ORIGINAL ARTICLE

PREVENTIVE STRATEGIES TO FIGHT COMPLICATIONS DURING PERCUTANEOUS MULTITRACK BALLOON VALVOTOMY "REFINING THE TECHNIQUE"

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Background: Percutaneous mitral valvuloplasty (PMV) is still the treatment of choice in selected cases of mitral stenosis (MS). Multitrack balloon (MTB) catheter is one of the techniques used for PMV with optimal results. We describe a novel refinement of appropriate balloon sizing and wire placement to reduce mitral regurgitation (MR) and Left ventricular (LV) apical perforation, respectively. **Methods:** Ninety four consecutive patients with moderate to severe rheumatic mitral stenosis (MS) were selected for PMV with MTB catheter. Balloon sizing was done by effective balloon dilatation area (EBDA), using standard geometric formula. 0.35″ PMV wire was placed in aortic arch /ascending aorta (AA) to avoid LV apical perforation. **Results:** Mild MR was present in 28 (29.8%). Post-procedure MR was present in 50 (53.2%). Out of 50 MR cases 44(88%) had mild and 6 (12.0%) had moderate MR. No patient had severe MR. With placement of wire in AA and arch of aorta none of the patients developed complication of LV apical perforation. **Conclusion:** EDBA as balloon sizing for multitrack system can be used to reduce severity of mitral regurgitation. Placement of PMV guide wire in Aortic arch/AA ascending aorta can eliminate/substantially reduce dreadful complication of LV perforation.

Keywords: Multitrack Balloon Catheter, Balloon Sizing, PMV Guide Wire

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INTRODUCTION

Rheumatic heart disease (RHD) is still the most common cardiovascular disease in children and young adults.[1] In Pakistan RHD is one of the leading causes of premature death and disability.[2] In a large epidemiological study, mitral stenosis (MS) was the commonest lesion among patients with RHD.[3] Similar trend was shown in other local studies.[4,5]

Percutaneous mitral valvuloplasty (PMV) is treatment of choice in symptomatic patients with moderate to severe MS and acceptable valve morphology. Worldwide three techniques are used for PMV: Inoue, Metallic valvotome, and Multitrack balloon (MTB). The majority of centres in Pakistan use Inoue technique.[4] Experience at our centre, using these three techniques of PMV has been published.[6] The advantage of low incidence of perforation in Inoue technique as compared to MTB is compromised by higher balloon cost. Thus, due to high cost with Inoue balloon, >95% of cases at our centre are being done with MTB.

Bonhoeffer *et al*[7] in 1999, reported the technique of PMV with the Multi-Track System. Adapting the original (Bonhoeffer) technique, MTB was introduced at our Institute in 2001. However, we encountered numerous patients of severe iatrogenic MR and life threatening guide wire induced haemopericardium, due to LV apical perforation with MTB. Similar complications were reported by Bonhoeffer.[7]

With intention to reduce these complications, we modified the Bonhoeffer technique by refining the methodology of balloon sizing[8] and placement of PMV guide wire in arch/ascending aorta.

MATERIAL AND METHODS

This single centre descriptive case series study was conducted in National Institute of Cardiovascular Diseases, Karachi, from January to September 2011. Ninety four symptomatic patients as per New York Heart Association (NYHA) functional classification NYHA III/IV) with moderate to severe Rheumatic MS were selected by consecutive non-probability sampling technique for PMV.

Patients with moderate to severe MR, Wilkonsons score >8 were excluded. Informed consent was taken and the study was approved by the ethical committee of the institute. PMV was performed by Multitrack technique after atrial septal puncture as previously described[6] except for the balloon selection and guide wire parking. Left atrial (LA), right ventricle and pulmonary artery pressures were measured before and immediately after PMV. Pre and post procedure, Mitral valve (MV) area and MR were graded by Echocardiography.

The Multitrack balloon sizing was done by EBDA by using standard geometric formula, derived and published by Roth *et al*[8]. The expected normal Mitral area (ENMA) for any individual was calculated by multiplying Body surface area (BSA) with a constant 2.8cm^2. Mitral Valve annular areas increase linearly in relation to body size[9] 2.8cm^2 is the minimal mitral annular area derived from table-2, i.e., 3.149-0.283 cm^2. The appropriate pair of balloon was selected by matching the ENMA with the EBDA[8] (Table-1). For example if the ENMA is 4.02, pair of balloon sizing will be selected as 14, 16.

