Original Article

Procedural success and outcomes after percutaneous balloon mitral valvuloplasty in rheumatic mitral stenosis with moderate mitral regurgitation: a retrospective cohort study

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Background: Percutaneous balloon mitral valvuloplasty (PBMV) is contraindicated in mitral stenosis (MS) with moderate mitral regurgitation (MR) according to the European guidelines. However, small-sized studies have demonstrated the feasibility and safety of PBMV in these patients. We aimed to study the procedural success and mid-term outcomes of PBMV in MS patients with moderate MR.

Methods: The present study was a retrospective cohort study in consecutive patients with severe rheumatic MS who underwent PBMV with the Inoue technique in Songklanagarind hospital. The severity of mitral regurgitation was assessed with qualitative Doppler. The patients were grouped according to their MR severity before PBMV into moderate MR or less-than-moderate MR. Procedural success and a composite of all-cause death, mitral valve surgery or re-PBMV were compared between the two groups.

Results: Of 618 patients with rheumatic MS who underwent PBMV in Songklanagarind hospital between January 2003 and October 2020, 598 patients (96.8%) had complete information of pre-PBMV MR severity and procedural success. Forty-nine patients (8.2%) had moderate MR before PBMV. Moderate MR before PBMV was not associated with a lower chance of PBMV success (moderate MR *vs.* less-than-moderate MR before PBMV; adjusted OR 0.65, 95% CI: 0.32–1.29, P=0.22). Survival probability of all-cause death, MV surgery or re-PBMV in the group with moderate MR before PBMV was not different from the group with less-than-moderate MR (adjusted HR 1.30, 95% CI: 0.98–1.62, P=0.10).

Conclusions: PBMV is an effective and safe treatment in rheumatic MS with moderate MR.

Keywords: Rheumatic mitral stenosis; mitral regurgitation (MR); percutaneous balloon mitral valvuloplasty (PBMV); procedural success

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Introduction

Although the incidence of rheumatic heart disease is declining worldwide, it is still an important disease in low to middle-income countries (1). Mitral stenosis (MS) is one of the common consequences of rheumatic heart disease. Patients with severe rheumatic MS usually experience symptoms that limited their daily activities. The quality of life of these patients is often impaired, and they are at high risk for heart failure, stroke, and arrhythmia (2,3).

Percutaneous mitral valvuloplasty (PMV) is one of the effective treatments for rheumatic MS (4). The rates of restenosis, re-intervention, or symptom improvement after percutaneous balloon mitral valvuloplasty (PBMV) were comparable with surgical commissurotomy (5). PMV has several advantages, including being less invasive, having a shorter procedural time, and lower cost. In addition, patients treated successfully with PMV had no increased risk of prosthesis-related complications such as valve thrombosis or infection.

PMV suitability and the prediction of success rate are determined by morphology of the mitral valve. New or acute deterioration of mitral regurgitation (MR) is a common complication of PMV. Approximately one-fifths of patients underwent PBMV developed new MR after the procedure (5). In the majority of cases, post-PMV MR is mild and tolerable, however, it can be severe and result in hemodynamic instability. Several mechanisms can be responsible for MR after PBMV, including tearing of the commissure, leaflet rupture, rupture of subvalvular structures of the mitral valve, or incomplete closure of the mitral valve due to calcification or shortening of the chordae tendinae after commissural splitting (6). Both the ESC and ACC/AHA guidelines for valvular heart disease recommend PMV in symptomatic severe rheumatic MS with favorable anatomy (pliable valve, no LA clot and less than moderate MR) (7,8). Mitral valve replacement is recommended in severe rheumatic MS with at least moderate MR. Severe rheumatic MS with more than mild MR is contraindicated for PMV per the 2021 ESC guidelines for valvular heart disease (7). However, according to the 2020 ACC/AHA guidelines, PMV can be performed in non-surgical candidate patients with severe rheumatic MS who have severe symptoms with unfavorable anatomy (i.e., non-pliable valve or moderate MR) (8).

Percutaneous balloon mitral valvuloplasty (PBMV) using an Inoue balloon is widely used in current practice. Some studies have reported a decrease in MR severity after PBMV (9,10). PBMV with the Inoue technique allows stepwise dilatation of the stenotic valve and may prevent MR progression. In addition, PBMV may be suitable in rheumatic MS patients with moderate MR, particularly in whom long-term exposure to a mechanical valve should be avoided. In this study, we aimed to assess the safety and efficacy of PBMV in patients with severe rheumatic MS with moderate MR in our hospital. We present the following article in accordance with the STROBE reporting checklist (available at https://cdt.amegroups.com/article/view/10.21037/cdt-22-140/rc).

