Aortic valve replacement with a new sutureless aortic valve Perceval S prosthesis: 12 months of Polish experience

Implantacja nowego typu bezszwowej aortalnej zastawki biologicznej Perceval S – dwunastomiesięczne doświadczenie polskie

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Kardiochirurgia i Torakochirurgia Polska 2012; 2: 165–169

Abstract

Introduction: The increasing number of high-risk patients with narrow aortic root undergoing major cardiac surgery has led to the need for alternative treatment options and the development of new techniques for valve replacement. These patients have frequently multiple comorbidities that impose an increased risk of perioperative complications. Recent data from a multicenter registry have demonstrated a big success rate of transcatheter aortic valve implantation (TAVI) procedures. However, because of many adverse events it is necessary to introduce another device assigned for this group of patients. Implantation of a sutureless valve seems to be the right choice, especially those implanted from a miniinvasive approach.

Aim of the study: The aim of the study was to analyze the implantation procedure, hemodynamic and clinical parameters of the new sutureless Perceval S valves and compare them to other prostheses implanted in a narrow aortic root.

Material and methods: 14 Perceval S sutureless bioprosthetic valves were successfully implanted: eight valves size 23, four size 25, and two size 21. There were 3 early explantations by the surgeon's decision because of valve malposition and unacceptable perivalvular leak. In those patients other bioprostheses were implanted. Eight implantations were made by minithoracotomy. All patients are alive. In the postoperative period most of the patients changed their NYHA class from III or II to I (72%) or II, with evident improvement of exercise capacity. The mean diameter of the native aortic annulus measured in TEE before the operation was 21.9 mm and the mean size of the implanted Perceval S valves was 23.9.

Results: The mean transvalvular gradient changed significantly from 54.5 mmHg before the operation to 13 mm Hg in follow-up. The ejection fraction (EF) was the same before and in

Streszczenie

Wstęp: Zgodnie z danymi *Euro Heart Servey*, ok. 30% chorych kwalifikowanych do leczenia istotnej stenozy aortalnej nadal nie jest leczona z uwagi na zaawansowany wiek, towarzyszące obciążenia lub bardzo wąskie, natywne ujście aortalne. Przełomem w ostatnich latach stało się leczenie przezskórne oraz dobre wyniki implantacji zastawek bezstentowych. Niestety, część chorych nie spełnia kryteriów leczenia metodą TAVI lub ma istotne obciążenia wykluczające ich z klasycznego krążenia pozaustrojowego. Wprowadzenie zastawki o bardzo krótkim czasie implantacji, dającej optymalne parametry przepływu u chorych z wąskim pierścieniem, pozwala mieć nadzieję na uzupełnienie brakującej opcji leczenia powyższych chorych.

Cel pracy: Celem badania była ocena skuteczności implantacji oraz parametrów hemodynamicznych i klinicznych nowego typu biologicznej zastawki bezszwowej oraz porównanie z innymi zastawkami implantowanymi w wąskie ujście aortalne.

Materiał i metody: W ramach wieloośrodkowego badania Cavalier w Śląskim Centrum Chorób Serca w Zabrzu skutecznie wszczepiono 14 zastawek Perceval S. U 3 innych chorych z uwagi na suboptymalny efekt implantacji potwierdzony przeciekiem okołozastawkowym w śródoperacyjnym badaniu TEE wymieniono zastawkę Perceval na klasyczną zastawkę biologiczną. Średni wiek leczonych chorych wynosił 71,7 roku.

Wyniki: Średni gradient przedoperacyjny wynosił 54,5 mm Hg, zaś średnica natywnego pierścienia oceniona w badaniu TEE wyniosła 21,9 mm. Pomimo to implantowano 8 zastawek o średnicy 23 mm, 4 o średnicy 25 mm oraz 2 protezy 21 mm. Średni czas implantacji zastawek wynosił 8,9 min, co znacząco skróciło długość zabiegu operacyjnego, a tym samym czas krążenia pozaustrojowego, który wyniósł średnio 39,2 min. Implantowane zastawki spowodowały istotny spadek maksymal-

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follow-up echo: 54.4 and 55%. The value of follow-up mean effective orifice area (EOA) calculated in follow-up transthoracic echo was 1.71 cm^2, which is a very good value for biological aortic prostheses. The mean total extracorporeal circulation time was 39.2 and implantation time 8.9 minutes. We compared Perceval S sutureless prostheses with other stentless and mechanical valves in patients from our clinical material after aortic valve replacement (AVR) of isolated severe aortic stenosis and narrow aortic annulus, with good EF and without significant concomitant diseases in 12 months observation. Perceval S valves as well as SOLO stentless bioprostheses revealed the best performance in aortic position with significant improvement of NYHA class and good EOA in 12 months' observation. In patients with AS and good LV function implantation of mechanical small prostheses intended for implantation in narrow roots (OnX©) gave in our observation borderline mismatch of these valves.

