

Patient-prosthesis mismatch after mitral valve replacement: is it a fact or myth?

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Background

Patient-prosthesis mismatch (PPM) is present when the effective orifice area (EOA) of the inserted prosthetic valve is too small in relation to body size, which results in an increased postoperative transvalvular gradient. This study was conducted to determine the incidence and identify the risk factors associated with this phenomenon.

Patients and methods

In total, 46 patients undergoing cardiac surgery for mechanical mitral valve replacement were enrolled. The EOA of the prostheses was estimated by the continuity equation (CE), pressure half-time, and reference values to determine the incidence of the mismatch, then the EOA was estimated by the CE only to determine the risk factors of the mismatch. The mismatch was defined as an indexed EOA less than or equal to $1.2\text{cm}^2/\text{m}^2$. The mean clinical and echocardiographic follow-up was 6 months postoperatively.

Results

The incidence of mitral PPM ranged from 15% in pressure half-time method (seven patients) to 26% in the referred EOA method (12 patients) to 54% in CE method (25 patients). PPM was identified in patients with preoperative rheumatic mitral valve pathology ($P=0.043$), higher preoperative New York Heart Association class ($P=0.016$), preoperative atrial fibrillation ($P=0.048$), mitral valve stenosis ($P=0.020$), and smaller left ventricular dimensions.

Conclusions

PPM in mitral position is a fact and its incidence is variable according to the different methods of determining EOA of the prosthetic valve.

Keywords:

incidence, mechanical valve, mitral valve replacement, patient-prosthesis mismatch

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Introduction

Mitral patient-prosthesis mismatch (PPM) is actually not a new concept, it was first described in 1978 by Rahimtoola as follows: 'Mismatch can be considered to be present when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal human valve.' Inherent in this concept is that a smaller-than-expected effective orifice area (EOA) in relation to the patient's body-surface area will result in higher transvalvular gradients [1].

Previous studies reported that PPM after aortic valve replacement is quite frequent (20–70%) and associated with worse hemodynamics, left ventricular hypertrophy, more adverse cardiac events, and a major impact on short-term and long-term mortality. On the other hand, mitral PPM remained unexplored for a long time and its incidence has been reported to vary. In addition, studies on the clinical impact of PPM following mitral valve replacement (MVR) on survival have shown conflicting results [2–4].

The majority of these studies have concentrated on studying the clinical consequence of PPM as they equated PPM after MVR to residual mitral stenosis and studied its effects on persistent postoperative pulmonary hypertension, atrial fibrillation, recurrent heart failure, mortality, and long-term survival [3,5,6]. The most important reason for the discrepancy among the previous studies might be that the methods used to define PPM were different as the investigators used different parameters and criteria to define PPM, such as the indexed effective orifice area (IEOA) of the prosthesis and the indexed internal geometric orifice area [4–6].

The prevention of PPM in the mitral position represents a much greater challenge than in the aortic position. Indeed, mitral valve surgery does not allow annular

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enlargement, and the implantation of a homograft or stentless prosthesis is technically more demanding and associated with poor long-term durability. Thus, the only alternative at present is the implantation of a prosthesis with a larger EOA for a given annulus size, which unfortunately may not be sufficient to completely avoid PPM in some cases [4,6]. Also, repair of the mitral valve is generally preferable to replacement, but unfortunately, a substantial proportion of patients are not good candidates for repair, thus, it needs MVR by a prosthetic valve [5,6].

Thus, our objective was to determine the incidence of PPM after MVR and the possible risk factors associated with this phenomenon.

Patients and methods

Study population

This prospective cohort study was conducted on 46 adult patients who had primary MVR with or without concomitant tricuspid valve repair from November 2017 to December 2019. We excluded patients scheduled for double-valve replacement (mitral and aortic), MVR due to ischemic mitral valve regurgitation, MVR with bioprosthetic valves, and those scheduled for other cardiac surgeries. The patients were identified by coded number to maintain privacy. No unexpected risks appeared during the course of the research, written informed consents were obtained from all patients involved in this study. The local ethical committee approved data collection for this study with reference number (31851/10/17). The American Heart Association/American College of Cardiology (AHA/ACC) guidelines for MVR in 2008 [7] and its update in 2014 [8] were followed.