6F" end hole flow directed (FD) balloon Catheter was pushed across the mitral valve and was then made to loop at the LV apex into aorta. The 0.035″ stiff guide-wire with 6 cm floppy J-Tip was positioned through FD balloon and placed in the Ascending aorta or descending aorta. Balloon was then deflated and pulled out carefully taking care that the tip of the wire remained parked in the AA or descending aorta. The remaining procedure was the same as described[7] (Figure-1). Special safety measures were taken, particularly during crossing of MV and placement of guide wire. Prevention of transchordeal passage of the FD balloon was accomplished by strict measures like FD balloon was always inflated in the LA prior to crossing the MV. If resistance was encountered in free movement of FD balloon at the LV inflow, it was deflated and pulled back into LA and procedure repeated. Similarly if after crossing the MV, any distortion of the balloon shape was noticed, it was deflated and the manoeuvre was repeated. To avoid trauma of MV and LV apical perforation, the stiff PMV was pushed across the MV and aortic valve only when the FD balloon position was secured in the aorta. Stiff PMV guide wire was always parked in the AA/descending aorta through FD. In some cases it was difficult to loop FD balloon into LV. 0.032″ diagnostic guide wire support was used to cross the aortic valve. This was done by making an inverted j loop which is passed in the flow guided catheter to make a loop at the apex. Care is taken that the wire and remains within the catheter tip. The tip of the catheter is advanced with gentle pull back of the hard wire and as the catheter advances in the ascending and arch of the aorta the guide wire is pulled back.

SPSS-17 was used for data analysis. Frequencies and percentages were calculated for categorical variables and mean±SD were calculated for quantitative variables. To observe pre and post differences among quantitative variables paired *t*-test was used. For the same differences in the case of categorical variables, McNemars and Marginal homogeneity tests were applied respectively where applicable. Level of significance was set at $p \leq 0.05$ in all significance testing.

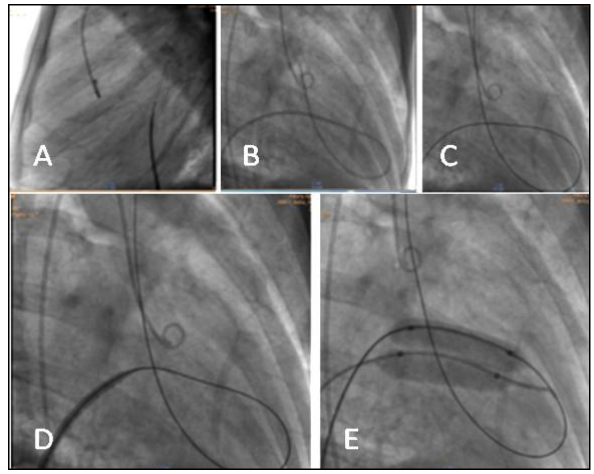

Figure-1: (a). Percutaneous mitral valvuloplasty (PMV) with multitrack balloon catheter.
(A) Atrial Septal Puncture **(B)** Inflated end-hole catheter looped in left ventricular outflow track. **(C)** PMV guide wire placed in ascending aorta. **(D)** Septal dilatation with 14 Fr. dilator. **(E)** Multitrack balloon inflation on apical wire preventing the tip of catheter away from left ventricular apex.

Table-1: Effective balloon dilating area*

Balloon Sizes	14	16	18	20
4	3.52	4.02	4.60	5.23
16	4.02	4.57	5.16	5.82
18	4.60	5.16	5.78	6.45
20	5.23	5.82	6.46	7.14

*Numbers shown in the table for the locally available balloon sizes were derived by modification of the Figure-2 Roth *et al*[4]

RESULTS

The demographics and baseline information of 94 patients included in the study are given in table-2. There were 26 (27.7%) males and 68 (72.3%) females. The mean age of the patient was 27.81±8.51 years. Pre-procedure mitral and tricuspid regurgitation was observed in 28 (29.8%) and 68 (72.3%) patients respectively. Comparing the pre and post procedure, statistically significant ($p<0.001$) increase in Mean MV area and marked reduction in Right Ventricular Systolic Pressure (RVSP) and gradient across the MV was observed (Table-3).

Pre-procedure MR was observed in 28 (29.8%) and Post procedure additional 22 patients developed MR and overall post-procedure MR was observed in 50 (53.2%). Out of 50 cases of Post procedure MR, 44 (88.0%) patients had mild and 6 (12.0%) had moderate MR. None of the patient had severe MR (Table-3). On applying McNemar test on pre and post procedure MR statistically significant difference ($p<0.001$) was observed.

