JACC Vol. 23, No. 7
June 1994:1604–9

Percutaneous Mitral Balloon Valvotomy in Patients With Calcific Mitral Stenosis: Immediate and Long-Term Outcome

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Objectives. **This study analyzed the immediate and long-term outcome of percutaneous balloon mitral valvotomy in patients with and without fluoroscopically visible mitral valve calcification.**

Background. **Mitral valve calcification has been shown to be an important factor in determining immediate and long-term outcome of patients undergoing surgical mitral commissurotomy. Patient selection has an important impact on the outcome of percutaneous balloon mitral valvotomy.**

Methods. **The immediate and long-term results of percutaneous balloon mitral valvotomy were compared in 155 patients with and 173 patients without mitral valve calcification. The patients with calcified valves were assigned to four groups according to severity of calcification.**

Results. **Patients with calcified mitral stenosis more frequently were in New York Heart Association functional class III or IV and more frequently had atrial fibrillation, previous surgical commissurotomy, echocardiographic score >8, higher pulmonary artery and left atrial pressures, higher pulmonary vascular resistance and mean mitral valve gradient and lower cardiac output and smaller mitral valve area. Mitral valve area after valvotomy was significantly smaller in patients with calcified valves (1.8 ± 0.06 vs. 2.1 ± 0.06 cm^2) and was ≥ 1.5 cm^2 in 65% of patients with and 83% of patients without calcified valves ($p = 0.004$). A successful outcome, defined as mitral valve area >1.5 cm^2 without significant mitral regurgitation and left to right shunting, was achieved in 52% of patients with and 69% of patients without uncalcified valves ($p = 0.001$). The success rate was 59%, 48%, 35% and 33% in subgroups with 1+, 2+, 3+ and 4+ calcification, respectively. The rates of significant left to right shunting and mitral regurgitation after valvuloplasty were similar in the two groups. Estimated survival rate (80% vs. 99%, respectively, $p = 0.0001$), survival rate without mitral valve replacement (67% vs. 93%, respectively, $p < 0.00005$) and event-free survival rate (63% vs. 88%, respectively, $p < 0.00005$) at 2 years were significantly better in the patients with uncalcified valves. Survival rate curves became progressively worse as the severity of calcification increased.**

Conclusions. **These findings indicate that immediate and long-term results of mitral valvuloplasty are not as successful in patients with fluoroscopically visible mitral valve calcification as in those without calcification.**

(J Am Coll Cardiol 1994;23:1604–9)

Percutaneous mitral balloon valvotomy is an alternative to surgical treatment for symptomatic mitral stenosis. Patient selection has an important impact on the outcome of percutaneous mitral balloon valvotomy (1,2). We have shown that echocardiography helps in decision making before mitral valvotomy by using a morphologic "scoring" of the mitral valve (3). Before the era of open heart surgery, calcification of the mitral valve was considered to be an important factor in determining the immediate outcome of patients undergoing surgical closed commissurotomy (4,5). Calcification of the mitral valve decreases the chances of favorable immediate outcome and long-term event-free survival after surgical commissurotomy (2,6). Furthermore, we have found that the absence of calcium visible under fluoroscopy is an independent predictor of event-free survival after percutaneous mitral balloon valvotomy (2). Thus, this study was undertaken to evaluate the effect of fluoroscopic calcification of the mitral valve on the immediate and long-term outcome of percutaneous mitral balloon valvotomy.

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Manuscript received December 17, 1992; revised manuscript received January 3, 1994, accepted January 3, 1994.

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Methods

Study patients. The study group included 328 (267 women, 61 men; mean [±SEM] age 54 ± 1 years) consecutive patients who underwent percutaneous mitral balloon valvotomy at the Massachusetts General Hospital between August 1986 and September 1989. Of these 328 patients, 155 had fluoroscopically visible calcium involving the mitral valve leaflets. The remaining group included 173 patients who did not have fluoroscopically visible mitral valve calcification.

All patients were screened clinically and by echocardiography. Transesophageal echocardiography was used routinely in patients with a suboptimal transthoracic study or a

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history of a previous embolic event or possible left atrial thrombus. Patients with left atrial thrombus, atrial fibrillation or history of thromboembolism received anticoagulation with warfarin for 2 to 3 months before a second evaluation.

