JACC Vol. 21, No. 2
February 1993:390–7

Percutaneous Balloon Mitral Valvotomy With the Inoue Single-Balloon Catheter: Commissural Morphology as a Determinant of Outcome

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Objectives. The aim of this study was to determine the importance to outcome and the predictability of commissural splitting in patients undergoing percutaneous mitral valvotomy with the Inoue single-balloon catheter.

Background. Echocardiographic scoring systems devised to predict mitral valvotomy outcome are based on assessment of leaflet and subvalvular morphology, but the specific importance of commissural morphology has not been examined.

Methods. In 30 consecutive patients, commissural splitting was predicted on the basis of the two-dimensional echocardiographic commissural morphology: the extent of fusion, fibrosis or calcification of each commissure. Valve morphology also was evaluated according to a previously described echocardiographic scoring system.

Results. Splitting of one or both commissures occurred in 24 patients (80%) and was associated with a significantly greater mean increase in valve area (85%) than if neither commissure was split (13%). A good outcome from valvotomy (defined as valve area >1.5 cm^2 and increase in valve area >25%) was achieved in 96% of those in whom one or both commissures split, but in none of the patients in whom neither commissure split. Whether or not splitting of at least one commissure would occur was predicted accurately in 28 (93%) of the 30 patients. Consequently, the prediction that one or both commissures would split was associated with a good outcome in 23 (89%) of 26 patients, whereas the prediction that neither commissure would split was not associated with a good outcome in any patient. There was no significant difference in the increase in mitral valve area between those with a mitral echocardiographic score <8 and those with a score ≥8. New or worsening mitral regurgitation occurred in nine patients, most commonly as a jet directed through a split commissure.

Conclusions. Commissural splitting is the dominant mechanism by which mitral valve area is increased with the Inoue balloon technique, and it can be predicted by echocardiographic assessment of commissural morphology. Commissural morphology is a better predictor of outcome than is the mitral echocardiographic score.

(J Am Coll Cardiol 1993;21:390–7)

Since first described in 1984 (1), percutaneous balloon mitral valvotomy with single- or double-balloon techniques has been used successfully in patients with rheumatic mitral stenosis as an alternative to open or closed surgical valvotomy (2–7). In vivo (8,9) and in vitro (10–13) studies suggest that commissural splitting is the dominant mechanism by which mitral valve area is increased with both single- and double-balloon techniques. Consequently, the extent of fusion, fibrosis or calcification of one or both commissures might be expected to be a major determinant of the outcome of mitral valvotomy. Despite this, echocardiographic scoring systems devised to predict the outcome of mitral valvotomy have been based on qualitative assessment of leaflet and subvalvular morphology (7,9): the specific importance of commissural morphology has not been examined.

The purposes of this study were 1) to determine the importance of commissural splitting to the outcome of mitral valvotomy with the Inoue balloon technique, 2) to determine whether the likelihood of commissural splitting could be predicted on the basis of the echocardiographic assessment of commissural morphology in individual patients, and 3) to evaluate the relative value of a previously described echocardiographic scoring system (9) and commissural morphology in the prediction of the outcome of mitral valvotomy with the Inoue balloon technique.

Methods

Study patients. Percutaneous balloon mitral valvotomy was performed with the Inoue technique after informed consent was obtained from 30 consecutive patients (26 women and 4 men) with symptomatic mitral stenosis. The mean age was 47 years (range 25 to 73). Two patients were in

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Manuscript received March 3, 1992; revised manuscript received July 9, 1992, accepted July 21, 1992.

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0735-1097/93/$6.00

New York Heart Association functional class II, 27 were in class III and 1 patient was in class IV. Eleven patients had atrial fibrillation and 19 had sinus rhythm.

