Mitral restenosis and mitral regurgitation 1 year after Inoue mitral balloon valvotomy in a population of patients with pliable mitral valve stenosis

To determine the rate of mitral restenosis and mitral regurgitation increase 1 year after mitral valvotomy using the Inoue balloon catheter, 66 consecutive patients with severe, pliable mitral stenosis had their mitral valve area (MVA) calculated by two-dimensional echocardiography (2DE) and Doppler before, immediately after balloon valvotomy, and at 1-year follow-up. Color Doppler studies were also done to detect small atrial septal defects (ASDs) and mitral regurgitation. The mean age of the patients was 31 ± 12 years. Three patients were in New York Heart Association (NYHA) class II and 63 patients were in NYHA class III to IV. Sixty-two of the 66 patients had an echo score (Boston) of ≤8. After Inoue balloon valvotomy (IBV), the MVA (2DE) increased from 0.8 ± 0.2 to 1.9 ± 0.3 cm$^2$ ($p < 0.001$), and the Doppler MVA increased from 0.8 ± 0.2 to 1.8 ± 0.3 cm$^2$ ($p < 0.001$). We detected 4 of 66 cases (6%) with significant residual mitral stenosis (MVA < 1.5 cm$^2$). Mitral regurgitation increased in 14 of 66 patients (21%), but no patient developed severe mitral regurgitation. Fourteen out of 66 patients (20%) had ASDs that were detected on color Doppler. At 1-year follow-up the mean Doppler MVA was maintained at 1.8 ± 0.4 cm$^2$, with 6 of 66 patients (9%) exhibiting significant mitral valve restenosis. Residual significant mitral stenosis must be differentiated from mitral restenosis. The degree of mitral regurgitation was unchanged in 59 of 66 patients (90%); it increased in 5 of 66 patients (8%), being severe in 3 of 66 patients (5%), and decreased in 2 of 66 patients (2%). ASDs closed spontaneously in 9 of 14 patients (64%). At 1 year after Inoue mitral balloon valvotomy in a population of patients with severe pliable mitral valve stenosis, mitral restenosis and the onset of severe mitral regurgitation jeopardized the initial favorable results in 14% of patients. (AM HEART J 1993;126:136-140.)

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Mitral balloon valvotomy is an established therapeutic alternative to the surgical treatment of severe mitral valve stenosis. The manner in which the mitral valve area is increased by single- and double-mitral balloon valvotomy is similar to that of surgical valvotomy, that is, commissural splitting. The double-balloon mitral valvotomy technique achieves a mean 100% increase in mitral valve area, and these results are maintained at 1-year follow-up. For the single-balloon technique using the Inoue catheter, the mean mitral valve area achieved was similar to that obtained with the double-balloon technique.

The natural history of mitral stenosis and the rate of restenosis after balloon valvotomy was evaluated at an average of 8 months' follow-up in the study of Nobuyoshi et al. The rate of recurrent symptoms was 6% in the population with a mean of 53 years—that is two decades older than our population of patients. We prospectively selected patients with pliable rheumatic mitral valve stenosis with a low echocardiographic score. We studied 66 patients before, after, and at 1 year after Inoue mitral balloon valvotomy. The objectives of the study were threefold: (1) to determine the incidence of significant re-
Table IV. NYHA class symptoms in the 66 patients before Inoue mitral balloon valvotomy and at follow-up

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Before</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0</td>
<td>56</td>
</tr>
<tr>
<td>II</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>III</td>
<td>53</td>
<td>1</td>
</tr>
<tr>
<td>IV</td>
<td>10</td>
<td>0</td>
</tr>
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Abbreviations as in Table II.

ously reported the results in 60 patients before and after Inoue mitral balloon valvotomy, with a mean increase in mitral valve area (Gorlin formula) from 0.7 ± 0.2 to 1.6 ± 0.4 cm² (p < 0.001) and a decrease in mean mitral valve gradient from 15 ± 4 to 6 ± 2 mm Hg (p < 0.001).

Complete two-dimensional echocardiographic and color Doppler studies using a Hewlett-Packard phased array system (Hewlett-Packard Co., Medical Products Group, Andover, Mass.) were done before, 2 days after, and at 1 year follow-up in all 66 patients. The Doppler mitral valve area was measured using the pressure half-time method.¹² Standard two-dimensional echocardiographic views were obtained and their images were recorded for subsequent analysis. The mitral valve area was calculated from the short-axis parasternal view, as described by Henry et al.¹³ Color flow Doppler was used to detect small iatrogenic atrial septal defects after mitral balloon valvotomy and at 1-year follow-up. The degree of mitral regurgitation was evaluated using color Doppler.¹⁴ Patients below the age of 30 were on long-term prophylaxis for acute rheumatic fever with penicillin or erythromycin.