Procedure. After right and left heart catheterization, transseptal left heart catheterization and hemodynamic measurements, percutaneous mitral balloon valvotomy was performed as previously described (7). The single-balloon technique was used in 25 patients in the earlier part of our experience and the double-balloon technique in the remaining patients (7). Oxygen saturation of blood samples from the superior vena cava, pulmonary artery and aorta were determined before and after valvuloplasty. When there was evidence of left to right shunting (≥7% step-up in oxygen saturation measurements between the right atrium and pulmonary artery), or when significant tricuspid regurgitation was present by physical examination or echocardiography, or both, cardiac output was calculated according to the Fick principle rather than by thermodilution. In the presence of left to right shunting, the oxygen content of a blood sample from the superior vena cava was used as the mixed venous blood sample. Oxygen consumption was measured by an MRM-2 oxygen consumption monitor (Waters Instrument Inc.). A left ventriculogram was performed in the right anterior oblique projection before and after mitral valvotomy to assess severity of mitral regurgitation.

Data collection. The following variables were prospectively entered into the computerized data base: *demographic variables*—age, gender, body surface area; *clinical variables*—functional class, presence of atrial fibrillation, previous surgical commissurotomy; *laboratory variables*—echocardiographic score (3), severity of mitral regurgitation as graded according to the Sellers classification using contrast left ventriculography (8), fluoroscopically visible mitral valve calcification graded from 0 to 4+ (0 = no, 1+ = mild, 4+ = severe calcification) (7); *hemodynamic variables before and after percutaneous mitral balloon valvotomy*—mean pulmonary artery and left atrial pressures, pulmonary vascular resistance, mean mitral valve gradient, cardiac output and calculated mitral valve area.

To assess the interobserver variability in determining the severity of valvular calcification according to the semiquantitative (0 to 4+) grading system, 50 randomly selected cineangiograms were examined by two independent physicians. There was complete agreement in the grading of calcification in 42 of the 50 cases. Agreement was not present in eight cases, but the disagreement was not by more than one grade in any of the cineangiograms. The first observer graded three cases as 3+ and two cases as 1+, whereas the second observer graded them 2+ and 0+, respectively. The first observer graded one case 2+, one case 1+ and one case 0+, whereas the second observer graded them 1+, 2+ and 0+, respectively. The interobserver variability was determined using the kappa statistic; kappa was calculated as 0.73, representing excellent agreement between the observers ($p < 0.001$).

Follow-up. Patients were interviewed by telephone every 6 months. When necessary, local physicians were contacted for further information or records. Follow-up information included survival status, mitral valve replacement, and clinical status represented by functional class. The mean follow-up period was 20 ± 1 months.

Method of analysis. Patients with mitral valve calcification were assigned to four subgroups according to the severity of calcification (1+, 2+, 3+, 4+, respectively). Successful outcome was defined as a final mitral valve area ≥1.5 cm^2 without a ≥2+ increase in mitral regurgitation and without a left to right shunt with a pulmonary/systemic ratio of ≥1.5:1 after valvuloplasty. Procedure-related death was defined as in-hospital deaths that were directly or indirectly caused by valvuloplasty. In-hospital deaths that clearly had unrelated causes were not considered procedure-related deaths. The following complications of mitral valvuloplasty were analyzed: pericardial tamponade, thromboembolism, high grade atrioventricular block, ≥2+ mitral regurgitation and left to right shunt with a pulmonary/systemic ratio ≥1.5:1.

Statistical analyses were carried out with the use of the BMDP statistical package (Release 7 of 1992 from BMDP Statistical Software, Inc.). Continuous variables were compared with one-way analysis of variance followed by intergroup comparison corrected for multiple comparisons by the Bonferroni theorem, an option in the BMDP program. A p value of <0.05 was used as the minimal value for statistical significance. Values are expressed as mean values ± 1 SEM. The interobserver variability was determined using the kappa statistic (9). The time-related events noted during follow-up were examined using the Cox model (10). Actuarial survivorship, actuarial survivorship with freedom from mitral valve replacement and functional class III or IV were analyzed. Estimated survival curves with the Cox model were constructed for patients with no calcification and for those with 1+, 2+, 3+ and 4+ calcification.

