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Sutureless bioprosthesis for aortic valve replacement: Surgical and clinical outcomes

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Abstract

Background: Aortic valve stenosis is the most common adult valve disease in industrialized countries. The aging population and the increase in comorbidities urge the development of safer alternatives to the current surgical treatment. Sutureless bioprosthesis has shown promising results, especially in complex procedures and in patients requiring concomitant surgeries.

Objectives: Assess the clinical and hemodynamic performance, safety, and durability of the Perceval® prosthetic valve.

Methods: This single-center retrospective longitudinal cohort study collected data from all adult patients with aortic valve disease who underwent aortic valve replacement with a Perceval® prosthetic valve between February 2015 and October 2020. Of the 196 patients included (mean age 77.20 ± 5.08 years; 45.4% female; mean EuroSCORE II 2.91 ± 2.20%), the majority had aortic stenosis.

Results: Overall mean cross-clamp and cardiopulmonary bypass times were 33.31 ± 14.09 min and 45.55 ± 19.04 min, respectively. Mean intensive care unit and hospital stay were 3.32 ± 3.24 days and 7.70 ± 5.82 days, respectively. Procedural success was 98.99%, as two explants occurred. Four valves were reimplanted due to intraoperative misplacement. Mean transvalvular gradients were 7.82 ± 3.62 mmHg. Pacemaker implantation occurred in 12.8% of patients, new-onset atrial fibrillation in 21.9% and renal replacement support was necessary for 3.1%. Early mortality was 2.0%. We report no structural valve deterioration, strokes, or endocarditis, and one successfully treated valve thrombosis.

Conclusions: Our study confirms the excellent clinical and hemodynamic performance and safety of a truly sutureless aortic valve, up to a 5-year follow-up. These results were consistent in isolated and concomitant interventions, solidifying this device as a viable option for the treatment of isolated aortic valve disease.

KEYWORDS

aortic valve disease, aortic valve replacement, aortic valve stenosis, Perceval® valve, sutureless bioprosthesis

1 | INTRODUCTION

Aortic valve stenosis is the most frequent type of adult valvular heart disease in industrialized countries.[1] Its prevalence increases with age up to 9.8% in the 80–89 year cohort.[2,3]

Conventional aortic valve replacement (AVR) through median sternotomy is the established gold standard for the treatment of severe and/or symptomatic disease in patients with low-surgical risk.[4] However, the continuous increase in patients age[5] and comorbidities, the growing percentage of patients who need concomitant surgical procedures, combined to the fact that the duration of aortic cross-clamping and cardiopulmonary bypass (CPB) are independent predictors of survival[6,7] have created the need for interventions that minimize operative times and reduce surgical risk.

Sutureless bioprosthesis has emerged as a viable alternative combining the best of both worlds. By avoiding sutures, it allows reduced aortic cross-clamping, CPB, and global surgical times, as well as the possibility of complete excision of the native aortic valve and annular decalcification, helping prevent paravalvular leaks, which is particularly useful in patients with severe aortic stenosis and an intermediate to high operative risk.[8,9] Sutureless bioprostheses are especially beneficial in (1) patients who are more sensitive to ischemia; (2) in technically difficult procedures (such as small and/or highly calcified aortic roots, reoperations, and in patients who require concomitant procedures)[10]; (3) in patients with a high risk of patient-prosthesis mismatch (PPM); and (4) in patients who require faster recovery. Furthermore, by avoiding stitching through the annulus and suture knotting, the risk of tearing the aortic annulus and wall or embolizing foreign material is reduced.[11] However, these advantages must be weighed against the apparent increased risk of permanent pacemaker implantation (PPI) when compared with conventional AVR.[12]

The Perceval® valve (Sorin Group) is currently the only truly sutureless valve available, with extensive research supporting its excellent hemodynamic performance, safety, and versatility of use. However, several questions remain unanswered, namely, long-term survival and valve durability, risk of endocarditis, the impact of the apparent increased need for postoperative PPI, and the safety of concomitant valvular procedures.[13]

Our study aims to analyze the clinical and hemodynamic performance, safety, and durability of the Perceval® valves implanted in patients with aortic valve disease, both in isolated AVR as well as in patients who underwent concomitant procedures, over a period of 5 years in a tertiary single European center.