Mitral valvotomy procedure. Percutaneous balloon mitral valvotomy was performed with the Inoue technique, as described in detail previously (1,7). Patients were treated with heparin (5,000 IU administered intravenously during initial catheter positioning, and a further 5,000 IU administered after transseptal puncture). Early in our series, balloon size was selected according to patient weight, as recommended by Inoue in the balloon manufacturers' (Toray) original instruction manual. With further experience, this manual was revised, so that recommendations for the selection of balloon size were based on patient height: a 26-mm balloon in patients <165 cm tall, a 28-mm balloon in patients 165 to 179 cm tall and a 30-mm balloon in patients >180 cm tall. Stepwise balloon inflation was performed commencing with an inflation volume up to 4 ml less than the maximal volume for each balloon diameter. After each inflation, two-dimensional and Doppler echocardiographic examination was performed (see later), including color flow mapping in the apical four-chamber and parasternal short-axis views. The mitral valve gradient was monitored directly from recordings of left atrial (or pulmonary capillary wedge) and left ventricular pressures, and estimated from the Doppler velocity profile. Balloon inflations of increasing volume were repeated, if necessary, until the reduction in the transmitral pressure gradient was deemed adequate, provided that there was no significant development, or worsening, of mitral regurgitation, and that a stable balloon position across the valve could be maintained during inflation.

Echocardiography. Transthoracic echocardiography was performed in all patients with a Hewlett-Packard ultrasonograph (HP77020AC or HP77030A) and a 2.5-MHz transducer, with images obtained of the parasternal long- and short-axis, and the apical four- and two-chamber views. Continuous wave Doppler studies were performed from the apical position to obtain the maximal mitral inflow velocity profile. Assessment of mitral valve morphology and hemodynamics was made before and during valvotomy and within 24 to 72 h after the procedure. Transesophageal echocardiography was performed in all patients 24 to 48 h before valvotomy, with a 5-MHz phased array transducer mounted on the tip of a modified gastroscope (Hewlett-Packard 21362A) to exclude left atrial thrombus.

Mitral valve mean pressure gradients were estimated from the continuous wave Doppler recordings of the mitral inflow velocity, and mitral valve areas were derived by the pressure half-time method (14). The presence of mitral regurgitation was detected by color flow and spectral Doppler imaging, with estimation of severity based on the width and extent of propagation of the color jet, and its intensity on continuous wave Doppler interrogation (15,16). The severity of mitral regurgitation was graded semiquantitatively on a scale from 0 to 4+ (15) by the consensus of two observers. Left atrial diameters were estimated from M-mode tracings in the parasternal long axis view at the level of the aortic valve (17).

Mitral commissural morphology was examined independently by two observers. From the parasternal short-axis view, the extent of fusion, fibrosis or calcification of each commissure was determined and commissural splitting was predicted according to the following criteria. If both commissures were diseased and the extent of involvement was *symmetric*, both commissures were predicted to split (Fig. 1, no. 17 to 26) unless there was heavy fibrosis or calcification (indicated by intense echocardiographic reflections), in which case neither was predicted to split (Fig. 1, no. 28 to 30). If both commissures were diseased and the extent of commissural involvement was *asymmetric*, the less diseased commissure was predicted to split (Fig. 1, no. 1 to 6, 9 to 16). When one commissure was not diseased, splitting of the single diseased commissure was predicted (Fig. 1, no. 7 and 8), unless there was heavy fibrosis or calcification (indicated by intense echocardiographic reflections), in which case the commissure was predicted not to split (Fig. 1, no. 27). The two observers disagreed as to whether one or both commissures would split in two cases, and the final prediction was reached by consensus. There were no interobserver differences in the prediction that neither commissure would split.

In addition, each observer assigned an echocardiographic score for mitral valve morphology according to the criteria of Wilkins et al. (9,18), with individual scores from 0 to 4 assigned for mobility, thickness and calcification of the mitral leaflets, and involvement of the subvalvular apparatus. The final total score assigned to each valve was determined by the consensus of both observers.

Commissural splitting after valvotomy was determined from examination of the parasternal short-axis view by two independent observers, without knowledge of the hemodynamic outcome of the procedure. Because mitral valve orifice shape varied depending on the pattern of commissural splitting, with single commissural splitting resulting in a triangular orifice and splitting of both commissures resulting in a more parallel separation of the leaflets, commissural splitting was defined as either an increased apparent opening angle of either commissure (8) or increased leaflet separation associated with an increased transverse diameter of the orifice, or both. There were no interobserver differences in the determination of commissural splitting.

