Indications, Complications, and Short-term Clinical Outcome of Percutaneous Transvenous Mitral Commissurotomy

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Percutaneous transvenous mitral commissurotomy was performed in 106 consecutive patients. Significant symptomatic improvement was achieved in 97 patients (92%). Mean left atrial pressure decreased (from 18±8 to 11±8 mm Hg, \( p<0.00001 \)), mean mitral diastolic pressure gradient decreased (from 12±7 to 7±6 mm Hg, \( p<0.00001 \)), and mitral valve area increased (from 1.40±0.40 to 2.00±0.50 cm\(^2\), \( p<0.00001 \)). Based on echocardiographic characteristics of the mitral apparatus, patients were grouped retrospectively in three categories: pliable (group 1, \( n=37 \)), semipliable (group 2, \( n=59 \)), and rigid (group 3, \( n=10 \)). Clinical success was achieved in 36 patients of group 1 (97%) and in 55 patients of group 2 (93%). Only six patients in group 3 (60%) improved symptomatically (\( p<0.001 \) vs. group 1, \( p<0.001 \) vs. group 2). The severity of mitral regurgitation increased in five patients of group 1 (14%), in 12 of group 2 (20%), and in three of group 3 (33%). Six patients had recurrent symptoms at 9 months after commissurotomy. Recurrence of symptoms was significantly more frequent in group 3 compared with the other two groups (group 1, 3%; group 2, 4%; and group 3, 50%; \( p<0.0001 \) vs. groups 1 and 2). Multiple regression analysis identified the previously mentioned echocardiographic characteristics of the mitral apparatus as the significant predictor for clinical outcome. Thus, percutaneous transvenous mitral commissurotomy can be considered a safe and effective treatment for patients with pliable valves. Patients with semipliable or with rigid valves should be selected for operation very carefully. (Circulation 1989;80:782–792)

Percutaneous transvenous mitral commissurotomy was first used by Inoue in 1982.1 Immediate symptomatic and hemodynamic improvement after this procedure has been reported.2,3 Although its clinical application has been widely adopted, its indications and potential complications have not been thoroughly defined, and only a few follow-up studies have been reported. This study was designed to clarify the scope of the indications and the extent of the anticipated results immediately and several months after commissurotomy by echocardiographic study of the mitral apparatus before operation. If patients are not selected properly, commissurotomy has the potential of inducing severe mitral regurgitation requiring valve replacement.

Methods

Patients

From February 1987 to March 1988, percutaneous transvenous mitral commissurotomy was attempted in 106 consecutive patients with symptomatic mitral stenosis. There were 25 male and 81 female patients; the mean age was 53±11 years (range, 24–75). Informed consent was obtained from all patients. Forty patients were in atrial fibrillation, and the remainder were in normal sinus rhythm. Eight patients had undergone open or closed mitral commissurotomy previously. Patients with left atrial thrombus according to two-dimensional echocardiography and severe mitral regurgitation greater than Seller’s grade 3+ by cine left ventriculography were excluded.
Cardiac Catheterization and Percutaneous Transvenous Mitral Commissurotomy

All patients underwent diagnostic left and right heart catheterization and coronary arteriography before percutaneous transvenous mitral commissurotomy. Twenty-four patients had concomitant mild mitral regurgitation, and 25 patients had mild aortic valve disease. Coronary arteries were normal in all patients. In 80 patients, supine ergometer exercise test was performed under hemodynamic monitoring to assess exercise capacity. After baseline hemodynamics were measured (pulmonary artery wedge pressure, pulmonary artery pressure, and cardiac output by thermodilution method through right jugular vein), exercise was begun with an exercise load at 35 W. After achievement of a steady-state level of exercise for 3 minutes, all hemodynamics were repeatedly measured.

