



Predictors of Long-Term Outcomes of Percutaneous Mitral Valvuloplasty in Patients with Rheumatic Mitral Stenosis

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Purpose: We determined factors associated with long-term outcomes of patients who underwent successful percutaneous mitral balloon valvuloplasty (PMV).

Materials and Methods: Between August 1980 and May 2013, 1187 patients underwent PMV at Severance Hospital, Seoul, Korea. A total of 742 patients who underwent regular clinic visits for more than 10 years were retrospectively analyzed. The endpoints consisted of repeated PMV, mitral valve (MV) surgery, and cardiovascular-related death.

Results: The optimal result, defined as a post-PMV mitral valve area (MVA) $>1.5 \text{ cm}^2$ and mitral regurgitation \leq Grade II, was obtained in 631 (85%) patients. Over a mean follow up duration of 214 ± 50 months, 54 (7.3%) patients underwent repeat PMV, 4 (0.5%) underwent trido-PMV, and 248 (33.4%) underwent MV surgery. A total of 33 patients (4.4%) had stroke, and 35 (4.7%) patients died from cardiovascular-related reasons. In a multivariate analysis, echocardiographic score [$p=0.003$, hazard ratio=1.56, 95% confidence interval (CI): 1.01–2.41] and post-MVA cut-off ($p<0.001$, relative risk=0.39, 95% CI: 0.37–0.69) were the only significant predictors of long-term clinical outcomes after adjusting for confounding variables. A post-MVA cut-off value of 1.76 cm^2 showed satisfactory predictive power for poor long-term clinical outcomes.

Conclusion: In this long-term follow up study (up to 20 years), an echocardiographic score >8 and post-MVA $\leq 1.76 \text{ cm}^2$ were independent predictors of poor long-term clinical outcomes after PMV, including MV reintervention, stroke, and cardiovascular-related death.

Key Words: Mitral stenosis, percutaneous mitral balloon valvuloplasty, outcome

INTRODUCTION

Although the incidence of rheumatic valvular heart disease is decreasing in Korea, mitral stenosis (MS) is still an important cause of valvular heart disease. Percutaneous mitral balloon

valvuloplasty (PMV) has become an effective and safe procedure for symptomatic or hemodynamically significant MS with favorable valve anatomy since its first introduction.¹⁻³ Recent guidelines recommend PMV as the first therapeutic option for hemodynamically significant or symptomatic MS when mitral valve (MV) morphology favors PMV.⁴ While recent studies have reported long-term (≥ 10 year) outcomes of PMV, these studies analyzed a predominantly Caucasian population.⁵⁻¹² Although previous studies have shown that echocardiographic scores based on valve morphology correlate with immediate clinical outcomes, these scores do not predict long-term clinical outcomes.¹³ Thus, recent studies have focused on identifying long-term predictive factors, including hemodynamic, clinical, and/or echocardiographic characteristics. However, most of these studies are based on predominantly Caucasian populations and have relatively limited follow up

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durations (≤ 10 years).^{7,14} Moreover, Asian patients tend to be younger than those in Western countries; therefore, long-term clinical outcomes in Asian populations must be investigated as a distinct subgroup.

The aim of this study was to analyze the long-term results (≥ 20 years) of PMV at a single center. In addition, we determined the predictive factors of late clinical outcomes after successful PMV.

MATERIALS AND METHODS

Study population

Between August 1980 and May 2013, 1187 patients underwent PMV at Severance Hospital, Seoul, Korea (Baseline characteristics of 1187 patients are described at Supplementary Table 1, only online). Of these patients, we retrospectively analyzed those who had regular follow up visits for more than 10 years ($n=742$). Clinical status was determined by the New York Heart Association classification system. The indications of PMV were as follows: symptomatic moderate/severe MS with favorable valve morphology, asymptomatic moderate/severe MS with pulmonary hypertension and favorable valve morphology, and symptomatic moderate/severe MS with unfavorable valve morphology and unable/refused to undergo surgery. This study was approved by the Institutional Review Board of our institute (IRB No: 2013-2099-001).