Methods

Study population

The present study was a retrospective cohort study in Songklanagarind hospital, a tertiary center in the South of Thailand. Eligible patients were those with severe rheumatic MS who underwent PBMV with the Inoue technique between January 2003 and October 2020. In patients who had more than one PBMV procedure, information of the first procedure during the study period was counted, and any subsequent procedures counted as outcomes. Patients who had missing information on the procedural success were excluded from the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of the Faculty of Medicine, Prince of Songkla University approved the study protocol with a waiver of informed consent due to the retrospective nature of the study (No. REC 64-358-14-1).

Echocardiographic assessments

During the study period, echocardiography for rheumatic MS patients undergoing PBMV was performed by eight cardiologists in our hospital. Transthoracic echocardiography was performed to evaluate the severity of MS, MR and mitral valve morphology before PBMV. The mitral valve area (MVA) was measured with transthoracic echocardiography using 2-dimensional planimetry in parasternal short axis view. If planimetry was not available, MVA using the pressure half-time method was used. Severity of mitral and tricuspid regurgitation were assessed with qualitative Doppler based on the color flow jet area and the distance of regurgitant jet in the atrium (11,12). The severity was graded as follows: none or trivial (0), mild (1+), moderate (2+), moderate to severe (3+) or severe

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(4+) (13). Right ventricular systolic pressure (RVSP) was measured by the continuous wave Doppler tricuspid regurgitation (TR) jet velocity. The Wilkins score was based on semiquantitative grading of mitral valve morphology in four components; leaflet mobility, valve thickening, subvalvular fibrosis and valvular calcification (14). Each component was scaled from 0 to 4 in which the higher scores represented more severe valvular or subvalvular pathology. Follow-up transthoracic echocardiography was performed within 4 weeks after the procedure.

PBMV

Transesophageal echocardiography was used to assess left atrial thrombus before PBMV and to definitively evaluate severity of MR in borderline cases. The procedure was postponed if thrombus was present in left atrium. If the left atrium was free of thrombi, the PBMV was performed using an Inoue balloon via and antegrade transeptal approach under local anesthesia. An interatrial septum puncture was performed under transesophageal echocardiographic guidance. We used the following formula to guide maximal balloon size; (height of patient in centimeters/10) +10. The decision to adjust the balloon size and re-inflation was at the discretion of the operator.

Primary and secondary outcomes

The primary outcome of the study was PBMV success which was defined as post-procedural MVA ≥1.5 cm^2 or ≥50% increase in MVA and MR less than grade 3+ without death, stroke, mitral surgery and cardiac tamponade (15). The secondary outcome was the composite of all-cause mortality, mitral valve surgery or repeat PBMV after discharge. All-cause mortality was obtained from the civil registry, while information on mitral valve surgery or repeat PBMV (re-PBMV) were obtained from the medical records.

Statistical analysis

Categorical variables are presented as number and percentage. Chi-square or Fischer Exact test was used to test differences in categorical variables. Continuous variables are presented in mean (standard deviation) or median (interquartile range) depending on data distribution. *T*-test or Mann-Whitney U test was used to test differences in continuous variables.

The patients were categorized into two groups according to the MR severity (less than moderate or moderate) before the PBMV. We compared short-term outcomes (PBMV success rate and emergency surgery) between the two groups in a logistic regression model adjusted for age, functional class IV, presence of atrial fibrillation, history of prior commissurotomy, right ventricular systolic pressure greater than 50 mmHg, severe tricuspid regurgitation, very small pre-PBMV MVA (MVA <1.0 cm^2), and Wilkins score more than 8. These variables were listed in the most recent ESC guideline for valvular heart disease as factors associated with unfavorable PBMV outcomes (7).

The survival rate of all-cause death, mitral valve surgery or re-PBMV of the two groups at long-term are presented with Kaplan-Meier curves and were compared with the log-rank test. Time to the first event and the longest available follow-up information were used in the analysis. We compared long-term survival probability of outcomes between the two groups. Survival curves based on full parametric modelling adjusted for variables are presented with adjusted variables similar to those in the adjusted logistic regression. Weibull distribution was used in the survival model. Survival probability of all-cause death, mitral valve surgery or re-PBMV of the two groups were compared. Adjusted hazards ratios (HR) and 95% confidence intervals (CI) were reported. We used the survreg function in the R-software survival package for fully-parametric survival modelling (16).

Patients who were discharged alive and did not receive mitral valve surgery during the index PBMV admission were included in the analysis of the impact of MR severity after PBMV. Patients were classified into 4 groups according to MR severity after PBMV: no or trivial, mild MR, moderate MR and more than moderate MR. The survival probability on the composite of all-cause death, mitral valve surgery or re-PBMV adjusted for post-PBMV MVA among the patients with different MR severities after PBMV was assessed.

A P value less than 0.05 was considered statistically significant. All analyses were performed with the R program version 4.0.3.

