Clinical Investigation

Percutaneous Balloon Versus Surgical Closed Commissurotomy for Mitral Stenosis
A Prospective, Randomized Trial

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Background. We performed a prospective, randomized trial comparing percutaneous balloon commissurotomy with surgical closed commissurotomy in 40 patients with severe rheumatic mitral stenosis.

Methods and Results. Data were analyzed by investigators who were masked to treatment assignment or phase of study. Patients randomized to balloon (n=20) or surgical (n=20) commissurotomy had severe mitral stenosis without significant baseline differences (left atrial pressure, 26.1±4.2 versus 27.6±6.2 mm Hg; mitral valve gradient, 18.0±4.2 versus 19.7±6.3 mm Hg; mitral valve area, 1.0±0.2 versus 1.0±0.4 cm², respectively). At 1-week follow-up after balloon commissurotomy, pulmonary wedge pressure was 14.3±7.2 mm Hg; mitral valve gradient was 9.6±5.1 mm Hg; and mitral valve area was 1.6±0.6 cm² (all p<0.0001). At 1-week follow-up after surgical closed commissurotomy, wedge pressure was 13.7±5.4 mm Hg; mitral valve gradient was 9.4±4.2 mm Hg (both p<0.0001); and mitral valve area was 1.6±0.7 cm² (p<0.003). At 8-month follow-up, improvement occurred in both groups: Mitral valve area was 1.6±0.6 cm² in the balloon commissurotomy group (p<0.002) and was 1.8±0.6 cm² in the surgical closed commissurotomy group (p<0.0001). There was no difference between the groups at 1-week or 8-month follow-up (all p>0.4). One case of severe mitral regurgitation occurred in each group; complications were otherwise related to transseptal catheterization. There was no death, stroke, or myocardial infarction. Cost analysis revealed that balloon commissurotomy may substantially exceed the cost of surgical commissurotomy in developing countries, whereas it may represent a significant savings in industrialized nations.

Conclusions. We conclude that percutaneous balloon commissurotomy and surgical closed commissurotomy result in comparable hemodynamic improvement that is sustained through 8 months of follow-up. (Circulation 1991;83:1179–1185)

Although the prevalence of rheumatic mitral valve disease is declining in most industrialized nations, the disease continues to be endemic in much of Asia, Latin America, Africa, and the Middle East.1,2 Treatment of rheumatic mitral stenosis by surgical closed mitral commissurotomy was first attempted in 19233 and was reported successful beginning in the 1940s.4,5 Percutaneous balloon mitral commissurotomy was first described in 19846 as an alternative to the surgical approach. Descriptive studies have reported successful short-term results,7,8 without significant recurrence in early follow-up.9,10 Although both balloon commissuro-

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Methods

Patients

In February 1988, we studied 40 patients with severe rheumatic mitral stenosis recruited from the cardiology clinic at the Nizam’s Institute of Medical Sciences, Hyderabad, India. Patients in sinus rhythm (judged to be without severe pulmonary hypertension, leaflet calcification, subvalvular disease, or evidence of left atrial thrombus by echocardiography) were evaluated by both the cardiology (Z.G.T., V.P.R., B.S.R., A.R.R., and J.W.) and cardiac surgery (P.R., P.V.S., and D.P.R.) teams before study entry. An echocardiographic score was determined, assigning a maximum of four points for severity of each of four parameters: mitral valve leaflet calcification, mobility, thickening, and subvalvular disease. Only patients deemed acceptable as candidates for both procedures were enrolled in the study. Each patient signed an informed consent form that was approved by the Institutional Review Board of the Nizam’s Institute of Medical Sciences. The protocol was conducted in compliance with the Helsinki Declaration of 1975 on the Rights of Human Subjects Enrolled in Medical Research.

Cardiac Catheterization

Patients underwent right heart catheterization; oxygen saturation sampling from the superior vena cava, inferior vena cava, pulmonary artery, and femoral artery; atrial septal puncture; and retrograde left ventriculography by the femoral approach. Hemodynamics were recorded on an 8806 recorder (Hewlett-Packard Medical, Andover, Mass.). Cardiac output was assessed by the Fick technique; oxygen consumption was assumed at an O2 consumption index of 150 ml/min/m², determined from serial measurements in a similar group of patients with mitral stenosis undergoing cardiac catheterization at the same institution. After severe mitral stenosis without significant mitral regurgitation was confirmed, a randomization envelope was opened. Patients randomized to balloon commissurotomy underwent the procedure immediately; those randomized to surgical closed commissurotomy underwent surgery within the subsequent 3 days.

