PERCUTANEOUS MITRAL BALLOON COMMISSUROTOMY FOR PATIENTS WITH RHEUMATIC MITRAL STENOSIS

IGORF. PALACIOS, MD

SINCE ITS INTRODUCTION in 1984 by Inoue et al., percutaneous mitral balloon commissurotomy (PMV) has been used successfully as an alternative to open or closed surgical mitral commissurotomy in the treatment of patients with symptomatic rheumatic mitral stenosis. PMV produces good immediate hemodynamic outcome, low complication rate, and clinical improvement in the majority of patients with mitral stenosis. PMV is safe and effective and provides sustained clinical and hemodynamic improvement in patients with rheumatic mitral stenosis. The immediate and long-term results appear to be similar to those of surgical mitral commissurotomy. Today, PMV is the preferred form of therapy for relief of mitral stenosis for a selected group of patients with symptomatic mitral stenosis.

Patient Selection

Selection of patients for PMV should be based on symptoms, physical examination, and two-dimensional (2D) and Doppler echocardiographic findings. The criteria required for patients to be considered for PMV includes (1) symptomatic mitral stenosis (NYHA > II), (2) no recent embolic event, (3) < 2 grades of mitral regurgitation by contrast ventriculography (using the Seller's classification), and (4) no evidence of left atrial thrombus on 2-D echocardiography.

Transthoracic and transesophageal echocardiography should be performed routinely before PMV. Patients in atrial fibrillation and patients with previous embolic episodes should be anticoagulated with warfarin with a therapeutic prothrombin time for at least 3 mo before PMV. Patients with left atrium thrombus on 2D-echocardiography should be excluded. However, PMV could be performed in these patients if left atrium thrombus has resolved after warfarin therapy.

Technique of PMV

PMV should be performed in the fasting state under mild sedation. Antibiotics (dicloxacillin 500 mg p.o.q.16 h for 4 doses) are started before the procedure. Patients allergic to penicillin should receive Vancomycin 1 g intravenously at the time of the procedure. All patients carefully chosen as candidates for mitral balloon valvuloplasty should undergo diagnostic right and left and transseptal left heart catheterization. Following transseptal left heart catheterization, systemic anticoagulation is achieved by the intravenous administration of 100 units/kg of heparin. In patients older than 40 y, coronary arteriography should also be performed.

Hemodynamic measurements, cardiac output, and cine left ventriculography are performed before and after PMV. Cardiac output is measured by thermodilution and Fick method techniques. Mitral valve calcification and angiographic severity of mitral regurgitation (Seller's classification) are graded qualitatively from 0 to 4 as previously described. An oxygen diagnostic run is performed before and after PMV to determine the presence of left-to-right shunt after PMV.

There is not an unique technique of percutaneous mitral balloon valvuloplasty. Most
of the techniques of PMV require transseptal left heart catheterization and use of the antegrade approach. Antegrade PMV can be accomplished using a single2,3,6 or a double-balloon technique.3,4,5,7 In this latter approach, the two balloons could be placed through a single femoral vein and single transseptal punctures3,5,7 or through two femoral veins and two separate atrial septal punctures.4 In the retrograde technique of PMV, the balloons dilating catheters are advanced percutaneously through the right and left femoral arteries over guidewires that have been snared from the descending aorta.19 These guidewires have been advanced transseptally from the right femoral vein into the left atrium, the left ventricle, and the ascending aorta. A retrograde nontransseptal technique of PMV has also been described.20,21

**Antegrade Double-Balloon Technique**

In performing PMV using the antegrade double-balloon technique (Figure 1), a 7-French flow-directed balloon catheter is advanced through the transseptal sheath across the mitral valve into the left ventricle.22 The catheter is then advanced through the aortic valve into the ascending and then the descending aorta. A 0.038-in, 260 cm-long teflon coated exchange wire is then passed through the catheter. The sheath and the catheter are removed leaving the wire behind. A 5-mm balloon dilating catheter is used to dilate the atrial septum. A second exchange guide wire is passed parallel to the first guide wire through the same femoral vein and atrial septal punctures using a double-lumen catheter. The double-lumen catheter is then removed leaving the two guide wires across the mitral valve in the ascending and descending aorta. During these maneuvers, care should be taken to maintain large and smooth loops of the guide wires in the left ventricular cavity to allow appropriate placement of the dilating balloons. If a second guide wire cannot be placed into the ascending and descending aorta, a 0.038-in Amplatz type transfer guide wire with a preformed curl at its tip can be placed at the left ventricular apex. In patients with aortic valve prosthesis, both guide wires with preformed curl tips should be placed at the left ventricular apex. When one or both guide wires are placed in the left ventricular apex, the balloons should be inflated sequentially. Care should be taken to avoid forward movement of the balloons and guide wires to prevent left ventricular perforation.

