Title

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Factors influencing immediate results, complications, and short-term follow-up status after Inoue balloon mitral valvotomy: A North American multicenter study

Clinical trials with the Inoue mitral valvotomy balloon have recently begun in the United States. We assessed the effects of 17 demographic, echocardiographic, procedural, and hemodynamic variables on the immediate results, complications, and short-term follow-up of 200 patients in 15 centers undergoing valvotomy with this device. The study population had a mean age ± SD of 53 ± 15 years, and the total echocardiographic score was 7.2 ± 2.4. Valvotomy was technically successful in 96.5% of procedures and increased the mean mitral valve area from 1.0 ± 0.3 to 1.8 ± 0.7 cm^2 ($p < 0.001$); 72% had an increase in valve area ≥50%, and 67% had a final area ≥1.5 cm^2. Major procedural complications included cardiac tamponade during transseptal puncture (1.0%), systemic embolism (1.5%), and severe mitral regurgitation (2.4%); there were no procedural deaths and one hospital death. Multivariate analysis identified the absence of prior surgical commissurotomy and younger age as significant predictors of the gain in mitral valve area, but the correlation coefficients were low. Although the absence of subvalvular disease on echocardiograms was a predictor of a final valve area ≥1.5 cm^2, the total echocardiographic score did not correlate well with the immediate outcome ($r = 0.01$, p = NS). No variable was identified as predictive of restenosis, which occurred according to echocardiographic criteria in 14 of 66 (21%) patients evaluated 6 months after valvotomy. Good hemodynamic results with valvotomy were achieved in the majority of patients with low complication rates by many investigators with the use of the Inoue balloon device. In contrast to findings in previous studies that used other techniques, the immediate results with the Inoue procedure may be less influenced by age and echocardiographic valve morphology. (Am Heart J 1992;124:160.)

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Previous studies in which polyethylene balloon devices were used have identified several factors that influence the immediate outcome of percutaneous balloon mitral valvotomy; these factors include age, balloon size, valve morphology assessed by echocardiography, fluoroscopic valvular calcium, left atrial enlargement, and atrial fibrillation.[1-6] In short-term follow-up, echocardiographic valve characteristics have been the most important determinants of restenosis.[3] Recently clinical trials with the Inoue balloon have begun in North America. Unique features of this latex and nylon device include an hourglass inflation profile that allows self-positioning and fixation, adjustable size, steerability, and the absence of the need for a left ventricular guide wire.[7] Reports from China and Japan have documented the safety and efficacy of this balloon in large studies.[8,9] The early North American multicenter experience has confirmed these observations and demonstrated that the immediate valvotomy results do not depend on age or echocardiographic score.[10] In this report we extend those observations by using multivariate analysis to assess the effects of 17 demographic, echocardiographic, procedural, and hemodynamic variables on the immediate results, complications, and short-term follow-up of Inoue balloon mitral valvotomy.

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Table I. Demographic, echocardiographic, procedural, and hemodynamic variables for the study population (N = 200)

Variable (units)	*Value (mean ± SD)*	*Range*
Age (yr)	52.9 ± 14.7	13-90
NYHA class	2.8 ± 0.7	1-4
Echocardiographic score	7.2 ± 2.4	4-15
Leaflet mobility	1.7 ± 0.7	1-4
Leaflet thickness	2.1 ± 0.8	1-4
Subvalvular thickening	1.8 ± 0.7	1-4
Valvular calcification	1.7 ± 0.8	1-4
Left atrial enlargement	3.0 ± 0.8	1-4
Transvalvular gradient (mm Hg)		
Before	14 ± 6	4-39
After	6 ± 3	1-14
Mitral valve area (cm2)		
Before	1.0 ± 0.3	0.4-1.7
After	1.8 ± 0.7	0.6-4.4
Mitral regurgitation (grade)		
Before	0.5 ± 0.6	0-3
After	0.9 ± 0.9	0-4
Prior surgical commissurotomy	13.5%	—
No. of inflations	2.8 ± 1.6	1-10
Maximum balloon size (mm)	27.4 ± 1.7	23-31

NYHA, New York Heart Association.

