Balloon mitral valvotomy: comparison between antegrade Inoue and retrograde non-transseptal techniques


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Aims The results of percutaneous mitral valvotomy performed by the antegrade transseptal method using the Inoue balloon (n=1000; group 1) and by the retrograde non-transseptal technique using a polyethylene balloon (n=100; group 2) were compared in a retrospective, non-randomized study.

Methods and results Both the groups were similar with respect to baseline characteristics. The success rate was 95% in group 1 and 93% in group 2. There was a significant increase in mitral valve area estimated by Gorlin's equation (Group 1: from 0.8 ± 0.5 to 2.1 ± 0.8 cm²; Group 2: from 0.8 ± 0.3 to 1.9 ± 0.8 cm², both P<0.001) and by Doppler echocardiography using the pressure half-time method (Group 1: from 0.9 ± 0.4 to 2.2 ± 0.6 cm²; Group 2: from 0.9 ± 0.3 to 2.0 ± 0.7 cm², both P<0.001). However, the calculated immediate post-valvotomy mitral valve area was larger with the Inoue technique (2.1 ± 0.8 vs 1.9 ± 0.8 cm²; P<0.02). Results were considered optimal when the mitral valve area increased to ≥1.5 cm², the percentage increase was ≥50, and mitral regurgitation was ≤2/4. Out of the total successful procedures, optimal results were obtained in 95% patients in Group 1 and 94% in Group 2. Incidence of significant mitral regurgitation (≥grade 3/4) was similar in two groups (Group 1: 4% vs Group 2: 3%, P=ns). A significant left to right atrial shunt (Qp/Qs≥1:3:1) in 2-5% and tamponade in 2% of cases occurred exclusively with the Inoue technique, while conduction disturbances, such as transient (<24 h) left bundle branch block (28%) and complete heart block (2%) were noted with the retrograde technique (Group 2). Local complications were significantly higher in Group 2 (3% vs 0.5%, P<0.01). The procedure time with the Inoue technique was shorter than with the retrograde (Group 1: 15 ± 8, range 10 to 35 min; Group 2: 22 ± 14, range 15 to 45 min, P=0.05). Echocardiographic follow-up at 1 year showed no significant difference in mitral valve area between the two groups (Group 1 (n = 300): 1.8 ± 0.8 vs Group 2 (n = 60): 1.9 ± 0.9 cm²; P=0.3).

Conclusions Balloon mitral valvotomy using the Inoue balloon and the retrograde non-transseptal technique results in significant immediate haemodynamic and symptomatic improvement. The Inoue technique achieved a larger immediate post-valvotomy mitral valve area, but the difference was not apparent at 1 year follow-up. Incidence of significant mitral regurgitation was similar with both the techniques; however, local complications occurred more frequently with the retrograde technique. Both techniques may complement each other in technically difficult cases.

Key Words: Balloon mitral valvotomy, retrograde non-transseptal balloon mitral valvotomy, Inoue balloon.

Introduction

Balloon mitral valvotomy is an established non-surgical technique for treating patients with symptomatic rheumatic mitral stenosis. Since its introduction in 1984 by Inoue and colleagues, various strategies have been developed for performing this procedure. These include the antegrade approach using single and double balloons, the transseptal trans-arterial approach and the non-transseptal retrograde approach. Basically all the techniques, except the one advocated by Stefanadis et al., require transseptal puncture with its inherent complication of cardiac tamponade in 1–9% cases. Amongst the antegrade approaches, the Inoue balloon technique has gained considerable popularity over the years due to its ease of performance and a unique balloon configuration, minimizing the procedure time. The recently described retrograde non-transseptal technique, using a specially designed...
Table 1  Baseline characteristics of 1100 patients undergoing balloon mitral valvotomy: The Inoue balloon vs the retrograde non-transseptal balloon mitral valvotomy (RNBMV) technique