The self-positioning single balloon (Inoue balloon) was used for the commissurotomy in all patients. The Inoue balloon is made of a double layer of latex rubber, between which is a nylon micromesh. The proximal half of the nylon mesh is wound with thin rubber bands, more tightly in the central region and more loosely at the two ends, so that the shape of the balloon changes in three stages depending on the extent of inflation; inflation occurs first at the distal half and then the proximal half; the constriction remains in the middle section until full inflation (Figure 1). The Inoue balloon was designed so that adjusting injection volume would change the diameter of the balloon. The upper limit of the balloon diameter is chosen according to the patient’s body weight (26-mm dilating diameter for patients ≤50 kg, 28-mm dilating diameter for patients 50–60 kg, and 30-mm dilating diameter for patients >60 kg). Inflation is started at less than the predetermined upper-limit diameter. If the hemodynamic results are suboptimal, the procedure is repeated by increasing the balloon diameter to the predetermined level. If optimal hemodynamic results are not obtained at the balloon’s maximum diameter, additional inflation is not attempted as a general rule.

After administration of local anesthesia, right heart catheterization was performed through the right femoral vein. Right atrioangiography was performed to determine the septal puncture site for the Brockenbrough needle. Transseptal catheterization was followed with an 8F Mullins transseptal dilator (USCI, Billerica, Massachusetts). After entry into the left atrium, 10,000 units heparin was administered. A 5F pigtail catheter from the left femoral artery was positioned in the left ventricle, and simultaneous pressure tracings of the left atrium and the left ventricle were recorded. The previously inserted 7F Swan-Ganz catheter that had been

Figure 1. Photographs of the shape of the Inoue balloon in three stages depending on the inflation volume. Panel 1: Deflated; Panel 2: Inflation at the distal half; Panel 3: Inflation at the proximal half; and Panel 4: Fully inflated.
temporarily removed was reinserted through the right internal jugular vein, and cardiac output was measured just before the balloon commissurotomy. A 0.28-in. stainless steel guide wire was advanced into the left atrium and was used to place the Inoue balloon catheter in the left atrium. Once the balloon catheter tip traversed the interatrial septum, the stiffening cannula for the central lumen was used to facilitate passage of the balloon portion into the left atrium. Once in the left atrium, the tip of the balloon was inflated with 1–2 ml CO₂ gas, allowing blood flow to direct the balloon tip into the left ventricle. The CO₂ was removed, and the balloon was inflated with diluted contrast material until the waist of the balloon disappeared. Immediately after the procedure, all hemodynamic measurements were repeated, including the determination of transvalvular gradient and cardiac output. To evaluate the severity of the resultant mitral regurgitation, if any, cine left ventriculography in the left anterior oblique view was performed in all patients except the first 10 patients. The severity of mitral regurgitation was graded by the Seller’s classification from 0 to 4+.⁴ One day after percutaneous transvenous mitral commissurotomy, right heart oximetric study and supine ergometer exercise test were performed to evaluate the interatrial septal perforation and its resultant left-to-right shunt as well as the exercise response. Most patients were discharged 2 days after percutaneous transvenous mitral commissurotomy.

**Serial Echocardiographic Studies**

Two-dimensional and Doppler echocardiography were performed the day before and after percutaneous transvenous mitral commissurotomy in 105 patients. One patient requiring emergency operation could not undergo Doppler echocardiography after percutaneous transvenous mitral commissurotomy. The Toshiba SSH 65A system was used for this study. Mitral ejection fraction slope, mitral valve excursion, left atrial diameter, and mitral valve area by the pressure half-time method⁵ were determined. The presence and severity of mitral regurgitation was assessed by pulsed Doppler and real-time two-dimensional flow imaging system before and after percutaneous transvenous mitral commissurotomy. The severity of the mitral regurgitation was graded as none, mild, moderate, or severe based on the extension of the regurgitant jet in the left atrium. In addition, Doppler echocardiography was used to assess the atrial septal defect after percutaneous transvenous mitral commissurotomy.

Based on the characteristics of the anatomic structures of the mitral valve according to echocardiography, primarily the leaflets and secondarily the subvalvular apparatus, patients were divided into three groups (Figure 2).