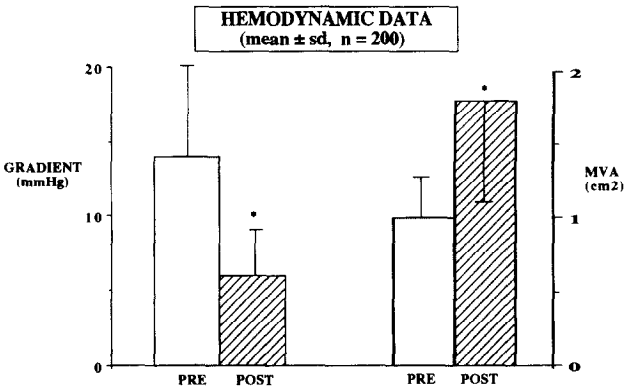

Fig. 1. Effects of Inoue balloon valvotomy in 200 patients before *(pre)* and after *(post)* valvotomy on mean transmitral gradient *(left)* and calculated mitral valve area *(MVA; right)* (*$p < 0.001$).

Table II. Major complications

Complications	*N/Total (%)**
Cardiac tamponade	2/200 (1.0)
Systemic embolism	4/200 (2.0)
Death (in-hospital)	1/200 (0.5)
Regurgitation (increase ≥3 grades)	4/169 (2.4)
Qp:Qs ratio ≥2.0†	4/144 (2.8)
Total‡	14/200 (7.0)

*Percentage calculated on the basis of total number of procedures in which the complication variable was reported in the registry.
†Assessed by oximetry after Inoue balloon was removed using (3SVC + IVC)/4 (superior vena caval flow plus inferior vena caval oxygen saturation) to calculate mixed venous saturation (Qp:Qs = pulmonary-to-systemic flow).
‡The patient who died also had a systemic embolism.

METHODS

Patients and procedures. The study population consisted of 200 patients who underwent valvotomy at 15 centers over a 2-year period from June 1989 to May 1991. Data were collected by a central registry on standardized report forms. The number of procedures performed at each center varied from 2 to 31 (mean = 13.4 ± 9.8). Hemodynamic data were calculated and echocardiographic scoring was performed by individual investigators. The initial hemodynamic data were measured with catheters in the left atrium and ventricle, and cardiac output was determined by the thermodilution (63%), Fick (33%), or dye-dilution (1%) technique. Echocardiographic scores were assessed by means of the Massachusetts General Hospital scoring system.[11]

Inoue balloon mitral valvotomy was performed with the antegrade transseptal technique.[7] Maximum balloon size was empirically chosen according to the patient's height: 26 mm for height ≤5 feet 4 inches, 28 mm for 5 feet 4 inches <height ≤5 feet 8 inches, and 30 mm for >5 feet 8 inches. The balloon was introduced into the left atrium in its stretched ("slenderized") configuration over a 0.025 inch stainless steel guide wire. The stretching tube was removed, and the balloon was maneuvered across the mitral valve with the aid of a steering stylet. In most centers the initial inflation was usually performed at 4 mm diameter less than the maximum size and subsequent inflations at 1 mm larger increments until adequate transmitral gradient reduction was achieved or mitral regurgitation developed. The final gradient and cardiac output were measured with the balloon catheter in the left atrium, thereby minimizing the contribution of any atrial septal defect blood flow to these measurements.

Definitions. The hemodynamic results of valvotomy were examined by assessing the change in mitral valve area three ways: the percentage increase calculated according to the Gorlin formula immediately before and after the procedure, the absolute increase in area (cm^2), and the proportion of patients with final valve areas ≥1.5 cm^2. Patients were considered to have had a major complication if cardiac tamponade, systemic embolism, or death occurred, if the grade of mitral regurgitation increased ≥3 angiographic grades (Sellers criteria), or if the pulmonary-to-systemic shunt ratio across the iatrogenic atrial septal defect was ≥2.0.

Procedures were considered successful if the mitral valve area increased by ≥50% or the final valve area was ≥1.5 cm^2 and there were no major complications. Follow-up data 6 months after the procedure were available in 66 successful procedures and included the Doppler-derived pressure half-time–calculated mitral valve area. For these patients, restenosis was defined as a follow-up valve area <1.5, and <50% improved compared to the catheterization-derived prevalvotomy valve area.