Results

Baseline variables. Baseline characteristics of the patients are shown in Table 1. Patients with calcified valves were significantly older than those free of calcifications (61 ± 1 vs. 47 ± 1, respectively, $p < 0.00001$). There was a positive correlation between severity of calcification and patient age ($p < 0.005$, $r = 0.46$). Significantly more patients were in functional class III or IV in the group with (85%) than without (65%) calcifications ($p < 0.00001$). Atrial fibrillation and history of previous commissurotomy were also more common in the group with than without calcifications (64% vs. 35%, $p < 0.0001$; 29% vs. 13%, $p = 0.005$, respectively). Mean echocardiographic score and percent of patients with an echocardiographic score >8 were significantly higher among patients with than without calcifications (8.9 ± 0.2 vs. 6.8 ± 0.1, $p < 0.00001$; 60% vs. 13%, $p < 0.00001$, respectively).

Hemodynamic variables. Hemodynamic findings before and after mitral valvotomy are shown in Table 2. Mean

Table 1. Baseline Clinical Characteristics of Patients With and Without Calcified Mitral Valves

	Pts Without Calcifications	Pts With Calcifications				
		All Pts	1+	2+	3+	4+
Age (yr)	47 ± 1	61 ± 1	59 ± 2	61 ± 2	67 ± 3	73 ± 3
F/M	143/30	124/31	60/15	43/11	14/3	7/2
NYHA class						
I	6 (4%)	1 (1%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)
II	54 (31%)	23 (15%)	10 (13%)	10 (18%)	2 (12%)	1 (11%)
III	103 (60%)	89 (57%)	50 (67%)	30 (56%)	7 (41%)	2 (22%)
IV	9 (5%)	42 (27%)	15 (20%)	13 (24%)	8 (47%)	6 (67%)
Atrial fibrillation	60 (35%)	99 (64%)	53 (71%)	30 (56%)	11 (65%)	5 (56%)
Previous commisurotomy	23 (13%)	44 (29%)	24 (32%)	13 (24%)	5 (29%)	2 (22%)
Echo score	6.8 ± 0.1	8.9 ± 0.2	8.1 ± 0.2	9.2 ± 0.3	10.7 ± 0.6	10.8 ± 0.6
>8	22 (13%)	93 (60%)	35 (47%)	36 (67%)	13 (77%)	9 (100%)

Data presented are mean values ± SD or number (%) of patients (Pts). Echo = echocardiographic; F = female; M = male; NYHA = New York Heart Association; 1+ to 4+ = grade of calcification.

mitral gradient and left atrial pressure were similar in the two groups before valvuloplasty but were significantly higher in the group with than without calcifications after valvuloplasty (6 ± 0.2 vs. 5 ± 0.2 mm Hg, respectively, p = 0.007). Mean pulmonary artery pressure before and after valvuloplasty was higher in the group with than without calcifications (41 ± 2 vs. 35 ± 1, p = 0.0001; 33 ± 1 vs. 27 ± 1 mm Hg, p < 0.00001, respectively). Mean left atrial pressure was similar in the two groups before valvuloplasty but was higher in the group with than without calcifications after valvuloplasty (25 ± 1 vs. 24 ± 1, p = NS; 17 ± 1 vs. 15 ± 1 mm Hg, p = 0.0002, respectively). Mean mitral valve area before and after valvuloplasty was smaller among patients with than without calcifications (0.8 ± 0.2 vs. 0.9 ± 0.2, p = 0.004; 1.8 ± 0.6 vs. 2.1 ± 0.6 cm^2, p = 0.0002, respectively). Cardiac output before and after valvuloplasty was lower in the group with than without calcifications (3.7 ± 0.1 vs. 4.1 ± 0.1, p = 0.001; 4.3 ± 0.1 vs. 4.6 ± 0.1 liters/min, p = 0.003, respectively). Pulmonary vascular resistance before and after valvuloplasty was higher in the group with than without calcifications (416 ± 32 vs. 247 ± 17, p < 0.00001; 321 ± 21 vs. 222 ± 11 dynes·s^{-1}·cm^{-5}, p < 0.00001, respectively).