Results

Characteristics of study patients

Of the 618 patients with rheumatic MS who underwent PBMV in Songklanagarind hospital during the study period, 598 patients (96.8%) had complete information of pre-PBMV MR severity and procedural success (*Figure 1*). The majorities were female (84%) with an overall mean age and body mass index of 41.7 years and 23.1 kg/m^2,

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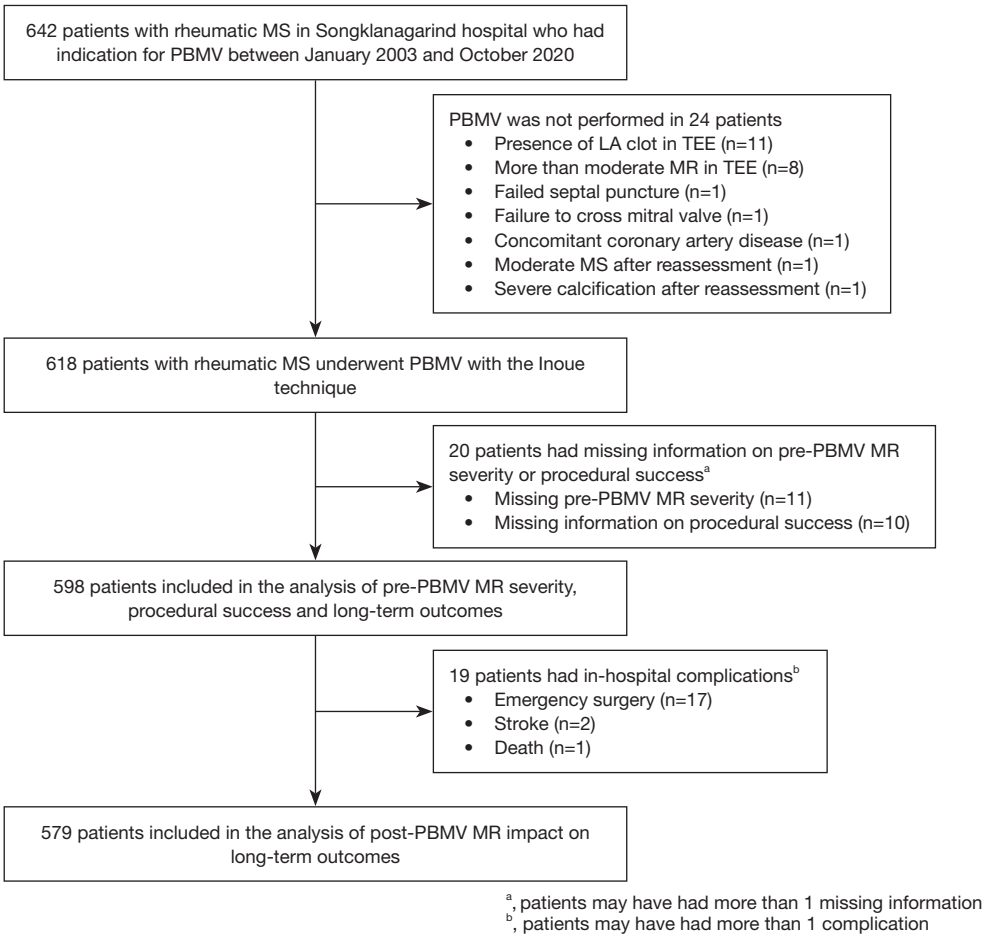

Figure 1 Flow of study population. MS, mitral stenosis; PBMV, percutaneous balloon mitral valvuloplasty; LA, left atrium; TEE, transesophageal echocardiography; MR, mitral regurgitation.

respectively (*Table 1*). The prevalence of atrial fibrillation was 39.4% while 1.7% of the patients had a history of prior commissurotomy. Pre-PBMV MVA was assessed with planimetry in 591 patients (98.8%) (Table S1). Mitral valve area equal to or lesser than 1.0 cm^2 was found in 63.1% with an average mean pressure gradient of 13.1 mmHg. The proportion of patients with RVSP greater than 50 was 55% while 5.6% had severe TR. The median Wilkins score was 8. The median initial and maximum balloon sizes were 24 and 25, respectively.

Forty-nine patients (8.2%) had moderate MR before PBMV. Of the 549 patients with less than moderate MR, 334 patients (55.9%) had no or trivial MR, whereas 215 patients (35.9%) had mild MR. No patients had moderate to severe or severe MR before PBMV. The patients in the moderate MR group were older (46.1 *vs.* 41.3 years, P=0.01) and had a higher prevalence of atrial fibrillation (59.2% *vs.* 37.6%, P<0.01) (*Table 1*). The pressure gradient across the mitral valve in patients with less than moderate MR was higher than in patients with moderate MR. The mean MVA before PBMV was 0.91 cm^2 and 1.01 cm^2 in the less-than-moderate MR and the moderate MR group respectively (P=0.01). The proportion of patients with a very small MVA was higher in the less than moderate MR group than in the moderate MR group (65% *vs.* 42.9%, P<0.01). The proportions of patients with functional class IV, prior commissurotomy, RVSP >50 mmHg and severe TR were not different between the moderate MR and less than moderate MR groups. Wilkins score, initial and maximum balloon size were similar between the two groups.