A good outcome from valvotomy was defined as a final mitral valve area exceeding 1.5 cm^2 *and* an increase in valve area exceeding 25% of the baseline value (19).

Statistical analysis. The statistical significance of differences in the mitral valve areas and mean gradients observed before and after mitral valvotomy in the total population was determined with the paired Student *t* test. The significance of differences in hemodynamic changes between subgroups of patients was determined with the unpaired Student *t* test,

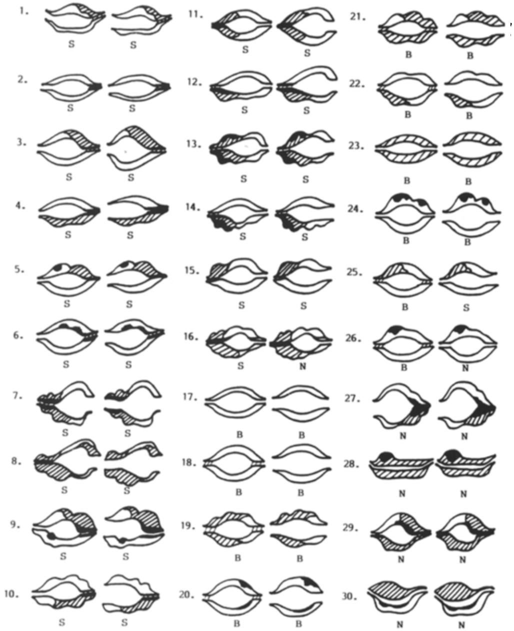

Figure 1. Diagrammatic representation of mitral valve orifice morphology observed in the parasternal short-axis view on two-dimensional echocardiography, before (**left column**) and after (**right column**) balloon mitral valvotomy in 30 patients. The letters below each valve orifice refer to the predicted pattern of commissural splitting for that patient (**left column**) and the achieved pattern of commissural splitting (**right column**). B = both commissures split; N = neither commissure split; S = single commissure split. **White segments** indicate thickening; **hatched segments** indicate more extensive fibrosis; **black segments** indicate calcification.

after expressing such changes as a percent of baseline values in order to normalize for baseline differences among individual patients. To assess the significance of age as a determinant of outcome of valvotomy, the patients were classified into two subgroups, those above or below the median age of 45 years. Similarly, to assess the significance of left atrial size as a determinant of outcome of valvotomy, the patients were classified into two subgroups, those with a larger or smaller median left atrial diameter of 50 mm. To determine the statistical significance of 1) predicted commissural splitting, 2) achieved commissural splitting, and 3) the echocardiographic score as a determinant of a good outcome as defined in this study, we employed the Fisher exact test. A p value < 0.05 was considered significant. To overcome the problem that the same data were analyzed several times, the Bonferroni adjustment was applied to the overall significance level of alpha = 0.05. Hence, an individual significance level of alpha = 0.008 was applied to each comparison performed. Unless indicated otherwise, data are expressed as mean value ± SD.

Results

Hemodynamic and symptomatic outcome (Table 1). After mitral valvotomy, the mean mitral valve area increased from 1.3 ± 0.3 to 2.1 ± 0.5 cm^2 ($p < 0.001$), and the mean mitral valve gradient decreased from 10.1 ± 5.1 to 5.0 ± 2.1 mm Hg ($p < 0.001$). The procedure was unsuccessful in two patients. One of these patients developed severe mitral regurgitation due to chordal rupture (see later) and the other developed cardiac tamponade secondary to inadvertent aortic puncture during the atrial septostomy procedure, which was repaired successfully at operation. All of the remaining 28 patients experienced some improvement in New York Heart Association functional class (mean improvement 1.7 grades) when assessed up to 2 weeks after the procedure. After valvotomy, 20 patients were in functional class I and 8 were in class II; 23 patients had a good outcome from valvotomy, as defined under Methods (19).

