

Long-Term Outcome of Active Surveillance in Severe But Asymptomatic Primary Mitral Regurgitation

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ABSTRACT

OBJECTIVES This study sought to assess the long-term outcome of active surveillance in these patients.

BACKGROUND The optimal timing of mitral valve surgery in asymptomatic primary mitral regurgitation (MR) remains controversial.

METHODS Between 1997 and 2015, 280 consecutive patients with severe asymptomatic primary MR were enrolled in our heart valve clinic follow-up program. They were prospectively followed up every 6 months clinical and echocardiographical examinations until surgical criteria were reached. Event-free survival and overall survival as compared with the age- and gender-matched general population were assessed.

RESULTS During a median potential follow-up of 93.4 (quartiles 55.3 to 152.9) months, 161 patients developed an indication for surgery and 13 patients died. Event-free survival rates were 78.0% (95% confidence interval [CI]: 73.2% to 83.2%) at 2 years, 52.2% (95% CI: 46.3% to 59.0%) at 6 years, 35.5% (95% CI: 29.3% to 43.1%) at 10 years, and 18.7% (95% CI: 12.3% to 28.5%) at 15 years. Overall survival rate was 99.6% (95% CI: 98.9% to 100%) at 2 years, 94.6% (95% CI: 91.7% to 97.6%) at 6 years, 85.6% (95% CI: 80.3% to 91.2%) at 10 years, and 74.5% (95% CI: 66.6% to 83.4%) at 15 years. Overall survival of patients managed according to an active surveillance strategy was comparable with the expected cumulative survival and early survival rates were even better in the study population (standardized mortality ratio: 0.667; 95% CI: 0.463 to 0.963; $p = 0.013$).

CONCLUSIONS Patients with severe asymptomatic primary MR may remain free of indications for surgery for extensive periods of time. In such patients, active surveillance performed in experienced centers is associated with a favorable prognosis, resulting in timely referral to surgery, excellent long-term survival, and good surgical outcomes.

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Primary mitral regurgitation (MR) is the second most frequent valve disease requiring surgery (1). In these patients, mitral repair is associated with excellent outcomes in terms of perioperative mortality, postoperative left ventricular (LV) function, and long-term survival (2) with age- and gender matched life expectancy and good quality of life (3) when performed before the onset of severe symptoms, LV dysfunction or dilatation, pulmonary hypertension (PHT), and atrial fibrillation. Patients

exhibiting these Class I or IIa indications for surgery should, thus, be referred to mitral repair without delay (4,5). However, the optimal timing of surgery in asymptomatic patients without any of these criteria remains controversial; the American College of Cardiology/American Heart Association guidelines (4) state that elective mitral valve repair should be considered if the operative risk is low and the likelihood of successful repair is >90% whereas the European Society of Cardiology/European Association for

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**ABBREVIATIONS
AND ACRONYMS****CI** = confidence interval**CPR** = cardiopulmonary resuscitation**ECG** = electrocardiogram**HVC** = heart valve clinic**LA** = left atrium**LV** = left ventricle**LVSF** = left ventricular systolic function**MR** = mitral regurgitation**MRI** = magnetic resonance imaging**PHT** = pulmonary hypertension**SMR** = standardized mortality ratio

Cardio-Thoracic Surgery guidelines (5) are more restrictive, recommending the consideration of surgery only when the LV is enlarged (left ventricular endsystolic diameter ≥ 40 mm) in the presence of either a flail leaflet or significant left atrial (LA) dilatation when a durable repair is likely, surgical risk is low, and the repair is performed in a heart valve center.

We previously found that asymptomatic patients with severe primary MR can be safely followed up in the setting of a dedicated heart valve clinic (HVC) until Class I or IIa indications for surgery are reached, resulting in excellent mid-term survival, not different from an age- and gender-matched population (6).

Nevertheless, some registries have suggested a potential survival benefit of early elective surgery (7,8). However, patients may remain asymptomatic for extended periods and surgical results may be inhomogeneous. Furthermore, particularly in the absence of LV or LA dilatation, the diagnosis of severe MR might be erroneous (9,10).

Therefore, the present study sought to assess the 20-year outcome of an active surveillance strategy in a large population of patients with severe primary MR managed in a dedicated HVC.

METHODS

PATIENT POPULATION. All consecutive patients with severe primary mitral regurgitation (prolapse or flail leaflet) who were studied in our outpatient HVC between 1997 and 2015 were included in the study when they were asymptomatic, had an ejection fraction $\geq 60\%$, a left ventricular end-systolic diameter < 45 mm, a Doppler sonographically estimated systolic pulmonary artery pressure ≤ 50 mm Hg, and presented with sinus rhythm. Exclusion criteria were previous cardiac surgery or additional hemodynamically significant valve lesions (moderate or severe) except for tricuspid regurgitation.

According to these criteria, 280 consecutive patients (88 females) were identified. The study protocol was approved by the ethics committee of the Medical University of Vienna and written informed consent was not demanded due to the observational study design.

CLINICAL DATA. At baseline, a comprehensive clinical assessment, including medical history, current medication, physical examination, electrocardiogram (ECG), blood tests, and transthoracic echocardiography, was performed.

The following data were collected: age, gender, body mass index, and body surface area; the patient's symptomatic status; and presence of comorbidities (coronary artery disease [history of myocardial infarction, angioplasty, coronary artery bypass surgery, or angiographically documented coronary artery stenosis], arterial hypertension [blood pressure $\geq 140/90$ mm Hg at repeated measurements or use of antihypertensive agents], hypercholesterolemia [total serum cholesterol ≥ 240 mg/dl or cholesterol-lowering medication], and diabetes [fasting blood glucose level > 126 mg/dl or use of antidiabetic medication]).

ECHOCARDIOGRAPHIC DATA. All patients underwent a comprehensive echocardiographic examination by an experienced echocardiographer.

Apical 4- and 2-chamber views were used for calculation of ventricular volumes and ejection fraction using Simpson's biplane formula. A left ventricular ejection fraction $\geq 60\%$ was considered normal.

Quantification of MR severity was based on an integrated approach (11,12); valve morphology, cavity sizes, and LV function were assessed. Mitral valve prolapse was defined as displacement of 1 or both leaflets by at least 2 mm below the mitral annulus level into the LA during systole. Flail mitral leaflet was defined as a freely moving leaflet edge located in the LA. Systolic pulmonary artery pressure was derived from tricuspid regurgitant velocity.

HVC PROGRAM AND FOLLOW-UP. Asymptomatic patients free of any Class I or IIa indications for surgery were followed up prospectively at every 6 months in the HVC until surgical criteria according to the prevailing guidelines (4,5) were reached. At each HVC visit, a thorough medical history was taken by a physician experienced in the management of patients with valvular heart disease with a specific focus on inquiring about the presence of MR-related symptoms. In addition to echocardiography, patients underwent a physical examination, blood testing, blood pressure measurement, and 12-lead ECG. Patients were instructed to recognize symptoms related to MR and to report any symptom onset without delay. Exercise testing was performed in selected patients when doubt about whether they were truly asymptomatic existed. The decision to perform an exercise test was made on an individual basis according to clinical judgment. The only criterion used to refer a patient to surgery after an exercise test was the occurrence of symptoms during exercise.

Patients developing an indication for surgery were immediately referred to surgery and underwent a systematic preoperative work-up (including coronary angiography).

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