Percutaneous Balloon Versus Surgical Closed and Open Mitral Commissurotomy
Seven-Year Follow-up Results of a Randomized Trial

Mohamed Ben Farhat, MD; Mokdad Ayari, MD; Faouzi Maatouk, MD; Fethi Betbout, MD; Habib Gamra, MD; Mourad Jarrar, MD; Mabrouk Tiss, MD; Sonia Hammami, MD; Rafik Thaalbi, MD; Faouzi Addad, MD

**Background**—Percutaneous balloon mitral commissurotomy (BMC) has been proposed as an alternative to surgical closed mitral commissurotomy (CMC) and open mitral commissurotomy (OMC) for the management of rheumatic mitral valve stenosis (MS).

**Methods and Results**—We conducted a prospective, randomized trial comparing the results of the 3 procedures in 90 patients (30 patients in each group) with severe pliable MS. Cardiac catheterization was performed in all patients before and at 6 months after each procedure. All patients had clinical and echocardiographic evaluation initially and throughout the 7-year follow-up period. Gorlin mitral valve area (MVA) increased much more after BMC (from 0.9±0.16 to 2.2±0.4 cm²) and OMC (from 0.9±0.2 to 2.2±0.4 cm²) than after CMC (from 0.9±0.2 to 1.6±0.4 cm²). Residual MS (MVA <1.5 cm²) was 0% after BMC or OMC and 27% after CMC. There was no early or late mortality or thromboembolism among the three groups. At 7-year follow-up, echocardiographic MVA was similar and greater after BMC and OMC (1.8±0.4 cm²) than after CMC (1.3±0.3 cm²; P<.001). Restenosis (MVA <1.5 cm²) rate was 6.6% after BMC or OMC versus 37% after CMC. Residual atrial septal defect was present in 2 patients and severe grade 3 mitral regurgitation was present in 1 patient in the BMC group. Eighty-seven percent of patients after BMC and 90% of patients after OMC were in New York Heart Association functional class I versus 33% (P<.0001) after CMC. Freedom from reintervention was 90% after BMC, 93% after OMC, and 50% after CMC.

**Conclusions**—In contrast to surgical CMC, BMC and OMC produce excellent and comparable early hemodynamic improvement and are associated with a lower rate of residual stenosis and restenosis and need for intervention. However, the good results, lower cost, and elimination of drawbacks of thoracotomy and cardiopulmonary bypass indicate that BMC should be the treatment of choice for patients with tight pliable rheumatic MS. (Circulation. 1998;97:245-250.)

**Key Words:** balloon valves mitral commissurotomy

Since its introduction by Inoue et al in 1984 as an alternative to surgical mitral commissurotomies for treatment of rheumatic MS, percutaneous BMC has been successfully and safely performed in large series of patients at numerous centers. The advent of this new technique resurrected a debate regarding the respective merits and pitfalls of OMC under direct vision compared with the two other blind techniques. A few studies recently compared the early results of BMC with those of CMC, and only one study compared midterm (3 years) results of BMC with those of OMC. This prospective randomized trial was designed to compare the early invasive and long-term (7-year) clinical and echocardiographic follow-up results of BMC with those of OMC and CMC for the treatment of tight pliable rheumatic MS.

**Methods**

**Patient Selection**

Among 130 patients referred to our institution between November 1987 and October 1988, 90 patients with severe pliable MS were randomly assigned to have BMC (group 1, n=30 patients), OMC (group 2, n=30 patients), or CMC (group 3, n=30 patients). Forty patients were excluded because MS was moderate in 15, moderately or severely calcified in 12, and associated with aortic disease (n=10) or MR (n=3) in the remaining patients. Inclusion criteria were rheumatic tight MS (MVA ≤1.3 cm²), absence of other cardiac valvular disease, no history of thromboembolism, absence of mitral valve calcifications on fluoroscopy and two-dimensional echocardiography, and absence of left atrium thrombus on transthoracic echocardiography. Patients in atrial fibrillation and those with severe pulmonary hypertension or mild-to-moderate tricuspid regurgitation were not excluded. The protocol was approved by the human investigation committee of our institution. Informed consent was obtained from all patients, and the study was conducted in accordance with the guidelines of the 1975 Helsinki Declaration on the Rights of Human Subjects Enrolled in Medical Research. The randomization sealed envelope was opened after severe MS was confirmed at catheterization.