Immediate outcome and complications. A final mitral valve area ≥1.5 cm^2 was achieved in 101 (65%) patients with

Table 2. Hemodynamic Findings Before and After Mitral Valvuloplasty in Patients With and Without Calcified Valves

	Pts Without Calcifications	Pts With Calcifications				
		All Pts	1+	2+	3+	4+
mPAP						
Pre-PMV	35 ± 1	41 ± 1	41 ± 2	40 ± 2	48 ± 5	42 ± 5
Post-PMV	27 ± 1	33 ± 1	32 ± 1	32 ± 2	37 ± 4	42 ± 5
mLAP						
Pre-PMV	24 ± 1	25 ± 1	24 ± 1	25 ± 1	28 ± 2	25 ± 2
Post-PMV	15 ± 1	17 ± 1	17 ± 1	17 ± 1	18 ± 2	21 ± 3
MVG						
Pre-PMV	15 ± 1	15 ± 1	14 ± 1	15 ± 1	17 ± 1	17 ± 2
Post-PMV	5 ± 0.2	6 ± 0.2	5 ± 0.3	6 ± 0.4	7 ± 0.7	7 ± 1
CO						
Pre-PMV	4.1 ± 0.1	3.7 ± 0.1	3.8 ± 0.1	3.5 ± 0.1	3.6 ± 0.3	3.7 ± 0.3
Post-PMV	4.6 ± 0.1	4.3 ± 0.1	4.3 ± 0.1	4.3 ± 0.2	4.3 ± 0.4	4.2 ± 0.5
MVA						
Pre-PMV	0.9 ± 0.02	0.8 ± 0.02	0.9 ± 0.03	0.8 ± 0.04	0.6 ± 0.08	0.8 ± 0.07
Post-PMV	2.1 ± 0.06	1.8 ± 0.36	2.0 ± 0.08	1.7 ± 0.01	1.5 ± 0.02	1.4 ± 0.1
PVR						
Pre-PMV	247 ± 17	416 ± 32	434 ± 55	378 ± 40	487 ± 84	351 ± 68
Post-PMV	222 ± 11	321 ± 21	307 ± 28	344 ± 43	365 ± 46	353 ± 37

Data presented are mean values ± SD. CO = cardiac output (liters/min); mLAP = mean left atrial pressure (mm Hg); mPAP = mean pulmonary artery pressure (mm Hg); MVA = mitral valve area (cm^2); MVG = mean mitral valve gradient (mm Hg); Pre (Post)-PMV = before (after) percutaneous balloon mitral valvotomy; PVR = pulmonary vascular resistance (dynes·s·cm^{-5}); other abbreviations and symbols as in Table 1.

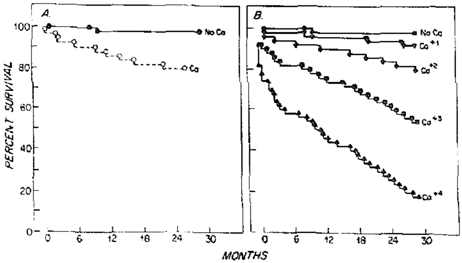

Figure 1. Estimated survival rate at 2 years after percutaneous mitral valvotomy, stratified by severity of calcification. Ca^{+1} to Ca^{+4} = calcification grades; No Ca = no calcifications.

and 144 (83%) without calcifications ($p = 0.004$). Of the patients who had a final mitral valve area ≥1.5 cm^2, a ≥2+ increase in mitral regurgitation occurred in 11 patients with and 12 patients without calcifications, and a ≥1.5:1 left to right shunt was detected in 7 patients with and 11 patients without calcifications. Thus, a successful immediate outcome was achieved in 80 (52%) patients with and 120 (69%) patients without calcifications ($p = 0.001$). The success rate was 59%, 48%, 35% and 33% in the 1+, 2+, 3+ and 4+ subgroups, respectively.