Changes in MR severity after PBMV

The severity of MR was unchanged in 48.7 % of the

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Table 1 Characteristics of study patients according to pre-PBMV MR severity

Characteristic	Overall	Pre-PBMV mitral regurgitation severity		P value
		Less than moderate (n=549)	Moderate (n=49)	
Female	500 (83.6)	460 (83.8)	40 (81.6)	0.85
Age (years), mean (SD)	41.7 (11.7)	41.3 (11.4)	46.1 (14.6)	0.01
Body mass index (kg/m^2), mean (SD)	23.1 (21.9)	23.1 (22.9)	23.4 (4.3)	0.92
Atrial fibrillation	235 (39.4)	206 (37.6)	29 (59.2)	<0.01
Functional class before PBMV				0.72
I	14 (2.4)	12 (2.2)	2 (4.1)	
II	306 (52.3)	281 (52.4)	25 (51.0)	
III	251 (42.9)	231 (43.1)	20 (40.8)	
IV	14 (2.4)	21 (2.2)	2 (4.1)	
Prior commissurotomy	10 (1.7)	9 (1.6)	1 (2.0)	1
Mitral valve area before PBMV (cm^2), mean (SD)	0.92 (0.24)	0.91 (0.24)	1.01 (0.22)	0.01
Mitral valve area ≤1.0 cm^2	377 (63.1)	356 (65.0)	21 (42.9)	<0.01
Peak pressure gradient, mean (SD)	22.1 (8.7)	22.3 (8.8)	19.6 (6.8)	0.04
Mean pressure gradient, mean (SD)	13.1 (6.3)	13.3 (6.4)	11.1 (4.8)	0.02
Right ventricular systolic pressure >50 mmHg	299 (55.0)	280 (56.2)	19 (41.3)	0.07
Severe tricuspid regurgitation	33 (5.6)	30 (5.5)	3 (6.1)	1
Wilkin score, median [IQR]	8.0 [7.0, 9.0]	8.0 [7.0, 9.0]	8.0 [7.0, 10.0]	0.18
Initial balloon size, median [IQR]	24.0 [23.0, 24.0]	24.0 [23.0, 24.0]	23.0 [23.0, 24.0]	0.14
Maximum balloon size, median [IQR]	25.0 [24.1, 26.0]	25.0 [24.5, 26.0]	25.0 [24.0, 26.0]	0.20
Mitral valve area after PBMV (cm^2), mean (SD)	1.57 (0.27)	1.57 (0.27)	1.59 (0.23)	0.57

Categorical variables are presented as n (%). PBMV, percutaneous balloon mitral valvuloplasty; MR, mitral regurgitation; SD, standard deviation.

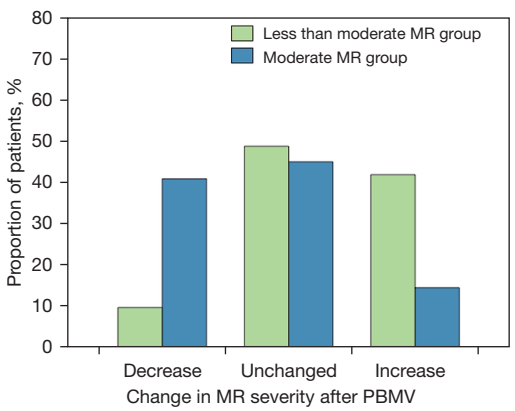

Figure 2 Changes in MR severity after PBMV according to pre-PBMV MR severity. PBMV, percutaneous balloon mitral valvuloplasty; MR, mitral regurgitation.

patients with less than moderate MR and in 44.9% of patients with moderate MR (*Figure 2*). In the group with moderate MR before PBMV, 7 patients (14.3%) developed moderate to severe MR after PBMV. Neither severe MR required emergency surgery nor in-hospital stroke occurred in these 7 patients. The proportion of patients with worsening MR after PBMV in the less-than-moderate MR group was 41.8%. MR severity decreased after PBMV in 40.8% and 9.5% in the groups with moderate MR and less than moderate MR, respectively.

