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ORIGINAL RESEARCH

Impact of Degree of Commissural Opening After Percutaneous Mitral Commissurotomy on Long-Term Outcome

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OBJECTIVES We sought to evaluate the prognostic value of the degree of commissural opening (CO) on outcome.

BACKGROUND Commissural opening is the main mechanism by which the mitral valve area (MVA) increases after percutaneous mitral commissurotomy (PMC) but its impact on long-term outcome has never been evaluated.

METHODS Of 1,024 consecutive patients with severe MS who underwent PMC, degree of CO was prospectively evaluated in 875 patients (age 48 ± 13 years, female 83%, New York Heart Association (NYHA) functional class III/IV 75%) with good immediate PMC results (MVA ≥1.5 cm^2 and no mitral regurgitation >2/4). These 875 patients were divided into 3 groups: both commissures only partially opened or not split (Group 1, n = 189), 1 commissure completely split (Group 2; n = 459), and both commissures completely split (Group 3; n = 227). During a follow-up of 55 ± 28 months, following clinical end points were collected: death, cardiovascular death, need for mitral valve surgery or repeat dilation, and NYHA functional class.

RESULTS Before PMC, patients in Group 1 were older, more often in NYHA functional class III/IV, but MVA and mean gradient were not different ($p \geq 0.50$). Immediately after PMC, there were significant differences between groups with regard to mean gradient (Group 1, 5.1 ± 2.1 mm Hg; Group 2, 4.5 ± 1.7 mm Hg; Group 3, 4.0 ± 1.6 mm Hg; $p < 0.0001$) and MVA (Group 1, 1.8 ± 0.2 cm^2; Group 2, 1.9 ± 0.2 cm^2; Group 3, 2.1 ± 0.3 cm^2; $p < 0.0001$). The 10-year rate of good functional results (survival without need for mitral surgery or repeat dilation and NYHA functional class I or II at last follow-up) was significantly higher in Group 3 (76 ± 5%) than in Groups 1 and 2 (39 ± 8% and 57 ± 11%, respectively; $p < 0.0001$). In multivariable analysis, either the degree of CO or the MVA was an independent predictor of good late functional results ($p < 0.05$).

CONCLUSIONS Complete CO is associated with larger MVA, smaller gradients, and functional improvement. The degree of CO provides important prognostic information and thus should be systematically evaluated during and after PMC and considered as a complementary measure of the procedural success in addition to the MVA, not always easy to assess. (J Am Coll Cardiol Img 2009;2: 1–7) © 2009 by the American College of Cardiology Foundation

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Since its development by Inoue in 1989, percutaneous mitral commissurotomy (PMC) has become an efficient and frequently used procedure to treat mitral stenosis (MS). Its safety and immediate efficacy have been widely demonstrated (1), and PMC is considered as the first-line treatment for symptomatic patients with a favorable anatomy (2,3).

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Commissural splitting is the main mechanism by which the mitral valve area (MVA) increases after PMC. Due to the heterogeneity of mitral valve alterations (degree of commissural fusion, valve fibrosis, and leaflet calcification), the anatomy of the mitral orifice after PMC is not uniform and widely varies from 1 patient to another with various degrees of commissural opening (CO): 1 or both commissures; complete, partial, or no commissural opening (4). In small pioneering series, CO has been associated with larger MVA (5–7), better leaflet mobility, and a better outcome (4). However, the impact of the degree of CO on long-term outcome has never been evaluated in a large population. We hypothesized that it may provide important prognostic information.

After a successful PMC, defined as an MVA $\geq$1.5 cm^2 or $\geq$1 cm^2/m^2 with no regurgitation >2/4, we identified 7 predictive factors of poor late functional results in 912 patients. Four are pre-procedural characteristics (advanced age, high New York Heart Association [NYHA] functional class, less favorable mitral valve anatomy, and atrial fibrillation [AF]), and 3 are related to the immediate results (low post-procedure MVA, high post-procedure mean transmitral gradient, and grade 2 post-procedure mitral regurgitation [MR]) (8). The aim of the present study was to evaluate, in this population, the prognostic value of the degree of CO.