Commissurotomy

Balloon commissurotomy was performed with a modification of the technique described by Zaibag et al: two balloons (Mansfield Scientific, Mansfield, Mass.) were used in each patient (20 mm/20 mm, two patients; 20 mm/18 mm, four patients; 20 mm/15 mm, eight patients; 18 mm/15 mm, one patient; 15 mm/15 mm, three patients). Left atrial and left ventricular pressures were recorded immediately after commissurotomy. Surgical closed commissurotomy was performed with the standard left lateral thoracotomy approach, with a Tubbs dilator inserted by a left ventriculotomy. The Tubbs dilator was extended a minimum of 2.5 cm and a maximum of 3.5 cm, with dilatation proceeding until full opening was achieved or until the surgeon sensed a regurgitant jet.

Follow-up

Patients (18 balloon commissurotomy and 20 surgical closed commissurotomy) underwent follow-up catheterization at 1 week; this included hemodynamic measurements and left ventriculography. Transseptal catheterization was not repeated; pulmonary artery wedge pressures were recorded at follow-up. One randomized patient who did not have balloon dilatation and one patient who underwent urgent mitral valve replacement did not undergo follow-up catheterization. Catheterization was repeated after 7.8±2.5 months in 15 balloon commissurotomy patients and after 7.6±1.6 months in 16 surgical closed commissurotomy patients. Seven patients living in rural areas of India could not be contacted at the 8-month follow-up despite vigorous attempts.

Costs

The cost of undergoing each procedure in India and in the United States was calculated based on hospital and physician charges for balloon commissurotomy and surgical closed commissurotomy at the Nizam’s Institute of Medical Sciences and at Harper Hospital, Detroit, Mich. Hospital room charges assumed an average of 2 days of hospitalization in a regular room for balloon commissurotomy patients, and 5 days for surgical closed commissurotomy patients, including 1 day in an intensive care unit. The charge for disposables for balloon commissurotomy included one-time use of two femoral sheaths, right heart catheter, left heart catheter, Mullens sheath, guide wires, septotomy balloon, two commissurotomy balloons, recording paper, transducers, syringes, medications, and intravenous fluids.

Data Analysis

Prospectively determined end points were pulmonary artery wedge pressures, mitral valve gradients, and mitral valve areas at 1 week and at 8 months. All hemodynamic tracings were photocopied, were labeled with randomly assigned numbers, were separated from other identifying data, and were analyzed by an investigator (P.F.) remote from the study site who was unaware of group assignment or phase of the study. Intraobserver reliability was tested, and measurements were found to be reproducible within 3.4±4.3% for both left atrial pressure and diastolic filling period, 2.2±3.2% for heart rate, and 7.8±5.3% for mitral valve gradient. Analysis of variance for repeated measures was used to assess baseline and follow-up data for changes over time and for the effect of treatment. If the analysis of variance indicated statistical significance, it was followed by comparisons within groups by use of paired Student’s t test and comparisons between groups by use of unpaired Student’s t test. All tests were two sided. To adjust for multiple testing, a p value less than 0.005 was specified as indicating significance. Results are reported as mean±SD.
Results

Baseline
The two groups were equivalent in age, sex, duration and nature of symptoms, medications received, and New York Heart Association functional classification (Table 1). There was no significant difference in left atrial and pulmonary artery pressures, mitral valve gradients, mitral valve areas, or echocardiographic score.