Two balloon dilating catheters, chosen according with the patients body surface area, are then advanced over each one of the guide wires and positioned across the mitral valve parallel to the longitudinal axis of the left ventricle. The balloon valvotomy catheters are then inflated by hand until the indentation produced by the stenotic mitral valve is no longer seen. Generally, one but, occasionally, two or three inflations are performed. After complete deflation the balloons are removed sequentially.

Figure 1. Sequential steps of double-balloon PMV. Two 0.038-in guide wire are advanced into the ascending and descending aorta with the tip at the level of diaphragm. Two balloon catheters are placed straddling the stenotic mitral valve; markers identifying the proximal end of the balloons are inflated by hand until the waist produced by the stenotic valve disappears.
Inoue Technique of PMV

PMV can also be performed using the Inoue technique (Figure 2). The Inoue balloon is a 12-French shaft, coaxial, double-lumen catheter. The balloon is made of a double layer of rubber tubing with a layer of synthetic micromesh in between.

Following transseptal catheterization, a stainless steel guide wire is advanced through the transseptal catheter and placed with its tip coiled into the left atrium and the transseptal catheter removed. A 14-French dilator is advanced over the guide wire and used to dilate the femoral vein and the atrial septum. A balloon catheter chosen according to the patient's height is advanced over the guide wire and used to dilate the mitral plane until resistance is felt. The balloon is then rapidly inflated to its full capacity and then deflated quickly. During inflation of the balloon, an indentation should be seen in its mid portion.

The catheter is withdrawn into the left atrium and the mitral gradient and cardiac output measured. If further dilatations are required, the stylet is introduced again and the sequence of steps described above repeated at a larger balloon volume. After each dilatation, its effect should be assessed by pressure measurement, auscultation, and 2D-echocardiography. If mitral regurgitation occurs, further dilation of the valve should not be performed.

Mechanism of PMV

The mechanism of successful PMV is splitting of the fused commissures toward the mitral annulus, resulting in commissural widening. This mechanism has been demonstrated by pathological, surgical, and echocardiographic studies. In addition, in patients with calcific mitral stenosis, the balloons could increase mitral valve flexibility by the fracture of the calcified deposits in the mitral valve leaflets. Although rare, undesirable complications such as leaflet tears, left ventricular perforation, tear of the atrial septum and rupture of chordae, mitral annulus, and papillary muscle could also occur.

Immediate Outcome

Table 1 shows the changes in mitral valve area reported by several investigators using the double-balloon and the Inoue techniques of PMV. In most series, PMV is reported to increase mitral valve area from less than 1.0 cm² to ~2.0 cm². Recently, the results from 564 patients with mitral stenosis who underwent PMV at the Massachusetts General Hospital between July 1985 and September 1992 were presented. There were 460 females and 104 males with a mean age of 54 ± 11 (range, 13 to 87) y. Before PMV, 71 (13%) patients were in New York Heart Association (NYHA) functional class IV, 356 (63%) patients were class II, and 4 patients class I. One hundred and two patients had previously undergone surgical mitral commissurotomy and presented with mitral restenosis. Two hundred and ninety-one (52%) patients were in normal sinus rhythm and 273 (48%) had atrial fibrillation. Evidence of mitral...
TABLE 1. Hemodynamic results of PMV.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Author</th>
<th>Patient no.</th>
<th>Age</th>
<th>Pre-PMVMVA</th>
<th>Post-PMV MV A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass General</td>
<td>Palacios et al</td>
<td>564</td>
<td>57±1</td>
<td>0.9±0.1</td>
<td>2.0±0.1</td>
</tr>
<tr>
<td>Tenon</td>
<td>Vahanian et al</td>
<td>1058</td>
<td>44±1</td>
<td>1.0±0.2</td>
<td>1.9±0.3</td>
</tr>
<tr>
<td>Lorna Linda</td>
<td>Ruiz et al</td>
<td>238</td>
<td>51±1</td>
<td>0.6±0.3</td>
<td>2.6±0.7</td>
</tr>
<tr>
<td>Beth Israel</td>
<td>Cohen et al</td>
<td>146</td>
<td>59±1</td>
<td>1.0±0.4</td>
<td>2.1±0.9</td>
</tr>
<tr>
<td>Takeda</td>
<td>Inoue et al</td>
<td>527</td>
<td>50±1</td>
<td>1.13±0.02</td>
<td>1.97±0.04</td>
</tr>
<tr>
<td>Chang Gung</td>
<td>Hung et al</td>
<td>204</td>
<td>44±1</td>
<td>1.0±0.3</td>
<td>2.0±0.7</td>
</tr>
<tr>
<td>George Washington</td>
<td>Chen et al</td>
<td>149</td>
<td>35±1</td>
<td>1.06±0.21</td>
<td>2.04±0.32</td>
</tr>
<tr>
<td>Kokura</td>
<td>Nobuyoshi</td>
<td>106</td>
<td>53±1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Guangdong</td>
<td>Chen CR et al</td>
<td>85</td>
<td>1.1±0.3</td>
<td>2.0±0.4</td>
<td></td>
</tr>
<tr>
<td>Athens University</td>
<td>Stefanadis et al</td>
<td>156</td>
<td>49±1</td>
<td>1.0±0.2</td>
<td>2.2±0.5</td>
</tr>
<tr>
<td>North American</td>
<td>Herman et al</td>
<td>200</td>
<td>53±1</td>
<td>1.0±0.3</td>
<td>1.8±0.7</td>
</tr>
<tr>
<td>Multicenter Study</td>
<td>Inoue Balloon Registry</td>
<td>290</td>
<td>54±1</td>
<td>1.0±0.3</td>
<td>1.7±0.6</td>
</tr>
</tbody>
</table>

