

## BALLOON MITRAL VALVOTOMY: IMMEDIATE OUTCOMES, SUCCESS, FAILURE AND COMPLICATIONS

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### Contribution

BA conceived the idea and designed the study. Data collection and analysis was done by AH, KS and SE. Final review was done by SE. All authors contributed equally to the submitted manuscript.

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### ABSTRACT

**Objective:** To determine procedure related safety, complications, and failure.

**Methodology:** This cross-sectional analysis of PTMC data obtained from the record of 1003 patients suffering from symptomatic severe rheumatic MS who underwent PTMC from 1994-2010. The study was conducted at Department of Cardiology, Mayo Hospital, Lahore. Data of patients who underwent PTMC was analyzed, including information regarding their age & gender, the success, failure, and complications of the procedure and available hemodynamic or echocardiographic findings.

**Results:** Data of 1003 patients (700 females & 303 males, age range 7-77 years) was included, with mean age (in years) of  $27.75 \pm 10.82$  years. Pre-PTMC mean mitral valve area was  $0.80 \pm 0.26$ . Success was achieved in 946 patients. Posts PTMC mean MVA was  $1.83 \pm 0.28 \text{cm}^2$ . PTMC could not be completed or was abandoned in 57 patients who either developed dreadful complications causing instability or had actual procedure related difficulties. Severe MR requiring emergency MVR occurred in 6 patients. Cardiac tamponade and CVA developed in 19 patients and 16 patients respectively. Balloon ruptured in 6 patients. Atrial fibrillation occurred in 27 patients during procedure.

**Conclusion:** Balloon mitral valvuloplasty is a safe procedure for management of patients suffering from moderate to severe mitral stenosis.

**Key Words:** PTMC, CVA, Mitral Regurgitation, Cardiac Temponade

## INTRODUCTION

Since the first clinical application of percutaneous trans venous mitral balloon commissurotomy by Inoue and his fellows in 1984, it has been accepted internationally becoming the standard technique for the management of haemodynamically significant rheumatic mitral stenosis, when it is not contraindicated, for example; Mixed Mitral Valve Disease with more than moderate MR or thrombus in left atrium etc. PTMC has shown good immediate and mid-term results ever since its introduction.<sup>2,3</sup> It has almost preferably replaced surgical commissurotomy as a safe, economical, and efficient way of intervention, especially in patients with rheumatic mitral stenosis. It is also appropriate for patients who have moderate to severe MS with non-pliable, calcified valve, are in NYHA-FC III and are on high or prohibitive surgical risk.<sup>4,5</sup>

A number of randomized trials have shown that balloon dilation give haemodynamic, echocardiographic and symptomatic results almost comparable to CMV and open mitral valvotomy. BMV can be undertaken safely in older patients who are otherwise fragile and may provide palliative symptomatic improvement.<sup>6,7</sup> Elderly patients, with non-rheumatic MS caused by degeneration annular calcifications encroaching into the base of mitral leaflets and patients having severe mitral in-flow obstruction due to severe sub-valvular disease with no or little commissural fusion, are not suitable candidates for PMTC and should not undergo PMBV. Earlier, when closed surgical valvotomy (CMV) began in 1950s, only physical signs and fluoroscopic imaging was available to predict anatomy,<sup>8</sup> however, later in 1980s, when Inoue Balloon Valvotomy technique was introduced, the echocardiographic imaging also became available and made the examination of mitral valve more vivid and detailed. To help predict the results of PMTC, the pre procedure assessment of mitral valve morphology is also very important because the success of procedure is preeminent in patients having thin pliable leaflets, higher commissural fusion, calcification with little or no infra-valve disease.<sup>9,10</sup>

The Wilkin's Score is a widely used echocardiographic scoring system that assesses the suitability of mitral valve morphology for PTMC.<sup>11,12</sup> This assigns approximate measurement to assess mitral leaflets thickening, mobility, calcification and severity of sub-valvular disease. A score of less than or equal to 8, signifies more favorable outcomes than those with a score of more than 8.<sup>13</sup> It does not include the assessment of commissural morphology and calcification to its score thus 'Commissural Fusion and Commissural Calcification Score' is used to calculate it. These two scores, then, correlate significantly with outcomes; higher the commissural fusion score, higher is the success rate with desirable results. Contrarily, a greater the commissural calcification score represents the latency of complications leading to failure of procedure.

