

## Clinical Investigations

# Predicting Mitral Regurgitation Following Percutaneous Mitral Valvotomy with the Inoue Balloon: Comparison of Two Echocardiographic Scoring Systems

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### Summary

**Background:** Percutaneous balloon mitral valvotomy (PBMV) has become the procedure of choice for many patients with symptomatic mitral stenosis. However, the development of significant mitral regurgitation (MR) remains an infrequent but very important complication. The echocardiographic scoring system described by Padial *et al.* has been successful in predicting the development of severe MR following PBMV using the double balloon technique.

**Hypothesis:** We aimed to assess the applicability of this new scoring system in predicting a significant increase in MR with the Inoue balloon and to compare it with the established Wilkins score.

**Methods:** The echocardiograms of 23 patients who had undergone PBMV for symptomatic mitral stenosis were analyzed retrospectively using both scoring systems, and the severity of MR was determined from pre- and postprocedural studies.

**Results:** Post PBMV, significant MR occurred in four patients (17%) while severe MR occurred in two patients (9%). Padial scores [mean (standard error of the mean)] in the group of patients with and without significant MR were [9.1 (0.8)] and [6.0 (0.3)], respectively ( $p = 0.002$ ), while the Wilkins score was [7.5 (1.0)] and [6.4 (0.5)], respectively ( $p = 0.3$ ). Using 8 as a cutoff point, the sensitivity and specificity of the newer scoring system was 83 and 100%, respectively, while the sensitivity and specificity of the Wilkins score was 50 and

50%, respectively. The positive predictive value  $> 8$  was 100% (4/4) for the Padial and 25% (1/4) for the Wilkins system. Accordingly, the negative predictive value  $< 8$  was 89% (17/19) for the Padial and 73% (14/19) for the Wilkins system.

**Conclusion:** The newer scoring system is better at reliably identifying patients at risk of developing significant MR from PBMV with the Inoue balloon.

**Key words:** mitral commissurotomy, mitral valvotomy, mitral regurgitation, echocardiography

### Introduction

Percutaneous balloon mitral valvotomy (PBMV) has become the procedure of choice for many patients with symptomatic mitral stenosis. However, the development of significant mitral regurgitation (MR) remains an infrequent but very important complication.<sup>1–3</sup> The widely accepted Massachusetts General Hospital score described by Wilkins *et al.*<sup>4</sup> (an assessment of mobility, valvular and subvalvular thickening, and calcification), although useful in the selection of patients for PBMV and in the prediction of short- and long-term outcome,<sup>4–8</sup> has not been useful in predicting the development of an increase in MR in these patients.<sup>1, 9</sup> Indeed, Feldman *et al.*<sup>10</sup> reported that increases of +2 or more in MR occurred almost entirely in patients with low echocardiographic Wilkins scores.

Although the influence of mitral valve morphology in the production of MR is still controversial, most investigators would agree that the development of significant MR is an unpredictable event. Previous studies were unable to demonstrate any correlation between procedure-related factors and the development of severe MR.<sup>9, 11, 12</sup> However, Padial *et al.*<sup>13</sup> proposed a new echocardiographic scoring system that successfully predicts severe MR following PBMV with the double balloon technique. The scoring system was developed on anatomic information of surgically excised valves from previous studies<sup>14–16</sup> that have shown three common characteristics: (1) heterogeneity of thickening of the leaflets, (2) thickening and foreshortening of the subvalvular apparatus, and (3)

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calcification of one or both commissures. When the double-balloon technique is used, leaflet tearing has been described more frequently as the dominant mechanism of severe MR.<sup>1</sup> With the Inoue balloon, chordal rupture, particularly to the anterior leaflet, appears to be the single most common cause, with posterior leaflet tears being less frequent.<sup>2</sup> The aim of our study, therefore, was to assess the applicability of this new scoring system in predicting the development of significant MR following percutaneous transatrial mitral commissurotomy (PTMC) in patients treated exclusively with the Inoue balloon and to compare this scoring system with the established Wilkins score.