Four patients subsequently required mitral valve replacement. Mitral valve repair was performed 2 months after

Table 1. Hemodynamic Data Before and After Valvuloplasty

	Patients (No.)	Mitral Valve Area (cm^2)			Mitral Valve Gradient (mm Hg)		
		Before	After	p Value	Before	After	p Value
All patients	30	1.3 ± 0.3	2.1 ± 0.5	<0.001	10.1 ± 5.1	5.0 ± 2.1	<0.001
Single CS	16	1.3 ± 0.3	2.1 ± 0.4	0.150	11.8 ± 5.7	4.9 ± 1.8	0.310
Dual CS	8	1.3 ± 0.4	2.5 ± 0.3		8.2 ± 3.6	4.5 ± 2.1	
Single/dual CS	24	1.3 ± 0.4	2.2 ± 0.4	0.004	10.6 ± 5.3	4.7 ± 1.9	0.078
No CS	6	1.3 ± 0.3	1.5 ± 0.3		7.0 ± 4.9	6.0 ± 2.9	
Echo score <8	23	1.3 ± 0.4	2.2 ± 0.5	0.353	10.4 ± 5.2	5.0 ± 2.2	0.129
Echo score ≥8	7	1.3 ± 0.3	1.9 ± 0.4		9.1 ± 5.0	5.2 ± 2.0	
Sinus rhythm	19	1.2 ± 0.3	2.2 ± 0.4	0.002	11.0 ± 5.8	5.1 ± 2.3	0.719
Atrial fibrillation	11	1.4 ± 0.4	1.8 ± 0.4		8.6 ± 3.4	4.8 ± 1.8	
Age ≤45 years	15	1.4 ± 0.3	2.2 ± 0.5	0.487	10.3 ± 6.4	5.3 ± 2.4	0.546
Age >45 years	15	1.3 ± 0.3	2.0 ± 0.4		10.0 ± 3.8	4.7 ± 1.8	
Left atrium ≤50 mm	15	1.4 ± 0.3	2.2 ± 0.5	0.964	8.8 ± 3.7	4.7 ± 2.2	0.444
Left atrium >50 mm	15	1.2 ± 0.3	2.0 ± 0.5		11.5 ± 6.1	5.3 ± 2.0	

After and Before = after and before, respectively, percutaneous balloon mitral valvotomy; CS = commissural splitting; Echo = echocardiographic score. Bracketed p values refer to the statistical significance of differences between the means of the percent changes in valve area or gradient in each subgroup (see Methods). Values are expressed as mean value ± SD.

valvotomy in the one patient who developed severe mitral regurgitation but valve replacement was required after 12 months because of persistent mitral regurgitation. One patient had a satisfactory increase in mitral valve area initially but recurrence of stenosis at 19 months (Fig. 1, no. 5). Two patients with concurrent aortic stenosis had initial symptomatic improvement but recurrence of symptoms after 2 and 12 months, respectively, with subsequent replacement of both the mitral and the aortic valve.

Determinants of outcome (Fig. 1). Diagrammatic representations of the mitral valve and commissural morphology observed before and after valvotomy in each patient are presented in Figure 1. Splitting of one or both commissures was observed after valvotomy in 24 patients (80%); one commissure was split in 16 patients (anterior in 6, posterior in 10), and both commissures were split in 8. Six patients had no evidence of commissural splitting. The mean mitral valve area increased from 1.3 ± 0.4 to 2.2 ± 0.4 cm^2 (mean increase 85%) if one or both commissures were split, and from 1.3 ± 0.3 to 1.5 ± 0.3 cm^2 (mean increase 13%) if neither commissure was split. The mean mitral valve gradient decreased from 10.6 ± 5.3 to 4.7 ± 1.9 mm Hg (mean decrease 44%) if one or both commissures were split, and from 7.0 ± 4.9 to 6.0 ± 2.9 (mean decrease 13%) if neither commissure was split. The difference in mitral valve area between those with and those without commissural splitting was highly significant statistically ($p = 0.004$). The difference in mitral valve gradient between those with and without commissural splitting was marginally significant ($p = 0.078$). There were no statistically significant differences in the changes in valve area or gradient between those with splitting of two commissures and those with splitting of one commissure (Table 1). Twenty-three (96%) of the 24 patients with splitting of one or both commissures had a good outcome from valvotomy, as defined under Methods (19), whereas no patient without commissural splitting had a good outcome ($p < 0.0001$).