Patients' demographics, preoperative, operative, and postoperative data were collected. The database captured detailed information on a wide range of preoperative, intraoperative, and postoperative variables for all patients undergoing cardiac surgery at the study center, in addition to the follow-up data.

Surgical procedure

Routine preoperative clinical assessment and echocardiography workup were performed for all patients. Standard surgical techniques were done via median sternotomy, including cardiopulmonary bypass and mild systemic hypothermia. Myocardial protection was achieved by intermittent antegrade blood cardioplegia on arrested heart, mitral valve was inspected. Valve excision was done with or without preservation of the posterior leaflet and related subvalvular apparatus. Prosthesis brand was selected at the discretion of the surgeon and valve sizing was performed according to the guidelines provided by the

manufacturers. Concomitant tricuspid valve repair was performed when indicated.

Warfarin therapy was started on the first postoperative day to maintain the INR within a range of 2.5–3.5.

Follow-up methods

The patients' follow-up was carried out in the ICU, then periodically in outpatient clinics, medical examination focused on the determination of functional status, and the occurrence of valve-related complications and echocardiography was performed 6 months postoperatively.

Evaluation of the EOA of the prostheses was determined by the continuity equation (CE) using the stroke volume measured in the left ventricular outflow tract divided by the integral of the mitral valve transprosthetic velocity during diastole. IEOA is defined as EOA indexed to body-surface area. PPM was defined using the IEOA as suggested in previous studies as follows [2,4]:

- (1) Not significant if IEOA less than 1.3 and more than 1.2 cm²/m².
- (2) Moderate if IEOA less than or equal to 1.2 cm²/m² and more than 0.9 cm²/m².
- (3) Severe if IEOA less than or equal to 0.9 cm²/m².

Endpoints

The primary endpoint of this study is determination of the incidence of PPM after MVR in our population. The secondary endpoint is analysis of variables as risk factors such as age, sex, hypertension, diabetes mellitus, chronic pulmonary disease, New York Heart Association (NYHA) class, mitral valve pathology, atrial fibrillation, preoperative echocardiographic findings, mechanical prosthesis type, posterior mitral leaflet preservation, concomitant tricuspid valve repair, and postoperative echocardiographic findings.

Statistical analysis

The collected data were organized, tabulated, and statistically analyzed using computer program SPSS, version 25.0 (SPSS Inc., Armonk, New York, USA). Parametric numerical data were presented as mean and SD, median and interquartile range for nonparametric numerical data, and frequency and percentage for nonnumerical data. Student *t* test and analysis of variance test were used to assess the statistical significance of the difference between study-group means. χ^2 test and Fisher's exact test were used to examine the relationship between two qualitative variables. Person's χ^2 test was used for univariate statistics to assess the strength of association between two quantitative variables.

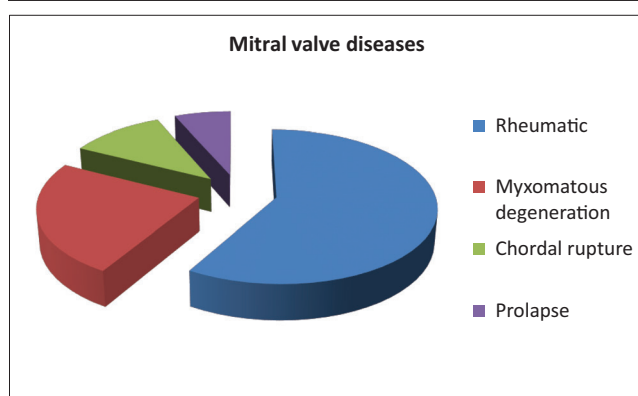
A value of *P* value less than 0.05 was considered statistically significant and *P* value less than 0.01 was considered highly significant.

