Catheterization and Cardiovascular Diagnosis 38:9–14 (1996)

Advantage of Inoue Balloon Catheter in Mitral Balloon Valvotomy: Experience With 220 Consecutive Patients

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Percutaneous mitral balloon valvotomy (PMV) using the Inoue balloon catheter was attempted in 220 consecutive patients with severe symptomatic mitral stenosis. Their age range was 10–63 mean 30 ± 10 years; 161 patients were females and 59 were males; 29 patients were in atrial fibrillation. Eleven patients were pregnant; 14 patients underwent previous surgical commissurotomy. The procedure was technically successfully performed in 215 (97.7%) patients. The mean fluoroscopy time was 15.5 ± 6.4 min and mean procedure time was 109 ± 79 min. Optimal results (group I) was achieved in 207 patients who have mitral score of 7 ± 1. PMV resulted in decrease in left atrial pressure from 23 ± 5 to 14 ± 4 mm Hg ($P < 0.001$), the mean mitral valve gradient (MVG) decreased from 15 ± 4 to 6 ± 3 mm Hg ($P < 0.001$). The mitral valve area (MVA) by catheter increased from 0.7 ± 0.2 to 1.7 ± 0.5 cm^2 ($P < 0.001$) and MVA as determined by echocardiography (2DE) increased from 0.8 ± 0.1 to 1.9 ± 0.3 cm^2 ($P < 0.001$). The results were suboptimal in eight patients who have a mitral score of 10 ± 1 (group II) MVA by catheter increased from 0.7 ± 0.2 to 1 ± 0.1 cm^2 and Doppler MVA increased from 0.8 ± 0.1 to 1.3 ± 0.1 cm^2. There were no deaths or thromboembolism. Two patients developed cardiac tamponade; mild mitral regurgitation (MR) developed in 24 patients (11%) and increased by one grade in another 22 patients (10%). Severe MR was encountered in three patients (1.4%). A small ASD (QP/QS ≤1.3) was detected by oximetry in 5% of patients and by color-flow mapping in 26% of patients. One hundred fifty-eight patients from group I were followed up, for a mean of 32 ± 12 months; MVA remained at 1.7 ± 0.4 cm^2. Seven patients developed mitral restenosis in group I, and 5 out of 8 patients developed restenosis in group II. We conclude that the hemodynamic results are good and comparable with those reported with double balloon technique. However, the Inoue balloon has several advantages over the double balloon technique: (1) low incidence of mitral regurgitation and ASDs; (2) shorter procedure and fluoroscopy time; and (3) low complication rates and the valve anatomy affects the immediate and late outcome of mitral balloon valvotomy.

Key words: balloon valvotomy, mitral valve, Inoue balloon

INTRODUCTION

Percutaneous balloon mitral balloon valvotomy (PMV) has emerged as an alternative to surgical mitral commissurotomy for the treatment of symptomatic patient with mitral stenosis. After its introduction in 1984 by Inoue et al. [1], the technique evolved rapidly. Several investigators reported improved hemodynamic states and low procedure-related complications [2–11]. We present our experience with 220 consecutive young patients undergoing mitral balloon valvotomy, using the Inoue balloon catheter and pointing out the advantages of this technique compared to the reported double balloon technique.

METHODS

Study Patients

From December 1989 to May 1994, PMV was attempted in 220 consecutive patients with symptomatic mitral stenosis using the Inoue balloon technique at King Faisal Specialist Hospital and Research Centre. The study consisted of 187 adult patients with a mean age of 30 years (range 19–63) and 33 children with a mean age of 15.9 (range 10–18) years. One hundred sixty-one patients were females, and 59 patients were males.

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Received August 1, 1994; revision accepted August 21, 1995.

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This work was presented in part at the British Cardiac Society Meeting, May 1993, London, England.

Twenty-nine patients were in atrial fibrillation. Twelve patients were in New York Heart Association (NYHA) functional class IV, 180 in class III, and 23 in class II. Fourteen patients had undergone previous surgical commissurotomy. Eleven patients were pregnant, and two patients had previously undergone aortic valve replacement, using mechanical prosthesis. Seven patients had previous cerebral embolism with mild to moderate residual hemiplegia. The patients were prospectively selected for mitral balloon valvotomy according to the following criteria: (1) severe symptomatic mitral valve stenosis with mitral valve area ≤1.1 cm; (2) mitral valve regurgitation ≤1 + by Doppler; (3) absence of left atrial clot on transthoracic two-dimensional echocardiography; (4) echocardiographic mitral valve score (Boston) of ≤8 [12]; and (5) absence of calcification in the mitral valve commissures on echocardiography. Eight patients were exceptions to these criteria, with echocardiographic score [10±1].