The Inoue balloon technique is most commonly employed today, despite the existence of alternative techniques. Amongst them are: Double Balloon technique, also primarily used by Inoue and his colleague; and Multitrack technique described by Bonheoffer as a refinement of the double balloon technique as it allows easier dilation of valve, nevertheless, its clinical experience is still limited.<sup>14</sup> Another technique, Metallic Commissurotomy technique introduced by Cribier in 1990, is an efficient way of

balloon valvotomy but requires more adroitness from its operator than that of Inoue balloon technique.<sup>15</sup> It also carries a higher rate of hem-pericardium due to the presence of a stiff guide wire in left ventricle. The dilation is redo able and cost efficient.

## METHODOLOGY

This cross-sectional study included records of patients, who underwent mitral balloon valvotomy at our tertiary care center from 1994-2010, were included in the research. Data regarding age, gender, viral status, NYHA class, ECG, echocardiographic findings regarding Wilkin's score and immediate hemodynamic results including success rate, procedure related difficulties and complications were obtained. The self-positioning single balloon Inoue technique was used for commissurotomy in all patients through right femoral vein approach except one patient who had left femoral vein approach. The balloon sizing was done according to formula, height divided by 10 and +10. The mean balloon size was  $24 \pm 2.5$  mm, (range: 22 to 26 mm) The data was stored and analyzed and SPSS 20. Mean  $\pm$  SD was calculated for numerical variables. Frequency and Percentages were calculated for categorical variables

## RESULTS

Percutaneous trans-venous mitral commissurotomy was attempted in 1003 patients (642 retrospectively and 361 prospectively) from 1994 to 2010, 700 (69.79%) were female and 303 (30.20%) male, overall mean age in years was  $27.75 \pm 10.08$  (Male:  $26.03 \pm 9.76$ , Female:  $28.50 \pm 10.13$   $p < 0.0001$ : 286 (28.44%) patients were in the age group of 20 or less, 629 (62.7%) were between 21-40 years of age, 83 (8.27%) were in age group of 41-60 and only 5 patients were above 60 years of age (Table 1). About 21 female patients were pregnant (18 patients 2nd trimester, 3 patients were in 3rd trimester), 12 patients had had coronary angiography done before PTMC procedure, only two patients had coronary artery disease (1 patient with single vessel and 1 with 3 vessels CAD), 14 patients had previous history of surgical intervention (CMV: 11, OMV:3). Previous PTMC was carried out in 8 patients, 36% patients were in NYHA functional class II, 60% were in NYHA functional class III and 14% were in functional class IV. Overall mean pre-PTMC mitral valve area was  $0.80 \pm 0.26$  (Female:  $0.80 \pm 0.17$  cm<sup>2</sup>, Male:  $0.80 \pm 0.41$  cm<sup>2</sup>,  $p = 0.91$ ) and for patients with procedural success mean MVA was  $0.80 \pm 0.41$  cm<sup>2</sup> for male (285) and  $0.80 \pm 0.17$  cm<sup>2</sup> for females (661),  $p = 0.91$ . About 967 patients had a Wilkins score of less than 8, 36 patients had Wilkins score of  $> 8$  to 12 score (Range: 3-12). Mean Wilkin score was  $6.5 \pm 1.5$ . A total of six female patients had PFO. Procedure was successfully completed in 946 patients (94.3%), (success in patient with first time PTMC was 94.80% while it was 72.72% for redo cases.), however, it could not be completed in 57 patients (5.68%) (Female: 40, (5.72%) and Male: 17 (5.61%)  $P = 0.557$ ) (Table 2). On cardiac catheterization, mean pulmonary artery systolic pressure was  $67.02 \pm 23.85$  mm of Hg; mean right ventricular systolic pressure was  $66.84 \pm 24.53$  mm of Hg. Mean pre-PTMC LA pressure was  $37.97 \pm 10.33$  mm of Hg. Mean pulmonary wedge pressure  $31.36 \pm 8.61$  mm of Hg, pre-PTMC mean mitral valve diastolic LA-LV gradient was  $18.84 \pm 7.89$ , Post PTMC LA mean pressure was  $22.04 \pm 8.6$  and post PTMC mean LA-LV diastolic mitral valve gradient was  $2.21 \pm 4.08$ .