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

CO = commissure opening

MR = mitral regurgitation

MS = mitral stenosis

MVA = mitral valve area

NYHA = New York Heart Association

PMC = percutaneous mitral commissurotomy

METHODS

Study population. From March 1986 to March 1995, 1,024 consecutive patients with severe MS (valve area <1.5 cm^2) residing in France underwent a PMC in our department. Contraindications to PMC were severe calcification of both commissures, left atrial thrombus on transesophageal echocardiography, and mitral regurgitation of grade >2. A good immediate result (MVA $\geq$1.5 cm^2 or $\geq$1 cm^2/m^2 with no regurgitation >2/4) was obtained in 912 patients. The degree of CO was prospectively recorded in 875 (96%) patients. These 875 patients constituted our study population.

Procedure. All procedures were performed by the anterograde trans-septal approach. A double balloon was used in 541 cases, and the Inoue balloon in the 334 cases (after October 1990), according to the stepwise technique, under echocardiographic guidance.

Echocardiographic measurements. Echocardiography was performed the day before and 24 to 48 hours after the procedure by experienced operators. MVA was measured by 2-dimensional echocardiography in parasternal short-axis view (planimetry). Mitral valve anatomy was classified into 3 classes according to transthoracic echocardiography and fluoroscopy, as previously described (1): flexible valves and mild subvalvular disease (chordae $\geq$10 mm long), flexible valves and extensive subvalvular disease (chordae <10 mm long), and calcified valves confirmed by fluoroscopy. Of note, in a subset of 40 patients, the mean $\pm$ SD (range) the Wilkins (9) score was 8.0 $\pm$ 0.8 (7 to 9) for echocardiographic Class 1, 9.9 $\pm$ 1.3 (8 to 12) for Class 2, and 12.5 $\pm$ 1.3 (10 to 15) for Class 3. Mean transmitral gradient was assessed by continuous-wave Doppler. Measurement of the systolic pulmonary artery pressure was based on the maximal velocity of the tricuspid regurgitation. Mitral regurgitation was semiquantitatively graded from 0 to 4 (10). The degree of CO was prospectively and semiquantitatively evaluated as none, partial (up from only several millimeters from the valve orifice), or complete (up to the level of the mitral annulus) in a parasternal short-axis view from a detailed echocardiographic examination with multiple scanning of the entire mitral valve apparatus from the left ventricle to the left atrium. A complete CO was defined as a complete disruption of the mitral valve co-optation line at the level of the annulus in diastole; a partial CO was defined as a partial disruption with a clear co-optation point between the anterior and posterior leaflets (Fig. 1). Patients were divided into 3 groups: Group 1 if both commissures were either not split or only partially open, Group 2 if 1 commissure was completely split, and Group 3 if both commissures were completely split (Fig. 1).

Follow-up. Follow-up was based on visits to the department or on a standardized questionnaire sent to