2 | MATERIALS AND METHODS

2.1 | Study design

In this retrospective longitudinal cohort study, data from all adult patients with aortic valve disease who underwent AVR with a Perceval® prosthetic valve between February 2015 and October 2020 in Hospital de Santa Maria (Lisbon, Portugal) was retrospectively collected from an available hospital database.

2.2 | Patients

Data collected included demographics and preoperative characteristics, such as comorbidities, EuroSCORE II, presence of atrial fibrillation or pacemaker, left ventricular (LV) function, and history of previous cardiac surgery. We also collected intraoperative data, such as the aortic cross-clamping and CPB times, size of the valves implanted, and transvalvular gradients, as well as in-hospital stay and postoperative complications.

Endpoints were the clinical and hemodynamic performance, safety and durability of the Perceval® valve in AVR, evaluated through the following criteria: Mortality and overall long-term survival, structural valve deterioration, operatory times (aortic clamping and CPB times), mean intensive care unit (ICU) and total hospital stay, postoperative complications—including PPI and infection rates (respiratory, urinary, wound and/or of unknown origin using clinical and/or microbiological criteria leading to antibiotic-therapy), endocarditis, stroke, early mortality (defined as in-hospital or up to 30 days after surgery), abnormal bleeding (defined as >2 ml/kg/h in first 2–3 h, >1 ml/kg/h in the next 3 h, and/or >0.5 ml/kg/h in 12 h), new-onset atrial fibrillation (paroxysmal, persistent or permanent), any renal dysfunction (defined by the Acute Kidney Injury Network criteria),[14] and need for intra-aortic balloon pump, surgical exploration for bleeding, renal replacement support (performed through continuous venovenous hemodiafiltration), or aminergic support >24 h (performed with at least one of the following: epinephrine, norepinephrine, and dobutamine)—and postoperative echocardiographic findings.

High-risk patients were discussed with the heart team the decision ON the most optimal treatment for each patient. Perceval® implantation was favored in high-risk patients or when other risk factors were present, including advanced age, reduced ejection fraction, severe comorbidities, concomitant procedures, and calcification of the aortic root.

2.3 | The Perceval® valve

The Perceval® prosthetic valve (Sorin Group) consists of three bovine pericardial cusps mounted on a self-expanding nitinol stent comprising two rings, allowing for stabilization simultaneously at the aortic annulus and at the sinotubular junction (STJ), and nine vertical struts covered by a thin coating of Carbofilm™, to improve biocompatibility. The stent holds the valve in place without any permanent suture, by exerting radial force on the patient's aortic annulus and aortic root. It is also flexible, allowing it to adapt to the anatomy of the aorta and its movements, thus relieving the stress on the leaflets. The valve is folded up by collapsing the inflow and outflow rings with an atraumatic compression device, allowing the pericardial leaflets not

to be crimped and remain mobile, ensuring they are not damaged[15]—in contrast to the necessary crimping of the transcatheter aortic valve implantation (TAVI), in which the leaflet's collagen fibers are damaged.[10] The Perceval® valve is currently available in four sizes: small (S), to be implanted in annular sizes from 19 to 21 mm, medium (M) from 22 to 23 mm, large (L) from 24 to 25 mm, and extra large (XL) for patients with annular sizes of 27 mm.[6]

Although the concept of sutureless bioprosthesis exists for over 40 years,[16] the first reports evaluating implantation feasibility and valve safety in humans were only released in 2007. It was CE approved in 2011 and Food and Drug Administration approved in 2016.[17]

2.4 | Surgical technique

Indications for AVR were in agreement with the European Society of Cardiology/European Association for Cardio-Thoracic Surgery Guidelines for the management of valvular heart disease at the time of the interventions.[18] The surgical approach was either standard median sternotomy or upper J-ministernotomy. All patients were operated on or supervised by an experienced surgeon in this procedure. Anesthetic and surgical techniques were standardized. A high transverse aortotomy close to the epiaortic fat pad was performed, leaving a free edge for closure after implantation of the device. The native calcified aortic valve was excised, and the aortic annulus was completely decalcified. Sizing of the annulus was done using dedicated sizers.

