism of development of MR but most studies are done with Inoue balloon or double balloon.

When we look at complications, in a multicentre study Chen et al[l6] reported the procedural success rate was 99.3%. MVA increased from 1.1 + 0.3cm2 to 2.1 +0.2cm^2. Mean LA pressure reduced from 26.2+7.6mmHg to 11.4+6.1 mmHg. MR >3+/4+ occurred in 1.4%. In a large Indian series by Arora et al[l7] in which PTMC was done in 4850 patients MVA increased from 0.7+0.2 to 1.9+0.3cm^2. Mean diastolic gradient reduced from 29.5+7.0 to 5.9+2.1. MR appeared on worsened in 42 patients and severe MR occurred in 1.4%.

Crifier et al[l8] which used a metallic commissurotomy in 153 patients found MR in 20 patients with severe MR in 2 patients. In Joseph's series[7] MVA increased from 0.82+0.2cm^2 to 1.96+0.31cm$^{2.}$ The mean diastolic gradient reduced from 15+7 to 2+2mmHg. Severe MR developed in 2.5%. Mitral Regurgitation is reported in upto 50% of patients after percutaneous balloon valvotomy for acquired mitral stenosis[1]. In most cases it is of no significant consequence. However severe Regurgitation may occur in 7 to 15%[15] of procedures requiring intensive medical and surgical management.

Mechanism of progression or development of mitral regurgitation are not well understood. This study was planned with a view to look at factors that could predict mitral regurgitation after percutaneous balloon mitral valvuloplasty. Regardless of the absence of technical mistakes during the procedure, MR may progress in different degrees after balloon dilatation. The causes of that progression are not known. Until now, only anatomic descriptions of the valve were available from surgical findings in patients with severe

MR after balloon valvuloplasty. It showed tears and detachment of the leaflets and / or damage of the sub valvular apparatus. However major degrees of MR would probably have a different mechanism. Only few studies have investigated the determinants of progression of MR after valvuloplasty. The group from Boston having had no success in detecting significant predictors of progression in previous reports, ultimately found that higher ratio of effective balloon dilating area to body surface area can influence progression of MR[6].

Nobuyashi et a1[5] reported that only significant predictor of progression of MR was the anatomic characteristic of the mitral valve according to echocardiography. In another study Manuel Sancho from Spain[8] reported that none of parameters evaluating valve anatomy were significant predictors of progression of MR. Although the incidence of progression of MR is quite different between studies, these discrepancies might be explained by differences among the studies in terms of techniques, definition of progression of MR and diagnostic methods in evaluating MR. In this study they found that anatomic features did not predict progression of MR. However, an older age, a higher ventricular size and a lower ejection fraction were independent predictors of progression of MR after balloon valvuloplasty. All these factors probably indicate a mere advanced state of rheumatic disease as the main cause of that progression and should be considered before indicating balloon valvuloplasty.

In M-Heart PBMV Registry Howard Hermann et al[l4] reported mitral regurgitation by grade-I in 19% of cases > grade 2 in 13% of case. The cause of mitral Regurgitation could not be predicted by valve anatomy or balloon size. However, they found that a posterior mitral leaflet tear may lead to severe MR in some patients with a calcified valve and extensive sub valvular disease.

In a study of 157 patients with severe MS Robert B. Roth et a1[3] showed an increase in MR (Minor Degrees) occur in 44% of cases. Severe MR >3 grades occur only in 1.2% of cases whereas undesirable increase in MR >2 grades occur in 12.5% of patients. Only effective balloon dilating surface area was significant predictor of increase in MR. In this study, single balloon BMV was done. The patients who had single balloon PMV had a lower incidence of sever MR as the effective balloon dilation area was less. None of the other variables did not predict the increase incidence or progression of MR.

In North American Inoue Balloon investigator group Howard Herrmann et al[l] in 280 patients tried to assess the incidence, mechanism and outcome of severe mitral regurgitation after PTMC with Inoue balloon Severe MR occur in 15% of cases after PMTC. The cause of regurgitation was rupture of chordae tendinea of the anterior and posterior mitral leaflet. Tearing of a leaflet (usually the posterior one) occurred in 30% of patients and no recognisable structural abnormality, wide splitting of the commissures and a central regurgitant jet, was present in 20% of cases: All patients with definite posterior leaflet tears have heavily calcified leaflets patients who developed severe regurgitation had fewer balloon inflation and a higher grade of pre-existing mitral regurgitation but were otherwise similar to the remaining patients without severe regurgitation. They concluded careful balloon positioning may help avoid chordal rupture and

heavily calcified posterior leaflets may be at greater risk of tearing most patients who develop severe regurgitation will require non-emergency mitral valve replacement.