**Group 1.** Group 1 patients had pliable leaflets. If any restriction of the leaflets' tip mobility occurred, it was minimal. Leaflets were without calcification and were free of subvalvular disease as judged by the relative thickness of the subvalvular area compared with the thickness of the posterior wall of the left ventricle.

**Group 2.** Group 2 patients had semipliable leaflets. The mobility of the leaflets was restricted not

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**Figure 2.** Echocardiograms depicting criteria for subgrouping. Group 1, pliable and noncalcified valve; free of subvalvular lesion. Group 2, semipliable and locally calcified valve with shortening or thickening of the subvalvular apparatus. Group 3, rigid or generalized calcification of the valve with fused subvalvular apparatus.
only at the tip but also in the leaflets, although they were not totally immobile as yet. Only localized calcification occurred if any; some shortening or thickening of the subvalvular apparatus occurred.

Group 3. Group 3 patients had rigid leaflets. Total immobility of the valve occurred, or leaflets were with generalized calcification, and fusion of the subvalvular apparatus with marked thickening of that area was present.

Clinical Follow-up

With the exception of a few patients living far from the hospital who were followed up by telephone interview, most patients were followed up in our department with two-dimensional and Doppler echocardiographic assessment.

Data and Statistical Analysis

Two-dimensional and Doppler echocardiographic recordings were analyzed by experienced echocardiographers who were unaware of the hemodynamic results. To determine the reproducibility of the echocardiographic assessment, 106 randomly selected echocardiograms were independently reviewed by two observers. Interobserver discordance between two observers for echocardiographic subgrouping was six of 106 patients (6%). Mean and standard deviations were determined for all hemodynamic variables and for calculated mitral valve area. Student’s t test and χ² test were used for comparing hemodynamic parameters and clinical results. Multiple linear regression analysis was used to identify the predictive factors for symptomatic improvement after the procedure, mitral valve area after the procedure, incidence of mitral regurgitation after the procedure, symptomatic status during the follow-up period, and mitral valve area during the follow-up period. The examined factors were age, sex, cardiac rhythm, history of commissurotomy, echocardiographic subgrouping, mitral valve area before and after the procedure, mean mitral pressure gradient before and after the procedure, mean left atrial pressure before and after the procedure, balloon diameter normalized to body surface area, symptomatic improvement after the procedure, and new mitral regurgitation according to left ventriculography. A probability value less than 0.05 was considered significant.

Results

Clinical and Hemodynamic Improvement

The balloon could be dilated as planned in 104 of 106 patients (98%). Significant symptomatic improvement defined as reclassification by one or more New York Heart Association (NYHA) functional Classes was achieved in 97 of 106 patients (92%), from NYHA Class IV to I in two patients, from III to I in nine patients, from II to I in 64 patients, from IV to II in two patients, and from III to II in 20 patients). The resting hemodynamic variables are shown in Figure 3. The mean left atrial pressure decreased from 18±8 to 11±8 mm Hg (p<0.00001), and the mean diastolic mitral valve pressure gradient measured from simultaneous left atrial and left ventricular pressure tracings fell from 12±7 to 7±6 mm Hg (p<0.00001). The mitral valve area calculated by the pressure half-time method increased significantly from 1.40±0.40 to 2.00±0.50 cm² (p<0.00001).

Hemodynamic Response to Exercise

Supine ergometer exercise testing revealed a significant decrease in peak pulmonary artery pressure (systolic, from 68±17 to 57±14 mm Hg, p<0.0001; diastolic, from 30±9 to 23±8 mm Hg, p<0.00001) and a significant increase in cardiac index (from
5.28±1.12 to 6.16±1.45 l/min/m², p<0.0001) before and after percutaneous transvenous mitral commissurotomy (Figure 4).

