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Initial experience with the Perceval S sutureless aortic valve

Tatjana Raickovic[1], Igor Zivkovic[1], Tatjana Ragus[1], Slobodan Tomic[2], Petar Vukovic[1], Dusko Nezic[1], Miodrag Peric[1], Slobodan Micovic[1]

[1]Department of Cardiac Surgery, Dedinje Cardiovascular Institute, Belgrade, Serbia
[2]Department of Cardiology, Dedinje Cardiovascular Institute, Belgrade, Serbia

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Abstract

Introduction: Surgical treatment of the aortic valve represents the gold standard, and thus aortic valve replacement (AVR) is one of the most commonly performed cardiac operations.

Aim: To evaluate the early outcome of aortic valve replacement with the Perceval S sutureless aortic bioprosthesis.

Material and methods: This was a retrospective analysis of 24 patients (mean age: 71 ±5 years), who underwent aortic valve replacement with a Perceval S valve. Concomitant coronary artery bypass grafting (CABG) was performed in 9 patients. Patients were evaluated preoperatively, at hospital discharge, and once during follow-up.

Results: A total of 15 of 24 patients underwent isolated sutureless aortic valve replacement (mean aortic cross-clamp time: 60 ±14 minutes; mean bypass time: 90 ±23 minutes). Coronary bypass grafting was performed in 9 patients (mean aortic cross-clamp time: 78 ±23 minutes; mean bypass time: 111 ±31 minutes). Hospital mortality was nil. Mean and peak transvalvular pressure gradients were 10 ±2 mm Hg and 21 ±3 mm Hg at follow-up, respectively. Moderate or severe aortic regurgitation did not develop in any patients during the follow-up period. No valve thrombosis, thromboembolic events, or structural valve deterioration were observed.

Conclusions: In our experience with sutureless aortic valve replacement, the surgical procedure is shown to be safe. The early haemodynamic performance seems favourable. By shortening the aortic cross-clamp and bypass times we can notice advantages, especially in high-risk patients. Minimally invasive access seems to be facilitated. Larger studies are needed to confirm our data and determine the long-term durability of the Perceval S sutureless bioprosthesis.

Key words: sutureless valve, Perceval S bioprosthesis, aortic valve replacement.

Streszczenie

Wprowadzenie: Leczenie chirurgiczne wad zastawki aortalnej stanowi złoty standard w terapii, dlatego też wymiana zastawki aortalnej (AVR) należy do najczęściej wykonywanych operacji kardiochirurgicznych.

Cel: Ocena wczesnych wyników wymiany zastawki aortalnej przy zastosowaniu bezszwowej bioprotezy zastawki Perceval S.

Materiał i metody: Do retrospektywnej analizy włączono 24 pacjentów (średnia wieku: 71 ±5 lat), u których przeprowadzono wymianę zastawki aortalnej przy zastosowaniu bioprotezy Perceval S. U 9 pacjentów wykonano jednocześnie pomostowanie aortalno-wieńcowe (CABG). Ocenę stanu pacjentów przeprowadzono przedoperacyjnie, przy wypisie ze szpitala oraz jeden raz podczas obserwacji pooperacyjnej.

Wyniki: U 15 spośród 24 pacjentów wykonano izolowany zabieg wszczepienia bezszwowej zastawki aortalnej (średni czas zakleszczenia aorty: 60 ±14 minut; średni czas krążenia pozaustrojowego: 90 ±23 minuty). Pomostowanie aortalno-wieńcowe przeprowadzono u 9 pacjentów (średni czas zakleszczenia aorty: 78 ±23 minuty; średni czas krążenia pozaustrojowego: 111 ±31 minut). Nie wystąpiła śmiertelność szpitalna. Średnie i szczytowe gradienty ciśnień przezzastawkowych podczas oceny pooperacyjnej wyniosły odpowiednio 10 ±2 mm Hg i 21 ±3 mm Hg. U żadnego pacjenta podczas obserwacji pooperacyjnej nie wystąpiła umiarkowana ani ciężka niedomykalność zastawki aortalnej. Nie stwierdzono także zakrzepicy zastawki, zdarzeń zakrzepowo-zatorowych oraz uszkodzenia strukturalnego zastawki.

