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# Is Redo Percutaneous Mitral Balloon Valvuloplasty (PMV) Indicated in Patients With Post-PMV Mitral Restenosis?

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**OBJECTIVES** The purpose of this study was to assess the immediate and long-term outcome of repeat percutaneous mitral balloon valvuloplasty (PMV) for post-PMV mitral restenosis.

**BACKGROUND** Symptomatic mitral restenosis develop in 7% to 21% of patients after PMV. Currently, most of these patients are referred for mitral valve replacement. However, it is unknown if these patients may benefit from repeat PMV.

**METHODS** We report the immediate outcome and long-term clinical follow-up results of 36 patients (mean age 58 ± 13 years, 75% women) with symptomatic mitral restenosis after prior PMV, who were treated with a repeat PMV at 34.6 ± 28 months after the initial PMV. The mean follow-up period was 30 ± 33 months with a maximal follow-up of 10 years.

**RESULTS** An immediate procedural success was obtained in 75% patients. The overall survival rate was 74%, 72% and 71% at one, two, and three years respectively. The event-free survival rate was 61%, 54% and 47% at one, two, and three years respectively. In the presence of comorbid diseases (cardiac and noncardiac) the two-year event-free survival was reduced to 29% as compared with 86% in patients without comorbid diseases. Cox regression analysis identified the echocardiographic score ($p = 0.03$), post-PMV mitral valve area ($p = 0.003$), post-PMV mitral regurgitation grade ($p = 0.02$) and post-PMV pulmonary artery pressure ($p = 0.0001$) as independent predictors of event-free survival after repeat PMV.

**CONCLUSIONS** Repeat PMV for post-PMV mitral restenosis results in good immediate and long-term outcome in patients with low echocardiographic scores and absence of comorbid diseases. Although the results are less favorable in patients with suboptimal characteristics, repeat PMV has a palliative role if the patients are not surgical candidates. (J Am Coll Cardiol 1999; 34:49–54) © 1999 by the American College of Cardiology

Since its first introduction in 1984 (1,2), percutaneous mitral balloon valvuloplasty (PMV) has been shown to be a safe and effective treatment for patients with rheumatic mitral stenosis (3–7). The immediate and long-term results of PMV are similar to those of closed and open surgical commissurotomy in comparable groups of patients (8,9). After PMV, approximately 7% to 21% of patients develop recurrent heart failure due to mitral restenosis (3,6,10–14). Although most of these patients currently undergo mitral valve replacement (MVR) (5), it is unknown whether some of these patients may benefit from a repeat PMV. In this study, we report our experience with redo PMV in 36 patients who developed post-PMV symptomatic mitral restenosis.

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## METHODS

**Patient population.** Between July 1986 and December 1996, 735 patients underwent 780 PMV at the Massachusetts General Hospital in Boston. From this group, we identified a cohort of 36 patients who underwent redo PMV because of symptoms of mitral restenosis at 34.6 ± 28 months after an initial PMV. They constitute the study population. Early in our experience, nine patients underwent repeat double-balloon PMV due to a suboptimal initial PMV result using a single-balloon technique and were therefore excluded from this analysis.

Baseline clinical and echocardiographic characteristics of the study population are summarized in Table 1. All patients presented with symptomatic heart failure, 78% being in New York Heart Association (NYHA) class III or IV and 22% NYHA class II. Of the overall group, 58% of the patients were considered to be at increased risk for cardiac surgery due to older age (>70 years) and presence of important cardiac and noncardiac coexisting conditions such

**Abbreviations and Acronyms**
MVR = mitral valve replacement
NYHA = New York Heart Association
PMV = percutaneous mitral balloon valvuloplasty

as coronary artery disease, previous aortic valve replacement, severe left ventricular dysfunction, severe chronic lung disease, previous stroke, cancer and chronic renal failure. Of the 36 patients, 12 had at least one, 4 had two and 5 had three or more associated comorbid conditions.

In an attempt to compare results of redo PMV with those of MVR for the treatment of post-PMV mitral restenosis, we also report the long-term outcome of 33 patients with symptomatic mitral restenosis successfully treated with MVR 35 ± 25 months after an initial successful PMV.