Balloon Valvotomy Procedures

We followed the technique described by Inoue et al. [1]. The balloon catheter size was selected according to the patient's height: 24-mm diameter for patients with a height of ≤147 cm, 26 mm for patients with a height of >147 cm, 28-mm diameter for those patients who measured 160–179 cm, and 30 mm for patients ≥180 cm. Right- and left-sided cardiac catheterization was done using the standard technique. Cardiac output was estimated using the thermodilution technique. The computer (Micor-Siemens, Siemens-Elema AB, Solna, Sweden) calculated the mean mitral valve gradient (MVG) and mitral valve area (MVA). Transseptal catheterization was accomplished by the Brockenbrough technique. After successful entry into the left atrium, 150 U/kg of heparin was administered. Left atrial and left ventricular pressures were recorded simultaneously using the Inoue catheter in the left atrium and a pigtail catheter in the left ventricle. The MVG and MVA were calculated both before and after each dilation. After crossing the mitral valve orifice the balloon catheter was inflated slightly (Fig. 1A) and pulled back to anchor it in the mitral orifice, followed by inflation of the balloon until the waist disappeared (Fig. 1B,C). We used stepwise dilation techniques, as recommended by Inoue et al. [1], in which the diameter at initial dilation was 4 mm less than the maximum diameter of the balloon. The diameter at subsequent dilations increased by 1–2 mm at a time. The decision to make a further dilation depended on: (1) degree of commissural splitting as determined by two-dimensional echocardiography, (2) increased MVA, and (3) resultant mitral regurgitation (MR) assessed by color Doppler echocardiography. All hemodynamic measurements were repeated after valvotomy; left ventriculography was repeated to assess the degree of MR, graded by the Seller's classification from 0 to 4+ [13]. Oximetry of the right side of the heart was performed for the detection of iatrogenic atrial septal defect (ASD) in 100 patients; also, the ASD was evaluated using color Doppler. Protamine was given at the end of the procedure, to reverse the effect of the heparin. Two-dimensional and Doppler echocardiography were performed before balloon valvotomy, after each dilation, and at the end of the procedure, simultaneous with the hemodynamic measurements. The MVA was calculated using two-dimensional echocardiography from short-axis parasternal view, as described by Henry et al. [14]. The Doppler MVA was calculated using the pressure half-time method as described by Hatle and Angelson [15]. In 11 pregnant patients, the procedure was done with abdominal shielding and without angiography. Results were considered optimal when the MVA increased to ≥1.5 cm^2 and the mitral regurgitation was ≤2/4. One hundred sixty-three patients were followed up for 18–60 (mean 32±16) months by clinical examination and repeat echocardiography. Restenosis was defined as loss of 50% of initial gain in MVA or valve area <1.0 cm^2.

Statistical Analysis

All results were summarized as mean ±SD. Hemodynamic data before and after valvotomy were compared using a paired *t*-test. The relationship between various variables were studied using correlation analysis. A *P*-value <0.05 was considered significant. A JMP computer package from the SAS Institute was used for statistical analysis.

RESULTS

Immediate Results

PMV was successful in 215 patients (97.7%); the procedure could not be completed in five patients (2.3%) because of an inability to perform septal puncture in three patients and failure to cross the mitral valve in two patients. The mean fluoroscopy time was 15.5 ± 6.4 min, and the mean procedure time was 109 ± 79 min (Table I).

Optimal results defined as MVA ≥1.5 cm^2 with mitral regurgitation ≤2+ (group I) were achieved in 207 patients (96%) with a mitral score of 7 ± 1. The only predictor of the final result of PMV was valve anatomy. A significant inverse relation was found between the echocardiographic score and postprocedure MVA ($r = -0.3$; $P<0.001$) ($y = 2.41 - 0.06 \times$ score).

In group I, PMV resulted in decreased in left atrial pressure from 23 ± 6 to 14 ± 4 mm Hg ($P<0.001$). The mitral valve mean gradient decreased from 15 ± 4 to 6 ± 3 mm Hg ($P<0.001$) MVA (Gorlin) increased from 0.7

