A heart team's perspective on interventional mitral valve repair: Percutaneous clip implantation as an important adjunct to a surgical mitral valve program for treatment of high-risk patients

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Objective: Surgical mitral valve repair carries an elevated perioperative risk in the presence of severely reduced ventricular function and relevant comorbidities. We sought to assess the feasibility of catheter-based mitral valve repair using a clip-based percutaneous edge-to-edge repair system in selected patients at high surgical risk with mitral regurgitation grade 3 or worse.

Methods: Between 2002 and January 2011, 202 consecutive patients without prior mitral valve surgery (age 75 ± 9 years; 63% were male) with symptomatic functional (65%), degenerative (27%), or mixed (8%) mitral regurgitation were treated with a percutaneous clip system for approximation of the anterior and posterior mitral leaflets. Risk for mitral valve surgery was considered high in terms of a mean logistic European System for Cardiac Operative Risk Evaluation of 44% (range, 21%–54%). Preprocedural left ventricular ejection fraction was 35% or less in 36% of patients. An interdisciplinary heart team of cardiologists and cardiac surgeons discussed all patients.

Results: Percutaneous clip implantation was successful in 186 patients (92%). Patients were treated with 1 clip (n = 125; 62%), 2 clips (n = 64; 32%), or 3 or more clips (n = 7; 3%). Reduction in mitral regurgitation from pre- to postprocedure was significant ($P < .0001$) and remained stable within the first 12 months in the majority of patients. Thirty-day mortality was 3.5% (7/202 patients). Hospital stay was 12 ± 10 days, and median intensive care unit stay was 1 day (range, 0–45 days). Eleven patients required surgical valve repair/replacement at a median of 38 days (0–468 days) after percutaneous clip implantation.

Conclusions: Clip-based percutaneous mitral valve repair is a safe, low-risk, and effective therapeutic option in symptomatic patients with a high risk for surgery and does not exclude later surgical repair. (J Thorac Cardiovasc Surg 2012;143:78-84)

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Surgical mitral valve repair (MVR) is the gold standard treatment for severe mitral regurgitation (MR) in degenerative disease and has superseded mitral valve replacement as the treatment of choice in the majority of patients in the United States and Western Europe. In experienced centers, surgical MVR can be performed with approximately 0% mortality and extremely low complication rates.[1] Successful surgical MVR in patients with preserved ventricular function restores quality of life and life expectancy and is therefore recommended as treatment even in asymptomatic patients if the likelihood of repair is high.[2] In addition, the invasiveness of surgical MVR is favorably reduced if minimally invasive techniques through a right-sided lateral minithoracotomy are implemented as the standard of care.[3]

In functional mitral valve disease, however, the results of surgical MVR are worse and procedural risks are higher.[4] If MR is caused by ventricular dysfunction (eg, dilated cardiomyopathy), repair of the valve may restore valve function but does not treat the underlying ventricular disease. Comorbidities such as renal dysfunction, previous cardiac surgery, and a history of stroke or myocardial infarction are common, thereby also increasing the risk of surgical treatment. With an aging population and improved medical therapy, the number of patients with functional MR and relevant comorbidities will further increase. The Euro Heart Survey revealed that patients with reduced ventricular function or significant comorbidities and patients aged more than 80 years were unlikely to be referred for mitral valve surgery at all.[5] It is for this growing population of high-risk patients that less-invasive treatment alternatives have been explored.

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Abbreviations and Acronyms

CABG = coronary artery bypass grafting
euroSCORE = European System for Cardiac Operative Risk Evaluation
EVEREST II = Endovascular Valve Edge-to-Edge Repair Study
MR = mitral regurgitation
MVR = mitral valve repair
NYHA = New York Heart Association
TR = tricuspid regurgitation

Percutaneous MVR techniques currently have been developed for annuloplasty (direct or through a coronary sinus approach), left ventricular chamber remodeling, chordae replacement, or leaflet repair.