Prediction of commissural splitting. Single commissural splitting was predicted before valvotomy in 16 patients and was achieved in 15 patients (94% accuracy). Splitting of both commissures was predicted in 10 patients and was achieved in 8 patients (80% accuracy). It was predicted that neither commissure would split in four patients, and this prediction was correct in all four patients (100% accuracy). The predicted outcome did not occur in three patients. One patient (Fig. 1, no. 26) with equivalent mild fusion of both commissures and mild leaflet calcification, in whom splitting of both commissures was predicted, had no commissural splitting or significant improvement in mitral valve area after valvotomy. The commissures and valve area were also unchanged in one patient (Fig. 1, no. 16) with marked fusion and fibrosis of the posterior commissure who was predicted to have splitting of the anterior commissure. One patient (Fig. 1, no. 25) with equivalent mild fusion of both commissures, in whom splitting of both commissures was predicted, did have a successful outcome, however, in that splitting of a single commissure and a good outcome were achieved. Overall, therefore, the prediction that one or both commissures would split was associated with a good outcome of valvotomy in 23 (89%) of 26 patients, whereas the prediction that

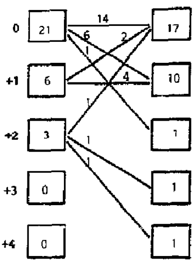

Figure 2. Mitral regurgitation before and after balloon mitral valvotomy. The grade of mitral regurgitation is indicated by the bold figures (left) with increasing severity from 0 (none) to +4 (severe). Boxed figures refer to the number of patients with each grade of regurgitation before (left column) and after (right column) valvotomy. The figures on diagonal lines indicate the outcome of patients with each grade of mitral regurgitation.

neither commissure would split was not associated with a good outcome in any patient ($p < 0.0001$).

Mean echocardiographic score. Before valvotomy, the mean echocardiographic score (9) for all valves was 5.9 ± 2.1. The mean mitral valve area increased from 1.3 ± 0.4 to 2.2 ± 0.5 cm^2 in the 23 patients with a prevalvotomy score <8, and from 1.3 ± 0.3 to 1.9 ± 0.4 cm^2 in the seven patients with a score ≥8. The mean mitral valve gradient decreased from 10.4 ± 5.2 to 5.0 ± 2.2 mm Hg in the patients with a score <8 and from 9.1 ± 5.0 to 5.2 ± 2.0 mm Hg in the patients with a score ≥8. Neither of these differences between patients with a score <8 and or ≥8 was statistically significant. Twenty (87%) of the 23 patients with a score <8 had a good outcome as did 3 (43%) of the 7 patients with a score ≥8 ($p = 0.033$).

Other factors. Patients with atrial fibrillation had a significantly worse outcome than that of patients with sinus rhythm. The mean mitral valve area increased from 1.4 ± 0.4 to 1.8 ± 0.4 cm^2 in patients with atrial fibrillation but increased from 1.2 ± 0.3 to 2.2 ± 0.4 cm^2 in patients in sinus rhythm ($p = 0.002$). The mean mitral valve gradient decreased from 8.6 ± 3.4 to 4.8 ± 1.8 mm Hg in patients with atrial fibrillation and decreased from 11.0 ± 5.8 to 5.1 ± 2.3 mm Hg in patients in sinus rhythm (p = NS). There were no significant differences in the changes in valve area or gradient between that half of the patient group <45 years old and the older half of the patient group, nor between that half of the patient group with a left atrial diameter less than the median diameter of 50 mm and that half of the patient group with a larger left atrium (Table 1).

