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SUTURELESS AORTIC VALVES IN ISOLATED AND COMBINED PROCEDURES: THIRTEEN YEARS OF EXPERIENCE IN 784 PATIENTS

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KEYWORDS: aortic valve, aortic valve replacement, sutureless aortic valve replacement, Perceval valve

ABSTRACT

Objective: The aim of this study was to evaluate the outcome and experience of the Perceval sutureless valve at our institution (UZ Leuven).

Methods: Between 2007 and 2019, 784 patients underwent sutureless aortic valve replacement using the Perceval valve (isolated or combined with other procedures). We performed a retrospective analysis of the postoperative and follow-up data.

Results: Mean age was 78 years with a median European System for Cardiac Operative Risk Evaluation II score of 4.2% (interquartile range, 2.6%-7.2%). Isolated aortic valve replacement accounted for 45% of cases; 30% of cases were aortic valve replacement in combination with coronary artery bypass grafting and the remaining 25% were other combined procedures. The median crossclamp times were 38 minutes in single aortic valve replacement, 70 minutes in cases with coronary artery bypass grafting, and 89 minutes in multiple valve cases. Device success was 99.1% and in-hospital mortality was 3.3%. Postoperative stroke or transient ischemic attack occurred in 1.9% of patients and 1% of patients had a new need for dialysis after surgery and median survival time was 7.0 years with a cumulative follow-up of 2797.8 patient-years. The 1-, 5-, and 10-year freedom from reintervention were 99%, 97%, and 94%, respectively.

Conclusions: These data represent the longest follow-up available, to our knowledge, for the Perceval sutureless valve. We observed favorable early outcomes, and low rates of early mortality, stroke, and other major complications. Valve durability is promising with low rates of valve degeneration and a limited need for reintervention. (J Thorac Cardiovasc Surg 2022;-:1-9)

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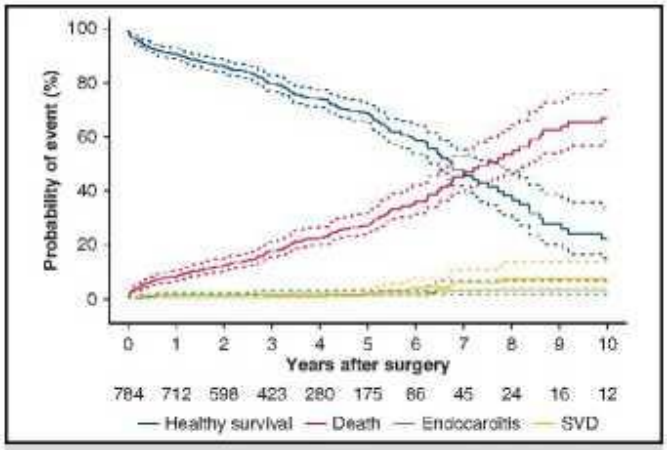

Competing risk analysis accounting for mortality without endocarditis or SVD, with endocarditis or SVD as competing events.

CENTRAL MESSAGE

Perceval offers a safe treatment for aortic valve disease for minimally invasive single valve and in combined cases. Long-term outcome showed a stable performance, with low need for reintervention.

PERSPECTIVE

Sutureless valves provide safe outcomes after surgical aortic valve replacement. The speed and ease of implantation aid in minimally invasive and in combined cases and showed stable hemodynamic performance with low rates of major events during follow-up. A wide variety of patients can benefit from this technology, challenging the outcomes of the currently expanding use of transcatheter treatment.

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With the recent guidelines regarding aortic valve (AV) replacement (AVR) in an elderly population (older than 75 or 80 years) and the preference for transcatheter treatment if feasible, less-invasive surgical valves remain an important field to research.[1,2] Sutureless AV prostheses have been developed to combine fast implantation and the benefits associated with a surgical approach.[3,4] The Perceval AV (Corcym; previously manufactured by the Sorin Group and LivaNova) is a sutureless bioprosthetic valve made of bovine pericardium attached to a selfexpandable nitinol stent.[5] It was introduced in 2007 and has shown a stable hemodynamic performance with acceptable gradients, safety, and versatility.[6,7] Despite these promising results, little is known on about longer-term durability.[7,8] Complications caused by oversizing, with increased pacemaker implantation rates and elevated gradients, are now solved using an established new sizing strategy, issued in 2017.[9-12] The purpose of this study was to evaluate the outcome of the Perceval valve after 13 years of continued use, in 784 patients at our institution.

