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Predictors of Complications during Percutaneous Multitrack Balloon Mitral Valvuloplasty

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Abstract

Background: Percutaneous mitral balloon valvuloplasty is the main procedure in mitral stenosis (MS). It can replace surgical commissurotomy in many cases; however, mitral regurgitation (MR) remains the major procedure complication. **Objectives:** This study was conducted to investigate predictors of MR as a complication following percutaneous mitral valvuloplasty (PMV) using multitrack balloon technique. **Methods:** This cohort study was conducted at both Menoufia University Hospital and Mabaret Misr Elkadima Hospital. We enrolled 121 patients with moderate to severe MS who were subjected to PMV using multitrack balloon technique during the period from October 2017 to October 2019. Transthoracic echocardiographic evaluation was performed for all patients before and after the procedure. Patients who developed severe MR post procedure were compared with other patients to identify important distinction points. **Results:** Most patients (N = 109, 90.1%) developed no/mild MR (group A), whereas 12 (9.9%) patients developed severe MR (group B) after PMV. Those who developed severe MR had significantly higher weight, height, body mass index, and body surface area (P value < 0.001 for each). Also, there was a significant difference between both groups regarding pre-operative Wilkins score (8.7 ± 1.3 for severe MR versus 7.9 ± 1.2 for No/Mild MR, P = 0.046). Patients who developed severe MR had higher incidence of other valvular lesions such as mild aortic regurgitation (91.7% versus 36.7%, P < 0.001), higher mitral valve (MV) commissural calcification (50.0% versus 14.7%, P = 0.008), pre-operative MR (100.0% versus 35.8%, P < 0.001), higher prevalence of atrial fibrillation (100.0% versus 38.5%, P < 0.001). Regarding balloon sizing, it was significantly higher among patients who developed severe MR compared with those having mild or no MR (P = 0.001). Multivariate regression analysis identified MV balloon sizing

(OR 3.877, CI 95% 1.131 - 13.289, P = 0.031) and MV commissural asymmetry of calcification (OR 67.48, CI 95% 5.759 - 790.72, P = 0.001) as significant predictors of outcomes of MV commissurotomy. **Conclusion:** Mitral valve calcification, balloon sizing, and MV asymmetry are significant factors that can predict the development of MR after balloon valvuloplasty.

Keywords

Mitral Stenosis, Mitral Regurgitation, Multitrack Balloon Mitral Valvuloplasty

1. Introduction

Mitral stenosis (MS) is characterized by a decrease in mitral valve (MV) orifice area leading to compromised left ventricular filling. The consequence is blood stagnation proximal to MV leading to elevated left atrial, pulmonary venous, and pulmonary artery pressures [1].

Mitral stenosis usually occurs decades after the occurrence of rheumatic fever [2]. However, in developed countries, calcific changes of the mitral annulus can induce degenerative MS in a sizeable proportion of patients, especially in the elderly [3].

Before the appearance of percutaneous therapy, the treatment of MS included open or closed commissurotomy and replacement with biological or mechanical prostheses. Later, the development of percutaneous devices allowed percutaneous mitral valvuloplasty (PMV) to emerge; beginning in the 1980s, not only as a valid alternative to surgery but also the procedure of choice for all MS patients with favorable valve anatomy. Percutaneous mitral valvuloplasty is a safe and cheap procedure that does not require general anesthesia. It is not a contraindication for subsequent surgical valvuloplasty or valve replacement, and it does not require permanent anticoagulant therapy [4].

Despite the considerably high success rates and low complication rates in both short- and long-term follow-ups, mitral regurgitation (MR) remains the commonest procedure-related complication [5]. This complication is usually mild and well tolerated. Even in a few patients, the severity of MR has been reported to be decreased [6]. However, severe MR requiring valve replacement may be seen [7] [8].

Although the development of MR after valvuloplasty is frequently seen, the determinant factors of severe MR have not been adequately studied. Given that, this study was designed to investigate the predictors of severe MR as a complication following percutaneous multitrack balloon mitral valvuloplasty.

2. Patients and Methods

This cohort study was conducted at both Menoufia University Hospital and Mabaret Misr Elkadima Hospital.

We enrolled a convenient sample of 121 patients with MS who were subjected to PMV using multitrack balloon technique during the period from October 2017 to October 2019. We included patients (males and females) with severe MS who had suitable mitral valve morphology and symmetric commissural morphology. Patients with left atrial thrombi, moderate to severe MR, severe calcification of commissures, and high echocardiographic scores were excluded from the study.