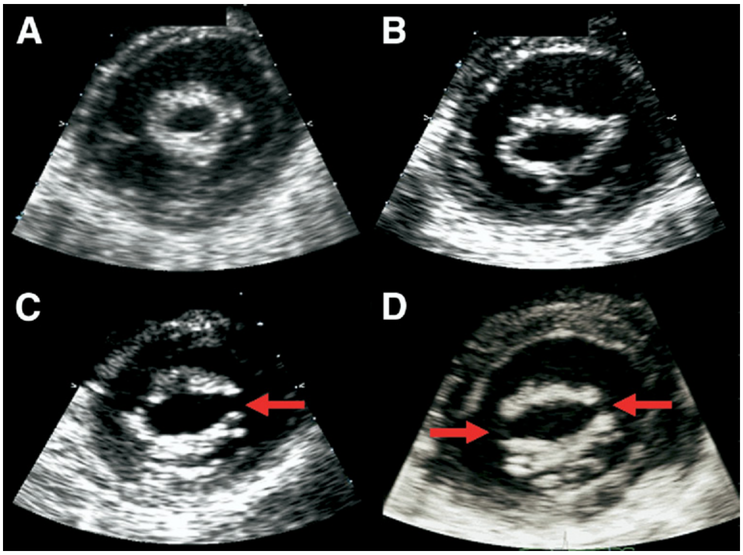

Figure 1. Mitral Orifice Before Commissurotomy and Commissural Openings

(A) Examples of mitral orifice before commissurotomy and commissural openings in the 3 groups. **(B)** In Group 1, both commissures were either not split or only partially open. **(C)** In Group 2, 1 commissure is completely open **(arrow)**. **(D)** In Group 3, both commissures are completely open **(arrows)**.

the patient's cardiologist. The following clinical end-points were collected: death, cardiovascular death, need for mitral surgery or repeat dilation, and NYHA functional class. A good functional result (composite end point) was defined as survival considering only cardiovascular death with no need for mitral surgery or repeat dilation and a patient in NYHA functional class I or II at most recent follow-up.

Statistical analysis. Results were expressed as mean ± SD or percentage. Group comparisons were performed with analysis of variance, and the chi-square or *t* test as appropriate. Cumulative survival curves were determined for the clinical events and the composite end point of good functional results according to the Kaplan-Meier method. Survival status was censored at the time of surgery or repeat dilation. The log-rank test was used for comparison of rates of long-term functional results among the 3 groups of patients. A Cox proportional hazards analysis was performed to evaluate the predictive value of the degree of CO after adjustment for the 7 previously identified predictive factors of long-term functional results (age, NYHA functional class, mitral valve anatomy class, rhythm, post-procedure MVA, post-procedure MR grade, and post-procedure mean gradient). The multivariable analysis was also performed including all pre- and post-procedural variables. When included in the multivariable analysis, continuous variables were divided into subgroups with the same clinically chosen cutoff points that have been used in a previous analysis of this series (8).

Agreement between operators and for the same operator (interobserver and intraobserver variability) of the degree of CO assessment was evaluated by the kappa value. Analyses were performed using SAS statistical software (SAS Institute, Cary, North Carolina). A p value <0.05 was considered significant.

RESULTS

Baseline characteristics. The mean age of the 875 patients was 48 ± 13 years (range 16 to 86 years) and 726 were females (83%). Approximately one-third were in AF. Most of the patients were in NYHA functional class III/IV. A previous commissurotomy had been performed in 130 (15%) patients, a mean of 15 ± 8 years earlier (surgical commissurotomy in 120 patients and PMC in 10 patients). In all, 130 (15%) patients had flexible valve and mild subvalvular disease (chordae ≥10 mm long), 513 (59%) patients had flexible valve and extensive subvalvular disease (chordae <10 mm long), and 232 (26%) patients had calcified mitral valve confirmed by fluoroscopy. Baseline characteristics of these 875 patients are summarized in Table 1.

Table 1. Clinical and Echocardiographic Characteristics of the Study Population Before and After PMC

	Overall (n = 875)	Group 1 (n = 189)	Group 2 (n = 459)	Group 3 (n = 227)	p Value Between Groups
Clinical variables					
Age, yrs	48 ± 13	53 ± 13	47 ± 13	47 ± 13	<0.0001
Female	726 (83%)	161 (85%)	382 (83%)	183 (81%)	0.46
NYHA functional class III/IV	657 (75%)	155 (82%)	333 (72%)	169 (75%)	0.04
Sinus rhythm	543 (62%)	105 (56%)	291 (63%)	147 (65%)	0.11
Previous commissurotomy	130 (15%)	30 (16%)	64 (14%)	36 (16%)	0.73
Cardiothoracic index	51 ± 5	52 ± 5	51 ± 5	50 ± 5	0.0009
Echocardiographic variables					
Before PMC					
Mitral valve area, cm^2	1.08 ± 0.22	1.09 ± 0.22	1.07 ± 0.22	1.08 ± 0.23	0.55
Mean gradient, mm Hg	10.1 ± 4.5	9.9 ± 4.2	10.2 ± 4.7	10.1 ± 4.1	0.68
Mitral regurgitation grade 1 or 2	311 (36%)	78 (41%)	162 (35%)	71 (31%)	0.10
After PMC					
Mitral valve area, cm^2	1.94 ± 0.27	1.77 ± 0.19	1.93 ± 0.25	2.10 ± 0.27	<0.0001
Mean gradient, mm Hg	4.5 ± 1.8	5.1 ± 2.1	4.5 ± 1.7	4.0 ± 1.6	<0.0001
Mitral regurgitation grade 2	184 (21%)	42 (22%)	111 (24%)	31 (14%)	0.0006