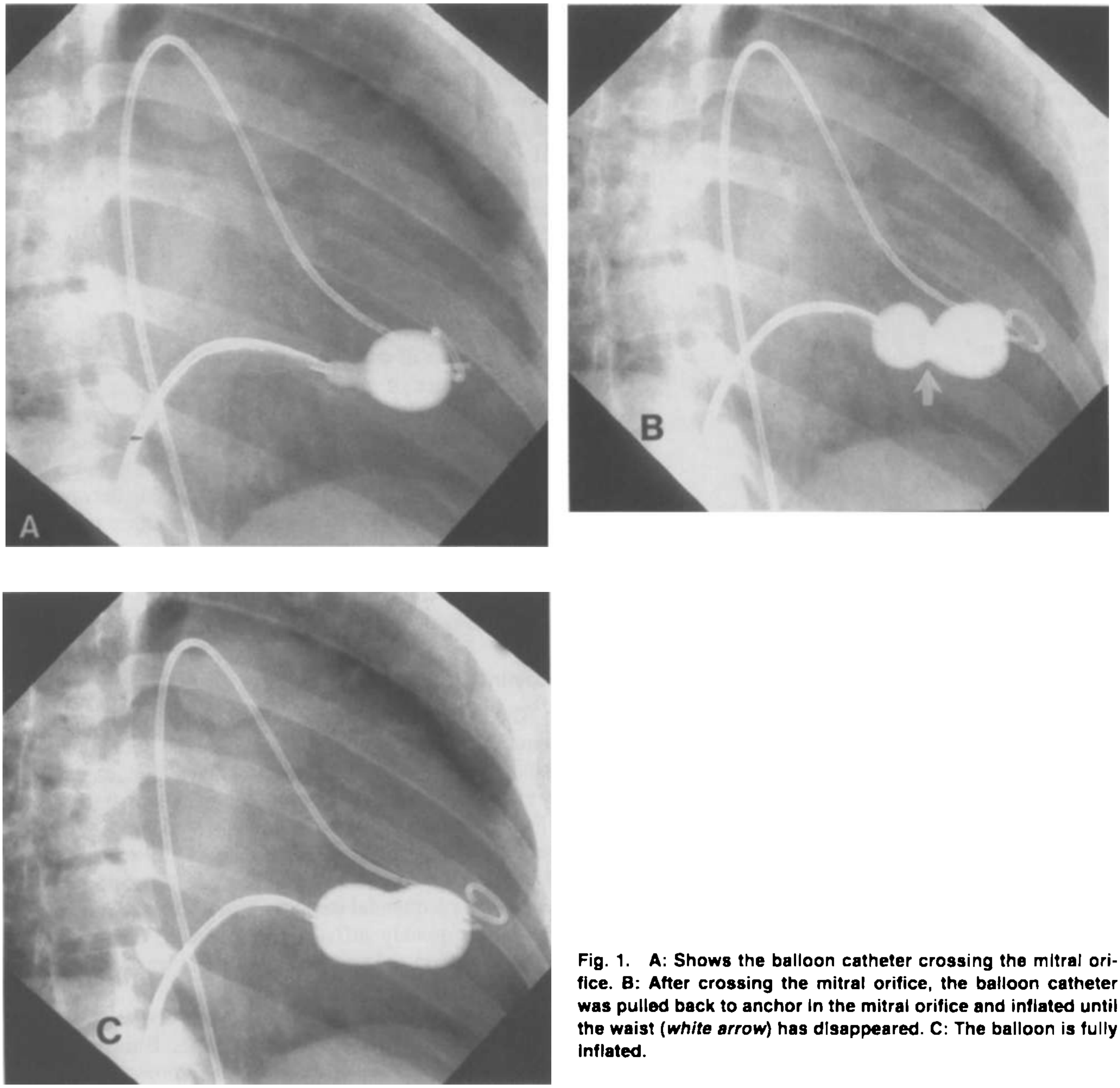

Fig. 1. A: Shows the balloon catheter crossing the mitral orifice. B: After crossing the mitral orifice, the balloon catheter was pulled back to anchor in the mitral orifice and inflated until the waist (*white arrow*) has disappeared. C: The balloon is fully inflated.

$\pm$ 0.2 to 1.7 $\pm$ 0.5 cm^2 ($P<0.001$). The Doppler MVA increased from 0.8 $\pm$ 0.2 to 1.9 $\pm$ 0.3 cm^2 ($P<0.001$), and the Doppler mean gradient decreased from 13 $\pm$ 4 to 5 $\pm$ 2 mm Hg ($P<0.001$). The cardiac index increased from 2.3 $\pm$ 0.6 to 2.9 $\pm$ 0.6 L/min/m^2 ($P<0.001$) pulmonary artery systolic pressure decreased from 45 $\pm$ 14 to 37 $\pm$ 12 mm Hg ($P<0.001$) and pulmonary vascular resistance decreased insignificantly from 231 $\pm$ 194 to 231 $\pm$ 188 dyn/sec/cm^{-5}.