Conclusion: Sutureless self-expandable Perceval S valves seems to be a promising future option for older patients with a lower logistic score (than for TAVI procedures) and small aortic annulus because of the possibility of implantation of a larger valve than the measured annulus with significant shortening of implantation time.

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

nego i średniego gradientu przezzastawkowego do wartości 13 mm Hg z zachowaniem dobrej frakcji wyrzutowej LK – śr. 55%. Zastawki Perceval o średnicy 21–23 mm wykazały bardzo dobre parametry efektywnego pola ujścia oraz indeksu EOA 1,71 cm^2 i 0,97 cm^2/m^2 w porównaniu z identyczną grupą zastawek bezstentowych SOLO 1,50 cm^2 i 0,94 cm^2/m^2 oraz mechanicznych zastawek OnX© 1,53 cm^2 i 0,84 cm^2/m^2 określanych jako optymalne w wąskim ujściu aortalnym. W obserwacji 12-miesięcznej u 5 chorych obserwowano śladowy przeciek okołozastawkowy, a u 2 śladowy centralny. W przebiegu pooperacyjnym u 2 chorych wystąpiło niegroźne krwawienie ze śluzówki przewodu pokarmowego, co wiązano z brakiem standaryzacji leczenia przeciwkrzepliwego u chorych z zastawką biologiczną nowego typu. Nie obserwowano nowych zaburzeń rytmu i przewodnictwa oraz powikłań neurologicznych.

Wnioski: Na podstawie wyników własnych oraz wstępnych danych można wnioskować na obecnym etapie badania, iż w wybranej grupie chorych zastawka Perceval S daje możliwość skutecznego i bezpiecznego leczenia ciężkiej stenozy aortalnej (w tym dostępu z ministernotomii z krótszym czasem krążenia). Obserwacja 6- i 12-miesięczna wykazała bardzo dobre parametry hemodynamiczne, echokardiograficzne oraz kliniczne wszystkich chorych, u których skutecznie implantowano zastawkę Perceval S o większej średnicy pierścienia niż mierzona w badaniu echokardiograficznym.

Słowa kluczowe: zastawka bezszwowa, zastawka biologiczna, Perceval S, wymiana zastawki aortalnej, proteza zastawkowa.

Introduction

In the general population, the number of elderly patients referred for aortic valve surgery is still growing. Due to ageing, patients undergoing valve surgery are older than in the past and approximately one third of patients aged more than 70 years with valvular heart disease do not undergo surgical aortic valve replacement (AVR) because of risks arising from age and comorbidities. Introduction of new options for aortic valve implantation into clinical practice have been developed to minimize the surgical risk. Nowadays a debate is ongoing over the indication criteria for transcatheter aortic valve implantation (TAVI) versus conventional aortic valve replacement and current risk scoring to predict the operative risk in the decision to perform surgery [2, 6]. The presence of a heavily calcified ascending aorta is considered a potential indication for TAVI, but the TAVI procedure cannot be performed in combination with myocardial revascularization for ischemic heart disease, except cases with suitable anatomy for coronary stenting. Transcatheter procedures should be associated with lower mortality and morbidity compared with surgical AVR in elderly patients, but procedures have the potential risk for serious complications related to the transcatheter placement, such as vascular complications, aortic dissection/perforation, stroke, myocardial infarction or atrioventricular block. Overall 30-day major adverse cardiovascular and cerebral events range from 3% to 35%. The relationship between the degree of calcification and the high incidence of paravalvular leakage and not removal of the stenosed native valve raises questions on the stability of valve function over time [3-5, 7]. These findings stimulated the interest in an alternative development, that is a collapsible, stent-mounted aortic valve prosthesis which can be placed in a sutureless fashion with a conventional surgical technique. Sutureless implantation of heart valves has a significant advantage over the classic technique of suturing the valve in place, because it shortens the necessary aortic crossclamp time and the myocardial ischemia time. This technology includes a classic extracorporeal circulation, cross-clamping of the aorta and an aortotomy, allowing complete removal of the diseased native valve [1].

The Perceval S aortic valve

The Perceval S prosthetic valve comprises a functional component in bovine pericardium fixed in a metal cage made from a super-elastic alloy (Fig. 1). The cage design is characterized by two ring segments, on the proximal and distal ends, and connecting elements designed to support the valve; these allow the prosthesis to anchor to the aortic root, in the sinuses of Valsalva. The material used to construct the cage is nitinol, material able to accept strong deformation and return to its original shape. After the force is removed the cage can be compressed for the implantation and then released to reach its final diameter. The functional valve component is identical to the Sorin Pericarbon prosthesis, fixed into the cage by sutures. The Perceval S ring has three loops corresponding to each valve sinus through which guide

Fig. 1. Perceval S sutureless bioprosthesis (Sorin Biomedica Italy)

threads are passed to aid prosthetic positioning. The three valve sizes 21, 23 and 25 are available for use.