Results

Preoperative and operative data

In total, 46 patients (19 males, 27 females with mean age 45 ± 9.3 years) with mitral valve diseases were included in our study (Fig. 1). Table 1 summarizes the preoperative patient characteristics, risk factors, and preoperative echocardiographic data.

Figure 1



Causes of mitral valve lesion.

Table 1 Preoperative data

Variables	Value
Age (years)	45 ± 9.3
Body weight (kg)	69.5 ± 12.7
Height (cm)	163 ± 9.5
BMI (kg/m^2)	26.1 ± 4.2
BSA (m^2)	1.7 ± 0.2
Sex	
Male sex	19 (41.3)
Female sex	27 (58.7)
NYHA class	
I-II	16 (35)
III-IV	30 (65)
Hypertension	25 (54.4)
Cardiac failure	1 (2.2)
Atrial fibrillation	20 (43.5)
COPD	5 (11)
Mitral lesion	
Regurgitation (MR)	13 (29)
Stenosis (MS)	23 (50)
Mixed (MR, MS)	10 (21)
Tricuspid regurgitation	40 (87)
Pulmonary hypertension (n)	36 (78)
Ejection fraction%	58.03 ± 8.61
End-diastolic dimension (mm)	55.8 ± 10.2
End-systolic dimension (mm)	36.43 ± 7.62
Left atrial diameter (mm)	45.78 ± 10.98

Data are presented as mean \pm SD and *n* (%).

BSA, body-surface area; COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association.

All patients had MVR with mechanical prosthetic valve mostly St Jude Medical prosthesis (74%), while the mean valve size was 27.1 ± 1.8 mm and the native posterior mitral leaflets were preserved in 29 (63%) patients.

Postoperative data

Postoperatively, the NYHA class improved in most cases with mean hospital stay 10 ± 4.8 , while 10 (21%) patients developed atrial fibrillation (Table 2).

Significant decreases and improvement were observed over time by comparing preoperative and postoperative echocardiographic data (Fig. 2).

Incidence of mitral patient-prosthesis mismatch among our patients

The incidence of mitral PPM is different according to the methods used to calculate EOA, as this mismatch was present in seven (15%) patients in pressure half-

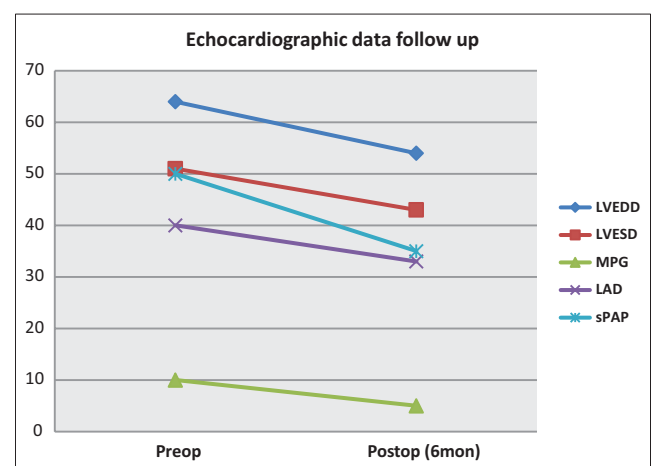
Table 2 Postoperative outcomes (N=46)

Parameters	Value
ICU stay (days)	2.7 ± 1.8
Hospital stay (days)	10 ± 4.8
Creatinine (mg/dl)	0.8 ± 0.2
Atrial fibrillation	10 (21)
Pulmonary failure	1 (2.2)
Renal failure	0
CV complications	1 (2.2)
Cardiac failure	2 (4.3)
Infections	2 (4.3)
NYHA class	
I-II	42 (92)
III-IV	4 (8)

Data are presented as mean \pm SD and *n* (%).

