Percutaneous edge-to-edge repair in high-risk and elderly patients with degenerative mitral regurgitation: Midterm outcomes in a single-center experience

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Objective: The study objective was to report the midterm outcomes of MitraClip implantation in inoperable or high-risk surgical candidates with degenerative mitral regurgitation.

Methods: From October 2008, data of all high-risk or elderly patients with severe degenerative mitral regurgitation who underwent MitraClip implantation were prospectively collected.

Results: Forty-eight high-risk consecutive patients with severe degenerative mitral regurgitation underwent MitraClip implantation (mean age, 78.5 ± 10.8 years; 56.6% of the patients were aged ≥80 years). Mean Society of Thoracic Surgeons score was 12% ± 10%, and 71% were in New York Heart Association class III or IV. Mean left ventricular ejection fraction was 57% ± 11%. The device was successfully implanted in 47 of 48 patients (98%). In-hospital mortality was 2%. The median intensive care unit stay was 22 hours; patients were discharged from the hospital in an average of 4.5 ± 2.4 days. Predischarge echocardiography showed a mitral regurgitation reduction to grade 2+ or less in 43 of 47 patients (91.5%). Actuarial survival was 89% ± 5.2% and 70.2% ± 9% at 1 and 2 years, respectively (82% ± 9% in patients aged <80 years and 95% ± 4.4% in patients aged ≥80 years at 1 year; $P = .9$). Freedom from mitral regurgitation 3+ or greater was 80% ± 7% at 1 year and 76.6% ± 7% at 2 years. At 1 year, 93% of survivors were in New York Heart Association class I or II (100% of patients aged <80 years and 88% of patients aged ≥80 years; $P = .4$). Significant quality of life improvements were documented. A significant improvement in 6-minute walk test performance was observed.

Conclusions: MitraClip therapy is a valuable alternative to surgery in high-risk and elderly patients with degenerative mitral regurgitation. Clinical benefits also are obtained in octogenarians. (J Thorac Cardiovasc Surg 2014;148:2743-50)

See related commentary on pages 2750-1.

Surgical repair represents the optimal treatment for severe degenerative mitral regurgitation (DMR) because of its well-documented advantages over valve replacement in terms of perioperative mortality, preservation of postoperative left ventricular function, and long-term survival.[1,2] Indeed, if performed before the onset of limiting symptoms or the development of left ventricular dysfunction, mitral valve (MV) repair is able to restore normal life expectancy and quality of life.[3] Currently, more than 90% of degenerative lesions can be repaired successfully in high-volume centers, with low morbidity and fast recovery.[4-6] In view of these results, elective MV repair may be indicated even in asymptomatic patients with severe DMR.[7]

However, in real-world clinical practice, a large number of patients with severe mitral regurgitation (MR) are denied surgery: The Euro Heart Survey conducted by the European Society of Cardiology showed that up to 50% of the patients with severe MR currently are denied surgical treatment because they are thought to be at too high risk for surgery because of advanced age or comorbidities.[8] Moreover, the prevalence of DMR increases in elderly persons,[9] and advanced age is one of the main risk factors of mortality and major morbidity after cardiac surgery.[10] Therefore, over the past years, new transcatheter techniques have been developed to treat MR with less-invasive approaches. Although less effective in reducing MR compared with surgical repair,[11,12] MitraClip therapy (Abbott Vascular Inc, Menlo Park, Calif) has been shown to improve functional and clinical outcome in inoperable or high-risk patients.[13-18] Few data are available today on the midterm clinical outcomes of high-risk patients with DMR after MitraClip implantation.

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Abbreviations and Acronyms

ACCESS-EU = ACCESS-EUROPE
DMR = degenerative mitral regurgitation
euroSCORE = European System for Cardiac Operative Risk Evaluation
EVEREST = Efficacy of Vasopressin Antagonism in Heart Failure Outcome Study with Tolvaptan
IQR = interquartile range
MLHFQ = Minnesota Living with Heart Failure Questionnaire
MR = mitral regurgitation
MV = mitral valve
NYHA = New York Heart Association
6MWT = 6-minute walk test
SF-36 = 36-Item Short-Form Health Survey
STS = Society of Thoracic Surgeons

The aim of this study is to report the midterm clinical and echocardiographic results of MitraClip therapy to treat symptomatic high-risk or elderly patients with severe DMR in a single high-volume center experience to validate the use of MitraClip treatment in this specific setting.