Techniques

All procedures were performed via the antegrade transvenous approach by experienced physicians. The Inoue balloon technique or the double-balloon technique was used.¹⁵ The effective balloon-dilating area was calculated using standard geometric formulas and normalized to body surface area as previously described.¹⁶ The procedure was considered effective when full expansion of the balloon was accompanied by improvement in the mitral pressure gradient without detection of significant mitral regurgitation (MR) or any other mechanical complication.¹⁶ Optimal PMV results were defined as mitral valve area (MVA) ≥ 1.5 cm² with MR \leq GII/IV;^{1,3} suboptimal results were defined as MVA < 1.5 cm².^{2,14,17}

Echocardiographic evaluation

Comprehensive 2-dimensional transthoracic echocardiography (TTE) was performed in all patients before PMV and within 48 hours after PMV. The total echocardiographic score was obtained as previously described by adding the scores of the following morphological features: leaflet mobility, thickness, calcification, and subvalvular lesions using Wilkins scores.¹³ The MVA was measured by direct planimetry of the mitral orifice in a 2-dimensional short axis view early in diastole and also by the pressure half-time method.^{18,19} Continuous wave Doppler was used to calculate the mitral gradient and the peak pres-

sure gradient of tricuspid regurgitation (TR).¹⁵

Follow up

Demographic, clinical, and procedural variables were collected retrospectively by medical record review and by telephone contact. Clinical and echocardiographic assessments were carried out 6 months after PMV. Event-free TTE was performed once every 3–5 years. Patients were followed up for a mean duration of 214 ± 50 months after PMV. Restenosis was defined as MVA < 1.5 cm² from follow up TTE. Composite endpoints included repeated MV intervention, stroke, or cardiovascular-related death. Regarding repeated MV intervention, patients were analyzed with respect to whether they underwent any form of MV intervention, including redo PMV, trido PMV, or MV surgery.

Statistical analysis

Continuous variables are expressed as mean \pm SD, and categorical variables are expressed as percentage. Chi-square analysis was used to compare continuous and categorical variables. Kaplan-Meier estimates were used to determine overall and event-free survival rates. Cox regression hazard analyses were used to identify independent correlates of long-term event-free survival. Additive predictive value was assessed by comparing the global chi-square values. All analyses were performed using SPSS software version 20 (IBM Corp., Armonk, NY, USA).

RESULTS

Baseline characteristics and immediate PMV outcomes

The baseline characteristics of the 742 patients are described in Table 1. The mean patient age was 41.2 ± 11.1 years, and 75% of the patients were female. Optimal results (MVA ≥ 1.5 cm² and post MR \leq GII) were obtained in 631 (85%) patients. Post PMV MR $>$ GII was documented in 58 (8%) patients. After PMV, the mean MVA increased significantly from 0.92 cm² to 1.72 cm² ($p < 0.001$), and the mean diastolic pressure gradient (MDPG) decreased from 9.63 mm Hg to 4.15 mm Hg ($p < 0.001$). Severe MR requiring surgery (repair or replacement) was performed in 6 (0.8%) patients, and pericardiocentesis was performed in 5 (0.6%) due to cardiac tamponades. None had mitral annular rupture.

The baseline characteristics of patients who achieved optimal results differed significantly from those who achieved suboptimal results. Specifically, patients with optimal results were significantly younger and had sinus rhythm. Moreover, patients with optimal results had significantly lower echocardiographic score, larger pre MVA, smaller left atrium diameter, and less frequent significant TR (\geq GII) (Fig. 1).

Table 1. Baseline Characteristics

Variables	Optimal (n=631)	Suboptimal (n=111)	p value
Clinical characteristics			
Age (yr)	41±11	44±11	0.006
Women, n (%)	473 (75)	83 (75)	0.525
NYHA classification ≥III, n (%)	331 (53)	52 (43)	0.303
Atrial fibrillation, n (%)	238 (44)	66 (59)	<0.001
Pre-OMC history, n (%)	28 (6)	7 (8)	0.473
Echocardiographic parameters			
Echocardiographic score	7.8±1.2	8.4±1.4	<0.001
Echocardiographic score >8, n (%)	88 (14)	29 (26)	0.003
Pre-MVA, cm ² (2D planimetry)	0.94±0.31	0.81±0.38	<0.001
LV end diastolic dimension (mm)	48±8	50±8	0.066
LV end systolic dimension (mm)	36±8	38±9	0.054
Pre MDPG (mm Hg)	8.8±5.3	9.6±6.2	0.302
LV ejection fraction (%)	62±9	69±20	0.002
LAAP diameter (mm)	51±8	55±12	0.002
TR≥GII, n (%)	94 (15)	45 (41)	<0.001