Data presented are number of patients (%) or mean ± SD.
NYHA = New York Heart Association; PMC = percutaneous mitral commissurotomy.

Immediate results. After PMC, the mean MVA increased from 1.08 ± 0.22 cm^2 to 1.94 ± 0.27 cm^2, and the mean transmitral gradient decreased from 10.1 ± 4.5 mm Hg to 4.5 ± 1.8 mm Hg (both $p < 0.0001$). Both commissures were either only partially open or not split in 189 (22%) patients (Group 1), 1 commissure was completely split in 459 (52%) patients (Group 2), and both commissures were completely split in 227 (26%) patients (Group 3). Intraobserver and interobserver variability was assessed in 20 patients. Agreement was good, with a kappa value of 0.74 and 0.78, respectively. Of note, most of the discrepancies observed were between partial and not opened commissures.

Patients in Group 1 were older and more often in NYHA functional class III/IV, but pre-procedure mean gradient and MVA were not different between groups. In contrast, there were significant differences with regard to post-procedure mean transmitral gradient (5.1 ± 2.1 mm Hg in Group 1, 4.5 ± 1.7 mm Hg in Group 2, and 4.0 ± 1.6 mm Hg in Group 3; $p < 0.0001$) and MVA (1.77 ± 0.19 cm^2 in Group 1, 1.93 ± 0.25 cm^2 in Group 2, and 2.10 ± 0.27 cm^2 in Group 3; $p < 0.0001$) (Table 1, Fig. 2). Thus, mean transmitral gradient decreased and MVA increased with the degree of CO.

Impact of commissural splitting on late functional results. Follow-up was complete in all patients. Mean follow-up duration was 55 ± 28 months

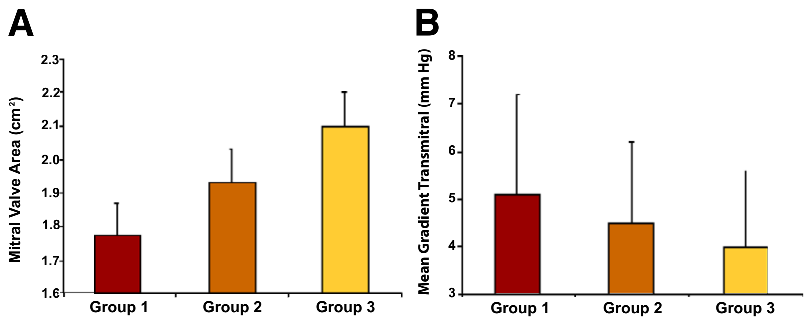

Figure 2. Differences in Post-Procedure Mean Mitral Gradient and Mitral Valve Area Among the 3 Groups

Post-procedure mean mitral gradient and mitral valve area according to groups as defined in Figure 1. Mitral valve area progressively increased and mean gradient progressively decreased with the number and the extent of commissural openings.