Table III. Comparison of patients with and without restenosis assessed by hemodynamic data (catheterization) at the time of the procedure or Doppler echocardiography at follow-up 6 months later

Variable (method)	*Restenosis*	*No restenosis*	p* *Value*
N	14 (21%)	52 (79%)	
MVA (pre catheterization) (cm^2)	1.2 ± 0.3	1.0 ± 0.3	NS
MVA (post catheterization) (cm^2)	2.1 ± 1.0	1.9 ± 0.6	NS
Initial gain in MVA (catheterization) (cm^2)	1.0 ± 0.8	0.9 ± 0.6	NS
MVA (follow-up echocardiography) (cm^2)	1.2 ± 0.2	1.7 ± 0.4	0.0001
Loss in MVA (echocardiography-catheterization) (cm^2)	−1.0 ± 0.9	−0.2 ± 0.6	0.0004
Pre-NYHA class	2.8 ± 0.8	2.7 ± 0.6	NS
Follow-up NYHA class	1.8 ± 0.7	1.4 ± 0.6	0.04

MVA, Mitral valve area; *NYHA*, New York Heart Association.
*Comparisons made by unpaired *t* test.

Table IV. Percentage change in mitral valve area after valvotomy in the presence or absence of several factors

		% Δ *MVA*		
Factor	*n*	*With factor*	*Without factor*	*p Value*
Age ≥65 yr	43	81	91	NS
Age ≥75 yr	12	67	90	NS
Echoscore ≥8	54	86	91	NS
Echoscore ≥12	8	89	104	NS
Prior SC	27	55	94	0.005

SC, Surgical commissurotomy; *Echoscore*, total echocardiographic score.

Statistical analyses. Data from all 200 procedures were entered into a spreadsheet (Microsoft Excel version 2.2, Redmond, Wash.) on a Macintosh IIcx computer (Apple Computer, Cupertino, Calif.). Means ± standard deviation for all variables were calculated with standard formulas (Statview Statistical Software, Brainpower, Inc., Calabassa, Calif.). The effects of 17 demographic, echocardiographic, procedural, and hemodynamic variables (shown in Table I) on the outcome of increases in mitral valve area, complications, restenosis, and overall success were assessed by means of SPSS statistical analysis software (Release 4 for the Macintosh, SPSS Inc., Chicago, Ill.). Univariate predictors of outcome were assessed by linear regression analysis. Multivariate analysis was performed with multiple stepwise linear regression for the continuous outcomes of percentage and absolute change in mitral valve area or forward stepwise logistic regression for the other dichotomous outcome events. In all analyses, variables were entered into the model and results considered significant if $p < 0.05$.

RESULTS

Study population (Table I and Fig. 1). The study population included 200 patients (84% female) with a mean age of 53 ± 15 years (range 13 to 90) and a baseline New York Heart Association classification of 2.8 ± 0.7 (Table I). Echocardiographic morphology was assessed in 90% of the patients, and the total score ranged from 4 to 15 (mean 7.2 ± 2.4); mean left atrial enlargement was 3.0 ± 0.8 on a scale of 1 (smallest) to 4 (largest). Twenty-seven patients (13.5%) had undergone prior open (n = 17) or closed (n = 10) surgical commissurotomy 16 ± 10 years earlier. Initial hemodynamic variables are shown in Fig. 1.

Results of valvotomy (Fig. 1 and Tables II and III). The immediate hemodynamic results of valvotomy are shown in Fig. 1. The mean transmitral gradient fell from 14 ± 6 to 6 ± 3 mm Hg ($p < 0.001$), and the mean mitral valve area increased from 1.0 ± 0.3 to 1.8 ± 0.7 cm^2 ($p < 0.001$). Seventy-two percent of patients had an increase in valve area of at least 50%, and the final valve area was ≥1.5 cm^2 in 67%. The procedure was successful in 74% of attempts; unsuccessful procedures were due to inadequate hemodynamic results (16%), failure to cross the valve with the balloon (3.5%), and major complications (7.0%). These complications are listed in Table II. All three perforations occurred during the transseptal procedure; two of these resulted in tamponade, which was successfully managed with pericardiocentesis. One 85-year-old patient with aortic and mitral stenosis, recent stroke, left ventricular dysfunction, and respiratory failure died of multisystem failure 7 days after an unsuccessful attempt at palliation with valvotomy. Mitral regurgitation was assessed by left ventriculography in 85% of procedures, and the mean grade increased from 0.5 ± 0.6 to 0.9 ± 0.9 ($p < 0.0001$); regurgitation increased by two grades in 6% and by three grades in 2.4% of assessed procedures. Full oxygen saturation data after valvotomy were available in 144 patients; the pulmonary-to-systemic shunt ratio was ≥1.5 in 9.7% of patients and ≥2.0 in 2.8% of these patients (mean = 2.2 ± 0.2, range 2.1 to 2.5).

