Balloon Mitral Valvotomy after Surgical Commissurotomy: Clinical and Hemodynamic Results of a Large, Single-Center Study

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Background and aim of the study: **Patients with restenosis after open or closed surgical commissurotomy (SC) often demonstrate more severe valve degeneration than patients without prior surgery. This may affect the result of balloon mitral valvotomy (BMV) in this patient group.**

Methods: **The immediate- and long-term results (maximum 106 months; mean 26 months) of BMV with the Inoue balloon in patients with prior SC were compared with findings in patients without prior surgery. Between February 1989 and July 2001, a total of 1,156 BMV interventions was performed, of which 127 were conducted in patients (106 women, 21 men; mean age 56 ± 12 years) with prior SC.**

Results: **After BMV, the mitral valve area (MVA) increased from 1.0 ± 0.2 cm² to 1.6 ± 0.4 cm² after SC compared with 1.0 ± 0.3 cm² to 1.8 ± 0.4 cm² without SC. After three months, the average MVA was 1.7 ± 0.3 cm² in both patient groups. The mean NYHA class improved from 2.8 to 2.0 (after SC) versus 2.7 to 1.8 (no SC) three months after BMV. The main complications were cardiac tamponade in three patients (2.4 %), and more than moderate mitral regurgitation (grade 2+) in six (4.7 %) compared to 5.8% in no-SC patients.**

Conclusion: **In view of the satisfactory clinical and hemodynamic results, BMV with the Inoue balloon can be considered the treatment of choice for mitral valve restenosis after SC in selected patients.**

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Balloon mitral valvotomy (BMV), which was first described by Inoue et al. in 1984 (1), is a widespread and effective method for the treatment of patients with symptomatic mitral stenosis and suitable valvar morphology. Good immediate- and long-term results have been documented in numerous single-center and multicenter studies (2-8). Many series have included patients with previous surgical commissurotomy (SC). However, studies comparing patients with and without previous surgical interventions are scarce, or report only on small numbers of cases. Herein are presented the results of a large, single-center series in which the immediate- and long-term outcome was determined of patients with and without previous SC who underwent BMV.

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Clinical material and methods

Patients

Between February 1989 and July 2001, a total of 1,156 BMV investigations was performed using the Inoue balloon. Of these procedures, 127 were conducted in patients who had undergone SC of the mitral valve at a mean of 20.4 ± 5.1 years previously. The mean age of the patients (106 women, 21 men) was 56 ± 12 years; this was almost identical to the age in the non-surgical group. The clinical characteristics of both patient groups are summarized in Table I.

Patients with mitral restenosis after SC were excluded from treatment with BMV and referred for surgery only in case of: more than moderate mitral regurgitation (MR) (grade 2+); significant coexistent disease of another valve; significant coronary artery disease; thrombi in the left atrium visualized by transesophageal echocardiography; and significant, especially eccentric calcification of the mitral valve (Wilkins score >12), except for one patient with an expected high perioperative risk due to severe obstructive lung disease. These included 29 of 156 consecutive patients (18.7%) during the study period, of whom 28 under-

Table I: Clinical features of patients with and without prior surgical commissurotomy (SC).

Parameter	Prior SC (n = 127)	No prior surgery (n = 1,029)	p-value
Age (years)			
Mean*	56 ± 12	56 ± 13	NS
Range	24-78	20-85	
Female gender	106 (83)	819 (80)	NS
NYHA class			
I	0	0	
II	42 (33)	401 (39)	
III	83 (65)	604 (59)	
IV	2 (2)	24 (2)	NS
Atrial fibrillation	80 (63)	540 (52)	0.06
Previous embolism	26 (20)	215 (21)	NS
Cardiothoracic ratio*	0.58 ± 0.08	0.53 ± 0.06	0.027

*Values are mean ± SD.
Values in parentheses are percentages.
NS: Not significant.

went mitral valve replacement with an operative mortality of 7.1% (n = 2). One patient refused to undergo the recommended reoperation.

