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ORIGINAL ARTICLE

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Feasibility of clinical application of Perceval sutureless bioprostheses in emergency patients with unexpected intraoperative findings

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ABSTRACT

Introduction: Sutureless aortic prostheses provide an attractive opportunity for high-risk patients with difficult surgical anatomy of the aortic root.

Aim of the study: To assess the outcomes of emergent aortic valve replacement (AVR) with Perceval sutureless bioprostheses in a group of high-risk patients in whom their implantation had not been considered before surgery.

Material and methods: Since 2018, 53 sutureless aortic bioprostheses have been implanted in our center. In this single-center retrospective study, 7 high-risk (median EuroSCORE II 9.43%) patients (4 women and 3 men; median age 63 [28 to 73] years) were identified to undergo emergent procedures. They were operated on for active endocarditis on the native valves with extensive destruction of the annulus (n = 4), endocarditis on a previously implanted bioprosthesis (n = 1), organizing thrombus of the mechanical valve (n = 1), and diffuse aortitis (n = 1). Implantation feasibility, as well as postprocedural mortality and morbidity, were evaluated.

Results: The following sizes of bioprostheses were used: XL (n = 3); L (n = 2); M (n = 1), and S (n = 1). The median (minimum; maximum) cross-clamping aortic time was 64 (37; 73) minutes while cardiopulmonary bypass time was 86 (49; 188) minutes, respectively. All patients survived operations and the first 30 days. Two of them died in the hospital because of multiorgan failure on 35th and 45th postoperative days. The follow-up period ranging from 6 to 40 months was completed by all who were discharged alive.

Conclusions: Despite the well-known advantages of sutureless valves, they can be also used successfully in patients in whom standard prosthesis implantation is either impossible or highly demanding, including emergency cases with unexpected intraoperative findings.

Key words: sutureless aortic prosthesis, endocarditis, Perceval, outcomes

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Introduction

In developed countries, the estimated prevalence of valvular heart disease is about 2.5%. A few years ago, post-rheumatic valvular defects represented 22% of all acquired cardiac malformations in Europe [1]. In the elderly population, the most common pathology is aortic stenosis, with a prevalence of approximately 3% [2]. Infective endocarditis is much less common disease with an incidence between 1 and 11/100 000 people per year [3].

Aortic valve replacement (AVR) is one of the most common cardiac surgical procedures. According to the 2010 annual report of the Society of Thoracic Surgeons (STS), more than 20 000 isolated AVR procedures and 16 000 combined with coronary artery bypass grafting (CABG) were performed in the United States [4].

There are two commercially available types of prostheses. One of them are the mechanical valves usually with two tilting discs made of pyrolytic carbon. They are characterized by unlimited durability, but due to the risk of thromboembolic complications, patients must be anticoagulated. The leaflets of biological valves are made from the animal pericardium, predominantly bovine, or bioprostheses are swine aortic roots attached or not to the stent (stented and stentless prostheses, respectively). Patients, after biological valve implantation, do not need to be treated with anticoagulants. Unfortunately, many of them have to be reoperated 15 to 20 years after primary surgery due to structural valve deterioration (SVD). This prevents their widespread application in relatively young adult patients. For about ten years, there has been an increasing interest in both minimally invasive bioprostheses implanted during transcatheter procedures (TAVI – transcatheter aortic valve implantation) and surgically deployed sutureless aortic valves. Among the latter ones, the most commonly used is the Perceval prosthesis which can be used in high-risk surgical patients and is considered optimal for implantation through minimally invasive approaches [5]. Alternatively, in some surgical cases of unexpected intraoperative findings (e.g., extensive digestion of the aortic annulus by invasive bacteria or other microorganisms), these bioprostheses can be the only solution to treat complex aortic valve pathology [2]. A Perceval valve is a self-expanding aortic valve prosthesis whose leaflets are made from bovine pericardium. It is preserved in glutaraldehyde followed by a neutralization procedure for aldehyde compounds, which enables its immediate implantation without rinsing. The alloy used for the anchoring system is a Nickel/Titanium equiatomic compound called Nitinol, capable of carrying large deformations and recovering its initial design when stress is applied [6]. The nitinol stent is designed for future circumferential expansion which enables to transcatheter „valve in valve" procedure [2].

This study aims to assess the outcomes of emergent AVR with Perceval sutureless bioprostheses in a group of high-risk patients in whom their implantation had not been considered before surgery.