Sixty-six patients with an initially successful procedure reached the 6-month follow-up evaluation. Hemodynamic evidence of restenosis was present in 14 of them (21%). Patients with restenosis had

smaller mitral valve areas at follow-up (1.2 ± 0.2 vs 1.7 ± 0.4 cm^2, $p < 0.0001$) and were more symptomatic despite similar initial increases in valve area (Table III).

Predictors of outcome (Fig. 2 and Table IV). Linear regression of all prevalvotomy and procedural variables (n = 14) with the percentage increase in mitral valve area identified four variables to be significant predictors of an increase in valve area: a small mitral valve area before valvotomy ($r = 0.32$, $p = 0.0001$), a high gradient before valvotomy ($r = 0.3$, $p = 0.0001$), no prior surgical commissurotomy ($r = 0.2$, $p = 0.005$), and younger age ($r = 0.16$, $p = 0.03$). All of these variables except the prevalvotomy mitral valve area were also significantly correlated with the absolute increase (cm^2) in valve area.

In multiple stepwise linear regression, significant predictors of the percentage change in valve area included a small prevalvotomy mitral valve area ($p = 0.0001$), a high prevalvotomy gradient ($p = 0.004$), a large maximum balloon size ($p = 0.003$), and a smaller number of inflations ($p = 0.01$). The absence of prior surgical commissurotomy ($p = 0.01$) and younger age ($p = 0.03$) were predictors of the absolute increase in valve area. The total echocardiographic score did not correlate well with the immediate outcome ($r = 0.01$, $p > 0.5$), as is illustrated graphically in Fig. 2. The effects of age, total echocardiographic score, and prior surgery on the increase in mitral valve area at specific cutoff values is shown in Table IV. In multiple logistic regression an increase in valve area ≥50% was predicted by a small prevalvotomy valve area ($p = 0.003$) and by the absence of prior surgical commissurotomy ($p = 0.05$). Similarly a final valve area ≥1.5 cm^2 was predicted by a large prevalvotomy valve area ($p = 0.0001$) and by the absence of subvalvular disease ($p = 0.008$).

The effects of all variables on complications and restenosis were also assessed by logistic regression. The only variable entered into the model for complications was a lower number of balloon inflations ($p = 0.04$). None of the variables were identified as significant predictors of restenosis. Finally two variables were entered into the model for a successful procedure: a high prevalvotomy gradient ($p = 0.005$) and a large prevalvotomy mitral valve area ($p = 0.04$).

DISCUSSION

This article reports the results of 200 percutaneous balloon valvotomy procedures performed by North American multicenter investigators with the Inoue balloon. The hemodynamic data, complications, and rates of early restenosis are similar to those reported by other investigators using different techniques.[12, 13]

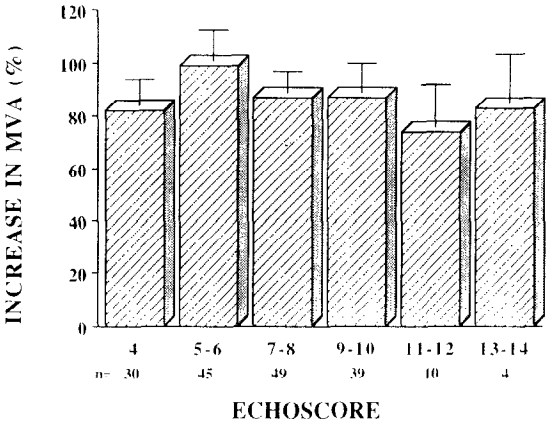

Fig. 2. Mean percentage increase in mitral valve area *(MVA)* for various ranges of total echocardiographic score. Number *(n)* of patients is shown below corresponding score interval.

Analysis of factors influencing the results has revealed a successful outcome in the majority of adult patients with acquired mitral stenosis with a few useful predictors of outcome.