## Methods

### Patients

We studied 27 consecutive patients who underwent PBMV with the Inoue balloon at our Institution. All patients had symptomatic mitral stenosis, and the decision to proceed was based on the clinical situation and the morphology of the valve on two-dimensional (2-D) echocardiography. Four patients were not included in the analysis (unsuccessful PBMV, cardiac tamponade, poor quality study, and unrelated death in one patient each). The remaining 23 patients (19 women, 4 men) were the subject of our study. The mean standard error of the mean (SEM) age of the patients was  $61 \pm 14$  years (range 21–80 years). Before PBMV, 4 patients (17%) were in New York Heart Association (NYHA) functional Class II, 18 patients (78%) in Class III, and 1 patient (4%) in Class IV.

### Procedure

In all cases, PBMV was performed using the Inoue balloon as first described by Inoue *et al.*<sup>17</sup> with continuous hemodynamic measurements. Maximum balloon size was chosen according to patient height, and incremental stepwise inflations were performed. This stepwise process was repeated until the transmitral gradient was reduced without a significant increase in MR (assessed by left ventriculography after each inflation according to the Sellers criteria).<sup>18</sup> Intraoperative transesophageal echocardiographic guidance has been employed since 1996 in the majority of cases.

### Echocardiography

All patients underwent 2-D color flow and Doppler studies shortly before and within 2 days after the procedure with a Hewlett-Packard Sonos 2500. Pre- and postprocedural echocardiograms were analyzed independently by two investigators. Predilatation mitral area was calculated by Doppler using the pressure half-time method and by direct cross-sectional planimetry at the level of the leaflet tips when Doppler signals were not suitable for pressure half-time calculations. Postdilatation area was calculated predominately by planimetry (21/23 patients). This latter method gives the most reproducible results immediately after dilatation.<sup>19</sup> Successful dilatation of

the mitral valve was defined as an increase in mitral valve area of  $> 25\%$  and a final area of  $\geq 1.5$  cm.<sup>2</sup>

The severity of MR was assessed by color flow imaging and pulsed Doppler and was determined by the ratio of maximal jet area to left atrial area in the same view. It was graded as +1 if the regurgitant jet/left atrial area ratio was  $< 20\%$ , +2 if the ratio was between 20 and 39%, +3 if  $> 40\%$ , and +4 if  $> 50\%$ , accompanied by attenuation of systolic flow or inverted flow in the pulmonary veins. Significant MR after the procedure was defined as an increase of 1 or more in the grading, plus a minimal total grade of 2. Severe MR was defined as a total grade of 3–4.

Prevalvotomy echocardiograms were examined and each patient was assigned two echocardiographic scores, one described by Wilkins *et al.*,<sup>4</sup> and the other by Padial *et al.*<sup>13</sup> (Table I). For the Padial score, the mitral valve was studied in the parasternal short-axis view at the level of the leaflet tips and the subvalvular apparatus in both parasternal and apical views (Figs. 1 and 2). The distribution of leaflet thickening and/or calcification of both leaflets was scored from 0–4 (each leaflet scored separately). Commissural calcification and/or fibrosis was also scored from 0–4. Calcification was defined as an intense echocardiographic reflection, brighter than the adjacent aortic root. The assessment of the subvalvular disease was performed as in the Wilkins score. The total score in both systems ranged from 0 (normal) to 16 (uneven distribution of leaflet thickening with thin segments near normal, severe calcification of both commissures, and extensive thickening of the subvalvular apparatus). In addition to the echocardiographic analysis, the surgical and histologic reports of patients with severe MR who had mitral valve replacement were obtained.

