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Four-Year Follow-Up of Patients Undergoing Percutaneous Balloon Mitral Commissurotomy

A Report From the National Heart, Lung, and Blood Institute Balloon Valvuloplasty Registry

LARRY S. DEAN, MD, FACC, MARY MICKEL, MS,* RAOUL BONAN, MD, FACC,†
DAVID R. HOLMES, JR., MD, FACC,‡ WILLIAM W. O'NEILL, MD, FACC,§
IGOR F. PALACIOS, MD, FACC,‖ SHAHBUDIN RAHIMTOOLA, MD, FACC,¶
JAMES N. SLATER, MD, FACC,# KATHRYN DAVIS, PHD, FACC,*
J. WARD KENNEDY, MD, FACC*

Birmingham, Alabama; Seattle, Washington; Montreal, Quebec, Canada; Rochester, Minnesota; Royal Oak, Michigan; Boston, Massachusetts; Los Angeles, California; and New York, New York

Objectives. **This study reports the long-term outcome of patients undergoing percutaneous balloon mitral commissurotomy who were enrolled in the National Heart, Lung, and Blood Institute (NHLBI) Balloon Valvuloplasty Registry.**

Background. **The NHLBI established the multicenter Balloon Valvuloplasty Registry in November 1987 to assess both short- and long-term safety and efficiency of percutaneous balloon mitral commissurotomy.**

Methods. **Between November 1987 and October 1989, 736 patients ≥18 years old underwent percutaneous balloon mitral commissurotomy at 23 registry sites in North America. The maximal follow-up period was ≤ 2 years.**

Results. **The actuarial survival rate was 93 ± 1% (mean ± SD), 90 ± 1.2%, 87 ± 1.4% and 84 ± 1.6% at 1, 2, 3 and 4 years, respectively. Eighty percent of the patients were alive and free of mitral surgery or repeat balloon mitral commissurotomy at 1 year. The event-free survival rate was 80 ± 1.5% at 1 year, 71 ± 1.7% at 2 years, 66 ± 1.8% at 3 years and 60 ± 2.0% at 4 years. Important univariable predictors of actuarial mortality at 4 years included age >70 years (51% survival), New York Heart Association functional class IV (41% survival) and baseline echocardiographic score >12 (24% survival). Multivariable predictors of mortality included functional class IV, higher echocardiographic score and higher postprocedural pulmonary artery systolic and left ventricular end-diastolic pressures ($p < 0.01$).**

Conclusions. **Percutaneous balloon mitral commissurotomy has a favorable effect on the hemodynamic variables of mitral stenosis, and long-term follow-up data suggest that it is a viable alternative with respect to surgical commissurotomy in selected patients.**

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Percutaneous balloon mitral commissurotomy, first described by Inoue et al. (1) in 1984, has been shown (2–4) to produce a satisfactory hemodynamic result in patients with rheumatic mitral stenosis. Long-term follow-up data for these patients at various centers appear to be favorable (5,6). However, many of these centers are outside North America, and their patients are generally younger and have fewer comorbid diseases and more favorable valve pathology. These factors may lead not only to different short-term results but also to possible differences in long-term follow-up data.

The National Heart, Lung, and Blood Institute funded the Balloon Valvuloplasty Registry in November 1987. The purpose of the registry was to collect detailed baseline and postprocedural data and to provide long-term follow-up information on patients undergoing the procedure at 23 centers in North America (24 centers were involved in the registry; however, one did not enroll patients in the mitral registry. The present report provides long-term follow-up information for patients undergoing this procedure in the Registry. The in-hospital and 30-day hemodynamic and clinical outcomes have been previously reported (4,7).

From the Department of Medicine, University of Alabama at Birmingham, Birmingham, Alabama; *Department of Medicine, University of Washington, Seattle, Washington; †University of Montreal, Montreal, Quebec, Canada; ‡Mayo Clinic and Mayo Foundation, Rochester, Minnesota; §Division of Cardiology, William Beamont Hospital, Royal Oak, Michigan; ‖Cardiac Unit, Massachusetts General Hospital, Boston, Massachusetts; ¶Division of Cardiology, University of Southern California, Los Angeles, California; and #Cardiac Catheterization Laboratory, St. Luke's/Roosevelt Hospital, New York, New York. This study was presented in part at the 67th Scientific Sessions of the American Heart Association, Dallas, Texas, November 1994 and was supported by Grant 01-HV-78100 from the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland.