Investigations

Before BMV, all patients underwent resting and exercise electrocardiography, phonocardiography, chest X-radiography and transthoracic and transesophageal echocardiography. The mitral valve was evaluated according to the Wilkins score (9), and the present authors' score, as published previously (10). The latter score describes the position of the residual mitral valve ostium in correlation to the mitral annulus (central or eccentric), the pliability of the leaflets, the degree of calcification of the commissures, and the thickening/fusion of the subvalvar structures with a maximum of 12 points for pathological findings with eccentricity as the most predictive parameter. The pre-interventional echocardiographic findings are summarized in Table II.

Prior to BMV, hemodynamics were evaluated by complete right and left heart catheterization via the femoral approach. Trans-septal puncture was performed using the Brockenbrough technique. Aortic

Table II: Echocardiographic parameters before balloon mitral valvotomy (BMV).

Parameter	Prior SC	No prior surgery	p-value
Left atrium (mm)*	55 ± 10	53 ± 8	0.0025
MR grade I-II	50 (39)	427 (41)	NS
Mitral valve area (cm^2)*	1.0 ± 0.2	1.0 ± 0.3	NS
Bad Oeynhausen score			
No. of patients	91	774	
0-4	48 (53)	426 (55)	
5-8	32 (35)	286 (37)	
>8	11 (12)	62 (8)	0.26 (NS)
Wilkins score			
No. of patients	86	739	
1-4	1 (1)	33 (4)	
5-8	54 (63)	434 (59)	
9-12	30 (35)	272 (37)	
>12	1 (1)	0	0.4 (NS)

*Values are mean ± SD.
Values in parentheses are percentages.
MR: Mitral regurgitation; NS: Not significant; SC: Surgical commissurotomy.

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Table III: Hemodynamic parameters before and after balloon mitral valvotomy (BMV) in both groups.

Parameter*	Prior SC	No prior surgery	p-value
MVA (cm^2) before BMV	1.0 ± 0.2	1.0 ± 0.3	NS
MVA (cm^2) after BMV	1.6 ± 0.4	1.8 ± 0.4	<0.0001
MVG (mmHg) before BMV	13 ± 5	14 ± 6	NS
MVG (mmHg) after BMV	8 ± 3	7 ± 3	0.0008
LAm (mmHg) before BMV	23 ± 6	23 ± 7	NS
LAm (mmHg) after BMV	18 ± 6	16 ± 6	0.1 (NS)
PAm (mmHg) before BMV	31 ± 10	32 ± 10	NS
PAm (mmHg) after BMV	29 ± 10	28 ± 9	0.4 (NS)
CI ($l/min/m^2$) before BMV+	2.4 ± 0.5	2.4 ± 0.6	NS
CI ($l/min/m^2$) after BMV+	2.7 ± 0.6	2.7 ± 0.7	0.3 (NS)

*Values are mean ± SEM.
+Determined by the thermodilution method.
CI: Cardiac index; MVA: Mitral valve area; MVG: Mitral valve gradient; LAm: Mean left atrial pressure; PAm: Mean pulmonary artery pressure; SC: Surgical commissurotomy.

and pulmonary oxygen saturations were measured before and after BMV (with the Inoue balloon left in place to eliminate the influence of atrial left to right shunting). Cardiac output was measured according to both, the Fick formula and thermodilution. Mitral valve area (MVA) was calculated with the Gorlin formula, and the mean mitral valve gradient by planimetry from simultaneous left atrial and left ventricular pressure recordings. The balloon size was chosen according to the echocardiographic measurement of the valve annulus diameter utilizing the formula:
Balloon diameter (mm) = [patient height (cm) - 100 + 10]/3.

Valve dilation was performed stepwise, starting with a balloon which was approximately 2 mm smaller than the target balloon. After each inflation, and before choosing a large diameter, simultaneous measurements of left atrial and left ventricular pressure were repeated and the degree of MR assessed by echocardiography. The procedure was terminated in case of a new or increasing MR, or when the commissures were opened fully or as much as could be expected from the echocardiographic findings. After the procedure, a potential left to right shunt was assessed oxymetrically.

