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ORIGINAL ARTICLE

Percutaneous Mitral Valve Repair in a High-risk Australian Series

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Background The prognosis for patients with symptomatic, severe mitral regurgitation (MR) who have comorbidities precluding mitral valve surgery is poor. Treatment of MR using a percutaneous edge-to-edge technique may improve survival, quality of life and reduce hospitalisations. To date, there are few studies reporting outcomes after percutaneous mitral valve repair in high-risk patients and none reported from Australia.

Methods The first 25 patients undergoing percutaneous mitral valve repair using the MitraClip in our Institution had follow-up to six months. These patients had severe, symptomatic MR and were deemed too high-risk for mitral valve surgery by a multidisciplinary heart team, including an interventional cardiologist and cardiothoracic surgeon.

Results There were no peri-procedural deaths; the only peri-procedural morbidity was blood transfusion in three patients. Three patients had died at six months and there were six readmissions to hospital. There was a significant improvement in heart failure symptoms, 6-minute walk test and quality of life at six months. There was a significant improvement in the proportion of patients with MR $\leq$2+, but no significant change in other echocardiographic parameters.

Conclusions Percutaneous mitral valve repair is safe in patients at high-risk for surgery, and improves symptoms and quality of life.

Keywords Mitral regurgitation • Heart valve prosthesis • Mitraclip • Aged • Comorbidity

Introduction

Mitral valve surgery is recommended for patients with severe mitral regurgitation (MR) who are symptomatic, or have evidence of left ventricular dysfunction or dilatation [1–3]. Peri-operative mortality and morbidity for mitral valve surgery is low, but increases significantly with age, severity of symptoms (NYHA IV, presentation with heart failure, cardiogenic shock) and various other co-morbidities [4,5]. With the aging of the population, mitral surgery is increasingly considered in older and sicker patients; the proportion of patients undergoing isolated mitral valve surgery that were $\geq$75 years was 21.2% in the Society of Thoracic Surgeons Database [5].

The MitraClip percutaneous edge-to-edge repair mechanism reduces MR by approximating the edges of the mitral valve leaflets. There is enthusiasm for its use as an alternative to mitral valve surgery in patients who are considered at high-risk to undergo an operation – it has been included in the recently published European Guidelines for consideration (Class IIb indication) when there is agreement of the heart team that the patient is at high-risk from surgery [3].

To date several trials have examined the echocardiographic and clinical efficacy of the MitraClip. The EVEREST

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II trial, recruiting patients eligible to undergo either surgical or percutaneous repair, has recently reported results to four years. There was no difference in the rates of death and MR at four years follow-up, but a greater need for reoperation at one (MitraClip 20.4% vs. 2.2%, p<0.001) and four years (24.8% vs. 5.5%, p<0.001) [6]. Several series have reported outcomes in high-risk patients with MR after MitraClip, but only few with results beyond the peri-operative period [7–15]. A recently published systematic review has reported significantly lower observed than predicted surgical risk of mortality at 30 days (between 0% – 7.8%); and lower grade of MR, NYHA class and improved quality of life after percutaneous mitral valve repair compared to pre-operative baseline [16].

Herein, we report the six-month follow-up of clinical, quality of life and echocardiographic results from the first 25 patients in our Institution's MitraClip experience.

Methods

Patient selection and follow-up

Twenty-five patients underwent MitraClip procedure at Sir Charles Gairdner Hospital between March 2011 and March 2013. Criteria for selection included MR grade ≥3+, symptoms of heart failure and/or echocardiographic evidence of deteriorated left ventricular function. Patients considered for the program were assessed by a heart team comprising an interventional cardiologist and cardiac surgeon and were accepted by consensus if deemed to be at high-risk of mortality or morbidity following isolated operative mitral surgery, or if deemed inoperable. Anatomical criteria for inclusion was based on those used in the EVEREST II study [17]; however eight treated patients with functional mitral regurgitation had coaptation depth or length outside EVEREST II parameters.

A total of 44 patients were screened to yield 25 eligible MitraClip candidates. Twelve eligible patients were deemed 'inoperable' by a cardiac surgeon, the remaining patients, of high surgical risk. Of the 19 that were not accepted, 12 were excluded for anatomical reasons (commisural MR, evidence of rheumatic valvular disease or previous infective endocarditis, excessive leaflet calcification, inadequate coaptation or previous mitral repair). Five were excluded for clinical reasons (excessive comorbidity rendering the procedure too hazardous, or competing diagnosis suggesting other cause for symptoms). Two patients were deemed surgical candidates and underwent mitral valve surgery.

Follow-up was routinely performed at day 1, 30 and 6 months and included clinical and echocardiographic examination, 6-minute walk test and completion of quality of life questionnaires.

Echocardiography

Transoesophageal (at baseline) and transthoracic (at baseline and follow-up) echocardiography (TOE and TTE, respectively) were performed by experienced operators. Three cardiac cycles were stored in a cine loop for offline analysis. MR was graded by colour Doppler and the width of vena contracta. The mitral regurgitant fraction was calculated using the proximal isovelocity surface area and MR velocity-time-integral, according to standard methods. Left ventricular ejection fraction (LVEF) and end-diastolic volume (LVEDV) were calculated using Simpson's biplane method. End-diastolic dimensions (LVEDD) and end-systolic dimensions (LVESD) were obtained using 2-dimensional or M-mode echocardiography.

MitraClip procedure

All procedures were performed using a 24-French MitraClip device (Abbott Vascular, Santa Clara, CA, USA) using techniques similar to those previously described [17]. Procedures were performed under general anaesthesia and guided by TOE. Femoral venous haemostasis was achieved using deployment of a Perclose suture (Abbott Vascular).

Definitions

Renal failure was defined as an increase in creatinine >50% pre-operative baseline. Stroke was defined as neurological deficit (as assessed by a neurologist) that persisted beyond 24 hours. Myocardial infarction was defined as troponin-I increase >20mcg/L and either new ECG changes (Q-waves in 2 leads) or new regional wall motion abnormality. Infection was defined as either superficial groin wound infection or septicaemia (positive blood cultures). Unplanned readmission was defined as admission to hospital for any reason that was not elective.

Quality of life assessment

New York Heart Association (NYHA) functional class and 6-minute walk test (6MWT) distance, in metres, were recorded at baseline and subsequent follow up timepoints. General and heart failure-specific quality of life was measure using the Australian Quality of Life index (6 Domain, AQoL-6D) [18,19] and Minnesota Living with Heart Failure questionnaire (MLWHF) [20], respectively. In both the AQoL-6D and MLWHF, a lower score indicates a better quality of life.

Statistics

Data are expressed as mean ± standard deviation or median (range) depending on whether or not data was normally distributed. Student's t-test and repeated measures ANOVA (with Dunnett's post-test) were used, as appropriate. Graphpad Prism software was used for analysis.

Results

Our first 25 patients undergoing the MitraClip procedure were included in the analysis – details of their pre-operative characteristics are found in Table 1. The majority of patients were male and 75 years or older. All patients had congestive heart failure, MR ≥3+ (mostly of functional aetiology) and the majority had NYHA class III or IV symptoms. All patients