PMV = percutaneous mitral balloon commissurotomy; MV A = mitral valve area.

valve calcification under fluoroscopy was present in 255 (45%) patients. A mild degree of mitral valve regurgitation (≤ 2 grades) was demonstrated by cine left ventriculography in 212 (39%) patients before PMV.

In this group of patients, PMV resulted in a significant decrease in mitral gradient from 15 ± 1 to 5 ± 1 mm Hg. The mean cardiac output increased from 3.9 ± 0.1 to 4.5 U/min and the calculated mitral valve area from 0.9 ± 0.1 to 2.0 ± 0.1 cm². In addition, mean pulmonary artery pressure decreased from 37 ± 1 to 28 ± 1 mm Hg (P < .0001). The mean left atrial pressure decreased from 25 ± 1 to 16 ± 1 mm Hg (P < .0001) and the calculated pulmonary vascular resistances decreased significantly following PMV.

A successful hemodynamic outcome (defined as a post-PMV mitral valve area ≥ 1.5 cm², < 2 grade increase in mitral regurgitation by angiography and a QP/QS < 1.5/1) was obtained in 79% of the patients. Although a suboptimal result occurred in 21% of the patients, a postPMV mitral valve area ≥ 0.4 cm² (critical mitral valve area) was present in only 7% of these patients.

Univariate analysis demonstrated that the increase in mitral valve area with PMV is directly related to the balloon size employed as it reflects in the effective balloon dilating area (EBDA) and inversely related to the echocardiographic score, the presence of atrial fibrillation, the presence of fluoroscopic calcium, the presence of previous surgical commissurotomy, older age, NYHA prePMV and presence of mitral regurgitation before PMV. Multiple stepwise regression analysis demonstrated that the increase in mitral valve area with PMV is directly related to balloon size (P < .02) and inversely related to the echocardiographic score (P < .0001), presence of atrial fibrillation (P < .009), and mitral regurgitation before PMV (P < .03).

Predictors of the Increase in Mitral Valve Area with PMV

Echocardiographic Score

The echocardiographic score is the more important predictor of the immediate outcome of PMV. In this morphologic score each of the following is scored from 0 to 424:27: leaflet rigidity, leaflet thickening, valvular calcification, and subvalvular disease. A higher score would represent a heavily calcified, thickened, and immobile valve with extensive thickening and calcification of the subvalvular apparatus. Among the four components of the echocardiographic score, valve leaflets thickening and subvalvular disease correlate the best with the increase in mitral valve area produced by PMV. The increase in mitral valve area with PMV is inversely related to the echocardiographic score (Figure 3). The best outcome with PMV occurs in those patients with echocardiographic scores ≤ 8. The increase in mitral valve areas is significantly greater in patients with echocardiographic scores ≤ 8 than in
Figure 3. Relationship between the echocardiographic score and change in mitral valve area after PMV and relationship between the echocardiographic score and the percentage of patients that had a successful immediate hemodynamic outcome. (Modified with permission from Block PC, Palacios IF. Aortic and mitral valvuloplasty: the United States experience. In: Topol EJ, editor. Textbook of interventional cardiology. Philadelphia: WB Saunders, 1993:1198.) We have demonstrated that severe mitral regurgitation (4 grades by angiography) occurs in about 2% of patients undergoing PMVP. An undesirable increase in mitral regurgitation (~ 2 grades by angiography) occurred in 12.5% of patients. This undesirable increase in mitral regurgitation is well tolerated in most patients. Furthermore, more than half of them have less mitral regurgitation at follow-up cardiac catheterization. We have demonstrated that the ratio of the EDBA to body surface area (EBDN BSA) is the only predictor of increased mitral regurgitation after PMV. The EBDAs is calculated using standard geometric formulas. The incidence of mitral regurgitation is lower if balloon sizes are chosen so that EBDNBSA is ~ 4.0 cm²/m². The single-balloon technique results in a lower incidence of mitral regurgitation but provides less relief of mitral stenosis than the double-balloon technique. Thus, there is an optimal balloon size between 3.1 and 4.0 cm²/m².

