Early and intermediate outcome after aortic valve replacement with a sutureless bioprosthesis: Results of a multicenter study

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Objective: The aim of this study was to evaluate the outcome of aortic valve replacement with the sutureless Perceval S aortic valve bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy).

Methods: This is a retrospective analysis of 314 patients (mean age, 77.9 ± 5.0 years, mean European System for Cardiac Operative Risk Evaluation II, 9.0% ± 7.6%) who underwent aortic valve replacement with the Perceval S valve with (94 patients) or without (220 patients) concomitant coronary artery bypass surgery at 5 European centers.

Results: The Perceval S valve was successfully implanted in all but 1 patient (99.7%). The mean aortic crossclamping time was 43 ± 20 minutes (isolated procedure, 39 ± 15 minutes; concomitant coronary surgery, 52 ± 26 minutes). Severe paravalvular leak occurred in 2 patients (0.6%). In-hospital mortality was 3.2% (1.4% after isolated procedure and 7.4% after concomitant coronary surgery). In-hospital mortality was 2.8% and 4.0% among patients with a European System for Cardiac Operative Risk Evaluation II less than 10% and 10% or greater, respectively ($P = .558$). Octogenarians had slightly higher in-hospital mortality (5.2% vs 2.0%, $P = .125$; after isolated procedure: 2.7% vs 0.7%, $P = .223$; after concomitant coronary surgery: 9.5% vs 5.8%, $P = .491$) compared with younger patients. Full sternotomy did not increase the in-hospital mortality risk compared with ministernotomy or minithoracotomy access (1.3% vs 1.4%, when adjusted for baseline covariates: $P = .921$; odds ratio, 0.886; 95% confidence interval, 0.064-12.346). One-year survival was 90.5%. Freedom from valve-related mortality, stroke, endocarditis, and reoperation was 99.0%, 98.1%, 99.2%, and 98.3%, respectively.

Conclusions: The sutureless Perceval S valve is associated with excellent early survival in high-risk patients, particularly among those undergoing an isolated procedure. Further studies are needed to prove the durability of this bioprosthesis. (J Thorac Cardiovasc Surg 2014;148:865-71)

Severe aortic valve stenosis is a common cardiac disease among the elderly,[1,2] and aortic valve replacement (AVR) is still the treatment of choice.[3] Among octogenarians, AVR has been shown to provide late survival similar to that in an age- and gender-matched general population.[4] The expected significant aging of the population and the evidence of a survival benefit in patients with a low gradient severe aortic valve stenosis[5] will soon lead to a significant increase in the need for AVR, particularly in very elderly patients with multiple comorbidities. Transcatheter aortic valve replacement (TAVR) has been embraced with enthusiasm and has expanded the therapeutic possibilities to patients ineligible for conventional AVR. Conversely, the significantly increased costs, the inability to remove the calcified aortic valve, and the resultant high incidence of paravalvular leakage have been recognized as important limitations of TAVR. Accordingly, a number of sutureless aortic valve bioprostheses[6] have been developed during the last few years to facilitate surgical AVR and circumvent prolonged aortic crossclamping and cardiopulmonary bypass time and their related increased risk of mortality and morbidity.[7] Therefore, the aim of this study was to assess the early and intermediate outcome after AVR with the sutureless Perceval S aortic valve bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy) in a multicenter European study.

METHODS

We performed a retrospective analysis of a consecutive series of patients who underwent operation between September 2007 and September 2013 at 5 European institutions (Belgium, Finland, Germany, Italy, and Sweden).

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Abbreviations and Acronyms

AVR = aortic valve replacement
CABG = coronary artery bypass grafting
CI = confidence interval
euroSCORE = European System for Cardiac Operative Risk Evaluation
OR = odds ratio
TAVR = transcatheter aortic valve replacement

The baseline and operative characteristics of these patients are summarized in Tables 1 and 2. The operative risk of these patients was estimated according to the European System for Cardiac Operative Risk Evaluation (euroSCORE) II.[8]

Permission to perform this study was granted by the ethical committees of each participating center. The inclusion criterion for this study was any isolated AVR with or without concomitant coronary artery bypass grafting (CABG) using the Perceval S sutureless aortic valve prosthesis. Patients undergoing any other concomitant cardiac procedure were excluded. Data on patients' characteristics and operative details were retrieved retrospectively from patients' records. Follow-up data were retrieved by reviewing hospital records or contacting the patient or her/his cardiologist or general practitioner.