**Echocardiographic Evaluation**

Transsthoracic two-dimensional pulsed, color, and continuous-wave Doppler echocardiographic examinations were performed 1 day before initial catheterization and at 6-month and 7-year follow-up. The echocardiographic score described by Wilkins et al was used to assess baseline anatomic features of the mitral valve: a score from 0...
performed through a median sternotomy. Both commissures could be properly opened in 20 cases (66%). OMC was performed in 14 patients and in 16 patients. Both unsatisfactory results, larger balloons were used to redilate the mitral valve annulus. In 4 patients with immediate after BMC, the color Doppler echocardiography was used to screen left-to-right atrial shunts.

Cardiac Catheterization
Before and 6 months after mitral commissurotomy, all 90 subjects underwent right- and left-sided heart catheterization at rest. At 6-month control, 25 patients in each group who had a pulmonary capillary wedge pressure of ≤18 mm Hg exercised the lower extremity in which no catheter was inserted. Pressures were measured with Statham P23BD transducers (Spectramed; Critical Care Division) and recorded with a computer-assisted system (Meddars 300; Honeywell). Cardiac output was measured with the thermodilution technique, and MVA was calculated according to Gorlin’s formula. A minimum of five cardiac cycles were considered in patients with atrial fibrillation. Left-to-right shunting through the atrial septum was determined from a complete oxymetric study at the 6-month evaluation in the BMC group patients and was defined as a ≥1.5-vol% increase in oxygen content in the pulmonary artery compared with that of calculated mixed venous blood content. At baseline and at 6 months, hemodynamic control left ventricular angiography was performed to quantify MR.

Commissurotomy Technique
BMC was performed as previously described. Two pigtail balloons Triad AT catheters (Mansfield, Boston Scientific) were used through the atrial septum was determined from a complete oxymetric study, correlation was better (r = 0.5, 0.05) with transthoracic color Doppler echocardiography according to the jet extension in the left atrium. After BMC, color Doppler echocardiography was used to screen left-to-right atrial shunts.

Statistical Analysis
Prospectively determined end points were pulmonary artery wedge pressure, mitral valve gradient, cardiac index, Gorlin MVA at 6 months after any commissurotomy. The transmitral pressure halftime method and that determined with Gorlin’s formula was not as good (r = 0.68). By excluding the 6 patients with ≥grade 2 MR and the 5 patients with left-to-right shunting at oxymetric study, correlation was better (r = 0.88, P<.0001). With transthoracic color Doppler echocardiography, the rate of shunting was higher (33%) than at catheterization; the rate of MR also was higher: 6 patients (20%) in group 1 and 3 patients of groups 2 and 3, and grade 3 in 1 patient of group 1. Left-to-right interatrial shunt was present in 5 patients (17%) of BMC group and was ≤1.4:1 in all.

Noninvasive Results
In the overall group, two-dimensional echo MVA was well correlated with that obtained with Gorlin’s formula (r = 0.92, P<.0001). Echo MVA increased from 0.9 ± 0.2 to 2.1 ± 0.5 cm² in group 1, from 0.9 ± 0.2 to 2.0 ± 0.4 cm² in group 2, and from 0.9 ± 0.2 to 1.6 ± 0.3 cm² in group 3. The mean increase was 1.2 cm² in groups 1 and 2 versus 0.7 cm² in group 3 (P<.00001). Correlation between MVA determined by the pressure halftime method and that determined with Gorlin’s formula was not as good (r = 0.88). By excluding the 6 patients with ≥grade 2 MR and the 5 patients with left-to-right shunting at oxymetric study, correlation was better (r = 0.88, P<.0001). With transthoracic color Doppler echocardiography, the rate of shunting was higher (33%) than at catheterization; the rate of MR also was higher: 6 patients (20%) in each group; it was grade 1 in 2 patients of each group, grade 2 in 1 patient of group 1 and 2 patients of groups 2 and 3, and grade 3 in 1 patient of group 1. Early Results
There was no death or thromboembolism among the three groups and no cardiac tamponade after transseptal puncture in the BMC group.