Balloon Size and EBDAs

The increase in mitral valve area with PMV is directly related to balloon size. This effect was first demonstrated in a subgroup of patients who underwent repeat PMV. One group initially underwent PMV with a single balloon resulting in a mean mitral valve area of 1.2 ± 0.2 cm². Another group underwent repeat PMV using the double-balloon technique; this increased the EBDAs normalized by the body surface area (EBDAIBSA) from 3.41 ± 0.2 to 4.51 ± 0.2 cm²/m². The mean mitral valve area in this group after repeat PMV was 1.8 cm² ± 0.2 cm². The increase in mitral valve area in 529 patients who underwent PMV at the Massachusetts General Hospital using the double-balloon technique (EBDA of 6.4 ± 0.03 cm²) was significantly greater than the increase in mitral valve area achieved in 29 patients who underwent PMV using the single-balloon technique (EBDA of 0.02 cm²). The mean mitral valve areas were 2.0 ± 0.1 and 1.4 ± 0.1 cm² for patients who underwent PMV with the double-balloon and the single-balloon techniques, respectively. However, care should be taken in the selection of dilating balloon catheters so as to obtain an adequate final mitral valve area and no change or a minimal increase in mitral regurgitation.

Mitral Valve Calcification

The immediate outcome of patients undergoing PMV is inversely related to the severity of valvular calcification seen by fluoroscopy. Patients without fluoroscopic calcium have a greater increase in mitral valve area after PMV than patients with calcified valves. Patients with either no or 1+ fluoroscopic calcium have a greater increase in mitral valve area after PMV (2.1 ± 0.1 and 1.9 ± 0.1 cm², respectively) than those patients with 2, 3, or 4+ of calcium (1.7 ± 0.1, 1.5 ± 0.1 and 1.4 ± 0.1 cm², respectively).

Atrial Fibrillation

The increase in mitral valve area with PMV is inversely related to the presence of atrial fibrillation; the post-PMV mitral valve area of 291 patients in normal sinus rhythm was 2.1 ± 0.1 cm² compared with a valve area of 1.7 ± 0.1 cm² of 273 patients in atrial fibrillation.

Previous Surgical Commissurotomy

Although the increase in mitral valve area with PMV is inversely related to the presence of previous surgical mitral commissurotomy, PMV can produce a good outcome in this group of patients. The mean mitral valve area in 102 patients with previous surgical commissurotomy was 1.7 ± 0.1 cm² compared with a valve area of 2.0 ± 0.1 cm² in patients without previous surgical commissurotomy. In this group of patients, an echocardiographic score ~ 8 was again the most important predictor of a successful hemodynamic immediate outcome.

Age

The immediate outcome of PMV is directly related to the age of the patient. The percentage of patients obtaining a good result with this technique decreases as age increases. A successful hemodynamic outcome from PMV was obtained in only less than 50% of patients; 65 ± 10 ± 14. This inverse relationship between age and the immediate outcome from PMV is due to the higher frequency of atrial fibrillation, calcified valves, and higher echocardiographic scores in elderly patients.
**Mitral Regurgitation Before PMV**

The presence and severity of mitral regurgitation before PMV is an independent predictor of unfavorable outcome of PMV. The increase in mitral valve after PMV is inversely related to the severity of mitral regurgitation determined by angiography before the procedure. This inverse relationship between presence of mitral regurgitation and immediate outcome of PMV is in part due to the higher frequency of atrial fibrillation, higher echocardiographic scores, calcified mitral valves under fluoroscopy, and older age in patients with mitral regurgitation before PMV.