Post procedure frequency of MR and its severity is shown in table-3. Post procedure tricuspid regurgitation (TR) was observed in 62 (66.0%) patients whereas in the case of pre procedure it was found in 68 (72.3%) as shown in table-3. On applying McNemar and marginal homogeneity test the difference in pre procedure TR and its severity was statistically not significant (p>0.05).

Table-2: Demographic characteristics

Variables	N (%)
Gender	
Male	26 (27.7)
Female	68 (72.3)
Age in years (Mean±SD)	27.81±8.50
Height in cm (Mean ± SD)	152.89±7.39
Weight in Kg (Mean ± SD)	48.79±9.58
BMI (Mean ± SD)	20.87±3.91
Body Surface Area in m^2 (Mean±SD)	1.43±0.16
***Annulus Size in cm^2 (Mean±SD)**	3.149±0.283
Wilcons Score (Mean±SD)	6.43±0.97
Left Atrial Pressure mmHg (Mean±SD)	46.74±9.35
Left ventricular ejection fraction (%)	61.79±11.93
Mean Pressure Gradient in mm Hg (Mean±SD)	17.11±4.91
Sinus rhythm	80 (85.1)
Atrial fibrillation	14 (14.9)
Aortic stenosis	4 (28.6)
Aortic regurgitation	4 (57.1)
Aortic stenosis & regurgitation	2 (14.3)
Tricuspid Regurgitation (Pre)	68 (72.3)
Mitral Regurgitation (Pre)	28 (29.8)

Table-3: Comparison of pre and post-dilatation characteristics

Variables	Pre	Post	*p*
Mitral valve area Mean±SD cm^2	0.94±0.11	1.763±0.216	<0.001[a]
MPG [d] Mean±SD (mmHg)	217.11±4.91	6.297±2.65	<0.001[a]
RVSP [e] Mean±SD	61.04±16.35	30.13±13.95	<0.001[a]
Tricuspid Regurgitation	68 (72.3)	62 (66.0)	<0.007[b]
Severity of TR Mild	42 (61.8)	40 (64.5)	<0.007[c]
Moderate	20 (29.0)	18(29)	
Severe	6 (8.8)	4 (6.5)	
Total	68	62	
Mitral Regurgitation	28 (29.8)	50 (53.2)	<0.001[b]
Severity of MR Mild	28 (100)	44 (88.0)	<0.001[b]
Moderate	0 (0)	6(12.0)	
Severe	0 (0)	0 (0)	
Total	28	50	

a. Paired *t*-Test, b. McNemar Test. c. Marginal Homogeneity Test, d. Mean Pressure Gradient, e. Right Ventricular Systolic Pressure

DISCUSSION

Severe mitral regurgitation is a potential complication of PMV and is due to tearing of mitral leaflets or rupture of chordate.[10] The frequency of severe MR ranges from 2 to 19% in different series.[11] Post procedure in our study only mild to moderate MR was observed (Table-3). PMV with multitrack system in the Egyptian study was shown to have an immediate increase in grade of MR as compare to other techniques.[12]

In our study overall mild to moderate mitral regurgitation was observed in 53.2% of patients and none developed severe MR. The decrease in severity is probably due to two reasons. Firstly, the size of balloon selected according to effective balloon dilatation area (Table-1) and secondly, care was taken that the flow directed catheter passed through the mitral orifice with balloon inflated to avoid transchordal passage and subsequent trauma to sub-valvular mitral apparatus.

Haemopericardium was reported in the Egyptian series due to transeptal puncture and wire perforation of left ventricle apex.[12] Wire perforation with MTB at left ventricle apex was also observed in our centre in a few cases (unpublished data). With the placement of wire in the arch of aorta no perforation was observed. The reason for apical perforation was found to be the exchange catheter which when inflated the tip of the catheter get erected and cause trauma to left ventricular apex. With the wire placed in the ascending aorta the tip of the catheter was prevented by the stretched loop of the wire at the apex and thus this complication can be avoided.

Cost of the procedure is a major issue for treatment of mitral stenosis as this disease is endemic in low socioeconomic groups.[7] The major problem with inoue balloon is difficulty in sterilization.[11] Multitrack catheter system can be reused after re-sterilization with ethylene oxide[7] and for the same reasons is been followed in this centre.

The limitation of the study was that this was a single centre study with this technique. All other centres in the country use inoue technique.

CONCLUSION

In conclusion we think that balloon sizing with EBDA for Multitrack system can be used to avoid severe iatrogenic Mitral Regurgitation and secondly placement of wire in the ascending aorta/aortic arch can prevent dreadful complications of apical ventricular rupture.

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