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Address for correspondence: Dr. Larry S. Dean, Division of Cardiovascular Diseases, University of Birmingham at Alabama, UAB Station, Birmingham, Alabama 35294. E-mail: ldean@cardio.tht.uab.edu.

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Methods

Data collection. Percutaneous balloon mitral commissurotomy was performed at the individual sites under institutional review board approval. All patients ≥18 years old undergoing the procedure at the registry sites were included in the registry. Of the original 738 patients who were identified, 2 were noted on review to have been enrolled twice at different centers. Therefore, this report provides follow-up data for 736 patients. Details regarding data collection have been reported elsewhere (4).

Follow-up information was obtained at hospital discharge, 5 weeks after the procedure and thereafter at 6-month intervals until October 31, 1992, when the registry was closed. The maximal follow-up period was 5.2 years (mean [±SD] 3.2 ± 1.3). The data were collected on a standardized form by a research nurse at each clinical site. Events (e.g., death, repeat percutaneous balloon mitral commissurotomy, valve surgery) were collected at the follow-up visits. The records of all patients who died were reviewed by a mortality review committee for adjudication of cause of death.

Statistical analysis. Clinical status was reported at baseline, 6 months and yearly thereafter. The status of patients who died was considered "worse" than that at baseline. Results were censored at the time of mitral valve surgery or repeat balloon mitral commissurotomy. Data are reported as mean value ±SD.

Kaplan-Meier time to event curves were constructed for two outcomes: 1) survival, censored at mitral valve surgery or repeat balloon mitral commissurotomy; 2) event-free survival, with event defined as mitral valve surgery or repeat balloon mitral commissurotomy. Rate estimates, standard errors and 95% confidence intervals are reported for each year of follow-up. Event rates in subgroups determined by baseline and postprocedural variables were compared by the log-rank test.

Multivariate Cox regression was used to identify independent predictors of the three outcomes. Because the large number of potential covariates, separate stepwise models were initially constructed for clinical, echocardiographic, catheterization and "miscellaneous" data. Variables that were significant at $p = 0.05$ in these analyses were then considered for inclusion in the overall models. Interactions between selected variables were allowed to enter if they had additional predictive power. The proportional hazards assumption was verified by stratification of the final models by each independent variable.

Results

Patients. The mean age of the patients was 54 ± 15 years, and 81% were female. The mitral valve area increased from 1.0 ± 0.3 cm^2 before the procedure to 2.0 ± 0.8 cm^2 after the procedure. Details of the hemodynamic and early clinical outcomes have been reported elsewhere (1,2,8). Echocardiographic assessment (performed at the study site) showed a mitral valve area of 1.09 ± 0.29 cm^2 before the procedure,

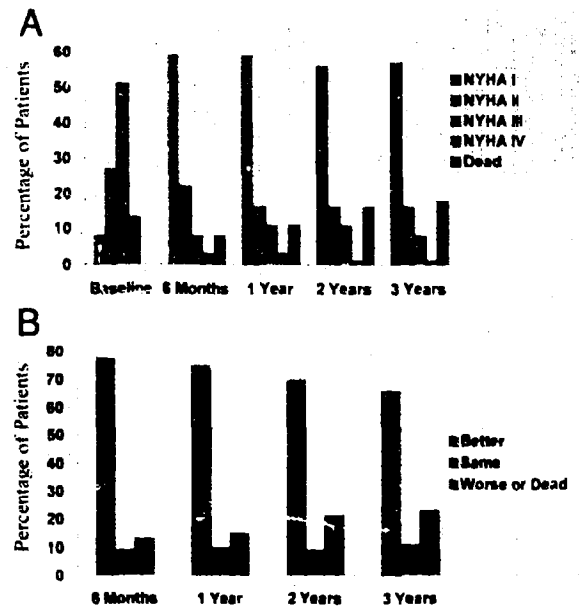


Figure 1. A. Percentage of patients in New York Heart Association (NYHA) functional classes I to IV before balloon mitral commissurotomy, at 6 months and yearly thereafter to 3 years. Note that the majority of patients remain in functional class I throughout follow-up. **B.** Percentage of patients after balloon mitral commissurotomy who report their overall health status as better, the same or worse than at baseline (vs. baseline status at 6 months and then yearly thereafter to 3 years). Their impression of original overall health status closely mirrors the percentages in functional classes I and II.