Abbreviations and Acronyms	
AV	= aortic valve
AVR	= aortic valve replacement
CABG	= coronary artery bypass grafting
CPB	= cardiopulmonary bypass
EOA	= effective orifice area
EuroSCORE	= European System for Cardiac Operative Risk Evaluation
iEOA	= indexed effective orifice area
IQR	= interquartile range
NYHA	= New York Heart Association
PPM	= patient prosthesis mismatch
SU-AVR	= sutureless aortic valve replacement
SVD	= structural valve deterioration
TAVR	= transcatheter aortic valve replacement
TIA	= transient ischemic attack
VARC-2	= Valve Academic Research Consortium-2

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METHODS

STUDY DESIGN

We performed a retrospective analysis of all patients who underwent sutureless AVR (SU-AVR) using the Perceval valve between 2007 and 2019 at our institution (University Hospitals Leuven). The inclusion criteria was any SU-AVR using the Perceval valve (Perceval S valve) with or without concomitant procedures such as coronary artery bypass grafting (CABG) or multiple valve repair/replacement.

Data on patient's characteristics, operative data, and follow-up data were retrospectively extracted from patient's records, in accordance with regulations on data protection. Follow-up data were included until March 31, 2021. In 3 patients, the intended Perceval placement was not successful, and another type of tissue valve was placed; these patients were not included in the analysis, except for valve implant success.

PATIENT SELECTION

All patients with an implanted Perceval valve were included in this analysis. Patients with redo AVR were not seen as a contraindication for the use of Perceval, neither were type 1 bicuspid valves or a heavily calcified aortic root and/or ascending aorta. Type 0 bicuspid valves were not treated with Perceval. Perceval is mainly used for its key benefits: short crossclamp and procedure times and the minimal manipulation needed to place the valve. Important to mention is that Belgium is limiting the reimbursement of transcatheter AVR (TAVR), resulting in many patients being referred to surgery.

ETHICS STATEMENT

Permission to perform this analysis was granted by the ethics committee UZ/KU Leuven on December 7, 2020, with approval number s64845. Informed consent was not required because of the retrospective nature of this study.

OUTCOME MEASURES

The main outcome measures of this study were long-term survival and freedom ofAV reintervention at 10 years, with incidence rates calculated by the number of events divided by the total patient-years. Secondary outcome end points were immediate procedural death (defined as mortality within 72 hours of index procedure), procedural death (defined as mortality within 30 days or within index hospitalization), as defined by the Valve Academic Research Consortium-2 (VARC-2).[13] Other secondary end points were 1-year mortality, implantation success, postoperative complications, and hemodynamic performance using transthoracic echocardiography at discharge and latest available follow-up. Timing of echocardiographic follow-up was variable, and assessment was most often performed at referring hospitals. Although follow-up was often at local peripheral hospitals, patients with any valvular complication were always referred back to our center. Patient prosthesis

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mismatch (PPM) was defined by the indexed effective orifice area (iEOA) in accordance with VARC-2. The iEOA was calculated for all patients of whom the effective orifice area (EOA) was measured at discharge. PPM was defined as an iEOA ≤ 0.85 (≤0.9 when body mass index >30).[13] Severe structural valve deterioration (SVD) was defined as presence of central valve insufficiency of >2/4, an increase in mean gradient >20 mm Hg or a mean gradient >40 mm Hg, in accordance with the suggested definitions by Capodanno and colleagues.[14]

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS version 27 (IBM Corp) and RStudio 2021.09.0 + 351 for Windows (RStudio Team). The Shapiro–Wilk test was used to check normality. Continuous data are presented as mean ± SD or median and interquartile range (IQR). Categorical data are presented as frequency and percentage.

Three subgroups were analyzed on the basis of procedure: isolated AVR, AVR with CABG, and AVR with other/multiple concomitant procedures (multiple valves, septal myectomy, ablation, or any of these procedures in combination with CABG). We also stratified patients according to urgency level of the index surgery (statistical analysis of these subgroups was limited to "elective" and "urgent" because of low numbers of patients the "emergency" and "salvage" subgroups). Comparisons were made using the c^2 test or Fisher exact test for categorical data or Mann–Whitney U test for continuous data. Survival and competing risk analysis with all-cause mortality, onset of endocarditis of the bioprosthetic valve, or SVD as competing events was performed using Rstudio using the Survival pack- age.[15] Multiple imputation was used to impute missing variables of patients with an available discharge or follow-up echocardiography. Variables that were imputed included peak gradient (discharge: 5.1%, follow-up: 18.1% missing), mean gradient (discharge: 6.9%, follow-up: 47.3% missing), EOA and iEOA (discharge: 14.3%, follow-up: 53.3% missing). The imputation method was a fully conditional specification, with linear regression as model for scale and the number of imputations was 5. The imputation model was used separately for discharge and follow-up data. The predictor parameters used were age, sex, body surface area, obesity, preoperative left ventricular function, pulmonary hypertension, European System for Cardiac Operative Risk Evaluation (EuroSCORE) II, implanted valve size, paravalvular leakage grade, centrovalvular leakgage grade, and left ventricle function.