**Table 1: Gender wise distribution of patients.**

-	Number (n)	Percentage (%)		Success			HCV	HBS-Ag
Males	303	30.21	yes	946	94.3	positive	8	5
Females	700	69.79	no	57	5.68	negative	995	998
Distribution of patients according to age groups								
Age in years	Frequency (n)		Percentage (%)			Total		
20 or less	286		28.5			286		
21-40	629		62.7			629		
41-60	83		8.3			83		
>60	5		0.5			5		
Age group wise distribution of no of patients and no of complications. (p<0.000)								
Age group	Females	Males	Yes	No	Total			
20 or less	24	14	38(54)	248	286			
21-40	82	15	97 (144)	532	629			
41-60	14	3	17(35)	66	83			
>60	0	1	1(2)	4	5			
Gender wise distribution of complication (P-Value: 0.118)								
	Yes		No		Total			
Females	120		580		700			
Males	33		270		303			
Total	153		850		1003			
Percentage	15.25		84.74		-			

**Table 2: Procedure and its complication in study population**

	Valid	Mean	S.D	Range	P-Value
Overall age of Patients (years)	1003	27.75	10.082	7 to77	
Age of female Patients (years)	700	28.5	10.13	7 to77	0.0001
Age of male patients (years)	303	26.03	9.76	9 to 65	
Age of successful female patients	661	28.3	10.11	7 to77	0.0001
Age of successful male patients	285	25.99	9.65	9 to 61	
Wilkin Score (<8=967,>8=36)	1003	6.5	1.5	3 to 12	
Overall mean MVA cm <sup>2</sup>	1003	0.8	0.26	0.5 to 1.1	0.91
Overall mean MVA cm <sup>2</sup> (female)	700	0.8	0.17	0.5 to1.5	
Overall mean MVA cm <sup>2</sup> (male)	303	0.8	0.41	0.5 to 1.1	
Pre-PTMC mean RV systolic pressure	614	66.84	24.53	20 to160	
Mean PASP (pre)	544	67.02	23.85	20 to160	
Mean LASP (pre)	798	37.97	10.33	10 to 48	
Mean LA -LV PG (pre)	268	18.84	7.89	5 to 46	
Mean PCWP (pre)	87	31.36	8.65	16 to 48	
Mean post PTMC MVA	1003	1.83	0.28	1.3 to 3.2	
Mean post PTMC PASP	544	41.29	14.16	20 to80	
Mean post PTMC LASP	529	22.04	8.68	10 to84	
Mean post PTMC LA-LV PG	261	2.2	4.08	0 to 26	

Post PTMC mean PAPS was  $41.29 \pm 14.16$ , (Table: 2). A total of 235 complications (175 in females and 60 in males), occurred in 153 patients, (females: 120 (17.14%) and male: 33, (10.81%). Mitral Regurgitation (66, mild: 42, moderate: 18 and severe: 6), Atrial Fibrillation (27), Cardiac Tamponade (19), and CVA (16) were among the most common complications. Unsuccessful septal puncture, failure to cross mitral valve, and hemodynamic instability were the main reasons of procedural.

