Immediate Results of Percutaneous Mitral Balloon Valvuloplasty in Patients with Mitral Stenosis

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ABSTRACT
Introduction: Mitral stenosis is a prevalent valvular disease in developing countries. Percutaneous mitral balloon valvuloplasty (PMBV) is the gold standard treatment. The main objective of this study was to assess the initial results of PMBV in patients with mitral stenosis during 16 years (2002-2018) in Mashhad, Iran.

Material and Methods: From April 2002 to March 2018, 770 patients underwent PMV in department of cardiology. PMV was performed by the antegrade transseptal method using the Inoue balloon.

Results: The obtained success rate was 97%. In this study, the valve area increased from 0.9±1.1 to 1.8±0.2 cm² (P<0.0001). There was no case of peri-procedural death or cardiac tamponade. Additionally, 0.25% of the patients required mitral valve replacement. Severe mitral regurgitation occurred in 0.9% of the subjects. There was no case of cerebrovascular accident, transient ischemic attack, embolic myocardial infarction, or cardiac perforation. Supraventricular tachycardia occurred in 2.59% of the patients.

Conclusion: The PMBV by the Inoue technique is a feasible and easy procedure with a short crossing times and low complications.

Introduction
Mitral stenosis (MS) is a prevalent valvular disease in developing countries. Acute rheumatic fever is the leading cause of this disorder (1). In 1982, the first percutaneous mitral valvuloplasty (PMV) was performed on a 33-year-old man with severe MS by a Japanese surgeon named Inoue. The initial report was published in 1984 (2).

The splitting of fused commissures is the mechanism, by which PMV and surgical techniques reduce stenosis (3). The hemodynamic outcomes of PMV and surgical commissurotomy in several randomized trials. However, surgical patients had more peri-procedural complications (4-6). Therefore, the surgical technique has been supplanted by PMV (7). The main objective of this study was to assess the initial results of PMV in patients with MS during 16 years (2002-2018) in Mashhad, Iran.

Materials and Methods
Patient Selection for Balloon Valvuloplasty
From April 2002 to March 2018, 770 patients underwent PMV in department of cardiology, Mashhad Iran. Echocardiographic examination was performed on the day before the procedure. Planimetry by two-dimensional echocardiography was the reference measurement used to calculate mitral valve area.
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Table 1. Wilkins Scoring System for Mitral Valvuloplasty

<table>
<thead>
<tr>
<th>Grade</th>
<th>Leaflet Mobility</th>
<th>Valve Thickening</th>
<th>Calcification</th>
<th>Subvalvular Thickening</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Highly mobile</td>
<td>Minimal thickening</td>
<td>Single area of brightness</td>
<td>Minimal chordal thickening</td>
</tr>
<tr>
<td>2</td>
<td>Reduced mobility</td>
<td>Thicker tips</td>
<td>Scattered areas at leaflet margins</td>
<td>Chordal thickening up to one-third</td>
</tr>
<tr>
<td>3</td>
<td>Basal leaflet motion only</td>
<td>Entire leaflet thickened</td>
<td>Brightness extends to mid leaflets</td>
<td>Distal third of chordae thickened</td>
</tr>
<tr>
<td>4</td>
<td>Minimal motion</td>
<td>Marked leaflet thickening</td>
<td>Extensive leaflet brightness</td>
<td>Extensive thickening to papillary muscles</td>
</tr>
</tbody>
</table>

A desirable score is 8 or lower.

A Wilkins score (Table 1) of less than 8 was considered to be a predictor of favorable outcomes. PMV was recommended for symptomatic patients with moderate to severe MS (i.e., valve area <1 cm²/m² of body surface area or <1.5 cm² in normal-sized adults) and with favorable valve morphology. Furthermore, asymptomatic patients with very severe MS (<1 cm²) with favorable valve anatomy or AF rhythm were included. Patients with moderate or greater MR or LA appendage thrombus were excluded. We assessed initial results of PMV in patients with mitral stenosis during 16 years (2002-2018) in Mashhad, Iran.

Techniques

PMV was performed by the antegrade transseptal method using the Inoue balloon (8). The procedure was performed using a transfemoral approach through a 9F and 5F catheter sheath in the vein and artery, respectively, with patients under conscious sedation. After the bolus administration of 1000 U heparin, right heart catheterization was performed.

Thereafter, right atriography was carried out to determine the optimal puncture site using a Brockenbrough needle. Transseptal cardiac catheterization was performed using standard Brockenbrough technique. While the Brockenbrough catheter was slowly flicked up from the superior vena cava into the atrial septum, it was advanced through the atrial septum.

Then, a coiled-tip guidewire was inserted into the left atrium through the Brockenbrough sheath. In addition, 9000 U heparin was administered to reduce the risk of a thromboembolic event during the manipulation of catheters and wires in the left atrium. In the next step, the Inoue balloon catheter was advanced over the coiled-tip wire.

Once the balloon catheter had crossed the atrial septum, the catheter was placed in the left atrium, and it formed a loop with the tip facing toward the mitral valve orifice. The tip of the balloon was inflated with 1 to 2 ml of contrast material, allowing blood flow to carry the balloon tip through the left ventricle. Once the balloon catheter had been inserted into the left ventricle, its distal portion was inflated with contrast material. The catheter was then pulled back until resistance was met.