Concomitant procedures were performed in line with current department practices and always with the goal of minimizing aortic cross-clamping and CPB times. For instance, aortic graft anastomosis, when needed, was performed before cannulation using tangential aortic cross-clamping.

After aortotomy closure in the usual fashion, thorough de-airing with CO_2, the release of the aortic cross-clamp, and weaning from CPB were performed. Valve function was evaluated by intraoperative transesophageal echocardiography in all patients. Following the procedure, patients were transferred to the ICU and managed accordingly. Antiplatelet therapy was instituted.[19]

In concomitant procedures with ascending aorta replacement, the proximal anastomosis of the tubular prosthesis needs to be performed first. The Perceval® valve is then safely pushed through the tubular prosthesis and properly implanted. The distal anastomosis is subsequently completed and the remaining surgery is performed as usual.

2.5 | Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics v27.1. Categorical variables are reported as absolute and relative frequencies. For continuous data, means, median, and standard deviations were calculated. Cumulative survival and freedom from events were estimated using the Kaplan–Meier method, with 95% confidence intervals.

3 | RESULTS

3.1 | Preoperative characteristics

Between February 2015 and October 2020, 198 patients were submitted to AVR with a Perceval® prosthetic valve in Hospital de Santa Maria. A of total 2 patients were excluded due to valvular explantation, resulting in a total of 196 patients analyzed. Aortic stenosis was the main surgery indication (96.4%), followed by aortic regurgitation (1.53%), native valve endocarditis (1.02%), prosthetic valve endocarditis (0.51%), and mechanic valve dysfunction (0.51%).

Preoperative baseline characteristics of the cohort are shown in Table 1. The mean overall age was 77.20 ± 5.08 and 45.4% of patients were female. EuroSCORE II predicted an in-hospital

TABLE 1 Preoperative baseline characteristics and risk factors (mean ± standard deviation)

Patients	% (±SD)
Demographics	
Sex (female)	45.4
Age (in years)	77.20 ± 5.08
EuroSCORE II	2.91 ± 2.20
Preserved LV function (LVEF > 55%)	69.4
Mean aortic transvalvular gradient (mmHg)	50.01 ± 14.67
Risk factors	
Chronic kidney disease[a]	85.2
Arterial hypertension	88.3
Overweight/obesity[b]	75.8
Dyslipidemia	71.9
Diabetes mellitus (DM)	41.8
DM Insulin treated	2.6
Coronary artery disease	34.7
Atrial fibrillation/flutter	17.9
Smoking history[c]	18.9
Chronic Respiratory disease	14.3
Peripheral arterial disease	4.6
Previous stroke or transient ischemic attack	8.7
Preoperative permanent pacemaker	3.1
Previous cardiac surgery	2.0

Abbreviations: LV, left ventricle; LVEF, left ventricular ejection fraction.
[a]Impaired renal function was defined as glomerular filtration rate <85%
[b]Overweight/obesity was defined as a body mass index >25.
[c]Former or active.

mortality risk of 2.91 ± 2.20%. The most prevalent preoperative risk factors were impaired renal function (85.2%), arterial hypertension (88.3%), overweight or obesity (75.8%), and dyslipidemia (71.9%). Coronary disease was present in 34.7% of the cohort, atrial fibrillation in 17.9%, and 8.7% had a history of stroke or transient ischemic attack. Most patients (69.4%) had preserved LV function, defined as an ejection fraction higher than 55%. For those with aortic valve stenosis, the preoperative mean transvalvular gradient was 50.01 ± 14.67 mmHg.

3.2 | Intraoperative outcomes

Intraoperative outcomes of the cohort are shown in Table 2. Overall mean total surgery time was 131.67 ± 56.71 min, with mean aortic cross-clamping and CPB times of 33.31 ± 14.09 min and 45.55 ± 19.04 min, respectively. Of all surgeries, 15 (7.65%) were minimally invasive, via upper J-ministernotomy. For isolated aortic valve procedures, the cross-clamping and CPB times were 27.30 ± 8.14 and 37.45 ± 11.32 min (in comparison, nonisolated aortic valve procedures had 46.55 ± 14.82 and 63.93 ± 19.97 min, respectively).

Minimally invasive procedures account only for 7.65% of all cases.