NYHA, New York Heart Association; OMC, open mitral commissurotomy; MVA, mitral valve area; 2D, two-dimensional; LV, left ventricle; MDPG, mean diastolic pressure gradient; LA, left atrium; AP, anterior-posterior; TR, tricuspid regurgitation.

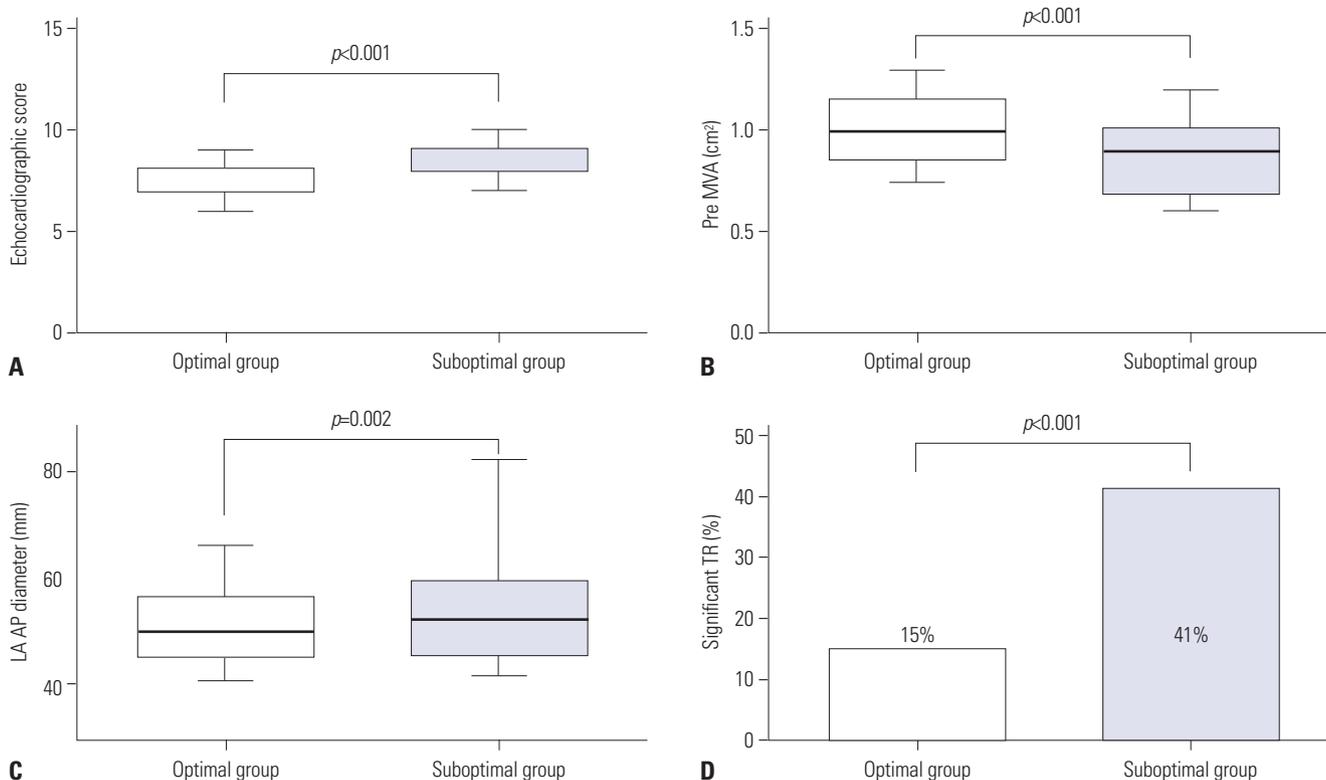


Fig. 1. Comparisons of pre-PMV echocardiographic score, MVA, LA AP diameter, and significant TR (≥GII) between patients with optimal and suboptimal PMV results. PMV, percutaneous mitral balloon valvuloplasty; MVA, mitral valve area; LA, left atrium; AP, anterior-posterior; TR, tricuspid regurgitation.