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RESULTS

STUDY POPULATION

Between 2007 and 2019, 784 patients underwent SU- AVR using the Perceval valve at our institution. Commercial use at our center started in January 2014, meaning that 62 patients were treated with the Perceval valve in a trial setting and the remaining 722 patients were treated

with the Perceval valve in a commercial setting. The mean age of our patients was 78.5 ± 5.8 years with 362 octogenarians (46.2% octogenarians; 51.7% female; Table 1). Most patients were in New York Heart Association (NYHA) class II or III (86.1%) and the median EuroSCORE II was 4.2% (IQR, 2.6-7.2). Of 784 patients, most underwent elective (81%) or urgent surgery (17.9%); only 7 patients (0.9%) needed emergency surgery and 2 patients needed salvage surgery (0.3%).

Most (541 patients, 69%) underwent a full median sternotomy; for the other 243 (31%) patients, a minimally invasive approach was used (Table 2). The minimally invasive approaches were either partial upper ministernotomy (227 patients, 29%) or an anterior right minithoracotomy (16 patients, 2%).

Of all Perceval implantations, 349 cases (44.5%) were isolated AVR, 239 patients (30.5%) had AVR in combination with CABG, and the remaining 196 patients (25%) underwent multiple/different concomitant procedures. The median cardiopulmonary bypass (CPB) time for single AVR was 61 minutes (IQR, 51-72.8 minutes) and a median crossclamp time of 38 minutes (IQR, 32-89.8 minutes). AVR combined with CABG had a median CPB time of

108 minutes (IQR, 78.8-128 minutes) and a mean crossclamp time of 70 minutes (SD, 26.6 minutes). For the multiple concomitant procedure subgroup, the median CPB time 118 minutes (IQR, 91-153 minutes) and a median crossclamp time of 86 minutes (IQR, 59-106 minutes). The most frequent implanted valve sizes were M (23 mm) and L (25 mm).

Of the 787 patients with the intention to be treated with a Perceval valve, initial implant success was 97.3% (766 patients). Of the 21 patients (2.7%) who had initial implant failure, implant was successful after repositioning the valve in 14 patients (1.8%), 4 patients received a different valve size (0.9%). The remaining 3 patients received a different valve type (0.4%) and were not included in further analysis.

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TABLE 1. *Preoperative characteristics*

Clinical variable	Overall (N = 784)	Single AVR (n = 349)	AVR with CABG (n = 239)	Multiple procedures (n = 196)
Age at operation, y	78.5 i 5.8	79.4 i 5.5	79.0 i 4.7	76.5 i 6.9
Male sex	279 (48.3)	132 (37.8)	149 (62.3)	98 (50)
Body surface area, m^2	1.8 i 0.2	1.8 i 0.2	1.8 i 0.2	1.9 i 0.2
Obesity (BMI >30)	210 (26.8)	112 (32.1)	50 (20.9)	48 (24.5)
Previous cardiac surgery	33 (4.2)	16 (4.6)	0 (0.0)	17 (8.7)
IDDM	30 (3.8)	12 (3.4)	10 (4.2)	8 (4.1)
Recent MI	62 (7.9)	10 (2.9)	37 (15.5)	15 (7.7)
Creatinine clearance, mL/min	56.0 i 20.3	57.3 i 19.7	54.1 i 20.4	55.9 i 20.9
Receiving dialysis	27 (3.4)	7 (2.0)	14 (5.9)	6 (3.1)
Chronic lung disease	119 (15.2)	58 (16.6)	32 (13.4)	26 (14.8)
Peripheral arterial disease	196 (25)	59 (16.9)	85 (35.6)	52 (26.5)
Active endocarditis	12 (1.5)	4 (1.1)	2 (0.8)	6 (3.1)
NYHA class				
I	45 (5.7)	18 (5.2)	19 (7.9)	8 (4.1)
II	333 (42.5)	160 (45.8)	101 (42.3)	72 (36.7)
III	342 (43.6)	145 (41.5)	96 (40.2)	101 (51.5)
IV	64 (8.2)	26 (7.4)	23 (9.6)	15 (7.7)
LV ejection fraction, %	60 (50-63)	60 (55-65)	60 (50-65)	55 (45-60)
>50%	632 (80.5)	302 (86.5)	190 (79.5)	139 (70.9)
31%-50%	124 (15.8)	42 (12)	34 (14.2)	48 (24.5)
30%-21%	25 (3.2)	5 (1.4)	12 (5)	8 (4.1)
<21%	4 (0.5)	0 (0.0)	3 (1.3)	1 (0.5)
Pulmonary hypertension				
<31 mm Hg	349 (44.5)	155 (44.4)	127 (53.1)	67 (34.2)
31-55 mm Hg	353 (45)	166 (47.6)	93 (38.9)	94 (48)
>55 mm Hg	82 (10.5)	28 (8)	19 (7.9)	35 (17.9)
Urgency				
Elective	635 (81%)	315 (90.3%)	156 (65.3%)	164 (83.7%)
Urgent	140 (17.9%)	32 (9.2%)	79 (33.1%)	29 (14.8%)
Emergency	7 (0.9%)	1 (0.3%)	4 (1.7%)	2 (1%)
Salvage	2 (0.3%)	1 (0.3%)	0 (0.0)	1 (0.5%)
EuroSCORE II (%)	4.2 (2.6-7.2)	2.9 (1.9-4.4)	5.7 (3.7-9.1)	6.4 (3.9-10.2)