which improved to 1.80 ± 0.15 cm^2 after the procedure and declined to 1.68 ± 0.48 cm^2 at 6-month restudy ($p < 0.0001$).

Clinical symptoms: functional capacity. As depicted in Figure 1A, 64% of patients were in New York Heart Association functional class III or IV before the procedure. At 6 months there was a marked reduction of symptoms, with 81% of patients in functional class I or II and only 11% remaining in functional class III or IV and 8% dead. The percent of patients in functional class I or II remained remarkably stable during follow-up. Functional improvement was also reflected in the overall health status as perceived by the patient, >65% of whom reported feeling better throughout the follow-up period (Fig. 1B).

Survival. The survival rate was 93 ± 1.0% at 1 year, 90 ± 1.2% at 2 years, 87 ± 1.4% at 3 years and 84 ± 1.6% at 4 years (Fig. 2). Of the 122 registry patients who died, the cause of death was determined in 112 (92%). The most frequent cause of death was cardiac (71%), with congestive heart failure the most common (29%). Survival in elderly patients >70 years old was worse than that in younger patients at all periods of time. At 4-years of follow-up, the survival rate was 89% in those ≤70 years old versus 51% in those >70 y old. In addition, survival was higher in women than men; at 4 years, 87% of women compared with 73% of men were alive ($p = 0.003$). Patients in functional classes I and II did equally well at follow-up. However, only 41% of patients in functional class IV before the procedure were alive at 4 years ($p < 0.0001$). The effect of

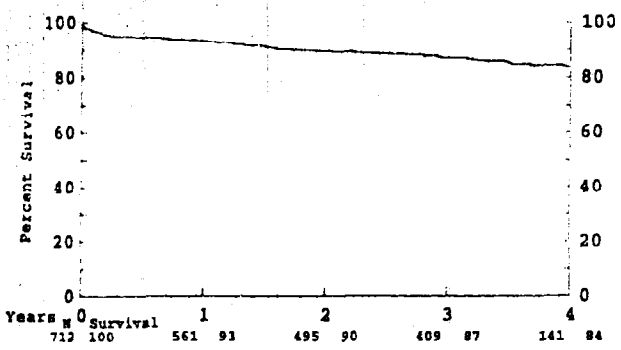


Figure 2. Overall survival: censored at mitral valve surgery or repeat balloon mitral commissurotomy in those patients after percutaneous balloon mitral commissurotomy.