Long-term clinical outcomes

All 742 patients underwent regular follow up for more than 10 years. Over a mean follow up duration of 214±50 months, 54 (7.3%) patients underwent redo PMV, and 4 (0.5%) underwent trido-PMV. MV surgery was performed in 248 (33.4%) patients due to progression of MS, and mean time interval to MV sur-

gery was 126±72 months. A total of 33 patients (4.4%) experienced stroke, and 35 (4.7%) patients died from cardiovascular-related causes. The freedom from composite endpoint rates differed significantly between the optimal result group and suboptimal result group ($p<0.001$) (Fig. 2). The percentage of freedom from restenosis was 75% at 10 years and 53% at 15

years. The event-free survival rate of the composite endpoints was 75% at 10 years and 43% at 15 years.

A univariate analysis indicated that age ($p=0.041$), pre-procedural atrial fibrillation ($p<0.001$), echocardiographic score >8 ($p<0.001$), post-MVA ($p<0.001$), post-MR \geq GII ($p<0.001$), and post-TR \geq GII ($p<0.001$) were associated with poor long-term clinical outcomes (Table 2). Multivariate analysis showed that echocardiographic score [$p=0.003$, hazard ratio=1.56, 95% confidence interval (CI): 1.01–2.41] and post-MVA ($p<0.001$, relative risk=0.39, 95% CI: 0.37–0.69) were significant predictors of long-term clinical outcomes after adjusting for confounding variables. A post-MVA cut-off value of 1.76 cm² showed statistically significant predictive power for poor long-term clinical outcomes [area under curve (AUC): 0.63, 95% CI: 0.59–0.67, sensitivity: 66%, specificity: 56%, $p<0.001$]. Preoper-

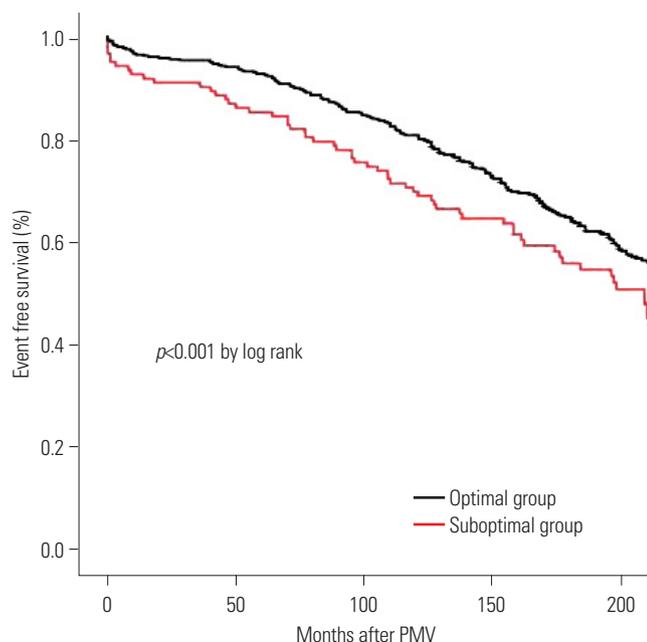


Fig. 2. Kaplan-Meier analysis of event-free survival rates for patients with optimal results after PMV and patients with suboptimal results after PMV. PMV, percutaneous mitral balloon valvuloplasty.

ative clinical parameters (age, pre-atrial fibrillation), echocardiographic score >8 , and post-MVA showed significant additive predictive value for poor long-term clinical outcomes (Fig. 3).