<table>
<thead>
<tr>
<th></th>
<th>Inoue balloon technique (n=1000)</th>
<th>Retrograde technique (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>24 ± 12</td>
<td>28 ± 8</td>
</tr>
<tr>
<td>Females</td>
<td>540 (54%)</td>
<td>42 (42%)</td>
</tr>
<tr>
<td>Body surface area (m²)</td>
<td>1-44 ± 0-6</td>
<td>1-48 ± 0-7</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>180 (18%)</td>
<td>15 (15%)</td>
</tr>
<tr>
<td>NYHA functional class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>100 (10%)</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>III</td>
<td>760 (76%)</td>
<td>83 (83%)</td>
</tr>
<tr>
<td>IV</td>
<td>140 (14%)</td>
<td>10 (10%)</td>
</tr>
<tr>
<td>Mitral valve area (Gorlin) (cm²)</td>
<td>0-8 ± 0-5</td>
<td>0-8 ± 0-3</td>
</tr>
</tbody>
</table>

NYHA = New York Heart Association
Comparisons of differences between treatment groups are all non-significant.

Material and methods

Patients

The first 1000 consecutive patients undergoing percutaneous transvenous mitral commissurotomy (PTMC) using the Inoue balloon (Group 1) were compared with the first 100 patients who underwent retrograde non-transseptal balloon mitral valvotomy (RNBMV) using polyethylene balloons (Group 2) during simultaneous time periods. The baseline characteristics of the patients were similar (Table 1). All patients were symptomatic with critical non-calcific mitral stenosis, without significant mitral regurgitation on a left ventricular angiogram.

Echocardiographic examination was done in all cases to exclude left atrial/appendage clot, to determine mitral valve area (Doppler pressure half-time method) and concomitant valvular lesions, and to assess mitral valve morphology and subvalvular structures. None of the patients was excluded on the basis of valve thickening, mobility or subvalvular fibrosis.

Procedure

After obtaining informed consent, baseline right and left heart catheterization was performed. Cardiac output was determined by the Fick principle and mitral valve area was calculated by Gorlin's formula. Percutaneous transvenous mitral commissurotomy (PTMC) using the Inoue balloon was performed by the antegrade transseptal technique. The slenderized Inoue balloon was inserted percutaneously without a sheath. The optimal size of the balloon was decided according to the height of the patient, i.e. [Height(cm)/10] + 10 = maximum permissible balloon size (mm).

Retrograde non-transseptal balloon mitral valvotomy (RNBMV) using polyethylene bifoil balloons was performed by the transarterial route since 1992, and give below a non-randomized comparison of the immediate results of the two techniques.

Results

Haemodynamics

In both groups, balloon mitral valvotomy resulted in a significant increase in mitral valve area (both Gorlin and Doppler determined) and cardiac output, with a
significant decrease in transmitral gradients, pulmonary artery pressures and pulmonary capillary wedge pressures ($P<0.001$, Table 2). Comparison of immediate post-valvotomy haemodynamics revealed a significantly larger mitral valve area achieved using the Inoue technique as compared to the retrograde technique (21 ± 0.8 vs 1.9 ± 0.8; $P<0.02$ by Gorlin's equation and 2.2 ± 0.6 vs 2.0 ± 0.7; $P<0.006$ by Doppler echocardiography).

**Procedure outcome: success rate**

The technical success rate was 95% (951 of 1000) in Group 1 and 93% (93 of 100) in Group 2. Unsuccessful procedures in the Inoue series (Group 1) were due to inability to cross the mitral valve in four patients, transseptal puncture failure in five patients and significant mitral regurgitation (> grade 3/4) in 40 patients. In the RNBMV (Group 2) series, failures were due to inability to enter the left atrium in two cases and severe mitral regurgitation (> grade 3/4) in five cases.

**Cross over to other technique**

The Inoue technique was started earlier than the retrograde technique at our centre (February 1992 and December 1992, respectively). Out of a total 1000 Inoue procedures, 820 were performed during the time period when both techniques were available. In Group 1, four failed procedures out of 820 (0.5%) were performed with the retrograde technique, while in Group 2, two out of 100 (2%) were relieved with the Inoue technique ($P<0.01$).