The M size of Perceval® valve was the most frequently implanted prosthesis, accounting for 69 patients of the entire cohort (35.6%), followed by the size L in 64 patients (33.0%), XL in 35 (17.0%), and the size S in 28 (14.4%).

Isolated AVR was performed in 122 (62.24%) patients. Concomitant single CABG surgery was performed in 22 (11.22%) patients, double CABG surgery in 23 (11.73%), and triple CABG surgery in 4 (2.04%). Other concomitant procedures included mitral and/or tricuspid valvular repair/replacements in 12 patients (6.12%), Morrow procedure in 10 (5.10%), supracoronary ascending aorta replacement in 2 (1.02%), and Dor procedure in 1 (0.51%) patient. Two patients (1.02%) had already undergone previous cardiac surgery.

The Perceval® valve was successfully implanted in 196 patients (98.98%), whereas in two cases (2/198 = 1.01%), conversion to conventional bioprosthesis (Edwards Perimount Magna Ease®) was required after valve explantation due to severe displacement. In seven cases (7/196 = 3.5%), reimplantation was necessary. Three due to initial misplacement and four due to paravalvular leaks.

TABLE 2 Intraoperative outcomes (mean ± SD)

Patients	*n* = 196	%
Operatory data		
Total surgery (min)	131.67 ± 56.71	–
Cardiopulmonary bypass (min)	45.55 ± 19.04	–
Aorta cross-clamping (min)	33.31 ± 14.09	–
Valve size		
S (*n*)	28	14.4
M (*n*)	69	35.6
L (*n*)	64	33.0
XL (*n*)	35	17.0
Intraoperative valve complications		
Reimplantation	4	2.0
Significant paravalvular leaks	0	0.0
Operation details		
Isolated aortic valve replacement	122	62.24
+CABG × 1	22	11.22
+CABG × 2	23	11.73
+CABG × 3	4	2.04
+Mitral/tricuspid repair/replacement	12	6.12
+Morrow miectomy	10	5.10
+Ascending aorta replacement	2	1.02
+Dor procedure	1	0.51
Previous cardiac surgery	2	1.02
Mean transvalvular gradients (mmHg)	7.82 ± 3.62	–

Abbreviations: CABG, coronary artery bypass graft; L, large; M, medium; S, small; XL, extra large.

3.3 | Postoperative outcomes

Postoperative results are shown in Table 3. The average ICU stay was 3.32 ± 3.24 days and the average total hospital stay was 7.70 ± 5.82 days. Mean transvalvular gradients were 7.82 ± 3.62 mmHg. Mean gradient for size S was 9.4 ± 4.5 mmHg, size M 7.6 ± 4.2 mmHg, size L 5.8 ± 1.5 mmHg, and size XL 8.0 ± 2.1 mmHg. Four patients (2.04%) died, one due to refractory cardiogenic shock, two due to septic shock and multiorgan failure following urgent surgery for native valve endocarditis, and one after neurologic complications related to an underlying type A aortic dissection.

The most common immediate postoperative complications over the entire cohort were the need for aminergic support for over 24 h (45.1%), new-onset atrial fibrillation (21.9%), PPI (12.8%) all due to third-degree atrioventricular block, and significant acute kidney injury (AKI) (10.5%). Less prevalent postoperative complications included infections (10.2%), abnormal bleeding (9.2%), renal replacement support (3.1%), early mortality (2.0%), intra-aortic balloon pump implantation (2.0%), and the need for surgical exploration for bleeding (1.0%).

During follow-up, no structural valve deterioration, strokes, or endocarditis were reported. One patient developed valve thrombosis (0.5%), which was successfully treated with oral anticoagulants. Using information provided by the manufacturer (minimal effective orifice area possible for each valve size), we calculated the projected indexed effective orifice area (iEOA). There were no cases of PPM nor need for reintervention due to symptomatic of PPM (Figure 1).