Complications

Complications of percutaneous transvenous mitral commissurotomy are shown in Table 1. There were no deaths or thromboembolic events associated with the procedure. The severity of mitral regurgitation increased in 20 patients (19%) as evaluated by cine left ventriculography or Doppler echocardiography. In six patients, new mitral regurgitation was shown only by Doppler echocardiography. Greater than Seller’s grade 3+ severe mitral regurgitation occurred in five patients (5%). The severity of mitral regurgitation increased from 2+ to 3+ in one patient, from 0 to 3+ in three patients, and from 1+ to 4+ in one patient. In three of these five patients and in one patient with mild mitral regurgitation according to Doppler echocardiography, mitral valve replacement was required. Mitral valve replacement was uneventful in all patients. Bleeding from the right femoral vein associated with balloon catheter insertion occurred in seven patients (7%), and two (2%) of them required blood transfusion. Doppler echocardiography showed the presence of a hemodynamically insignificant interatrial shunt in five patients (5%). In two patients, transseptal puncture resulted in cardiac tamponade requiring emergency subxyphoid drainage.

Relationship Between Anatomic Features and Clinical and Hemodynamic Results

Clinical and hemodynamic results are shown in Table 2. Clinical success defined as significant symptomatic involvement based on NYHA classification was achieved in 36 patients (97%) of group 1 (improvement from NYHA Class IV to I in one, from III to I in two, from II to I in 26, from IV to II in one, and from III to II in six patients) and 55 patients (93%) of group 2 (improvement from NYHA Class IV to I in one, from III to I in seven, from II to I in 35, from IV to II in one, and from III to II in 11 patients). In contrast, only six patients (60%) of group 3 improved symptomatically (improvement from NYHA Class III to II in three and from II to I in three patients; p<0.001 vs. group 1; p<0.001 vs. group 2). The hemodynamic improvement correlated well with the symptomatic improvement. Group 3 patients were the least benefited symptomatically, and they were significantly less improved hemodynamically than group 1 patients (Table 2).

Significant mitral regurgitation according to echocardiography or cine left ventriculography occurred in five patients of group 1 (14%), 12 of group 2 (20%), and three of group 3 (33%). Greater than Seller’s grade III severe mitral regurgitation developed in one patient of group 1, two of group 2, and two of group 3.

**Table 1. Complications After Percutaneous Transvenous Mitral Commissurotomy**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Patients (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral regurgitation (Doppler or LVG)</td>
<td>20</td>
<td>19</td>
</tr>
<tr>
<td>Severe mitral regurgitation (≥Seller’s grade 3+)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Bleeding</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Atrial septal defect</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Thromboembolism</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Total number of patients was 106.
LVG, left ventriculography.
Clinical Follow-up

Ninety-seven patients had symptomatic improvement immediately after percutaneous transvenous mitral commissurotomy and underwent follow-up study. Mean follow-up interval was 9±4 months (range, 3–17 months), and symptomatic status grading by NYHA classification was confirmed in all 97 patients. Follow-up data are shown in Figure 5. Among the patients with successful balloon commissurotomy, six patients (6%) had recurrent symptoms (from NYHA Class I to II in four, from I to III in one, from II to III in one patient) at a mean of 8±4 months after the procedure. Mitral valve areas calculated by pressure half-time method were 1.38±0.40 before, 1.90±0.67 immediately after, and 1.33±0.25 cm² 8–9 months after commissurotomy. Thirty-five patients of group 1 (97%) had symptomatic improvement. One patient developed recurrent symptoms 6 months after the procedure (from NYHA Class I to II), but because her symptoms were better than before the commissurotomy, medical follow-up was continued. Fifty-one patients of group 2 (93%) had symptomatic improvement; symptomatic deterioration occurred in two patients at 3 and 6 months of follow-up (from NYHA Class I to II, from II to III), and one was observed medically as an outpatient because his complaints were not as severe as before the procedure. One patient died from cerebral infarction 5 months after a successful procedure, and another patient died from unknown causes. Fifty percent of group 3 patients had symptomatic improvement, but three patients had recurrence of severe symptoms (from NYHA Class I to II in two, from I to III in one patient). This recurrence rate of symptoms was significantly higher than that of the other two groups (p<0.0001 vs. groups 1 and 2). Repeat commissurotomy was performed in these patients, and significant symptomatic improvement was achieved in all patients (from NYHA Class II to I in two, from III to II in one patient). Four months after repeat procedure, one patient had recurrent and worsening symptoms (from NYHA Class II to III), and subsequent mitral valve replacement was carried out. Both two-dimensional and Doppler echocardiography were performed in 89 patients of the 97 successful cases (92%) at 9±4 months after balloon commissurotomy. In patients of group 1, mitral valve area determined by the pressure half-time method was 1.53±0.48 cm² before balloon commissurotomy and increased to 2.18±0.39 cm² after balloon commissurotomy. Mitral valve area at follow-up remained unchanged from that immediately after commissurotomy (2.18±0.39 vs. 2.02±0.42 cm², NS, Figure 6). In patients of groups 2 and 3, mitral valve area during follow-up was not significantly different compared with that immediately after commissurotomy (group 2, 1.92±0.39 vs. 1.87±0.42 cm², NS; group 3, 1.43±0.35 vs. 1.36±0.23 cm², NS; Figure 6).