Data are presented as mean ± SD, median (interquartile range), or n (%). AVR, Aortic valve replacement; CABG, coronary artery bypass grafting; BMI, body mass index; IDDM, insulin-dependent diabetes mellitus; MI, myocardial infarction; NYHA, New York Heart Association; LV, left ventricle; EuroSCORE, European System for Cardiac Operative Risk Evaluation

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TABLE 2. *Procedural data*

Variable	Overall (N = 784)	Single AVR (n = 349)	AVR with CABG (n = 239)	Multiple procedures (n = 196)
Median sternotomy	541 (69)	166 (47.6)	207 (86.6)	168 (85.7)
Minimally invasive approach	243 (31)	183 (52.4)	32 (13.4)	28 (14.3)
Limited sternotomy	227 (29)	167 (47.9)	32 (13.4)	28 (14.3)
Anterior right minithoracotomy	16 (2)	16 (4.6)	0 (0.0)	0 (0.0)
Perceval valve size				
Small	63 (8)	29 (8.3)	14 (5.9)	20 (10.2)
Medium	267 (34.1)	131 (37.5)	71 (29.7)	65 (33.2)
Large	291 (37.1)	128 (36.7)	95 (39.7)	68 (34.7)
Extra large	163 (20.8)	43 (21.9)	59 (24.7)	43 (21.9)
Cardiopulmonary bypass time, min	81 (61-119)	61 (51-72.8)	108 (79-128)	118 (91-153)
Crossclamp time, min	51 (37-84)	38 (32-45)	70 (48-90)	89 (59-106)
Implant failure*	21 (2.7%)	12 (3.6)	7 (2.9)	2 (1)
Perceval valve repositioning	14 (1.8)	8 (2.3)	5 (2.1)	1 (0.5)
Different size implanted	4 (0.5)	2 (0.6)	1 (0.4)	1 (0.5)
Different valve type implanted	3 (0.4)	2 (0.6)	1 (0.4)	0 (0.0)

Data are presented as median (interquartile range) or n (%). AVR, Aortic valve replacement; CABG, coronary artery bypass grafting. *N = 787 (study population + 3 implant failures).

TABLE 3. *Postoperative data*

Variable	Overall (N = 784)	Single AVR (n = 349)	AVR with CABG (n = 239)	Multiple procedures (n = 196)
ICU length of stay, d	2 (1-4)	2 (1-3)	3 (1-5)	3 (1-6)
Hospital length of stay, d	11 (8-15)	10 (7-14)	11 (11-15)	12 (8-18)
Immediate procedural death	4 (0.5)	0 (0.0)	2 (0.8)	2 (1.0)
Procedural death	26 (3.3)	5 (1.4)	12 (5.0)	9 (4.5)
1-y mortality	68 (8.7)	20 (5.7)	28 (11.7)	20 (10.2)
New pacemaker at 30 d	69 (8.8)	32 (9.2)	22 (9.2)	15 (7.7)
Stroke/TIA	15 (1.9)	7 (2)	4 (1.7)	5 (2.6)
Dialysis	8 (1.0)	2 (0.6)	3 (1.3)	3 (1.5)

Data are presented as median (SD) or n (%). AVR, Aortic valve replacement; CABG, coronary artery bypass grafting; ICU, intensive care unit; TIA, transient ischemic attack.