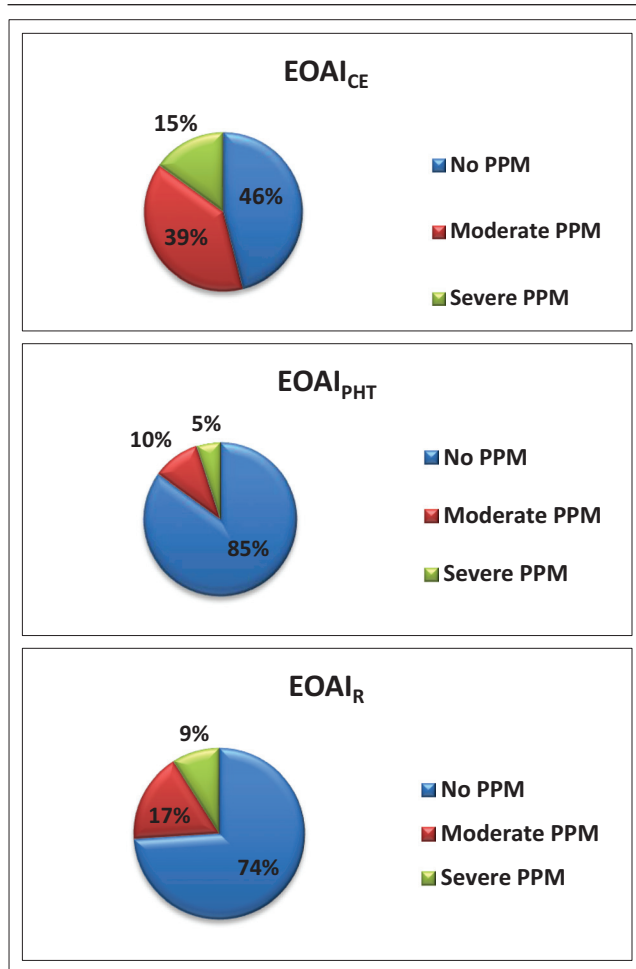
CV, cerebrovascular; NYHA, New York Heart Association.

Figure 2



Echocardiographic data assessment. LAD, left atrium diameter; LVEDD, left ventricle end-diastolic dimension; LVESD, left ventricle end-systolic dimension; MPG, mean pressure gradient; postop, postoperative; preop, preoperative; sPAP, systolic pulmonary artery pressure.

Figure 3



Incidence of mitral PPM. EOA_{CE}, effective orifice area indexed by continuity equation; EOA_{PHT}, effective orifice area indexed by pressure half-time; EOA_R, effective orifice area indexed by referred method; PPM, patient-prosthesis mismatch.

time (PHT) method, 15 (26%) patients in referred EOA method, and in 25 (54%) patients in CE method. Based on IEAOA reference value 1.2 cm²/m² measured with CE method, our patients were classified into three groups with 21 (45%) patients who had no PPM, 18 (39%) patients had moderate PPM, and seven (15%) patients had severe PPM (Fig. 3).

The mitral PPM is significantly associated with preoperative rheumatic mitral valve pathology ($P=0.043$), mitral valve stenosis ($P=0.020$), associated preoperative tricuspid regurgitation ($P=0.01$), higher preoperative NYHA class ($P=0.016$), preoperative atrial fibrillation ($P=0.048$), and smaller left ventricular dimensions (Tables 3, 4).

All patients received mechanical mitral prostheses; 74% of them received St Jude, while 11% patients received Carbomedics prosthesis with no statistical difference between the different prosthesis types regarding the occurrence of PPM ($P=0.302$). The highest proportion of the inserted mechanical prosthesis size was 27 mm in 19 (41%) patients with 68.4% of them who had PPM, while the least proportion received valve of size 25 in three (6.5%) patients, who all had PPM, so the univariate analysis showed that the smaller prosthesis size has high significant correlation with occurrence of PPM ($P=0.001$), while posterior mitral leaflet preservation was statistically not a significant factor on univariate analysis ($P=0.389$) (Table 5).