In group II, suboptimal results defined as MVA <1.5 cm^2 obtained in eight patients with a mitral score of 10 $\pm$ 1 (suboptimal results), the Doppler MVA increased from 0.8 $\pm$ 0.1 cm^2 to 1.3 $\pm$ 0.1 cm^2 ($P<0.001$), the catheter valve area increased from 0.7 $\pm$ 0.2 to 1 $\pm$ 0.3 cm^2, and the mean gradient decreased from 14 $\pm$ 4 to 7 $\pm$ 4 mm Hg ($P<0.001$).

Complications

No deaths or systemic emboli were encountered in our patients.

Cardiac Tamponade

Two patients developed cardiac tamponade (0.9%) drained in the catheter laboratory without untoward ef-

TABLE I.

	Group I (207 patients)	Group II (8 patients)
Mitral score	7 ± 1	10 ± 1
Mean age (years)	30 ± 10	30 ± 11
Mean LA (mm Hg)		
Pre-PMV	23 ± 5	25 ± 8
Post-PMV	14 ± 4	19 ± 4
Mean gradient (mm Hg)		
Pre-PMV	15 ± 4	14 ± 4
Post-PMV	6 ± 3	7 ± 4
MVA (Gorlin) cm^2		
Pre-PMV	0.7 ± 0.2	0.7 ± 0.2
Post-PMV	1.7 ± 0.5	1.0 ± 0.3
MVA (Doppler) cm^2		
Pre-PMV	0.8 ± 0.2	0.8 ± 0.1
Post-PMV	1.9 ± 0.3	1.3 ± 0.1
Cardiac index (L/min/m^2)		
Pre-PMV	2.5 ± 0.5	2 ± 0.6
Post-PMV	2.9 ± 0.6	2.5 ± 0.7
PA systolic pressure (mmHg)		
Pre-PMV	45 ± 14	40 ± 10
Post-PMV	37 ± 12	39 ± 11

fect. One patient, a 10-year-old, underwent open commissurotomy, and the second patient underwent balloon valvotomy two months later.

Mitral Regurgitation

MR occurred in 52 patients (24%). Mild MR (grade 1/4) occurred in 24 patients (11%) and increased by one grade (from 1+ to 2+) in another 22 patients (10%). Moderate MR +2 occurred in three patients (1.4%), severe MR occurred in three patients (1.4%). Mild MR did not increase after PMV in 65 patients, and 98 patients had no MR before or after PMV. Two of the patients who developed severe MR underwent mitral valve replacement within 24 hr of the procedure. The third patient was treated medically. Two patients with severe MR had splitting of the anterior leaflet in the middle. The third patient had tear of the lateral commissure. None of the morphologic or technical characteristics studied predicted the development of severe MR after balloon dilation.

Atrial Septal Defect

Fifty-six patients (26%) showed evidence of a small left-to-right shunt at the atrial level by color-flow mapping. Oximetry, however, showed small ASD with QP/QS ≤1.3 in only 5% of patients. Four patients out of 158 had small ASD by color Doppler at a mean follow-up 32 ± 12 months.

Follow-up

One hundred fifty-eight patients from group I were followed up for a mean of 32 ± 12 months. The Doppler MVA was 1.7 ± 0.4 cm^2, and the mean gradient by Doppler was 5 ± 3 mm Hg. Cardiac symptoms significantly improved post-PMV; before balloon dilation, it was class IV in eight patients, class III in 135, and class II in 15 patients; at follow-up it was class I in 145, class II 12, and class III in one patient. Seven patients developed restenosis (4.4%) in group I, however, five out of eight patients developed restenosis (62.5%) in group II.

DISCUSSION

Mitral stenosis in Saudi Arabia affects the young population, most of whom have suitable valve anatomy with a mitral score of ≤8. The echocardiographic score has been the most significant predictor of hemodynamic results in many studies [7,8,12,16,17]. In our study, we found patients with a mitral score of ≤8 to have optimal results, and we noted an inverse relationship between the postprocedure, MVA, and mitral score. Other investigators [18] found no correlation between the echocardiographic score and the immediate outcome; however, they found final MVA of ≥1.5 cm^2 predicted by the absence of subvalvular fusion.

Advantages of Mitral Balloon Technique

The hemodynamic results of the Inoue balloon technique are similar to those reported by the double balloon technique [19–22]. The Inoue balloon technique exhibits several advantages over the double balloon technique: (1) it requires one single transseptal puncture, and the balloon is easily placed across the mitral orifice; (2) it does not slip from the valve during inflation; and (3) it also allows sequential stepwise mitral valve dilation. The balloon is quickly inflated and deflated; consequently, no hypotension or loss of consciousness was encountered in our patients.

