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Sutureless Valve in Repeated Aortic Valve Replacement: Results from an International Prospective Registry

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Abstract

Objective: To report early and midterm results registry of patients undergoing repeated aortic valve replacement (RAVR) with sutureless prostheses from an international prospective registry (SURE-AVR). **Methods:** Between March 2011 and June 2019, 69 patients underwent RAVR with self-expandable sutureless aortic bioprostheses at 22 international cardiac centers. **Results:** Overall mortality was 2.9% with a predicted logistic EuroSCORE II of 10.7%. Indications for RAVR were structural valve dysfunction (84.1%) and infective prosthetic endocarditis (15.9%) and were performed in patients with previously implanted bioprostheses (79.7%), mechanical valves (15.9%), and transcatheter valves (4.3%). Minimally invasive approach was performed in 15.9% of patients. Rate of stroke was 1.4% and rate of early valve-related reintervention was 1.4%. Overall survival rate at 1 and 5 years was 97% and 91%, respectively. No major paravalvular leak occurred. Rate of pacemaker implantation was 5.8% and 0.9% per patient-year early and at follow-up, respectively. The mean transvalvular gradient at 1-year and 5-year follow-up was 10.5 mmHg and 11.5 mmHg with a median effective orifice area of 1.8 $cm^2$and 1.8 cm^2, respectively. **Conclusions:** RAVR with sutureless valves is a safe and effective approach and provides excellent clinical and hemodynamic results up to 5 years.

Central Message
Results from an international prospective registry found redo aortic valve surgery with Perceval provided excellent hemodynamic performance and clinical outcomes at early and midterm follow-up.

Keywords
sutureless, AVR, redo surgery

Introduction

The number of patients undergoing repeated aortic valve replacement (RAVR) is growing and will continue to increase because of the effect of the aging population and the preference of biological valves in young patients for better quality of life.[1] It has been estimated that after AVR, 10% of patients receiving biological valves and 2%-4% receiving mechanical valves require a reoperation in the first 10 years. After 15 years, the proportion of patients rises up to 30% and 10%, respectively.[2] RAVR is a technically demanding procedure because of the presence of adhesions and tissue scars, the risk of iatrogenic injury to cardiovascular structures and the long operative times, which increase the risk of bleeding and transfusion-related morbidity.[3] Redo surgery is associated with higher mortality and morbidity compared to primary AVR and the overall

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in-hospital mortality ranges from 2.3% to 17.6%.[4–8] This risk has brought surgeons to consider alternative strategies to improve surgical outcomes.[9,10] Valve-in-valve (ViV) transcatheter aortic valve implantation (TAVI) is considered a less invasive strategy; however, it is associated with specific complications and requires extensive preoperative work-up planned by the heart team.[11] Moreover, not all patients are suitable for this procedure. Specifically, active endocarditis, mechanical prosthetic dysfunction, multiple valve disease and biological valve dysfunction with small annuli are not indication for ViV TAVI. Nevertheless, a recent international panel consensus recommends considering the use of sutureless valves in case of redo operation due to prior AVR or as ViV procedure in calcified aortic homografts and degenerated porcine aortic root.[12] Perceval (LivaNova, London, UK) is a self-expandable sutureless aortic bioprosthesis and has shown excellent postoperative outcomes and hemodynamic performances.[13] However, clinical benefit of sutureless valves in RAVR is limited to few experiences.[14–16] Therefore, the aim of this study is to report early and midterm results from an international AVR registry in patients undergoing RAVR with Perceval valve.

Methods

Registry Design

The SURE-AVR registry (NCT02679404), sponsored by LivaNova PLC, is an ongoing, prospective, international, observational registry conducted at 60 sites in Europe, USA, Canada, and Australia. Any of the commercially available LivaNova aortic products are eligible for enrollment. Between March 2011 and June 2019, of 1226 patients included in the prospective observational SURE-AVR registry, 69 patients underwent RAVR with self-expandable sutureless aortic bioprosthesis in 22 international institutions. Preoperative, periprocedural, follow-up clinical and echocardiographic parameters, as well as clinical outcomes, were analyzed for all patients.