TABLE 2. Comparison of Clinical and Hemodynamic Results Among the Three Patient Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients (n)</th>
<th>Clinical success n %</th>
<th>Mean left atrial pressure (mm Hg) Before After</th>
<th>Mitral valve area (cm²) Before After</th>
<th>Pressure gradient (mm Hg) Before After</th>
<th>Incidence of mitral regurgitation n %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>37</td>
<td>36 97*</td>
<td>16.4±6.37 9.4±4.8†</td>
<td>1.51±0.52 2.14±0.49</td>
<td></td>
<td></td>
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<tr>
<td>Group 2</td>
<td>59</td>
<td>55 93*</td>
<td>17.9±9.4 11.7±9.2†</td>
<td>1.37±0.42 1.95±0.44</td>
<td></td>
<td></td>
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<tr>
<td>Group 3</td>
<td>10</td>
<td>6 60</td>
<td>19.6±7.9 14.4±7.62</td>
<td>0.99±0.35 1.56±0.66†</td>
<td>13.2±6.1 6.4±3.6†</td>
<td>3 33</td>
</tr>
</tbody>
</table>

Pressure gradient was measured from simultaneous left ventricular and left atrial pressure tracings. Mitral valve area was calculated by pressure half-time method.

*p<0.001 vs. group 3; †p<0.05 vs. before; ‡p<0.05 vs. group 1; §p<0.05 vs. group 3; ||p<0.05 vs. group 3.
Predictive Factors for Successful Percutaneous Transvenous Mitral Commissurotomy

Multiple linear regression analysis identified first the mitral regurgitation after balloon commissurotomy and second the echocardiographic classification as the significant predictors for symptomatic improvement after the procedure \( r=0.50, p<0.01 \). Significant predictors for mitral valve area immediately after the procedure and at follow-up were echocardiographic classification before commissurotomy and history of commissurotomy \( r=0.48, p<0.01 \). The only significant predictor for new production or deterioration of mitral regurgitation was the preprocedural echocardiographic classification \( r=0.45, p<0.05 \). Significant predictor for sustaining symptomatic improvement at follow-up was also the preprocedural echocardiographic classification \( r=0.33, p<0.01 \).

To illustrate the complications and limitations of the procedure, four patients requiring subsequent mitral valve replacement are described in detail. The first patient was a 43-year-old woman of group 2. Two-dimensional echocardiography revealed a moderate subvalvular lesion and relatively well-preserved mobility of the anterior leaflet, which are consistent with a semipliable valve. Percutaneous transvenous mitral commissurotomy was performed with a 29-mm diameter dilating balloon. Immediately after the procedure, tall “v” waves in the left atrial pressure tracing became evident. Mean left atrial pressure increased from 38 to 65 mm Hg and mitral regurgitation of Seller’s grade 3+ was documented by left ventriculography. Acute left heart failure ensued, and the patient required intra-aortic balloon counterpulsation. On the next day, the patient underwent urgent mitral valve replacement. At surgery, tearing of the midportion of the anterior mitral leaflet instead of separation of the fused commissures was observed (Figure 7). In addition, fusion of the subvalvular apparatus to the posterior ventricular wall was evident.