Although there is a statistically significant association between postoperative pulmonary hypertension and

Table 3 Univariate analysis of preoperative characteristics

Variables	PPM			P value
	No	Moderate	Severe	
	Mean±SD (N=21)	Mean±SD (N=18)	Mean±SD (N=7)	
Age	43.33±11.56	42.15±10.79	45.03±8.11	0.419
Sex				
Male	9 (43)	8 (44)	2 (28.5)	0.755
Female	12 (57)	10 (66)	5 (71)	
Body-surface area	1.82±0.19	1.83±0.2	1.85±0.22	0.648
Hypertension	12 (57)	10 (55)	3 (43)	0.799
Diabetes mellitus	2 (9.5)	6 (33)	1 (14)	0.162
Smoking	7 (33)	6 (33)	2 (28)	0.970
COPD	2 (9.5)	2 (11)	1 (14)	0.940
Atrial fibrillation	13 (62)	6 (33)	1 (14)	0.048*
NYHA class				
II	9 (43)	7 (39)	0	0.016*
III	8 (38)	7 (39)	1 (14)	
IV	4 (19)	4 (22)	6 (86)	

Data are presented as mean±SD and n (%).

COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association; PPM, patient-prosthesis mismatch.

*Significant relation with P value<0.05.

Table 4 Preoperative echo data of the patients stratified according to patient-prosthesis mismatch severity

Variables	PPM			P value
	No	Moderate	Severe	
	Mean±SD (N=21)	Mean±SD (N=18)	Mean±SD (N=7)	
Mitral pathology				
Rheumatic	8 (38.1)	13 (72.2)	6 (85.7)	
Prolapse	2 (9.5)	0	1 (14.3)	
Myxomatous degeneration	6 (28.6)	5 (27.8)	0	0.043*
Chordal rupture	5 (23.8)	0	0	
MR	12 (57.14)	8 (44.4)	3 (42.8)	0.672
MS	11 (52.4)	15 (83.3)	7 (100)	0.020*
TV regurge degree				
No	5 (23.8)	1(5.6)	0	0.010*
Mild	5 (23.8)	5(27.8)	0	
Moderate	9(42.9)	6(33.3)	1 (14)	
Severe	2 (9.5)	6(33.3)	6 (85.7)	
EF%	57.25±9.01	58.51±8.93	59.29±5.56	0.621
EDD (mm)	57.8±5.08	53.05±6.18	51.29±6.39	0.018*
ESD (mm)	39.2±5.42	34.82±6.59	33.11±5.23	0.021*
LAD (mm)	53.91±8.05	51.78±13.05	51.82±12.78	0.583
PAP	52.89±17.56	52.34±21.57	52.39±20.85	0.981

Data are presented as mean±SD and *n* (%).

EDD, end-diastolic dimension; EF, ejection fraction; ESD, end-systolic dimension; LAD, left atrial dimension; MR, mitral regurgitation; MS, mitral stenosis; PAP, pulmonary artery pressure; PPM, patient-prosthesis mismatch; TV, tricuspid valve.

*Significant relation with *P* value<0.05.

Table 5 Univariate analysis of intraoperative data of the patients

Variables	PPM			P value
	No	Moderate	Severe	
	N=21	N=18	N=7	
Type of prosthesis				
St Jude Medical	17 (80.9)	14 (77.8)	3 (43)	0.302
ON-X	3 (14.3)	2 (11.1)	2 (28.5)	
Sorine	1 (4.8)	2 (11.1)	2 (28.5)	
Mechanical prosthesis size				
25	0	0	3 (43)	0.001*
27	6 (28.6)	10 (55.6)	3 (43)	
29	7 (33.3)	7 (38.8)	0	
31	5 (23.8)	0	0	
27–29	1 (4.8)	1 (5.6)	1 (14)	
31–33	2 (9.5)	0	0	
Post leaflet preservation	15 (71)	11 (61)	3 (43)	0.389

Data are presented as *n* (%).

PPM, patient-prosthesis mismatch; post, posterior.

*Significant relation with *P* value<0.05.

mitral PPM with *P* value of 0.037, it is thought to be a result rather than a risk factor, especially that the preoperative values were not significant (Table 6).