The registry was conducted according to the International Conference on Harmonization guidelines, Good Clinical Practice, and local regulations. Ethics committee and/or institutional review board approval was obtained as required by local regulations. All patients gave informed consent to participate. Patients were enrolled prospectively and treated according to the standard of care of participating sites. Inclusion and exclusion criteria were those reported by the Instructions for Use of the Perceval valve.

Study Device and Implantation Technique

Perceval valve is a self-anchoring, self-expanding, and sutureless bioprosthesis indicated for aortic valve replacement. This bioprosthesis has a functional component, made of bovine pericardium, stabilized in buffered glutaraldehyde solution, and a super-elastic metal alloy stent, which has the dual role of valve supporting and anchoring to the aortic root with no permanent sutures. Before implantation, the prosthesis is reduced to a suitable size for loading it onto a holder accessory. The valve is then positioned and released into the aortic root and subsequently post-dilated using a dedicated balloon catheter. The device is available in 4 sizes (small, medium, large, extra-large). Implantation can be performed using a traditional surgical approach, or through a minimally invasive approach. A horizontal aortotomy is performed at a height of 2 cm to 3 cm above the sinotubular junction. Careful removal of the prosthesis is of paramount importance to avoid annular defects. Aortic annulus is inspected and the excess of pannus or fibrotic tissue is removed with a blade to favor annular circularity. After sizing, 3 guiding 4-0 Prolene sutures are 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. In some cases, the previous prosthesis may alter annulus geometry, losing nadir points. To manage this problem, the surgeon can recreate 3 nadirs positioned at approximately 120 degrees. To achieve this result, the surgeon may use instruments such as a commercial sizer with 120 degree markings to recreate a normal nadir. Then, the valve is 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 valve is released into the aortic annulus and once coaptation of the 3 leaflets has been checked, a balloon was inserted into the sutureless valve and expanded with warm saline solution for 30 s at a pressure of 4 mBar. Finally, the 3 guiding sutures were removed; the valve is again checked for the correct position, and the aortotomy is closed using 4-0 or 5-0 running sutures.

Data Collection

Baseline characteristics, echocardiographic data and surgical data were entered into an electronic case report form by trained study coordinators. Follow-up visits were performed according to the centers' usual practices (telephone calls, referring physicians, or clinical visits) at 1 year and annually up to 5 years. An electronic data capture system was used to allow specific quality control checks. The sponsor's project team also applied checks to ensure an appropriate level of quality and compliance of the data; no source verification (monitoring) visits were used.

Clinical Outcomes

Data on multiple procedural and hospital discharge variables were collected, including implant success, cross-clamp time, and length of stay in the intensive care unit. Clinical success was defined as a successful valve implantation without the occurrence of major adverse events by the time of hospital discharge. Investigator-reported major adverse events were defined as death (all-cause, cardiovascular, noncardiovascular), stroke and reintervention (surgery or any other cardiac invasive therapy). Serious valve-related adverse events included

Table 1. Baseline Clinical Characteristics.

Baseline characteristics	*N* = 69
Age, year	71.7 ± 9.8
Female	30 (43.5)
Dyslipidemia	41/67 (59.4)
Diabetes	15/67 (21.7)
Pulmonary hypertension	10/46 (14.5)
Preoperative atrial fibrillation	12 (17.4)
Previous cerebrovascular event	9 (13)
Renal insufficiency	9 (13)
Peripheral vascular disease	4/42 (9.5)
Previous myocardial infarction	6/68 (8.7)
Chronic lung disease	6 (8.7)
Left ventricular ejection fraction	55.6 ± 12.3
NYHA Class III-IV	44/65 (63.8)
Previous cardiac surgery	
Biological AVR	55 (79.7)
Mechanical AVR	11 (15.9)
TAVR	3 (4.3)
Mitral valve surgery	4 (5.7)
Ascending aortic/aortic root procedure	3 (4.3)
CABG	10 (14.5)
EuroSCORE II	10.7 (4.4-16.6)