Material and methods

Patients

Since 2018, 53 sutureless aortic bioprostheses have been implanted in our center. In this single-center retrospective study cohort, 7 patients (4 women, 3 men; median age 63 [28 to 73] years) underwent emergent procedures. These individuals were operated on for active endocarditis on the native valves with extensive destruction of the annulus (n = 4), endocarditis on the previously implanted bioprosthesis (n = 1), organizing thrombus of the mechanical valve (n = 1), and diffuse aortitis (n = 1).

All but one patient were considered high-risk (median of logistic EuroSCORE II 9.43%) with markedly impaired functional status (most of them were found in class III according to the NYHA functional classification). Additionally, two of them experienced sudden cardiac arrest followed by successful cardio-pulmonary resuscitation (CPR) before surgery. The basic demographic parameters, concomitant disorders, and other potential risk factors of early mortality consistent with the EuroSCORE II calculator are listed in Table 1. The STROBE checklist was applied in this study.

According to the rules of the local Bioethical Committee of our university, ethics approval is not required for retrospective data analysis of patients treated using standard methods.

Surgical details

Patients were operated on through either partial (upper) sternotomy in 4 cases. Full median sternotomy was performed in 3 cases, including 2 reoperations. All surgeries were performed on cardio-pulmonary bypass (CPB) and with cold cardioplegic crystalloid arrest (Bretschneider solution) infused directly to the coronary ostia. In all but one patient, CPB was conducted through direct aortic and right atrial cannulation. The exception was the case of the reoperated patient in whom full femoral retrograde cannulation was performed. After either native or prosthetic valves were removed, sutureless prostheses were implanted as described previously [7]. The further stages of surgery were standard, including an epicardial electrode for pacing and drainage tube implantation. The chest was always closed in a typical way with sternal wire application.

Postoperative evaluation

Early (defined as within the first 30 days following surgery) and post-discharge clinical outcomes were assessed. Each patient was followed up regularly in the Cardiac Surgical Outpatient Clinic. The follow-up period that lasted from 6 to 40 months was completed by all survivors who were alive (5/7, 71.4%) at the time of discharge from the hospital. The clinical examinations and imaging studies using transthoracic echocardiography (TTE) were done 1, 6, and 12 months after procedures and then once a year.

Data management and analysis

The data analysis was performed anonymously. First, the quantitative variables were checked for normality using the Shapiro-Wilk test. Because they did not satisfy criteria of normal distribution, they were present-

Table 1. Patient demography, risk factors. and indications

Patients	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Age (years)	28	37	52	63	65	72	73
Sex	Male	Female	Male	Male	Female	Female	Female
BMI [kg/m2]	20.5	22.0	30.8	33.9	23.9	27.1	26.1
Diabetes	0	1	0	1	0	1	0
NYHA	III	III	II	III	III	III	III
Active endocarditis	Yes	No	No	No	No	No	Yes
Chronic lung disease	No	No	Yes	No	No	No	No
GFR < 50 mL/min	122	31	109	71	84	29	42
Previous cardiac surgery	No	No	No	Yes	No	Yes	No
Neurological incidents before	Yes	No	No	No	No	No	No
Urgency	Urgent	Urgent	Elective	Urgent	Urgent	Urgent	Urgent
Cardiac arrest before surgery	No	No	No	No	Yes	Yes	No
EuroSCORE II [%]	5.0	9.9	1.3	12.9	12.0	9.4	5.5
Indications	Endocarditis	Endocarditis	Aortitis	Thrombus on mechanical prosthesis	Endocarditis	Biological valve endocarditis	Endocarditis

BMI — body mass index; GFR — glomerular filtration rate; NYHA — New York Heart Association

Table 2. Perioperative and surgery characteristics

Patients	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Previous operation	0	0	0	AVR	0	AVR	0
Surgical approach	Minister-notomy	Minister-notomy	Minister-notomy	Sternotomy	Sternotomy	Sternotomy	Minister-notomy
Arterial cannulation	Aorta	Aorta	Aorta	Femoral	Aorta	Aorta	Aorta
Size of prosthesis	XL	XL	M	XL	L	S	L
Cross-clamp (min)	37	64	65	73	40	67	51
Time of CPB (min)	49	86	94	188	53	90	78
Summary		Maximal time of CPB	Median time of CPB	Minimal time of CPB	Maximal time of cross-clamp	Median time of cross-clamp	Minimal time of cross-clamp
		188	86	49	73	64	37

CPB — Cardiopulmonary bypass

ed as the medians with range (minimum-maximum). Categorical data were expressed as number (n) with percent (%). Statistical analysis was performed with the use of Statistica 13.3 (TIBCO Statistica) computer software. The P-value below 0.05 was considered significant.

Results

Surgical application

In all cases, the application of sutureless bioprostheses was technically successful. Intraoperative transesophageal echocardiography confirmed appropriate deployment with good hemodynamics and without any perivalvular leakage.