ACD

Indication for and Implantation Technique of Perceval S Prosthesis

The Perceval S sutureless aortic valve prosthesis was mostly indicated in patients with a perceived high operative risk. The implantation of this valve was considered feasible when the aortic annulus size was between 19 and 27 mm, and the ratio between the sinotubular diameter and the aortic annulus was no more than 1.3. The ascending aorta was incised transversally 1.5 cm above the sinotubular junction. The aortic valve was removed, and the annulus was decalcified in the usual fashion in patients at each center. Three 4/0 polypropylene guiding sutures were passed at the nadir of the aortic annulus. An appropriately sized prosthesis was collapsed in a side table and placed into the manufacturer's holder. The 3 guiding sutures were passed through the 3 green holes arising from the annular ring of the prosthesis, which was consequently seated on the debrided annulus. The aortic valve was opened, and the holder was removed. The field was rinsed with warm saline, and the prosthesis was dilated at 4 atm for 30 seconds. After closure of the aortotomy, transesophageal echocardiography was performed to assess the correct implantation of the prosthesis and the presence of any valve leak.

Outcome End Points

The main end points of this study were all-cause in-hospital and 1-year mortality. Secondary outcome end points were implantation success, aortic prosthesis valve-related mortality, stroke, reoperation on the aortic valve, and prosthesis endocarditis. Implantation success was defined as an implanted Perceval S that did not require replacement during the same operation with another Perceval S or conventional valve prosthesis.

Statistical Analysis

Statistical analysis was performed using SPSS version 20 (IBM SPSS Inc, Chicago, Ill). Fisher exact test, chi-square test, and Mann–Whitney test were used for univariate analysis. No attempt to replace missing values was made. Survival analysis was performed using the Kaplan–Meier and Cox proportional hazards methods. The area under the receiver operating characteristic curve was used to represent the discriminatory ability of the euroSCORE II. The accuracy of the euroSCORE II was assessed by the Brier score,[9] which is the average squared difference between the predicted probability and the true occurrence of operative mortality. A Brier score should be as close to 0 as possible, with 0.25 as an acceptable upper cutoff.

RESULTS

This analysis included 314 patients who underwent AVR with the sutureless Perceval S aortic valve (Table 1). In addition to the high prevalence of octogenarians (36.9%), there was a rather high prevalence of female patients (60.2%), patients with renal failure (creatinine clearance <50 mL/min or dialysis, 23.5%), patients with peripheral artery disease (23.9%), and patients with increased systolic pulmonary pressure (>30 mm Hg, 44.4%). However, most of these patients had a left ventricular ejection fraction greater than 50% (86.3%), and surgery was performed on elective basis in all but 2 patients (99.4%).

Concomitant CABG was performed in 94 patients (29.9%). Minimally invasive access was used in 140 patients (44.6%) (Table 2). In the overall series, the mean aortic crossclamping time was 43 ± 20 minutes, and cardiopulmonary bypass time was 73 ± 28 minutes. These were markedly shorter in patients undergoing isolated AVR (Table 2). In particular, the aortic crossclamping time was less than 30 minutes in 79 patients (25.2%), more specifically in 64 patients (29.1%) who underwent isolated AVR and in 15 patients (16.0%) who underwent concomitant CABG.

Early Outcome

The Perceval S valve was successfully implanted in all but 1 patient (99.7%). Severe paravalvular leak was detected intraoperatively in 2 patients (0.6%), mild paravalvular leak was detected in 38 patients (12.1%), and no paravalvular leak was detected in 274 patients (87.3%).

Redo conventional AVR was required during the same in-hospital stay in 3 patients: the 2 patients with the mentioned severe paravalvular leakage and 1 patient with prosthesis dislodgment.

In-hospital mortality in the overall series was 3.2% (1.4% after isolated aortic valve procedure and 7.4% after concomitant CABG, $P = .009$). Six patients died of multiorgan failure, 3 patients died of sepsis, and 1 patient died of respiratory failure. Among these early deaths, only 2 patients had mild paravalvular leak and the remaining 8 patients did not have any paravalvular leak. None of them required reoperation on the valve prosthesis, and no valve-related early mortality occurred in this series. Other early adverse events and length of stay in the intensive care unit and in hospital are summarized in Table 3.

The mean euroSCORE II in the overall series was 9.0% ± 7.6% (median, 7.0%; range, 1.08-60.0). The area under the