**Table 1.** Baseline Characteristics of the Patients Who Underwent Redo Percutaneous Mitral Balloon Valvuloplasty

| Characteristic | Value |
|---|---|
| Age (yr) | 58.3 ± 13.7 |
| Gender, no. (%) | |
| Male | 9 (25%) |
| Female | 27 (75%) |
| NYHA class, no. (%) | |
| II | 8 (22%) |
| III | 21 (58%) |
| IV | 7 (19%) |
| Rhythm, no. (%) | |
| Sinus | 14 (39%) |
| Atrial fibrillation | 22 (61%) |
| Previous commissurotomy, no. (%) | 6 (17%) |
| Fluoroscopic calcium | 26 (77%) |
| Associated cardiac disease, no. (%) | |
| Substantial aortic valve disease | 3 (8%) |
| Previous aortic valve replacement | 4 (11%) |
| Substantial coronary disease | 4 (11%) |
| Severe left ventricular dysfunction | 2 (5%) |
| Associated noncardiac disease, no. (%) | |
| Severe chronic lung disease | 8 (22%) |
| Cancer | 2 (5%) |
| Hypertension | 7 (19%) |
| Diabetes mellitus | 6 (17%) |
| Previous cerebrovascular accident | 4 (11%) |
| Chronic renal failure | 1 (3%) |
| Mitral valve morphologic score, no. (%) | |
| Mobility | 1.88 ± 0.7 |
| Thickening | 2.28 ± 0.7 |
| Calcification | 1.88 ± 0.8 |
| Subvalvular thickening | 2.16 ± 0.8 |
| Total echocardiographic score | 8.28 ± 2.3 (range: 4–14) |
| Score >8 | 18 (50%) |

NYHA = New York Heart Association

These 33 patients were identified from a cohort of 137 patients who underwent MVR at long-term follow-up after PMV. There were 26 women and 7 men with a mean age of 52 ± 2 (28 to 72) years. All were considered good surgical candidates.

**Mitral valvuloplasty procedure.** The technique of balloon mitral valvuloplasty has been previously described (15). Informed consent was obtained and PMV was performed in a fasting state under local anesthesia and mild sedation. Percutaneous mitral balloon valvuloplasty was performed by the antegrade transseptal approach with the Inoue balloon technique in nine patients and the double-balloon technique in the other 25 patients. Complete hemodynamic measurements of the right and the left heart, including simultaneous left atrial pressure, left ventricular pressure and cardiac output recordings were made immediately before and after the valvuloplasty. The corresponding pre- and post-PMV mitral valve areas were calculated using the Gorlin equation (16). A right heart oximetry saturation run was performed at baseline and after PMV to check for left to right shunt at the atrial level. A diagnosis of left to right shunting through the created atrial communication was made if an increase of ≥7% in oxygen saturation was detected between the superior vena cava and the pulmonary artery. In patients with severe tricuspid regurgitation or left to right shunt, cardiac output was measured by the Fick method. Oxygen consumption was obtained by using a metabolic rate meter (Waters Instruments, Rochester, Minnesota). Finally, cine left ventriculography (45° right anterior oblique projection) was performed before and after the PMV to assess the presence and severity of mitral regurgitation using the Seller's classification (17).

**Clinical follow-up.** Clinical follow-up was available in all patients at a mean duration of 30 ± 33 months. End points of follow-up were death, MVR and clinical evaluation according to the NYHA functional classification of congestive heart failure. Clinical evaluation was performed by trained medical personnel using direct examination or telephone interviews with the patients or the referring physicians and by review of hospital records.

