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Percutaneous Edge-to-Edge Mitral Valve Repair in High-Surgical-Risk Patients

Do We Hit the Target?

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Objectives This study sought to assess the feasibility and safety of percutaneous edge-to-edge mitral valve (MV) repair in patients with an unacceptably high operative risk.

Background MV repair for mitral regurgitation (MR) can be accomplished by use of a clip that approximates the free edges of the mitral leaflets.

Methods All patients were declined for surgery because of a high logistic EuroSCORE (>20%) or the presence of other specific surgical risk factors. Transthoracic echocardiography was performed before and 6 months after the procedure. Differences in New York Heart Association (NYHA) functional class, quality of life (QoL) using the Minnesota questionnaire, and 6-min walk test (6-MWT) distances were reported.

Results Fifty-five procedures were performed in 52 patients (69.2% male, age 73.2 ± 10.1 years, logistic EuroSCORE 27.1 ± 17.0%). In 3 patients, partial clip detachment occurred; a second clip was placed successfully. One patient experienced cardiac tamponade. Two patients developed inguinal bleeding, of whom 1 needed surgery. Six patients (11.5%) died during 6-month follow-up (5 patients as a result of progressive heart failure and 1 noncardiac death). The MR grade before repair was ≥3 in 100%; after 6 months, a reduction in MR grade to ≤2 was present in 79% of the patients. Left ventricular (LV) end-diastolic diameter, LV ejection fraction, and systolic pulmonary artery pressure improved significantly. Accompanied improvements in NYHA functional class, QoL index, 6-MWT distances, and log N-terminal pro–B-type natriuretic peptide were observed.

Conclusions In a high-risk population, MR reduction can be achieved by percutaneous edge-to-edge valve repair, resulting in LV remodeling with improvement of functional capacity after 6 months. (J Am Coll Cardiol Intv 2012;5:105–11) © 2012 by the American College of Cardiology Foundation

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Mitral valve regurgitation (MR) is an important clinical issue as MR represents >30% of native valve diseases (1). Patients with symptomatic MR have a poor prognosis, with a 5% annual mortality rate in the absence of surgery (2). Optimal medical management can improve symptoms of heart failure but does not affect survival (3). Therefore, surgery is recommended by the current guidelines for patients with symptomatic severe MR or asymptomatic severe MR with evidence of left ventricular (LV) dysfunction or dilation (4,5). Despite those guidelines, a recent European survey established that one-half of these patients are not referred for surgery, mainly because of advanced age and the presence of comorbidity (5,6). Mitral valve (MV) repair is the preferred surgical strategy whenever feasible and is associated with lower morbidity and mortality and better preservation of LV function, compared with MV replacement (7). Reported in-hospital mortality rates range from 1% to 2% in low-risk patients, increasing up to 25% in high-risk or elderly patients (8,9). Therefore, new percutaneous techniques are developed to avoid surgery in high-risk patients. The transcatheter edge-to-edge MV repair using the MitraClip system (Abbott Vascular, Santa Clara, California) creates a double MV orifice by means of a clip in the mid portion of the 2 leaflets and mimics the surgical procedure introduced by Alfieri et al. (10). The first clinical trials with the MitraClip showed very promising results regarding feasibility and safety of the device, and functional improvement of the patient (11–13). We report the 6-month outcomes of our patient cohort treated with this device.

Abbreviations and Acronyms

6-MWT = 6-min walk test
LA = left atrial/atrium
LV = left ventricular/ventricle
LVEDD = left ventricular end-diastolic diameter
LVEDV = left ventricular end-diastolic volume
LVEF = left ventricular ejection fraction
LVESD = left ventricular end-systolic diameter
MR = mitral regurgitation
MV = mitral valve
NT-proBNP = N-terminal pro–B-type natriuretic peptide
NYHA = New York Heart Association
QoL = quality of life
RA = right atrial
RVSP = right ventricular systolic pressure
TEE = transesophageal echocardiography

Methods

Patients. Between January 2009 and November 2010, the interdisciplinary team of cardiac surgeons and cardiologists at our hospital evaluated 52 patients suitable for MitraClip therapy. All patients had moderate-to-severe or severe (grade 3+ or 4) MR and were symptomatic or asymptomatic with LV dysfunction (ejection fraction <60%) or LV dilation (left ventricular end-systolic diameter [LVESD] >45 mm), and consequently had an indication for intervention according to the European Society of Cardiology Task Force recommendation (5). In addition, all patients were at high risk for conventional surgery (logistic EuroSCORE >20% or the presence of specific risk factors associated with excessive morbidity and mortality). Furthermore, echocardiographic parameters played a crucial role in the assessment of the suitability for clip implantation: the coaptation length had to be at least 2 mm, excessive calcification or cleft at the grasping area had to be absent, and in case of a flail leaflet, the flail gap had to be ≤10 mm and the flail width ≤15 mm (11).

All patients underwent a standard pre-procedural screening, containing physical examination, functional capacity assessment (New York Heart Association [NYHA] functional class and 6-min walk test [6-MWT]), quality of life (QoL) assessment using the Minnesota questionnaire, electrocardiogram, chest x-ray, laboratory measurements (including N-terminal pro–B-type natriuretic peptide [NT-proBNP]), transthoracic echocardiography, transesophageal echocardiography (TEE), coronary angiography, and right heart catheterization.

Procedural technique. All procedures were performed as previously described (14). In brief, the clip device system is delivered to the left atrium (LA) via a transseptal puncture, advanced into the LV, and then retracted during systole, grasping the MV leaflets. This results in permanent leaflet approximation and creation of a double orifice. The clip is a 4-mm-wide cobalt-chromium implant with 2 arms. On the inner portion of the clip arms are small "grippers" to secure the leaflets when the arms are closed. Correct positioning of the clip device over the mitral orifice, perpendicular to the line of leaflet coaptation, above the origin of the MR jet, is mandatory to prevent clip disengagement and to obtain an acceptable MR reduction. A second (or third) clip was placed if further reduction of MR was needed. The procedure was performed under general anesthesia and both fluoroscopic and TEE (2- and 3-dimensional) guidance (15).

Follow-up. All periprocedural and mid-term complications were reported. Major complications included hemorrhage requiring blood transfusion, occurrence of cardiac tamponade, need for procedure-related surgical intervention, endocarditis, clip detachment, clip dislodgement/embolization, stroke, and death. Minor complications were defined as MV injury, device thrombosis, bleeding not requiring blood transfusion, femoral arteriovenous fistula formation, and femoral hematoma.

Post-procedural anticoagulation management was based on an individualized protocol.

All patients were discharged on aspirin 100 mg once a day for a period of 6 months and clopidogrel 75 mg once a day for 1 month. In patients on oral anticoagulant therapy before the procedure, clopidogrel was added for 1 month. Infective endocarditis prophylaxis was recommended for 6 months.

Six months after the procedure, all patients underwent clinical examination, laboratory testing, TTE, and assessment