**Complications**

Table 2 shows the complications reported by several investigators using the double-balloon and the Inoue techniques of PMV.1-20;24-27 Mortality and morbidity with PMV are low and similar to surgical commissurotomy. There is a less than 1% mortality. In the series from the Massachusetts General Hospital, there was a 0.5% mortality with no procedural death occurring in the last 400 patients undergoing this procedure. Thromboembolic episodes and stroke incidence of 0% to 3.1% has been reported. Severe mitral regurgitation (4 grades by angiography) has been reported in 1% to 5.2% of the patients. Some of these patients required inhospital mitral valve replacement. Pericardial tamponade has been reported to occur in 0.2% to 4.1% of cases in these series. Pericardial tamponade can occur from transseptal catheterization and more rarely from ventricular perforation. PMV is associated with a 3% to 16% incidence of left-to-right shunt immediately after the procedure. However, the pulmonary-to-systemic flow ratio is ~ 2/1 in only a minimum number of patients.

We have demonstrated that severe mitral regurgitation (4 grades by angiography) occurs in about 2% of patients undergoing PMVP-29 An undesirable increase in mitral regurgitation (~ 2 grades by angiography) occurred in 12.5% of patients.27-29 This undesirable increase in mitral regurgitation is well tolerated in most patients. Furthermore, more than half of them have less mitral regurgitation at follow-up cardiac catheterization. We have demonstrated that the ratio of the EDBA to body surface area (EBDNBSA) is the only predictor of increased mitral regurgitation after PMV. The EBDNA is calculated using standard geometric formulas. The incidence of mitral regurgitation is lower if balloon sizes are chosen so that EBDNBBSA is ~ 4.0 cm2/m2. The single-balloon technique results in a lower incidence of mitral regurgitation but provides less relief of mitral stenosis than the double-balloon technique. Thus, there is an optimal balloon size between 3.1 and 4.0 cm2/m2 which achieves a maximal mitral valve area with a minimal increase in mitral regurgitation.29

Left-to-right shunt through the created atrial communication occurred in 3% to 16% of the patients undergoing PMV. The size of the defect is small as reflected in the pulmonary-to-systemic flow ratio of < 2:1 in the majority of patients.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Mortality</th>
<th>Severe MR</th>
<th>Embolism/Stroke</th>
<th>ASD</th>
<th>Tamponade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass General</td>
<td>0.5%</td>
<td>2.8%</td>
<td>1.0%</td>
<td>16%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Tenon</td>
<td>0.5%</td>
<td>2.8%</td>
<td>3.1%</td>
<td>14%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Lorna Linda</td>
<td>1.0%</td>
<td>1.0%</td>
<td>1.0%</td>
<td>12%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Beth Israel</td>
<td>6.6%</td>
<td>1.4%</td>
<td>2.1%</td>
<td></td>
<td>4.1%</td>
</tr>
<tr>
<td>Takeda</td>
<td>0.0%</td>
<td>1.9%</td>
<td>0.6%</td>
<td>12.8%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Chang Gung</td>
<td>0.2%</td>
<td>5.2%</td>
<td>2.1%</td>
<td>10.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>George Washington</td>
<td>0.0%</td>
<td>1.4%</td>
<td>1.4%</td>
<td>2.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Kokura</td>
<td>0.0%</td>
<td>4.8%</td>
<td>0.0%</td>
<td>4.8%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Athens University</td>
<td>0.6%</td>
<td>4.5%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>North American</td>
<td>0.0%</td>
<td>2.4%</td>
<td>1.5%</td>
<td></td>
<td>1.0%</td>
</tr>
<tr>
<td>Multicenter Study</td>
<td>1.4%</td>
<td>3.8%</td>
<td>0.9%</td>
<td>3.1%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

PMV = percutaneous mitral balloon commissurotomy; MR = mitral regurgitation; ASD = atrial septal defect.
Older age, fluoroscopic evidence of mitral valve calcification, higher echocardiographic score, pre-PMV lower cardiac output, and higher pre-PMV NYHA functional class are the factors that predispose patients to develop left-to-right shunt post-PMV. Clinical, echocardiographic, surgical, and hemodynamic follow-up of patients with post-PMV left-to-right shunt demonstrated that the defect closed in 59%. Persistent left-to-right shunt at follow-up is small (QP/QS < 2:1) and clinically well tolerated. In the series from the Massachusetts General Hospital, there is one patient in whom the atrial shunt remained hemodynamically significant at follow-up. This patient underwent percutaneous transcatheter closure of her atrial defect with a clamshell device. Desideri et al reported atrial shunting determined by color flow transthoracic echocardiography in 61% of 57 patients immediately after PMV. The shunt persisted in 30% of patients at 19 ± 6 months (range, 9 to 33) follow-up. Independent predictors of the persistence of atrial shunt at long-term follow-up include the magnitude of the post-PMV atrial shunt (QP/QS > 1.5:1), use of Bifoil balloon (2 balloons on 1 shaft), and smaller post-PMV mitral valve area.