**Statistical analysis.** All data are reported as means ± SD. Continuous variables were analyzed by Student *t* test. Kaplan-Meier estimates were used to determine total survival and event-free survival (defined as the absence of class III or IV congestive heart failure, MVR or death). Patients' demographic, hemodynamic, echocardiographic and procedural variables were evaluated by Cox proportional hazards regression to identify univariate predictors of event-free survival. The variables included in the analysis were age, gender, pre-PMV NYHA class, history of previous surgical commissurotomy, atrial fibrillation, echocardiographic score, post-PMV mitral valve area, post-PMV mitral regurgitation class and the post-PMV pulmonary artery pressure. To identify independent predictors of event-free survival,

**Table 2.** Hemodynamic and Procedural Variables for the Initial and Redo Percutaneous Mitral Balloon Valvuloplasty (PMV)

| | Pre | Post | p Value |
|---|---|---|---|
| Initial PMV | | | |
| Mean left atrial pressure (mm Hg) | 22 ± 7 | 15 ± 5 | 0.001 |
| Mean transmitral gradient (mm Hg) | 14 ± 5 | 6 ± 3 | 0.001 |
| Mean pulmonary artery pressure (mm Hg) | 35 ± 15 | 28 ± 11 | 0.03 |
| Cardiac output (liters/min) | 3.9 ± 1 | 4.5 ± 1 | 0.01 |
| Mitral valve area ($cm^2$) | 1.0 ± 0.3 | 1.9 ± 0.7 | 0.001 |
| Mitral regurgitation (Seller's class), no. (%) | | | |
| 0 | 22 (61%) | 14 (39%) | |
| I | 9 (25%) | 15 (42%) | |
| II | 2 (5%) | 3 (8%) | |
| III | 0 (0%) | 1 (3%) | |
| Redo PMV | | | |
| Mean left atrial pressure (mm Hg) | 20 ± 6 | 16 ± 5 | 0.003 |
| Mean transmitral gradient (mm Hg) | 11 ± 4 | 6 ± 2 | 0.001 |
| Mean pulmonary artery pressure (mm Hg) | 33 ± 12 | 30 ± 12 | NS |
| Cardiac output (liters/min) | 4.4 ± 1 | 4 ± 1 | NS |
| Mitral valve area ($cm^2$) | 1.1 ± 0.4 | 1.8 ± 0.7 | 0.001 |
| Mitral regurgitation (Seller's class), no. (%) | | | |
| 0 | 12 (33%) | 8 (22%) | |
| I | 17 (47%) | 16 (44%) | |
| II | 7 (19%) | 9 (25%) | |
| III | 0 (0%) | 2 (5%) | |

multiple stepwise Cox regression analysis was performed with significant variables from the univariate analysis. A p value of $<0.05$ was considered to indicate statistical significance. Analysis was performed with the JMP statistical software (SAS Institute, Cary, North Carolina, version 3.2).

## RESULTS

### *Immediate Results*

Percutaneous mitral balloon valvuloplasty was successfully completed in all the patients. Pre- and post-PMV hemodynamic parameters are listed in Table 2. There was a significant increase in the mitral valve area (1.1 ± 0.4 to 1.8 ± 0.7 $cm^2$; $p < 0.005$), and decreases in the mean transmitral gradient (11 ± 4 to 6 ± 2 mm Hg; $p < 0.005$) and mean left atrial pressure (20 ± 6 to 16 ± 5 mm Hg; $p < 0.005$). Mean pulmonary artery pressure and cardiac output did not change significantly with PMV. The degree of mitral regurgitation by left ventriculography was unchanged in 24 patients (67%), increased by one grade in 10 patients (28%) and decreased by one grade in 1 patient (3%). Successful procedural outcome (post-PMV mitral valve area $\geq 1.5$ $cm^2$, pulmonary/systemic flow ratio $\leq 1.5:1$ and $<2+$ increase in mitral regurgitation with a post-PMV mitral regurgitation $<3+$) was achieved in 75% of patients. Two patients developed severe mitral regurgitation (3+) after redo PMV. A suboptimal post-PMV mitral valve area ($<1.5$ $cm^2$) was found in seven (19.4%) patients, two of whom also had evidence of left to right shunt with a pulmonary/systemic flow ratio $>1.5:1$. No baseline or procedural variables were found to be independent predictors of successful immediate outcome by multivariate logistic regression analysis.

### *In-Hospital Outcome*

One patient suffered a large cerebrovascular accident and subsequently died. There were no other in-hospital deaths. None of the patients developed cardiac tamponade, severe mitral regurgitation or required mitral valve replacement during their hospitalization. Other complications consisting of peripheral vascular repair or blood transfusion were required in four patients.