Procedure Outcome
Thirty-nine of the 40 patients underwent balloon commissurotomy or surgical closed commissurotomy. One patient developed a hemothorax as a complication of transseptal catheterization; it resorbed with conservative therapy, but the patient refused further procedures. Of the remaining 20 patients randomized to balloon commissurotomy, 19 underwent the procedure. One patient developed pericardial tamponade also as a complication of transseptal catheterization, but before planned balloon dilatation of the mitral valve; the patient was stabilized and electively crossed over to surgical closed commissurotomy. This patient’s hemodynamic results are presented in the surgical closed commissurotomy group. Inclusion of this patient’s data in the balloon commissurotomy group based on the “intention-to-treat” principle did not alter the results. One patient who developed severe mitral regurgitation after balloon commissurotomy underwent mitral valve replacement and was discharged from the hospital without follow-up catheterization. All 19 patients randomized to surgery and the one patient who was crossed over to surgical closed commissurotomy were analyzed in the surgery group.

Hemodynamics
Hemodynamics in the two groups are presented in Figure 1. Pulmonary artery wedge pressure, mitral valve gradient, and mitral valve area improved significantly in both groups at 1 week (all \(p<0.003\) or better) and showed no significant deterioration during the average 8 months of follow-up. Similar results are noted with pulmonary artery systolic pressures. No difference is noted between the two groups at any time point (all between-group comparisons, \(p>0.4\)).

Immediate postprocedure data, which could be obtained only after balloon commissurotomy, demonstrated a decrease in left atrial mean pressure to 12.5±4.1 mm Hg (\(p<0.0001\)) and in mitral valve gradient to 7.2±2.8 mm Hg (\(p<0.0001\)). There was no significant increase in pulmonary wedge pressure or mitral valve gradient at 1 week (\(p=0.3\) and 0.07, respectively, immediately after commissurotomy versus 1 week), although a trend toward higher wedge pressure and gradient can be seen.

The results at 1 week of the seven patients who did not return for the 8-month follow-up were compared with the results of the 31 patients studied at 1 week who did return. Mean pulmonary artery wedge pressure (13.6±6.4 versus 14.1±6.4 mm Hg, \(p=0.8\)), mitral valve gradient (8.4±5.4 versus 9.8±4.4 mm Hg, \(p=0.5\)), and mitral valve area (1.8±0.8 versus 1.4±0.5 cm², \(p=0.2\)) were similar in both groups.

Complications
One patient in each group developed severe mitral regurgitation; the patient in the surgical group refused mitral valve replacement. The balloon commissurotomy patient (as noted above) underwent uncomplicated placement of a Bjork–Shiley prosthetic valve. Two balloon commissurotomy patients and four surgical closed commissurotomy patients without mitral regurgitation at baseline developed mild mitral regurgitation, and one patient in each group developed new, moderate mitral regurgitation as assessed at the 1-week follow-up. The pulmonary-to-systemic blood flow ratio was less than 1.5 in all patients immediately after balloon commissurotomy; there was no evidence of atrial septal defect detected by oximetry in any patient at follow-up. One additional posttransseptal pericardial tamponade occurred; after pericardiocentesis, this patient was brought back to the cardiac catheterization laboratory for subsequent uneventful balloon commissurotomy. One surgical patient was febrile for 3 days after surgery and was treated empirically with antibiotics without sequelae. No deaths, strokes, or myocardial infarctions occurred during hospitalization or follow-up.

Cost
Charges for balloon commissurotomy and surgical closed commissurotomy were compared for patients hospitalized in India and in the United States (Table 2). Although there is an approximately six times greater fee for balloon commissurotomy than for surgical closed commissurotomy in India, largely because of the cost of disposables, the charge for surgical closed commissurotomy in the United States is nearly double that for balloon commissurotomy, primarily because of physicians’ fees and room charges.

Discussion
Results after balloon commissurotomy and surgical closed commissurotomy and follow-up at 8 months demonstrate sustained improvement. There is a trend toward slightly higher gradients and left atrial pressures at 1 week follow-up than immediately after balloon commissurotomy; this may be consistent with recoil from a stretch mechanism for commissurotomy suggested by Nabel et al.\textsuperscript{14} occurring in combination with commissural splitting.\textsuperscript{15} No significant differences occurred in hemodynamic results between balloon commissurotomy and surgical closed commissurotomy.