Before discharge, patients were re-examined using echocardiography.

Follow up

Follow up examinations, which included resting and exercise electrocardiography, phonocardiography, chest X-radiography and transthoracic echocardiography, were performed after three months, and subsequently every one to two years.

Results

The pre- and post-interventional MVAs (invasive measurement), mean valvar gradients, mean left atrial and pulmonary artery pressures and cardiac index for the two study groups are summarized in Table III. In total, 107 of the 127 patients (84%) with prior SC had a satisfactory result (MVA ≥1.5 cm^2 or an increase in valve area by ≥50%). Ten patients had an unsatisfactory increase in MVA, and underwent mitral valve replacement at between 1 and 32 months after the intervention. In the group without prior surgery the success rate was 88% (909 of 1,029 patients) (p = 0.025 for the difference in success rate between the two groups).

Complications

Following SC, 116 of the BMV were uncomplicated. The remaining cases were complicated by cardiac tamponade requiring surgical drainage (n = 3); more than moderate (2+) MR (n = 6); and left to right shunts ≥30% following trans-septal puncture (n = 2). The complications rates for the two groups are listed in Table IV.

Three-month follow up

When assessed by echocardiography, the mean MVA was 1.7 ± 0.3 cm^2 in both patient groups (at three months.). The left atrial diameter decreased from 55 ± 10 mm to 53 ± 11 mm in the group with prior SC, and from 53 ± 8 mm to 50 ± 9 mm in the control group.

Sixty-five patients (51%) with prior SC had mild or moderate MR, and five (3.9%) had more than moderate (grade 2+) MR. Six patients (4.7%) had undergone mitral valve replacement during the first three follow up months. In the control group, 588 patients (57%)

Table IV: Complications (no significance for any complication specified).

Complication	Prior SC	No prior surgery
Pericardial tamponade	3 (2.4)	10 (1.0)
MR (grade 2+)	6 (4.7)	60 (5.8)
Left to right shunt of ca. 30%	2 (1.6)	13 (1.3)
Embolism (transient symptoms)	0 (0)	8 (0.8)
Periprocedural death (1-7 days after BMV)	1 (0.8)	3 (0.3)
Total	12 (9.4)	97 (9.4)

Values in parentheses are percentages.
BMV: Balloon mitral valvotomy; MR: Mitral regurgitation; SC: Surgical commissurotomy.

had mild to moderate MR, and 38 (3.7%) more than moderate (2+) MR. Twenty-three (2.2%) had mitral valve replacement. At three months, the average MR was significantly more severe in the group with previous SC ($p = 0.0049$).

The maximum workload achieved during bicycle exercise was increased from 73 ± 24 to 84 ± 30 W ($p = 0.0073$) in patients with previous SC, and from 77 ± 31 to 92 ± 35 W in those without surgery ($p <0.0001$).

The mean NYHA class improved from 2.8 to 2.0 after three months (patients with previous surgery) ($p <0.0001$), and from 2.7 to 1.8 ($p <0.0001$), respectively (Table V). Patients without prior surgery had a significantly lower NYHA class at three months after BMV than did patients with prior surgery ($p <0.0001$).

Long-term follow up

During a mean follow up of 26 months (range: 3 to 106 months), 98 of the patients with prior surgery (77%) presented with satisfactory clinical and echocardiographic results, while 27 patients underwent mitral valve replacement between 1 day and 80 months after BMV. Two patients died during the follow up period.

Among the non-surgical group, 860 patients (84%) had satisfactory results during a mean follow up of 39 months (range: 3 to 139) months, 140 had mitral valve replacement, and 29 died.