METHODS

We retrospectively analyzed the clinical and echocardiographic data of a cohort of consecutive patients who underwent MitraClip therapy between October 2008 and July 2013 for severe or moderately severe symptomatic DMR. All patients underwent preoperative coronary angiography and transesophageal Doppler echocardiography. Clinical, Doppler echocardiographic, operative, and outcome data were prospectively collected in a dedicated database. The study protocol was performed in accordance with the institutional ethics committee, and all patients gave written informed consent for the procedures and data collection.

Description of the Procedure

The procedure was performed under general anesthesia in a hybrid operating room, under transesophageal Doppler echocardiography and fluoroscopic guidance. Transseptal puncture was performed using a Brockenbrough needle (Medtronic Inc, Minneapolis, Minn) through peripheral venous access at the right groin. Live real-time 3-dimensional echocardiography was used to improve the conduct of the implantation. A steerable guide catheter was advanced in the left atrium through the transseptal puncture. The delivery system was inserted, and the MitraClip device was implanted in correspondence with the origin of the regurgitation jet, perpendicularly to the coaptation line. If the effect of the implant was satisfactory, the clip was deployed. When necessary, more than 1 clip was implanted. The comprehensive description of the procedure has been reported by Maisano and colleagues.[19]

Patient Selection

Patients were selected if they met basic criteria for intervention from the European Society of Cardiology Task Force recommendation on the management of valvular heart disease.[7] Indication for MitraClip therapy was given according to local institutional practice in consideration of current CE mark–approved labeling. Eligible patients included those with symptomatic moderate-to-severe (3+) or severe (4+) MR. Transthoracic and transesophageal echocardiograms studies were evaluated at baseline to assess patient eligibility.

All patients underwent a multimodality decision-making process by a dedicated multidisciplinary Heart Team, including evaluation of surgical risk by logistic European System for Cardiac Operative Risk Evaluation (euroSCORE) (http://www.euroscore.org/) and Society of Thoracic Surgeons (STS) score (http://riskcalc.sts.org/STSWebRiskCalc273/), as well as adjunctive risk evaluation, such as the presence of advanced liver cirrhosis and severe neurologic impairment. Frailty and biological status were evaluated by the institutional Heart Team after collegial discussion, according to the so-called eyeball test. Quality of life of all the patients was evaluated by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the 36-Item Short-Form Health Survey (SF-36); the 6-minute walk test (6MWT) was used to evaluate functional capacity.

Follow-up

All patients were followed up after discharge in a dedicated outpatient clinic with physical examination, electrocardiogram, transthoracic echocardiogram, and arrhythmology consultation whenever indicated. Follow-up visits were performed at 1 month, 6 months, and then yearly.

Statistical Analysis

Statistical analysis was conducted using JMP 11.0 software (SAS Institute Inc, Cary, NC). Continuous variables are presented as mean ± standard deviation or as median (interquartile range [IQR], Q1-Q3), and categoric variables are expressed as percentages. Univariable comparisons were performed with Student unpaired or paired *t* test for continuous normally distributed data, which were tested by the Shapiro–Wilk normality test. The Mann–Whitney rank-sum test was used for comparisons of nonparametric continuous data, and the chi-square test was used for categoric data. Survival and freedom from 3+ or greater MR were presented using the Kaplan–Meier method; comparisons were performed with the log-rank test. All reported *P* values are 2-sided.

RESULTS

Patient Characteristics

The study population consisted of 48 high-risk consecutive patients with severe or moderate to severe DMR who underwent MitraClip implantation between October 2008 and July 2013 in San Raffaele University Hospital, Milan. During the same period, 2370 patients underwent surgical mitral repair (with or without associated procedure), and 116 patients underwent MitraClip implantation for functional MR.

The mean age of the study population was 78.5 ± 10.8 years; 56.6% of the patients were aged 80 years or more. The mean logistic euroSCORE at baseline was 15.7 ± 11.2; the mean STS score was 12% ± 10% (range, 2%-36%; IQR, 4-18); 40% and 45.5% of patients had a baseline logistic euroSCORE 20% or greater and STS score 10% or greater, respectively. Patients presented multiple comorbidities. The baseline characteristics of all the patients are summarized in Table 1 (including data from ACCESS-EUROPE (ACCESS-EU) phase I DMR cohort for comparison).[13] Stratification into patients aged less than 80 years and patients aged 80 years or more revealed important demographic differences (mean logistic euroSCORE