EARLY OUTCOME

The median length of intensive care unit stay was 2 days (IQR, 1-4) and the median total hospitalization length was 11 days (IQR, 8-15; Table 3). A new pacemaker at 30 days was required in 69 patients (8.8%), but this rate changed over the years: before the sizing shift in 2017, the new permanent pacemaker implantation rate at 30 days was 11% and after the sizing shift it decreased to 6.1% ($P = .016$). There were 16 cases (2.0%) of postoperative stroke and/or transient ischemic attack (TIA). Stroke with persisting neurological damage or symptoms at discharge was present in 6 cases (0.8%). New dialysis was needed in 8 patients (1%). When outcomes for different urgency levels (elective vs urgent) were compared, there were several differences (Table E1). Intensive care unit and overall length of stay were longer in the urgent group ($P < .001$), and procedural mortality rate was higher ($P < .001$). Other outcome measures such as stroke, TIA, dialysis, and new pacemaker implantation at 30 days were not different.

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The overall procedural mortality was 3.3% (26 patients): for single AVR, AVR with CABG, and for multiple procedures procedural mortality was 1.4%, 5%, and 4.5%, respectively (Table 3). The median EuroSCORE II for the different procedure types were 2.9% (IQR, 1.9%-4.4%), 5.7% (IQR, 3.7%-9.1%), and 6.4% (IQR, 3.9%-10.2%; Table 1). The corresponding observed/expected mortality ratios were 0.48, 0.88, and 0.70 for single AVR, AVR with CABG, and multiple procedures, respectively.

At discharge, the median peak gradient over the Perceval prosthesis was 25 mm Hg (IQR, 20-32), median mean gradient and EOA were 14 mm Hg (IQR, 11-18) and 1.6 cm^2 (IQR, 1.3-1.9), respectively (Table 4). There were 3 cases (0.4%) with more than mild paravalvular regurgitation. PPM, defined according to the discharge EOA value, was present in 53.8% of patients. All hemodynamic parameters (gradients, EOA, iEOA, and PPM rates) improved over the years because of the new sizing technique.[12]

LATE OUTCOME

The cumulative follow-up included 2802.9 patient-years with a median follow-up time of 7.03 years (95% CI, 6.548.16 years) and a maximum follow-up of 13.6 years. The 1-year survival was 91.5%, 5-year survival was 70.8%, and 10-year survival was 27.3% (Figure 1). A competing risk analysis with mortality without endocarditis or SVD, endocarditis, and SVD as competing events is provided in Figure 2.

Valve-related complications during follow-up included endocarditis of the bioprosthetic valve and severe SVD.

TABLE 4. *Hemodynamic results*

Variable	Value
Discharge echocardiography (n = 768)	
AV peak gradient, mm Hg*	25 (20-32)
AV mean gradient, mm Hg*	14 (11-18)
EOA, cm^2*	1.6 (1.3-1.9)
iEOA, cm^2/m^2*	0.8 (0.7-1.0)
Paravalvular regurgitation > mild	3 (0.4)
LV function	
Normal (LVEF >50%)	626 (81.5)
Moderate (LVEF 31%-50%)	111 (14.5)
Poor (LVEF 20%-30%)	27 (3.5)
Very poor (LVEF <20%)	4 (0.5)
Patient prosthesis mismatch (n = 658)	354 (53.8)
Latest echocardiography (n = 689)	
AV peak gradient, mm Hg*	20 (14-27)
AV mean gradient, mm Hg*	11 (8-15)
EOA, cm^2*	1.6 (1.2-2.1)
iEOA, cm^2/m^2*	0.9 (0.7-1.2)
Paravalvular regurgitation > mild	9 (1.3)
LV function	
Normal (LVEF >50%)	541 (74.65)
Moderate (LVEF 31%-50%)	115 (16.7)
Poor (LVEF 20%-30%)	17 (2.4)
Very poor (LVEF <20%)	16 (2.3)
NYHA class	
I	366 (53.1)
II	216 (31.3)
III	65 (9.4)
IV	12 (1.9)

Data are presented as median (interquartile range) or n (%). *AV,* Aortic valve; **EOA**, effective orifice area; **iEOA**, indexed effective orifice area; **LV**, left ventricle; **LVEF**, left ventricular ejection fraction; **NYHA**, New York Heart Association. *Missing values imputed by multiple imputations.