Complications of balloon commissurotomy were primarily related to the transseptal technique. Our experience is consistent with admonitions to limit the performance of balloon mitral commissurotomy to centers performing transseptal catheterization in sufficient volume to maintain adequate skills, unless retrograde commissurotomy techniques not requiring transseptal catheterization become widespread.\textsuperscript{16}
Systemic embolization, including stroke, ventricular rupture, and death have been reported but did not occur in our study. The incidence of residual atrial septal defect after balloon commissurotomy has been reported in the 10–20% range, and appears to resolve in many cases during follow-up; significant left-to-right shunting did not occur in our patients. Similarly, although some increase in mitral regurgitation appears to be common (up to 46%) after both balloon commissurotomy and closed commissurotomy, severe mitral regurgitation is a less-frequent complication. One case of mitral regurgitation judged severe enough to require valve replacement occurred in each group.

Surgical closed commissurotomy was performed with a surgical technique established over the past 30 years and was conducted by an experienced group performing approximately 150 such operations each year. Balloon commissurotomy is a new procedure, conducted with largely prototype devices, and by a group (Z.G.T., V.P.R., and B.S.R.) with an aggregate experience of about 100 balloon commissurotomies at the time of the study. Despite logistical difficulties in coordinating two groups that normally perform procedures in laboratories and cultures 12,000 miles apart, the investigators spent several weeks performing balloon commissurotomies together 4 months before this study to optimize technique, equipment, and study design.

Because mitral valve replacement and possible long-term anticoagulation impose considerable financial and logistic burdens on the population being studied, we were intentionally conservative in our approach to treating mitral stenosis, with a strong preference for achieving modest hemodynamic improvement rather than dramatic results with a potentially greater complication rate. Complication rates may be lower and success somewhat greater if balloon commissurotomy were performed today with improved equipment and experience.

**Limitations**

The patients included in this study were young, were in sinus rhythm, and had a relative absence of baseline factors that may limit the success of the procedure. Although the baseline hemodynamics confirm the severity of mitral stenosis in these patients and although the mean echocardiographic scores

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**Figure 1.** Bar graphs of initial left atrial and subsequent pressures, pulmonary artery wedge pressures, pulmonary artery systolic pressures, mitral valve gradients, and mitral valve areas at 1-week and 8-month follow-up in patients randomized to percutaneous balloon mitral commissurotomy (PBMC) or surgical closed mitral commissurotomy (CMC). Immediate postprocedure left atrial pressures and mitral valve gradients are available only in the balloon commissurotomy group. *p<0.0001; **p<0.0008; ***p<0.002; ****p<0.003 vs. baseline. Comparison between treatment groups and among immediate, 1-week, and 8-month values are all nonsignificant.
TABLE 1. Baseline Demographics and Hemodynamics of Patients Undergoing Balloon Commissurotomy or Surgical Closed Commissurotomy

<table>
<thead>
<tr>
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<th>Balloon commissurotomy (n=20)</th>
<th>Surgical closed commissurotomy (n=20)</th>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>27.1±7.6 (14–45)</td>
<td>28.5±10.3 (14–50)</td>
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<tr>
<td>Sex</td>
<td>9 M/ 11 F</td>
<td>7 M/ 13 F</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
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<tr>
<td>Duration (mo)</td>
<td>32.7±31.6 (6–120)</td>
<td>29.6±26.6 (3–108)</td>
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<tr>
<td>Paroxysmal nocturnal</td>
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<td></td>
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<tr>
<td>dyspnea</td>
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<td>Palpitations</td>
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<td>18</td>
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<td>NYHA class (I/II/III/IV)</td>
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<tr>
<td>Diuretics</td>
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<tr>
<td>Hemodynamics</td>
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<tr>
<td>Left atrium (mm Hg)</td>
<td>26.1±4.2 (18–32)</td>
<td>27.6±6.2 (14–42)</td>
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<td>Pulmonary artery</td>
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<td>systolic (mm Hg)</td>
<td>53.0±20.4 (35–128)</td>
<td>58.9±15.9 (25–85)</td>
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<td>Mitral valve gradient</td>
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<tr>
<td>(mm Hg)</td>
<td>18.0±4.2 (10.1–24.8)</td>
<td>19.7±6.3 (7.9–31.7)</td>
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<tr>
<td>Mitral valve area (cm²)</td>
<td>0.8±0.2 (0.5–1.2)</td>
<td>0.9±0.4 (0.4–1.6)</td>
</tr>
<tr>
<td>Echocardiographic score</td>
<td>7.2±1.7 (4–10)</td>
<td>8.4±1.5 (6–11)</td>
</tr>
</tbody>
</table>

Continuous variables are expressed as mean±SD (range). NYHA, New York Heart Association functional class. Comparisons of differences between treatment groups are all nonsignificant.

