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RESEARCH ARTICLE

Comparison of short-term clinical outcome between first time and redo percutaneous mitral balloon valvuloplasty at patients with severe rheumatic mitral valve stenosis.

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Abstract: ***Background***: Patients with symptomatic severe rheumatic mitral valve stenosis may benefit from percutaneous mitral balloon valvuloplasty (PMV) rather than open or closed surgical mitral commissurotomy. Although the success of this procedure in treatment of severe mitral stenosis, the recurrence of stenosis is common and the PMV becomes more complicated, so the outcome of redo PMV is needed to be studied in comparison of PMV for the first time. ***Aim of the Work:*** To compare between the short-term clinical outcome after percutaneous mitral balloon valvuloplasty (PMV) for the first time in the patients of severe rheumatic mitral stenosis and the short-term clinical outcome after redo percutaneous mitral balloon valvuloplasty (PMV) for the patients of severe mitral valve re-stenosis. ***Patients and Methods:*** This study is a prospective cohort study included 102 patients who were divided into two groups: group A (51 patients) who undergone percutaneous mitral balloon valvuloplasty (PMV) for the first time and group B (51 patients) who undergone percutaneous mitral balloon valvuloplasty (PMV) for the second time due to recurrent severe mitral stenosis. All patients were followed up after the procedure for immediate postprocedural complications and for thirty days after hospital discharge then the outcome was compared between the two groups. ***Results:*** The most common co-morbidities between the studied patients were past history of rheumatic fever (70.6%) and atrial fibrillation rhythm (53.9%). The results of this ` revealed an increase of immediate procedural complications such as cardiac arrest, vascular access complications, severe mitral regurge development and pericardial tamponade in the redo PMV procedure more than PMV for the first time. The number of successful PMV procedures was higher at the first time (74.5%) than the redo (43%). High commissural score assessed by 3D transesophageal echocardiography and Wilkin score were associated with failed cases in both groups of PMV. ***Conclusion:*** The current study supported that despite similar improvement in valve area in primary PMV and redo procedure, the incidence of severe mitral regurgitation, tamponade, vascular access complications and arrhythmias was higher in the redo cases more than cases of primary PMV.

Keywords: first time procedure, redo percutaneous mitral balloon valvuloplasty, mitral valve stenosis.

INTRODUCTION

According to current European and American guidelines, percutaneous mitral balloon valvuloplasty (PMV) is recommended for patients with severe rheumatic mitral stenosis (mitral valve area (MVA) ≤ 1.5 cm2) who are symptomatic (NYHA II, III, or IV), have appropriate valve morphology, and do not have any contraindications, such as left atrial thrombus or moderate or severe mitral regurgitation (MR) [1]. A 50% or greater increase in MVA and a final MVA of at least 1.5 cm² without significant problems were considered successful mitral valve dilatation. Any of the following were considered major complications: cerebrovascular stroke, cardiac tamponade, grade II/IV MR, or periprocedural mortality [2]. Restenosis of the mitral valve, which is defined as mitral valve area (MVA) becoming less than 1.5 cm2 following successful immediate results of PMV, is a time-dependent process caused by progressive inflammatory activity or tissue degeneration and has been linked to poor long-term functional results [3]. In order to determine whether surgery or a second trial of intervention is the best option for treating mitral valve restenosis, the results of the redo PMV procedure are examined in this study and compared with the results of the first PMV procedure. This is because the second PMV procedure in the sitting of restenosis is typically challenging and extremely complex due to aggressive fibrosis and adhesions following the first balloon inflation [4].

AIM OF THE STUDY

To compare between the short-term clinical outcome after percutaneous mitral balloon valvuloplasty (PMV) for the first time in the patients of severe rheumatic mitral stenosis and the short-term clinical outcome after redo percutaneous mitral balloon valvuloplasty (PMV) for the patients of severe mitral valve re-stenosis.

Primary outcome: The immediate postprocedural complications including vascular access complications as (local hematoma at the site of puncture, arterio-venous fistula), hemo-pericardial tamponade, cardiac arrest, severe mitral regurge and systemic embolization.

Secondary outcome: Occurrence adverse clinical events within thirty days after hospital discharge which included: heart failure (HF), atrial arrhythmias (atrial tachycardia, atrial flutter and atrial fibrillation) and all-cause mortality which included both cardiac and non-cardiac death.