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Endocarditis of the Perceval valve was reported in 13 patients (1.7%), which corresponds to an incidence rate of 0.46% per patient-year. Of the 13 cases of endocarditis, 11 (1.4%) patients underwent an AV reoperation to replace the diseased valve. SVD of the Perceval valve was found in 15 cases (1.9%), corresponding to an incidence rate of 0.54% per patient-year. Three (0.4%) of the patients with severe SVD were successfully treated with TAVR valvein-valve. All 3 patients had a size large Perceval and received an Edwards Sapien 3 valve (Edwards Lifesciences) with valve size 23 or 26. Counting both of the reinventions for endocarditis and the TAVR valve-in-valves, a total of 14 patients needed an AV reintervention during follow-up, meaning overall freedom from AV reintervention was 94% at 10 years. General, nonvalve-related complications were limited to thromboembolic events, which consisted of 11 cases of stroke (1.4%) and 3 cases (0.4%) of TIA. Clinical follow-up data was 100% complete.

Of the 758 hospital survivors, 689 (90.9%) had at least 1 follow-up echocardiogram. Median echocardiographic follow-up time was 2.6 years (IQR, 1.5-4.1 years) and a maximum echocardiographic follow-up time was 13.5 years. At the last follow-up echocardiography, the median peak gradient, mean gradient, and EOA were 20 mm Hg (IQR, 14-26), 11 mm Hg (IQR, 8-16), and 1.5 cm^2 (IQR, 1.2-2), respectively. Paravalvular leakage greater than mild was found in 9 patients (1.3%; Table 4). Most patients were NYHA class I (366; 53.1%) or II (216; 31.3%) at the latest follow-up (Table 4). The number of hospital survivors with an echocardiogram follow-up time of more than 3, 5, and 7 years was 295 (38.9%), 105 (13.9%), and 26 (3.4%), respectively.

FIGURE 1. *Kaplan–Meier estimate of the cumulative survival of the overall study population. Dotted lines represent 95% CI and the number at risk are shown in black.*

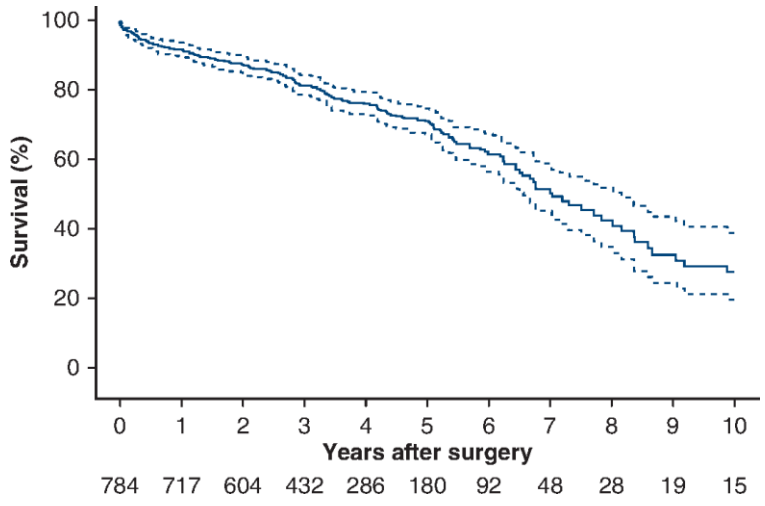

FIGURE 2. *Competing risk analysis accounting for mortality without endocarditis/SVD, endocarditis or SVD as competing events. Dotted lines represent 95% CI and the number at risk are shown in black. SVD, Structural valve deterioration*

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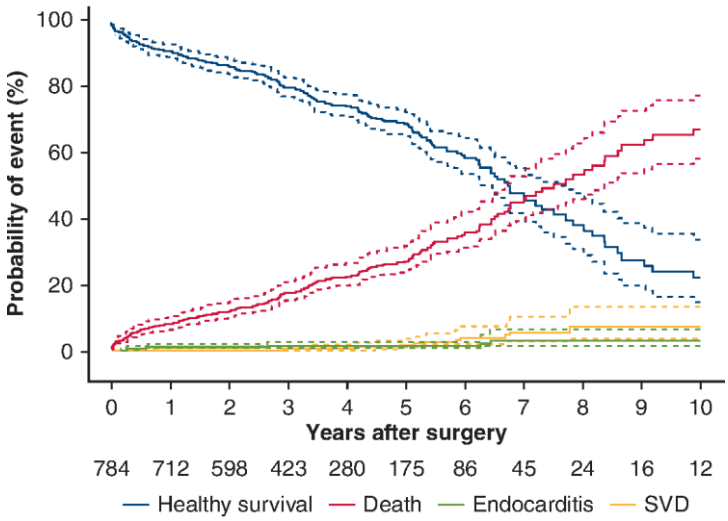

DISCUSSION

In the treatment of AV stenosis, increasing evidence is supporting the use of TAVR, even in low-risk patients.[16]

However, in randomized trials that compared TAVR with surgical AVR, only standard, sutured valve types were used.[17,18] Studies that compared SU-AVR with TAVR are currently limited in number and follow-up time.[17] Our center participated in the first-in-men experience with Perceval in 2007 and has used this sutureless valve throughout 13 years in a wide variety of isolated single AVR cases and combined cases, including redo cases or cases with complex anatomy.