(7.2±1.7 in the balloon group and 8.4±1.5 in the surgical group) confirm the presence of significant valvular and subvalvular disease, 72% of patients had an echocardiographic score of 8 or less, a finding associated with more favorable outcome.11 Hence, extrapolation of our results to the United States and other industrialized countries (where patients with mitral stenosis are likely to be older and more likely to be in atrial fibrillation with calcified, thickened, poorly mobile valve leaflets and significant subvalvular disease) should be done with caution.

Seven patients did not return for the 8-month follow-up; analysis of the 1-week hemodynamic data in this study group did not reveal significant differences from the patients who did return. We do not believe, therefore, that their follow-up results would have differed from the larger group that did return.

Although the size of the patient population is small and although the possibility of failure to detect small differences between the treatment modalities is therefore increased, we believe that this study yields information regarding the treat-

<table>
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<tr>
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<th>India</th>
<th>United States</th>
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<tr>
<td></td>
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<td>CMC ($)</td>
</tr>
<tr>
<td>Hospital room*</td>
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<td>8</td>
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<tr>
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<tr>
<td>Catheterization</td>
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<tr>
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<tr>
<td>operating room</td>
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<td>44</td>
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<td>Cardiologist or</td>
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<td>88</td>
</tr>
<tr>
<td>surgeon</td>
<td>1,975</td>
<td>314</td>
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</table>

Charges for patients in India are based on approximately 17 Indian rupees to the US dollar. Indian charges reflect fees at the Nizam's Institute of Medical Sciences, Hyderabad; US charges reflect fees from Harper Hospital, Detroit, and include an average of surgeons' fees.

PBMC, percutaneous balloon mitral commissurotomy; CMC, surgical closed mitral commissurotomy.

*Assumes 2 days for balloon commissurotomy patients and 4 days for surgical closed mitral commissurotomy patients.

†Includes one-time use; disposables in India are occasionally reused, and minimal charges for the reused disposables would decrease to $117; however, reusability of balloons, aside from infection control issues, is extremely limited because of changes in the properties of the catheters after exposure to blood, contrast material, and repeated sterilization.
ment of rheumatic mitral stenosis, particularly in developing countries, that is not available from historical comparisons. This study also provides serial cardiac catheterization data; because both balloon and surgical commissurotomy are palliative in nature, further follow-up is planned at 4 years, including exercise testing and quality of life assessment.

Our findings suggest that despite achieving results at least as favorable as surgical closed commissurotomy, with significantly less discomfort and a markedly shorter hospitalization, balloon commissurotomy likely will complement and not replace the currently available surgical alternatives. In industrialized countries, open mitral commissurotomy or mitral valve replacement may remain the first choice for many patients, despite much higher cost, because of less-favorable anatomy and because of the availability and presumed superiority of an approach using cardiopulmonary bypass where surgery can be performed under direct vision. This study is not intended to compare balloon commissurotomy to open mitral commissurotomy or mitral valve replacement, both of which may be more appropriate choices for those with severe subvalvular disease, left atrial thrombus, or severe leaflet calcification. A prospective study will be needed to compare open mitral commissurotomy and balloon commissurotomy in patients with favorable anatomy living in countries where cardiopulmonary bypass is readily available. However, closed commissurotomy is the most common surgical procedure in most countries where rheumatic mitral stenosis is endemic; where there are limited facilities and resources, closed commissurotomy is by far the less costly procedure.

A comparison of the costs of hospitalization, personnel, and disposables demonstrates that closed commissurotomy will probably continue to be the procedure of choice for this population of patients with severe mitral stenosis in most of the world, at least until the cost of disposables is reduced, even though the hemodynamic consequences of balloon commissurotomy appear to be at least as beneficial.

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• rheumatic heart disease • mitral stenosis
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