Cardiac Catheterization Analysis
The hemodynamic changes produced by the three procedures are shown in Fig 1. Pulmonary artery wedge pressure and mitral valve gradient decreased significantly by the same amount in the three groups. However, cardiac index increased more in BMC and OMC group patients than in CMC group patients, in whom the increase did not reach statistical significance. Similarly, MVA rose much more in groups 1 and 2 than in group 3. The mean increase was 1.3 cm² in groups 1 and 2 versus 0.7 cm² in group 3. Residual MS (MVA < 1.5 cm²) was 0% in groups 1 and 2 versus 27% in group 3. During exercise, there was significant increase in heart rate in the three groups (group 1, from 82 ± 12 to 120 ± 14 bpm; group 2, from 80 ± 18 to 122 ± 16 bpm; and group 3, from 84 ± 18 to 124 ± 20 bpm). However, pulmonary artery wedge pressure and mitral valve grade decreased more in the CMC group than in the BMC and OMC groups. Cardiac index increased more and MVA was larger in groups 1 and 2 than in group 3. MR was present in 4 patients (13%) in each group; it was grade 1 in 2 patients of each group, grade 2 in 1 patient of group 1 and 2 patients of groups 2 and 3, and grade 3 in 1 patient of group 1. Left-to-right interatrial shunt was present in 5 patients (17%) of BMC group and was ≤1.4:1 in all.

Seven-Year Follow-up Results
All 90 patients are alive and achieved a 7-year follow-up period. As shown in Fig 3, echocardiographic MVA slightly
TABLE 1. Baseline Characteristics of the Three Patient Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BMC (n=30)</th>
<th>OMC (n=30)</th>
<th>CMC (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>29±12</td>
<td>27±9</td>
<td>28±10</td>
</tr>
<tr>
<td></td>
<td>(11-48)</td>
<td>(12-50)</td>
<td>(14-46)</td>
</tr>
<tr>
<td>Sex, F/M</td>
<td>23/7</td>
<td>21/9</td>
<td>23/7</td>
</tr>
<tr>
<td>NYHA class, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>3 (10)</td>
<td>4 (13)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>III</td>
<td>21 (70)</td>
<td>20 (67)</td>
<td>22 (73)</td>
</tr>
<tr>
<td>IV</td>
<td>6 (20)</td>
<td>6 (20)</td>
<td>5 (17)</td>
</tr>
<tr>
<td>Hemodynamic variables</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Right atrial pressure, mm Hg</td>
<td>4.8±1.4</td>
<td>5.0±1.4</td>
<td>4.6±1.3</td>
</tr>
<tr>
<td></td>
<td>(1-14)</td>
<td>(2-16)</td>
<td>(3-12)</td>
</tr>
<tr>
<td>Systolic pulmonary pressure</td>
<td>52±21</td>
<td>51±25</td>
<td>49±23</td>
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<tr>
<td></td>
<td>(39-105)</td>
<td>(42-98)</td>
<td>(38-104)</td>
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<tr>
<td>Mean pulmonary pressure</td>
<td>38±12</td>
<td>36±11</td>
<td>35±11</td>
</tr>
<tr>
<td></td>
<td>(24-70)</td>
<td>(20-66)</td>
<td>(18-70)</td>
</tr>
<tr>
<td>Pulmonary wedge pressure</td>
<td>26±7</td>
<td>25±7</td>
<td>24±8</td>
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<tr>
<td></td>
<td>(17-46)</td>
<td>(15-44)</td>
<td>(14-48)</td>
</tr>
<tr>
<td>Mitral valve gradient</td>
<td>21±8</td>
<td>20±8</td>
<td>19±7</td>
</tr>
<tr>
<td></td>
<td>(11-40)</td>
<td>(10-38)</td>
<td>(9-42)</td>
</tr>
<tr>
<td>MVA, cm²</td>
<td>0.9±0.2</td>
<td>0.9±0.2</td>
<td>0.9±0.2</td>
</tr>
<tr>
<td></td>
<td>(0.6-1.2)</td>
<td>(0.7-1.2)</td>
<td>(0.7-1.2)</td>
</tr>
<tr>
<td>Cardiac index, L/min⁻¹-m⁻²</td>
<td>3.1±0.5</td>
<td>3.0±0.7</td>
<td>3.2±0.8</td>
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<td>(2-4.2)</td>
<td>(1.7-4.8)</td>
<td>(1.9-4.6)</td>
</tr>
<tr>
<td>Rhythm, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinus</td>
<td>23 (77)</td>
<td>22 (73)</td>
<td>22 (73)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>7 (23)</td>
<td>8 (27)</td>
<td>8 (27)</td>
</tr>
<tr>
<td>Echocardiographic data</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>MVA, cm²</td>
<td>0.9±0.2</td>
<td>0.9±0.2</td>
<td>0.9±0.2</td>
</tr>
<tr>
<td></td>
<td>(0.7-1.3)</td>
<td>(0.6-1.3)</td>
<td>(0.7-1.2)</td>
</tr>
<tr>
<td>Echocardiographic score</td>
<td>6.0±1.0</td>
<td>6.0±1.0</td>
<td>6.1±1.1</td>
</tr>
<tr>
<td></td>
<td>(5-8)</td>
<td>(5-8)</td>
<td>(5-8)</td>
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</tbody>
</table>