The second patient was a 43-year-old woman of group 2. Two-dimensional echocardiography revealed fair doming and a mildly calcified valve with mild subvalvular disease, consistent with a semipliable valve. Left ventriculography showed Seller’s 1+ mitral regurgitation. Percutaneous transvenous mitral commissurotomy was performed by increasing the balloon diameter gradually from 28.5 mm, to 29.5 mm, and then to 30 mm. Left atrial pressure decreased from 30, to 25, and then to 22 mm Hg respectively. Because the result was considered still suboptimal, the balloon diameter was increased to 31 mm. After dilatation, the left atrial pressure increased to 31 mm Hg with prominent “v” waves. Left ventriculography at this point showed Seller’s 4+ mitral regurgitation. Elective mitral valve replacement was performed 9 days later. Separation of the anterolateral commissure extending not only to but through the valve ring was present (Figure 7).

The third patient was a 55-year-old woman of group 3. Echocardiography revealed a rigid valve with severe subvalvular involvement but was limited to the chordae tendineae. Percutaneous transvenous mitral commissurotomy was performed with a 28.5-mm dilating balloon. Left atrial pressure increased from 24 to 26 mm Hg after dilatation. Left ventriculography revealed Seller’s 3+ mitral regurgitation after the procedure. Although the patient’s hemodynamics remained stable, elective surgery was performed 29 days later because of suboptimal clinical results. Tearing of the anterolateral commissure and avulsion of the anterolateral papillary muscle were present (Figure 7).

The final patient was a 42-year-old woman of group 1. Echocardiographic findings were consistent with a pliable valve. Percutaneous transvenous mitral commissurotomy was performed with a 28-mm diameter dilating balloon. Immediately after the procedure, the mean left atrial pressure fell from 20 to 18 mm Hg, but new mild mitral regurgitation was found by Doppler echocardiography. Because her condition was relatively good after the procedure, she was followed medically as an outpatient. However, her symptoms worsened gradually, and elective surgery had to be performed 9 months later. Tearing of the posterior mitral leaflet was present (Figure 7).

Discussion

In earlier studies, percutaneous balloon commissurotomy was used in patients with noncalcified mitral valves. More recently, McKay et al. reported the efficacy of balloon commissurotomy even in calcific disease. Our study showed that percutaneous transvenous mitral commissurotomy could induce clinical and hemodynamic improvement without major complications in patients with pliable mitral stenosis. Improvement in valvular function was documented by decreases in left atrial pressure, mitral pressure gradient, and pulmonary artery pressure during exercise as well as by the increase
FIGURE 7. Excised mitral valve from patients 1, 2, 3. Panel a: Excised mitral valve from patient 1. Note, tearing of the midportion of the anterior mitral leaflet (arrow). 1, Anterior mitral leaflet; 2, posterior mitral leaflet; 3, anterolateral commissure; and 4, posteromedial commissure. Panel b: Excised mitral valve from patient 2. Note, separation of the anterolateral commissure extending to the valve ring (arrow). 1, Anterior mitral leaflet; 2, posterior mitral leaflet; 3, anterolateral commissure; and 4, posteromedial commissure. Panel c: Excised mitral valve from patient 3. Note, rupture of the anterolateral papillary muscle (arrow) and tearing of the anterolateral commissure. 1, Anterior mitral leaflet; 2, posterior mitral leaflet; 3, anterolateral commissure; and 4, posteromedial commissure. Panel d: Operative findings from patient 4. Note, tearing of the midportion of the posterior mitral leaflet (arrow). 1, Anterior mitral leaflet; 2, posterior mitral leaflet; 3, anterolateral commissure; and 4, posteromedial commissure.
in cardiac index. However, patients with rigid valves might show minimal clinical improvement, and in some patients, mitral valve replacement within a few days to weeks of the procedure was required.