Wnioski: Na podstawie doświadczeń własnych można stwierdzić, że wszczepienie bezszwowej zastawki aortalnej jest bezpieczne. Wczesne parametry hemodynamiczne wydają się korzystne. Skrócenie czasu zakleszczenia aorty i czasu krążenia pozaustrojowego przynosi korzyści zwłaszcza u pacjentów z grupy wysokiego ryzyka. Bioproteza ułatwia wykonywanie zabiegu w sposób minimalnie inwazyjny. Niezbędne są badania na szerszą skalę, aby potwierdzić uzyskane przez nas dane i określić długoterminową trwałość bioprotezy bezszwowej Perceval S.

Słowa kluczowe: zastawka bezszwowa, bioproteza Perceval S, wymiana zastawki aortalnej.

Address for correspondence: Igor Slavoljub Zivkovic MD, Department of Cardiac Surgery, Dedinje Cardiovascular Institute, Heroja Milana Tepića 1, 11000 Belgrade, Serbia, e-mail: igor88zivkovic@gmail.com

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Introduction

Due to the constant aging of the general population, aortic stenosis has become the most common adult heart valve disease, and it is present in 4.6% of patients older than 75 years [1]. Surgical treatment of the aortic valve represents the gold standard, and thus aortic valve replacement (AVR) is one of the most commonly performed cardiac operations [2].

A considerable number of elderly patients with symptomatic aortic stenosis have significant comorbidities. Consequently, AVR with cardiopulmonary bypass can be associated with a high perioperative mortality and morbidity. Studies have shown that increased duration of cross-clamp time significantly correlates with major post-operative morbidity and mortality in both low- and high-risk patients. Therefore, attention has been paid to the development of procedures aimed at shortening the aortic cross-clamp and operative time [3].

Development of sutureless valves represents a turning point for patients undergoing surgical AVR. Their mechanism allows quick deployment of the valve, and thus has the potential to reduce complications associated with long cross-clamp and operative time, while still allowing implantation under direct vision. Furthermore, the Perceval S sutureless aortic valve has the absence of a sewing ring, resulting in a larger effective orifice area for any given valve size and improved haemodynamics when compared with other prostheses [4]. Another significant benefit of this sutureless valve is its utility in minimally invasive AVR. Sutureless valves eliminate the technical difficulty of putting annular sutures in minimally invasive AVR. The Perceval S valve (Sorin Biomedica Cardio Srl, Sallugia, Italy) is made of bovine pericardium leaflets fixed to a self-expanding nitinol alloy stent, which has the dual role of offering support to the bioprosthetic valve and fixating at the implantation site in the native aortic annulus. It has three buttonholes that provide the adequate position of the prosthesis in the native aortic root. The Perceval S valve is designed with an intra-annular and a supra-annular sealing collar, in order to minimise or avoid paravalvular leakage. It can be used for annulus sizes ranging from 19 mm to 27 mm [5, 6].

Aim

The aim of this study was to assess the early and intermediate outcome after AVR with the Perceval S sutureless aortic valve bioprosthesis.

Material and methods

Patients

We performed retrospective analysis of 24 patients who underwent operation between December 2016 and December 2018 at our institute. Mean age was 71 ±5 years, and the male-to-female ratio was 0.36. Patient characteristics are listed in Table I. The inclusion criteria were patients with symptomatic aortic stenosis undergoing AVR with or without accompanying coronary artery bypass graft (CABG) using the Perceval S sutureless aortic valve prosthesis. Patients' characteristics and operative details were collected retrospectively from medical records. All patients underwent clinical evaluation and transthoracic echocardiography at follow-up visit.

Procedure

The surgical approach was through a full sternotomy (16 cases), partial upper sternotomy (6 cases), and right anterior minithoracotomy (2 cases). Perioperative transoesophageal echocardiography was used in all patients. After central aortic and atrial cannulation, a cardiopulmonary bypass was initiated and cold blood cardioplegic arrest was achieved. A transverse aortotomy (2.5–3 cm above the annulus) was performed, and the native valve was completely resected. The annulus was carefully debrided. Three 4/0 polypropylene guiding sutures were passed at the nadir of the aortic annulus. An appropriately sized prosthesis was collapsed in a side table and placed into the manufacturer's holder. The three guiding sutures were passed through the three buttonholes arising from the annular ring of the prosthesis, which was consequently seated on the annulus. The aortic valve was opened, and the holder was removed. The prosthesis was dilated at 4 atm for 30 seconds, twice. After closure of the aortotomy, transoesophageal echocardiography was performed to assess the correct implantation of the prosthesis and the presence of any valve leak [7].