Perceval has 2 key benefits: a very short implantation time and minimal manipulation in the aortic root (only 3 temporary guiding sutures needed). These key benefits have several beneficial clinical consequences for the patient: low early mortality despite elevated risk profiles, low rate of major events such as stroke, and/or need for dialysis. The sutureless technique facilitates minimally invasive techniques in isolated AVR. In addition, experienced users frequently use Perceval as an elegant bailout in complex or challenging (redo) cases, such as heavily calcified roots, degenerated Freestyle valves, or homografts.[19] In isolated AVR as in combined cases, a favorable observed-to-predicted mortality ratio was seen. Rubino and colleagues[3] reported a similar finding, hypothesizing that this beneficial effect might be caused by the reduction of crossclamp and CPB time. Our results confirm previous studies with Perceval, showing low 30-day mortality.[3,20-22]

FIGURE 3. *Summary of the study methods and results. Left graph shows overall survival, competing risk analysis with mortality, endocarditis, and SVD as competing risks. Dotted lines represent 95% CIs. EuroSCORE, European System for Cardiac Operative Risk Evaluation; AVR, aortic valve replacement; CABG, coronary artery bypass grafting; SVD, structural valve deterioration.*

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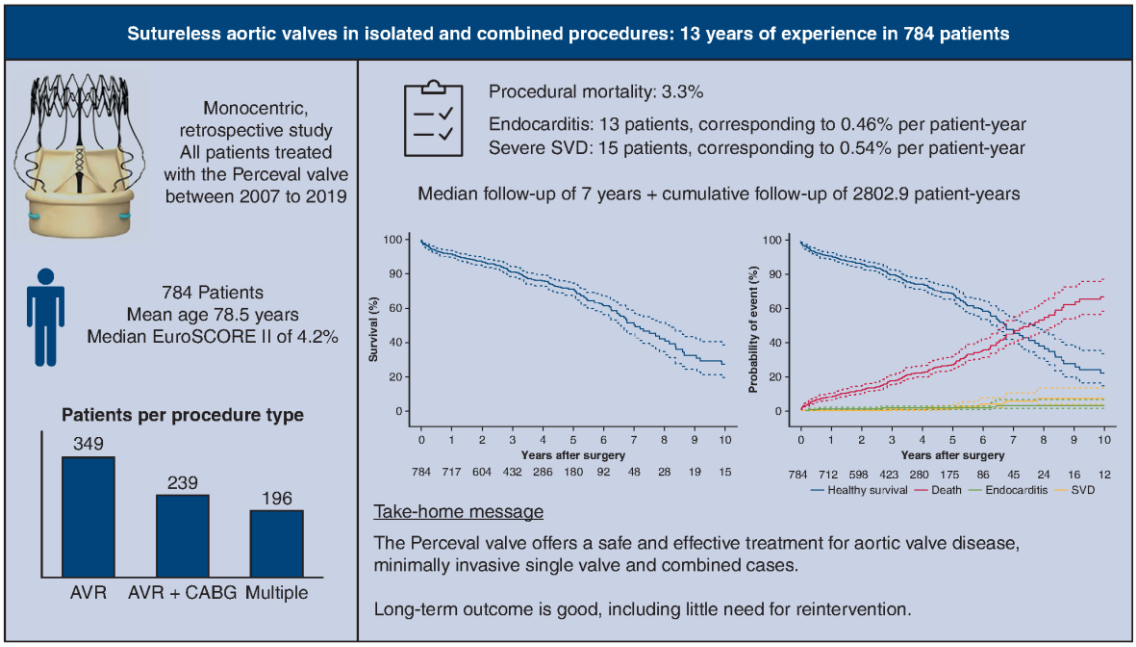

In isolated AVR, 47.9% of cases were done via a minimally invasive approach, which is remarkably higher than the current worldwide adoption, with approximately 20% to 25% of isolated cases.[23,24] When reviewing our most recent use (2020-2021), this percentage of minimal access surgery in single AVR has increased up to 84%. Overall, the incidence of postoperative complications was low. The incidence of postoperative neurological complications (TIA and stroke combined) was 1.9%[3,5,7,25] and the rate of new onset kidney injury requiring dialysis was low at 1%.[3] Transfers or discharge to secondary hospitals or rehabilitation centers is rarely used in our center, explaining the rather long length of hospitalization, certainly in this elderly patient cohort.