In one of the largest registries of BMV (National Heart Lung Blood institute Balloon valvuloplasty Registry) with 738 patients showed that 3% of patients developed Acute MR. They have shown that MR developed in similar frequency whether there is pre-existing MR or not. Total balloon diameter whether double or single balloon used. Body surface area, echocardiography scope was not significantly different in both the groups.

INTRODUCTION

Rheumatic heart disease has been documented in Indian literature since early 19th century. In Orissa RHD / RF cases constitutes a significant percentage of hospital admission[23]. Mitral stenosis (MS) constitutes 35% of all valvular lesions[2].

Elliot Cutler at Peterbent Brigham Hospital in Boston made first successful attempt at surgical treatment for MS when he inserted a knife through the apex of LV and blindly cut the valve at right angles to its natural orifice. On the basis of excellent results with surgical commissurotomy successful use of a balloon catheter for opening a stenotic mitral valve was introduced by Inoue in 1982[3]. Since then the method has become the preferred non-surgical technique to treat symptomatic mitral stenosis worldwide.

Several different balloons (Single balloon, double balloon, metal commissurotomy) has been used for doing percutaneous transvenous mitral commissurotomy (PTMC). If we look at all non-coronary cardiac interventions PTMC accounts for 79.4% in India in 2002. This reflects the higher prevalence of MS as well as the safety and cost effectiveness of the procedure.

In these procedures Inoue balloon was used in 70.1%, Accura balloon was used in 21.0%, Joseph balloon in 7.1% and metallic commissurotomy in 1.84%[25].

This study was undertaken in patients of severe mitral stenosis who have undergone PTMC by Joseph Mitral Valvuloplasty (JOMIVA) balloon catheter with a modified technique in our institution to predict mitral regurgitation in patients undergoing Balloon Mitral Valvotomy.

AIM & OBJECTIVE

To examine any clinical, echocardiographic, hemodynamic, or procedural characteristics that would most likely forecast the development of mitral regurgitation following balloon mitral valve valvotomy.

MATERIALS & METHODS

Between January 2018 to January 2021, 166 patients of symptomatic severe mitral stenosis who underwent BMV with use of JOMIVA balloon catheter at SCB Medical College, Cuttack comprised the study group.

In patients who either developed new MR or had progression of pre-existing MR were included in Group-I, whereas those who had no progression of MR were included in Group-II. Both groups were compared for their baseline clinical characteristics, haemodynamic parameters and various echo-cardiographic parameters in order to look for any variable that could predict MR following the intervention.

All patients underwent detailed clinical and radiological examination to assess for their suitability for the procedures. Detailed Echocardiography evaluation was done on the ATL ultramark-9 Echo machine. The severity of mitral stenosis was assessed by planimetry and Doppler pressure half ($P^{1/2}$) time method. The mitral valve was examined specifically for leaflet mobility, thickness, sub valvular fusion and calcification. Echo scoring was carried out as per Wilkin's scoring system[5]. A biplane TEE by ATL ultramark-9 was performed in all patients to rule out LAI-LA clot. Patients with echo score > 10, significant MR (>3/4) or with clot in left atrium were excluded from the study. BMV was performed by transeptal approach via femoral vein.

Balloon Catheter and Accessories:

The JOMIVA balloon catheter comprises three parts[6,7] The distal part is formed by the balloon, which is made from thin, tough, thermoplastic polymer and has a 4 cm working length with a distal blunt tip. The proximal part has two ports at its proximal end balloon inflation and deflation. The 11 FR shaft with unique co-axial construction allows for very rapid inflation and deflation of the balloon. The accessories required include a Brocken brough needle, Mullins sheath and dilator, septal dilator, left atrial (LA) wire, left ventricular (LV) wire Cournand, Pigtail and Swan-Ganz catheters. Mansfield balloon, sheaths, guide wires, stop cocks and syringes.

Procedure Details:

For line insertion, the right femoral artery and vein are cannulated with 6Fr and 7Fr sheaths, respectively. A 6Fr pigtail catheter is placed in the aortic root with its tip in the non-coronary aortic sinus this serves as a landmark during septal puncture and is also used for monitoring systemic pressure.

Septal Puncture:

PASP measured using 7Fr Cournand catheter, 0.032 exchange guide wire is positioned in SVC. Femoral venous sheath removal and 8Fr Mullins dilator positioned in the SOC over the exchange wire. The later is removed, and the Brocken brough septal puncture needle is then advanced inside the Mullins dilator, keeping the index finger of the right hand as a guard between the hub of the Mullins and the external pointer of the BB needle so that the tip of the needle does not pass outside the dilator. The hub of the BB needle is connected to fluid filled tubing for continuous pressure monitoring, with the external pointer directed towards the 4 to 5 0'clock position. The whole assembly is then with drawn under fluoroscopy guidance from the SVC to the right atrium until it falls into fossa ovalis. In the RAO 45^0 position the puncture site is in between the pigtail catheter and the anterior border of the spine antero-posteriorly, and 1 cm below the tip of the pigtail catheter vertically.