PBMV outcomes compared between moderate MR and less-than-moderate MR groups

The procedural success was 69.4% in the moderate MR and

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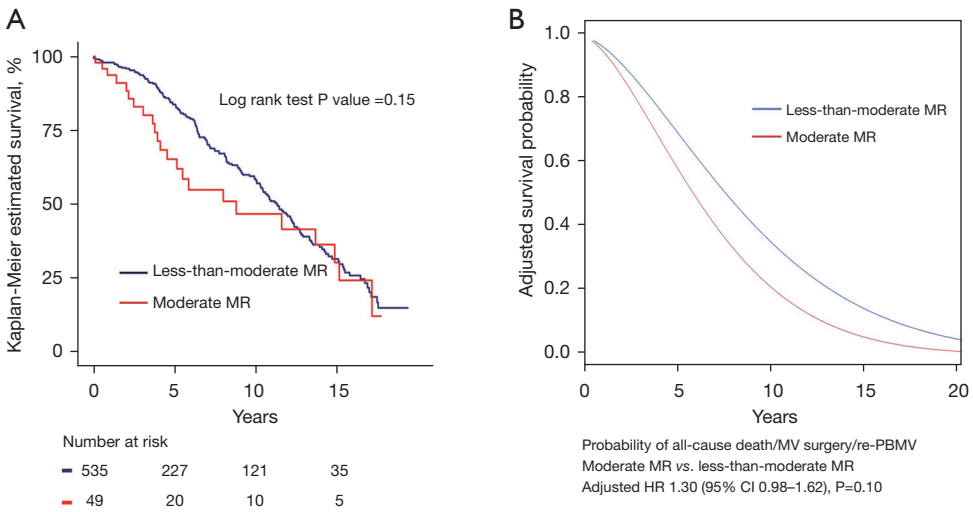

Figure 3 Kaplan-Meier survival curves (A) and adjusted survival probability of a composite of all-cause death, mitral valve surgery or re-PBMV (B) according to MR severity before PBMV. PBMV, percutaneous balloon mitral valvuloplasty; MR, mitral regurgitation.

79.2% in the less-than-moderate MR groups. Moderate MR before PBMV was not associated with a lower chance of PBMV success [moderate MR *vs.* less than moderate MR before PBMV: non-adjusted OR 0.59 (0.31–1.13), P=0.11, adjusted OR 0.65, 95% CI: 0.32–1.29, P=0.22]. The incidence of emergency mitral valve replacement was not significantly different between the two groups (2.7% in the group with less than moderate MR and 0% in the moderate MR group, adjusted P value =0.84). One patient in each group developed acute ischemic stroke during PBMV.

The median follow-up was 3.82 years. The Kaplan-Meier estimated survival of all-cause death, MV surgery or re-PBMV was similar between the two groups (Less-than-moderate MR *vs.* moderate MR; 14.6% *vs.* 12.1%, log rank P value 0.15) (*Figure 3A*). Survival probability of all-cause death, MV surgery or re-PBMV in the group with moderate MR before PBMV was not different from the group with less-than-moderate MR (adjusted HR 1.30, 95% CI: 0.98–1.62, P value =0.10) (*Figure 3B*). The Kaplan-Meier estimated survival and survival probability of all-cause death in the group with moderate MR (66.6%) was similar to the group with less-than-moderate MR (67.2%) (Figure S1).

Impact of MR after PBMV on long-term outcomes

A total of 579 patients who had no in-hospital complications following their PBMV (death, stroke, emergency surgery) were included in the analysis of post-PBMV MR impact on long-term outcomes. The proportions of patients with mild, moderate or more than moderate MR after PBMV were 32%, 22.1% and 4.2%, respectively. At a median follow up of 3.65 years, the group with more than moderate MR after PBMV had the lowest rate of Kaplan-Meier estimated survival of all-cause death, mitral valve surgery or re-PBMV, however, the log-rank test did not indicate any significant difference (*Figure 4A*). Patients with more than moderate MR after PBMV had the lowest survival probability (*Figure 4B*). The adjusted hazard risk for all-cause death, MV surgery or re-PBMV in the group with more than moderate MR after PBMV compared with the group without MR after PBMV was 1.46 (95% CI: 1.11–1.81).

Discussion

The salient findings of this study were (I) procedural success rate and incidence of emergency surgery in rheumatic MS patients with moderate MR before PBMV were not different from those with less than moderate MR. (II) The incidence of all-cause death, MV surgery or re-PBMV were similar between the two groups. (III) MR severity was unchanged or lessen in the majority of rheumatic MS patients who underwent PBMV in our hospital. (IV) The subsequent risk of all-cause mortality, MV surgery or re-PBMV in the group with more than moderate MR after PBMV was higher than in the group with no MR. The risk among the group with moderate or mild MR after PBMV