MATERIALS AND METHODS

Patient selection

This study is a comparative prospective clinical study that is conducted on patients with severe symptomatic mitral valve stenosis fulfilling the inclusion criteria and divided into two groups the first group of population was undergone first-time PMV and the second group of population was undergone redo PMV for severe rheumatic mitral valve restenosis.

Inclusion criteria

All patients were more than 18 years old, had symptomatic (NYHA II, III or IV) moderate to severe mitral stenosis MVA ≤1.5 cm^2 with favorable valve morphology according to Wilkins score less than 11 and commissural score less than 4.

The second group of population who undergone redo percutaneous mitral balloon valvuloplasty should have history of previous successful percutaneous mitral balloon valvuloplasty then developed MVA less than 1.5 cm^2.

Exclusion criteria

Patients with MVA >1.5 cm^2 left atrial appendage thrombus, more than mild mitral regurgitation, severe or bi-commissural calcification, absence of commissural fusion, severe concomitant other valve disease requiring surgery, or concomitant coronary artery disease requiring bypass surgery were not allowed to participate in the study.

Methodology

Medical history and demographic data were taken from all patients including age, rheumatic fever, history of long-acting penicillin drug, hypertension, Diabetes Mellitus, smoking and history of previous mitral balloon valvuloplasty. General and local cardiac then resting 12-lead ECG examination were done for all population. 2D Transthoracic echocardiography was performed by continuous wave doppler, pulsed wave doppler and color flow to assess the severity of mitral stenosis, valve morphology, mitral regurgitation and calculate Wilkins score prior to PMV and within 24 hours after the procedure. Transesophageal echocardiography (TEE) was ordered for all population of the study on the same day of the procedure to rule out the presence of left atrial appendage thrombus, asses intra-arterial septum and mitral regurge severity. The degree of calcification and commissural fusion of the valve were assessed using three-dimensional transesophageal echocardiography (TEE). Anterolateral (P1 and A1) and posteromedial (P3 and A3) commissural fusions were first classified as bilateral, unilateral, or no fusion.

Each valve was then scored based on whether calcification was present or not. When there was bilateral fusion on the commissures, the score was 1 if there was no calcification; if there was calcification, the score was 2; when there was unilateral fusion on the commissures, the score was 3 if there was no calcification on the fused area; if there was calcification on the fused area, the score was 4; and when there was no fusion on both commissures, the score was 5 if there was no calcification and 6 if there was calcification. All patients had bleeding profile before the mitral balloon valvuloplasty that was done by highly skilled operators in interventional cardiology through the antegrade trans-septal approach using the standard Inoue single balloon technique. All patients will be followed up after the procedure for immediate postprocedural complications including local hematoma at site of puncture, Femoral pseudoaneurysm, hemopericardium, tamponade, severe mitral regurge, cardiac arrest and systemic embolization. Post-operative transthoracic echocardiography to assess the result of the mitral balloon valvuloplasty as mitral valve area and degree of mitral regurge then follow up after thirty days from the hospital discharge to assess the degree of mitral valve regurge by echocardiography, presence of atrial arrhythmia by ECG and clinical heart failure.

Statistical Analysis

After the data was gathered, it was imported and analyzed using the Statistical Package for the Social Sciences (SPSS version 20.0) program. The following tests were employed to determine whether differences were significant, according on the type of data: quantitative statistical groups are represented by mean ± SD, whereas qualitative groups are represented by numbers and percentages. Chi square test for qualitative variable differences and associations (X2). quantifiable independent group differences using the t test. For significant results, the P value was set at <0.05, and for very significant results, it was set at <0.01.

