ISSN 2304-2354
Number 2, Volume 44, 2013

EARLY AND MID-TERM FUNCTIONAL AND HEMODYNAMIC EVALUATION OF THE ST. JUDE MEDICAL REGENT 17-MM AORTIC VALVE MECHANICAL PROTHESIS

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Abstract

Objective: The aim of the present study is to report the early and mid-term clinical and hemodynamic results of a prospective trial investigating the clinical performance of the St Jude Medical Regent 17-mm mechanical aortic valve prosthesis (SJMR-17).

Materials and Methods: Between January 2001 and January 2006, 20 patients with aortic valve stenosis underwent first time AVR with a SJMR-17. There were 18 females and two males. Mean age was 69.2±7.3 years and mean BSA was 1.68±0.2 m2. The mean follow-up was 18.7±9.2 months (range 10-32 months). All patients were monitored with serial echocardiograms; the first study was performed preoperatively, subsequent controls were at 2 months, 6 months, and within 1 year, respectively. All survivors underwent Dobutamine stress test at 1 year after surgery.

Results: There was one death. At six months follow-up the mean NYHA FC class was 1.3±0.6 significantly lower than preoperatively 2.75±0.86 ($p<0.0001$). The peak and mean transprosthesis gradients were 29±6.8 and 17.5±4.5 mmHg respectively, significantly lower than preoperatively. Left ventricular mass(gm) and indexed left ventricular mass (gm/m2) were 191±23.8 gm/m2 and 114.5±10.6gm/m2 significantly lower than preoperative values 258±43gm ($p<0.0001$) and 157±27.7 gm ($p=0.00003$).The M-TPG correlated well with the LVMi reduction ($p=0.033$). During DSE the P-TPG and M-TPG increased significantly to 73.8±17.7mmHg and 37±10.7mmHg respectively, significantly higher than at basal state. Differently, the EOA, EOAi and DVI increased during DSE but not significantly versus the values measured at rest. The multivariate regression analysis identified EOAi, BSA, age, postoperative LVMi as strong predictors for higher mean transprosthesic gradients.

Conclusions: The SJMR-17 prosthesis might be employed with satisfactory postoperative clinical and hemodynamic outcome in patients with small aortic annulus, especially in elderly patients, as an alternative to other valves' choice or alternative surgical strategies such as annulus enlargement.

Key words: St Jude Medical Regent 17-mm mechanical aortic prothesis, dobutamine stress test, indexed effective orficice area, indexed left ventricular mass.

Introduction

Aortic valve replacement (AVR) in patients with a small aortic annulus is often challenging for the surgeon in terms of prosthesis selection. AVR with a small prosthetic valve is technically straightforward and commonly performed, but it may result in a patient-prosthetic mismatch resulting in a high residual outflow gradient, the significance of which remains the subject of controversy (1-9). The use of stentless valves or homographs results in lower residual postoperative gradients, but implant procedures are technically more demanding, leading to increased total ischemic time (10-13). Annular enlargement allows for insertion of a larger aortic prosthesis, but it too may introduce increased surgical risks (14-15). On the other hand, bileaflet valves are still the most implanted cardiac valve substitutes in the aortic position. Their excellent durability and low incidence of cardiac-related complications have been widely reported in the medical literature (3,16-18). The St. Jude Medical Regent valve is the next-generation bileaflet mechanical prosthetic aortic valve, constructed of pyrolytic carbon which has a modified external profile that achieves a larger geometric orifice area without changing the existing design of the pivot mechanism or blood-contact surface areas.

The St Jude Medical Regent™ 17-mm aortic valve mechanical prosthesis (SJMR-17) is undergoing evaluation for clinical use by the US Food and Drug Administration, based also in the data provided by