Five-year results of the pilot trial of a sutureless valve

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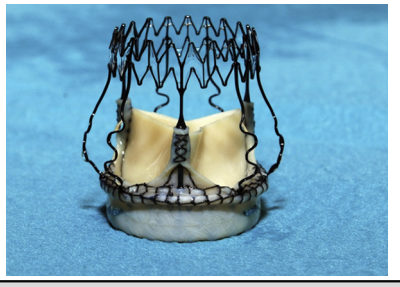
ABSTRACT

Objective: A prospective trial was designed to evaluate the feasibility of the Perceval sutureless aortic valve. We report the 5-year clinical and hemodynamic outcome.

Methods: A total of 30 patients (mean age: 80.4 ± 3.8 years; mean logistic European System for Cardiac Operative Risk Evaluation [euroSCORE]: 13.2 ± 7.3) received the valve in 3 European centers, between April 2007 and February 2008. Cumulative follow-up was 92.67 patient-years, with a median of 4.2 years. Patients with a small annulus were selected because only sizes 21 and 23 mm (covering annuli diameters from 19 to 23 mm) were available at this early stage of the trial. In 37% of the patients, a 21-mm valve was used; 63% received a 23-mm valve; 14 patients had concomitant coronary artery bypass grafting. Clinical and hemodynamic follow-up evaluation were performed annually, including echocardiography.

Results: Procedural success was 100%. Cardiopulmonary bypass time and cross-clamp time in isolated aortic valve replacement were 46.4 ± 6.7 minutes and 29.3 ± 8.0 minutes, respectively. One patient died during the hospital stay. Postoperative complications included 1 patient with mediastinal bleeding, and 1 with atrioventricular block that led to pacemaker implantation. No stroke occurred in either the early or late period. At the last available follow-up, 22 patients were alive. The mean gradient was 9.3 mm Hg, with an effective orifice area of 1.7 cm^2 at 5 years. No dislodgement, structural valve deterioration, hemolysis, or valve thrombosis was reported.

Conclusions: This study reports the first and longest experience with a truly sutureless valve, evaluating implantation feasibility and valve safety. Results from up to 5 years of follow up confirmed the performance and safety of this device, even in a medium- to high-risk patient population with a small aortic annulus. (J Thorac Cardiovasc Surg 2015;150:84-8)



The Perceval bioprosthesis is currently, worldwide, the most frequently used sutureless valve.

Central Message

Five-year outcomes of a sutureless aortic valve in 30 elderly patients showed survival at 71.3%, and a mean gradient of 9.3 mm Hg. Effective orifice area was 1.7 cm^2, without dislodgement, structural valve deterioration, hemolysis, or valve thrombosis.

Perspective

The current article summarizes the 5-year follow-up data of the 30 first Perceval valves that were implanted. This experience is the first and longest with humans, with a truly sutureless valve, to evaluate implantation feasibility and valve safety. Results for up to 5 years of follow up confirmed the performance and safety of this device, even in a medium- to high-risk patient population. The valve did not reveal any dislodgement, structural valve deterioration, hemolysis, or thrombosis.

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ACD

The Perceval sutureless valve prosthesis (Sorin Group Italia S.r.l., Saluggia, Italy) has gained wide popularity both in minimal invasive and conventional aortic valve replacement to reduce aortic cross-clamp time and maximize effective valve orifice area by complete resection of the calcified aortic valve. Several studies demonstrated safety and efficacy of the valve prosthesis in both isolated and combined procedures.[1-6] However, to date, only short-term results have been published, with outcomes of up to 12 months. In this paper, we present the midterm results (up to 5 years) for the first 30 patients included in this pilot trial (first use in humans) involving 3 centers.

METHODS

Approval for the study was granted by the institutional review boards of the university hospitals involved, and by the ethics committees of the hospitals; all patients provided written, informed consent.

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Abbreviations and Acronyms
NYHA = New York Heart Association
TAVI = transapical or transfemoral aortic valve implantation

Study Design

The pilot trial was designed as a prospective and nonrandomized study, on a maximum of 30 patients, and was conducted in 3 investigational centers (Hannover, Paris, and Leuven). The objective of the pilot trial was to assess the safety of aortic valve replacement with the sutureless Perceval valve in 30 symptomatic patients, aged ≥75 years. The primary endpoint was the assessment of the safety of the prosthesis, in terms of mortality and morbidity at 30 days, correlated to prosthetic valve performance. Secondary endpoints were the evaluation of mortality and morbidity, the evaluation of the clinical status on the basis of the New York Heart Association (NYHA) functional classification, and the evaluation of the hemodynamic performance by echocardiographic examination at 1, 3, 6, and 12 months after implantation. All echocardiography data underwent echo-core lab review.