Discussion

Recurrent mitral valve stenosis occurring within five to ten years is found in 10-30% of patients with successful mitral commissurotomy (11,12). The frequency, however, is estimated somewhat arbitrarily, as prospective echocardiographic or hemodynamic follow up studies are lacking. In patients with mitral valve restenosis after mitral commissurotomy, a second surgical commissurotomy carries a significantly higher mortality (6.7% versus 13%) than the first operation (12,13). The risk for bleedings with subsequent need for transfusions, as well as the risk for mediastinal infections, are also reported to be higher. Therefore, BMV - with its very low complication rates in experienced hands - must be considered an attractive therapeutic alternative.

The results of BMV after (open or closed) SC have been described in small series or from multicenter studies (14-19), and two larger cohorts were generated utilizing the NHLBI Balloon Valvuloplasty Registry (n = 133) (20) and the Paris database (n = 232) (21). These studies give inconsistent results, however. Whereas some authors found comparable clinical results for patients with and without previous SC (15,16,18,19), others noted a smaller gain in MVA and less sustaining results for patients with previous SC (20). Several authors reported on valvar morphology as a crucial factor for the result. For example, Serra et al. (16) found

Table V: Frequency of NYHA classes in both groups before and 3 months after balloon mitral valvotomy (BMV).

NYHA class	Prior SC		No prior surgery	
	Before BMV	3 months after BMV	Before BMV	3 months after BMV
I	0	33 (26)	0	330 (32)
II	42	70 (55)	401	650 (63)
III	83	24 (19)	604	49 (5)
IV	2	0	24	0

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valve morphology to be the most predictive factor for a successful BMV - independent of previous surgery. Jang et al. (17) reported on a slightly smaller increase in MVA if patients had had previous surgery, while results were comparable for patients with previous surgery but with an echocardiographic score <8. Medina et al. (20) suggested that the indication for BMV should mainly be based on clinical and echocardiographic findings, independent of previous surgery. In contrast, Gupta et al. reported similar results for young (mean age 28 years) unoperated and operated patients, despite a higher echocardiographic score of the operated subjects (18). Iung et al. (21) recently reported good initial hemodynamic results for 82% of their patients with previous SC who underwent BMV; notably, 48% of their patients still presented with favorable results after eight years.

Previous studies have also documented significant differences with respect to the incidence of technical failure, severe MR or death in patients with previous surgical commissurotomy. Serra et al. (16) identified technical failures and major complications in 11% of their patients, while Medina et al. (15) noted severe MR in 9.5% and death in 4.7% of cases. Other authors have reported a low complication rate however, and it is presumed that this might be due to the use of the Inoue balloon (which is shorter and more flexible than other devices and does not require stiff guidewires) and a stepwise dilatation method (as used by the present authors) instead of the one-step dilatation double-balloon technique (19,21).

The results of the present study, which was one of the largest single-center studies yet reported, also confirmed the safety of BMV using the Inoue balloon for patients who had previous SC. The total complication rate in this study was similar in patients with and without prior surgery. This was remarkable, as the average patient age (56 ± 12 years) - although identical in both patient groups - was much higher than in previously published series. The same age of patients with a first (BMV) versus second intervention (SC plus BMV) may be due to differences in the progression of MS after the initial rheumatic fever (22).

Patients with a previous SC had a higher prevalence of atrial fibrillation, a larger left atrium and cardiothoracic ratio, and a slightly less favorable valvar morphology. For the immediate hemodynamic results after BMV, there were small but statistically significant differences between the two groups with respect to MVA and valvar gradients, but not in mean pulmonary artery and left atrial pressures or cardiac index. During the follow up period, patients without prior SC had a better functional outcome, which at least in part may be related to the lower prevalence of atrial fibrillation in this group.

In conclusion, in view of the low incidence of complications and the satisfactory clinical and hemodynamic results, which were consistent in 77% of the present patients over a maximum follow up period of 106 months (mean 26 months), BMV with the Inoue balloon should be considered as the treatment of choice for patients with mitral restenosis after previous surgical commissurotomy in selected cases.

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