TABLE 3 Postoperative outcomes (mean ± SD)

Patients	%
In-hospital stay	
ICU stay (days)	3.32 ± 3.24
Hospital stay (days)	7.70 ± 5.82
Postoperative complications	
Aminergic support >24 h	45.1
New-onset Atrial fibrillation	21.9
PPI	12.8
Significant AKI	10.5
Infection	10.2
Abnormal bleeding	9.2
Renal replacement support	3.1
Early mortality	2.0
Intraaortic balloon pump	2.0
Surgical exploration for bleeding	1.0
Valve thrombosis	0.5
Stroke	0.0
Endocarditis	0.0
PPM	0.0
Pos-Op mean aortic transvalvular gradient (mmHg)	7.82 ± 3.62
Follow-up mean aortic transvalvular gradient (mmHg)	11.88 ± 4.39

Abbreviations: AKI, acute kidney injury; ICU, intensive care unit; PPI, permanent pacemaker implantation; PPM, prosthesis–patient mismatch.

The immediate postoperative mean aortic transvalvular gradient was 7.82 ± 3.62 mmHg and during the follow-up was 11.88 ± 4.39 mmHg.

Figure 2 shows the overall Kaplan–Meier cumulative survival curve and the life table, including patients at risk, throughout 5 years. The survival rate at the end of 1 year was 94%, at 3 years 86%, and at 5 years 71%.

4 | DISCUSSION

The Perceval® prosthetic valve (Sorin Group) has been increasingly used in European Cardiac Surgery Centers for the treatment of aortic valve disease since its first reports in 2007. As a truly sutureless bioprosthesis with proven excellent hemodynamic outcomes, safety, and a marked reduction in aortic cross-clamping and CPB times, it has been shown to reduce postoperative morbidity and mortality as well as cost reduction of up to 25% when compared with conventional biological heart valves,[8,20] especially when treating older patients and in those with comorbidities. However, several questions are yet unanswered, especially regarding long-term durability, endocarditis risk, and the need for postoperative PPI.

In our retrospective study, we sought to assess the clinical and hemodynamic performance, safety, and durability of the Perceval® valve for isolated AVR and concomitant procedures.

Our cohort is composed essentially of elderly patients, with an average overall age of over 77 years and a small standard deviation of approximately 5 years. Additionally, most patients had one or more preoperative risk factors and/or comorbidity, with an average in-hospital mortality risk measured by a EuroSCORE II of almost 3%, despite the majority having preserved LV function.