The included patients were divided into 2 groups according to the resultant MR. Group A included patients with no or mild mitral regurgitation, while Group B enrolled patients with severe mitral regurgitation. All patients were subjected to full history taking, through clinical examination, and transthoracic echocardiography before and after balloon commissurotomy.

We reported several variables including demographic (such as age, weight, height, BMI, and BSA), clinical, echocardiographic and catheterization data (such as right and left heart pressures, end-diastolic and end-systolic volumes, cardiac ejection fraction, valve morphology and calcifications, Wilkins score, MR severity, Balloon sizing, and the development of atrial fibrillation).

The severity of MR was based on the following criteria: regurgitation volume > 60 ml and vena contracta > 7 mm.

Before starting the research, we got ethical approval from Menoufia University Ethics Committee. An informed written consent was obtained from each patient before enrollment into the study.

Data were collected and analyzed using the Statistical Package for Social Sciences program, version 18 (Chicago, Inc, Illinois. Quantitative data were presented as means and standard deviation (SD). Qualitative data were expressed as frequency and percent (%). Independent sample t-test was done to measure association between 2 quantitative variables. P value < 0.05 was considered statistically significant.

3. Results

This study enrolled 121 patients; 71 females (58.7%) and 50 males (41.3%), and their mean age was 35.2 ± 9.7 years-old. We divided our patients into 2 groups according to the resultant MR post-commissurotomy; patients with no or mild MR (group A, N = 109) and those with severe MR (group B, N = 12). Their basic data are demonstrated in **Table 1**. Left ventricular ejection fraction (EF) was 69.9 ± 4.6%. Mitral valve annulus area was measured through planimetry (35.6 ± 2.3 mm^2) with Wilkins score 8.0 ± 1.2.

Transthoracic echocardiographic evaluation showed significant reductions of gradient pressure; right ventricular systolic pressure (RVSP) and left atrium (LA) pressure means (P < 0.001 for each) after MV commissurotomy (**Table 2**).

Regarding post-commissurotomy MR, 12 (9.9%) patients developed severe MR. They were compared with other patients to identify important distinction points. Sever MR group showed significantly higher weight, height, body mass

Table 1. Demographic and clinical data of the studied patients.

Parameters of comparison	Mean ± SD	Range
Age	35.2 ± 9.7	17.0 - 61.0
Weight (kg)	74.2 ± 7.3	60.0 - 90.0
Height (cm)	167.5 ± 5.7	155.0 - 179.0
BMI	33.1 ± 6.2	22.2 - 47.6
BSA	1.8 ± 0.1	1.6 - 2.1
LVESD	3.1 ± 0.5	2.2 - 4.1
LVED	4.4 ± 0.6	3.5 - 5.5
LA	5.3 ± 0.3	4.7 - 6.0
Ao	3.2 ± 0.5	2.5 - 4.0
EF%	69.6 ± 4.6	62.0 - 79.0
MV annulus	35.6 ± 2.3	30.0 - 40.0
Wilkins score	8.0 ± 1.2	5.0 - 10.0
Diastolic Mean Pressure Gradient	9.6 ± 2.3	5.0 - 16.0
RVSP	35.3 ± 3.2	26.0 - 42.0
Mean LA pressure	12.7 ± 2.6	9.0 - 18.0
Mean LV pressure	105.5 ± 10.6	90.0 - 132.0

BMI: Body mass index, BSA: Body surface area, LVES: Left Ventricular End Systolic, LVED: Left Ventricular End diastolic, LA: left atrium, LV: left ventricle, RVSP: right ventricular systolic pressure, EF: ejection fraction, Ao: aortic Dicemeter.

Table 2. Cardiac chamber pressures before and after mitral commissurotomy.

	Before commissurotomy		After commissurotomy		P value
	Mean	SD	Mean	SD	
Mean diastolic Pressure Gradient across MV (mmHg)	9.6	2.3	6.4	1.5	<0.001
RVSP (mmHg)	35.3	3.2	23.8	3.3	<0.001
LA pressure Mean (mmHg)	12.7	2.6	6.3	1.8	<0.001
LV pressure Mean (mmHg)	105.5	10.6	128.0	7.1	<0.001

LA: left atrium, LV: left ventricle, RVSP: right ventricular systolic pressure.