**Optimal results**

Of the technically successful procedures, optimal functional results were obtained in 95% (904 of 951) cases in Group 1 and 94% (88 of 93) cases in Group 2.
Table 3 Complications after balloon mitral valvotomy in two groups

<table>
<thead>
<tr>
<th>Complications</th>
<th>Inoue (group 1)</th>
<th>Retrograde (group 2)</th>
<th>*p. value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral regurgitation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase by 1 grade</td>
<td>140 (14%)</td>
<td>16 (16%)</td>
<td>ns</td>
</tr>
<tr>
<td>Severe (≥ grade 3/4)</td>
<td>40 (4%)</td>
<td>5 (5%)</td>
<td>ns</td>
</tr>
<tr>
<td>Tamponade</td>
<td>20 (2%)</td>
<td>0 (0%)</td>
<td>ns</td>
</tr>
<tr>
<td>Atrial shunt (Qp/Qs ≥ 1.5/1)</td>
<td>25 (2.5%)</td>
<td>0 (0%)</td>
<td>ns</td>
</tr>
<tr>
<td>Local complications:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematoma</td>
<td>5 (0-5%)</td>
<td>3 (3%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
<td>&lt;0.002</td>
</tr>
<tr>
<td>Loss of femoral pulse</td>
<td>1 (0-1%)</td>
<td>2 (2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thromboembolism</td>
<td>1 (0-1%)</td>
<td>0 (0%)</td>
<td>ns</td>
</tr>
<tr>
<td>Conduction disturbances:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transient LBBB</td>
<td>0 (0%)</td>
<td>28 (28%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Transient Complete</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Block</td>
<td>0 (0%)</td>
<td>2 (2%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

LBBB = Left bundle branch block.
*Chi-square test, two sided.

Follow-up

Clinical follow-up at the end of 11 ± 6 months (range 9–18) was available in 760 patients (690 in Group 1 and 70 in Group 2). Of these, 96% (661 of 690) in Group 1 and 97% (68 of 70) in Group 2 were in New York Heart Association functional Class I and II.

Mitrval valve area

One year follow-up of the mitral valve area was available in 300 Inoue technique cases and 60 retrograde technique cases, as assessed by Doppler echocardiography. Mitrval valve area before, after and at 1 year following valvotomy was 0.9 ± 0.4, 2.2 ± 0.6 and 1.8 ± 0.8 cm² in the Inoue group and 0.9 ± 0.3, 2.0 ± 0.7 and 1.9 ± 0.9 cm² (P = 0.3) in the retrograde group, respectively (Fig. 1).

Discussion

The Inoue single rubber nylon balloon[1–3,4] and polyethylene double balloon techniques[5–8] are the most widely used methods of balloon mitral valvotomy. Both techniques have been shown to produce comparable immediate and long-term follow-up results[22–28]. However, a transseptal puncture with its inherent complications[16,17] is required in both techniques. In an effort to avoid transseptal puncture/dilatation, Stefanidis et al.[14] designed a steerable catheter that easily and predictably enters the left atrium retrogradely via the left ventricle. Recently reported immediate and follow-up results of retrograde nontransseptal balloon mitral valvuloplasty are encouraging[29]. The present nonrandomized comparative study of Inoue and retrograde non-transseptal balloon mitral valvotomy techniques, the first one to our knowledge, shows favourable immediate haemodynamic results and symptomatic improvement with the use of either technique.

Haemodynamic results

Immediate haemodynamic improvement was observed with both techniques (Table 2); however, the calculated mitral valve area was found to be larger with the Inoue technique. The apparent difference in mitral valve area may simply be due to the effects of a left to right atrial shunt observed with transseptal techniques[30–33] overestimating the calculated mitral valve area. Previous studies comparing the results of transseptal single vs double balloon techniques have shown a larger calculated mitral valve area following the double balloon technique[22–23]. However, in the present study, although the retrograde non-transseptal technique
utilized bifoil balloons, the calculated immediate post-valvotomy mitral valve area was smaller with double balloons than the Inoue single-balloon technique. The results of such comparative studies should be interpreted carefully, taking into account the various confounding variables related to selection bias involved in a non-randomized study as well as technique related factors. Further, the clinical significance of this small magnitude of difference in immediate post-valvotomy mitral valve area with various techniques is uncertain, because on follow-up the mitral valve area has been found to be similar in two groups\textsuperscript{23}, as observed in the present study.