### *Clinical Follow-up*

**Patients with redo PMV.** The mean follow-up was 30 ± 33 months. Only one patient was lost to follow-up. He was last contacted 57 months after the redo PMV, when he was asymptomatic. Early symptomatic improvement after redo PMV of $\geq 1$ NYHA functional class was obtained in 90% of the patients. During the follow-up period, there were 12 (33%) deaths, and 14 (39%) patients required mitral valve replacement (18 ± 17 months after redo PMV) due to recurrent symptoms. Overall, 15 patients (41%) were alive without further valvular intervention 52 ± 38 months after redo PMV. All of these patients were in NYHA class I or II at follow-up. The one-, two-, and three-year overall survival rate by Kaplan-Meier estimates were 74%, 72% and 71% respectively (Fig. 1). The probability of event-free survival (alive and free of mitral valve replacement and/or NYHA class $\geq$III) at one, two and three years was 61%, 54% and 47%, respectively (Fig. 1). The outcome was significantly different when patients were stratified into subgroups based on the presence or absence of associated comorbid conditions. As shown in Figure 2, in patients without any comorbid diseases the overall survival and event-free survival at two years were 93% and 86% respectively, as compared with 56% and 29% in patients with associated comorbid conditions ($p < 0.03$ for both).

**Patients with MVR.** Follow-up was available in all 33 patients who underwent MVR for treatment of post-PMV restenosis. At a mean follow-up time of 58 ± 29 months, there were 2 (6.0%) deaths occurring at 86 and 93 months after MVR. No patient required redo MVR. From the 31 living patients, 4 (12.9%) were in NYHA functional Class

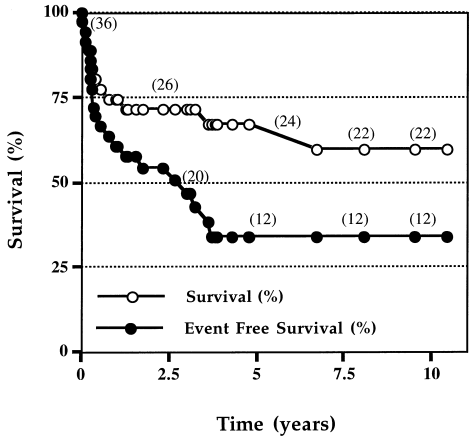


**Figure 1.** Survival and event-free survival of patients undergoing redo percutaneous mitral balloon valvuloplasty. Numbers in parentheses represent number of patients alive and uncensored **(top curve)** and alive and free of combined events uncensored **(bottom curve)** at the end of each time interval.

III or IV. In addition, there were 4 (12.9%) embolic strokes. Thus, although 81.2% of the patients were alive and free of MVR and/or NYHA functional class III–IV, only 68.3% of them were alive and free from redo MVR, NYHA class III–IV and embolic strokes at long-term follow-up.

### *Predictors of Event-Free Survival*

By univariate analysis age, history of previous surgical commissurotomy, pre-PMV NYHA functional class, echocardiographic score, post-PMV mitral regurgitation class, post-PMV pulmonary artery pressure and post-PMV mitral valve area were identified as univariate predictors of long-term event-free survival in the redo PMV group. Using these explanatory variables in the stepwise multivariate Cox regression analysis, the independent predictors of event-free survival were lower echocardiographic score ($p = 0.03$), larger post-PMV mitral valve area ($p = 0.003$), post-PMV mitral regurgitation $<3+/4+$ ($p = 0.01$) and lower post-PMV mean pulmonary artery pressure ($p = 0.0001$) (Table 3).

## DISCUSSION

This study demonstrates that a repeat PMV can be safely performed in patients presenting with mitral restenosis after an initial PMV. Our study shows that in this patient population, successful procedural outcome was achieved in 75% of patients and at three-year follow-up, good functional results without subsequent mitral valve replacement or death were obtained in 47% of patients. Furthermore, this study identified four independent predictors of long-term event-free survival in patients undergoing redo PMV: the mitral valve echocardiographic score, the post-PMV mitral valve area, the post-PMV pulmonary artery pressure and the severity of mitral regurgitation after PMV.