There were three procedure-related deaths in the group with calcifications: One patient in cardiogenic shock who had emergency percutaneous mitral balloon valvotomy died despite a technically successful and uncomplicated procedure; one patient died of left ventricular perforation and cardiac tamponade; and one patient died of intractable right ventricular failure during emergency mitral valve replacement. All deaths occurred early in our experience. There were no deaths in our last 200 patients.

Mitral regurgitation. Before percutaneous mitral balloon valvotomy, 76 (49%) patients with calcifications had a mitral regurgitation score of 1+ (63 patients) or 2+ (13 patients), and 42 (24%) patients without calcifications all had a score of 1+ ($p < 0.0001$). Increase in mitral regurgitation was similar in both groups (60 patients [39%] with, 69 patients [40%] without calcifications, p = NS). An increase ≥2+ occurred in 17 patients (11%) with and 16 patients (9%) without calcifications (p = NS).

Left to right shunting. A step-up between the oxygen saturations of right atrial and pulmonary artery blood samples ≥7% was detected in 27 patients (17%) with versus 24 patients (15%) without calcifications (p = NS). A left to right shunt with a pulmonary/systemic flow ratio ≥1.5:1 was detected after percutaneous mitral balloon valvotomy in 17 patients (11%) with versus 15 patients (9%) without calcifications (p = NS).

Follow-up. In addition to three procedure-related deaths there were 22 late deaths, 21 in patients with and 1 in patients without calcifications. The estimated survival rate at 2 years was significantly lower in patients with than without calcifications (80% vs. 99%, respectively, $p = 0.0001$) (Fig. 1). The estimated survival rate at 2 years in patients with calcifications became significantly poorer as the severity of calcification increased ($p < 0.00005$) (Fig. 1).

During the follow-up period, 31 patients underwent mitral valve replacement (21 patients with, 10 patients without calcifications). The estimated survival rate with freedom from mitral valve replacement at 2 years was significantly lower in patients with than without calcifications) (67% vs. 93%, respectively, $p < 0.00005$) (Fig. 2). The estimated survival rate with freedom from mitral valve replacement at 2 years in patients with calcifications became significantly poorer as the severity of calcification increased ($p < 0.00005$) (Fig. 2).

At the time of last follow-up contact, 76 patients with calcifications were in functional class I, 28 in class II, 8 in class III and none in class IV; 122 patients with calcifications were in functional class I, 26 in class II, 7 in class III and 1 in class IV. The estimated survival rate with freedom from mitral valve replacement and functional class III or IV at 2 years was significantly lower for patients with than without calcifications (63% vs. 88%, respectively, $p < 0.00005$). The actuarial survival rate with freedom from mitral valve replacement and functional class III or IV at 2 years in patients with calcifications became significantly poorer as the severity of calcification increased ($p < 0.00005$).

Discussion

Mitral valve calcification and immediate outcome of percutaneous mitral valvuloplasty. Our study demonstrates that the presence of fluoroscopically visible calcification on the mitral valve influences the success of percutaneous mitral valvuloplasty. The immediate and long-term outcome of percutaneous mitral balloon valvotomy in this study shows the importance of carefully evaluating the degree of mitral valve calcification by fluoroscopy to identify patients with mitral stenosis who are less likely to have a good outcome

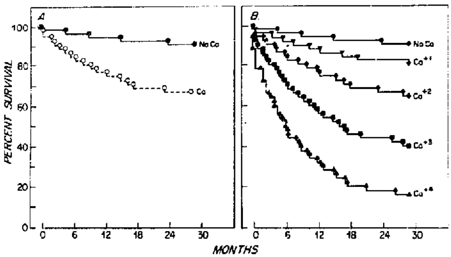

Figure 2. Estimated survival rate at 2 years with freedom from mitral valve replacement after percutaneous mitral balloon valvotomy, stratified by severity of calcification. Abbreviations as in Figure 1.