Another advantage of the Inoue balloon technique is short procedure and fluoroscopy time. Bassand et al. [21] reported shorter procedure and fluoroscopy time in the Inoue balloon series compared to the double balloon technique at 104 ± 13 versus 123 ± 23 min and 16 ± 6 versus 24 ± 12 min, respectively. Abdullah et al. [22] reported fluoroscopy time of 40 ± 12 min for the double balloon technique compared to 21 ± 10 min for the Inoue technique. Our fluoroscopy time was 15.5 ± 6.4 min, and the procedure time was 109 ± 79 min. Another advantage of the Inoue balloon catheter is its low complication rate compared to the reported double balloon technique. Systemic embolism has been reported in 2–4% of patients, using the double balloon technique [7]. No systemic embolism was encountered in this study or in others using the Inoue balloon technique [6,10,21]. No deaths were encountered in this study.

Mitral Regurgitation

MR has been reported to occur in 20–51% of patients who have undergone double balloon valvotomy. Roth et al. [23] reported a 45% incidence of MR (12.7% severe). Al-Zaibag et al. [24] reported a 37% incidence; Pin Pan et al. [25] reported a 45% incidence (3.3% severe). A low incidence of MR has been reported by investigators using the Inoue balloon technique. Chen et al. [19] reported a 15.7% incidence. Severe MR was reported by Inoue et al. [26] in only 10 of 713 (1.4%) patients. Bahl et al. [10] reported a 10% incidence of MR and 2% severe MR. Hermann et al. [18] reported 2.4% MR using the Inoue balloon. In this study, MR occurred in 24% of our cases. Mild MR occurred in 11% and increased by one grade in 10%; severe MR occurred in three patients (1.4%). Two required mitral valve replacement. Other operators reported a higher incidence of MR with the Inoue (44%) compared to the double balloon technique (25%) [11]. Bassand et al. [21] reported an equal incidence of severe MR with both techniques. We noted that none of the morphologic or technical characteristics studied predicted the development of severe MR similar to other investigators [27].

Atrial Septal Defect

The incidence of ASD after mitral balloon valvotomy using the double balloon technique varies from 9% to 53% [28–30]; most close after 3–12 months [28]. Arora et al. [11] reported (92%) incidence of ASD using transesophageal echocardiography and persisted in 4% at 6 months.

A low incidence of ASD has been reported by investigators using the Inoue balloon technique. Chen et al. [19] reported 15.2%, and Ishikura et al. [29] reported 15%, respectively. Bassand et al. [21] however, reported an equal incidence of ASD by both technique. ASD was detected in 26% of our patients using color-flow mapping, which is very sensitive in detecting small ASDs. Oximetry, however, detected ASD in only 5% of our patients. The low incidence of ASD and left-to-right-shunt following Inoue balloon valvotomy is because of the fact that the catheter has a low profile (4.5 mm) and can be stiffened by inserting a metal tube into the balloon catheter before crossing the interatrial septum and before withdrawing the catheter from the left atrium after dilation.

Restenosis

Restenosis appears to be related to the baseline characteristic of the mitral valve, Palacios et al. [31] showed that patients with an echocardiographic score of ≤8 had no evidence of restenosis at cardiac catheterization 9 months after balloon dilation, whereas patients with scores of >8 had a restenosis rate of 70%. Chen et al. [32] reported 6.8% restenosis at a mean of 5 ± 1 year follow-up. Arora et al. [11] reported 1.7% restenosis at a mean of 37 ± 8 months. Thomas et al. [33] reported 21% restenosis at 1 year.

In our study, 7 out of 158 patients (4.4%) with a mitral score of ≤8 developed restenosis and 5 out of 8 patients (62.5%) with mitral score >8 developed restenosis at a mean follow-up of 32 months. These findings are in agreement with other investigators [14,32,33] that the principal factor associated with restenosis is a high echo score.

CONCLUSIONS

Because the Inoue balloon catheter has a large diameter (20–30 mm) with low profile (4.5 mm), the hemodynamic results are good and comparable to those reported with the double balloon technique. It has several advantages over the double balloon technique: (1) low incidence of mitral regurgitation and ASDs; (2) shorter procedure and fluoroscopy time; and (3) low complication rates. The valve anatomy affects the immediate and late outcome of mitral balloon valvotomy.

ACKNOWLEDGMENTS

This work was supported by a grant from King Abdulaziz. We are grateful to Marites B. Mendoza for secretarial assistance.

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