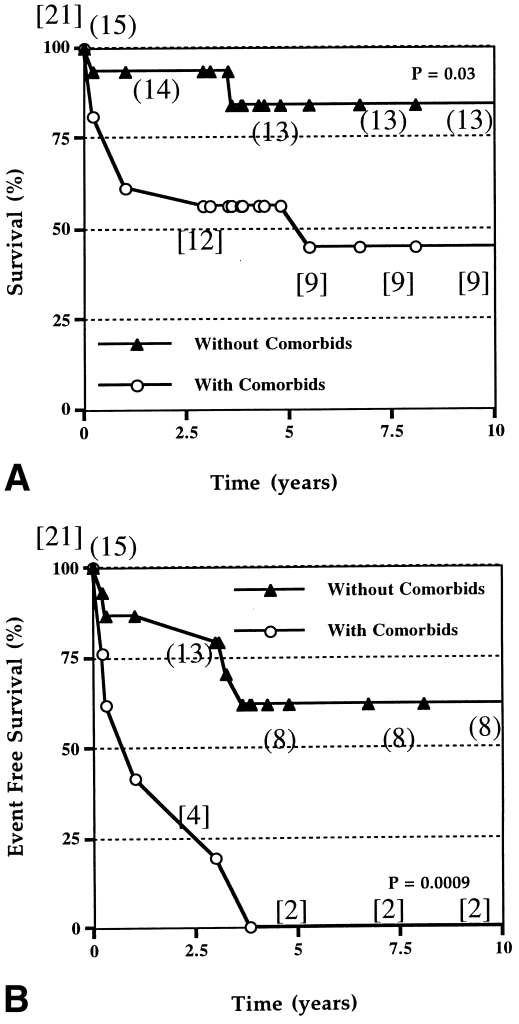


**Figure 2.** Comparison of long-term survival **(A)** and event-free survival **(B)** of patients undergoing redo percutaneous mitral balloon valvuloplasty without **(top curves)** and with **(lower curves)** associated comorbid diseases. Numbers in parentheses or brackets represent number of patients alive and uncensored **(A)** and alive and free of combined events uncensored **(B)** at the end of each time interval.

**Immediate and late results of redo PMV.** Our 75% success rate of redo-PMV is similar to previous studies of de novo PMV (4,7,9,10,13,18). However, the 47% three year event-free survival in patients with mitral restenosis undergoing redo PMV compares unfavorably with that reported in larger series from patients undergoing a de novo PMV (5,7,13,15,19). Although comparison of our results of redo PMV with those from other reports of PMV is difficult due to the heterogeneity of the patients, a greater extent of valve pathology and more comorbid diseases in our study group may in part account for the difference. In fact, in the present study, the long-term results of redo PMV in patients without associated comorbid diseases is comparable to previously published reports. Our patient population included a group of subjects with an increased frequency of

**Table 3.** Independent Predictors of Long-Term Event-Free Survival (Multivariate Cox Regression Analysis)

| Variable | Relative Risk | (95% CI) | p Value |
|---|---|---|---|
| Echocardiographic score | 1.42 | (1.02–1.99) | 0.04 |
| Post-PMV mitral valve area | 0.19 | (0.06–0.58) | 0.003 |
| Post-PMV ≥3+ mitral regurgitation | 26.2 | (2.1–32.3) | 0.01 |
| Post-PMV pulmonary artery pressure | 1.13 | (1.06–1.21) | 0.0001 |

CI = confidence interval; PMV = percutaneous mitral balloon valvuloplasty.

variables associated with decreased immediate and long-term good results after PMV such as older age, higher echocardiographic score, increased fluoroscopic calcium, history of previous surgical commissurotomy and higher incidence of atrial fibrillation. The follow-up results of our series are in agreement with those from series including patients with more extensive valvular deformity and comorbid diseases. Tuzcu et al. (20) reported a three-year event-free survival of 46% in an elderly population with significant comorbid diseases. Similarly, Cohen et al. (3) reported a five-year combined event-free survival of 51% in a group of 146 patients undergoing PMV, which included a greater proportion of patients with advanced age, higher echocardiographic scores and important coexisting conditions. Furthermore, it is possible that repeated valvular injury and healing response during multiple surgical or percutaneous balloon procedures may be adding to the valvular deformity.