## DISCUSSION

Since its first clinical application by Inoue and his fellows in 1984, Inoue Single Balloon ante-grade dilatation technique has gained popularity as one of the best and safe interventional approach with acceptable rate of complications in patients with severe symptomatic, especially rheumatic mitral stenosis provided valve morphology is suitable for commissurotomy and there are no contraindications for PTMC. We analyzed a data of 1003 patients who underwent percutaneous trans-venous mitral commissurotomy through right femoral vein approach except one with left femoral vein approach at our tertiary care center, from 1994 to 2010. About 69.79% were female and 30.20% were male, overall mean age in years was  $27.75 \pm 10.08$  (Male:  $26.03 \pm 9.76$  Female:  $28.50 \pm 10.13$ ). Mean age of patients with successful BMV was  $28.3 \pm 10.11$  years for female and  $25.99 \pm 9.65$  for male with a statistically significant gender difference of frequency of MS and age ( $p = < 0.0001$ ). Our 28.44% (286) patients were under 20 years of age. 62.75% were between 21-40 years of age and 83 were in the age group of 41-60, only 5 patients were above 60 years of age. Our findings were in agreement with two other studies.<sup>16,17</sup> WHO reported 67% and 75% of their study population as female and mean age in years of  $27.00 \pm 9.8$  (13-65 yrs) &  $32.05 \pm 9.0$  (7-58 yrs) respectively. In first study 27% patients and in later 11.6% patients were below 21 and 20 years of age. In later 72% patients were between 21-41 years of age and 13.2% were in age group 41-50 and only 3.2% were more than 50 years of age. The mean age reported was  $33.51 \pm 10.42$  (9-55) years. Female population reported by Sivas Subramanian was 69.4% with mean age of  $31.2 \pm 11.6$  in contradiction to mean age of patient in the developing countries the mean age reported by Western studies carried out by Feldman, Sutaria and Masakiyo were  $54 \pm 15$ ,  $59.8 \pm 12.7$  and  $53 \pm 11$  respectively, (range: Sutaria: 13-87 and for Masakiyo: 24-75), in their study groups, female population was 78% and 76.4% respectively, depicting the fact that rheumatic or non-rheumatic, mitral stenosis is more prevalent amongst female patients worldwide, however the age of onset of symptomatic MS is decades earlier in the developing Asian countries like Pakistan, India, Bangladesh and Malaysia probably due to poor sanitation and no focus on primary and secondary prophylaxis.<sup>5,18-20</sup> Disease also has more aggressive and fulminant course in developing countries as compared to developed countries where disease is well controlled and prevalence is just above zero due to improved and wide spread use of antibiotics. Most of our study population was in sinus rhythm (98%), only 20 patients had baseline atrial fibrillation (1.99%), In the above mentioned studies by Sutaria and Sarath the reported frequency of AF was in 215 patients (72%) and 12% of patients, respectively.<sup>5,13</sup> The difference in the frequency of baseline AF is probably due to younger patients in our study group when compared with Sutaria

