Minimally invasive aortic valve replacement with Perceval S sutureless valve: Early outcomes and one-year survival from two European centers

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Objective: The aim of our study was to evaluate the early outcomes and 1-year survival of patients undergoing minimally invasive aortic valve replacement with the Perceval S sutureless valve for severe aortic stenosis.

Methods: From March 2010 to March 2013, 281 high-risk patients underwent minimally invasive aortic valve replacement with the Perceval S sutureless valve through either right anterior minithoracotomy (n = 164) or upper ministernotomy (n = 117) at 2 cardiac centers.

Results: The overall in-hospital mortality was 0.7% (2 patients). The overall median cardiopulmonary bypass and crossclamp time was 81 minutes (interquartile range, 68-98) and 48 minutes (interquartile range, 37-60), respectively. Postoperative stroke occurred in 5 patients (1.8%). The incidence of paravalvular leak greater than 1 of 4 and atrioventricular block requiring pacemaker implantation was 1.8% (5 patients) and 4.2% (12 patients), respectively. No migration occurred, and the mean postoperative gradient was 13 ± 4 mm Hg. At a median follow-up of 8 months (interquartile range, 4-14), the overall survival was 90%.

Conclusions: Minimally invasive aortic valve replacement with the Perceval S sutureless valve in high-risk patients is a safe and reproducible procedure associated with excellent hemodynamic results, postoperative outcomes, and 1-year survival. (J Thorac Cardiovasc Surg 2014;148:2838-43)

See related commentary on pages 2843-4.

ACD

The clinical outcomes after elective isolated aortic valve replacement (AVR) have significantly improved in previous years.[1] According to the recent Fourth European Association for Cardio-Thoracic Surgery adult cardiac surgery database report, the overall operative mortality has ranged from 1.2 to ≤14%, depending on patient age and overall risk profile.[2] Despite these results, less invasive procedures have been developed as an alternative to the conventional technique to reduce the surgical trauma and preserve the same quality, safety, and efficacy of the full sternotomy approach.[3] Minimally invasive AVR (MIAVR) has shown excellent results in terms of mortality, morbidity, and patient satisfaction, providing less pain, faster recovery, and a shorter hospital stay.[4-7] However, traditionalists have claimed that MIAVR is technically more complex, requires a distinct learning curve, and that the only clear benefit to the patient is cosmesis.[8,9] Furthermore, the longer crossclamp and cardiopulmonary bypass (CPB) times associated with the MIAVR approach have raised some concerns regarding its safety in elderly and high-risk patients, because they are well-known risk factors for adverse outcomes after cardiac surgery.[10,11] In this setting, the implantation of sutureless valves might facilitate the MIAVR approach, reducing the operative times.

The Perceval S sutureless valve (Sorin Biomedica Cardio Srl, Salluggia, Italy) is a new self-expanding prosthesis made of bovine pericardium mounted in a nitinol stent, designed as an alternative to the traditional prostheses to simplify surgical implantation. Recently, the Perceval S has shown excellent results in term of postoperative outcomes and hemodynamic performance, decreasing the operative times.[12-15] The aim of our study was to evaluate the early outcomes and 1-year survival of patients who had undergone MIAVR for severe aortic valve stenosis with the Perceval S sutureless valve at 2 different institutions.

METHODS

Patient Selection and Data Collection

A retrospective, observational study was undertaken of prospectively collected data from consecutive patients with severe aortic stenosis

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Disclosures: Drs Santarpino, Pfeffer, Fischlein, Solinas, and Glauber disclose a financial relationship with Sorin Group. All other authors have nothing to disclose.

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Received for publication Nov 15, 2013; revisions received Feb 6, 2014; accepted for publication Feb 28, 2014; available ahead of print April 1, 2014.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2014.02.085

Abbreviations and Acronyms

AVR = aortic valve replacement
CPB = cardiopulmonary bypass
L = large
M = medium
MIAVR = minimally invasive AVR
MS = ministernotomy
PVL = paravalvular leakage
RT = right anterior minithoracotomy
S = small
STS = Society of Thoracic Surgeons
TAVI = transcatheter aortic valve implantation

(mean gradient > 40 mm Hg or an aortic valve area <1 cm^2) undergoing MIAVR from March 2010 to March 2013. The completed data collection forms were entered in a local databases and included several sections completed by the anesthetists, cardiac surgeons, and perfusionists involved in the care of the patients. A total of 281 consecutive patients with severe aortic stenosis underwent MIAVR with the Perceval S sutureless valve at 2 European cardiac centers (Fondazione Toscana G. Monsaterio, Massa, Italy; and Klinikum Nürnberg, Nürnberg, Germany). Of the 281 patients, 164 underwent right anterior minithoracotomy (RT) and 117 underwent a ministernotomy (MS) approach. The local committee of institutional review boards approved the study to meet ethical and legal requirements, and individual patient consent was waived.