Abbreviations: AVR, aortic valve replacement; CABG, coronary artery bypass grafting; EuroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; TAVR, transcatheter aortic valve replacement.
Data presented as mean ± SD, median (IQR), or *n* (%).

bleeding, thromboembolism, valve thrombosis, endocarditis, nonstructural dysfunction, and structural valve deterioration.

Early outcomes were defined as those occurring up to 30 days after the procedure and late outcomes as those occurring >30 days after the procedure.

Statistical Analysis

Variables are described as mean ± standard deviation or median (quartile Q1, Q3; range) for continuous variables, and as number (%) for categorical variables. Outcomes are reported as descriptive statistics. The rates of early adverse events were calculated as the total number of events divided by the total number of patients. Linearized complication rates (and 95% confidence intervals [CI]) were calculated as the number of late events divided by the number of late patient-years. The statistical analyses were performed using SAS® Release 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Study Population

A total of 1,226 patients with Perceval were prospectively enrolled in the SURE-AVR registry between March 2011 and June 2019. Of these, 69 (5.6%) patients underwent RAVR. Baseline characteristics are reported in Table 1. There were 30 (43.5%) female patients and overall mean age was 71.7 ± 9.8 years with a median logistic EuroSCORE II of 10.7%. The indication for RAVR was regurgitation in 44.9 %, stenosis in 31.9%, and steno-regurgitation in 8.7%. Structural valve dysfunction and degeneration occurred in most cases (84.1%), followed by infective endocarditis (15.9%), and were performed in patients with previously implanted bioprostheses (79.7%), mechanical valves (15.9%), and transcatheter valves (4.3%).

Surgical Procedures

Operative data are reported in Table 2. Surgery was performed through median sternotomy in 84.1%, ministernotomy in 8.7%, and minithoracotomy in 7.2% of patients. Associated procedures included mitral valve surgery (10.1%), tricuspid annuloplasty (7.2%), aortic replacement (7.2%), and CABG (2.9%). Perceval valve was successfully implanted in all patients. The most common size implanted was medium (42%), followed by large (27.5%), small (26.1%), and extra-large (4.3%). Mean overall aortic cross-clamp time was 72 min ± 30.8 min and overall cardiopulmonary bypass time was 116.6 min ± 43.7 min. Median length of stay in the intensive care and ward unit was 2 (IQR 1 to 2) and 10 (IQR 7 to 17) days.

Early Outcomes ≤30 Days

Two (2.9%) noncardiovascular deaths (multiorgan failure) were reported in the early period (Table 3). One Perceval valve (1.4%) was explanted after 23 days because of high postoperative gradients. At inspection, the valve was not fully expanded caused by the severe calcification of aortic annulus and root and the patient received a stented valve. One patient (1.4%) had a transient ischemic attack while one patient (1.4%) had a nondisabling stroke. No case of endocarditis, thromboembolism, myocardial infarction, or structural valve deterioration occurred at the early phase. One patient (1.4%) reported a minor paravalvular leak (PVL; ≤2+), 2 (2.9%) had minor intraprosthetic regurgitation (≤2+), and one had minor PVL and intraprosthetic regurgitation for a total of 4 patients (5.8%) with nonstructural valve dysfunction. Permanent pacemaker implant (PPI) was required in 4 patients (5.8%), of which one (1.4%) related to third-degree atrioventricular block. Outcomes for patients undergoing RAVR through minimally invasive approach and for active endocarditis are reported in Supplemental Table 1 and Supplemental Table 2.