Patients (cavalier trial)

Between May 2010 and September 2011 in the Silesian Center for Heart Diseases, 17 patients were entered into the CAVALIER study, a European, multicenter, prospective, non-randomized, clinical pilot trial designed to evaluate the feasibility of the Perceval S sutureless prosthesis in elderly patients requiring aortic valve replacement (AVR) with or without concomitant coronary artery bypass grafting via median sternotomy and extracorporeal circulation (ECC) and aortic cross-clamping. Inclusion criteria were aortic valve stenosis, age more than 65 years, and candidate for a standard surgical intervention with a biological prosthesis and rather a small and calcified aortic root/annulus. Exclusion criteria were multivalve lesion, dilatation/dissection of the ascending aorta, previous cardiac surgery, and an aortic valve annulus diameter less than 19 mm or greater than 25 mm by echocardiography and direct intraoperative measurement.

The study was approved by the Ethics Committee of the Silesian Medical University. All patients gave written informed consent and underwent detailed transthoracic echocardiography before the operation, at discharge and at 6 and 12 months postoperatively, together with a complete physical examination, electrocardiography registration, and blood sampling. Echocardiography included the measurement of peak and mean transvalvular gradients and effective orifice area. Regurgitation or leakage was visualized by color Doppler and scored as 0 = non-existent, 1 = trivial, 2 = mild, 3 = moderate and 4 = severe. Transoesophageal echo was performed in each patient intraoperatively.

Surgical procedure

The heart was exposed via a median sternotomy or ministernotomy. After systemic heparinization, the patient was placed on ECC. The aorta was cross-clamped and cardioplegia administered. A transverse aortotomy was made 1 cm distal to the sinotubular junction, so as to leave an edge free for closure of the aortotomy after implantation of the device. The diseased, native calcified aortic valve was removed and the aortic annulus mostly decalcified. In order to ensure correct positioning of the prosthesis, three guiding threads were used only as reference for accurate alignment of the inflow section of the prosthesis with the insertion plane of the native leaflets (Fig. 2).

These threads were positioned in the lowest part of the native leaflet insertion line for each valve sinus. At the prosthesis level, each thread was passed into a slot corresponding to the median part of the prosthetic sinus. The release device was inserted into the aorta to the point where it was blocked by pulling the previously positioned thread guides. The valve prosthesis, loaded into the delivery device, was released in two phases: first, the inflow section was opened, after which the outflow part was opened. Full release of the prosthesis is presented in Figure 3.

When the prosthesis had been completely deployed the thread guides were removed. In order to optimize the area of contact between the prosthesis and the aortic annulus,

Fig. 2. Prosthesis collapsed on holder fixed into the cage by sutures

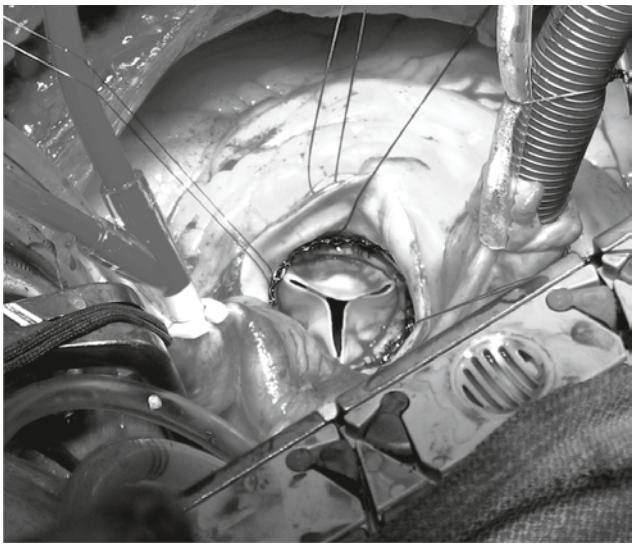

Fig. 3. Fully released valve, before removal of guiding sutures

Tab. I. Preoperative and 12 months clinical and echocardiographic results

	Age	EF1	MG1	ø TEE	ø PS	ECC	IT	MG2	AR/leak	EF2	EOA
1	70	56	50	24	25	53	16	17	1	57	1.78
2	70	55	88	23	23	29	8	16	0/1	55	1.6
3	75	55	55	21	23	36	3	12	0	56	1.8
4	77	52	50	20	21	54	5	9	0	60	1.88
5	65	40	65	21	25	63	20	14	0/1	51	1.73
6	73	60	64	22	23	35	5	12	0	60	1.72
7	70	60	56	23	23	46	7	15	1	54	1.58
8	72	55	55	22	25	35	5	8	0	50	1.82
9	71	68	49	20	21	34	12	16	0	58	1.68
10	74	59	56	21	25	33	4	18	0	55	1.64
11	72	60	50	23	23	41	12	14	0	63	1.63
12	65	45	43	21	23	30	9	8	0/1	48	1.78
13	70	50	40	23	25	32	11	13	0	50	1.6
14	71	47	42	23	23	36	8.5	10	0/1	52	1.64
M	71.0	54.4	54.5	21.9	23.5	39.7	8.9	13	–	55.0	1.71