Follow-up

Patients were evaluated preoperatively, at hospital discharge, and once postoperatively at a follow-up visit. Control evaluations were performed between 6 months and 2 years after the operation, and the mean follow-up period was 18 months. Three of the patients were unreachable, and 21 patients were contacted, among whom 16 were scheduled for follow-up evaluation; the remaining 5 patients provided us with data from regional cardiological units. During follow-up, transthoracic echocardiography was performed, and the mean and peak transvalvular gradient and presence of paravalvular leakages were measured.

Statistical analysis

Demographic and clinical data are expressed as mean ± standard deviation. Categorical variables are presented as numbers with percentages. Descriptive statistics for patient characteristics and postoperative outcomes were obtained.

Results

General clinical characteristics for all patients are detailed in Table I. The majority of our patients were female (15/24, 62.5%). The mean age was 71 ±5 years. The leading reason for cardiac surgery was symptomatic aortic stenosis due to degenerative valve disease. More than 70% of patients were in New York Heart Association class II. Preoperative peak and mean transvalvular gradient and left ventricular ejection fraction were measured. Preoperative

Table I. Preoperative characteristics (n = 24)

Characteristic	Mean ± SD or n (%)
Age [years]	71 ±5
Left ventricular ejection fraction (%)	51 ±11
Preoperative peak transvalvular gradient [mm Hg]	101 ±36
Preoperative mean transvalvular gradient [mm Hg]	60 ±23
AVA [cm^2]	0.65 ±0.15
Male gender	9 (37.5)
Female gender	15 (62.5)
Hypertension	22 (91)
Diabetes	8 (33.3)
NYHA class II	16 (66.7)
NYHA class III	8 (33.3)
Previous MI	3 (12.5)
Euro Score II	3.89 ±5.18

AVA – aortic valve area, NYHA – The New York Heart Association, MI – myocardial infarction.

Table III. Postoperative and follow-up data

Variable	Mean ± SD or n (%)
Death	0
Stroke	0
Endocarditis	0
NYHA class I	14 (67.7)
NYHA class II	7 (33.3)
Postoperative peak transvalvular gradient [mm Hg]	26 ±6
Postoperative mean transvalvular gradient [mm Hg]	12 ±3
Follow-up peak transvalvular gradient [mm Hg]	21 ±3
Follow-up peak transvalvular gradient [mm Hg]	10 ±2
Paravalvular leakage (trivial)	3 (14.2)

NYHA – The New York Heart Association.

ultrasound data are reported in Table I. Isolated implantation of a Perceval S sutureless valve was performed in 15 patients (62.5). Less than a half (7 patients) underwent full sternotomy. For the other 8 patients a less invasive approach was chosen: partial upper sternotomy (6 patients, 25%) and right anterior minithoracotomy (2 patients, 8.4%). In cases of isolated AVR, the mean cardiopulmonary bypass time was 90 ±23 minutes (range: 62–138 minutes) and the mean cross-clamp time was 60 ±14 minutes (range: 42–96 minutes). Nine (37.5%) patients underwent an accompanying procedure with coronary bypass surgery, with the range of one to four arterial or venous grafts per patient. When an accompanying procedure was performed the mean cardiopulmonary bypass time was 111 ±31 minutes (range: 81–172 minutes) and mean cross-clamp time was 78 ±23 minutes (range: 54–129 minutes). A summary

Table II. Perioperative outcomes

Outcome	Mean ± SD or n (%)
CPB time [min]:	
Isolated AVR	90 ±23
Concomitant coronary surgery	111 ±31
Aortic cross-clamp time [min]:	
Isolated AVR	60 ±14
Concomitant coronary surgery	78 ±23
Reclamping	0
Size of implanted prosthesis:	
S	2 (8.3)
M	7 (29.2)
L	7 (29.2)
XL	8 (33.3)
Surgical revision for bleeding	2 (8.3)
Atrioventricular block	1 (4.1)
Atrial fibrillation	3 (12.5)
Intensive care unit stay [days]	2
Hospital stay [days]	9 ±4

CBP – cardio-pulmonary bypass, AVR – aortic valve replacement.