Our study is unique in that all of the patients are alive and underwent early hemodynamic evaluation and 7-year echocardiographic assessment. The most striking and unsuspected finding at the inauguration of our study was the excellent long-term results obtained after BMC that were, like those of OMC, far superior to those after CMC. The better long-term improvement paralleled the early superior hemodynamic improvement produced by BMC and OMC, including greater increase in cardiac output, larger MVA, and better exercise tolerance. Residual MS is much higher after CMC. The absence of residual MS after BMC is in agreement with our previously published study,12 in which residual MS rate was 0.3% among 306 patients with pliable valves and 0% among 98 patients with semipliable valves. One of the earliest hemodynamic studies15 reported several years ago that the increase in MVA after CMC was by no means uniform or universal. We have been among the first21 to emphasize that MVA obtained by CMC often is unsatisfactory. Since then, three reports14–16 from countries in which the use of CMC is still widespread confirmed this disadvantage, even though a fourth study17 showed discordant results with significant and similar increases in MVA after BMC or CMC. The somewhat disappointing results after CMC are not related to the skills of different surgeons who have routinely performed this procedure for many years. The discrepancies between the two closed techniques are most likely related to technical problems: (1) the blades of the used dilators always open in the same plane,
whereas commissures are not; (2) strength is applied by the blades in two diametrically opposite points of the mitral orifice, whereas it is applied on the overall mitral orifice by the inflated balloons so operators were more likely to split commissures and to a greater extent; and (3) whenever immediate hemodynamic measurements taken during BMC indicated unsatisfactory relief of mitral obstruction, it is easy to redilate with larger balloons, as occurred in 13% of our patients.

Even though none was encountered in our study, systemic thromboembolism is probably the only common drawback of the two blind commissurotomies. Careful echocardiographic evaluation, including transesophageal echocardiography, may help avoid this potential problem.

There was no operative or late deaths in our study with the two techniques. Acute mortality was <1% in most previous reports with BMC, whereas it ranged from 3% to 8.7% in most large series of patients who underwent CMC in a much earlier era and ≈2% after OMC.

