

# Sutureless aortic bioprosthesis: Competitor or alternative for transcatheter aortic valve implantation? Single center experience with Perceval valves

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Currently, less invasive procedures draw a significant attention of valvular heart teams worldwide. Simultaneously, two concepts such as transcatheter aortic valve implantation (TAVI) and sutureless bioprosthesis have been developed. The latter one is represented by the Perceval prosthesis which cusps are made of bovine pericardium. This valve is mounted into a self-expanding nitinol stent, covered with a thin Carbofilm™ coating for biocompatibility improvement. The stent consists of two rings and nine connecting struts — inflow ring is located at the annulus level and outflow one at the sino-tubular junction. Struts support the valve and hold it in place with no need for sutures. After deployment the scaffold reaches the desired shape accommodating to the aortic root. Due to the absence of a suturing ring, the orifice area is maximized which provides optimized blood flow. The framework is smaller than conventional stented prostheses, which may help to achieve better hemodynamics and lower rate of patient-prosthesis mismatch (PPM). The purpose of the study was to collect the data regarding Perceval implantation outcome in a single-center all-comers registry. The study group comprised 50 patients (25 female, 25 male) with the mean age of  $68.8 \pm 10.3$  years scheduled for Perceval implantation between 2013 and 2021. All operations were performed in

the cardio-pulmonary bypass (CPB) from either full ( $n = 20$ ) or upper ministernotomy ( $n = 30$ ) (Table 1). After aortic annulus partial decalcification, the bioprostheses were deployed. The study was approved by our institutional committee. Patients' safety and Perceval performance were evaluated in in-hospital and follow-up observation. Adverse events were also recorded.

Data were reported as the means and standard deviations, or the medians with interquartile range (IQR), and discrete variables as counts or percentages. Kaplan-Meier method was applied to analyze probability of patients' survival. Statistical analysis was performed with use of JASP (2020, Version 0.13.1).

Implantation was technically successful in all patients. During in-hospital stay 6 patients died, including two within the first 30 days after surgery (1-month mortality rate 4%). Four of them (66.7%) were operated on urgently due to hemodynamic instability in a course of active endocarditis or prosthetic valve thrombosis. All patients completed follow-up period (median [IQR]) 23 (8, 38) months. Six-month, 1- and 3-year probability of survival stratified by means of Kaplan-Meier method were  $0.88 \pm 0.05$ ,  $0.85 \pm 0.05$  and  $0.82 \pm 0.06$ , respectively. Significant improvement in functional class at discharge was observed and persisted together

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**Table 1.** Clinical and procedural data (n = 50).

Male	25 (50%)
Age [years]	68.8 ± 10.3
EuroScore II [%]	4.1 ± 6.7
EuroScore II > 4%	10 (20%)
Active endocarditis	8 (16%)
Native valve	7 (14%)
Prosthetic valve	1 (2%)
Aortic stenosis pure or combined	41 (82%)
NYHA stages II–III	41 (82%)
NYHA stage IV	9 (18%)
Baseline PPG [mmHg]	88.8 ± 30.6
Baseline MPG [mmHg]	56.2 ± 18
Baseline LVEF [%]	58.3 ± 9.1
Size:	
S	3 (6%)
M	11 (22%)
L	18 (36%)
XL	18 (36%)
Surgical access:	
Ministernotomy	30 (60%)
Sternotomy	19 (38%)
Re-sternotomy	1 (2%)
Isolated AVR	41 (82%)
Isolated re-AVR	2 (4%)
Combined surgery (+CABG)	6 (12%)
Combined with other procedure	1 (2%)
Urgent or emergent surgery	10 (20%)
Cardiopulmonary bypass time [min]	72.3 ± 23.3
Cross-clamping time [min]	49.8 ± 12.7
30 days mortality	2 (4%)
3 months mortality	6 (12%)
All-cause long-term mortality	9 (18%)
Post-surgery AF	25 (50%)
Post-surgery permanent pacemaker implantation	3 (7%)
Post-surgery AKI	14 (33%)
Post-operative stay of survivors [days]	11.2 ± 8.6
Post-surgery new hemofiltration	3 (6%)
PPG [mmHg] — at discharge	23.9 ± 10.4
MPG [mmHg] — at discharge	13.5 ± 7.1
LVEF [%] — at discharge	56.7 ± 9.1
PPG [mmHg] — 3–12 months	20.7 ± 10
MPG [mmHg] — 3–12 months	11.8 ± 6.5
LVEF [%] — 3–12 months	59 ± 3.8
PPG [mmHg] — 1–7 years	24.5 ± 16
MPG [mmHg] — 1–7 years	13.7 ± 10.1
LVEF [%] — 1–7 years	58.6 ± 4.7