The selection criteria for the Perceval S sutureless valve were severe calcified aortic valve stenosis, or steno-insufficiency, age ≥65 years, EuroSCORE I >5%, and a small calcified aortic root and/or annulus. The exclusion criteria for valve implantation were acute endocarditis, bicuspid aortic valve replacement with asymmetric sinus of Valsalva, dilatation of the ascending aorta >4 cm in the sinotubular junction, and a ratio between the diameter of the sinus of Valsalva and diameter of the superior annulus >1.3 (a ratio >1.3 can prevent correct fixation of the valve stent on the aorta). Mortality was defined as any death occurring within 30 days of surgery. Postoperative stroke was diagnosed if evidence was found of a new neurologic deficit with morphologic substrate confirmed by computed tomography or nuclear magnetic resonance imaging. Before discharge, all patients underwent transthoracic echocardiography. The grade of paravalvular leakage (PVL) regurgitation was determined from the color Doppler imaging findings and classified into 4 grades: trivial, 1 of 4; mild, 2 of 4; moderate, 3 of 4; and severe, 4 of 4. The follow-up data were 100% complete.

Preoperative Planning and Surgical Procedures

All patients undergoing MIAVR underwent an accurate preoperative transthoracic echocardiographic study for a better evaluation of the aortic valve, aortic annulus diameter, and symmetry of the Valsalva sinuses. Patients who were a candidate for a RT approach underwent 64-slice thoracic computed tomography without contrast enhancement to evaluate the relationship among the aortic valve, sternum, and intercostal spaces. The patients were considered suitable for a RT approach if, at the level of the main pulmonary artery, the ascending aorta was rightward with respect to the right sternal border and the distance from the ascending aorta to the sternum did not exceed 10 cm. The MS and RT approaches were chosen according to center preferences. Specifically, MS was the main approach in Nuremberg (95%), and RT was mainly performed in Massa (90%, with the remaining not suitable for RT for anatomic reasons).

The surgical techniques have been previously reported.[16-18] In brief, RT was performed through a 5- to 7-cm skin incision placed at the level of the second intercostal space. Direct aortic cannulation was performed using flexible cannulas, such as Easyflow (Sorin, Sallugia, Italy), and venous drainage was achieved with a Bio-Medicus Multistage cannula (Medtronic, Minneapolis, Minn) or remote access perfusion cannula (Sorin) and inserted through the femoral vein into the right atrium, and the correct position was reached using the Seldinger technique under transesophageal echocardiographic guidance.[16] The MS sternotomy approach was achieved through a 6- to 10-cm midline vertical skin incision, performing a partial J sternotomy at the third to fifth intercostal space or a V-shaped ministernotomy at the level of the second intercostal space.[17,18] After CPB had been established, a left ventricular vent was placed through the right superior pulmonary vein, and the patients were cooled to 34°C. The ascending aorta was clamped with the DeBakey crossclamp or with the Glauber clamp (Cardiomedical GmbH, Langenhagen, Germany, distributed by Sorin), and antegrade cardioplegic solution was given into the aortic root or selectively into the coronary ostia using warm blood cardioplegia. In all cases, the surgical field was flooded with carbon dioxide until closure of the aortotomy.

Perceval S Implantation

The transverse aortotomy was performed approximately 1.5 to 2 cm higher than ordinary aortotomy for AVR. The reference point was the inferior margin of the Concato preaortic bundle. The diseased native valve was completely removed and the aortic annulus thoroughly decalcified and sized. The valve sizer was designed so that the intra-annular head of the sizer (yellow) has the same external diameter as the supra-annular head (white) of the smaller size. For the appropriate sizing, the native annulus should allow the passage of the intra-annular head but not the supra-annular head of the same sizer (eg, intra-annular head of size large [L] should correspond to the supra-annular head of size medium [M]). Afterward, 3 guiding 4-0 Prolene sutures were placed at the nadir point of each valve sinuses to act as a reference for accurate alignment of the inflow portion of the prosthesis into the aortic annulus. The valve was collapsed using a specific device system and connected to the guiding sutures through 3 bottom holes placed on the midpart of the inflow ring. The deployment system was parachuted down into the aortic root and the valve released into the aortic annulus. The inflow ring should completely cover the aortic annulus, such that no part of the native aortic annulus is exposed. Although not recommended by Sorin, it is still possible to adjust the valve position using the forceps. Once coaptation of the 3 leaflets had been checked, a balloon was inserted into the sutureless valve and expanded with warm saline solution for 30 seconds at a pressure of 4 mBar. Finally, the 3 guiding sutures were removed; the valve was again checked for the correct position, and the aortotomy was closed using 4-0 or 5-0 running sutures. The patient was weaned from CPB, and the valve was evaluated for the presence of PVL using transesophageal echocardiography.

Currently, 3 sizes are available: small (S) (21 mm), M (23 mm), and L (25 mm). The extra large (XL) size is still under investigation in a multicenter study for the European Commission (''Conformite Europeene'') approval and was used exclusively by the Nuremberg group.

Statistical Analysis

Continuous data are presented as the mean ± standard deviation or median and interquartile range (IQR) and categorical data as percentages. The Kolmogorov-Smirnov test was used to check for normality of the postoperative gradients before additional analysis. Differences between mean postoperative gradients and valve sizes were tested using the Kruskal-Wallis test. Kaplan-Meier estimates were used to determine total survival and event-free survival (defined as the absence of reoperation, endocarditis, stroke, and death). Statistical analysis was performed using the Statistical Package for Social Sciences, version 15.0 (SPSS, Chicago, Ill).

RESULTS

The baseline and intraoperative characteristics are reported in Tables 1 and 2. All valves were successfully