RESULTS AND OBSERVATIONS:

This study was cohort prospective comparative observational study included 102 patients with severe symptomatic rheumatic mitral valve stenosis and favorable valve morphology, absence of contraindications to percutaneous mitral balloon valvuloplasty (PMV) procedure then the study population was divided into two groups the first group of population

(group A) (n=51) was undergone first-time PMV and the second group of population (group B) (n=51) was undergone redo PMV for severe rheumatic mitral valve restenosis. All patients of this study were ranged in age from 26 to 64 years, with a mean age of 44.62 ± 7.90 years and a mean body mass index (BMI) of 31.68 ± 4.05 kg/m^2. The dominant sex category in this study was females (77.5%). The most common co-morbidities between the studied patients were past history of rheumatic fever (70.6%) and atrial fibrillation rhythm (53.9%) **(Table 1).**

Table (1): Demographic and clinical characteristics of the studied patients

		No. = 102
Age	Mean ± SD	44.62 ± 7.90
	Range	26 – 64
Sex	Females	79 (77.5%)
	Males	23 (22.5%)
BMI	Mean ± SD	31.68 ± 4.05
	Range	22 – 41
Rheumatic Duration	Mean ± SD	16.81 ± 5.91
	Range	5 – 30
Rheumatic Fever History		72 (70.6%)
Hypertension		26 (25.5%)
Diabetes Mellitus		36 (35.3%)
Active Smoking		21 (20.6%)
Atrial fibrillation rhythm		55 (53.9%)

The results showed a highly significant difference between the two groups regarding BMI, hypertension, diabetes mellitus, atrial fibrillation and history of rheumatic fever (p <0.001). The usage of beta blockers, diuretics, warfarin and long-acting penicillin as prophylaxis to rheumatic fever demonstrated a highly significant difference between the two groups **(Table 2).**

Table (2): Comparison between group A and group B regarding demographic, clinical characteristics and laboratory investigations of the studied patients

		Primary PMV	**Redo PMV**	**P-value**
		No. = 51	**No. = 51**	
Age	Mean ± SD	44.86 ± 7.73	44.37 ± 8.13	0.756
Sex	Females	40 (78.4%)	39 (76.5%)	0.813
	Males	11 (21.6%)	12 (23.5%)	
BMI	Mean ± SD	30.57 ± 3.70	32.78 ± 4.11	0.005
Hypertension		7 (13.7%)	19 (37.3%)	0.006
Diabetes Mellitus		10 (19.6%)	26 (51.0%)	0.001
Smoking		9 (17.6%)	12 (23.5%)	0.463
Rheumatic Fever History		21 (41.2%)	51 (100.0%)	0.000
Atrial fibrillation rhythm		14 (27.5%)	41 (80.4%)	0.000
Rheumatic Duration	Mean ± SD	15.57 ± 5.82	17.31 ± 5.93	0.259
Serum Creatinine	Mean ± SD	1.07 ± 0.17	1.07 ± 0.16	0.905
Platelet	Mean ± SD	292.51 ± 50.15	280.92 ± 35.09	0.179
Hb	Mean ± SD	11.65 ± 1.11	11.64 ± 0.95	0.924
WBCs	Mean ± SD	7.59 ± 1.69	6.19 ± 1.15	0.000
B blockers		30 (58.8%)	48 (94.1%)	0.000
Warfarin		6 (11.8%)	29 (56.9%)	0.000
Digoxin		8 (15.7%)	10 (19.6%)	0.603
Diuretic		10 (19.6%)	26 (51.0%)	0.001
Long-acting Penicillin		43 (84.3%)	18 (35.3%)	0.000

According to echocardiographic parameters, mitral valve area assessed by planimetry, Wilkin score and 3D trans-esophageal echocardiography (TEE) commissural score were statistically significant different between both groups (P value < 0.05). The size of balloon and number of inflations were higher in the redo group **(Table 3).**

Table (3): Comparison between group A and group B regarding pre-procedural echocardiographic parameters and procedural techniques of the studied patients

		Primary PMV No. = 51	Redo PMV No. = 51	P-value
LVESD	Mean ± SD	3.00 ± 0.45	3.07 ± 0.36	0.397
LVEDD	Mean ± SD	4.55 ± 0.60	4.55 ± 0.53	1.000
Echo Fractional shortening	Mean ± SD	33.17 ± 3.98	32.96 ± 3.67	0.069
Left ventricular EF	Mean ± SD	64.43 ± 5.56	63.69 ± 5.19	0.486
Mitral valve area (MVA) Planimetry (cm^2)	Mean ± SD	1.17 ± 0.22	1.07 ± 0.23	0.033
Mean pressure gradient (mmHg)	Mean ± SD	12.22 ± 4.15	11.00 ± 2.28	0.070
Echo Wilkins Score	Mean ± SD	8.22 ± 0.94	8.80 ± 0.85	0.001
Wilkins Score classification	Wilkins Score < 8	9 (17.6%)	4 (7.8%)	0.138
	Wilkins Score ≥ 8	42 (82.4%)	47 (92.2%)	
Left atrial dimension	Mean ± SD	4.84 ± 0.49	4.84 ± 0.46	0.965
Tricuspid regurge	Mild	44 (86.3%)	45 (88.2%)	0.603
	Moderate	6 (11.8%)	6 (11.8%)	
	Severe	1 (2.0%)	0 (0.0%)	
3D TEE Commissural Score	Mean ± SD	3.22 ± 0.90	3.80 ± 0.92	0.001
Inflation Number	1	4 (7.8%)	0 (0.0%)	0.041
	2	47 (92.2%)	51 (100.0%)	
Balloon Size	Mean ± SD	26.08 ± 0.63	26.84 ± 0.99	0.000