Follow-up

Clinical Follow-up

Follow-up studies after PMV are encouraging. Following PMV, the majority of patients have marked clinical improvement and become NYHA Class I or II. The symptomatic, echocardiographic, and hemodynamic improvement produced by PMV persists in intermediate and long-term follow-up. The best long-term results are seen in patients with echocardiographic scores ≤ 8. When PMV produces a good immediate outcome in this group of patients, restenosis is unlikely to occur at follow-up. Although PMV can result in a good outcome in patients with echocardiographic scores > 8, hemodynamic and echocardiographic restenosis is frequently demonstrated at follow-up despite ongoing clinical improvement.

Table 3 shows long-term follow-up results of patients undergoing PMV at different institutes. We recently reported an estimated 80-mo survival rate of 75 ± 4% in a large cohort of patients undergoing PMV at the Massachusetts General Hospital. Death at follow-up was directly related to age, post-PMV pulmonary artery pressure, pre-PMV NYHA functional class, and the echocardiographic score. In the same group of patients, the estimated 80-mo survival with freedom from mitral valve surgery (mitral valve replacement or mitral valve repair) was 46 ± 4%. The presence of mitral valve surgery at follow-up directly related to post-PMV Seller’s grade of mitral regurgitation, the history of previous surgical commissurotomy, pre-PMV NYHA class, and post-PMV mitral valve area. The 80-mo estimated event-free survival of this patient's cohort (survival with freedom from mitral valve surgery and NYHA functional class ~ III) was 43 ± 4%. Events at follow-up were directly related to age, pre-PMV NYHA class, post-PMV Seller’s grade of mitral regurgitation, history of surgical mitral commissurotomy, post-PMV pulmonary artery pressure, and the echocardiographic score.

Patients with echocardiographic scores ≤ 8 have a significantly greater survival, survival with freedom from mitral valve surgery, and event-free survival (death, mitral valve surgery, and NYHA class ~ III) than those patients with echocardiographic scores > 8. Patients with echocardiographic scores ≤ 8 have a 83 ± 6% 80-mo survival at 80-mo follow-up, 58 ± 5% of them were free of mitral valve surgery.

Table 3. Follow-up after PMV.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Mean follow-up</th>
<th>Survival (y)</th>
<th>Event-free survival (y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass General</td>
<td>32 ± 6 months</td>
<td>81 ± 5% (1)</td>
<td>41 ± 4% (1)</td>
</tr>
<tr>
<td>Mass General</td>
<td>20 ± 6 months</td>
<td>89 ± 5% (1)</td>
<td>66 ± 9% (1)</td>
</tr>
<tr>
<td>Toronto</td>
<td>18 ± 6 months</td>
<td>92 ± 6% (1)</td>
<td>68 ± 10% (1)</td>
</tr>
<tr>
<td>London</td>
<td>31 ± 6 months</td>
<td>78 ± 10% (1)</td>
<td>75 ± 10% (1)</td>
</tr>
<tr>
<td>Beil Israel</td>
<td>36 ± 6 months</td>
<td>76 ± 10% (1)</td>
<td>51 ± 10% (1)</td>
</tr>
</tbody>
</table>

PMV = percutaneous mitral balloon commissurotomy
valve surgery and 51 ± 6% of the patients were free of combined events. In contrast, patients with echocardiographic scores > 8 have a 48 ± 8% 80 mo survival. At 80-mo follow-up, 25 ± 5% of them were free of mitral valve surgery and only 22 ± 5% of them were free of combined events.26

Similar follow-up studies have been reported in other series with the double-balloon technique and with the Inoue technique of PMV.11,14-17,26,30-36 With the Inoue technique of PMV at intermediate long-term follow-up of 51 mo, young patients with pliable valves, in sinus rhythm and with no evidence of calcium under fluoroscopy were free of cardiovascular events. In contrast, 84% of patients with calcified valves and/or severe subvalvular disease were free of cardiovascular events at 48-mo follow-up,1S-17 Cohen et al18 reported the clinical follow-up of 146 patients undergoing PMV. The overall survival rate was 88% at 2 y and 76% at 5 y. Event-free survival was 74% at 2 y and 51% at 5 y. Ninety-six percent of patients alive at follow-up were NYHA class I or II. Independent predictors of longer event-free survival were a lower echocardiographic score, lower left ventricular end-diastolic pressure and final mitral valve area post-PMV. Their lower 5-y event-free survival can be explained by a larger number of patients with higher echocardiographic scores and mitral valve calcification. Furthermore, in that study 39% of the patients were considered to be high surgical risk candidates due to the presence of important coexisting conditions or advanced age.