TABLE I Echocardiographic score

I–II Valvular thickening (score each leaflet separately)
1. Leaflet near normal (4–5 mm) or with only a thick segment
2. Leaflet fibrotic and/or calcified evenly; no thin areas
3. Leaflet fibrotic and/or calcified with uneven distribution; thinner segments are mildly thickened (5–8 mm)
4. Leaflet fibrotic and/or calcified with uneven distribution; thinner segments are near normal (4–5 mm)
III Commissural calcification
1. Fibrosis and/or calcification in only one commissure
2. Both commissures mildly affected
3. Calcium in both commissures, one markedly affected
4. Calcium in both commissures, both markedly affected
IV Subvalvular disease
1. Minimal thickening of chordal structures just below the valve
2. Thickening of chordae extending up to one-third of chordal length
3. Thickening to the distal third of the chordae
4. Extensive thickening and shortening of all chordae extending down to the papillary muscle

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FIG. 1 Parasternal short axis showing a mitral valve with even distribution of thickening and absence of calcium in the commissures. Padiol score: anterior leaflet = 2, posterior leaflet = 2, commissural calcification = 0. The subvalvular apparatus was assessed from the parasternal long-axis and apical four-chamber views.

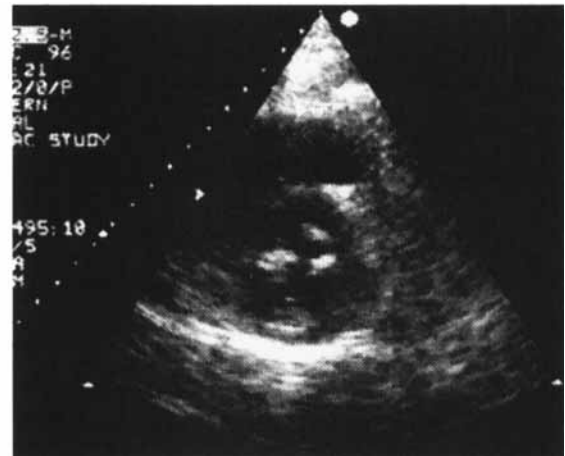


FIG. 2 Patient with uneven distribution of thickening. Padiol score: anterior leaflet = 4, posterior leaflet = 4, commissural calcification = 0. This patient developed severe mitral regurgitation after the procedure.

### Statistical Analysis

Patients were divided into two groups: patients who had developed significant or severe MR and those who did not develop MR or in whom MR did not change. Comparisons between these two groups were made using the nonparametric Mann-Whitney test. The sensitivity, specificity, and the positive and negative predictive accuracy using a score of  $\geq 8$  as a cut-off point were obtained. Data were expressed as mean and SEM and were considered significant at  $p < 0.05$ .

## Results

### Patients

Table II shows the baseline characteristics of the patients. Successful dilatation was achieved in 20 patients (87%). Of the remaining three patients who did not achieve optimum postdilatation area, two underwent elective mitral valve replacement for reoccurrence of symptoms. The degree of MR on echocardiography was unchanged in 15 patients (65%), increased by +1 in 5 patients (22%), and increased by +2 in 3 patients (13%). The incidence of significant MR was 17% (four patients) and of severe MR 9% (two patients).

### Echocardiographic Scores

Table III shows the echocardiographic scores and procedural data of all patients. The observer agreement was 93%. Padiol scores [mean(SEM)] in the group of patients with and without significant MR were [9.1 (0.8)] and [6.0 (0.3)], respectively ( $p = 0.002$ ) while the Wilkins score was [7.5 (1.0)] and [6.4 (0.5)], respectively ( $p = 0.3$ ). The Padiol score of the

two patients who developed severe MR was 10 and 8 whereas the Wilkins score was 8 and 6.

At a cut-off point of  $\geq 8$ , the sensitivity of the Padiol score was 83% and that of the Wilkins score was 50%. None of the patients in the group with nonsignificant MR had a total Padiol score  $> 8$ . In the same group, three patients had Wilkins scores 9, 10, and 11. Thus, the specificity was 100% for the Padiol score and 87% for the Wilkins score. The positive predictive value  $> 8$  was 100% (4/4) for the Padiol score and 25% (1/4) for the Wilkins score. Accordingly, the negative predictive value  $< 8$  was 89% (17/19) for the Padiol score and 73% (14/19) for the Wilkins score.

TABLE II Baseline clinical and echocardiographic characteristics of patients

No. of patients	23
Age	$61 \pm 14$ (range 21–80)
Sex	18 F, 4 M
NYHA	
II	4
III	18
IV	1
Predilatation MR	
0	11
+1	10
+2	2
Postdilatation MR	
0	8
+1	7
+2	6
+3	2

Abbreviations: F = female, M = male, NYHA = New York Heart Association, MR = mitral regurgitation.