Late Outcomes >30 Days

Median follow-up was 35.4 (17.8 to 67.9) months with a cumulative duration of 234.9 late patient-years (Table 3). There were 3 noncardiovascular late deaths with a linearized rate of 1.3% per patient-year. At 1 and 5 years, overall survival was 97% (95% CI, 93% to 100%) and 91% (95% CI, 83% to 98%). Median transvalvular gradient at 1-year and 5-year follow-up

Table 2. Operative Data.

Operative data	*N* = 69
Approach	
Sternotomy	58 (84.1)
Ministernotomy	6 (8.7)
Minithoracotomy	5 (7.2)
Concomitant procedures	22 (31.9)
Mitral valve repair	3 (4.3)
Mitral valve replacement	4 (5.8)
Tricuspid valve repair	5 (7.2)
Aortic replacement	5 (7.2)
CABG	2 (2.9)
Other	3 (4.3)
Overall operative times	
CPB, min	116.6 ± 43.7
Cross-clamp, min	72 ± 30.8
Isolated AVR operative times	
CPB, min	96.4 ± 31.8
Cross-clamp, min	60.2 ± 23
Overall implantation, min	12.6 ± 10.8
Successful implantation	69 (100)
Perceval size	
Small	18 (26.1)
Medium	29 (42)
Large	19 (27.5)
Extra-large mitral	3 (4.3)

Abbreviations: AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass.
Data presented as mean ± SD or *n* (%).

was 10.5 (7 to 15) mm Hg and 11.5 (10 to 15) mm Hg with a median effective orifice area (EOA) of 1.8 (1.4 to 2.4) and 1.8 (1.5 to 2) cm^2, respectively (Table 4). No patient had valve explants. One case of structural valve deterioration (0.4% per patient-year) was reported 58 months after surgery due to a leaflet tear and treated with TAVI. A transcatheter valve was implanted in one patient because of moderate regurgitation (nonstructural valve degeneration) as result of worsening of early intra regurgitation 1+ grade.

Discussion

This is the first multicenter, prospective observational study reporting early and midterm outcomes of patients undergoing RAVR with Perceval sutureless valves. We found that the implantation of Perceval undergoing RAVR is associated with low mortality and morbidity and offers excellent hemodynamic performance up to 5 years. Although the expected median mortality was 10.7%, overall early mortality was 2.9% and survival at 1 and 5 years were 97% and 91%, respectively. Interestingly, no cardiovascular death occurred and a single case of late endocarditis was reported. Furthermore, the early and late linearized incidence of PPI was 5.8% and 0.9% per patient-year. Finally, there were only 2 late valve-related reinterventions, one caused by structural valve deterioration and severe intraprosthetic regurgitation, which required ViV TAVI.

Our results overwhelm outcomes reported in the Society of Thoracic Surgeons (STS) Database.[17] Specifically, in patients undergoing RAVR with sutured valves, operative mortality was 4.7%, stroke rate was 1.8%, pacemaker requirement was 11.5%, and aortic regurgitation more than mild or greater was 3%. The use of sutureless has contributed to these excellent outcomes. Benefits may be related to their characteristics, which avoiding passing the suture stitches and suture knotting, reduces ischemic time, especially in combined procedures.[13] To date, only a few reports describe the clinical advantage of Perceval in redo surgery.[14–16] Interestingly, Perceval was also used as rescue procedure after TAVI failure.