Follow-up in the Elderly

Tuzcu et al14 reported the outcome of PMV in 99 elderly patients (~ 65 y). A successful outcome (valve area ~ 1.5 cm2 without ~ 2+ increase in mitral regurgitation and without left-to-right shunt of ~ 1.5:1) was achieved in 46 patients. The best multivariate predictor of success was the combination of echocardiographic score, NYHA functional class, and inverse of mitral valve area. Patients who had an unsuccessful outcome from PMV were in a higher NYHA functional class, had higher echo cardiographic scores, and smaller mitral valve areas pre-PMV compared to those patients who had a successful outcome. Actuarial survival and combined event-free survival at 3 y were significantly better in the successful group.

Mean follow-up was 16 ± 1 mo. Actuarial survival (79 ± 7% vs. 62 ± 10%; P = .04); survival without mitral valve replacement (71 ± 8% vs. 41 ± 8%; P = .002); and event-free survival (54±: 12% vs. 38 ±: 8%; P = .01) at 3 y were significantly better in the successful group of 46 patients than the unsuccessful group of 53 patients. Low echocardiographic score was the independent predictor of survival and lack of mitral valve calcification was the strongest predictor of event-free survival.

Follow-up of Patients with Calcified Mitral Valves

The presence of fluoroscopically visible calcification on the mitral valve influences the success of PMV. Patients with heavily (~ 3 grades) calcified valves under fluoroscopy have a poorer immediate outcome as reflected in a smaller post-PMV mitral valve area and greater post-PMV mitral valve gradient. Immediate outcome is progressively worse as the calcification becomes more severe. The long-term results of percutaneous mitral balloon valvuloplasty are significantly different in calcified and uncalcified groups and in subgroups of the calcified group.37 The estimated 2-y survival is significantly lower for patients with calcified mitral valves than for those with uncalcified valves (80% vs. 99%). The survival curve becomes worse as the severity of valvular calcification becomes more severe. Freedom from the mitral valve replacement at 2 y was significantly lower for patients with calcified mitral valves than for those with uncalcified valves (67% vs. 93%). Similarly, the estimated event-free survival at 2 y in the calcified group became significantly poorer as the severity of calcification increased. The estimated event-free survival at 2 y was significantly lower for the calcified than for the uncalcified group (63% vs. 88%). The actuarial survival curves with freedom from combined events at 2 y in the calcified group became significantly poorer as the severity of calcification increased.37 These findings are in agreement with several follow-up studies of surgical commissurotomy which demonstrate that patients with calcified mitral valves had a poorer survival compared to those patients with uncalcified valves.38-40
Follow-up of Patients with Previous Surgical Commissurotomy

PMV also has been shown to be a safe procedure in patients with previous surgical mitral commissurotomy. 10,41,42 Although a good immediate outcome is frequently achieved in these patients, follow-up results are not as favorable as those obtained in patients without previous surgical commissurotomy. 41,42 Although there is no difference in mortality between patients with or without a history of previous surgical commissurotomy at 4 y follow-up, the number of patients who required mitral valve replacement (26% vs. 8%) and/or were in NYHA class III or IV (35% vs. 13%) was significantly higher among those patients with previous commissurotomy. However, when the patients are carefully selected according to the echocardiographic score (:s; 8), the immediate outcome and the 4 y follow-up results are excellent and similar to those seen in patients without previous surgical commissurotomy. 10,41,42

