Three-dimensional valve repair—the better care? Midterm results of a saddle-shaped, rigid annuloplasty ring in patients with ischemic mitral regurgitation

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Objectives: Undersized ring annuloplasty is the treatment of choice for functional mitral regurgitation. However, recurrence of mitral regurgitation within the first years is frequent. The aim of this study was to analyze the functional and clinical outcome after mitral valve repair with the 3-dimensional saddle-shaped Edwards GeoForm (Edwards Lifesciences LLC, Irvine, Calif) annuloplasty ring in patients with ischemic mitral regurgitation.

Methods: Between November 2006 and November 2012, 70 patients (mean age, 68 ± 10 years; mean left ventricular ejection fraction, 40% ± 15%) with functional mitral regurgitation due to ischemic cardiomyopathy underwent mitral valve repair with the Edwards GeoForm annuloplasty ring. Concomitant procedures, such as coronary artery bypass grafting (75.7%), tricuspid valve repair (25.7%), aortic valve replacement (8.6%), and the Maze procedure (4.3%), were performed in 92.9% of patients. Follow-up is 97% complete (mean, 3.0 ± 1.7 years). Transthoracic echocardiography was obtained 2.4 ± 1.7 years postoperatively.

Results: Thirty-day mortality was 5.9%. Overall survival at 5 years was 71.3% ± 6.9%. At 4 years, overall freedom from recurrence of mitral regurgitation grade 3+ or greater was 92.5% ± 3.6%, and freedom from recurrence of mitral regurgitation grade 2+ or greater was 71.0% ± 8.7%. Three patients required a mitral valve–related reoperation for ring dehiscence. New York Heart Association functional class improved from 3.6 ± 0.6 to 1.6 ± 0.6 during follow-up ($P < .05$). Mean mitral valve pressure gradient was 3.3 ± 1.8 mm Hg across all ring sizes at the time of follow-up.

Conclusions: Mitral valve repair with the 3-dimensional saddle-shaped Edwards GeoForm annuloplasty ring in case of ischemic mitral regurgitation shows a low rate of recurrent regurgitation at 4 years. Clinically relevant mitral stenosis was not detected. The importance of secure anchoring of the device in the mitral annulus has to be emphasized to prevent ring dehiscence. (J Thorac Cardiovasc Surg 2014;148:176-82)

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Functional mitral regurgitation (FMR) as a consequence of regional or global left ventricular (LV) dysfunction despite a structurally normal mitral valve (MV) is a common complication in patients with ischemic heart disease or idiopathic dilated cardiomyopathy.[1] FMR is strongly associated with adverse outcome in patients with both ischemic and dilated cardiomyopathy.[2] The survival of patients with ischemic mitral regurgitation (IMR) was 30% after 5 years.[2] Moreover, its presence increases intermediate-term risk with a 2-year actuarial survival of 71% after surgical MV repair.[3] To date, the optimal strategy for the management of severe FMR is still controversial, and current guidelines recommend surgical treatment but do not indicate whether to repair or replace the MV.[4] In a recently published meta-analysis by Vassileva and colleagues,[5] MV repair for IMR is associated with better short- and long-term survival compared with MV replacement. On the other hand, Maltais and colleagues[6] showed in a single-center study that the surgical technique did not influence long-term survival in patients with ischemic cardiomyopathy.

In case of MV repair, undersized ring annuloplasty is currently used as the method of choice to treat FMR.[7] Although early results with this technique are satisfactory, late recurrence of FMR has been observed in a significant number of patients.[8,9] It is supposed that MV repair with an increased coaptation length is associated with more durable results, especially by application of an annuloplasty ring with a reduced anteroposterior (A-P) dimension.[10] To address this issue, the GeoForm annuloplasty ring (Edwards Lifesciences LLC, Irvine, Calif) was introduced to the market in 2005. The GeoForm

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Disclosures: Authors have nothing to disclose with regard to commercial support.
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Received for publication May 17, 2013; revisions received July 29, 2013; accepted for publication Aug 22, 2013; available ahead of print Oct 30, 2013.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2013.08.071

Abbreviations and Acronyms
AF = atrial fibrillation
A-P = anteroposterior
FMR = functional mitral regurgitation
IMR = ischemic mitral regurgitation
LV = left ventricular
MV = mitral valve
NYHA = New York Heart Association

annuloplasty ring is characterized by its reduced A-P distance (41% reduction compared with Carpentier-Edwards Physio [Edwards Lifesciences LLC]). In addition to the marked reduction of the A-P diameter, the 3-dimensional elevation of the ring in the middle of the P2 segment (6-mm lift) raises the posterior MV annulus to counteract the downward pull of the enlarged left ventricle and compensates the restriction of the posterior leaflet.

The aim of the present study was to analyze the clinical and functional outcome after MV repair with the GeoForm annuloplasty ring in patients with IMR.