**Late results of surgical techniques.** Surgical valvular interventions are another treatment option in patients with mitral restenosis after prior PMV. However, because of more extensive valvular and subvalvular involvement in this patient population, MVR, rather than reconstructive techniques, is usually used. Indeed, all the patients with mitral restenosis from this study who underwent mitral valve surgery at follow-up required MVR. Similarly, 84% of the patients from the NHLBI balloon valvuloplasty registry undergoing mitral valve surgery at follow-up had their mitral valve replaced (5). The risk of perioperative mortality and early death after MVR increases with age, high NYHA functional class and associated comorbid diseases (21–23). Hospital mortality between 8.9% and 9.6% for MVR has been reported (21,22). Furthermore, in elderly patients with combined MVR and coronary artery bypass surgery, the mortality may be as high as 50% (24). A surgical mortality of 5% occurred in our cohort of 137 patients who underwent MVR at long-term follow-up after PMV.

Although the procedural mortality was limited to only one (2.7%) patient in our series of redo PMV, the long-term outcome of our patients undergoing redo PMV is less favorable than those reported after MVR. However, late results after MVR or redo PMV must be analyzed according to the patient characteristics and associated comorbid diseases. The long-term results of our 33 patients undergoing MVR for treatment of post-PMV restenosis showed a 81.2% survival with freedom from redo MVR and severe congestive heart failure and a 68.3% survival with freedom from redo MVR, congestive heart failure and embolic strokes at long-term follow-up. These 33 patients were considered good surgical candidates for mitral valve surgery, whereas a large portion of our patients undergoing redo PMV were considered unsuitable for mitral valve surgery due to the presence of multiple adverse conditions. Although there are difficulties in comparing the long-term results of those patients with restenosis after PMV treated with MVR with those undergoing redo PMV, the survival and event-free survival of the patients without associated comorbid diseases undergoing redo PMV suggest that in patients with appropriate valve morphology, this technique can be performed safely with similar or better outcome than mitral valve replacement.

**Predictors of combined event-free survival.** The predictors of long-term outcome after redo PMV are in agreement with those of previous studies. They include higher echocardiographic score, ≥3+ post-PMV Sellers grade of mitral regurgitation, smaller post-PMV mitral valve area and higher postprocedural pulmonary artery pressure (3,5–7,25–27).

**Clinical role of repeat PMV.** Patients with low echocardiographic scores and no comorbid conditions have an overall survival and combined event-free survival similar to what has been reported for patients undergoing either a de novo PMV or mitral valve surgery. In such patients, repeat PMV should be the procedure of choice. In older patients and in those with higher echocardiographic scores and comorbid disease, the procedure appears to be more palliative. These patients generally do poorly in follow-up, and if they are acceptable candidates for MVR, this should be the preferred approach. However, there is still a small group of patients who cannot undergo surgical correction due to a high operative risk, and the use of PMV is reasonable in such patients.

**Conclusions.** Repeat percutaneous mitral valvuloplasty in patients with restenosis after a prior percutaneous valvuloplasty is feasible and can be accomplished with acceptable morbidity and mortality. Immediate procedural success is achieved in 75% of patients, and the three-year overall survival and event-free survival is 71% and 47%, respectively. In patients with low echo scores and no comorbid diseases, repeat PMV should be the procedure of choice. Although mitral valve surgery should be the treatment of choice for patients with more extensive valvular and subvalvular deformity, redo PMV can be used as a palliative technique in these patients when they are at high risk of morbidity and mortality with MVR due to the presence of associated significant comorbid diseases.

**Study limitations.** Although this a retrospective study of a small patient population undergoing redo PMV, our patient cohort was derived from a large population of patients undergoing PMV. These results are from a single center performing a high volume of PMVs and may not be applicable to the overall population of patients undergoing PMV. The comparison of redo PMV and MVR is not randomized, and prospective randomized studies of redo PMV versus mitral valve surgery in comparable patients with mitral restenosis after PMV will be necessary. Nevertheless, our study supports the conclusion that redo PMV should be the procedure of choice for those patients with post-PMV restenosis and favorable mitral valve morphology.

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