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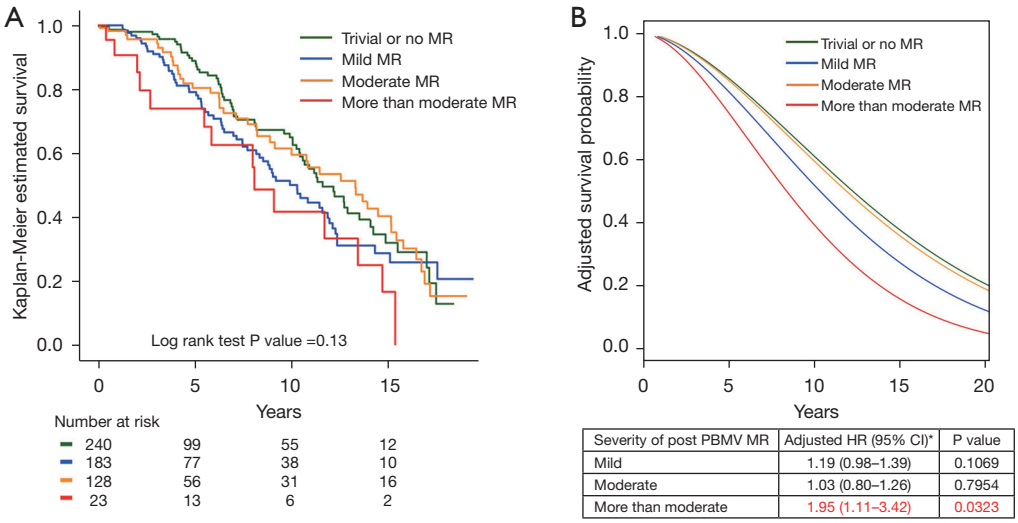

Severity of post PBMV MR	Adjusted HR (95% CI)*	P value
Mild	1.19 (0.98–1.39)	0.1069
Moderate	1.03 (0.80–1.26)	0.7954
More than moderate	1.95 (1.11–3.42)	0.0323

Figure 4 Kaplan-Meier survival curves (A) and adjusted survival probability of composite of all-cause death, mitral valve surgery or re-PBMV (B) among patients with different post-PBMV MR severity. *, Adjusted hazard ratio for the composite of all-cause death, MV surgery or re-PBMV using no or trivial MR after PBMV as a reference. PBMV, percutaneous balloon mitral valvuloplasty; MR, mitral regurgitation.

was similar to the group with no MR.

Percutaneous balloon mitral valvuloplasty

PBMV has been established as an effective intervention for rheumatic MS for almost 40 years (4). First described by Inoue *et al.* in 1982, the procedure is recommended by the guidelines of valvular heart disease as a treatment of choice in rheumatic MS patients with favorable valvular morphology (17). PBMV can be performed with two techniques, the double-balloon or Inoue technique. Left ventricular perforation caused by a balloon tip or guidewire are serious possible complications of the double-balloon technique. Currently, the procedure is commonly performed with the Inoue technique which allows stepwise dilatation of the stenotic valve with a low rate of procedural complications. A recent meta-analysis showed lower procedural morbidity associated with PBMV compared with mitral valve replacement, supporting the recommendation of PBMV in young patients with suitable anatomy (5).

Among the tools to assess mitral morphology, the Wilkins score is well-known and widely used in clinical practice (14). It has four components: leaflet mobility, leaflet thickness, subvavular thickening and calcification. A low Wilkins score indicates a pliable valve without severe thickening and predicts optimal results after PBMV (14). One study reported the Wilkins score was an independent predictor for long-term mortality, mitral valve surgery or re-PBMV (18). A Wilkin score higher than 8 indicated unfavorable anatomical characteristics for PBMV (7).

Complications after PBMV

The incidence of MR occurred immediately after PBMV was 19.9% in a recent meta-analysis. In the majority of cases, MR occurring after PMBV is mild and tolerable. However, MR can be severe and result in hemodynamic instability. The incidence of significant MR after PBMV has been reported to be 5.5–12.4% (4,6). One study reported that acute MR requiring emergent mitral valve replacement occurred only in a minority of cases (2%) (19).

Several mechanisms can be responsible for MR after PBMV, including tearing of the commissure, leaflet rupture, rupture of subvalvular structure of the mitral valve, or incomplete closure of the mitral valve due to calcification or shortening of chordae tendinae after commissural splitting (6). The long-term prognosis of MR after PBMV depends on the MR mechanism and residual valvular obstruction (20). Commissural splitting was the most common cause, with a better prognosis than with other mechanisms.

In our study, most of the patients who had pre-existing MR before PBMV had stable or improved MR severity after the PBMV. This finding is consistent with other studies (9,10). A small study in China reported a reduction in valvular regurgitation area after PBMV in rheumatic MS patients with pre-existing moderate or severe MR (21).