After each dilatation, the left atrial and ventricular pressures were simultaneously measured through the middle part of the Inoue catheter and the pigtail catheter, respectively. The balloon size was increased in 1-mm increments until the pressure gradient decreased or substantial worsening of mitral regurgitation (MR) occurred.

Statistical analysis

Quantitative variables were expressed as mean standard deviation. Good immediate results of percutaneous mitral commissurotomy were defined by the composite endpoint used in previous studies (9, 10), which associates a mitral valve area 1.5 cm² with no regurgitation >2/4. Comparison of variables before and after the procedure used the Paired T test. A p value < 0.05 was considered clinically significant. All statistical analyses were performed using Statistical Package of Social Science (SPSS) software (version 24, IBM Corporation).

Results

Immediate results

All patients had Wilkins score of less than 8. The immediate results of the procedure are demonstrated in Table 2. Good immediate results that were defined above were obtained in 97% of the patients. There was no case of peri-procedural death or cardiac tamponade. Additionally, mitral valve replacement was required in 0.25% of the subjects. Severe MR (Sellers' grade=3) occurred in 0.9% of the participants.

There was no case of cerebrovascular accident, transient ischemic attack, embolic myocardial infarction, or cardiac perforation. Supraventricular tachycardia was reported in 2.59% of the patients. The improvement in valve function, as assessed by planimetry, is shown in Table 2, with a valve area increasing from 0.9±1.1 to 1.8±0.2 cm² (P<0.0001).

90% of patients who were undergone angiography had huge collateral branch from left circumflex artery to left atrium.
Table2. Immediate results after Percutaneous Mitral Valvuloplasty (n=770)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean±SD [range] or n=770 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good results</td>
<td>747 (97%)</td>
</tr>
<tr>
<td>Mitral valve area (Pre)</td>
<td>0·9±1.1</td>
</tr>
<tr>
<td>Mitral valve area (Post)</td>
<td>1·8±0.2</td>
</tr>
<tr>
<td>Hospital mitral valve replacement</td>
<td>2 (0.25%)</td>
</tr>
<tr>
<td>Severe Mitral Regurgitation</td>
<td>7 (0.9)</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>0</td>
</tr>
<tr>
<td>Transient ischemic stroke</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td>0</td>
</tr>
<tr>
<td>Atrial Septal Defect (&gt;1.5mm)</td>
<td>2 (0.25%)</td>
</tr>
<tr>
<td>Vascular repair/transfusion</td>
<td>4 (0.5%)</td>
</tr>
<tr>
<td>Supraventricular tachycardia</td>
<td>20 (2.59%)</td>
</tr>
<tr>
<td>Embolic myocardial infarction</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
</tbody>
</table>

Discussion
Symptomatic patients with moderate to severe MS (i.e., valve to body surface area ratio less than 1 cm²/m² or <1.5 cm² in normal-sized adults) and with favorable morphology, as well as no or mild MR and no evidence of left atrial thrombus should undergo PMV. Even mild symptoms such as a subtle decrease in exercise tolerance are an indication for intervention because the procedure relieves symptoms and improves long-term outcome with a low procedural risk (11).

PMV is the gold standard treatment option in patients with MS. Surgical intervention is now reserved for patients, who require intervention and are not candidates for PMV (12). In the present study, it was explained that the Inoue balloon technique is a safe procedure. According to the literature, this technique is feasible and in association with short crossing time and low complication rates (13-15).

Regarding the results of the current study, the success rate was 97%. Given the evidence, the success rate in the total population is 79.6%, a result that fits within the reported range (73-99%) (16-18). It is confirmed that PMV is associated with less morbidity, shorter length of hospital stay, avoidance of the discomfort and other problems associated with thoracotomy, while the cost of surgery is at least twice that of balloon Valvotomy (19).

The immediate results of PMV appeared to be very similar to closed and open surgical commissurotomy (4-7). However, operative mortality following surgical commissurotomy (2.97%) was higher than that reported after PMV (0.05%) (20, 21). In other reports, the complications associated with PMV consisted of cerebrovascular embolism and cardiac perforation in approximately 1% of patients.

Furthermore, the prevalence of severe MR that requires operation was 2% (22). In this study, there was no case of cerebrovascular accident, transient ischemic attack, embolic myocardial infarction, or cardiac perforation. Other studies reported that approximately 5% of patients were discharged with a small, residual atrial septal defect.

Nevertheless, this defect closes or decreases in size in most of the cases. Rarely, the atrial septal defect is large enough to cause right-sided heart failure. This complication most often is seen in conjunction with an unsuccessful mitral valvotomy (22). In the present study, 0.25% of the patients left the hospital with an atrial septal defect. Another complication is supraventricular tachycardia, which occurred in 2.59% of the participants.

Conclusion
PMV is the gold standard treatment option for patients with MS. The Inoue balloon technique is a feasible and easy procedure with a short crossing time and low complication rates.

Acknowledgments
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Conflict of Interest
The authors declare no conflict of interest.

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