The septum is punctured in the RAO 45^0 or lateral position by advancing the needle along with a sudden jerk. Needle entry to left atrium is confirmed by the pressure tracing and by contrast injection. The dilator is then advanced over the needle to the left atrium in the post anterior Position and the needle then withdrawn. Heparin 5000 U or 100 U/kg in children is administered at this stage. Right atrial pressure is measured with the Mullins dilator, after advancing the pigtail catheter into left ventricle, the LA and LV pressure were recorded. Simultaneously in order to measure the pericardial effusion. On completion of the balloon mitral valvotomy, the pulmonary artery pressure is recorded before sheath removal.

166 consecutive patients of symptomatic severe non calcific rheumatic mitral stenosis who underwent balloon mitral valvotomy between January, 2018 to January, 2021 at our institute were the basis of the present study. There were 80 males and 86 females, their ages ranged from 9 to 39 yrs. (Mean 24+10) BMV was performed by trans septal approach in all patients. A routine diagnostic cardiac catheterization study was performed before and after the intervention after overnight fasting.

PAP, PCWP, MDG across the mitral valve were measured, cardiac output was estimated using Ficks principle and mitral valve area was calculated using Gorlin's formula. MR before and after each procedure was assessed by a left ventriculogram, mitral regurgitation was graded on the basis of Seller's criteria[7].

Echocardiographic assessment:

Each patient underwent 2D and colour doppler echocardiography day before and after the procedure. Images were obtained in standard views using ATL ultramark-9 system and 2.5/3.5 MHz transducer.

The following morphometric measurements of the mitral valve apparatus was obtained.

1. MV annulus diameter from inner age to inner age of MV annulus.
2. MV Excursion - mid annulus to tip of doomed mitral valve during maximum excursion in diastole.
3. Thickness of the leaflets for both anterior and posterior MV leaflets.
4. Chordal length from tip of mitral leaflet to tip of papillary muscle in systole.
5. Papillary muscle length: from tip to base of the papillary muscle in systole.
6. LV cavity length from mid MV annulus to LV apex in mid diastole.
7. Uniformity of leaflet thickness.

In addition to these measurements, an echo-cardiographic score for mitral valve was calculated as per standard criteria (Willkins scoring system). Ratio of mitral valve annulus to maximum balloon size used also calculated.

Statistical Analysis:

Variables in both groups were compared using unpaired students' test and level of significance was taken as ($p < 0.005$).

RESULTS

Out of 166 patients, 42 had either progression of pre-existing mild to trivial MR or appearance of new MR (Group-I). Of these, 24 had Grade 2+ MFR, 8 had Grade-III MR and 10 had Grade-IV 4+MR. Emergency MVR was performed in one patient with severe MR whereas others managed conservatively. Surgical findings revealed tear of AML. Remaining 124 patients who did not have any increase in MR because of BMV were included in Group-II. 22 out of 124 (17.65) patients in Group-II had pre-existing Grade 0-l MR which did not increase after BMV, whereas in Group-I pre-existing MR was present in 10 out of 42 (23.9%) of patients.

Baseline clinical characteristics i.e., age, sex, NYHA class, incidence of Atrial fibrillation, history of CMV in the past and incidence of associated AR were similar in both groups.

Mean PAP, mean PCWP, mean diastolic gradient across the mitral valve before and after the procedure were compared between the two groups and no significant difference was found (Table - II) calculated mitral valve area before and after the procedure was not significantly different between two groups. Net change in these variables as a result of BMV was also calculated and no significant difference was found between the two groups. Comparative analysis of echo cardiography variables between these two groups showed no significant difference in any of these parameters (Table - III).

Table – I

Baseline Clinical Variables

Variables	Group I	Group II	P VALUE
Age (44ys)	27 ± 10	25 ± 8	NS
Sex (M/F)	10/ 32	50/ 74	NS
NYHA Class III, IV	74%	76%	NS
H/O CMV	14 %	5%	NS
Atrial fibrillation	8%	16%	NS

*(**Abbreviations:** NYHA- New York Heart Association, CMV- Closed Mitral Valvotomy)*