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It was postulated that commissural splitting after PBMV improved valve mobility. Hence, the leaflet closed properly during systole and regurgitation flow was smaller (21). Furthermore, post-PBMV MR can improve over time. Various mechanisms for such improvement have been described in the literature (22).

It is important to carefully assess valve morphology and to predict the occurrence of significant MR to avoid this complication. Independent predictors for significant MR after PBMV were reported in some studies (23,24). However, the results were inconsistent among studies. The total MR-echo score was found to be an independent predictor for significant MR after PBMV in some studies, although the best cutoff to predict was different in them (23,24). The total MR-echo score performed better than Wilkins and other scores in significant MR prediction. Subvalvular thickening and commissural calcification predicted deterioration of MR after PBMV in another study (25).

PBMV in moderate MR

Although more than mild MR is considered as a contraindication for PBMV in the ESC guidelines, PBMV may be suitable in selected rheumatic MS patients with moderate MR, for example, patients who have a prohibitive risk for surgery in which PBMV would serve as a palliative treatment. PBMV may delay the need for MV replacement and reduce the time exposed to a prosthetic valve in young rheumatic MS patients with moderate MR. Hence, it may reduce the risk of prosthetic valve infective endocarditis or valve thrombosis.

The incidence of PBMV in MS patients with more than mild MR varied across studies (21,26,27). In a large, prospective, single-center study in Brazil including 1582 patients undergoing PBMV, only 8 patients (0.5%) had MR equal to or greater than 2+ (27).

Of 482 patients who underwent PBMV in an Italian center between 1991 and 2010, only 11% had MR severity greater than mild (26). In this and another study, pre-PBMV MR severity was not identified as a predictor for long-term cardiac death, mitral surgery or repeat PBMV (26,28). PBMV was reported to be feasible in rheumatic MS with moderate or severe MR in a small single-center Chinese cohort (21). Desabandhu *et al.* prospectively studied the safety and efficacy of PBMV in severe MS patients with moderate MR (29), and found the proportion of patients with moderate MR of 7.5%, which was lower than in our study (8.2%). Although the incidence of cardiovascular death or severe MR at 30 days following PBMV in moderate MR in that study was 3 times higher than in the less than moderate MR group, the difference did not reach statistical significance (11.7% *vs.* 3.85%, P=0.36) (29). However, patients with moderate MR had a higher risk of severe MR after PBMV than those with less than moderate MR (relative risk 4.87, 95% CI: 1.42–16.69). PBMV improved the functional capacity in two-thirds of the patients with moderate MR (29).

The larger number of patients in our study improved the statistical power. In addition, it allowed the balancing of prognostic factors between the two groups by adjusting them in the regression model. The results of our study are in line with the Desabandhu *et al.* study and have confirmed the efficacy and safety of PBMV in rheumatic MS with moderate MR. PBMV is feasible in patients with moderate MR although the ESC guidelines suggest it should be considered as a contraindication. Since MR is usually stable or even improves after PBMV, PBMV can be performed in selected rheumatic MS patients with more than mild MR.

In the present study, patients with more than moderate MR after PBMV had significantly higher risk of all-cause death, MV surgery or re-PBMV than patients without MR after PBMV. Significant MR after PBMV impacted the subsequent risk of adverse events in the studies by Kim *et al.* and Nunes *et al.* (6,20). These studies reported that the prognosis of significant MR after PBMV depended on the mechanism of MR, and non-commissural MR had a worse prognosis than commissural. Therefore, patient assessment before PBMV is vital to select candidates in whom the risk of MR progression and the occurrence of non-commissural MR are low. The decision to perform PBMV in rheumatic MS patients with moderate MR should consider clinical factors such as age, comorbidities, and atrial fibrillation. Echocardiographic information including degree and symmetry of commissural calcification have been reported to be predictive for MR deterioration (24,30). Novel parameters derived from the three-dimensional transesophageal echocardiography such as scallop tenting, prolapse volumes or heights of coaptation may be useful for predicting severe MR after PBMV (31,32). Other imaging modalities such as cardiac magnetic resonance imaging may provide additional information on calcium distribution and can be less operator dependent (33).

As the number of PBMV procedures are decreasing worldwide and the procedural complications are inversely related to the volume of procedures, PBMV in rheumatic MS with more than mild MR should be performed in

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experienced centers. PBMV with the Inoue technique might be a good option for patients with moderate MR to reduce the risk of MR deterioration since the technique allows stepwise dilatation. Balloon selection based on three-dimension transesophageal echocardiography or other imaging modalities may be better than selection based on patient height (34). Moreover, novel techniques combining various tools in a contemporary catheterization laboratory such as real-time three-dimension echocardiography, rapid pacing, steerable guiding to facilitate MV crossing and a transradial artery approach promise to make the procedure safer in the future (34).