Discussion

PPM in the mitral position is a quite common phenomenon with a highly variable rate that was reported, ranging from 30 to 85% by studies of Magne *et al.* [2] and Lam *et al.* [4]. These previous studies overweighed this wide variation to the different methods of measurement, whether PHT or the CE as the PHT tends to overestimate the EOA

of the prosthesis [9], the different definitions of PPM assessment whether indexed geometric orifice area or IE OA as the geometric orifice area grossly overestimates the EOA, especially for bioprostheses than for mechanical valves, the different populations of study with different body-surface areas [2,4], and the different percentage of bioprosthesis and mechanical valves and its sizes used in the studied patients [10].

On using IE OA reference value 1.2 cm²/m² presented in most of literatures [5,9–12], our results confirm this wide variation of mismatch incidence and it comes in the middle of the reported ranges (54% by CE method,

Table 6 Univariate analysis of postoperative echo characteristics

Variables	PPM			P value
	No	Moderate	Severe	
	Mean±SD (N=21)	Mean±SD (N=18)	Mean±SD (N=7)	
EF%	58.77±6.76	59.37±5.93	57.13±5.56	0.416
LVEDD (mm)	54.23±6.36	50.67±5.75	47.53±6.81	0.037*
LVESD (mm)	35.34±5.76	33.83±4.78	35.03±6.04	0.409
LAD (mm)	46.47±10.95	45.73±8.79	44.97±5.9	0.762
PAP (mmHg)	32.97±8.53	37.91±11.48	41.74±9.2	0.037*
EOA (mm)	2.58±0.41	2.01±0.25	1.74±0.25	<0.001*
IEOA	1.42±0.19	1.09±0.07	0.94±0.06	<0.001*
PG	9±3.26	9.93±2.33	10.03±2.51	0.496
MG	4.18±1.76	4.98±1.1	6.71±1.32	0.005*
TV regurge > moderate	6 (28.6)	4 (22)	3 (43)	0.589

Data are presented as mean±SD and n (%).

EF, ejection fraction; EOA, effective orifice area; IEOA, indexed effective orifice area; LAD, left atrium diameter; LVEDD, left ventricle end-diastolic dimension; LVESD, left ventricle end-systolic dimension; MG, mean gradient; PAP, pulmonary artery pressure; PG, peak gradient; PPM, patient-prosthesis mismatch; TV, tricuspid valve.

*Significant relation with P value<0.05.

26% by referred values method, and 15% by PHT method). This may be due to that the bioprosthesis-related statistical bias is eliminated by including patients receiving mechanical prosthesis only as it is the most common used type in our population. This may be explained by the predominance of rheumatic pathology of the mitral valve, resulting in a higher prevalence of mitral stenosis with subsequent higher proportion of smaller mechanical prosthesis insertion [10].

Several studies demonstrated the risk of PPM after MVR and reported the short-term and long-term results [2–6]. However, Little who demonstrated the risk factors associated with this quite common phenomenon. Li *et al.* [5] identified large body-surface area, high systemic hypertension, and small prostheses as relevant determinants in their patients with PPM. Their studies also reported a threefold increase in the incidence of PPM when small prosthesis 27 mm or less was employed. The mechanical prosthesis was used in 84% of their patients and the proportion of prosthesis less than 27 mm was 52%.

In other studies, Magne *et al.* [2] considered further characteristics that affect the PPM in their study, such as big body-surface area, male sex, mitral valve regurgitation, ischemic heart diseases, diabetes mellitus, renal failure, bioprosthesis implantation, small prosthesis less than 27 mm, concomitant coronary artery bypass grafting, low preoperative left ventricular ejection fraction, and longer cardiopulmonary bypass and aortic cross-clamp times. They also identified that the proportion of the employed mechanical prosthesis and small prostheses less than 27 mm was 84.9 and 53.1%, respectively, and was virtually identical to the previous study of Li *et al.* [5].

Although our findings are comparable to these results of Li *et al.* [5] and Magne *et al.* [2] and revealed that small prostheses 27 mm or smaller were installed in 48.5% of cases, the overall incidence of PPM was lower, we believe that it is attributable to the exclusion of bioprosthesis from our series and the limited number of patients included in our study.