index (BMI), and body surface area (BSA) ($P < 0.001$ for each) without significant differences regarding age and sex ($P = 0.383$ and 0.394, respectively). Also, there was significant differences between both groups regarding pre-operative Wilkins score (8.7 ± 1.3 for severe MR versus 7.9 ± 1.2 for No/Mild MR, $P = 0.046$), RVSP (37.3 ± 2.0 for severe MR versus 35.0 ± 3.2, $P = 0.002$), and MV balloon size (17.3 ± 1.0 for severe MR versus 16.5 ± 0.8 for No/Mild MR, $P = 0.001$). Pre-operative transthoracic echocardiography also showed that patients who developed severe MR had higher incidence of other valvular lesions, such as mild aortic regurgitation (91.7% versus 36.7%, P < 0.001), higher MV commissural calcification (50.0% versus 14.7%, P = 0.008), pre-operative MR (100.0% versus 35.8%, P < 0.001), higher prevalence of atrial fibrillation (AF) (100.0% versus 38.5%, P < 0.001) (Table 3).

Univariate regression was performed in this study to identify possible factors that could predict outcome of MV commissurotomy. It revealed that BMI, EF, MV commissural calcification, MV commissural asymmetry, and MV balloon size were significantly able to predict the development of severe MR (P = 0.045, 0.029, 0.006, <0.001, 0.004, respectively) (Table 4).

Multivariate regression analysis identified MV balloon sizing (OR 3.877, CI 95% 1.131 - 13.289, P = 0.031) and MV commissural asymmetry (OR 67.48, CI 95% 5.759 - 790.72, P = 0.001) as significant predictors of outcomes of MV commissurotomy (Table 5).

Table 3. Comparison of demographic and echocardiographic data of both groups of MR.

	No or mild MR		Severe MR		P value
	Mean	SD	Mean	SD	
Age	35.3	10.1	34.1	3.6	0.383
Gender (male)	46 (42.2%)		4 (33.3%)		0.394
Weight (kg)	73.6	7.5	79.7	0.9	<0.001
Height (cm)	166.9	5.4	173.7	4.9	<0.001
BMI	32.7	6.4	36.6	0.7	<0.001
BSA	1.8	0.1	2.0	0.0	<0.001
EF%	69.3	4.1	72.4	7.3	0.176
MV annulus	35.5	2.3	35.9	3.2	0.690
Wilkins score	7.9	1.2	8.7	1.3	0.046
Mean Pressure Gradient (mmHg)	9.7	2.4	9.6	1.6	0.924
RVSP (mmHg)	35.0	3.2	37.3	2.0	0.002
LA pressure Mean (mmHg)	12.7	2.6	13.2	2.6	0.532
LV pressure Mean (mmHg)	105.6	10.4	105.2	13.2	0.900
Balloon sizing (mm)	16.5	0.8	17.3	1.0	0.001
MV Annulus (mm)	35.7	2.7	36.1	3.4	0.655
RVSP (mmHg)	23.6	3.3	26.2	2.3	0.009
LA pressure Mean (mmHg)	6.3	1.8	6.6	1.7	0.636
LV pressure Mean (mmHg)	127.8	7.4	130.0	2.8	0.043
Mild AR	40 (36.7%)		11 (91.7%)		<0.001
MV commissural calcification	16 (14.7%)		6 (50.0%)		0.008
MV asymmetry	8	(7.3%)	9	(75.0%)	0.227
Mild MR	39	(35.8%)	12	(100.0%)	<0.001
AF	42	(38.5%)	12	(100.0%)	<0.001

BMI: Body mass index, BSA: Body surface area, LVES: Left Ventricular End Systolic, LVED: Left Ventricular End diastolic, LA: left atrium, LV: left ventricle, RVSP: right ventricular systolic pressure, EF: ejection fraction. AR: aortic regurgitation, MR: mitral regurgitation, AF: atrial fibrillation, MV: mitral valve.

Table 4. Univariate regression for predicting severe MR post commissurotomy.

	Exp (B)	P value	95% C.I. for EXP (B)	
BMI	1.108	0.045	1.002	1.224
EF	1.16	0.029	1.015	1.326
Wilkins score	1.785	0.052	0.996	3.200
MV commissures calcifications	5.812	0.006	1.666	20.283
MV commissures asymmetricity of calcification	37.875	<0.001	8.520	168.361
MR	4.97E+08	0.997	0	
Balloon sizing	2.592	0.004	1.366	4.918

BMI: Body mass index, EF: ejection fraction, MV: mitral valve, MR: Mitral regurgitation.

Table 5. Multivariate regression for predicting severe MR post commissurotomy.

	Exp (B)	P value	95% C.I. for EXP (B)	
Balloon sizing	3.877	0.031	1.131	13.289
BMI	1.159	0.208	0.921	1.459
EF	1.135	0.173	0.946	1.363
MV commissures calcifications	1.574	0.715	0.138	17.889
MV commissures asymmetricity	67.48	0.001	5.759	790.72

BMI: Body mass index, EF: ejection fraction, MV: mitral valve.