Continuous variables are presented as the means ± standard deviations whereas discrete one as numbers (n) with percentage (%); AF — atrial fibrillation; AKI — acute kidney injury; AVR — aortic valve replacement; BMI — body mass index; CABG — coronary artery bypass grafting; LVEF — left ventricular ejection fraction; MPG — mean pressure gradient; NYHA — New York Heart Association; PPG — peak pressure gradient

with good echocardiographic outcome in majority of patients in long term follow-up. One patient was diagnosed after 6 years with Perceval degeneration and underwent TAVI. One patient developed early mitral valve endocarditis without Perceval involvement and was re-operated.

Our single center experience with Perceval shows good procedural and clinical result, and low long-term mortality. Both 30-day and late survival in our group is comparable to previous reports and confirm safety and utility of Perceval prosthesis [1–8]. The first observation, by Shrestha et al. [7, 8] showed safety and efficacy of the Perceval in high-risk patients. In the largest prospective study performed in a cohort of 208 high-risk patients the reported in-hospital and 1-year mortality rates were 2.4% and 12.9%, respectively [2]. One of the main possible advantages of sutureless prostheses is the ease of implantation and consequently markedly reduced CPB and aortic cross-clamp (ACC) times. In the present study group prosthesis implantation was technically successful in all patients. However, regarding the aforementioned times, they were found to be relatively long. Of note, most of our procedures were carried out through ministernotomy. On the other hand, if we refer our CPB and ACC times to the previously reported upper ministernotomy surgical aortic valve replacement (SAVR) patients, they could be considered to be relatively short [9]. One of the most embarrassing issues after minimally invasive procedures is perivalvular leak (PVL). Perceval shows rate of PVL ranging from 1.6% to 15.8% [10]. We did not observe moderate or severe PVL and mild PVL was present in 3 patients.

Not uncommonly sutureless bioprostheses are compared to TAVI due to many technical and procedural similarities. They are both constructed on the nitinol cage with biological leaflets. There is no need for surgical suturing and the prostheses are anchored to the aortic root due to radial force. However, some specific conditions differ in these two types of procedures. Firstly, TAVI bioprosthesis is implanted into a calcified aortic valve, which is compressed towards the aortic sinus wall. Apart from the risk of PVL cerebral and peripheral embolism may occur. In the opposite, during Perceval implantation the calcified valve is completely removed and, if necessary, the annulus is decalcified. In TAVI patients, PVL results from preserved calcification, while in Perceval implantation from too excessive decalcification. TAVI is certainly contraindicated in active endocarditis, while currently Perceval not. Both sutureless bioprostheses represent an

excellent solution for a wide variety of patients. While inoperable patients would benefit best from the TAVI procedure, Perceval is a valuable option for patients with an additional disease requiring simultaneous intervention. A significant group of patients with low to moderate perioperative risk may be treated alternatively with both procedures.

Based on experience of our center, patients were distinguished who particularly benefit from Perceval implantation such as subjects at borderline risk between SAVR and TAVI, with a suboptimal surgical anatomy (e.g. extensive calcifications infiltrating aortic annulus, small annulus) and with infective endocarditis. Moreover, patients with perioperative risk considered to be too high for SAVR, but still not relevant enough for TAVI, may be qualified for Perceval implantation. A second group of beneficiaries are those with very small and severely calcified annulus who may present with intraoperative problems in implantation of the mechanical valve or classic bioprosthesis which may be impossible without an additional annulus enlargement procedure or which may generate PPM. Finally, patients with active bacterial endocarditis may also benefit from Perceval implantation. The use of sutureless prosthesis enables minimizing the presence of artificial material in the infected field.

In conclusion, Perceval prosthesis is a safe and valuable option for patients with severe aortic stenosis. Particularly, patients at a borderline operative risk between SAVR and TAVI, with suboptimal surgical anatomy and infective endocarditis will benefit from Perceval implantation.

**Conflict of interest:** None declared

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