The results of this study revealed an increase of immediate procedural complications such as cardiac arrest, vascular access complications, severe mitral regurge development and pericardial tamponade in the redo PMV procedure more than PMV for the first time. The number of successful PMV procedures was higher at the first time (74.5%) than the redo (43%). The procedure is considered successful if mitral valve area increased more than $1.5cm^2$, pressure gradient across mitral valve decreased more than 50% and no major complications as severe mitral regurge requiring surgery. After 30 days of hospital discharge, rise in the degree of mitral valve regurgitation was significant in the redo group with predominant clinical heart failure in these patients (P value <0.005) **(Table 4).**

Table (4): Comparison between group A and group B regarding immediate-procedural and post-procedural complications of the studied patients

Complications		Primary PMV No. = 51	Redo PMV No. = 51	P-value
immediate-procedural complications				
Cardiac arrest then ROSC after CPR		0 (0.0%)	2 (3.9%)	0.153
Pericardial Tamponade		0 (0.0%)	4 (7.8%)	0.032
Vascular accesses complications		2 (3.9%)	8 (15.7%)	0.046
Outcome	Failed PMV	13 (25.5%)	29 (56.9%)	0.001
	Successful PMV	38 (74.5%)	22 (43.1%)	
Severity of MR	Mild	42 (82.4%)	31 (60.7%)	0.008
	Moderate	7 (13.7%)	12 (23.5%)	
	Severe	2 (3.9%)	8 (15.7%)	
After 30 days of hospital discharge				
MVA by planimetry	Median	2 (1.9 – 2)	2 (1.9 – 2.4)	0.075
Severity of MR	Mild	48 (94.1%)	35 (68.6%)	0.002
	Moderate	3 (5.9%)	8 (15.7%)	
	Severe	2 (3.9%)	8 (15.7%)	
Atrial arrhythmia		4 (7.8%)	6 (11.8%)	0.505
Heart failure		0 (0.0%)	5 (9.8%)	0.008
Echo LVESD	Mean ± SD	2.96 ± 0.39	3.02 ± 0.33	0.532
Echo LVEDD	Mean ± SD	4.53 ± 0.61	4.49 ± 0.49	0.682
Echo FS	Mean ± SD	32.22 ± 3.44	31.98 ± 3.87	0.746
Echo LVEF	Mean ± SD	62.88 ± 5.23	62.80 ± 5.23	0.940
Mitral valve area (MVA) Planimetry	Mean ± SD	1.97 ± 0.28	2.06 ± 0.27	0.134
Echo Mean pressure gradient	Mean ± SD	4.88 ± 2.13	5.22 ± 1.77	0.392

A comparison between successful and failed cases after first time PMV for rheumatic severe mitral valve stenosis revealed that high commissural score assessed by 3D transesophageal echocardiography was associated with failed cases (3.46 ± 0.53 vs. 2.13 ± 0.81, P = 0.034). The Wilkin score was higher in the failed cases of primary PMV (8.32 ± 0.93 vs. 7.92 ± 0.95, P = 0.199) but did not reach to the significant difference when compared with the successful cases. The high pre-operative mean pressure gradient across the mitral valve was also predominant in-between the successful cases of primary PMV (13.18 ± 4.3 vs. 9.38 ± 1.8, P = 0.003) **(Table 5).**

Table (5): Comparison between failed and successful PMV regarding pre-procedural echocardiographic findings among the group A (first time PMV)