Recent long-term studies following BMC have demonstrated 4- to 5-year survival rates of 76 to 98%, whereas it ranged from 90% to 96% after CMC and 90% to 97% after OMC. Event-free survival rates ranged from 51% to 82% after BMC, from 72% to 95% after CMC, and from 80% to 95% after OMC. However, differences in patient characteristics make it difficult to establish direct comparisons among the three techniques. Most studies of either OMC or CMC many decades ago enrolled young patients with pliable mitral leaflets, little or no subvalvular disease, little valvular calcifications, and little other cardiac disease. Our excellent event-free survival rate of 90% at 7 years after BMC is undoubtedly due to the younger age of our patients, almost all of whom were women and had favorable mitral valve anatomy because we excluded patients with calcifications or severe subvalvular disease. It is noteworthy that all our patients had pliable valves with an echo score of ≤8/16, which represents a different population than that previously reported in Europe and America. The use of two large balloons may have played a role in producing such results. Late results are less satisfactory in European and North American population because patients are older and frequently have severe valve deformities. In the series of Cohen et al., the mean age was 59 years, and 5-year event-free survival was 51%; it was 68% in 84 patients with an echo score of ≤8 and 28% in 52 patients with an echo score of >8. In the series of Palacios et al., event-free survival was 79% among 211 patients with a mean age of 48 years and an echo score of ≤8 versus 39% among 116 patients with a mean age of 64 years and an echo score of >8. The National Heart, Lung, and Blood Institute Multicenter Balloon Mitral Valvuloplasty Registry showed an actuarial mortality of 49% at 4 years in patients aged >70 years and 76% in patients with an echo score of >12. In our younger population, 5-year event-free survival was 85% in patients without calcifications at fluoroscopy versus 65% in patients with densely calcified valves.

Mitral restenosis has been diagnosed with certainty because all patients underwent early postoperative hemodynamic and early and late two-dimensional and Doppler echocardiographic evaluations. In the BMC group, our restenosis rate of 6.6% at 7 years compares very favorably with those of other short-term studies in which it exceeds 20% and with the 3-year restenosis rate of 12% of the randomized trial of Reyes et al.

### TABLE 2. NYHA Functional Class Across Time for the Three Groups

<table>
<thead>
<tr>
<th>NYHA Functional Class</th>
<th>BMC</th>
<th>OMC</th>
<th>CMC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6 mo</td>
<td>7 y</td>
</tr>
<tr>
<td>I</td>
<td>0 (0)</td>
<td>27 (90)</td>
<td>26 (87)</td>
</tr>
<tr>
<td>II</td>
<td>3 (10)</td>
<td>3 (10)</td>
<td>2 (6.6)</td>
</tr>
<tr>
<td>III</td>
<td>21 (70)</td>
<td>0 (0)</td>
<td>2 (6.6)</td>
</tr>
<tr>
<td>IV</td>
<td>6 (20)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Values are given as n (%).
among a comparable young population. After surgical commisurotomy, most studies were based on the recurrence of symptoms alone, and therefore restenosis rates ranged widely. Two-dimensional echocardiography in two series with few patients reported a long-term restenosis rate of 28%\textsuperscript{33} within 10 to 14 years and of 10% within 6 years.\textsuperscript{25} In the BMC and OMC groups, all patients with restenosis returned to NYHA functional class III, whereas 6 of 8 patients with residual stenosis and 9 of 11 patients in CMC group returned to NYHA class III or IV.

An increase in MR was not observed in our series, and only 1 patient of the BMC group had a grade 3 MR, which required late mitral valve replacement. In general, BMC is probably a fair risk factor for induced severe MR of grade \(\geq 3\) as compared with the two other techniques. Its incidence was 4% to 6% in large series,\textsuperscript{25,27} whereas, for example, in the largest study of 3724 patients undergoing CMC, severe MR\textsuperscript{28} occurred in only 0.3%. After OMC, severe MR is rare because surgeons routinely correct MR with suture stitches and sometimes with prosthetic mitral valve replacement. Mitral valve replacement is undoubtedly a risk factor for OMC, and the number of valves that tend to be replaced ranged from 11%\textsuperscript{35} to 28%.\textsuperscript{33}

Even though double-balloon technique was used in this series, no left-to-right interatrial shunt required early or late surgical closure.

We conclude that in contrast to CMC, BMC and OMC produce excellent and comparable early and long-term improvements and have low rates of restenosis and need for reintervention. However, the good results, lower cost, and elimination of drawbacks of cardiopulmonary bypass indicate that BMC should be the treatment of choice of tight pliable rheumatic MS.

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