**Complications**

The possibility of causing significant mitral regurgitation with the retrograde technique due to entry into a false channel, other than the true mitral valve orifice, was not observed in our data as the incidence of significant mitral regurgitation was similar with both techniques (Group 1: 4\% vs Group 2: 5\%, \(P=\text{ns}\)). This may be because cardiac valves and subvalvular apparatus are generally deformed by the rapidly progressive course of the rheumatic process afflicting younger patients in India\textsuperscript{34}, and the subvalvular pathology may in fact help in forming a retrograde channel by the papillary muscle and chordae tendinae in the beating heart, prohibiting entry into the secondary orifice of the mitral valve. This hypothesis is also supported by the routine use of a metal dilator retrogradely during closed surgical mitral valvotomy with a low risk of causing significant mitral regurgitation\textsuperscript{35}.

The local arterial complications were more frequent with retrograde approach than with Inoue technique (3\% vs 0-5\%, \(P<0.01\)) in the present study. However, we feel that the younger patients (age 28 ± 8 years) in our series were less likely to have serious vascular problems than older patients with atherosclerotic arteries in most western studies.

**Technical aspects**

Balloon mitral valvotomy demands a high level of ability and experience on the part of the operator in order to ensure success and safety with the procedure\textsuperscript{37}. The influence of the learning curve phenomenon on the overall results was applicable to both groups to a similar extent, as all consecutive cases performed in our institution with the two techniques have been included in this study. The success rate was comparable in the groups (95\% vs 93\%). The overall results and complication rates were comparable with two techniques, although the duration of the procedure was significantly lower with the Inoue technique in our experience. With growing experience and continuous refinement of the retrograde technique we were able to minimize the time taken in performing the technique in last 50 cases, as compared to our initial experience\textsuperscript{15}. The recently reported use of the modified Inoue balloon catheter used retrogradely by Stefanadis et al.\textsuperscript{36} may result in further minimizing the total duration of the retrograde non-transseptal technique.

**Cost factor**

In a developing country like India, where rheumatic heart disease is prevalent on a very large scale, the cost of any interventional procedure becomes a determinant in its widespread acceptability. The duration of hospital stay was the same (24 h) with both techniques. The cost of the hardware consumed in performing the retrograde non-transseptal technique is one-third that of the Inoue technique, given the fact that the consumables could only be used once. Thus, despite the popularity of the Inoue balloon, its exorbitant cost is the biggest deterrent against its widespread application in developing nations, where, paradoxically, it is needed the most. Therefore, the retrograde technique may be accepted as the procedure of choice in terms of its cost analysis. However, re-use is a reality in developing countries, including in our centre, and therefore exact cost comparisons become difficult.

**Conclusions**

We conclude that both the Inoue and the retrograde non-transseptal balloon mitral valvotomy techniques result in significant clinical and haemodynamic improvement. The Inoue technique achieved a larger calculated immediate post-valvotomy mitral valve area but the difference was not apparent at 1 year follow-up. Both techniques have a similar incidence of significant mitral regurgitation. Cardiac tamponade and left ventricular perforation, an ever present threat with transseptal techniques, is avoided with the retrograde technique; however, local arterial complications are more frequently noted with the transarterial technique. Knowledge of an alternative approach does have the advantage of "bailing out" in case of a failed procedure and vice versa. Further, long-term randomized controlled trials are required to ascertain the exact status of the retrograde non-transseptal technique vis à vis the Inoue technique.

We are grateful to Dr C. Stefanadis, MD, Department of Cardiology, Medical School of University of Athens, Athens, Greece, who has introduced the retrograde non-transseptal technique to us.

**References**