		Failed PMV No. = 13	Successful PMV No. = 38	P-value
LVESD	Mean ± SD	3 ± 0.61	3 ± 0.4	1.000
LVEDD	Mean ± SD	4.65 ± 0.57	4.52 ± 0.61	0.501
Echo Fractional shortening	Mean ± SD	33.46 ± 4.14	33.47 ± 3.98	0.993
Left ventricular EF	Mean ± SD	64.23 ± 6.31	64.5 ± 5.37	0.882
Mitral valve area (MVA) Planimetry (cm²)	Mean ± SD	1.15 ± 0.25	1.17 ± 0.21	0.699
Mean pressure gradient (mmHg)	Mean ± SD	9.38 ± 1.8	13.18 ± 4.3	0.003
Echo Wilkins Score	Mean ± SD	8.32 ± 0.93	7.92 ± 0.95	0.199
Wilkins Score classification	Wilkins Score < 8	5 (13.2%)	4 (30.8%)	0.150
	Wilkins Score ≥ 8	33 (86.8%)	9 (69.2%)	
Left atrial dimension	Mean ± SD	4.88 ± 0.68	4.82 ± 0.41	0.675
Tricuspid regurge	Mild	10 (76.9%)	34 (89.5%)	0.299
	Moderate	3 (23.1%)	3 (7.9%)	
	Severe	0 (0.0%)	1 (2.6%)	
3D TEE Commissural Score	Mean ± SD	3.46 ± 0.53	2.13 ± 0.81	0.034

A comparison between successful and failed cases after redo PMV procedure for severe mitral valve restenosis showed that high Wilkin score ≥ 8 was predominant in the failed cases (86.2%, P = 0.001). The commissural score assessed by 3D transesophageal echocardiography was higher in the failed cases of redo PMV (3.09 ± 0.91vs. 2.97 ± 0.91, P = 0.150) but did not reach to the significant difference when compared with the successful cases **(Table 6).**

Table (6): Comparison between failed and successful PMV regarding pre-procedural echocardiographic findings among the group B (redo PMV)

		Failed PMV No. = 29	Successful PMV No. = 22	P-value
LVESD	Mean ± SD	3.16 ± 0.36	2.95 ± 0.32	0.345
LVEDD	Mean ± SD	4.62 ± 0.54	4.45 ± 0.52	0.276
Echo Fractional shortening	Mean ± SD	31.38 ± 3.44	32.73 ± 3.89	0.196
Left ventricular EF	Mean ± SD	62.97 ± 4.51	64.64 ± 5.94	0.259
Mitral valve area (MVA) Planimetry (cm²)	Mean ± SD	1.04 ± 0.26	1.11 ± 0.18	0.304
Mean pressure gradient (mmHg)	Mean ± SD	11.24 ± 2.56	10.68 ± 1.86	0.391
Echo Wilkins Score	Mean ± SD	8.86 ± 1.04	7.33 ± 0.63	0.041
Wilkins Score classification	Wilkins Score < 8	4 (13.8%)	22 (100.0%)	0.001
	Wilkins Score ≥8	25 (86.2%)	0 (0.0%)	
Left atrial dimension	Mean ± SD	4.84 ± 0.45	4.84 ± 0.47	0.982
Tricuspid regurge	Mild	25 (86.2%)	20 (90.9%)	0.606
	Moderate	4 (13.8%)	2 (9.1%)	
	Severe	0 (0.0%)	0 (0.0%)	
3D TEE Commissural Score	Mean ± SD	3.09 ± 0.91	2.97 ± 0.91	0.150

DISCUSSION

For symptomatic patients with anatomically appropriate severe rheumatic mitral stenosis [mitral valve area (MVA) ≤ 1.5 cm²], percutaneous mitral balloon valvuloplasty (PMV) is thot to be the first line of treatment. PMV can still be beneficial for certain patients with favorable anatomical and clinical features, especially if they are at high surgical risk [5]. Only mitral valve restenosis is associated with a delayed recurrence of symptoms after percutaneous mitral valvuloplasty. Research indicates that, depending on the centers and methods employed, the rate of restenosis may reach 40% during a seven-year follow-up. Although there haven't been many studies on redo PMV, it has been noted that

it produced favorable valve properties and excellent results [6].