Jamieson *et al.* [13] reported mitral PPM with male sex, obesity, concomitant coronary artery bypass grafting, severe left ventricular failure, valve size less than 25 mm, and pulmonary hypertension prevalence. In their studies, only 16.7% of the mechanical valves utilized were less than their standard reference value for the small prosthesis size of 25 mm, which was installed in 44.4% of the population investigated, while male sex, smoking, coronary artery disease, bioprosthesis, and smaller left atrial dimensions were all mentioned by Sato *et al.* [3] as risk factors for PPM.

Rheumatic mitral valve pathology, concomitant preoperative tricuspid regurge, greater preoperative NYHA class, preoperative atrial fibrillation, mitral valve stenosis, smaller prosthesis, and smaller left ventricular dimensions were all found to be important variables in our study.

These variables that have been identified are correlated and linked as the most common cause of mitral valve stenosis in our patients is rheumatic disease, which results in higher left atrial pressure, atrial fibrillation, and higher NYHA class [14]. This is consistent with the large percentage of the small prosthesis size, 27 mm or smaller, used in our study (48.5%). Furthermore, the size of the mitral valve annulus is determined by the left ventricle dimensions, so the smaller dimensions, the smaller the annulus.

Also, some of the previously recognized factors were related to one another, such as male sex that results in a higher body surface area, the small prosthesis and bioprosthesis that result in PPM, and other factors, such as other factors are associations like longer cardiopulmonary bypass and aortic cross-clamp times, and outcomes such as postoperative pulmonary hypertension [12,13].

However, our study found a link between the mitral PPM and postoperative pulmonary hypertension, we feel it is a result rather than a predictor [5,15].

Alhan *et al.* [16] did a study to evaluate if preserving all chordae tendineae in patients with mitral stenosis was useful; two groups were developed, total excision and complete preservation. They found that there was no significant difference between the two groups in the sizes of the inserted prosthetic valves, as well as the postoperative effective mitral orifice area and transvalvular gradient.

Similarly, Magne *et al.* [2] found no significant correlation between PPM and posterior leaflet chordal preservation, despite the fact that it was done in 40.5% of their studied patients.

These findings suggest that in patients with heavily calcified restricted mitral annulus, particularly those with rheumatic pathology, partial or total chordal preservation may be possible, rather than an intensive decalcification procedure and implantation of a largest prosthesis size possible, which has deleterious effects, especially the atrioventricular groove disruption [17,18].

Several studies have shown the risk of PPM after aortic valve replacement and have suggested the preventive strategies to avoid it, such as aortic root enlargement procedures or insertion of a new generation of mechanical valves. However, the prevention of PPM in the mitral position is not always feasible [19]. Although the mitral valve repair is the best choice for preventing PPM, it is not always practicable, especially in patients with rheumatic diseases.

Study limitations and strength

The current study has some limitations to consider, such as the fact that we only used three different mechanical valve prostheses in our patients, and that the prosthesis type was selected based on surgeon's preference, and that there were some differences between the different valve types due to the design specifications of each valve. Furthermore, the results may have influenced

by exclusion of bioprostheses, which have distinct mechanics; nevertheless, comparisons between different types of mechanical valves or between mechanical and bioprostheses were outside the scope of this study.

As a result, more research is needed to evaluate each valve type and brand separately, whether mechanical or bioprosthetic, in order to assess *in vivo* EOA calculation for individual prosthesis and the PPM outcome for each. Furthermore, the lack of a consistent approach for the valve replacement and the variations in the technical aspects of replacement by different surgeons may contribute to any bias that may alter the results.

Furthermore, because of the single-center, nonrandomized character of this study, the short follow-up period, and the small number of patients investigated, more research is needed to validate and expand these findings.

Conclusions

The incidence of PPM in mitral position was variable according to the different methods of determining EOA, and the identified factors associated with this phenomenon in the current study may provide an alarming sign before surgery to anticipate the postoperative PPM, so we recommend that a preoperative strategy should be structured on a wide range based on anticipating the risk of PPM and a proper calculation of the EOA in relation to the annular size, so that implantation of the prosthesis can give the largest IEAO.

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Conflicts of interest

There are no conflicts of interest.

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