The following sizes of bioprostheses were used: XL (n = 3), L (n = 2), M (n = 1), and S (n = 1). The median (minimum; maximum) cross clamping aortic time was 64 (37; 73) minutes while CPB time was 86 (49; 188) minutes, respectively.

In-hospital outcomes

All examined individuals survived operation, and nobody died during the first 30 days following surgery. In 4 cases, after surgery, acute kidney injury (AKI), defined according to VARC-2 criteria [8], was diagnosed,

Table 3. Postoperative course

Patients	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
AKI	Yes	Yes	No	Yes	No	Yes	No
Hemofiltration	No	No	No	Yes	No	Yes	No
IABP	No	No	No	Yes	No	No	No
Mechanical ventilation [h]	< 12 h	< 12 h	< 12 h	> 24 h	< 12 h	> 24 h	< 12 h
Permanent peacemaker	0	0	0	0	0	0	0
Time in ICU [h]	< 24 h	< 24 h	< 24 h	> 24 h	< 24 h	> 24 h	< 24 h
Peak transvalvular gradient [mmHg]	10	14	36	18	20	21	1
EF [%]	30	45	60	35	35	45	40
Neurological complications	No	No	No	Yes	No	Yes	No
Multiorgan failure	No	No	No	Yes	No	Yes	No
Blood transfusion	0 U	6 U	0	5 U	2 U	2 U	0
Re-exploration for bleeding	No	No	No	No	No	No	No
Time of hospitalization	6 days	9 days	7 days	45 days	19 days	35 days	7 days
30-day mortality	0	0	0	0	0	0	0

AKI — acute kidney injury; EF — ejection fraction; IABP — intra-aortic balloon pump; ICU — intensive care unit

Table 4. Transthoracic echocardiography after 6 months

Patients	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Peak prosthetic gradient [mmHg]	14	15	21	X	21	X	17
EF [%]	55	60	60	X	50	X	60

EF — ejection fraction

and in 2 of them, renal replacement therapy was necessary (CVVH, continuous venovenous hemofiltration). A group of 3 patients had at least one episode of atrial fibrillation; they were successfully treated medically with intravenous amiodarone. No other supra- and ventricular arrhythmias were observed. In one case, the temporary pacing was necessary. In another case, an intra-aortic balloon pump (IABP) to treat postcardiotomy low cardiac output syndrome (LCOS) was successfully applied.

In the majority of patients (71.4%), the duration of mechanical ventilation was less than 12 hours. Only 2 individuals required prolonged ventilation that lasted more than 24 hours. In one case, a tracheotomy was carried out. In two cases, we observed brain ischemia due to inadequate perfusion but without clear signs of ischemic stroke on computer tomography (CT). Moreover, in one case we observed gastrointestinal tract severe hypoperfusion followed by severe sepsis that eventually led to encephalopathy.

In all cases, blood products were transfused. The median (minimum; maximum) in-hospital stay was 9 (6; 45) days. In discharge echocardiography, the function of implanted prostheses was correct with maximal pressure gradients from 10 to 36 mmHg with and median EF of 40%. No cases of PVL were noted. All detailed data regarding early post-operative course are presented in Table 3.

Notably, two patients who survived the 30-day post-operative period died due to multi-organ failure (MOF) later (on 35th and 45th days) during hospitalization. We considered these events as directly related to operation.

Post-discharge follow-up

The follow-up period ranged from 6 to 40 months and was completed by all subjects who were discharged alive (5 patients [71.4%]).

In the last follow-up imaging studies, the correct prosthesis position and function were observed in all individuals. There were no graft dislocations, PVL, or signs of SVD. Notably, left ventricular systolic performance recovered completely, and EF was found within the normal range in all survivors (median [minimum; maximum] 60 [50; 60] %) (Tab. 4). Moreover, all of them were found in NYHA functional classes I and II.

Discussion

Sutureless prostheses were designed for high-risk patients considered borderline cases between TAVI and surgical AVR [2]. Their primary advantage is atraumatic collapse and sutureless implantation which seems to be especially useful in a minimally invasive surgical approach [2]. According to Kim et al. implantation of the Perceval valve could reduce the time of aortic cross-clamp and CPB, therefore, leading to shortening the procedure. Eventually, it can decrease mortality and morbidity, particularly in high-risk patients. The same authors group observed advantages of this bioprosthesis during minimally invasive surgery or complex and multiple valvular operations [9]. In that randomized study, it was demonstrated that implantation of a sutureless valve was associated with not only significantly shorter CPB and ischemic times in both isolated and combined procedures but also decreased incidence of bleeding, transfusion rates, and atrial fibrillation. The shorter intensive-care-unit and in-hospital stays were also reported [10]. The unique design of this valve, its initially squeezed shape, and implantation without sutures can be useful in every case when standard surgical implantation poses difficulty due to native annulus destruction in endocarditis or aortitis. In our report, we suggest the feasibility of using this type of prostheses in high-risk patients who were a real challenge for surgeons. Moreover, its applicability in this particular group of individuals was confirmed by favorable post-discharge outcomes, including clinical and echocardiographic findings.