who had more middle aged patients. Successful dilatation of critically stenosis mitral valve was achieved in 946 patients (M= 285 F= 661), with overall success rate of 94.3%, (M = 94.05% F= 94.42%). Our study population had 21 pregnant patients and valve was dilated in 20 patients, overall 22 patients (2.19%) had restenosis with previous history of CMV (11), OMV (3) and PTMC (8). Balloon dilatation with MVA  $> 1.5 \text{ cm}^2$  was achieved in 16 patients, (72.72%) of redo cases and success in first time PTMC cases was achieved in 94.80% of the patients while procedure failed or was abandoned in 57, (5.68%) patients (M= 17 F= 40). The main reasons for failure amongst these 57 patients were unsuccessful septal puncture (11 patients), failure to cross mitral valve because of distorted anatomy and very severe MS (12 patients). Cardiac Tamponade (14 patients), and tough septal puncture with inability to dilate septal puncture (6) were the other difficulties faced. Overall failure rate in other studies ranges from 1-17% (Ramin), it can result from unfavorable anatomy, for example distorted inter-atrial septum, gross LA enlargement, severe sub-valvular disease or heavy calcification, usually most of the failures occur during the early phases of operators learning curve often as a result unsuccessful trans-septal puncture or failure to position the balloon across the mitral valve correctly. Alkhalifa has reported tough septal puncture (4), failure to dilate septal puncture (2) and failure to cross mitral valve (2) patients.<sup>16,21</sup> Our success rate was in agreement with another study by Syed Dawood, who reported overall procedural success of 95% with an increase in mitral valve area from  $0.83 \pm 0.15$  to  $2.02 \pm 1.06$  ( $p = 0.0001$ ).<sup>22</sup> The peak LA systolic pressure, mean LA-LV pressure gradient and peak pulmonary artery pressures were observed to be significantly reduced from the pre-PTMC state  $26.8 \pm 6.4$  versus  $8.9 \pm 3.1$  mmHg ( $p = 0.001$ ),  $15.8 \pm 3.9$  versus  $4.0 \pm 1.5$  mm and  $60.0 \pm 21.0$  versus  $38.7 \pm 9.5$  ( $p < 0.001$ ). In his study, in-hospital death, emergency MVR and pericardial Tamponade occurred one in each. The procedural success achieved by MS Al Khalifa was 94.5%, and LA mean systolic pressure dropped from  $32 \pm 3.2$  to  $12 \pm 2.4$ , LA-LV gradient from 25 to 5 mm Hg and mean mitral valve area was increased from  $0.86 \pm 0.19$  to  $1.9 \pm 0.2$   $\text{cm}^2$  ( $p < 0.001$ ), Peak PAS pressure decreased from  $71 \pm 23$  to  $40 \pm 12$  mmHg ( $p = 0.01$ ).<sup>16</sup> He reported tough septal puncture in 4 patients, failure to cross MV and cardiac Tamponade and emergency MVR, two in each. There was no procedure related CVA or death in his study. In comparison with these two above mentioned studies, our study population showed mean increase in mitral valve area from  $0.80 \pm 0.26 \text{ cm}^2$  to  $1.83 \pm 0.28 \text{ cm}^2$  (Range: 1.3-3.2  $\text{cm}^2$ ), mean drop in LA systolic pressure was from  $37.97 \pm 10.33$  to  $22.04 \pm 8.68$ , mean drop LA-LV diastolic mitral valve gradient from  $18.84 \pm 7.89$  to  $2.12 \pm 4.08$  mm of Hg, mean right ventricular systolic pressure dropped from  $66.84 \pm 24.53$  to  $41.29 \pm 14.16$  mm of Hg. A total of 235 complications occurred in 153 patients (120: (17.14%) females and 33: (10.81%) males), complications were more frequent among females and middle aged patients,  $p < 0.118$  and  $< 0.0001$  respectively. In our catheterization lab, moderate to severe mitral regurgitation occurred in 18 and six patients respectively. Tear in AML occurred in 9 patients, emergency MVR and other cardiac surgery were needed in twenty (1.99%) patients. Cardiac Tamponade, CVA, and in hospital death occurred in 19, 16 and 3 patients respectively; one due to massive cerebral embolism and two due

to cardiac perforation after cardiac surgery. Our 3 patients with redo BMV had residual ASD. PFO was found in 6 patients. The reported frequency of severe mitral regurgitation by others is 24-26 surgical finding suggested its relation with non-commissural tearing of the posterior and anterior mitral leaflets.<sup>26</sup> The reported incidence of cardiac Tamponade is 0.5 to 12%.<sup>21</sup> The procedural mortality and frequency of embolic events occurred in 0 to 3% and 0.5-5.0% respectively, and can cause permanent disability or death.<sup>21</sup> Our complication rate was quite similar to many of the above mentioned studies. We also faced many other difficulties but still had high success rate and found the procedure cost effective and practicable in experienced hands.

## CONCLUSION

Balloon mitral valvuloplasty is a safe procedure for management of patients suffering from severe to very severe mitral stenosis. Trans-septal puncture and crossing mitral valve are the most crucial steps for performing PTMC as the distorted septal anatomy, valve morphology and inexperience could lead to technical difficulties and increases risk of serious complications.

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