With a focus on echocardiographic improvement, procedural success, and complication rates, as well as identifying predictors of outcome in both groups, the current study was carried out to systematically compare the immediate and short-term outcomes of first-time versus redo mitral balloon valvuloplasty in patients with severe rheumatic mitral stenosis. 102 patients who were recommended for PMV procedures at Capital University Badr Hospital and National Heart Institute were included in the current study. These patients were split equally into two groups: group A comprised 51 patients who underwent PMV for the first time, and group B comprised 51 patients who underwent redo PMV. The study's patients ranged in age from 26 to 64, with a mean age of 44.62 ± 7.90 years. This is consistent with the findings of Mutagaywa et al., who said that rheumatic mitral stenosis is typically clinically relevant in the fourth and fifth decades of life due to its chronic nature [5]. 77.5% of the study participants were female. This result is in line with the findings of Bouleti et al., who found that individuals with rheumatic mitral stenosis were much more likely to be female. The autoimmune mechanism and the course of rheumatic mitral valve disease in women have been linked to this female predominance [7].

In keeping with the World Heart Federation Guidelines (2023), which highlight that rheumatic fever continues to be the primary cause of mitral stenosis in developing nations, 70.6% of the study population had a history of rheumatic fever. Given the extended latent period between the initial rheumatic insult and the development of clinically significant valvular stenosis, the unusually long disease duration (16.81 ± 5.91 years) reported in our sample is likewise expected. Benzathine penicillin prophylaxis was administered on a regular basis to about 60% of our patients. In order to avoid recurring rheumatic fever and delay the evolution of rheumatic valvular disease, the World Heart Federation Guidelines (2023) strongly advise long-term secondary penicillin prophylaxis. Similarly, the redo PMV group had far higher rates of penicillin use and a history of rheumatic disease. Rather than penicillin's effect on restenosis, this likely reflects the chronic rheumatic nature of the disease and the requirement for long-term secondary prophylaxis in these individuals [8]. Atrial fibrillation (AF) was considerably more prevalent in the redo PMV group in the current study. This result is expected as AF is linked to chronic high intra-atrial pressure, left atrial enlargement, and long-term rheumatic mitral stenosis. Muhammad Ramzan et al. (2022) published similar findings, showing that patients undergoing redo PMV had a greater prevalence of AF [9].

According to our baseline data, patients in the Redo PMV group had substantially higher TEE Commissural scores (3.80 ± 0.92 vs. 3.22 ± 0.90, P = 0.001) and Echo Wilkins scores (8.80 ± 0.85 vs. 8.22 ± 0.94, P = 0.001) than those in the Primary PMV group. Our results are consistent with the study conducted by Kadriye Memic Sancar et al., which showed that the group of redo PMV with more extensive subvalvular involvement had a substantially higher pre-procedural Wilkins score [8 (7–9) vs. 8.5 (8–10), p = 0.046] [10]. A more complex valvular anatomy at the time of redo PMV may result from this return to the ongoing rheumatic process as well as progressive fibrotic remodeling after the initial intervention, which encourages increasing leaflet thickening, commissural fusion, calcification, and subvalvular fibrosisNevertheless, they also demonstrated that a thorough evaluation of commissural morphology and subvalvular illness using 3D TEE offers better patient selection, and that traditional Wilkin score alone is insufficient to predict operative success. The initial PMV group in the current study had a considerably greater procedural success rate than the redo group (74.5% vs. 43.1%, P = 0.001). Rifaie et al., on the other hand, found no significant changes in post-procedural mitral valve area, trans-mitral gradient, or procedural complications, and no comparable procedural success rates between primary and redo PMV (93.3% vs. 92.5%, P = NS) [11].

Despite this, Muhammad Ramzan et al. (2022) found that the redo operation had a higher immediate procedural success rate than the initial PMV (90.0% vs. 86.6%, respectively). [9] The disparity could be explained by variations in valve anatomy, disease severity, and patient selection. Redo patients in our sample seemed to have more advanced rheumatic valve pathology, as evidenced by less favorable baseline anatomical features and a higher frequency of procedural problems, which probably decreased the success of the procedure. Increasing anatomical complexity may have a negative impact on both procedural safety and efficacy, as evidenced by the significantly higher incidence of severe mitral regurgitation necessitating surgery, pericardial tamponade, and vascular access problems in our redo group. The more deformed valve morphology, commissural re-fusion, leaflet fibrosis, subvalvular scarring, and progressive calcification commonly seen in restenotic valves can account for this observation.