Table - II

Hemodyanomic Variables

MVA	**Group- I**	**Group- Il**	**P-VALUE**
Pre dilation	0.7 ± 0.18	0.73 ± 0.19	NS
Post dilation	1.77 ± 0.30	1.79 ± 0.39	NS
Change in Mitral Valve area	1 .07 ± 0.30	0.96 ± 0.36	NS
Mean Diastolic Gradient			
Pre dilation	20.8 ± 7.6	23.8 ± 7.1	NS
Post dilatation	7.8 ± 7.8	6.8 ± 4.1	NS
Change	12.9 ± 8.0	17.0 ± 7.1	NS
PA pressure (Mean)			
Pre dilation	40.4 ± 13.8	41.9 ± 73.7	NS
Post dilatation	23.2 ± 8.9	23.7 ± 9.6	NS
Change	17.1 ± 12.1	18.3 ± 9.91	NS
PA Wedge Pressure			
Pre dilation	27.8 ± 6.1	29.1 ± 7.6	NS
Post dilatation	14.1 ± 7.0	12.5 ± 3.8	NS
Change	16.6 ± 7.7	13.6 ± 7.6	NS

(Abbreviations: *MVA- Microvascular Angina, PA- Pulmonary Atresia)*

Table - III

Echocardiographic Variables

Variables	Group I	Group II	P Value
MV Mobility (CM)	3.2 ± 0.8	3.3 ± 0.1	NS
MV Excursion (CM)	1.2 ± 0.4	1.3 ± 0.4	NS
AML Thickness (CM)	0.3 ± 0.15	0.3 ± 0.14	NS
PML Thickness (CM)	0.3 ± 0.15	0.3 ± 0.13	NS
Chordal length (CM)	0.9 ± 0.4	0.8 ± 0.4	NS
Echo cardiographic Score	7 ± 2	7 ± 2	NS
Nodules of MV leaflet	82%	70%	NS

*(**Abbreviations:** MV- Mitral Valve Regurgitation, AML- Anterior Mitral Leaflet, PML- Posterior Mitral Leaflet)*

DISCUSSION

The extent and pattern of distortion of the mitral valve apparatus in patients with RHD is variable[6]. BMV has occurred as a procedure with high efficacy and safety in the treatment of severe symptomatic mitral stenosis. One of the major complications of this procedure is development of MR Identification of the subgroup of patients who are prone to develop this complication remains an enigma for the interventionist. In the present group of patients 25.3% incidence of increase in the Grade of MR was noted of which severe MR occurred in 6% of cases.

These figures are comparable to the previously reported of 33% and 8% respectively1-5, 9-11 incidence of MR was higher in the studies using doppler echocardiography[3,13] and was similar irrespective of size of Balloon and other echo cardiographic variables previously higher incidence of MR has been reported using double balloon[12].

Various criteria for sizing of the balloon used for dilating the mitral valves have been used, based on height. Body surfaced area etc. but none of these seems to help in reducing MR incidence. In an effort to exclude such variables that may not directly represent the true annular size, we tried to evaluate the mitral annulus size. In M-Heart multicentre registry[14] effective balloon dilating area was higher in those who developed MR. Similar result was found by Rath et a1[3] but other studies did not show such correlation.

In our study we calculated ratio of mitral annulus size to maximal balloon size and this ratio was similar in both groups irrespective of occurrence of MR.

Nobuyoshi et al[5] found high echo-cardiographic score as predictive of MR However no such correlation was found in North America Registry of Inoue balloon investigators[16] and study by Hermann et al[1].

In our study high echocardiography could not predict MR. In fact, none of the other echocardiographic scope could not predict MR in our study. Few numbers of balloon inflations were found to be associated with MR in one study [1] but no such relationship emerged from our data.

SUMMARY

We studied 166 consecutive patients if severe mitral stenosis who underwent Balloon mitral valvotomy at our institute, with the aim of looking for any clinical echocardiographic, hemodynamic or procedural factors that could predict occurrence of mitral regurgitation after Balloon mitral valvotomy.

42 patients (Group - I) who had either new mitral Regurgitation or progression of pre-existing mitral Regurgitation were compared to these 124 (Group - II) who did not have progression of mitral Regurgitation. There was no significant difference between age, sex, NYHA-class, incidence of past CMV, Atrial fibrillation or associated aortic regurgitation.

There were no significant differences between two groups between echocardiographic variables of MV annulus size, leaflet Exertion, Leaflet thickness, papillary muscle length, chordal length. LV Cavity length / MV annulus Ratio, and nodules on MV leaflets on haemodynamic study; mitral valve area, mean diastolic gradient, mean PA pressure and mean PA wedge pressure before and after BMV were also similar between two groups. MV Annulus to Maximum balloon size Ratio and number of balloon inflations were also similar between the two groups. Therefore, we concluded that none of the variables studied could predict occurrence of mitral Regurgitation after BMV.

CONCLUSION

The present study demonstrates that none of the clinical, hemodynamic and echo-cardiographic parameters is predictive of occurrence of MR as a complication of BMV. However further studies with larger number of patients would be needed for precise answer to the question of predicting MR in BMV.

CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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