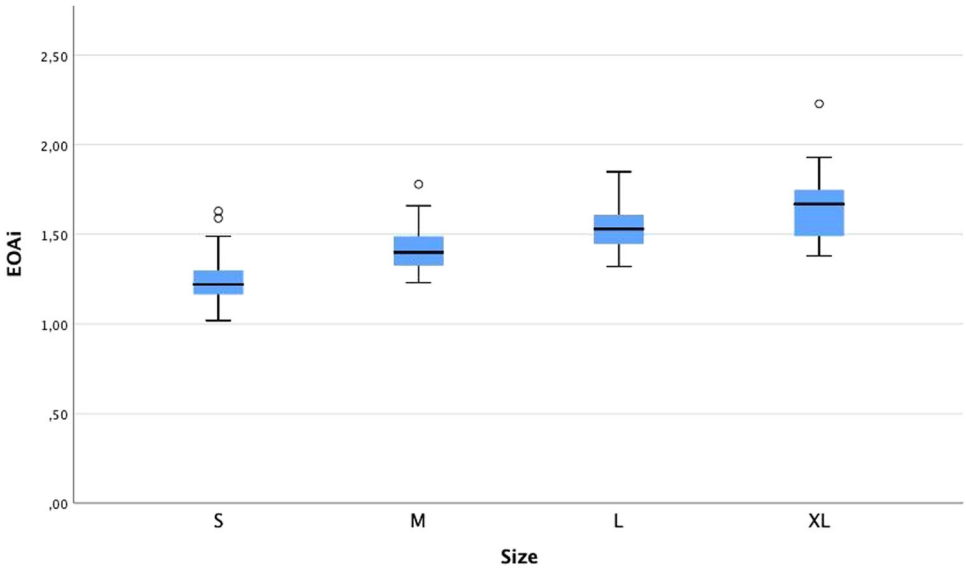
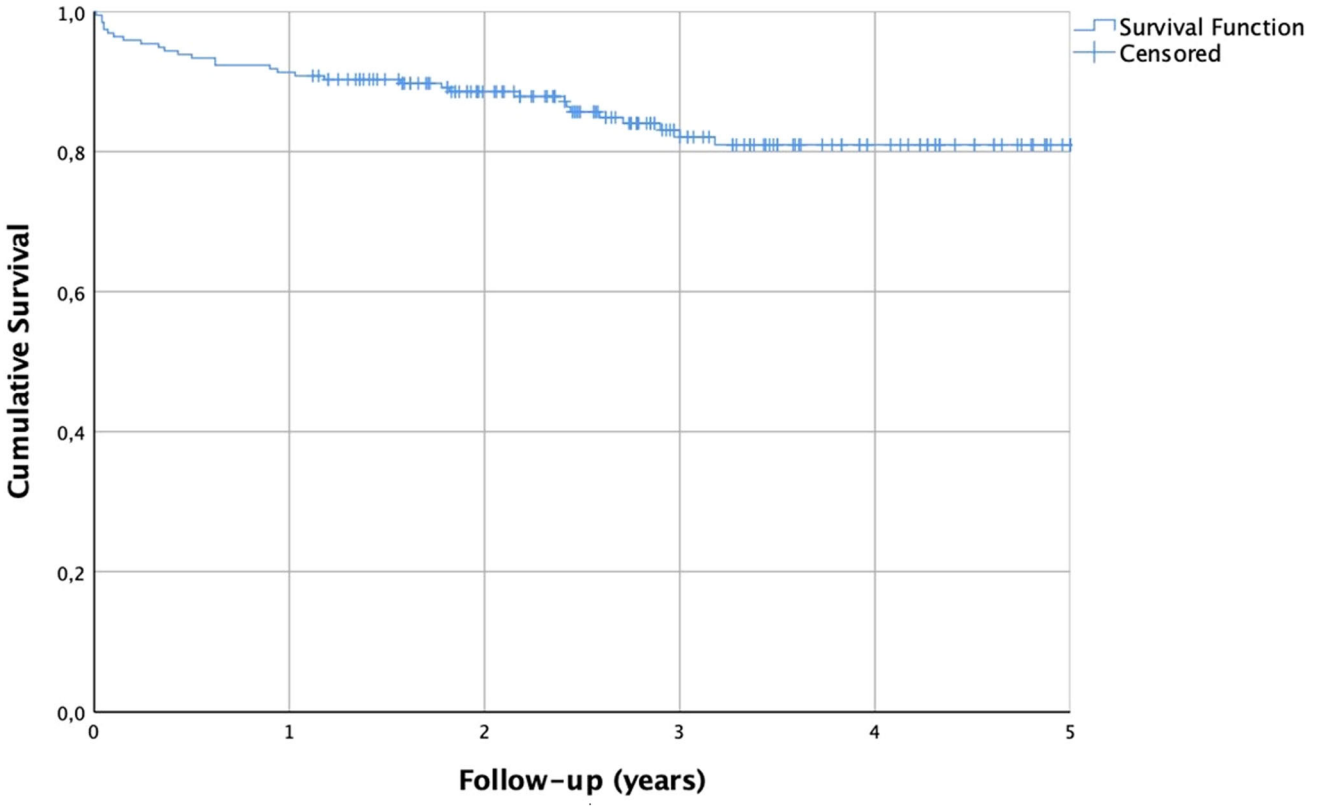


FIGURE 1 Projected indexed effective orifice area (cm^2/m^2) according to valve size. No patient-prosthesis mismatch cases were recorded. The calculations were made having into consideration the minimum possible effective orifice area for each valvular size provided by the manufacturer. iEOA, indexed effective orifice area; L, large; M, medium; S, small; XL, extra large



Life Table

Interval Start Time	Number Entering Interval	Number Withdrawing during Interval	Number Exposed to Risk	Number of Terminal Events	Proportion Surviving	Cumulative Proportion Surviving at End of Interval
0	196	0	196	17	,91	,91
1	179	37	161	5	,97	,88
2	137	48	113	7	,94	,83
3	82	31	67	2	,97	,81
4	49	27	36	0	1,00	,81
5	22	22	11	0	1,00	,81

a. The median survival time is 5,0

FIGURE 2 Follow-up overall mortality (Kaplan–Meier survival curve) and life table

