Impact of Failed Mitral Clipping on Subsequent Mitral Valve Operations

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Background. **This study analyzed the effect of failed percutaneous mitral intervention with the MitraClip device (Abbott Laboratories, Abbott Park, IL) on subsequent mitral valve (MV) operations.**

Methods. **Nineteen patients (74 ± 9 years) with treatment failure after implantation of 37 MitraClips (mean, 1.9 ± 0.8; range, 1 to 4) for functional or degenerative MV disease underwent operations a median of 12 days later (range, 0 to 546 days). All patients were studied before and after the operation by clinical investigation and echocardiographic analysis. Intraoperative findings and the effect on the operation were analyzed and are described in detail. Data before clipping and at the time of operation were compared, and the surgical outcome was recorded.**

Results. **There was a significant increase in risk between that at the time of clipping and that at subsequent operations, noted as a rise of the European System for Cardiac Operative Risk Evaluation II from a median 12.74% to 26.87%, respectively ($p < 0.0001$, Wilcoxon signed rank test). Severe clip implantation-induced tissue damage was found in most patients. Surgical MV repair could be performed in 5 of 6 patients (83%) with a 1-clip implant and in only 3 of 13 patients (23%) when 2 or more clips had been inserted ($p = 0.0188$, Wilcoxon–Mann-Whitney test). All patients required other associated procedures: closure of an artificial atrial septal defect that was caused by the clipping procedure (100%), tricuspid valve repair (37%), atrial fibrillation ablation operations (37%), coronary artery bypass grafting (16%), and aortic valve replacement (11%). Two early cardiac deaths (< 30 days) occurred. Survival at 1 year was 68%.**

Conclusions. **There is a remarkable impact of failed clipping procedures on MV operations. We observed a severely aggravated cardiac pathology in parallel with a reduced preoperative clinical state compared with the original condition. Moreover, the likelihood of an optimal surgical solution with valve reconstruction was reduced thereafter. However, operations in the critical situation of an unsuccessful mitral clipping procedure should be discussed immediately, because it still seems to be an option compared with conservative therapy.**

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For the treatment of relevant mitral regurgitation (MR), the MitraClip device (Abbott Laboratories, Abbott Park, IL) has been described as an alternative to operations or medical therapy and was outlined as an option for high-risk patients in the 2012 European Society of Cardiology/European Association for Cardio-thoracic Surgery Guidelines [1–5]. However, long-term data of larger patient cohorts after mitral clipping are nonexistent. In addition, little is known about surgical options after failed, insufficient, or unsuccessful MitraClip implantation, and the effects on subsequent operations are unknown. We report our clinical experience with 19 patients who underwent MV operations after failed mitral clipping procedures. Patient characteristics, intraoperative findings, and the effect on surgical strategy are analyzed and described in detail.

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Patients and Methods

The Hamburg General Medical Council Ethics Committee approved the protocol for this study.

Preoperative State

We investigated 19 consecutive patients who underwent open heart operations between October 2009 and July 2012. All patients had undergone a mean of 1.9 ± 0.8 MitraClip procedures (total, 37; range, 1 to 4) for MV disease that was functional or degenerative, or both, from September 2009 to June 2012. They were presented for surgical repair by the authorized cardiologists who had performed the clip implantations, consisting of two very experienced groups of interventional cardiologists who had started with mitral clipping in 2009 (together these groups perform, at the present time, about 150 to 200 clipping procedures per annum).

After intensive discussion, we accepted all patients for surgical intervention. We had no general exclusion criteria except severe sepsis or on-going cardiopulmonary resuscitation; these exclusion criteria did not apply. The operations were performed a median of 12 days after clip

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Abbreviations and Acronyms

AC = anterior commissure
ASD = atrial septal defect
EuroSCORE II = European System for Cardiac Operative Risk Evaluation II
EVEREST = Endovascular Valve Edge-to-Edge Repair Study
LA = left atrium
MR = mitral regurgitation
MV = mitral valve
MVA = mitral valve area
NYHA = New York Heart Association
PC = posterior commissure
TAVI = transcatheter aortic valve intervention

implantation (range, 0 to 546 days). Ten patients underwent procedures within 30 days after clip implantation, and 9 were operated on more than 30 days later (4 of them at > 1 year). The primary indication for percutaneous MV therapy had been assessment of high surgical risk (European System for Cardiac Operative Risk Evaluation [EuroSCORE] II >10%; median, 12.74% [lower quartile, 5.83%; upper quartile, 18.36]; n = 13), for example, because of prior open heart surgery in 7, advanced age exceeding 75 years in 7, or reduced left ventricular ejection fraction of 0.39 or less in 12. The EuroSCORE II uses 17 patient-related and cardiac-related factors.