DISCUSSION

This study showed the long-term (up to 20 years) clinical outcomes of patients who underwent PMV. An echocardiographic score >8 and post-MVA were significant predictors of poor long-term clinical outcomes. Up to now, only a few studies have reported long-term event-free survival rates. Previously reported 10-year event-free survival rates ranged from 61–88%,^{5,7,20} similar to our findings: Our result is in good agreement with previous studies regarding satisfactory 10-year and 15-year event-free survival rates. The rate of reintervention of MV, including redo/trido or MV surgery, over up to 20 years of follow up was 38%.

We found that an echocardiographic score >8 and post-

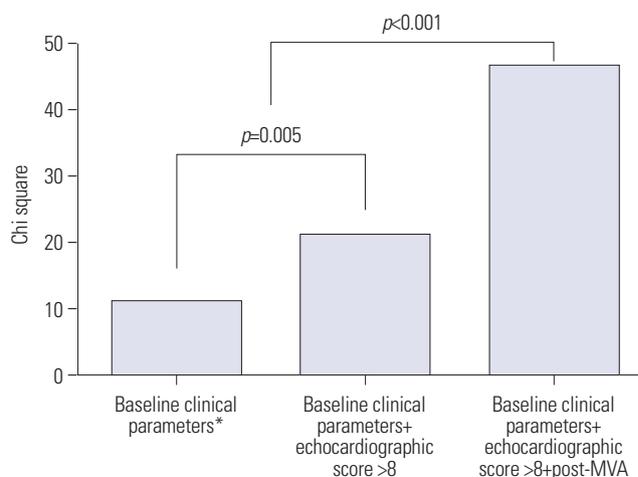


Fig. 3. Additive predictive value of echocardiographic score >8 and post-PMV mitral valve area (post-MVA) to baseline clinical parameters for predicting long-term clinical outcomes. *Age, atrial fibrillation. MVA, mitral valve area; PMV, percutaneous mitral balloon valvuloplasty.

Table 2. Predictors of Long-Term Clinical Outcomes after Percutaneous Mitral Balloon Valvuloplasty.

Variables	Univariate			Multivariate		
	HR	95% CI	p value	HR	95% CI	p value
Age	1.02	1.01–1.03	0.041	1.01	0.99–1.02	0.303
Female	1.42	0.81–2.51	0.072	0.85	0.63–1.15	0.289
History of OMC	1.94	0.97–3.91	0.061			
Atrial fibrillation	1.97	1.51–2.57	<0.001	1.58	0.94–1.61	0.144
Echocardiographic score >8	1.99	1.34–2.97	<0.001	1.56	1.01–2.41	0.003
Pre TR \geq GII	1.72	1.09–2.90	0.004	1.13	0.70–1.85	0.802
Pre MVA	0.99	0.69–1.42	0.972			
Post MVA	0.51	0.37–0.69	<0.001	0.39	0.27–0.57	<0.001
Post MR \geq GII	1.78	1.00–2.01	<0.001	1.45	1.02–2.05	0.062
Post TR \geq GII	7.55	4.50–12.6	<0.001	7.03	0.58–1.71	0.989

MR, mitral regurgitation; MVA, mitral valve area; OMC, open mitral commissurotomy; TR, tricuspid regurgitation.

MVA were independent predictors of long-term clinical outcomes after adjusting for confounding factors. In addition, they showed significant additive predictive value for predicting long-term clinical outcome in a consecutive manner. Favorable valve morphology, reflected by an echocardiographic score ≤ 8 , is known to be critical for optimal immediate results and event-free survival.^{13,21,22} Although patients with high echocardiographic score (>8) tend to have suboptimal results, however, others have suggested that suboptimal results are not necessarily associated with poor long-term clinical outcomes.²³ A few studies have suggested that long-term clinical outcomes are independent of echocardiographic scores.^{24,25} Our results showed that preprocedural echocardiographic score is an independent predictor of poor clinical outcomes after adjusting for confounding factors. Specifically, patients with suboptimal results had higher echocardiographic scores and showed significantly poorer long-term clinical outcomes compared to patients with optimal results.

