

# Early Surgery Versus Conventional Treatment for Asymptomatic Severe Mitral Regurgitation

## A Propensity Analysis



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- Objectives** This study sought to compare long-term outcomes of early surgery with a conventional treatment strategy in asymptomatic patients with severe mitral regurgitation (MR).
- Background** The timing of surgery in asymptomatic severe MR remains controversial.
- Methods** From 1996 to 2009, 610 consecutive asymptomatic patients (364 men,  $50 \pm 14$  years of age) with severe degenerative MR and preserved left ventricular function were evaluated prospectively. Early surgery was performed on 235 patients, and the conventional treatment strategy was chosen for 375 patients. We compared overall mortality, cardiac mortality, and cardiac events (operative mortality, cardiac mortality, repeat surgery, and urgent admission due to heart failure) between the 2 treatment strategies in the propensity score-matched cohort.
- Results** For the 207 propensity score-matched pairs, early surgery had a lower risk of cardiac mortality (hazard ratio [HR]: 0.109; 95% confidence interval [CI]: 0.014 to 0.836;  $p = 0.033$ ) and cardiac events (HR: 0.216; 95% CI: 0.083 to 0.558;  $p = 0.002$ ) than conventional treatment. On Cox proportional hazard model analysis, the risk of cardiac events was significantly lower in the early surgery group than in the conventional treatment group in patients aged 50 years of age and older (HR: 0.221; 95% CI: 0.086 to 0.567;  $p = 0.002$ ), but not significantly different in those younger than 50 years of age ( $p = 0.20$ ).
- Conclusions** Compared with conservative management, early surgery is associated with significant long-term reductions of cardiac mortality and cardiac events in asymptomatic severe MR. These benefits were evident among patients age 50 years of age and older. (J Am Coll Cardiol 2014;63:2398–407) © 2014 by the American College of Cardiology Foundation

Surgery is the only definitive therapy for severe mitral regurgitation (MR), and the guidelines recommend that severe MR in symptomatic or asymptomatic patients with left ventricular (LV) dysfunction should be managed with surgery (1,2). However, it remains unclear when asymptomatic patients with severe MR should undergo surgical intervention because randomized clinical trials comparing

early surgery with watchful waiting have not been performed (3,4). The benefit of early surgery has been suggested in prospective, observational studies (5–8), whereas a watchful waiting strategy seemed to be safe and effective in another prospective study (9). The consensus guidelines for performing early surgery in asymptomatic patients with severe

See page 2408

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MR are different, reflecting controversy. The current American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommend early surgery for asymptomatic patients if the success rate of mitral valve (MV) repair is expected to exceed 90%, but the 2012 European Society of Cardiology guidelines recommend watchful waiting for such patients (1,2).

The clinical outcomes of asymptomatic patients with MR are poorly defined (3), and it is important to identify

high-risk patients in whom early surgery may be warranted. Older patients and those with a larger effective regurgitant orifice area (EROA) showed increased mortality with medical management (6,10), but it is controversial whether early surgery would improve clinical outcome of such patients because the performance of surgery in high-risk patients may be associated with increased operative risk.

We previously compared clinical outcomes of early surgery with those of conventional treatment in asymptomatic severe MR. In our previous single-center study, early surgery was significantly associated with a reduction in cardiac events, but no significant differences in all-cause or cardiac mortality were found in a propensity analysis (8). In the present study, we sought to examine the hypothesis that early surgery is associated with a significant decrease in all-cause and cardiac mortalities using a propensity analysis of greater registry data collected prospectively at 2 centers and to confirm whether early surgery would be more beneficial to older patients with a larger EROA.

