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ORIGINAL ARTICLE

Rapid-Deployment Versus Conventional Bio-Prosthetic Aortic Valve Replacement☆

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Background The use of rapid-deployment aortic valve replacement (RD-AVR) has burgeoned in recent years. There are few studies comparing RD-AVR to conventional aortic valve replacement (cAVR) and no studies where both were inserted via full sternotomy. As such, we reviewed our experience and compared the two approaches.

Methods From 2008 to 2015, 597 patients underwent isolated aortic valve replacement ± coronary artery bypass grafting (CABG) at a single centre. During this period, 41 (7%) patients received RD-AVR and 556 (93%) received cAVR. Of those receiving RD-AVR, surgical access was via full median sternotomy in 40 (98%). Propensity score matching yielded 41 matched pairs. Perioperative outcomes were compared.

Results After propensity score matching, the RD-AVR group had shorter aortic cross clamp (X-clamp) (RD-AVR: 71±33 min vs. cAVR: 106±42 min, p<0.01) and cardiopulmonary bypass (CPB) times (95±42 min vs. 134 ±47 min, p<0.01). There was no difference in 30-day mortality (RD-AVR: 2% vs. cAVR: 2%, p>0.99). RD-AVR patients required shorter mean ventilation (17±25 vs. 63±131 hrs, p<0.01) and intensive care unit (ICU) stay (51±45 vs. 108±157 hrs, p=0.03) times. RD-AVR also had reduced rates of new postoperative atrial arrhythmias (8% vs. 20%, p=0.02). Total length of postoperative hospital stay was similar. Haemodynamic performance for the RD-AVR was within acceptable limits.

Conclusions The use of RD-AVR results in shorter X-clamp and CPB times and is associated with reductions in perioperative morbidity. RD-AVR is becoming a valuable component of the surgeon's armamentarium in selected patients. Long-term follow-up will reveal the full potential of these devices.

Keywords Aortic stenosis • Aortic valve • Rapid deployment aortic valve replacement • Thoracic surgery • Cardiac surgical procedures • Cardiopulmonary bypass.

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Introduction

The burden of aortic stenosis (AS) is expected to rise [1]. Surgical aortic valve replacement (AVR) with conventional, sutured, bioprotheses (cAVR) has long been the gold standard approach for management of AS [2,3]. cAVR has excellent postoperative and long-term outcomes in relatively lower-risk candidates [4–6].

However, as patients referred for AVR become increasingly older, frailer and with a greater number of co-morbidities, there is growing interest in the use of rapid-deployment (RD-AVR) or ''sutureless'' aortic valve prostheses designed to reproduce the excellent outcomes of cAVR [7].

RD-AVR is proposed to reduce cross-clamp (X-clamp) and cardiopulmonary bypass (CPB) times and thereby surgical risk [8–10]. The ease and speed of delivery is also proposed to facilitate minimally invasive surgical (MIS) techniques [11,12]. There is limited data from our region comparing the two techniques. Indeed, in studies that have compared RD-AVR to cAVR, the former have mostly been implanted via minimally invasive approaches which may have served as a confounding factor associated with perioperative outcomes.

As such, we aimed to review the perioperative outcomes of RD-AVR performed via a conventional full sternotomy as compared to a matched cohort of patients undergoing cAVR.

Methods

We conducted a retrospective review of prospectively collected data using the St Vincent's Hospital Melbourne's (SVHM), Australia and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) database. The database provides information on patient preoperative characteristics and risk factors, operative parameters, early postoperative outcomes and 30-day follow-up for complications [13]. Data from the database was supplemented by review of patients' medical records. Institutional Human Research Ethics Committee approval was obtained for this study (Approval Number - QA 009/15).

St Vincent's Hospital Melbourne was the first site in Australia to use a RD-AVR device in November 2012. St Vincent's Hospital Melbourne's RD-AVR program was initiated using the 3F Enable (Medtronic) device and subsequently included the Intuity (Edwards Lifesciences) in 2013. Thus far, we have performed RD-AVR predominantly using a full sternotomy.

Patients

We included patients undergoing isolated AVR ± CABG between 2008 and 2015. Patients were excluded if they had undergone prior cardiothoracic surgery. We included patients operated on between 2008-2012 — prior to the introduction of our RD-AVR — in order to include a sizeable number of patients undergoing cAVR and facilitate propensity-score-matching. This time-period after 2008 was selected, as the surgical techniques, perioperative management strategies and department personnel have remained relatively unchanged. We thus identified 597 patients. Of these 41 (7%) patients received RD-AVR and 556 (93%) of patients received cAVR. Of the 41 RD-AVRs, 17 were 'Enable' and 24 were 'Intuity' devices. RD-AVR was performed using the standard techniques as previously described [14]. While we have discontinued usage of the 3F Enable device since its withdrawal from the market, these patients have been included for analysis as this study primarily evaluates whether the introduction of a RD-AVR program is associated with more favourable postoperative outcomes rather than the performance of individual prostheses.

Our primary outcomes of interest were the rates of perioperative events, which were compared between patients receiving RD-AVR and cAVR. Haemodynamic performance for RD-AVR devices was assessed by mean aortic gradient and paravalvular leak (PVL) rate at discharge and follow-up. Haemodynamic data for patients receiving cAVR was not routinely collected and as such could not be analysed in this study.

Statistical Analyses

Statistical analysis was performed using IBM SPSS, Statistics for Macintosh, Version 22.0 (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as mean ± standard deviation and categorical variables are expressed as whole numbers and percentages. Patients' clinical profile and perioperative outcomes were compared. Continuous variables were compared using the unpaired T-test and the Wilcoxon rank-sum test. Categorical variables were compared using the Fisher's exact and Chi-square tests.

Propensity-score-matching analysis was performed to correct for biases in patient selection for valve type. A propensity-score was generated for each patient in the standard fashion, using logistic regression with RD-AVR (treatment type) set as the dependant variable. The choice of preoperative and surgical technique variables used in propensity-score-matching was based on those considered likely to influence surgical risk and thus the type of prosthesis chosen. Variables used within the logistic regression are listed in Table 1. The c-statistic was used to assess discriminatory ability of the propensity-score. Following this, a propensity-score-matched cohort was generated in a one-to-one fashion using the ''greedy'' matching method without replacement with a fixed calliper width of 0.02.

After propensity-score-matching, the degree of baseline characteristic balance between the two cohorts was assessed using p values and standardised differences. Usually a high degree of balance is reflected by standardised difference scores of $\leq$10%. However in small cohorts (n<100) very small discrepancies in totals can significantly affect standardised differences, therefore considering the relatively small size of our RD-AVR cohort we deemed standardised differences of $\leq$20% to be satisfactory.

In the propensity-score-matched patients, continuous variables were compared using the paired t-test and the

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