(range 1 to 132 months). During follow-up, 40 deaths (20 cardiovascular deaths) were observed, 102 patients underwent repeat PMC or mitral valve surgery, and 142 patients had worsening symptoms. In the entire population, 5- and 10-year event rates were, respectively, 95 ± 1% and 88% ± 4% for global survival (40 deaths), 97 ± 1% and 95 ± 2% for survival considering only cardiovascular-related death (20 deaths), 86 ± 1% and 68 ± 5% for survival with no need for surgery or repeat dilation (122 events), and 81 ± 2% and 62 ± 5% for good functional results (survival considering only cardiovascular death with no need for mitral surgery or repeat dilation and the patient in NYHA functional class I or II at most recent follow-up; 162 events). Rates for good functional results were significantly different among the 3 groups at 10 years (5 years): 39 ± 8% (73 ± 4%) in Group 1, 57 ± 11% (83 ± 2%) in Group 2, and 76 ± 5% (87 ± 3%) in Group 3 ($p < 0.0001$) (Fig. 3).

In multivariable analysis using a Cox model and the 7 previously identified predictive factors of poor late functional results (age, NYHA functional class, mitral valve anatomy, AF, post-procedure MVA, post-procedure mean transmitral gradient, and post-procedure MR grade), either the degree of CO or the MVA was an independent predictor of good late functional results ($p < 0.05$). Of note, similar results were observed when the multivariable analysis was performed including all pre- and post-procedure variables in the model.

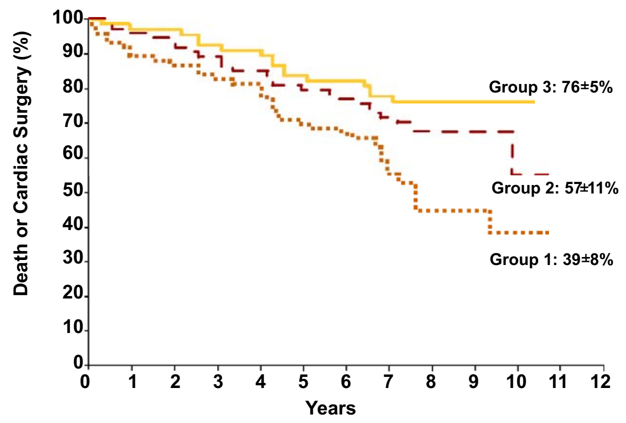

Figure 3. 10-Year Rates of Good Functional Results in the 3 Groups

Impact of commissural opening on late functional results. During a mean follow-up duration of 55 ± 28 months, the 10-year rates of good functional results (survival considering only cardiovascular death with no need for mitral surgery or repeat dilation and patient in New York Heart Association functional class I or II at most recent follow-up) was significantly different among the 3 groups ($p < 0.0001$). Groups are as defined in Figure 1.

DISCUSSION

In this large series of patients with MS, we show that complete CO is associated with larger MVA, smaller mean transmitral gradient, and functional improvement, and that the degree of CO provides important prognostic information.

Since its introduction by Inoue et al. (11) in 1984, PMC has been successfully and safely performed in large series of patients at numerous centers (8,12–15). PMC is now the treatment of choice for patients with MS and favorable anatomy (2,3). It provides results similar to those of surgical commissurotomy, even if the comparison of percutaneous and surgical series may be biased owing to differences in patients' clinical and mitral valve characteristics (16–18). Pioneering clinical and pathology studies have shown that CO is the main mechanism by which MVA increases after balloon valvuloplasty (percutaneous commissurotomy) (4). Commissural calcification, an important predictor of unsuccessful commissurotomy and failure of CO (19,20), is associated with a poor midterm event-free survival and a high incidence of mitral valve replacement. However, the relationship between the degree of CO and post-procedural MVA has never been extensively evaluated. In this large-scale study, we demonstrate that MVA progressively increases with the number and the extent of CO. It is worth noting that approximately two-thirds of patients referred for PMC had at least 1 completely open commissure.

Several important prognostic factors have been identified after successful PMC. Older age, less favorable anatomy (valve calcifications, severe subvalvular disease, echocardiography score), long-lasting disease (previous commissurotomy, atrial fibrillation, NYHA functional class IV, high systolic pulmonary artery pressure, severe tricuspid regurgitation), and less satisfactory immediate results (low post-procedure MVA and high post-procedure mean transmitral gradient) have been uniformly associated with a worst outcome (2,3,8,13,15). Few studies have aimed at evaluating the prognostic impact of the degree of CO on outcome. In a small pioneering study of 30 patients, Fatkin et al. (4) observed a better outcome for patients with than without CO. In a large and more recent study, commissural MR, as a surrogate for complete CO, was an independent predictor of restenosis and survival (21). In the present study, complete CO was associated with larger MVA, smaller mean gradient, and better functional outcome. In multivariable analysis, either the degree of CO or the MVA was an independent predictor of good late functional results ($p < 0.05$).