Mitral regurgitation (Fig. 2). Before valvotomy, mild or mild to moderate mitral regurgitation, which occurred through the center of the valve orifice, was observed in nine patients. New or increased mitral regurgitation resulted from valvotomy in nine patients. In eight (89%) of these patients, the mitral regurgitation was hemodynamically well tolerated, and in seven it appeared as a jet directed through a split commissure (Fig. 1, no. 1,2,4,11,13,21,22, and Fig. 3). In the remaining patient with well tolerated regurgitation, whose valve morphology was unchanged after valvotomy, new mitral regurgitation was central (Fig. 1, no. 16). Only one patient developed severe mitral regurgitation (see earlier), which resulted from chordal rupture (Fig. 1, no. 10). In two patients with mild mitral regurgitation and one patient with mild to moderate mitral regurgitation before valvotomy, no mitral regurgitation could be detected after the procedure.

Discussion

Commissural splitting as a determinant of successful valvotomy. Previous in vivo and in vitro studies suggest that commissural splitting is the major determinant of successful valvotomy with both single- and double-balloon techniques. In a study of double-balloon valvotomy in 12 adult patients, Reid et al. (8) found an increase in the transverse diameter of the mitral valve orifice and an increase in the anterior opening angles of the commissures after valvotomy, consistent with commissural splitting. Block et al. (10) reported commissural splitting in the autopsy specimens of two patients who had previously undergone single-balloon valvotomy. Commissural splitting was also demonstrated in experimental valvotomy with single or double balloons of stenotic mitral valves excised during mitral valve replacement (11–13). The present in vivo study demonstrates the importance of commissural splitting to the successful outcome of mitral valvotomy with the Inoue single balloon. A significantly greater increase in mitral valve area was observed if one or both commissures were split than if neither was split. Moreover, 96% of patients with splitting of one or both commissures had a good outcome from attempted valvotomy, compared with none of the patients in whom neither commissure was split.

Single-balloon versus double-balloon technique. The more recently available Inoue single-balloon catheter technique differs from the double-balloon technique in several important aspects. It is uniquely designed to change its shape in three stages, facilitating insertion, placement and inflation. The stability of the balloon across the mitral valve orifice during inflation does not depend on the placement of a guide wire, which is required with the double-balloon technique, and appropriate selection of balloon size and adjustable inflation pressure permit maximal balloon-dilating areas comparable to those obtained with the double-balloon technique. A recent large comparative study of the double-balloon and Inoue techniques (7) demonstrated similar efficacy but a significantly increased incidence of serious complications with the double-balloon technique, including cardiac tamponade due to chamber perforation and transient air embolism due to balloon rupture (occurring in >10% of cases). There were relatively few adverse effects with the

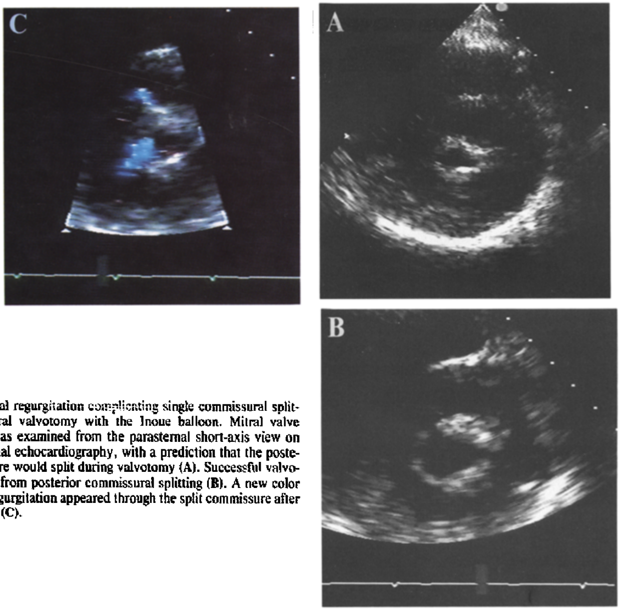

Figure 3. Mitral regurgitation complicating single commissural splitting after mitral valvotomy with the Inoue balloon. Mitral valve morphology was examined from the parasternal short-axis view on two-dimensional echocardiography, with a prediction that the posterior commissure would split during valvotomy (A). Successful valvotomy resulted from posterior commissural splitting (B). A new color jet of mitral regurgitation appeared through the split commissure after the procedure (C).