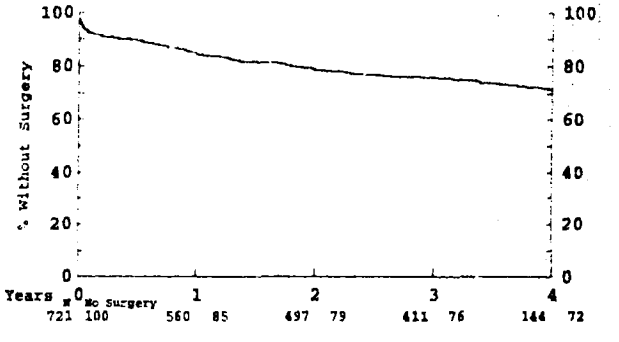


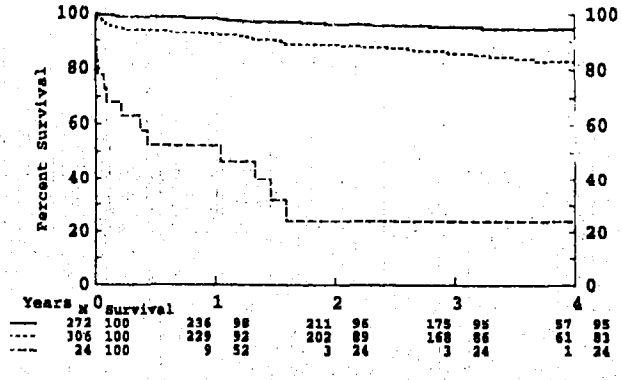
Figure 4. Time to mitral valve surgery after percutaneous balloon mitral commissurotomy. There is continued risk throughout the follow-up period.

functional class at 5 weeks of follow-up on subsequent outcome was similar. Patients with atrial fibrillation and those with a history of embolic events likewise had poorer survival (78% vs. 89% and 70% vs. 87%, respectively, at 4 years).

Baseline echocardiographic score also affected long-term survival (Fig. 3). The survival rate in patients with severely diseased mitral valves (i.e., echocardiographic score >12 [8]) was only 24% at 4 years. Patients with an echocardiographic score ≥8 also tended to be older than those with a score <8 (58 ± 15 vs. 49 ± 13 years, respectively, $p < 0.0001$). Echocardiographic assessment of left ventricular systolic function revealed that patients with reduced function did not do as well (survival rate 87% vs. 63% at 4 years for normal vs. reduced function respectively, $p < 0.0001$).

In the early experience of the registry, 114 patients had balloon mitral commissurotomy performed with a single, non-Inoue balloon catheter. These patients did not do as well as those undergoing the procedure with two balloons (survival rate 88% vs. 62% for double vs. single balloon, respectively, at 4 years). On average, these patients had a smaller change in mitral valve area, and fewer had a valve area ≥1.5 cm^2. It is likely that this suboptimal result probably explains most of their poor outcome, but they also did poorly at follow-up after single-balloon commissurotomy despite a valve area >1.5 cm^2 compared with those patients undergoing a two-balloon procedure.

Figure 3. Survival by baseline echocardiographic score: <8 (**solid line**), 8 to 12 (**short dashed line**) and echocardiographic score >12 (**long dashed line**). $p < 0.0001$ (log rank statistic 133.675).



For the overall registry, high volume centers (i.e., those performing >100 procedures) have the best survival at follow-up. However, when these data were stratified by year of enrollment, the effect was greatest during the first year, and by year 2 there were no differences between centers with respect to low, medium or high volume ($p = 0.23$).

Event-free survival. Event-free survival, defined as freedom from death, mitral valve surgery or repeat balloon mitral commissurotomy, was 80 ± 1.5% at 1 year, 71 ± 1.7% at 2 years, 66 ± 1.8% at 3 years and 60 ± 2.0% at 4 years. At 4 years, 72% of patients were free from mitral valve surgery after balloon mitral commissurotomy. Figure 4 depicts time to operation. Although the risk is greatest early after the procedure, there is constant hazard throughout the follow-up period.

Multivariate analysis. Multivariate predictors of death during follow-up (Table 1) show that functional IV, higher echocardiographic score, higher postprocedural pulmonary artery, and left ventricular end diastolic pressures and use of a single balloon catheter were all predictors of survival. Table 2 depicts the multivariable predictors of event-free survival (i.e., freedom from death, operation and repeat balloon mitral commissurotomy) during follow-up. Similarly, a higher pulmonary artery pressure, smaller balloon diameter (total balloon pair diameter with double balloon) and a smaller mitral valve area after the procedure were all predictive of poor outcome.

Table 1. Multivariable Predictors of Death During Follow-Up (censored at mitral valve surgery and repeat balloon mitral commissurotomy) for 494 Patients

Variable	p Value	Hazard Ratio (95% CI)
NYHA functional class IV	< 0.0001	5.87 (3.16–10.88)
Echo score ≥10	< 0.0001	4.34 (2.33–8.07)
Post-PA pressure ≥40 mm Hg	< 0.0001	3.76 (2.00–7.07)
Single balloon	0.0006	3.28 (1.67–6.44)
Post-LVEDP >15 mm Hg	0.009	2.40 (1.24–4.61)

CI = confidence interval; Echo = echocardiographic; LVEDP = left ventricular end-diastolic pressure; NYHA = New York Heart Association; PA = pulmonary artery; Post- = Postprocedural.