The overall total surgical time, aorta cross-clamping, and CPB times took into consideration the surgeries where reimplantation of the valve was necessary. The times obtained represent a significant reduction in comparison to the mean aorta cross-clamping and CPB times of 78 and 106 min reported in conventional AVR, according to the Society of Thoracic Surgeons database. This major reduction of over 50% in both times could translate into improved clinical results, especially in patients with comorbidities such as diabetes mellitus[7] or in a medium-high surgical risk profile, as aortic clamping and CPB times are considered independent predictors of morbidity and mortality in heart surgery.[10]

The Perceval® valve was successfully implanted in 98.99% as in two cases (2/198 = 1.01%) conversion to conventional bioprosthesis was required due to valve migration. One way of possibly reducing the likelihood of these events is by strictly obliging the manufacturer's preoperative echo-Doppler aortic root evaluation recommendations (a patient is suitable if the ratio between the diameter of the STJ and the annular diameter is ≤1.3).[21]

As mentioned, in seven cases (3.5%), reimplantation was necessary, either due to paravalvular leaks found in the intraoperative transesophageal echocardiography (four cases with subsequent aortic cross-clamping) or initial misplacement (three cases). The valve is infolded using two forceps at two opposite sites of the superior part of the stent and approximating them toward the center at the same time (known as the "x-movement" technique). The *"en bloc"* bioprosthesis excision allows a simple refolding and easy reimplantation without damage to the leaflets or the bioprosthesis structure. To facilitate the procedure cold water can be added.[22]

A final inspection before closing the aorta is mandatory, and allows the detection of severe misplacement, with immediate

reimplantation. After weaning from CPB echocardiography assures correct placement and function of the valve. If paravalvular leaks or misfunction are detected reclamping is necessary to remove and reimplant the valve.

In one of the cases, a severe migration was observed and was associated with cardiac manual manipulation due to additional manual de-airing.[23]

In our study, we report no significant paravalvular leaks, a result below the already low 1%–2% commonly observed in trials with the Perceval® valve.[6] In comparison, TAVI causes a greater number of moderate-to-severe paravalvular leaks (7%–12%), followed by conventional AVR (1.9%), which at 2 years have been shown to be independent predictors of mortality.[10,24] Consequently, correct measurement, placement, and final visual confirmation of correct valve placement in addition to CO_2 de-airing could help avoid these complications.

The most common immediate postoperative complications (Table 3) were in line with the expected for a major cardiac procedure. The relatively high rate of postoperative aminergic support might be related to the fluid restriction protocol used in our department. New-onset atrial fibrillation is usually multifactorial and is the most common dysrhythmic complication occurring after any cardiac surgery, affecting typically between 30% and 50% of the patients, more than we report.[25]

Although the incidence of AKI is relatively high (10.5%), only a reduced number of patients required renal replacement techniques (3.1%). The advanced age of the study population with more than 85% preoperative chronic kidney disease, in alliance with the tight criteria used in postoperative care, may justify these numbers.

Infection complications after cardiac surgery occur in 5%–21% of cases and are associated with the worst prognosis.[26] In our case, the infection rate was 10% and included any patient with confirmed or clinical suspicion of infection. Due to the complexity and high surgical risk of the majority of these patients, there is a low burden to initiate antibiotics in our ICU. Although the number is in-line the published data, they are still relatively high, which can reflect both the low threshold criteria for treatment and the high-risk studied population.

The overall incidence rate for PPI of 12.8% is within the interval incidence described in the literature, of 3.1%[27] to 17%[28] although it is above rates for conventional bioprosthesis reported of 3.0% to 11.8%[29] and comparable to the ones reported for TAVI.[30] Current best available evidence suggests baseline conducting system disease is the most powerful independent predictor of PPI requirement following AVR. Other patient-related predictors are advanced age, annular calcification.[28] Operative-related factors such as incomplete decalcification of the aortic ring, valve oversizing, valve and guiding sutures position, reoperations, longer perioperative CPB time, and procedural implanting steps and sizing's learning curve effect are also important.[13] In our center, all patients were operated on or supervised by an experienced surgeon in this procedure. That said, standardizing the implantation technique and better patient selection could offer benefits in reducing PPI incidence.