Technique. The technique was described by Inoue et al.,¹⁵ and we selected the balloon size according to the patient's height. Oral diazepam was given (10 mg) as premedication. All patients underwent diagnostic right and left heart cardiac catheterization. The Inoue balloon is made of a double layer of latex rubber between which there is a nylon micromesh.¹⁵ Approximately half of the narrow mesh is bound with thin rubber bands pulled 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 the inflation. Inflation occurs first at the distal half and subsequently at the proximal half; the balloon constriction remains in the middle section until full inflation is achieved. The Inoue balloon was conceived so that adjusting injection volume would alter the balloon diameter. The balloon size is selected according to the patient's height: 24 mm for patients less than 140 cm, 26 mm for patients taller than 140 cm, 28 mm for those patients measuring between 160 and 150 cm, and 30 mm diameter size balloons are used for patients who measure more than 180 cm. The initial inflated diameter is less than the predetermined upper limit of the stepwise increase in balloon size and is implemented if the valve dilatation is not considered adequate. The mitral valve area was measured by echo Doppler using a Hewlett-Packard phased array system (Hewlett-Packard Co., Medical Products Group) with color Doppler. Visual assessment of commissural splitting was corroborated by the hemodynamic decrease in the transmitral gradient. Transseptal cardiac catheterization was done using an 8F Mullins transseptal dilator, followed by the administration of 150 units/kg of heparin. A left ventriculogram was done before and after valvotomy. Protamine was given at the end of the procedure to reverse the effect of heparin. Stepwise mitral valve dilatation was done according to the Inoue criteria, and echocardiography was repeated after each dilatation to evaluate the degree of mitral valve regurgitation with the calculation of the mitral valve area. If a commissure was completely split, further attempts to dilate the other commissure were not done, as recommended by Inoue to prevent the development of intragenous mitral valve regurgitation.

Definitions. Significant residual mitral stenosis following balloon valvotomy was considered to be a Doppler mitral valve area of <1.5 cm². Mitral restenosis was defined as a Doppler mitral valve area of <1.5 cm², with a loss of at least 0.4 cm² of the mitral valve area gain.

Statistics. Mean and standard deviations were calculated in the usual way. Paired Student's t-test was used to test the significance between the means (p < 0.05).

RESULTS

Immediately after Inoue balloon valvotomy. After mitral balloon valvotomy the mean echo mitral valve area increased from 0.8 ± 0.2 (range 0.5 to 1.1) to 1.9 ± 0.3 (range 1.0 to 2.4) cm² (p < 0.001), and from 0.8 ± 0.2 (range 0.4 to 1.1) to 1.8 ± 0.3 (range 0.9 to 2.5) cm² (p < 0.001) by Doppler (Table I). We detected 4 of 66 cases (6%) of significant residual mitral stenosis, defined as a mitral valve area of <1.5 cm². Two of the four patients exhibited an echocardiographic score of >8 (Table II). Color Doppler studies demonstrated that 14 of 66 patients (20%) had an iatrogenic atrial septal defect. The color Doppler degree of mitral regurgitation was unchanged in 50 of 66 patients (76%), 26 with grade 1+ and 24 with grade 0 mitral regurgitation. In 14 of 66 patients (21%) the degree of mitral regurgitation increased from grade 0 to 1+ (eight patients), from grade 1+ to 2+ (four patients), and from grade 0 to 2+ (two patients). The degree of mitral regurgitation decreased in 2 of 66 patients (3%), from grade 1+ to 0. No patient developed severe mitral valve regurgitation. There were no major complications including death or thromboembolic episodes.

Results 1 year after Inoue mitral balloon valvotomy (Tables I through IV). The NYHA class before and at follow-up is summarized in Table IV. Persistent significant residual mitral stenosis—that is, mitral valve area of <1.5 cm²—persisted in 4 of 66 patients (6%). Significant mitral valve restenosis developed in 6 of 66 patients (9%) 1 year after Inoue mitral balloon valvotomy; two of these six patients exhibited an
echocardiographic score of >8 (Table III). The majority of these patients were virtually asymptomatic (Table IV). The mean echocardiographic valve areas for the 66 patients were 1.7 ± 0.4 cm² and 1.8 ± 0.4 cm² by Doppler (Table I).