Table 2. Multivariate Predictors of Event-Free Survival During Follow-Up for 581 Patients*

Variable	p Value	Hazard Ratio (95% CI)
NYHA functional class (I–IV)	<0.0001	1.78 (1.46–2.17)
Post-PA pressure ≥40 mm Hg	<0.0001	2.42 (1.76–3.33)
MV gradient decrease <10 mm Hg	<0.0001	2.44 (1.70–3.51)
Post-MV area <1.5 cm^2	0.001	1.68 (1.24–2.29)
Balloon diameter <25 mm	0.02	2.11 (1.13–3.95)

*Event = death, mitral valve surgery or repeat balloon mitral commissurotomy. MV = mitral valve; other abbreviations as in Table 1.

Functional class was associated with event-free survival such that for every increase in functional class from I to IV, the risk increased concomitantly (i.e., for class I the hazard was 1.0 and 5.64 for class IV).

Discussion

We report the results in 736 patients undergoing percutaneous balloon mitral commissurotomy at the NHLBI Balloon Valvuloplasty Registry sites in North America. To our knowledge, this is the largest report of prospectively collected data on patients undergoing this procedure. The maximal follow-up period was 5.2 years (mean 3.2 ± 1.3). Although the present data represent information from a nonrandomized but prospective registry, they are nonetheless helpful in assessing the long-term outcome of patients undergoing this procedure. The registry data have several advantages, including enrollment of patients from many institutions rather than a single-center experience and patients with varying severity of disease, and probably represent a more "real world" assessment of the procedure.

The initial hemodynamic results are similar to those previously reported with the double-balloon technique described by Lock et al. (3) and Al Zaibag et al. (9). It is also similar to the hemodynamic results obtained after use of the Inoue single-balloon mitral valvuloplasty catheter (10–12). Of note, the Inoue balloon was not available during the registry period. The improved hemodynamic results mirror improvement in functional classification as well as the patients' overall feeling of well-being after the procedure. There was remarkable consistency in the percent of patients who improved after the procedure at each time period of follow-up.

Survival. The overall survival rate was excellent, being 93% at 1 year and 84% at 4 years. Event-free survival likewise is good. Predictors of death during follow-up are generally in agreement with previously published results from smaller groups of patients (13), except that we found that use of a single balloon (non-Inoue) predicted a lower survival rate during follow-up even when adjusted for postprocedural mitral valve area. It appears that patients with the most severe valve disease, manifest by high echocardiographic scores, severe preprocedural symptoms and a high postprocedural left ventricular end-diastolic pressure are those who do not do well at follow-up. This outcome may be due to the increased preload resulting from the procedure in the setting of underlying diastolic dysfunction from other causes, such as hypertension, aortic stenosis or valvular regurgitation. This finding is in agreement with previous reports (13).

Patients who were the most symptomatic before the procedure and those who had continued pulmonary hypertension or minimal changes in transmitral gradient after the procedure were most likely to have an event during follow-up.

Although we did not evaluate the effect of residual tricuspid regurgitation on subsequent outcome, it has been reported (14) to have a negative impact. It appears that despite a good result after mitral commissurotomy, patients with severe tricuspid regurgitation do poorly during follow-up despite improved mitral hemodynamic status. This factor may have impacted the results of the registry because tricuspid regurgitation, if present, would have affected the outcomes of these patients and is clinically more likely to be present with more severe, long-standing disease.

Mitral valve surgery as an event remained a continued risk throughout the follow-up period. It is well established that the rheumatic process is not altered by this procedure or, for that matter, by surgical commissurotomy; therefore, it would be expected that patients would undergo mitral valve surgery as a result of progression of the underlying disease process. The multivariate predictors of mitral valve surgery are all consistent with a poor result of balloon mitral commissurotomy. Our results suggest that patients will require operation if the percutaneous procedure leads to an inadequate result. Of those undergoing operation, 84% had mitral valve replacement, not surgical commissurotomy.