The most common surgical indication for RAVR is bioprosthetic structural valve deterioration and our study confirms the rising trend toward implantation of biological versus mechanical valves in the last decade.[8,18,19] With the introduction of the ViV TAVI concept, more patients will choose biological valve in order to avoid the risk of surgical procedure. Despite ViV TAVI is a less invasive strategy, ViV TAVI may complicate with coronary obstruction, high postprocedural gradients, malposition, and valve migration.[11] In addition, ViV TAVI has shown lower 1-year survival compared to conventional RAVR.[20–22] Nevertheless, no study has compared ViV TAVI and RAVR with Perceval. Major advantages of the sutureless valves are low postoperative gradients and low incidence of PVL.[13,23–27] Perceval allows implanting larger valves and avoids the risk of patient prosthesis mismatch (PPM), a common problem associated with ViV TAVI in bioprostheses ≤ 23 mm and associated with increased risk of structural valve disease.[28] Interestingly, Silashi et al. reported that 46.5% of patients undergoing ViV TAVI had a mean gradient ≥20 mm Hg.[21] Furthermore, Zenzes et al. demonstrated that 57% of patients receiving ViV TAVI harbored suboptimal valve hemodynamic and only one third of patients had restoration of valve hemodynamic function to the early post AVR level.[29] Conversely, our study showed excellent hemodynamic results, even in small annuli. Previously, Villa et al. demonstrated that Perceval provides good hemodynamic results in small annuli (<21 mm) and allows implantation of valve larger than 21 mm in 83%.[30] Furthermore, Rubino et al. showed that under stress, Perceval size S had the highest increase of EOA index at a mean follow-up of 19.5 months, and this benefit was also observed in those patients with severe PPM.[31] Finally, an in vitro study by Tasca et al. demonstrated that Perceval shows the greatest EOA when compared with other stented valves on small annuli.[32] These results are probably related to its stentless property. Being an expandable prosthesis, the internal diameter can adapt in size to that of the ventricular-arterial junction, resulting in less flow disturbance and reduced mechanical energy, with benefit in fluid dynamic performance. PVL has always been considered the Achille's heel of TAVI procedure and associated with poor survival.[33,34] In ViV setting, PVL has been reported up to 22%; on the contrary, in our study, only 1

Table 3. Early and Late Outcomes.

	Early (*N* = 69)	Late (*N* = 65)	
	n (%)	*n*	% per patient-year (95% CI)
Death	2 (2.9)	3	1.3 (0.4-3.4)
Stroke or TIA	2 (2.9)	2	0.9 (0.2-2.7)
TIA	1 (1.4)	1	0.4 (0-2)
Nondisabling stroke	1 (1.4)	0	0
Disabling stroke	0	1	0.4 (0-2)
Bleeding	1 (1.4)	1	0.4 (0-2)
Reintervention	3 (4.3)	2	0.9 (0.2-2.7)
Valve-related	1 (1.4)	2	0.9 (0.2-2.7)
Not valve-related	2 (2.9)	0	0
Explants	1 (1.4)	0	0
Endocarditis	0	1	0.4 (0-2)
Valve thrombosis	0	0	0
Structural valve degeneration	0	1	0.4 (0-2)
Nonstructural dysfunction	4 (5.8)	1	0.4 (0-2)
Intraprosthetic regurgitation	2 (2.9)	1	0.4 (0-2)
Minor (≤2+)	2 (2.9)	1	0.4 (0-2)
Major (>2+)	0	0	0
PVL	1 (1.4)	0	0
Minor (≤2+)	1 (1.4)	0	0
Major (>2+)	0	0	0
Intraprosthetic regurgitation and PVL	1 (1.4)	0	0
Minor (≤2+)	1 (1.4)	0	0
PPI implantation	4 (5.8)	2	0.9 (0.2-2.7)

Abbreviations: PPI, permanent pacemaker implant; PVL, paravalvular leak; TIA, transient ischemic attack.

patient experienced a mild PVL and remained stable at follow-up.[29,35] We recorded only a case of early valve explants. This was probably related to an oversized Perceval into a very calcified aortic root. In this regard, oversizing causes a not complete valve expansion, causing postoperative gradients.