Color Doppler studies showed that the majority of iatrogenic small atrial septal defects had spontaneously closed, and persisted in only 5 of 66 patients (15%) (Table I). The degree of mitral regurgitation was unchanged in 59 of 66 patients (90%), increasing in 5 of 66 (8%) from grade 0 to 1+ in one patient, from grade 2+ to 3+ in one patient, from grade 1+ to 2+ in another patient, and from grade 2+ to 4+ in one patient. Therefore at follow-up 3 of 66 patients (5%) developed severe mitral regurgitation. The degree of mitral regurgitation decreased in 2 of 66 patients (3%) from grade 1+ to 0.

DISCUSSION

Our study showed that in a population of patients with pliable mitral valves, mitral restenosis and severe mitral regurgitation developed in 14% of patients within 1 year of the intervention. This complication may reflect the high prevalence of subclinical rheumatic fever in developing countries. We demonstrated that 1 year following mitral balloon valvotomy, 15% of patients exhibited mitral valve areas of <1.5 cm². The suboptimal results usually indicate mitral restenosis, though they must be differentiated from significant residual mitral stenosis.

The rate of mitral restenosis in this study using the Inoue balloon catheter is much higher than the reported rate using the double-balloon technique in a similar population of patients with mitral stenosis. The difference in results between these studies may simply indicate that the populations have noncomparable degrees of mitral valve disease. Alternatively, the double-balloon technique may achieve better long-term results when compared with the Inoue balloon technique. This possibility is unlikely, as the mechanism of action of both the Inoue and double-balloon valvotomy techniques are similar, that is, commissural splitting. A randomized study is warranted to answer this research question.

The incidence of iatrogenic mitral regurgitation after balloon valvotomy is variable. A severe degree of mitral regurgitation occurs in less than 5% of patients. We did not detect any case of severe mitral regurgitation immediately after balloon valvotomy. These different results may be explained by our patient selection criteria—young with pliable mitral valves. The incidence of severe mitral regurgitation at follow-up was high in our series. This finding is in contrast with the results reported in the series of Pan et al. The age of our patient population, in which acute rheumatic fever is still prevalent, may explain the difference in the results.

In patients who underwent the double-balloon valvotomy technique and with echocardiographic evidence of valve thickness, deformity, and calcification, the restenosis rate was 70%. This finding appears to corroborate the original assessment of Abascal et al. that the mitral valve and subvalvular morphology by two-dimensional echocardiography may identify those patients at risk of restenosis after balloon valvotomy. A high echocardiographic mitral score was a significant predictor of restenosis.

Nobuyoshi et al. reported the short-term follow-up results after Inoue balloon valvotomy in a population of patients with a mean age of 53 years. From the preballoon valvotomy echocardiographic assessment, these authors showed that the rate of restenosis was 50% in patients with rigid valves—that is, total immobility of the leaflets—who had generalized calcification with severe subvalvular thickening. Similar results have been reported after surgical mitral valvotomy, showing that a greater degree of mitral calcification and leaflet immobility was associated with poorer long-term results. Another large series of patients demonstrated that an echocardiographic score of >8, valvular calcification, and subvalvular disease were independent predictors for suboptimal results.

In vitro mitral balloon valvotomy studies show that the degree of commissural splitting correlates poorly with an increase in mitral valve area. In those mitral valves with severe subvalvular fusion, the mitral valve commissural splitting does not lead to a good mitral valve area result, as subvalvular mitral stenosis persists. The in vitro studies demonstrated a wide variability of mitral valve areas achieved when using similar-sized balloon catheters. These results indicate that the major determining factors of mitral valve areas achieved after balloon valvotomy are the status and texture of the mitral valve apparatus. These data indicate that to study the long-term results of mitral balloon valvotomy using either the single Inoue or the double-balloon technique, the type of underlying valve pathology and the subvalvular apparatus need to be defined, as we did in this study.

The incidence of iatrogenic atrial septal defects detected by Doppler using the Inoue technique was 5% in the study of Nobuyoshi et al. We detected a 20% incidence of small atrial septal defects using the sensitive method of color Doppler studies. An oximetry series done immediately after valvotomy showed
that these atrial septal defects were small and did not have a repercussion in the oximetry series. The great majority of atrial septal defects closed spontaneously at 1 year after mitral balloon valvotomy. This corroborates the findings of Block et al., who used the double-balloon technique, in which most of the atrial septal defects had closed at a 2-year follow-up. We conclude that 1 year after the Inoue mitral balloon valvotomy in a population of patients with severe pliable mitral valve stenosis, mitral restenosis and new onset of severe mitral valve regurgitation jeopardized the initial favorable results in 14% of patients.

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