Inoue balloon technique, and the procedure and fluoroscopy times were significantly shorter. Compared with the elliptic dilating shape produced by the double-balloon technique, inflation of the circular Inoue balloon produces radial dilating forces on the stenotic mitral valve orifice. While this feature of the Inoue balloon design has not been shown to increase the risk of leaflet tearing (7), which might have been expected, it is an important factor in balloon stability during dilation. After splitting of a single commissure, instability of the balloon position in the orifice may limit the success of further inflations because of the tendency of the balloon to prolapse back into the left atrium. For this reason, adequate balloon size and initial inflation volume are important for optimal outcome.

Prediction of outcome. In the present study, single commissural splitting was the most common outcome, occurring in 16 patients (53%). Single commissural splitting was predicted if there was *asymmetric* involvement of the commissures and at least one commissure was not heavily fibrosed or calcified, with splitting of the less diseased commissure anticipated. Splitting of a single commissure was also predicted if one commissure was initially fully open and the other was not extensively diseased. Predictions of single commissural splitting were accurate in 94% of cases. Splitting of both commissures occurred in eight patients (27%). Both commissures were predicted to split if there was equivalent fusion of the commissures, with a characteristic cigar-shaped valve orifice (Fig. 1); splitting of both commissures was predicted accurately in 80% of cases. Splitting of neither commissure occurred in six patients (20%); a prediction that neither commissure would split was made if there was marked fibrosis or calcification of both commissures. This appearance was sometimes associated with inversion of the anterior leaflet margin, so that it was parallel to the posterior leaflet margin (Fig. 1, no. 30). The prediction that neither commissure would split was accurate in all cases. Overall, the assessment of commissural morphology enabled reliable predictions of the outcome of valvotomy in the majority of cases: 89% of those in whom at least one commissure was predicted to split had a good outcome, compared with none of those in whom neither commissure was predicted to split.

Other determinants of outcome. The assessment of mitral valve morphology with an echocardiographic scoring system in which scores of 0 to 4 are allocated for thickening, mobility and calcification of the leaflets, and thickening of the subvalvular apparatus, was proposed by Wilkins et al. (9) as a basis for selection of patients for balloon valvotomy and prediction of both early and long-term outcome (9,19–21). In 130 patients who underwent valvotomy with single or double balloons, Abascal et al. (19) found that 84% of patients with an echocardiographic score ≤8 had a good outcome (final valve area >1.5 cm^2 and an increase in valve area >25%), but so did 42% of patients with a score >8. In fact, analysis of individual score components showed that valve thickening alone had a higher correlation ($r = -0.47$) than the total score ($r = -0.40$) with the change in valve area, with a large scatter in the data for both correlations (19). Bassand et al. (7) recently described a similar 3-point echocardiographic scoring system in which scores of 0 to 3 were allocated for the extent of leaflet pliability and thickness, leaflet calcification and involvement of the subvalvular apparatus. In their series of 232 patients who underwent valvotomy with either the double-balloon technique (161 patients) or the Inoue balloon technique (71 patients), they found that this echocardiographic score and valvular fluoroscopic calcification were the only correlates of postprocedure mitral valve area, although the correlation for fluoroscopic calcification ($r = -0.40$) was actually somewhat stronger than for the echocardiographic score ($r = -0.31$), and both correlations were weak.

Thus, although echocardiographic scoring systems have been shown to correlate with the outcome of valvotomy in large groups of patients, their value in the prospective *selection* of individual patients for balloon valvotomy is brought into question by the weakness and large scatter of these correlations, and particularly by their poor negative predictive accuracy. It is questionable, for example, whether an echocardiographic score >8, according to the criteria of Wilkins et al. (9), should be used to exclude patients from attempted balloon valvotomy when the findings of the same group of investigators indicate that 42% of such patients would achieve a good outcome (20). In the present study, there was no statistically significant difference in the improvement in the mitral valve area or gradient between patients with a prevalvotomy echocardiographic score <8 and those with a score ≥8. In this study, the assessment of commissural morphology was of much greater predictive value in individual patients than the total echocardiographic score.