Hemodynamic effects. The hemodynamic effects of Inoue balloon valvotomy (Fig. 1) are similar to the results reported for double-balloon techniques,[3, 4, 12-14] large single balloons,[15, 16] and the Inoue balloon in patient populations in the Far East.[8, 9] Previous studies of factors influencing the results of mitral valvotomy have identified several predictors of the immediate outcome. The total echocardiographic score has been the most significant predictor of a suboptimal hemodynamic result in many studies.[1, 2, 4, 8, 9] Other factors influencing results include older age,[3, 9] atrial fibrillation,[1, 9] fluoroscopic calcium,[3, 9] left atrial enlargement,[1, 9] and balloon size.[1, 2, 4]

In the present study, successful procedures most often resulted in patients with high prevalvotomy gradients and small valve areas. The total echocardiographic valvular score had only a weak correlation with immediate outcome and was not significant in multivariate analysis. This finding confirms those of an earlier report from our multicenter group[10] and another preliminary report.[17] Nobuyoshi et al.,[8] with the use of the Inoue balloon, demonstrated that a more abnormal echocardiographic morphology predicted less symptomatic improvement and a smaller postprocedure valve area, but their patients with the worst valve morphology also had smaller initial mitral valve areas making comparisons of subgroups difficult.[8] These results contradict the large single-operator experience of Hung et al.,[9] in which echocar-

Table V. Comparison of techniques for balloon valvotomy

Technique	*Advantages*	*Disadvantages*
Double balloon	Good hemodynamic results	Cumbersome Requires transseptal puncture Creates ASD
Inoue	Good hemodynamic results Faster and simpler than double balloon Lower rate of left ventricular perforation Graded sizing Rapid inflation-deflation cycle	Requires transseptal puncture Creates ASD
Single large polyethylene	Good hemodynamic results Simpler than double balloon	Requires transseptal puncture Creates larger ASD
Retrograde transarterial	May not require transseptal puncture Smaller ASD	Risk of arterial trauma ? Aortic valve trauma

ASD, Atrial septal defect.

diographic morphology was an important predictor of suboptimal outcome.

Factors that may have reduced the influence of the echocardiographic score on outcome in our study include the relatively small number of patients with high score characteristics and a greater variability in subjective scoring by multiple investigators. Abascal et al.[5] found valvular thickening to be the most important individual echocardiographic predictor of absolute change in valve area, whereas Reid et al.[2] found leaflet motion to be the most significant predictor of postprocedure valve area. In the present study subvalvular disease was the only individual echocardiographic variable that influenced outcome; its absence was a significant predictor of a final mitral valve area ≥ 1.5 cm^2.

Rediker et al.[18] demonstrated the feasibility of using balloon valvotomy in patients with previous surgical commissurotomy. In the present study prior surgical commissurotomy was a significant factor affecting hemodynamic outcome in multivariate analysis. However, the effect on the change in mitral valve area was small, reducing the mean percentage increase with valvotomy from 94% to 55%, and the result was a successful procedure in 78% of patients. Furthermore, prior commissurotomy was not associated with either increased complications or a higher rate of early restenosis. Thus it seems reasonable to treat these patients with balloon valvotomy before recommending repeat surgery.

Complications. The complication rate in this study was similar to those in previous multicenter studies. Specifically, cardiac perforation as a complication of the transseptal procedure occurred in 1.5% of procedures compared with a total perforation rate of 6.7% in the M-Heart study[12] and 6% in the National Heart, Lung, and Blood Institute registry.[19] There was one death (0.5%) compared with mortality rates ranging from 0.5% to 2.7% in other reports,[9, 12-14] and systemic embolism occurred in 2.0% compared with previously reported rates of 0% to 4%.[4, 8, 9, 12, 14] Lower complication rates, particularly for perforation, have been reported in large single-institution or single-operator studies with both the double balloon[13, 14] and the Inoue[8, 9] technique, which probably reflects the learning curve of increased operator experience.[13] Although perforation and tamponade can sometimes be managed conservatively or with pericardiocentesis alone, it may also require emergency surgery and be a fatal complication.[12, 20] The lack of a need for a left ventricular guide wire and the ability to inflate the distal portion of the Inoue balloon first and pull it back against the valve apparatus and away from the left ventricular apex before full inflation may explain the absence of left ventricular perforation and rupture in this and other Inoue series.[8, 9]

The only variable identified by logistic regression as predictive of complications was a lower number of balloon inflations. The effect of the number of inflations on the complication rate may reflect early discontinuation of the procedure because of the development of a complication or the earlier occurrence of a complication in susceptible patients. In this regard the maximum balloon size used was the same in patients with and without complications. Inoue balloon valvotomy is usually performed with a stepwise technique for repeated inflations with increasing balloon diameters. This approach maximizes the increase in valve area while avoiding the creation of severe mitral regurgitation.[15, 21] Mitral regurgitation increased by two or three grades in 8.4% of patients. Similar rates have been observed in other large studies in which a variety of techniques were used.[4, 11-13]