Perceval was used with success for the treatment of prosthetic valve endocarditis (despite this is not a current indication in all the geographies) and mechanical valve dysfunction, diseases absolute contraindications for TAVI. More than 30% percent of our patients presented with these conditions and Perceval showed excellent outcomes. Infection that extends to the mitro-aortic continuity is the only contraindication for the use of sutureless valve in prosthetic aortic valve endocarditis, as it requires a more complex surgery. According to our experience, these valves are faster and less traumatic than conventional sutured valves. The lack of foreign materials, such as pledgets and threads may reduce the risk of recurrent prosthetic endocarditis. Despite the low number of patients ($n = 11$), this represents the largest experience described in literature. These results are similar to those reported by Rosello-Diez et al.[36]

Finally, the use of sutureless valve has led to a higher adoption of minimally invasive approach in AVR. Despite more demanding in redo setting, minimally invasive approach has shown to be a viable option in surgical candidates for RAVR, as it has shown reduced cardiopulmonary and cross clamp time as well as the need for renal replacement therapy, especially when

Table 4. Echocardiography Data.

Echocardiography data	Discharge	1-year	5-year
LVEF, %	55 (50-60)	55 (52-60)	60 (50-60)
Mean aortic gradient, mm Hg	13.5 (10-17.5)	10.5 (7-15.0)	11.5 (10-15)
Peak aortic gradient, mm Hg	22.8 (18-38)	20 (12-25.1)	21 (18-25)
EOA, cm^2	—	1.8 (1.4-2.4)	1.8 (1.5-2)
EOA index, cm^2/m^2	—	1 (0.9-1.2)	1 (0.8-1)

Abbreviations: EOA, effective orifice area; LVEF, left ventricular ejection fraction.
Data presented as median (IQR).

used in combination with sutureless valves.[37,38] Excluding combined procedures, the rate of minimally invasive RAVR was only 15.9% in our study, but this trend is expected to increase as more centers involved in the SURE-AVR registry have shifted to a minimally invasive approach. Advantages of minimally invasive RAVR are to avoid large dissection, minimize trauma as well as the risk of injury of cardiac structure. These factors combined with the benefits of sutureless valves explain the good postoperative outcomes and propose this approach as a valid alternative to TAVI procedures.[39] Finally, incidence of PPI was 5.8%, lower than reported by the STS registry.[17] This success is probably related to placing the guiding sutures at the leaflet insertion line rather than 2 to 3 mm below, as it was recommended by the manufacturer in the past.[40]

This study has some limitations. First, it is a case series of patients undergoing RAVR and the lack of a comparison group, such as patients undergoing RAVR with stented/stentless valves or ViV-TAVI, does not allow showing the potential benefits of sutureless over other strategies. Second, this study is based on the retrospective analysis of an international prospective registry, and we are unable to account for the influence of any unmeasured factors that could affect the adverse outcomes. Third, results are based on limited sample size and more data are required to confirm these outcomes. Database does not account for the types of valves explanted, as well as no information is provided regarding intensive care unit complications such as inotrope support and lactate levels. Then, we do not have information regarding the number of redo procedures performed in each center, where the learning curve of each center might have an impact on outcomes. Finally, we recognize that the heterogeneity of patients and cardiac centers may represent a bias. We included in our analysis patients who had associated procedures and minimally invasive surgery, which usually lead to increased surgical time. This may have an impact on outcomes, but the aim of the SURE-AVR registry is to report surgical outcomes in an unselected, real-world population.

Conclusions

In conclusion, RAVR with Perceval valve is a safe and effective alternative to traditional AVR, providing excellent hemodynamic performance and clinical outcomes, both in the early and at midterm follow-up. TAVI is a potential alternative strategy for these patients; however, it is contraindicated in some cases, such as no peripheral vascular access, low coronary take off, small diameter of prior implanted valve, prosthetic valve endocarditis, or mechanical prosthetic dysfunction. RAVR with sutureless has been demonstrated to be a valid solution, associated with excellent mortality and morbidity.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Drs Miceli, Kent, Troise, Baghai, and Glauber are consultants for LivaNova. Dr Kent also reports a relationship with Edwards Lifesciences.

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Supplemental Material

Supplemental material for this article is available online.

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