Three patients with a lower risk profile had initially refused an open heart operation and definitely wanted an interventional approach instead. All patients now suffered from severe recurrent or persistent MV disease after clipping, despite adequate medical therapy. Before and after their operations, they received standard heart failure medications. Before their operations, 12 patients were in sinus rhythm, and 7 had atrial fibrillation. Two patients were accepted for operations in an emergency situation. Detailed data of patient characteristics are given in Table 1.

Table 1. Patient Characteristics

Variable[a]	Value
	(n = 19)
Age, y	74 ± 9
Sex	
Female	8
Male	11
NYHA class	3.6 ± 0.5
Etiology of mitral disease	
Chronic ischemic	8 (42)
Degenerative	5 (26)
Dilated cardiomyopathy	3 (16)
Combined	3 (16)
Implanted MitraClips, No.	1.9 ± 0.8
1	6 (32)
2	9 (47)
3	3 (16)
4	1 (5)
Time since clipping, d	12 (0–546)
Mitral regurgitation grade	2.8 ± 0.2
Left atrium diameter, mm	54 ± 7 (40–69)
Left ventricular ejection fraction	0.36 ± 0.11 (0.19–0.60)
Prior open heart operation	7 (37)
Prior intervention	16 (84)
Percutaneous coronary intervention	11 (58)
Implantable cardioverter-defibrillator	5 (26)
Percutaneous MV intervention[b]	2 (11)
TAVI	1 (5)
ASD occluder implantation	1 (5)
Ventricular tachycardia ablation	1 (5)
Artificial ASD	19 (100)
Atrial fibrillation	7 (37)
Relevant functional tricuspid valve disease[c]	7 (37)
Relevant coronary artery disease	3 (16)
Aortic valve disease	2 (11)
Emergency operation	2 (11)
EuroSCORE II, %	26.87 (3.31–89.03)
Lower quartile, upper quartile	17.08, 42.20

[a] Continuous data are shown as the mean ± standard deviation (minimum–maximum), the median (minimum–maximum), or as indicated, and discrete data as number (%). [b] Intervention (direct/indirect percutaneous anuloplasty) at the mitral annulus. [c] Tricuspid annulus > 40 mm or grade of regurgitation ≥ 2, or both.

ASD = atrial septal defect; EuroSCORE II = European System for Cardiac Operative Risk Evaluation II; NYHA = New York Heart Association; TAVI = transcatheter aortic valve intervention.

Surgical Strategy

Our explicit aim was to perform surgical mitral repair, if possible; therefore, the operations were performed by an experienced team specializing in reconstructive mitral operations. Clip explantation training had been performed before and was repeated after the first four operations. The operations were done on cardiopulmonary bypass with antegrade Bretschneider cardioplegia. After sternotomy and initiation of cardiopulmonary bypass, the distal anastomoses for conventional coronary artery bypass grafting were performed when indications of revascularization were apparent.

The left atrium (LA) was opened by standard left atriotomy, and the MV was exposed using the Cosgrove retractor. Etiologic, functional, and segmental MV analyses were applied according to the criteria formulated by Carpentier [6]. The characteristics of clip implantation failure and the degree of tissue damage were assessed. Clips were explanted as follows: the lock harness and a conventional small suction tube were passed with a 4-0 Gore-Tex suture (W.L. Gore and Associates, Flagstaff, AZ; Fig 1). By pulling the suture and pushing the tube toward the clip, the surgeon carefully attempted to open the arms and the grippers of the clip without damaging the leaflet tissue. If that was not successful, the clips were cut out with scissors.

After clip explantation, we determined whether mitral repair was feasible. Before mitral repair or replacement,