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Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

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ABSTRACT

BACKGROUND In EVEREST II (Endovascular Valve Edge-to-Edge Repair Study), treatment of mitral regurgitation (MR) with a novel percutaneous device showed superior safety compared with surgery, but less effective reduction in MR at 1 year.

OBJECTIVES This study sought to evaluate the final 5-year clinical outcomes and durability of percutaneous mitral valve (MV) repair with the MitraClip device compared with conventional MV surgery.

METHODS Patients with grade 3+ or 4+ MR were randomly assigned to percutaneous repair with the device or conventional MV surgery in a 2:1 ratio (178:80). Patients prospectively consented to 5 years of follow-up.

RESULTS At 5 years, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ MR in the as-treated population was 44.2% versus 64.3% in the percutaneous repair and surgical groups, respectively ($p = 0.01$). The difference was driven by increased rates of 3+ to 4+ MR (12.3% vs. 1.8%; $p = 0.02$) and surgery (27.9% vs. 8.9%; $p = 0.003$) with percutaneous repair. After percutaneous repair, 78% of surgeries occurred within the first 6 months. Beyond 6 months, rates of surgery and moderate-to-severe MR were comparable between groups. Five-year mortality rates were 20.8% and 26.8% ($p = 0.4$) for percutaneous repair and surgery, respectively. In multivariable analysis, treatment strategy was not associated with survival.

CONCLUSIONS Patients treated with percutaneous repair more commonly required surgery for residual MR during the first year after treatment, but between 1- and 5-year follow-up, comparably low rates of surgery for MV dysfunction with either percutaneous or surgical therapy endorse the durability of MR reduction with both repair techniques. (EVEREST II Pivotal Study High Risk Registry; NCT00209274) (J Am Coll Cardiol 2015;66:2844–54) © 2015 by the American College of Cardiology Foundation.

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The MitraClip device (Abbott Vascular, Menlo Park, California) was developed as a percutaneous means to reduce mitral regurgitation (MR) by approximating the mitral valve (MV) leaflets. The procedure is modeled after the surgical Alfieri double-orifice technique of MV repair, which has been shown to have durable results when performed in conjunction with an annuloplasty ring for degenerative MR (1,2). We previously reported the results of the randomized EVEREST II (Endovascular Valve Edge-to-Edge Repair Study), in which percutaneous MV repair using this percutaneous approach was compared with conventional surgery (3–5). The primary outcome at 1 year demonstrated that conventional surgery was more effective than percutaneous repair for reducing MR. However, improvements in left ventricular (LV) remodeling and clinical outcomes were similar for both approaches and the percutaneous approach demonstrated a greater level of safety than did surgery (3).

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Several important clinical questions remain unanswered regarding percutaneous MV repair for moderate-to-severe MR. Given the increased prevalence of residual MR and the lack of annuloplasty with this device, the durability of percutaneous repair relative to conventional surgery, and the impact of MV repair technique on long-term survival, symptoms, and LV remodeling, is unknown. We sought to address these questions based on the 5-year, final results of the EVEREST II randomized trial.

METHODS

STUDY DESIGN AND ELIGIBILITY. EVEREST II is a multicenter, randomized, nonblinded trial of the MitraClip system compared with conventional surgery for the treatment of MR with pre-specified 5-year follow-up. Details of the device, study design, and 1-year primary endpoint analysis have been previously reported (3,4). Briefly, 279 patients were enrolled at 37 study centers in North America between September 2005 and November 2008. Eligible patients had moderate-to-severe (3+) or severe (4+) chronic MR and were either symptomatic with left ventricular ejection fraction (LVEF) >25% and LV end-systolic diameter ≤55 mm or asymptomatic with 1 or more of the following: LVEF 25% to 60%, LV end-systolic diameter ≥40 mm, new-onset atrial fibrillation, or pulmonary hypertension (pulmonary artery systolic pressure >50 mm Hg at rest or >60 mm Hg with exercise), all according to the 1998/2006 American College of Cardiology/American Heart Association Joint Task Force recommendations for surgical intervention for MR (6,7). Eligible patients had to be candidates for mitral repair or replacement surgery. Anatomic inclusion criteria required that the primary regurgitant jet originated from malcoaptation of the A2 and P2 scallops of the MV. Patients with both functional and degenerative MR were included.

Baseline and follow-up echocardiograms were assessed by an independent echocardiographic core laboratory (University of California, San Francisco).

ABBREVIATIONS AND ACRONYMS

LV = left ventricular

LVEF = left ventricular ejection fraction

MR = mitral regurgitation

MV = mitral valve

NYHA = New York Heart Association

SLDA = single leaflet device attachment

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