The MitraClip device (Abbott Vascular, Menlo Park, Calif) uses a steerable catheter to deliver 1 or more clips to the anterior and posterior leaflet via transseptal access. The procedure imitates the surgical technique previously described by Alfieri and colleagues,[6] which connects the anterior and posterior mitral leaflets with a suture and thus creates a ''double orifice'' mitral valve, thereby reestablishing leaflet coaptation and reducing MR. The procedure has been described in detail.[7,8]

Because of the excellent surgical results of surgical MVR, MitraClip therapy is only performed in patients carrying a high surgical risk at the University Heart Center. A heart team consisting of interventional cardiologists, experienced mitral valve surgeons, and echocardiographers reviews every case and decides on the appropriate therapy. Figure 1 demonstrates a flow-chart on how treatment decisions are made by the heart team at the University Heart Center. The majority (80%) of patients treated with the MitraClip device would have fulfilled the exclusion criteria for the recently published Endovascular Valve Edge-to-Edge Repair Study (EVEREST II) trial,[9] a randomized comparison of surgical and interventional MVR using the MitraClip device, mainly because of severely reduced ventricular function in functional MR. Nevertheless, the number of patients presenting with severe MR and high surgical risk has markedly increased since the introduction of percutaneous techniques at the University Heart Center. This makes a change in referral policy obvious because we now see patients who had not been referred to the University Heart Center for MVR before.

We report on our results of percutaneous MVR using the MitraClip system in a consecutive series of 202 patients who were deemed high risk for surgical MVR. All procedures were performed in a hybrid operation theater by a dedicated team of cardiologists and cardiac surgeons. The primary objective of this analysis was to assess the efficacy of the MitraClip system in reduction of MR grade and functional patient improvement as expressed by New York Heart Association (NYHA) functional class.

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MATERIALS AND METHODS

Patients

From 2002 to 2010, a total of 1764 patients underwent isolated mitral valve operations and interventions at the University Heart Center, of whom 202 consecutive patients with a mean age of 75 ± 9 years (range, 47–93 years) were treated with the MitraClip system for approximation of the anterior and posterior mitral leaflet (September 2008 to January 2011). Severity of MR was graded in accordance with the American Society of Echocardiography guidelines.[10] The majority of patients (98.5%) presented with grade 3+ or 4+ symptomatic MR of functional (65%), degenerative (27%), or mixed (8%) origin and underwent joint evaluation by an interdisciplinary panel consisting of cardiovascular surgeons and cardiologists. High surgical risk was based on logistic European System for Cardiac Operative Risk Evaluation (euroSCORE) calculation[11] or the presence of severely reduced ventricular function or relevant comorbidities. The overall mean logistic euroSCORE was 36% (range, 21%–54%).

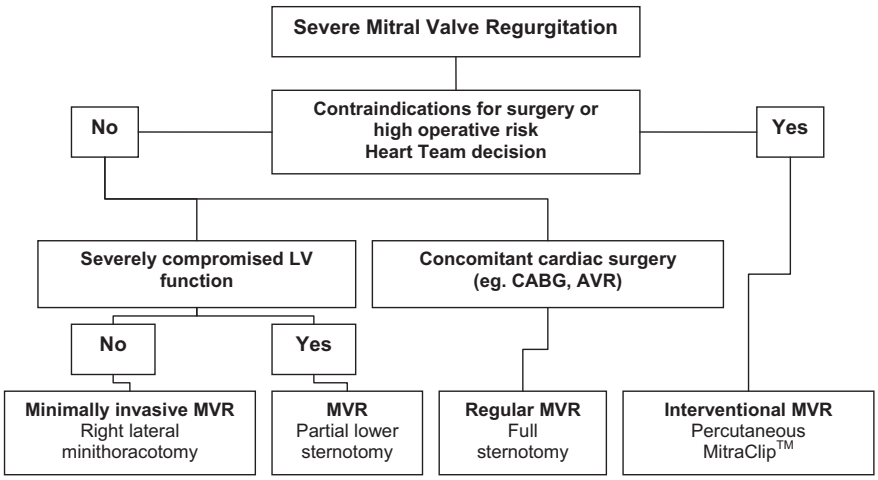

FIGURE 1. Flow-chart on Heart Team decisions in patients with severe MR at the University Heart Center Hamburg. *AVR,* Aortic valve repair; *CABG,* coronary artery bypass grafting; *LV,* left ventricular; *MVR*, mitral valve repair.