Comparison with other studies. It is difficult to compare the results from this registry with those from other reports because the patient group are potentially very different. The unique feature of this registry is that it reports experiences across the North American continent involving a very heterogenous cohort. Reports of the experience with both surgical and percutaneous mitral commissurotomy in more homogenous populations, such as those seen in Asia and South America, are likely to be different. Generally, patients in these countries are younger than those reported in NHBLI experience. This younger age in turn may reflect a lesser extent of valve pathology, potentially resulting in less subvalvular disease, calcification and severe deformity of the valve. Furthermore, the primary pathologic finding in these younger patients is likely to be fusion of the mitral commissures, thereby making these patients more amenable to commissurotomy techniques. In addition, younger patients generally have fewer comorbid diseases. The patients in the NHBLI registry represent a cross section of patients, some of whom would have been deemed not suitable for commissurotomy, either surgically or percutaneously. When these considerations are taken into account, the results from the NHBLI registry are comparable to previously published results (15–17) in patients undergoing the procedure in other countries.

Several important questions cannot be answered by this

registry, including comparison of the percutaneous approach with the established surgical procedures of closed and open commissurotomy. The limitations of using a registry cohort to answer these issues are well appreciated. Comparison of nonrandomized groups of patients undergoing different procedures is difficult because of the potential bias in patient selection for various procedures and the different patient groups involved.

However, there have been a small number of randomized trials (18–21) suggesting that the percutaneous procedure is comparable to open and closed surgical mitral commissurotomy in similar patients. In a recent report by Reyes et al. (22) of a group of 60 patients randomized to open surgical commissurotomy versus percutaneous balloon mitral commissurotomy, similar results were obtained at 3-year follow-up. Interestingly, the balloon commissurotomy group, in general, had a larger mitral valve area than the surgical group. Only one patient with a balloon mitral commissurotomy died during follow-up. Those patients also did well clinically; 72% of patients in the balloon mitral commissurotomy group and 57% of those in the open surgical commissurotomy group were in functional class I at 3 years. Although that was a small randomized study comparing the two techniques, it nonetheless strongly suggests that in appropriately selected patients, the procedures are probably equivalent. It must be stated that that was a select group of patients, very dissimilar to those in our registry. Their mean age was 30 years, all were in sinus rhythm, and all patients in the trial were deemed excellent candidates for commissurotomy with suitable mitral valve pathology.

Conclusions. We reported the results of percutaneous balloon mitral commissurotomy in a heterogenous group of patients undergoing the procedure at multiple centers in North America. Our results indicate the importance of appropriate patient selection. Younger patients with lower echocardiographic scores and those who were less symptomatic before the procedure generally have excellent results that are maintained throughout follow-up. In older patients and those with severe preprocedural symptoms and higher echocardiographic scores, especially >12, the procedure appears to be more palliative. These patients do poorly in follow-up and if otherwise deemed candidates for surgical valve replacement, this is perhaps the preferred approach. However, even in this subgroup of patients there will be a small group of patients who cannot undergo surgical correction for various reasons, and the use of this technique for palliation seems reasonable.

The patient population in North America with rheumatic heart disease is small compared with other geographical areas of the world. Therefore, on the basis of previous reports (7), it seems prudent that this procedure be performed by individual centers experienced in the technique.

The Inoue balloon catheter (Toray, Inc.), recently approved by the Food and Drug Administration for the percutaneous relief of mitral stenosis, was not available during this registry experience. Although this catheter makes the procedure less technically difficult and probably decreases the complications associated with the procedure (in particular, left ventricular perforation and tamponade) (23), we suspect that its use would not have affected the subsequent outcome of our patients. It appears that obtaining an adequate hemodynamic result is the most important predictor of subsequent events during follow-up and may have little to do with the actual catheter system used.

There is mounting evidence both by retrospective analysis (24,25) and prospective randomized trials (22) that the use of this technique in patients with severe, symptomatic mitral stenosis is a viable alternative to surgical commissurotomy in selected patients.

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