Our study, showing for the first time the prognostic value of the degree of CO, has important clinical implications. Pre- and post-procedural evaluations of PMC results are based on echocardiographic assessment of the MVA. PMC is usually guided by echocardiography, and a decision to stop the procedure, in the absence of complications, is often based on MVA measurement. Planimetry is considered as the reference method but must be precisely performed at the tip of the leaflets, and therefore requires experienced operators (2). Moreover, the planimetry is not always feasible. Other methods also have their own limitations. The pressure half-time method (22) is commonly used, but it has been demonstrated that this method should be used cautiously especially for patients older than 60 years, in AF, or immediately after percutaneous balloon commissurotomy (23,24). The continuity equation is invalidated by the commonly associated aortic or mitral regurgitation (25). The proximal isovelocity surface area method is accurate and reproducible (26) but reputedly technically demanding and time-consuming; consequently, it is rarely used in practice.

All these limitations are even more important during the procedure in the catheterization laboratory where echocardiographic conditions are suboptimal. In contrast, degree of CO is relatively easy to assess and can be considered as a complementary measure of procedural success. These results also strengthen the importance of echocardiographic guidance of the procedure because hemodynamic variables are still used by some operators as the only criteria to determine when the procedure should be stopped. We recommend that further inflations with larger balloon volumes (30-mm balloon fully inflated with 30 ml) should be performed, and the procedure (in the absence of complication) not terminated before a complete opening of least 1 commissure is achieved. It is worth noting that even with this aggressive attitude, we could not obtain a complete CO in 22% of our patients. Thus, the achievement of a complete and bicommissural opening must remain a major goal during PMC, and the degree of CO is an easy and simple predictor of long-term functional result.

The present study deserves several comments. First, degree of CO is the cornerstone of our results. In contrast to the MVA, which is quantitative and continuous, the degree of CO was assessed semi-quantitatively, as described in Methods, but the intraobserver and interobserver variability was good. In our opinion, the degree of CO is difficult to measure quantitatively because it is hard to define exactly where the commissure starts. Second, the degree of CO was evaluated using 2-dimensional echocardiography. We have previously shown that 3-dimensional echocardiography provides a better assessment of the degree of CO than 2-dimensional echocardiography (27). The impact of this new modality of commissural assessment needs further evaluation. Third, when both the MVA and degree of CO were entered in the model, the degree of CO was not an independent predictor of outcome, meaning that the degree of CO and MVA is closely related and that its prognostic value is superseded by that of the MVA. The same results were observed overall and for patients above or below the median MVA. Furthermore, when the multivariable analysis was performed in the total population (whether or not PMC was successful, excluding patients with severe mitral regurgitation), the degree of CO provided additional prognostic value. A possible mechanistic explanation is that in patients with intermediate PMC results, a complete CO may provide a better adaptation to exercise. These results further emphasize the importance of achieving at least 1 complete CO during the procedure. Finally, we did not assess the morphology of the commissure before the procedure and thus examine the relationship between pre-procedural commissural anatomy and the degree of CO after PMC.

CONCLUSIONS

The present study demonstrates, in a large series of patients, that CO degree and MVA are closely related. After PMC, MVA increases and mean transmitral gradient decreases with the degree of CO. The degree of CO provides important prognostic information, and complete CO is associated with better late functional results. Thus, degree of CO should be systematically evaluated during and after PMC and can be considered as a complementary measure of the procedural success in addition to the MVA, which is not always easy to assess.

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Key Words: mitral stenosis ■ percutaneous mitral commissurotomy ■ functional improvement ■ echocardiography ■ mitral valve area.