Receiver operating characteristic analysis was also done to determine possible MV balloon size that can be associated with possibility of severe MR post-commissurotomy. It showed that size of ≥17 had sensitivity of 66.7% and specificity of 77.1% with area under the curve (AUC) of 0.719.

4. Discussion

The results of the current study showed that multitrack balloon technique can significantly improve MS as proved by significant reduction of the means of gradient pressure, RVSP, and LA pressure. Actually, PMV is an effective procedure for MS with any of its technique either by Inoue balloon, metallic commissurotome, or multitrack double balloon as reported by Sharieff *et al.* [9], Sherif *et al.* [10], Sowdagar and Subba [11], Alkhouly *et al.* [12].

The second outcome of this study is that the twelve patients who developed severe MR had significantly higher weight, height, BMI, and BSA. Higher incidence (13.3%) of severe MR was observed by Elsawy *et al.* [13]. However, in the study of Sadaka *et al.* [14], no one developed severe MR even after follow up for 3 months. Actually, Sherif *et al.* [10] noticed that Multi-Track technique of PMV can result in immediate increase in the grade of MR more than other techniques of PMV. Farman *et al.* [15] reported that 8.1% of 258 patients who performed PMV developed MR (more than mild degree). However, these patients had less weight, height, and BSA compared with other patients, in contrast to the current results. In fact, the annular dimensions of the mitral valve have been reported to increase linearly with body surface area. [16] This is probably the reason for the tendency of using a more aggressive approach as the use of a bigger balloon that was significantly correlated with the outcome of severe MR as will be demonstrated later in this study.

Also, in this study, there was a significant difference between the both groups regarding pre-operative Wilkins score. Similarly, Elasfar and Elsokkary [17] noticed a significant higher Wilkins score among patients with severe MR compared to patients without severe MR. Zhang *et al.* [18] reported patients with lower echocardiographic scores as Wilkins score benefit more from percutaneous balloon mitral valvuloplasty than patients with higher scores. In contrast, Paiva *et al.* [19] noticed none significant differences between patients with score 9 - 11 and patients with score < 8 regarding major complication or success rate.

Pre-operative transthoracic echocardiography also showed that patients who developed severe MR had higher incidence of other valvular lesions, MV commissural calcification, pre-operative MR, and higher prevalence of AF. The study of Sharma *et al.* [20] delineated that AF, higher functional class, and worse valve morphology were independent predictors of a poor balloon MV outcome. Regarding pre-operative MR, Palacios *et al.* [21] identified MR that is ≥2+ to be associated with worse outcome of PMV.

Regarding balloon sizing, it was significantly higher among patients who developed severe MR compared with patients with mild or no MR. Tastan *et al.* [22] studied 2 groups of patients undergoing percutaneous balloon mitral valvuloplasty. One group was subjected to conventional height-based balloon reference sizing (the HBRS group) and the other was assigned to balloon sized by echocardiographic measurement of the diastolic inter-commissural diameter (the EBRS group). They noticed that the mean of the calculated balloon reference sizes was significantly higher in the HBRS than in the EBRS group and MR > 2+ was less in the EBRS group.

Univariate regression analysis revealed that BMI, EF, MV commissural calcification, MV commissural asymmetry, and MV balloon size were significant predictors of the development of severe MR. In the study of Aslanabadi *et al.* [23], patients with increased MR post procedure had a significantly higher calcification score before the procedure compared to other patients. In contrast, Dreyfus *et al.* [24] reported that the rate of post-PMC mitral regurgitation of grade ≥ 3 was not different among different groups of mitral calcification.

In the current study, multivariate regression analysis identified MV balloon sizing and MV commissural asymmetry as significant predictors of outcome of MV commissurotomy. Receiver operating characteristic analysis also showed that the size of ≥17 had a sensitivity of 66.7% and specificity of 77.1% with AUC of 0.719. Farman *et al.* [15] reported that there was significant difference between patients with successful and unsuccessful (more than mild MR) PMV regarding balloon size, and the size of 14 × 16-mm was the most successful.

To the best of our knowledge, this study is the first to shed light on predictors of severe MR after multitrack PMV.

5. Study Limitations

The most important limitations of the current study were the relatively small sample size and the absence of long-term follow-up data for those patients.

6. Conclusion

In this study, we identified several factors that can predict the development of severe MR after multitrack PMV including MV calcification, balloon sizing, and MV asymmetry.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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