TABLE III Echocardiographic scores and procedural data

Patients	Padial score	Wilkins score	MR pre	MR post	MVA pre (cm <sup>2</sup> )	MVA post (cm <sup>2</sup> )
1	7	6	0	0	1.2	2.4
2	9	8	0	2 <sup>a</sup>	1.6	2.3
3	5	5	0	1	0.8	2
4	5	5	0	0	0.0	1.6
5	6	7	0	0	1	1.8
6	5	6	1	1	0.8	1 <sup>b</sup>
7	6	5	1	1	1.2	2.2
8	6	7	0	0	0.8	1.7
9	5	4	0	0	1.1	1.7
10	5	4	0	1	1	1.8
11	9	5	1	2 <sup>a</sup>	1.1	1.8
12	8	9	1	1	1.2	1.9
13	10	8	1	3 <sup>a</sup>	0.7	1.6
14	8	8	2	2	1	1.3 <sup>b</sup>
15	5	6	2	2	1	2
16	11	12	1	2 <sup>a</sup>	0.9	2.2
17	8	6	1	3 <sup>a</sup>	1.2	1.9
18	5	4	0	0	0.9	1.9
19	8	10	1	1	0.8	1.3 <sup>b</sup>
20	8	6	1	2 <sup>a</sup>	0.8	1.8
21	5	5	0	0	1.2	2.1
22	7	11	0	0	1	2.2
23	6	7	1	1	0.9	2.3

<sup>a</sup> Significant mitral regurgitation.

<sup>b</sup> Unsuccessful dilatation.

Abbreviations: MR = mitral regurgitation, MVA = mitral valve area.

### Findings in the Patients with Severe Mitral Regurgitation

Two patients underwent mitral valve replacement for severe postprocedural MR, one semielectively at 1 month and the second at 15 months. The first had rupture of the posterior leaflet and ruptured chordae tendinae while the second patient had rupture of the posterior leaflet. The first patient had a total Padial score of 10 (anterior leaflet thickening = 4, posterior leaflet thickening = 4, commissural calcification = 0, subvalvular thickening = 2) and a total Wilkins score of 8 (mobility = 2, valvular thickening = 2, subvalvular thickening = 2 and valvular calcification = 2) as shown in Figure 2. The second patient had a total Padial score of 8 (3, 3, 0, 2, respectively), and a total Wilkins score of 6 (2, 2, 0, 2, respectively).

### Follow-Up of Patients with Significant Mitral Regurgitation

Four patients (17%) developed significant MR after the procedure (defined as an increase of  $\geq 1$  in the grading, plus a minimal total grade of 2). These patients were followed up for a mean period of 27.7 months (range 4–57). At follow-up, two patients were in New York Heart Association (NYHA) class II, one patient in class III, and one in class IV. The last patient developed mitral valve restenosis also and underwent mitral valve replacement.

### Discussion

Our study shows that the echocardiographic score proposed by Padial *et al.*<sup>13</sup> can predict the development of significant MR following PBMV with the Inoue balloon. This scoring system is based on anatomic characteristics of the mitral valve obtained mainly from the parasternal short-axis view. Its individual components include the distribution of leaflet thickening and calcification, and the degree of commissural calcification. The severity of the subvalvular disease is assessed from the long-axis and apical views, as in the Wilkins score. The development of this scoring system was based on anatomic features of surgically excised valves such as (a) unevenly thickened leaflets; (b) calcification of one or both commissures; and (c) thickening, foreshortening, and fusion of the subvalvular apparatus.<sup>14,15</sup>

### Echocardiographic Scores and Mechanisms of Severe Mitral Regurgitation

The dominant mechanism by which balloon dilatation increases the mitral valve area is commissural splitting.<sup>20,21</sup> The importance of the assessment of commissural morphology as a predictor of outcome has been demonstrated in several studies. In a study designed to identify factors related to the development of severe MR, Hernandez *et al.*<sup>12</sup> showed that of six

patients requiring early mitral valve replacement for severe MR, five had evidence of commissural calcium. It has been shown that the assessment of commissural calcification on 2-D echocardiography is a better predictor of intermediate-term outcome than the Wilkins score.<sup>22</sup> Operative reports of patients who underwent mitral valve replacement confirmed the presence of unilateral commissural calcification in all four patients with torn leaflets.