Earlier pathologic studies showed that the most important component in mitral stenosis was fusion of the commissures resulting from the rheumatic damage of the mitral valve leaflets. Inoue et al performed balloon mitral commissurotomy during open mitral commissurotomy and observed that at least one commissure was adequately separated in all cases. McKay et al reported a feasibility study in five postmortem balloon valvuloplasties, and separation of one or both commissures was achieved in all five cases. Neither tearing of the valve leaflets nor disruption of the valve ring was documented. McKay et al reported that the same mechanism occurred even in calcified mitral stenosis. However, Reid et al documented that the anterior and posterior angles at the commissure as seen by two-dimensional echocardiography were significantly increased in successful but not in unsuccessful procedures, and they suggested that the presence of rigid leaflets or subvalvular disease prevented the slit of the commissures and contributed to the failure. In our study, patients with a pliable valve had better clinical results than those with a calcified or rigid valve.

Mitr al regurgitation is an important complication to be kept in mind because production of mitral regurgitation after surgery was reported to be associated with poor prognosis. In patients undergoing surgery, production of significant mitral regurgitation was reported to be associated with a tear of the leaflets or rupture of the chordae tendineae. In fact, our operative findings in patients requiring valve replacement for severe mitral regurgitation were similar to those previous findings. Production of mitral regurgitation was less frequent in patients with pliable valve, and when it occurred, the severity was mild and clinically insignificant in all but one patient. In patients with semipliable or rigid valves, the incidence and severity of significant mitral regurgitation increased, and three patients in these groups required surgery. Morrow et al reported that in 11 of 12 patients with completely mobile valve leaflets, the left atrial pressure returned to normal after closed mitral commissurotomy, but in six of seven patients with totally immobile valves, the left atrial pressure remained high because of significant residual stenosis or mitral regurgitation induced at operation. These results of closed commissurotomy predicted that commissural separation would be the more common response to balloon mitral commissurotomy. This may be the case in patients with pliable valves. In patients with more rigid valves, however, splitting of the commissures did not occur consistently. Inadvertent tearing of valve leaflets or disruption of the valve ring and chordae tendineae may lead to production of significant mitral regurgitation. Multiple linear regression analysis identified echocardiographic subgrouping as the significant predictor for symptomatic improvement, mitral valve area, and new or deterioration of preexisting mitral regurgitation immediately after balloon commissurotomy. Thus, in patients with pliable leaflets, with no or low-grade calcification of the leaflets, and with no severe subvalvular lesions, significant symptomatic improvement is anticipated by restoration of sufficient mitral valve area without the concurrence of significant mitral regurgitation.

Palacios et al reported that there was one death (3%) and one thromboembolic episode (3%) after valvuloplasty. McKay also reported one death (2%) and two embolic cerebrovascular accidents (3%) in a large series involving 63 patients. We had no deaths nor thromboembolic accidents in our 106 patients. Because fatalities in the studies of Palacios et al and McKay occurred in severely ill patients, we cannot make simple comparisons with our results. We speculate that our results are related to the nature of the Inoue balloon, especially its flow-directed passage from the left atrium to the left ventricle. Left-to-right shunt after valvuloplasty was reported in 11% of patients by Palacios et al and in 21% by McKay, but it was hemodynamically insignificant in all patients. In our series, five patients (5%) had evidence of interatrial shunting, but it was insignificant in all. We ascribe this low incidence of defect creation to the low profile of the Inoue balloon and to the stretching and thinning of the balloon portion attainable by reinsertion of the stiffening cannula before pulling the balloon out across the septum. Subcutaneous hematoma from the right femoral vein occurred in seven patients (7%), of whom two required subsequent blood transfusion.