Post-MVA was also an independent predictor of long-term clinical outcomes. In particular, post-MVA ≤ 1.76 cm² showed statistically predictive value for predicting poor long-term clinical outcomes (AUC: 0.63, 95% CI: 0.587–0.672, sensitivity: 66%, specificity: 56%, $p < 0.001$). Among our cohort, 250 patients (34%) had post-MVA ≤ 1.76 cm². However, discriminatory power was not very powerful. This finding is similar to those of previous mid-term follow-up studies. Song, et al.²⁵ suggested that post-MVA ≥ 1.9 cm² was a good negative predictor for poor clinical outcomes with AUC value of 0.63 (sensitivity 72%, specificity 58%, $p < 0.001$). The modest discriminatory power of post-MVA for long-term clinical outcome after PMV could be explained by numerous other factors, such as commissural MR or atrial fibrillation.

Pre-MVA was not significantly associated with long-term clinical outcomes. Although patients with optimal results had significantly larger pre-MVA than those with suboptimal results, pre-MVA was not significantly associated with long-term clinical outcomes. However, younger patients (aged < 50 years) with pre-MVA ≤ 1.0 cm² had significantly worse event-free long-term clinical outcomes ($p = 0.030$) than those with pre-MVA 1.0–1.5 cm² (Supplementary Fig. 1, only online). This finding may reflect current trends of preferring PMV over MV surgery with mechanical valve, even with unfavorable valve morphology, when MV intervention is indicated in younger patients.

Bouleti, et al.¹² suggested that older patients (aged ≥ 50 years) have significantly increased risk for surgery after PMV (57.3% vs. 32.3%, $p < 0.001$). Our findings are consistent with these results. Specifically, the event-free survival rate was significantly better in younger patients (aged < 50 years) than older patients (aged ≥ 50 years, $p < 0.001$). Although the univariate analysis in the current study showed that age was a significant predictor ($p = 0.041$) of long-term clinical outcomes, it was not, however, a significant predictor in the multivariate analysis.

Some studies have also reported that significant post-MR

(\geq GII) is a strong predictor of event-free survival.²⁶ However, we found that significant post-MR (\geq GII) was not an independent predictor of long-term clinical outcomes. Thus, severity alone does not reflect the influence of post-MR on long-term clinical outcomes after PMV. The mechanism of MR should be taken into consideration. After PMV, such mechanisms can be classified into commissural and non-commissural MR.²⁷ Commissural MR is thought to be the most frequent type of MR after PMV. This type is caused by splits in fused commissures, which are often considered clinically not important.²⁷ However, non-commissural MR is caused by subvalvular damage that leads to chordae rupture or leaflet tearing, which could result in poor prognosis.²⁶ In fact, some studies have reported that the clinical outcomes of PMV differ depending on the mechanism of post-MR.^{26,27} Kim, et al.²⁶ demonstrated that non-commissural MR was a useful predictor for determining poor long-term clinical outcomes (mean follow up > 7 years) among patients with atrial fibrillation and higher MDPG. Unfortunately, the retrospective nature of our study limited the assessment of the mechanism of MR, which could explain non-significant association between post-MR \geq GII and long-term clinical outcomes.

Limitations

Because of the observational nature of the study, a cause-and-effect relationship cannot be conclusively established between the predictors and the long-term outcomes. Moreover, these data were obtained from an Asian population at a single center, both of which should be considered in the interpretation of our data. Additionally, regular long-term follow up was not possible in all patients; therefore, the follow up TTE intervals differed between the patients. Furthermore, since we included only patients who had follow up data for more than 10 years, those with poor compliance might have been excluded. Regarding echocardiographic parameters, detailed information on valvular calcification, the type of post-MR (commissural vs. non commissural) or 3D measurement of MVA could have yielded additional insight regarding predictors of long-term clinical outcomes. Further studies with novel echocardiographic techniques could shed additional light on such predictors.

Conclusion

This study reported long-term clinical outcomes after PMV in a large cohort of Asian individuals. In this long-term follow up study, an echocardiographic score > 8 and post-MVA were independent predictors of poor long-term clinical outcomes after PMV, including MV reintervention, stroke, and cardiovascular-related death. Post-MVA ≤ 1.76 cm² showed satisfactory predictive value for predicting poor long-term clinical outcomes.

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