We report one case of valvular thrombosis (0.51%), which was successfully treated with oral anticoagulants (vitamin K antagonist). Following the procedure, all patients received antiplatelet treatment according to the standard protocol in use in our center, consisting of acetylsalicylic acid or clopidogrel for a period of 3–6 months when sinus rhythm was present. Antiplatelet and anticoagulation management after sutureless valve placement is not standardized, as no specific recommendations have been made in recent guidelines.[17]

We found no structural valve deterioration, endocarditis cases, or strokes up to the 5-year follow-up, presumably because the Perceval® valve allows less manipulation of the aortic root and annulus, zero permanent contact with foreign material such as sutures,[13] and it has been shown to present high resistance against endocarditis in comparison with conventional prostheses. Nevertheless, 5 years of follow-up is still a short time compared with the data available for conventional prostheses of up to 25 years.[31]

The mean postoperative transvalvular gradients after surgery and the absence of PPM cases confirm the excellent hemodynamic performance of the Perceval® valve, coherent with other studies[6] and significantly lower when compared with the ones provided by conventional prostheses[29] and TAVIs.[30]

The nature of the valve allows a significant range of iEOA (two annular diameters). We used the minimum value for each valvular size provided by the manufacturer and the VARC-II criteria to calculate the indexed iEOA and the presence of PPM.[32,33]

ICU and total in-hospital stays were markedly lower when compared with reports of conventional bioprostheses[34] and similar when compared to TAVIs.[30]

Early overall mortality (in-hospital or up to 30 days after surgery) was 2.0%, below the one predicted by the initial EuroSCORE, in line with the 2.8% reported for conventional prostheses and significantly lower than with TAVIs.[10,30,33,34] Of the four patients who died, none of their deaths were caused directly by a failure in the prosthetic valve or the procedure themselves (cardiogenic and septic shock, neurological complications). These results show good short-term clinical outcomes despite the risk profile and advanced age of the cohort.

Overall cumulative survival at 1, 3, and 5 years and the correspondent Kaplan–Meier curve are the ones expected taking into consideration our cohort's age, comorbidities, and type of interventions. It is up to par with the mean corresponding cumulative survival of conventional AVR[35,36] and better than with TAVIs up to 2 years,[29] showing the safety of use and good midterm durability, with no structural valve deterioration.

Additionally, the Perceval® valve enables standardization and simplification of management information system (MIS) approaches, in a way conventional prostheses have not yet made possible. MIS is associated with significant technical difficulty due to reduced visualization that increases aortic cross-clamping and CPB time, extending the learning curve. The latter, in addition to the high number of combined procedures, may explain the reduced number of MIS procedures observed in this study (only 7.65%).[10,38]

4.1 | Limitations

As with all single-center retrospective cohort studies, this study is subject to various limitations due to the research design. In some cases, the health records did not contain all of the desired information. A large number of patients were referred from other hospitals. This complicated the collection of patient data, especially during the follow-up period. Since this was a single-center study, only a small number of patients were eligible for inclusion, which may limit the generalizability of our findings. Follow-up time is still short. A multicenter medium-/long-term randomized control trial study should be completed to create a larger group and draw more generalizable conclusions.

5 | CONCLUSIONS

All patients with an indication for AVR with a biological bioprosthesis could potentially benefit from a shorter and easily reproducible treatment. This seems to be especially beneficial in patients more sensitive to ischemia, technically difficult procedures, patients with a high risk of PPM, and patients who require faster recovery.

Our study further confirms the excellent clinical and hemodynamic performance and safety of the Perceval® valve, a truly sutureless aortic prosthesis, in a moderately large cohort of patients, even up to the 5-year follow-up. Consistent with current literature, the Perceval® valve allowed reduced aortic cross-clamping, CPB, and surgical times due to its easy and rapid implantation technique as well as low rates of mortality, complications, or dysfunctions early and up to 5 years, even in our cohort of mostly older patients with comorbidities. Additionally, it has been proven to facilitate the reproducibility and resurgence of minimally invasive approaches, reducing additional postoperative complications.

ETHICS STATEMENT

Approval of the study and access to the data was granted by the ethical committee of the hospital involved (Comissão Ética Centro Hospitalar Lisboa Norte, identification number: 510/18).

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