Echocardiographic and Hemodynamic Follow-up

Follow-up studies have shown that the incidence of hemodynamic and echocardiographic restenosis is low 2 y after PMV.11,13,15-17,31 A study of a group of patients undergoing simultaneous clinical evaluation, 2D-Doppler echocardiography and transseptal catheterization 2 y after PMV reported 90% of patients in NYHA classes I and II and 10% of patients in NYHA class III. In this study, hemodynamic determination of mitral valve area using the Gorlin equation showed a significant decrease in mitral valve area from 2.0 cm² immediately after PMV to 1.6 cm² at follow-up. However, there was no significant difference between the echocardiographic mitral valve areas immediately after PMV and at follow-up (1.8 cm² and 1.6 cm², respectively; P = NS). Although there was a significant difference in the mitral valve area after PMV determined by the Gorlin equation and by 2D-echocardiography (2.0 cm² vs. 1.8 cm²), there was no significant difference between the mitral valve area determined by the Gorlin equation and the echocardiographic calculated mitral valve area (1.6 cm² for both) at follow-up. The discrepancy between the 2D-echocardiographic and Gorlin equation determined post-PMV mitral valve areas is due to the contribution of left-to-right shunting (undetected by oximetry) across the created interatrial communication which results in both an erroneously high cardiac output and an overestimation of the mitral valve area by the Gorlin equation. 43 Desideri et al showed no significant differences in mitral valve area (measured by Doppler echocardiography) at 19 ± 6 (range, 9 to 33) mo follow-up between the post-PMV and follow-up mitral valve areas. Mitral valve areas were 2.2 ± 0.5 cm² and 1.9 ± 0.5 cm², respectively. 31 Echocardiographic restenosis (mitral valve area ≤; 1.5 cm² with > 50% reduction of the gain) was seen in 21% of the patients. 34 Predictors of restenosis included age, smaller post-PMV mitral valve area, and higher echocardiographic score. 31

With the Inoue technique, Chen et al 16 showed no significant differences in mitral valve area determined by 2D-Doppler echocardiography in 85 patients at a mean follow-up of 5 ± 1 Y (range, 43 to 79 mo). Post-PMV and follow-up mitral valve areas were 2.0 ± 0.4 and 1.8 ± 0.5 cm², respectively (NS).

PMV vs. Surgical Mitral Commissurotomy

Results of surgical closed mitral commissurotomy have demonstrated favorable long-term hemodynamic and symptomatic improvement from this technique. A restenosis rate of 4.2 to 11.4 per 1000 patients per year was reported by John et al in 3724 patients who underwent surgical closed mitral commissurotomy. 44 Survival after PMV is similar to that reported after surgical mitral commissurotomy. Although freedom from mitral valve replacement (87% vs. 92%) and freedom from all events (67% vs. 80%) after PMV are lower than reported after surgical commissurotomy, 26,31,39,40,44-52 freedom from both mitral valve replacement and all events in patients with echocardiographic scores ≤; 8 are similar to that reported after surgical mitral commissurotomy. 26,31,39,40,44-52

Restenosis after both closed and open surgical mitral commissurotomy has been well documented. 44-51 Although surgical closed mitral commissurotomy is uncommonly performed in the United States, it is still used frequently in
other countries. Long-term follow-up of 267 patients who underwent surgical "transventricular mitral commissurotomy at the Mayo Clinic showed a 79%, 67%, and 55% survival at 10, 15, and 20 years, respectively. Survival with freedom from mitral valve replacement were 57%, 36%, and 24%, respectively. In this study age, atrial fibrillation, and male gender were independent predictors of death, while mitral valve calcification, cardiomegaly, and mitral regurgitation were independent predictors of repeat mitral valve surgery. Because of similar patient's selection and mechanism of mitral valve dilatation, similar long-term results should be expected after PMV. Indeed, prospective, randomized trials comparing PMV and surgical closed mitral commissurotomy have shown no differences in immediate and 3-y follow-up results between both groups of patients.54,55 Furthermore, restenosis at 3-y follow-up occurred in 10% and 13% of the patients treated with mitral balloon valvuloplasty and surgical commissurotomy, respectively.55 Results of randomized clinical trials comparing PMV and surgical open commissurotomy show similar results.

Conclusion

We conclude that (1) PMV produces a good immediate outcome and good clinical long-term follow-up results in a high percentage of patients with mitral stenosis; (2) patients with echocardiographic scores ~ 8 have the best results particularly if they are young, are in sinus rhythm, and have no evidence of calcification of the mitral valve under fluoroscopy. The immediate and long-term results of PMV in this group of patients are similar to those reported after surgical mitral commissurotomy; (3) patients with echocardiographic scores > 8 have only a 50% chance to obtain a successful hemodynamic result with PMV and long-term follow-up results are less good than those from patients with echocardiographic scores ~ 8; (4) in patients with echocardiographic scores ~ 12, it is unlikely that PMV could produce good immediate or long-term result. They preferably should undergo open heart surgery. However, PMV could be performed in these patients if they are nonhigh-risk surgical candidates; and (5) surgical therapy for mitral stenosis should be reserved for patients who have ~ 2 grades of Seller's mitral regurgitation by angiography which can be better treated by mitral valve repair and for those patients with severe mitral valve thickening and calcification or with significant subvalvular scarring to warrant valve replacement.

References