MATERIALS AND METHODS

Inclusion Criteria

Between November 2006 and November 2012, 70 patients with FMR due to ischemic cardiomyopathy underwent MV repair with the Edwards GeoForm annuloplasty ring at the German Heart Center Munich. A diagnosis of FMR was made in patients in whom MR was present with regional wall motion abnormalities with normal valve leaflets and intact papillary muscles (Carpentier Class IIIb). All patients with other types of MR (ie, FMR due to dilated cardiomyopathy or degenerative MV disease) or patients with endocarditis were excluded. Clinical symptoms, hemodynamic data, and functional outcome were obtained from medical records, patients' follow-up visits, mailed questionnaires, telephone interviews with the patient or family members, and communications from the referring physicians.

Echocardiography

Echocardiographic examinations were performed with a Siemens Sequoia Acuson System (Munich, Germany) using a 2.5-MHz imaging transducer and included M-mode, continuous-wave 2-dimensional, pulsed-wave Doppler, and color Doppler analyses. The severity of regurgitation was classified as none/trivial (0+), mild (1+), moderate (2+), moderate-severe (3+), or severe (4+) and assessed in a semi-quantitative manner by means of color Doppler flow mapping. For detection of regurgitation, a color flow Doppler was used with a Nyquist limit (aliasing velocity of 50–60 cm/sec) and a color gain that just eliminated random color speckle from nonmoving areas. The vena contracta was measured in the parasternal long-axis view as the narrowest portion of the jet that occurred at the orifice. The color flow sector was as narrow as possible with the least depth to maximize lateral and temporal resolution. All evaluations were carried out according to standard techniques recommended by the American Society of Echocardiography.[11]

Operative Technique

All operations were performed on cardiopulmonary bypass under moderate systemic hypothermia (30°C-32°C). Myocardial protection was achieved using cold (4°C) antegrade crystalloid (Custodiol, Koehler Chemie; Alsbach-Haehnlein, Germany) or antegrade blood cardioplegia, and the MV was exposed through a left atrial or a trans-septal approach, depending on the preference of the surgeon.

Sizing was primarily based on the length of the anterior mitral leaflet. Because of the significantly reduced A-P distance of the Edwards GeoForm ring, downsizing is not necessary and was never performed. Thus, ring size was chosen so that the provided sizer totally covered the anterior leaflet for sufficient coaptation. In addition, the intertrigonal distance serves as an additive tool to find an optimal correlation between the height and the width of the anterior leaflet.

All patients were discharged with a regimen of phenprocoumon (Marcumar; MEDA Pharma, Bad Homburg, Germany) for the first 3 months postoperatively. After 3 months, anticoagulant therapy was continued only in patients with permanent atrial fibrillation (AF) or severely depressed LV function.

Follow-up

Complete follow-up was achieved in 97.1% of patients (68/70), yielding a cumulative total of 173 patient-years. The follow-up was closed on January 31, 2013. As of January 2013, 55 patients are alive (mean, 3.0 ± 1.7 years). Postoperative complications were analyzed according to the "Guidelines for Reporting Morbidity and Mortality after Cardiac Valvular Operations" approved by the Society of Thoracic Surgeons. The study protocol was approved by the local governmental ethics committee (approval reference number: 5247/11).

Statistical Analysis

Statistical analysis was performed with IBM SPSS Statistics 21 (SPSS Inc, Chicago, Ill). Continuous variables are reported as mean ± standard deviation or median (range) for skewed data. Categoric variables are reported as absolute and relative frequencies. To test for changes in New York Heart Association (NYHA) classification and MR grade, the sign test was used. The Kaplan–Meier method was used to estimate overall survival. Survival estimates are reported as the mean ± standard deviation. All reported *P* values are 2 sided and have not been adjusted for multiple testing.

RESULTS

Preoperative Variables

The mean age at operation was 68 ± 10 years (range, 42-88 years), and 46 of 70 patients (65.7%) were male. Preoperative clinical and hemodynamic data are summarized in Table 1. Preoperative echocardiographic assessment was performed in every patient by the referring cardiologist and repeated after patients' admission, usually 1 or 2 days before surgery. Eight patients (11.4%) showed MR 4+ (vena contracta ≥7 mm), 55 patients (78.6%) showed MR 3+ (vena contracta ≥5 mm and <7 mm), and 7 patients showed MR 2+ (vena contracta ≥3 mm and <5 mm). Thirty-seven patients (52.9%) had a history of preoperative myocardial infarction at an average of 5.5 ± 8.0 years before the operation. The preoperative NYHA functional class was assessed at the time of admission; 5 patients (7.1%) presented with NYHA class II, 21 patients (30.0%) presented with NYHA class III, and 44 patients (62.9%) presented with NYHA class IV. Five patients (7.1%) had previous cardiac surgery other than on the MV.

All patients were preoperatively treated with medication for congestive heart failure. Medication at the time of

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