## Methods

**Study population.** A prospective registry, started in 1996 at Asan Medical Center and in 2001 at Samsung Medical Center, has included all consecutive patients with MR undergoing echocardiography at our hospitals. Case report forms, including patient demographics, clinical presentation, and echocardiographic data, were stored in an electronic database (8). Comorbidity was assessed using the Charlson comorbidity scale, which assigns weights to specific comorbid disease states (11). Clinical and echocardiographic follow-up data of study patients were collected annually and entered into the database. From 1996 to 2009, 1,505 patients had a diagnosis of severe degenerative MR at the time of enrollment, but 93 patients who had an EROA  $<0.4$  cm<sup>2</sup> were not included in the analysis. Of the 1,412 patients who had an EROA  $\geq 0.4$  cm<sup>2</sup> and received a diagnosis of severe degenerative MR, 601 patients with exertional dyspnea were excluded; 811 patients were assessed for eligibility, 16 of whom were not candidates for surgery and 185 of whom were excluded according to the recommendations of the 2006 ACC/AHA guidelines for surgical indications of asymptomatic severe MR (1). Because the presence of coronary artery disease is an important prognostic factor, and concomitant coronary artery bypass graft operation may increase the operative risk, patients with a history of coronary artery disease or regional wall motion abnormalities were also excluded, but 25 patients with incidental coronary artery disease detected on pre-operative coronary angiography were not excluded. Of the 786 patients requiring surgery and excluded from the study, 649 (83%) underwent surgery with 9 (1.4%) operative mortalities. MV repair and replacement were performed in 503 (78%) and 146 (22%) patients, respectively (Online Table 1). Baseline clinical and echocardiographic characteristics of excluded patients are listed in Online Table 2. The primary cohort

comprised 610 asymptomatic patients (364 men,  $50 \pm 14$  years of age) with chronic severe degenerative MR who were potential candidates for early surgery (Fig. 1). The treatment groups were not assigned randomly. Instead, the choice of early surgery or conventional treatment for each patient was at the discretion of the attending physician, who explained the potential benefits and procedural risks of early surgery in detail and, most importantly, took the preferences of the individual patients into account. Early elective surgery was performed on 235 patients (early surgery group) within 6 months of the initial echocardiographic evaluation, and the conventional treatment strategy was chosen for 375 patients (conventional treatment group). Because in the absence of hypertension, there is no known indication for the use of medical therapy in asymptomatic patients with MR and preserved LV systolic function, patients in the conventional treatment group were observed without medical therapy and were referred for surgery if exertional dyspnea developed and they had an LV ejection fraction (EF)  $\leq 0.60$ , LV end-systolic dimension  $\geq 40$  mm, Doppler estimated pulmonary artery pressure  $>50$  mm Hg, or atrial fibrillation. Informed consent was obtained from each patient, and the study protocol was separately approved by the ethics committees of our institutions.

**Echocardiographic evaluation.** Echocardiographic evaluation was performed at baseline and annually during follow-up. Two-dimensional echocardiography and Doppler color flow imaging were performed on all patients using a Hewlett-Packard Sonos 2500, 5500, or 7500 imaging system (Hewlett-Packard, Andover, Massachusetts) and a VIVID 7 or E9 ultrasound system (General Electric Healthcare, Little Chalfont, United Kingdom). End-diastolic dimension and end-systolic dimension of the left ventricle were measured from parasternal M-mode acquisitions, and the end-systolic volume, end-diastolic volume, and EF of the left ventricle were calculated with the biplane Simpson method (12). Comprehensive echocardiographic evaluation of MR was performed using the integrated approach of 2-dimensional, Doppler, and color flow imaging. With the simplified proximal isovelocity surface area (PISA) method, the degree of MR was graded as mild (PISA radius  $<4$  mm), moderate (PISA radius  $<8$  mm), and severe (PISA radius  $\geq 8$  mm) (13). Severe degenerative MR was defined as severe prolapse and/or flail leaflet of the MV with an EROA of holosystolic MR  $\geq 0.4$  cm<sup>2</sup>. The EROA was determined by dividing the regurgitant flow rate, calculated as  $2\pi r^2 \times$  aliasing velocity, where  $r$  is the PISA radius, by peak MR velocity (14). In the patients

### Abbreviations and Acronyms

<b>ACC/AHA</b> = American College of Cardiology/ American Heart Association
<b>CHF</b> = congestive heart failure
<b>EDD</b> = end-diastolic dimension
<b>EF</b> = ejection fraction
<b>EROA</b> = effective regurgitant orifice area
<b>LV</b> = left ventricular
<b>MR</b> = mitral regurgitation
<b>MV</b> = mitral valve
<b>PISA</b> = proximal isovelocity surface area

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