Older age, atrial fibrillation, larger left atrial size and a low ratio of effective balloon-dilating area to body surface area are other factors previously identified in multivariate analysis to be associated with a suboptimal result after balloon valvotomy (9,21,22). In the present study, patients with atrial fibrillation had a significantly worse outcome than that of patients with sinus rhythm. Atrial fibrillation in these patients may reflect the chronicity of the disease process in association with more extensive morphologic abnormalities of the mitral valve. In this study, age and left atrial size were not predictive of outcome, although this observation may reflect the small size of the study group.

Mechanisms of mitral regurgitation. Mitral valvotomy was associated with the development of new or increased mitral regurgitation in nine patients (30%). In eight of these patients, mitral regurgitation increased by only 1 or 2 grades, and was not clinically significant. In previous studies of single- and double-balloon techniques (16,21,22), increased mitral regurgitation was observed after valvotomy in up to 50% of patients. The mechanisms of the development of mitral regurgitation after mitral valvotomy have not been fully elucidated, and no features of valvular morphology have been identified previously as predictive of its development. In a very recent study of 40 patients who underwent mitral valvotomy with the double-balloon technique, Essop et al. (22) reported that a mild increase in mitral regurgitation was frequently observed after the procedure, and occurred at the site of commissural splitting, or was associated with prolapse of the anterior mitral valve leaflet. In the present study of the Inoue balloon technique, new or increased mitral regurgitation was most commonly observed as a jet directed through a split commissure (Fig. 3), which was well tolerated hemodynamically. Separated but fibrotic commissural margins may not fully appose during ventricular systole, with consequent regurgitation. Only one of our patients developed hemodynamically significant mitral regurgitation; it was due to chordal rupture and mitral valve replacement was eventually required. This complication emphasizes the need to ensure that the Inoue balloon is positioned freely in the ventricular cavity before being drawn back through the valve orifice. We did not observe any cases of mitral regurgitation due to leaflet fracture, which may occur during balloon valvotomy, particularly when there are marked focal deposits of calcium in either of the valve leaflets (22). In three patients, mild or mild to moderate central mitral regurgitation observed before valvotomy was absent after the procedure. In these patients, improved mobility of the leaflets may have permitted better valve apposition during systole.

Limitations of the study. Although the size of our patient group was adequate to establish statistically the importance of commissural splitting to the outcome of mitral balloon valvotomy with the Inoue technique, and to establish that commissural splitting can be predicted on the basis of the echocardiographic assessment of commissural morphology, confirmatory studies of the predictive value of commissural morphology in larger groups of patients are warranted. The relatively small size of the study group probably did obscure the importance of weaker correlates of patient outcome, particularly age and left atrial size, which are likely to be indirect indicators of the chronicity of the rheumatic disease process and, thus, valve and commissural morphology. The subjective nature of the echocardiographic assessment of commissural morphology might also be questioned, but previously described echocardiographic scoring systems (7,9) are also subjective, the scores reflecting only an arbitrary grading of the subjective observations. Because the decision as to whether to proceed to attempted percutaneous balloon valvotomy in an individual patient is binary (Yes or No), by definition, the value of applying a continuous grading scale to such subjective observations is open to question unless some particular value on the scale can be shown to discriminate clearly between those who will or will not benefit from the procedure. This has not been shown for previously described echocardiographic scoring systems (7,9,19). The present study suggests that the binary decision as to whether commissural splitting will or will not occur provides a more reliable basis for the binary decision as to whether or not to proceed with attempted balloon valvotomy.

Conclusions. Percutaneous balloon mitral valvotomy with the Inoue single-balloon catheter produced hemodynamic and symptomatic improvement in the majority of patients studied. Commissural splitting was the major mechanism of successful valvotomy, and could be predicted reliably by echocardiographic examination of commissural morphology. Commissural morphology was more accurate than a previously described echocardiographic scoring system (9) in predicting the outcome of balloon mitral valvotomy. New or increased mitral regurgitation was usually a direct consequence of commissural splitting, and was well tolerated hemodynamically. These findings suggest that detailed echocardiographic examination of commissural morphology may provide the best basis for selecting patients for balloon mitral valvotomy.

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