with mitral valvotomy. Although the amount of calcification does not affect procedural mortality or complications, patients with heavily (3+, 4+) calcified valves have a poorer immediate outcome than those with uncalcified valves, as reflected in a smaller mitral valve area and greater mitral valve gradient after percutaneous mitral balloon valvotomy. Immediate outcome is progressively worse as the calcification becomes more severe. Our findings are in agreement with those in previously reported studies. In the early years of closed commissurotomy, inadequate opening of the valve and early recurrence of symptoms were noted in patients with palpable calcium on the mitral valve (6). Radiologically visible mitral valve calcification was also found to be an adverse factor in surgically closed mitral commissurotomy (11). With open commissurotomy, mildly calcified valves can be successfully treated by commissurotomy, but heavily calcified valves are best treated by mitral valve replacement (12).

In this study, in contrast to poorer immediate hemodynamic outcome, the impact of calcification on procedural mortality and complications was not significant. There were no significant differences in postvalvuloplasty mitral regurgitation, left to right shunting or procedure-related mortality between the two groups.

The factors that predict mitral regurgitation after percutaneous mitral balloon valvotomy are controversial. Abascal et al. (13), in a relatively small study, showed that valvular anatomy is not a predictor of significant mitral regurgitation after mitral valvotomy. Roth et al. (14) reported that balloon size was the only predictor of significant mitral regurgitation after percutaneous mitral balloon valvotomy. Others (15) have shown the importance of the severity of valvular and subvalvular disease. In this study, patients with heavily calcified valves are not more likely to have mitral regurgitation than those with no or mild calcification. Sancho et al. (16) reported similar findings showing no relation between valvular calcification and mitral regurgitation after percutaneous mitral balloon valvotomy. Although our data suggest that patients with heavily calcified valves do not have a higher risk for developing significant mitral regurgitation, this cannot be taken as conclusive evidence because of the relatively small number of patients with heavily calcified valves and the low incidence of mitral regurgitation after percutaneous mitral balloon valvotomy in our study.

Mitral valve calcification and long-term follow-up after percutaneous mitral valvuloplasty. Mitral valve calcification also has a significant negative impact on the clinical follow-up of patients undergoing percutaneous mitral balloon valvotomy. Patients with calcified mitral valves have a lower survival rate, lower survival with freedom from mitral valve replacement and lower survival with freedom from both mitral valve replacement and functional class III or IV than patients with uncalcified valves. The results are worse as the severity of mitral valve calcification increases. For example, of patients with 3+ or 4+ mitral valve calcification, only 40% and 20%, respectively, were alive and free of mitral valve replacement at 2 years. In contrast, of patients without calcification, 85% were estimated to be alive, free of mitral valve replacement and in a functional class <III or IV at 2 years. These results are in agreement with several follow-up studies of surgical mitral commissurotomy that have shown that patients with calcified mitral valves had a significantly poorer survival rate than patients free of calcification (17,18).

Our study seems to indicate that it is wise not to advocate percutaneous mitral balloon valvotomy as the procedure of choice in patients with heavily calcified mitral valves because of the poor immediate and long-term results of the procedure. However, in the present study 25% of patients with 3+ calcification were alive, free of mitral valve replacement and in a functional class <III at 2-year follow-up. This percent should not be ignored because percutaneous mitral balloon valvotomy can markedly reduce a patient's physical and economic burdens compared with surgical treatment. What differentiates this 25% of patients with 3+ calcification who are good candidates for percutaneous mitral balloon valvotomy from the remaining 75% who are unfavorable candidates for this procedure is unknown. Although surgical treatment could be a better option for those patients with mitral stenosis and heavily calcified valves, percutaneous

mitral balloon valvotomy may be of use as a palliative procedure in those patients who are not surgical candidates because of associated major comorbid conditions.

Study limitations. Even though grading of mitral valve calcification was done by two of the investigators according to the same criteria, it was still an arbitrary classification. The semiquantitative grading of calcification may be a source of error. Cardiac output measurements were generally made by the thermodilution technique unless there was evidence of left to right shunt detected by oximetry. Shunts that were too small to be detected by oximetry were undoubtedly present in some patients. The presence of the shunts might have affected calculation of final mitral valve area; however, it is unlikely that these alterations had a major impact on the outcome of this study.

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