A minimum of 7 patients had to be enrolled at each investigational center. Inclusion criteria were being aged >75 years, and having aortic valve stenosis. The patients had to be eligible for standard surgical care. Further inclusion criteria were NYHA functional class III and/or IV, small (<23 mm) and calcified aortic root or annulus. Exclusion criteria comprised aneurysmal dilation (>4 cm) of the ascending aorta, as well as an aortic annulus that was too large, as measured intraoperatively, after decalcification. During this experience with the first implantation in humans, only valve sizes 21 mm and 23 mm were available.

The enrollment was carried out in a sequential, prospective manner, such that all elderly patients with medium to high surgical risk were offered the possibility of participating in the assessment and were therefore evaluated according to the selection criteria defined in the protocol. Clinical and echocardiographic examinations were carried out at 1, 3, 6, and 12 months after implantation. At completion of the 12-month visits, follow-up of up to 5 years was implemented, to monitor the patients' clinical and hemodynamic status.

Sutureless Valve

The valve is a prosthesis consisting of a bovine pericardium valve fixed in a stent of superelastic alloy (equi-atomic alloy of nickel and titanium). The design features 2 ring segments, 1 on the proximal and 1 on the distal end, and connecting elements designed to support the valve and allow the prosthesis to anchor to the aortic root and the sinuses of Valsalva. Corresponding to each valve sinus, the inflow ring has 3 loops through which temporary guiding threads are passed, to aid the positioning of the prosthesis (Figure 1).

The superelastic alloy can undergo strong deformation and return to its original shape after the source of force is removed. Therefore, the stent can be compressed for the implantation and then released to reach its final diameter. Before implantation, the prosthesis is collapsed and loaded onto a holder. The valve is positioned and released in the aortic root, where the stent self-anchoring design allows stable seating of the device.

Surgical Procedure

Within the pilot trial, all patients underwent a standard median sternotomy. Under extracorporeal circulation and cross-clamping, a transverse aortotomy was performed 1 cm distal to the sinotubular junction (approximately 1 cm higher than a routine transverse aortotomy).

After the calcified native aortic valve was removed and the aortic annulus decalcified and measured, 3 guiding sutures were positioned 2 mm below the nadir of the native leaflet insertion line of each valve sinus. These sutures were passed through the corresponding eyelets in the prosthetic inflow ring, as a reference for alignment of the inflow section of the prosthesis with the insertion plane of the native leaflets.

The valve prosthesis was loaded onto the delivery device and inserted to the point where it was blocked by the temporary guiding sutures. The prosthetic valve was released in 2 phases: first, the inflow section of the valve, followed by the opening of the outflow part. To optimize the area of contact between the prosthesis and the aortic annulus, a postimplant dilatation was done with a specifically designed balloon catheter at pressures of 4 atm for 30 seconds, while warm water was applied to the valve. Once the prosthesis was completely deployed, the guiding sutures were removed.

After closure of the aortotomy in the usual fashion, and release of the aortic cross-clamp, the valve function was assessed by transesophageal echocardiography in all patients. After the procedure, the patients received anticoagulation treatment according to the standard protocol in use at each center for aortic bioprostheses.

Reporting on Adverse Events and Statistical Analysis

Adverse events were reported according to current guidelines.[7] Analyses for descriptive statistics were done with SAS software, version 9.2 (SAS Institute, Cary, NC). All data are expressed as mean ± SD, or as median and quartiles, if not normally distributed. Kaplan-Meier analysis was performed for medium-term survival.

RESULTS

Between April 2007 and February 2008, a total of 30 patients underwent aortic valve replacement with the prosthesis. Characteristics of the patients and intraoperative data are given in Table 1. Three patients had undergone previous cardiac surgery.

Operative results and follow-up evaluation at 12 months have been reported previously.[3] Follow-up evaluation was available on a yearly basis for up to 5 years. Cumulative follow-up time was 92.7 years. One patient died during hospital stay, from sudden cardiac arrest (3.3%). Six patients in total died during the first postoperative years, between 45 and 1665 days after surgery, as reported previously,[3] but only 1 of the deaths was valve related (endocarditis and sepsis on day 264). Overall 5-year survival was 71.3% (Figure 2).

Freedom from valve explant was 100% at 5-year follow-up evaluation. One patient had early mediastinal bleeding that led to tamponade and re-exploration on day 3, with a further uneventful course. Two late bleeding events occurred: 1 was gastrointestional bleeding that led to rehospitalization on day 36, and 1 was retinal bleeding on day 350 without further treatment. One thromboembolic event was observed on day 6: limb ischemia, successfully treated with heparinization. Aside from the patient dying from severe endocarditis and sepsis, a second patient suffered from prosthesis endocarditis, leading to rehospitalization and complete resolution under antibiotic therapy on day 789. One patient underwent pacemaker implantation early after surgery, owing to new-onset atrioventricular block.

Linearized rates (events per 100 patient-years) and actuarial probabilities of freedom from postoperative mortality and morbidity at 5 years were, respectively: late mortality, 6.5 (95% confidence interval (CI) 1.5-11.5) and 71.3%; bleeding, 2.2 (95% CI 0.0-5.1) and 89.2%; endocarditis,

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