At a median follow-up of 7 years now, a favorable longterm performance was shown in our patient population, with a limited need for reintervention. The 1-year survival of 91.5% with a freedom from reoperation of 99.2% in the first year are comparable with other studies.[5,20] A 5- and 10-year survival of 70.8% and 27.3%, respectively, are to be expected in an elderly population, with a mean age of 78 years at implantation (Figure 1). Still, healthy survival at 10 years without serious valve-related complications such as SVD or endocarditis is low at 22.3% (Figure 2).

Serious adverse events requiring AV-related reintervention were rare, with a 10-year freedom from reintervention of 94.0%. Reinterventions were mainly done for endocarditis and for 3 cases of SVD. The incidence of endocarditis was low at 0.46% per patient-year, which is on the same order of magnitude as for other valve prostheses.[7,21,26] SVD, which is rarely reported in early to mid-term follow-up, was limited in our study to 0.54% per patient-year (Figure 3).[27] In the literature, freedom from AV reintervention remains high throughout longer follow-up times, although most studies are still limited in follow-up length. In case of valve degeneration, TAVR valve-in-valve is a valid and safe treatment option for patients with degenerated Perceval valves.[28]

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Hemodynamic results remained stable over time, with peak and mean gradients at 20 mm Hg and 11 mm Hg at the latest follow-up, with an EOA of 1.5 cm^2 throughout the follow-up period. Paravalvular leakage was only seen in 1.3% of patients. NYHA class evolution is

beneficial, although functional status in this patient cohort is frequently compromised by concomitant diseases, mainly oncologic or orthopedic in nature.

Correct sizing (with mainly avoiding oversizing) remains an important aspect in decreasing postoperative complications. A subanalysis of this patient group by Szecel and col- leagues[12] regarding the sizing shift in 2017 clearly showed reduction of peak and mean gradients at discharge and pacemaker implant rates. Implantation techniques that contribute to lower permanent pacemaker implantation rates were investigated by Vogt and colleagues.[8,11]

LIMITATION

The main limitation of this study is its retrospective nature. Nevertheless, this patient population included a wide variety of procedure types and was not limited to elective procedures, giving a reasonably accurate image of a real- world patient population. Other limitations are the absence of a control group such as AVR with conventional bio- prosthetic valves or TAVR and the lack of established criteria for valve failure (eg, the VARC-2 criteria for SVD, non-SVD, endocarditis, and thrombosis). Furthermore, the follow-up time of most patients is still limited and is expected to grow in the forthcoming years. Prolonging the follow-up data is necessary to provide stronger evidence. Particular attention is needed to more systematic and protracted echocardiographic follow-up to obtain a more comprehensive understanding of SVD with Perceval, because some cases of severe SVD might not be clinically evident in an elderly population, or might be concealed at the time of death. This lack of protracted data regarding hemodynamic valve performance is partially related to an increasing number of patients being treated late in the course of the study, as well as a partial loss of follow-up related to the COVID-19 pandemic, leading to delay of follow-up appointments.

CONCLUSIONS

To our knowledge, these data represent the longest follow-up available for the Perceval sutureless valve. We observed favorable early outcomes, with low rates of early mortality, stroke, and other major complications. Valve durability is promising with only a limited number of cases with SVD. Perceval facilitates minimal access techniques in isolated AVR, and is an elegant solution for combined and complex procedures leading to shorter implantation times. In an era dominated by transcatheter technologies, taking on younger and low-risk patients, it is crucial that also the surgical treatment options demonstrate safe and durable results.

CONFLICT OF INTEREST STATEMENT

Bart Meuris: consultant to Corcym. All other authors reported no conflicts of interest.

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The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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TABLE E1. *Postoperative outcome stratified according to urgency*

Variable	Elective (n = 635)	Urgent (n = 140)	*P* value
ICU length of stay, d	2 (1-3)	3 (2-7)	<.001
Hospital length of stay, d	10 (8-14)	13 (8-19)	<.001
Procedural mortality	8 (1.3)	15 (10.7)	<.001
Stroke/TIA	10 (1.6)	3 (2.1)	.714
Dialysis	5 (0.8)	2 (1.4)	.616
New pacemaker at 30 d	54 (8.5)	15 (10.7)	.406

ICU, Intensive care unit; *TIA*, transient ischemic attack.

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