Uneven mitral leaflets (thick areas coexisting with thin areas) and extensive disease of the subvalvular apparatus were also findings that have consistently been associated with patients who developed severe MR following PBMV. In our study, two patients required mitral valve replacement for severe MR. Their histologic reports showed that both had rupture of the posterior leaflet with the additional finding of ruptured chordae tendinae in the second patient. Our findings agree with those of Hernandez *et al.*<sup>12</sup> who found that all six patients who required early mitral valve surgery had rupture of a leaflet which occurred along these thin areas.

Several studies using the Wilkins score as a predictor of outcome have failed to identify a subgroup of patients at risk for developing severe MR. Abascal *et al.*<sup>9</sup> showed that the echocardiographic score did not distinguish between patients with and without an increase in MR. In the study by Feldman *et al.*,<sup>10</sup> significant increases of +2 or more in MR occurred paradoxically in patients with low Wilkins score. In our study, the difference in total Wilkins score between significant versus nonsignificant MR groups was not statistically significant ( $p = 0.3$ ). In contrast, the same difference in total Padiol score was statistically significant ( $p = 0.002$ ). Our findings are in agreement with those of Padiol *et al.*<sup>13</sup> who showed in the same groups  $p$  values of 0.23 and 0.001, respectively.

### Incidence and Prediction of Significant Mitral Regurgitation

The incidence of significant and severe MR in our study was 17 and 9% respectively. The reported incidence of clinically significant MR following PBMV varies from 7 to 17%.<sup>1, 2, 9</sup> These differences could be explained by the heterogeneity in study populations and by the criteria by which significant MR is defined. In the patients who developed severe MR in our study, the echocardiographic assessment of severity correlated well with the angiographic findings.

The best diagnostic accuracy of the new scoring system was obtained at a cut-off value of  $\geq 8$ . The Padiol score was more sensitive than the Wilkins score (83 vs. 50%) and more specific (100 vs. 83%). Positive and negative predicting values were also higher with the Padiol score (100 vs. 25% and 89 vs. 73%, respectively).

### Study Limitations

This was a retrospective study and was subject to the limitations attributed to such a study. The decision to proceed to PBMV was based mainly on clinical rather than echocardiographic criteria. The echocardiographic scores of valve morphology was semiquantitative and was graded subjectively, but this is an inevitable drawback in all similar studies.

The echocardiographic criteria for defining significant MR were also semiquantitative. Estimation of the severity of regurgitation by color flow and Doppler mapping of the extent of the regurgitant jet has been proposed and is widely acceptable for clinical use. However, the accuracy of this method immediately after PBMV can be affected by several factors such as the left atrial compliance, the left ventricular systolic pressure and function, and the direction of regurgitant jet. In our study, the addition of Doppler study of pulmonary venous flow may have improved the diagnostic criteria of severe MR.

Assessment of the value of the new scoring system in predicting immediate procedural outcome was beyond the scope of this study; however, we have previously reported the sensitivity and specificity of the Padiol score in predicting long-term restenosis following PBMV with the Inoue balloon.<sup>23</sup>

### Conclusions

Despite the differences in the mechanisms of genesis of MR between the Inoue and the double-balloon technique, the new scoring system is applicable in patients treated with the Inoue balloon and can identify patients at risk of developing significant MR post valvotomy. In particular, patients with uneven distribution of leaflet thickening, assessed in the parasternal short-axis view, and with a total Padiol score  $\geq 8$ , have a higher incidence of mitral valve replacement at short and intermediate follow-up. Further prospective studies are needed to test the feasibility of the new scoring system in larger populations and to assess its value in predicting the short- and long-term outcome.

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