In addition to making repeat transseptal balloon intervention more difficult technically, these structural alterations raise the possibility of leaflet damage and procedural issues during redo PMV. In a similar vein, Aslanabadi et al. found that in certain patients with restenosis following prior PMV, redo PMV is still a viable option to mitral valve replacement [12]. However, because of severe mitral regurgitation, patients with unfavorable valve characteristics had lower procedural success and were more likely to need surgery, which is consistent with the greater incidence of surgery for severe MR shown in our failed group. Our findings contradict those of Zhang et al., who showed that, when properly chosen, repeat PMV is a safe and successful

treatment option for patients with mitral restenosis. Only three surgeries in their series failed due to serious complications, such as acute severe mitral regurgitation and cardiac tamponade, whereas 92.3% of patients had successful procedures. Wilkins scores were substantially higher in the failed PMV group than to the successful group in this study (P=0.001) [13]. This outcome is in line with the findings of Sutaria et al., who showed that a higher Wilkins score is linked to less successful procedures due to more widespread leaflet thickening, calcification, decreased mobility, and subvalvular fibrosis [14].

Similarly, the first-time failed PMV group had a significantly higher 3D TEE commissural score than the redo group (P=0.034). This result is consistent with the findings of Kadriye Memic Sancar et al., who demonstrated that the immediate outcome of balloon mitral valvotomy is independently predicted by commissural morphology as determined by trans-esophageal echocardiography [10]. Higher rates of severe mitral regurgitation, tamponade, heart failure associated with valve regurgitation, procedure failure, and arrhythmias in redo cases were found in the current study. These findings probably indicate irreversible structural changes in rheumatic valves following initial intervention, such as fibrosis, calcification, and altered stress distribution across commissures. These modifications make the balloon more vulnerable to uncontrollable tearing and leaflet rupture during inflation. These results imply that rigorous pre-procedural evaluation employing sophisticated imaging, especially 3D TEE commissural analysis, may enhance risk stratification and assist in identifying patients who might benefit from repeat surgery, and that patient selection is crucial in redo PMV. Surgical valve replacement may be a safer option for patients with severe calcification or a high commissural score [15].

CONCLUSION

The current study emphasized the concept that redo PMV should not be considered equivalent to first-time PMV in terms of safety profile. Although similar improvements in valve area, the incidence of severe mitral regurgitation, tamponade, vascular access complications and arrhythmias was higher in the redo cases more than cases of primary PMV.

Declarations

Author Contributions: Methodology development: Mohamed.G.Elbahnasawy, A.Gaafar and M.Osama.; **clinical supervision:** Mohamed.G.Elbahnasawy and M.Osama.; operators of the procedures: T.Elashkar, Mohamed.G.Elbahnasawy, A.Gaafar and M.Osama.; **data interpretation:** Mohamed.G.Elbahnasawy.; study conception: A.Hussien, T.Elashkar and M.Osama.; patient recruitment, data collection, data organization, **literature review, and manuscript drafting:** A.Hussien.; methodology review and clinical interpretation: A.Gaafar.; critical manuscript revision: Mohamed.G.Elbahnasawy., A.Gaafar, T.Elashkar and M.Osama. Each author accepted responsibility for the accuracy and integrity of the work and approved the final draft of the paper.

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Ethical Approval and Consent: The Capital University Faculty of Medicine's Research Ethics Committee gave its approval to the project. Approval number: 80-2024. Approval date: 8/07/2024. The Declaration of Helsinki governs the organization and operations of REC-FMHU. Prior to participation, each subject provided written informed permission. The Declaration of Helsinki's tenets and institutional research protocols were adhered to in all study procedures.

Consent for Publication: Not applicable.

Data Availability: Subject to institutional ethical and administrative permissions, the corresponding author will provide the anonymized data supporting the study's conclusions upon reasonable request.

Clinical Trial Registration: Not applicable.

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Originality Statement: The authors attest that this work is unique, hasn't been published before, and isn't being considered anywhere else.

Accountability Statement: Each author pledges to take responsibility for the work's accuracy and integrity.

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