Two large prospective multicenter and international trials showed safety, as well as good early and mid-term outcomes [11, 12]. Due to the novel and simple technique of implantation characterized by a short learning period they have gained supporters [12]. Moreover, they were shown to present optimal hemodynamics [11]. The rates of early adverse events such as early dysfunction (requiring explanation), stroke, and endocarditis were 0.6, 2.1, and 0.1%, respectively [11]. In another paper, a meta-analysis published in the Journal of the Heart Association, implantation of the Perceval valve was also associated with fewer blood transfusions [13]. One-month mortality and in-hospital stay were very similar to the findings of our current analysis, but our group comprised only selected high-risk and challenging subjects.

Since only case reports have described the potential use of sutureless and rapid deployment valves in active endocarditis, the current guidelines do not recommend using them for this indication. Recently, Mashhour et al. have described a group of 128 patients with infective endocarditis and bicuspid valves, in whom sutureless bioprostheses were implanted. They reported no PVL cases and relatively low 30-day mortality (2.3%) [14]. Roselló-Díez et al. reported a mortality rate of 22.2% (2 patients out of 9) in endocarditis indication and satisfactory short-term follow-up with low gradients and a mild periprosthetic regurgitation incidence [15].

Endocarditis

Patients with active endocarditis and hemodynamic instability usually require urgent operation and are considered at high risk of perioperative mortality and morbidity. In addition to commonly found vegetations on valve cusps that pose a risk of emboli, the active infection may involve the annulus of the aortic valve making surgery technically challenging. This process, if it involves the aortic annulus, can make it impossible to put the sutures correctly. In some cases, using additional and larger felt pledgets is insufficient. Moreover, using foreign materials like sutures or standard Teflon pledgets may sustain or promote recurrence of endocarditis. Eventually, it can lead to hemodynamically significant PVL and a need for reintervention. If the aortic annulus is actively infected, PVL and valve dehiscence rates can reach even 60%. In our group, in 4 subjects, Perceval prostheses were implanted due to endocarditis, and our results suggested their feasibility with good post-discharge outcomes.

We must remember that TAVI procedures, although dedicated to extremely high-risk patients [13], are still contraindicated in endocarditis. Contrary to TAVI, when all infected tissues are left, surgeons are obligated to excise all of them during implantation of a sutureless prosthesis. Moreover, a minimal amount of foreign material (only a stent) should promote easy access of intravenous antibiotics and appropriate healing of infections. The stability is not provided by pledged sutures but by radial forces of nitinol stent.

Prosthetic valve endocarditis and prosthetic valve thrombosis

Patients who need redo surgery due to prosthetic valve endocarditis or thrombosis are an extremely high-risk group of patients [16, 17]. In our study, 2 cases with prosthetic valve dysfunction had to be reoperated. In a female patient with endocarditis on the biological aortic valve prosthesis, the aortic ring was found to be split by active infection making it impossible to place sutures safely, thus a decision was made to implant the Perceval prosthesis. In the second case, an organizing thrombus made removal of a well-healed mechanical prosthesis very difficult. The remnants of the aortic annulus were of very poor quality, therefore, the only solution, in our opinion, was to implant a sutureless valve.

Aortitis

In our group, one patient with aortitis diagnosed intraoperatively underwent sutureless valve implantation. A narrow aortic orifice was suspected in preoperative echocardiography. However, due to the young age, a biological valve was not considered. Extensive involvement of the ascending aorta, which is very rare [18], enabled us to use a standard prosthesis. Moreover, involvement of the upper part of the sinuses of Valsalva and the proximal segments of the coronary arteries discouraged us from extensive reconstructive surgery (e.g., root enlargement, valve-sparing procedures) of the aortic root. The squeezed prosthesis shape enabled it to pass through the narrowest segments of the ascending aorta and finally, the size M valve was properly positioned and implanted.

Conclusions

Sutureless valves have well-known advantages, and they can be also used successfully in some patients in whom standard prosthesis implantation is either impossible or highly demanding, including emergent cases with unexpected intraoperative findings.

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