Finally, significant atrial septal defects occurred in approximately 10% of patients. Studies have shown that many of these shunts, particularly the smaller ones, close spontaneously.[6, 22] The occurrence of shunts with the Inoue technique does not appear to be markedly different from that observed with the double-balloon technique[4, 12, 13] but may be lower than with single, large ($\geq$25 mm diameter) balloons.[15] The lowest incidence of atrial septal defects

can be achieved with retrograde arterial techniques of balloon introduction.[23-25] In addition to balloon size, the development of atrial septal defects probably depends on the location of the transseptal puncture in muscular or membranous septum and the amount of balloon manipulation required to dilate the valve.[26] In this regard there was no significant difference in the mean number of balloon inflations between patients with and without shunts.

Short-term follow-up. In a 6-month follow-up of a subset of our patients, there was echocardiographic evidence of partial restenosis in 21%, which was associated with more symptoms. A similar rate of clinical restenosis (16%) was reported in the M-Heart registry.[12] This may represent an overestimation of the true rate of restenosis, inasmuch as the immediate catheterization-determined valve area can be increased by stretching of the valve.[27] In contrast to other investigations,[3, 8, 9] the development of restenosis was unrelated to echocardiographic scoring of valve morphology. However, this finding may be difficult to detect with the low number of patients in whom restenosis developed.

Techniques for balloon mitral valvotomy. Although the double-balloon technique[12, 13] remains the most widely used percutaneous valvotomy procedure, several other techniques have been developed, including the use of single, large polyethylene balloons in single, bifoil, and trefoil configurations[4, 15, 16] and retrograde techniques that do not require septal dilatation[23] or avoid the need for transseptal catheterization altogether.[24, 25] The advantages and disadvantages of these techniques are compared in Table V. The Inoue antegrade technique was first performed by Inoue et al.[7] in 1982 but has only recently become available in the United States. This latex and nylon mesh balloon has several unique features including its segmental hourglass inflation profile, which aids in positioning in the valve and reduces the risk of ventricular perforation, the ability to be stretched and slenderized to reduce its profile when entering the femoral vein and crossing the interatrial septum, tip steerability to assist in crossing the valve, absence of the need for a left ventricular guide wire, compliance to allow progressively larger balloon inflations, rapid inflation-deflation times, and the ability to measure left atrial pressure through the central lumen after each inflation. These characteristics have allowed simpler and faster procedures to be performed.[28]

Limitations of the study. The hemodynamic predictors of outcome of valvotomy may be affected by the choice of outcome variable. For example, an increase in mitral valve area $\geq 50\%$ or a final area ≥ 1.5 cm^2 is more likely if the prevalvotomy valve area is either small or large, respectively. For this reason we examined the effects of the variables on several different hemodynamic outcomes. Similarly, a single hemodynamic criterion for a successful procedure was considered insufficient. A patient whose valve area increases from 0.6 to 1.4 cm^2 may have symptomatic relief without achieving a final area ≥ 1.5 cm^2.[12] Therefore we characterized a successful procedure as one in which the mitral valve area increased by $\geq 50\%$ or a final area ≥ 1.5 cm^2 was obtained. Some of our results may have been influenced by highly variable or incomplete data collection, frequent problems in multicenter investigations. However, the conclusions generated may have greater applicability because they represent the collective smaller experience of a large number of institutions. This is particularly important for an uncommon procedure such as balloon mitral valvotomy in which it is unlikely that any future center or investigator beginning a valvotomy program will be able to achieve the experience of the large single centers.

Clinical implications. Percutaneous balloon mitral valvotomy is an important treatment modality for adult patients with acquired mitral stenosis. In this report from the North American investigators with the use of the Inoue balloon technique, we have demonstrated that good hemodynamic results can be achieved in the majority of patients with low rates of complications including death (0.5%), embolism (2.0%), and perforation (1.5%) and a rate of restenosis of approximately 20% at 6 months. The Inoue technique has several advantages over other currently available ones that may allow safer, simpler, and more efficient procedures. In contrast to previous studies with other techniques, the immediate results of the Inoue procedure may be less influenced by age and echocardiographic morphology. Although studies of the long-term effectiveness of this procedure are needed, Inoue balloon valvotomy is an effective technique for the initial treatment of patients with mitral stenosis.

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