of the intraoperative and hospital stay data can be seen in Table II. Intraprocedural success of the valve implantation was 100%. Repetition of cross-clamping, repositioning of the valve, or replacing the valve with a different size was unnecessary. All available valve sizes were implanted; the most frequently used valve was the XL (25–27 mm) size valve implanted in 8 patients. Distribution of the valve sizes is shown in Table II. Re-thoracotomy in the early postoperative period was performed in 2 (8.3%) patients due to cardiac tamponade; no clear points of surgical bleeding were found, and we found that both patients had signs of coagulopathy. Perioperative arrhythmias in the form of atrial fibrillation were registered in 3 (12.5%) patients. Transient atrioventricular block (first degree) was registered in 1 (4.1%) patient during the early postoperative period. There was no need for a permanent pacemaker in any of our patients. Mean hospital stay was 9 ±4 days. There was no hospital mortality. At discharge the mean and peak transvalvular gradient were 12 ±3 mm Hg and 26 ±6 mm Hg, respectively. At follow-up, 14 patients were in NYHA class I, 7 were in class II, and none was in class III. NYHA functional class improved by 1 level. The mean and peak transvalvular gradients were 10 ±2 mm Hg and 21 ±3 mm Hg, respectively. In 3 (14.2%) patients trivial paravalvular leakage was detected. Moderate or severe aortic regurgitation was not detected in any patients in the follow-up period. There was no valve thrombosis, embolisation, or structural valve deterioration. Clinical characteristics and ultrasound data at discharge and follow-up are reported in Table III.

Discussion

As the general population is constantly aging, aortic stenosis is becoming a highly prevalent disease with a ten-

dency of increasing incidence. The sutureless implantation represents a novel technique in the surgical treatment of severe aortic stenosis. Multiple comorbidities such as low ejection fraction, calcified aorta, and renal dysfunction are major risk factors for mortality and morbidity. According to the international literature, cross-clamp time is an independent predictor of mortality and morbidity in low- and high-risk cardiac patients [8], showing that prolonged aortic cross-clamp time significantly correlates with worse clinical outcomes [6]. The fact that there is no need to position the sutures, along with its rapid deployment, allows reduction of aortic cross-clamp and total cardiopulmonary bypass times. Our cross-clamp time may be related to a learning curve, and we hope it will decrease in time. Also, in the group of patients who underwent concomitant procedures (37.5%), cross-clamp and bypass times were mainly dependent on the number of CABGs performed. Avoiding multiple stitches at the aortic annulus ensures fewer complications while still allowing annular decalcification. Prosthesis of a larger size could be implanted using a sutureless method because no pledgets or sutures are present inside the aortic root. This is particularly convenient for patients with small aortic annulus, because they are at high risk of prosthesis-patient mismatch, especially those with a high body mass index [4]. The Perceval S sutureless prosthesis has overcome this problem because it is available in a broad range of sizes and it has shown satisfactory haemodynamic parameters in the early postoperative period.

Access to the aortic valve via minimally invasive procedures has improved in recent years. The sutureless technique represents a further step toward truly minimally invasive cardiac surgery. Minimally invasive AVR can be technically more challenging and is associated with longer cardiopulmonary bypass and cross-clamp times. Sutureless valves have the potential to overcome these shortcomings. The Perceval S sutureless prosthetic valve showed a clear reduction of transvalvular gradients in all valve sizes. Importantly, paravalvular leakage was absent.

There are several limitations to this study. This was a retrospective analysis, and the findings were not compared with those of a control group. Furthermore, we analysed a small sample size of patients, and further longer-term experience is needed to determine the potential clinical benefits of sutureless technique.

Conclusions

Sutureless aortic valves are new and promising tools in the treatment of aortic valve stenosis. Rapid deployment, considerable reduction in implantation time, and the surgical precision of the implantation on a decalcified aortic annulus are the main pros of sutureless aortic valve prosthesis. It is convenient for surgical aortic valve replacement in elderly pateients with reduced cardiac reserve and severe comorbidities. Moreover, it is helpful in minimally invasive surgery due to the ease of implantation and rapid insertion. In our experience, the best usage of the Perceval S sutureless prosthesis is in elderly patients with small calcified aortic annuli, concomitant procedures, and during operations carried out through a minimally invasive approach. Our early results are encouraging. Larger studies are needed to confirm our data and compare long-term outcomes.

Disclosure

The authors report no conflict of interest.

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