Limitations

Our study had a retrospective design in a single tertiary center. The success rate of PBMV depends on the experience of the operator and may vary across different centers (35). It is unknown if the efficacy and safety of PBMV in moderate MR would be similar in other centers with different degrees of experience and case volumes. Number of new PBMV cases is decreasing, therefore, a large prospective multicenter study in patients undergoing PBMV may help elucidate this issue.

PBMV with a single Inoue balloon was the only technique used in our study. This technique allows a stepwise dilatation of the stenotic valve, therefore, the risk of acute severe MR may be lower than with other techniques (4). Clinical data on the efficacy and safety of PMV with other techniques such as double-balloon or metallic commissurotomy in rheumatic MS patients with moderate MR are limited.

The qualitative Doppler method was used in our study to assess MR severity. Although it was suggested as the method to assess MR severity before rheumatic MS intervention by the 2020 ACC/AHA guidelines on valvular heart disease, other quantitative methods which are currently used in practice, such as vena contracta width or proximal isovelocity surface area, are more accurate and objective. Mechanisms of MR before and after PBMV were not recorded in our database. One mechanism responsible for the improvement of MR after PBMV was reported in one study to be better leaflet coaptation in shortened papillary muscle and tendons (21). Four mechanisms of MR after PMV and their impact on outcomes have been recently described (20).

The duration of follow-up after PBMV varied among patients. The vital status of patients was obtained from medical records or the civil registry. It is mandatory to report the death of a Thai citizen to the civil authority. However, the incidence of MV surgery or re-PBMV may be underestimated in our study since patients may receive the procedure in other hospitals. Long-term echocardiographic data and symptoms burden at follow-up were not systematically recorded in our database.

Conclusions

PBMV success, incidence of emergency surgery and mid-term outcomes in rheumatic MS patients with moderate MR who underwent PBMV were not different from those with less than moderate MR. PBMV is an effective and safe treatment in rheumatic MS patients with moderate MR.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://cdt.amegroups.com/article/view/10.21037/cdt-22-140/rc

Data Sharing Statement: Available at https://cdt.amegroups.com/article/view/10.21037/cdt-22-140/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://cdt.amegroups.com/article/view/10.21037/cdt-22-140/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of the Faculty of Medicine, Prince of Songkla University approved the study protocol with a waiver of informed consent due to the retrospective nature of the study (No. REC 64-358-14-1).

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Supplementary

Table S1 Method of mitral valve area assessment before and after PBMV in the study patients

Method of MVA assessment	Number of patients
Before PBMV	
Planimetry	591
No planimetry, pressure half-time method used	6
Neither planimetry nor pressure half-time available (missing information on MVA before PBMV)	1
After PBMV	
Planimetry	581
No information of MVA after PBMV	17
Emergency surgery	15
MVR	13
MVR + surgery for tamponade	1
Surgery for tamponade	1
Stroke immediately after PBMV	1
Moderate to severe MR, no surgery	1

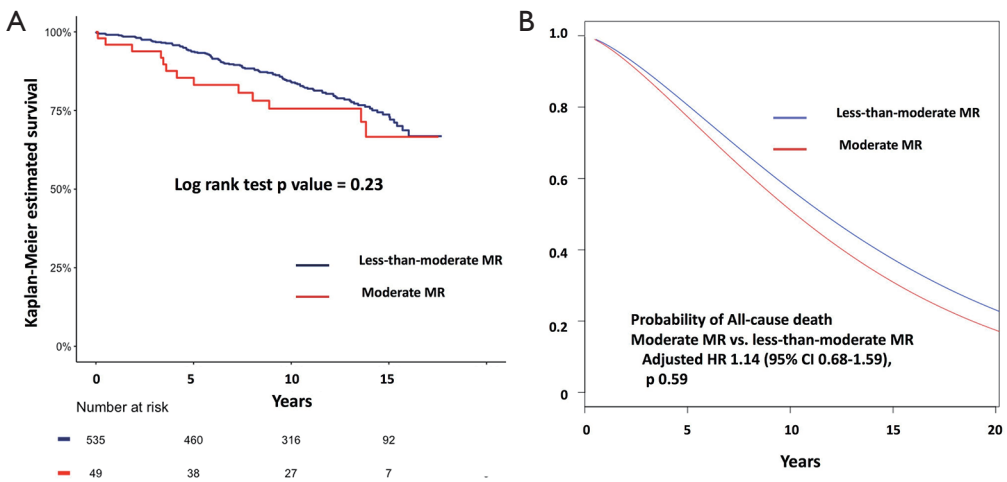

Figure S1 Kaplan-Meier survival curves (A) and adjusted survival probability of a composite of all-cause death (B) according to MR severity before PBMV. PBMV, percutaneous balloon mitral valvuloplasty; MR, mitral regurgitation.

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