a post-dilatation was performed using a balloon catheter at a 30' pressure of 4 atm. The aortotomy was closed, and the clamp was removed. Postoperatively, the patients received treatment with coumadin and/or acetylsalicylic acid, for two months, according to the standard anticoagulation protocol following biological AVR. Fourteen Perceval S valves were successfully implanted: 7 valves of size 23, four size 25 and two valves size 21. All patients are alive. There were also 3 early explantations by the surgeon's decision because of valve malposition and bigger than small perivalvular leakage. In those patients other prostheses were implanted, one Solo and two Magna valves. The mean extracorporeal circulation (ECC) time was 39.7 min with short mean valve implantation time (IT) 8.9 min. The first group of implantations was performed with the help of proctors Dr. Eric Manasee, Dr. Bart Meuris and Prof. Francois Laborde (Fig. 4).

In the postoperative period most of the patients changed their NYHA class from II or II to I (72%) or II with evident improvement of their exercise capacity. The mean diameter of the native aortic annulus measured in TEE before the operation was 21.9 mm (ø TEE) and the mean size of implanted Perceval valves was 23.9 (ø PS). Mean transvalvular gradient (MG) changed significantly from 54.5 mm Hg before the operation to 13 mm Hg in follow-up. The ejection fraction (EF) was the same before and in follow-up echo: 54.4 and 55%. The value of follow-up mean EOA calculated in follow-up transthoracic echo was 1.71 cm^2, which is a very good value for biological aortic prostheses.

The results are presented in Table I.

We also compared Perceval S sutureless prostheses with stentless and mechanical valves in patients after AVR because of isolated severe aortic stenosis and narrow aortic annulus, with good EF and without significant concomitant diseases from our clinical material in 12 months observation (Tab. II).

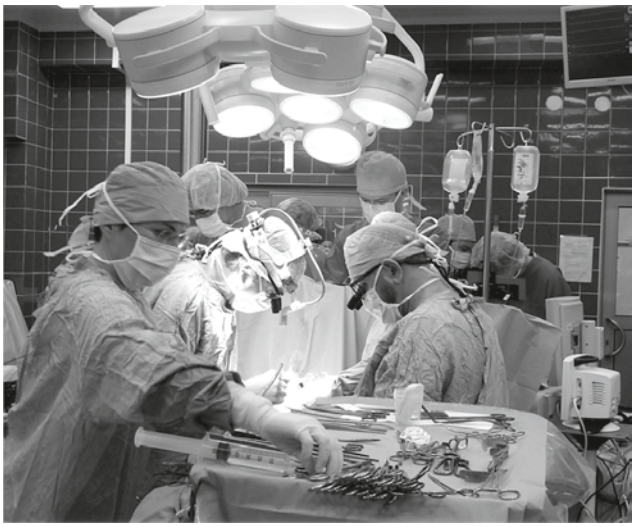

Fig. 4. 17.05.2010 the first Perceval S implantation in Zabrze (Dr Krzysztof Filipiak, Prof. Marian Zembala with team and proctor Eric Manasee)

Tab. II. Comparison of Solo, OnX and Perceval S valves in homogeneous group in 12 months observation

Valve	EF	BSA (m^2)	MG	EOA	EOAI	NYHA I (%)
SOLO (n = 15)	55.6	1.87	11.2	1.5	0.94	70
Perceval S (n = 14)	55	1.8	13	1.71	0.99	72
OnX (n = 20)	55.1	1.78	12.3	1.53	0.84	80

Perceval S valves as well as Solo bioprostheses revealed the best performance in aortic position with significant improvement of NYHA class and EOA in 12 months observation. In patients with AS and good LV function implantation of mechanical small prostheses intended for implantation

in narrow roots (OnX) gave in our observation borderline mismatch of these valves.

Conclusion

The increasing number of high-risk patients undergoing major cardiac surgery has led to the need for alternative treatment options and the development of new techniques for valve replacement. In addition, these patients frequently have multiple comorbidities that impose an increased risk of complications both during and after surgery. Recent data from a multicenter registry have demonstrated a high success rate of TAVI with moderate in-hospital complications.

Sutureless self-expandable Perceval S valves seem to be a promising future option for older patients with a small aortic annulus also because of the possibility of implantation of a larger valve than the measured annulus and significant shortening of implantation time.

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