The method of balloon commissurotomy has not been standardized, and a number of balloons have been reported. Recently described larger balloons or double balloons may yield greater reduction in mitral pressure gradient and good clinical outcome. In our study, we used the single Inoue balloon with a 26–31-mm diameter. Clinical results of group 1 seemed to be satisfactory; mean mitral pressure gradient fell to 5.5 mm Hg, and calculated mitral valve area increased to 2.14 cm². These results are comparable to other results in series in which single- or double-balloon systems have been used. Palacios et al reported new or an increase in severity of mitral regurgitation in 43% of patients, and it was severe in one patient (3%). Similarly, McKay et al detected an increase in the severity of mitral regurgitation in approximately 50% of patients with either the single- or double-balloon technique. Although we have no experience with the double balloon, the reported incidence of mitral regurgitation is apparently higher than the incidence in our series with the Inoue single balloon, and this incidence may suggest the greater propensity of double balloons to produce mitral regurgitation.
In our 9 months of follow-up, six patients (6%) had recurrent symptoms, and the calculated mitral valve area by pressure half-time method revealed restenosis after a successful initial percutaneous transvenous mitral commissurotomy. This recurrence was particularly prevalent in patients of group 3, 50% of whom had recurrence of symptoms, which was a significantly higher incidence than in the other two groups with more pliable valves. Multiple linear regression analysis identified the preprocedural echocardiographic subgrouping as the significant predictor for sustained symptomatic improvement and mitral valve area during follow-up. Thus, patients with pliable, noncalcified valves without severe subvalvular lesion will have predictably good results after commissurotomy. Abascal et al\textsuperscript{14} reported that assessments of valvular morphology by two-dimensional echocardiography may be useful for identifying patients with restenosis. In their series, 20 patients were followed up by echocardiography, which revealed that four patients had valvular restenosis defined as more than 25% reduction in the mitral valve area at follow-up. Echocardiographic score of valvular morphology was significantly higher (with increasing abnormality) in patients with restenosis, and this score was the significant predictor of percent decrease in valve area. Surgical reports have also stressed that the most important factor influencing long-term results was mitral valve calcification.\textsuperscript{15} Although the precise mechanism of restenosis remains unclear in our study, surgical reports suggest that restenosis is the result of the inexorable progress of the fibrotic process, namely deposits of calcium and scarring of the valves.\textsuperscript{16,17} If parallels can be drawn to surgical commissurotomy, the same mechanism may be the modus operandi in restenosis after transvenous valve commissurotomy.

In clinical practice, recognizing the clearly favorable and unfavorable types of valves is usually not difficult. From our results, patients with pliable valves without mitral valve calcification and without subvalvular disease appeared to be the best candidates for percutaneous transvenous mitral commissurotomy. Extending the indications to rigid valves resulted in higher incidence of mitral regurgitation or residual stenosis after percutaneous transvenous mitral commissurotomy. Based on this experience, our current policy is to recommend surgery if a rigid and calcified valve or a severe subvalvular lesion is present. The use of smaller dilating balloons for group 3 patients might have resulted in fewer complications, and the technique may still be useful in nonsurgical candidates. The semipliable valve is more difficult to recognize echocardiographically and anatomically than the two extreme types. Still, in our study, clinical success was achieved in 93% patients with semipliable valve, and the mean mitral pressure gradient decreased to 7.1±8.0 mm Hg and the calculated mitral valve area increased to 1.95±0.44 cm\textsuperscript{2} on the average. It must be mentioned, however, that the incidence of mitral regurgitation was 20%, and in two patients, surgery was required after percutaneous transvenous mitral commissurotomy. Although these results were less optimal than those in patients with pliable valves, most patients showed excellent results after percutaneous transvenous mitral commissurotomy. Moreover, the procedure is performed with local anesthesia without the need of a thoracotomy. If stenosis persists or recurs after percutaneous transvenous mitral commissurotomy, the procedure can be repeated, or if needed, cardiac surgery can still be performed for the first time, which is distinctly easier to perform than repeated cardiac surgery.

**Conclusion**

The present study shows that percutaneous transvenous mitral commissurotomy achieves immediate hemodynamic and clinical improvement in patients with a pliable valve but not in patients with a rigid valve. We conclude that the most important factors determining the hemodynamic and clinical outcome after percutaneous transvenous mitral commissurotomy are the anatomic and pathologic features of the mitral apparatus. Follow-up studies will be needed to assess the long-term efficacy of the procedure, but results comparable at least to closed commissurotomy might be anticipated.

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