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ORIGINAL ARTICLE

Early Outcomes of Sutureless Aortic Valve Replacement With the Perceval S Bioprosthesis

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Background Sutureless aortic valve replacement (SU-AVR) offers an alternative to traditional aortic valve replacement (AVR) and is becoming widely performed in many hospitals. The aim of the current study was to evaluate the early experience in SU-AVR with the Perceval S bioprosthesis at Monash Medical Centre.

Methods Fifty-two (52) patients who underwent SU-AVR were retrospectively analysed (mean age: 74.8 ± 6.5 years). Data regarding preoperative and operative details, hospital stay, postoperative outcomes within 30 days after surgery, re-admissions and longer term echocardiographic data were collected from the relevant hospital databases.

Results In isolated SU-AVR, the mean aortic cross-clamp and cardiopulmonary bypass times were 48.8 and 67.8 minutes, respectively. There were no deaths within 30 days after surgery. Rhythm disturbances developed in 46.2% of patients, with atrial fibrillation (32.7%) and heart block (9.6%) being most common. Mean and peak transaortic gradients reduced from 46.2 and 77.9 mmHg preoperatively, to 10.7 and 19.7 mmHg at 12 months postoperatively, respectively.

Conclusions The absence of early mortality and the satisfactory clinical and haemodynamic results demonstrated the overall safety and efficacy of the Perceval S valve. Although sutureless valves seem to be a promising alternative to traditional sutured valves, the high rate of new postoperative rhythm disturbances, particularly heart block, is potentially a concern with SU-AVR.

Keywords Sutureless aortic valve replacement • Perceval S • Early experience

Introduction

Aortic valve stenosis (AS) is the most common cardiac valve disease, with the current gold-standard treatment being aortic valve replacement (AVR) surgery [1]. Due to the increasing age of patients, surgeons are faced with more severe cases of valve leaflet and aortic root calcification, coupled with the presence of comorbid diseases [2]. This increases the operative risk for traditional sutured AVR and has led to the development of sutureless bioprosthetic valves to ameliorate this risk [3]. Whilst transcatheter aortic valve implantation (TAVI) has also been developed for high-risk patients, this procedure is only currently suitable for patients with isolated aortic valve disease.

The Perceval S valve (LivaNova, London, UK) is a sutureless aortic bioprosthesis designed to facilitate safe and rapid implantation. The leaflets of this bioprosthesis are derived from bovine pericardium which are fixed on a self-expanding nitinol frame [1]. The main advantage of using such

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sutureless valves is a reduction in aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB) times [4,5]. This reduction in the overall duration of the procedure is particularly beneficial for higher-risk patients, which ultimately reduces the risk of morbidity and mortality [6].

This study provides a retrospective, single-centre assessment of the early safety and efficacy of the Perceval S bioprosthesis.

Materials and Methods

Study Population

Between June 2015 and December 2016, 52 patients underwent sutureless aortic valve replacement (SU-AVR) with the Perceval S bioprosthesis at Monash Medical Centre, and were included in the current study. All were first-time AVR. The mean age of the study population was 74.8 ± 6.5 years and 30 (57.5%) patients were male.

Ethics approval for this study was granted from the Monash Health Human Research Ethics Committee (Ref: RES-17-0000-146Q). All patients provided written informed consent prior to their procedure, except in cases of emergency surgery.

Data Collection

Data regarding preoperative and operative details, hospital stay, postoperative outcomes within 30 days after surgery, re-admissions and longer term echocardiographic data were retrospectively collected from the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) National Database, and Cardiobase (Magnus Medical Software, Melbourne, Victoria, Australia)—a patient database system.

Early postoperative outcomes (≤30 days) were defined in accordance with the Society of Thoracic Surgeons/American Association for Thoracic Surgery/European Association for Cardio-Thoracic Surgery's Guidelines for Reporting Mortality and Morbidity After Cardiac Valve Interventions [7]. Early mortality was regarded as death occurring within 30 days after surgery.

Surgical Procedure

The surgical procedures were performed by six surgeons at Monash Medical Centre. All patients were operated through a median sternotomy. A detailed description of the valve deployment procedure is provided elsewhere [8], and is briefly outlined here.

Prior to deploying the prosthesis, the calcified native aortic valve was removed, followed by decalcification of the aortic annulus. The annulus was then sized with LivaNova's designated obturators to determine its diameter. The appropriate prosthesis size was indicated by the sizer in which the transparent obturator passed through the annulus but the white obturator did not.

The prosthesis was inserted with a delivery device until it was blocked by the guiding sutures. The valve was then released at the inflow segment, and then at the outflow segment. A balloon catheter (4 atmospheres) was used for post-implant valve dilatation for 30 seconds while warm saline was applied to the valve. The guiding sutures were then removed.

Statistical Analysis

All statistical analyses were performed with IBM SPSS Statistics, Version 24 (IBM Corporation, Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation (SD) or median with the interquartile range, whilst categorical variables are reported as frequencies (percentage).

Results

Preoperative Details

The majority of patients initially presented with isolated AS (n = 35/67.3%). The mean EuroSCORE II was 4.7 ± 6.1% (range, 0.78–35.12%), indicating a moderate operative risk, overall. The preoperative data are summarised in Table 1.

Operative Details

Bicuspid aortic valves were present in three (5.8%) patients. For these patients, the operating surgeons proceeded with the implantation of the Perceval S bioprosthesis as the most suitable form of treatment. Further operative details, and mean ACC and CPB times, are reported in Tables 2 and 3, respectively.

Procedural Outcomes

The median length of hospital and intensive care unit stay were 10 (Q1:Q3 7–17) and 1.9 (Q1:Q3 1–3) days, respectively. No early deaths (≤30 days) occurred within the study population. The success rate of prosthesis implantation was 96.2% (n = 50).

Postoperatively (≤30 days), valve-related complications only occurred in the form of new rhythm disturbances (Table 4). All patients who developed heart block or bradycardia (n = 6/11.5%) received a permanent pacemaker. Among the remaining patients (n = 17/32.7%) who developed a new rhythm disturbance, nine (17.3%) patients were treated with medication.

Several non-valve related and non-cardiac related complications also occurred within 30 days after surgery. Table 4 provides further details of the postoperative outcomes (≤30 days).

Haemodynamic Performance

Transthoracic echocardiography (TTE) was performed at follow-up to assess the function of the prosthesis. Twenty-six (26) (50.0%) patients returned for follow-up assessment at Monash Medical Centre, albeit at various times across the 12-month postoperative period. The number of patients who did return for follow-up assessment and the specific times at which they returned are provided in Table 5. Although all patients underwent preoperative TTE, four (7.7%) TTE reports were not available on the database.

The mean and peak transaortic gradients reduced substantially across the 12-month postoperative period. Table 5 provides a summary of the mean and peak transaortic

Table 1 Patient demographics and baseline preoperative data.

Patient	n = 52	%
Mean age ± SD (range)	74.8 ± 6.5 (60-88)	
Age (years)		
< 65	5	9.6
65-69	6	11.5
70-74	12	23.1
75-79	16	30.8
80-84	12	23.1
≥85	1	1.9
New York Heart Association (NYHA) Functional Classification		
I	9	17.3
II	12	23.1
III	25	48.1
IV	6	11.5
Aortic valve lesion		
Stenosis	35	67.3
Stenosis and regurgitation	10	19.2
Information not available	7	13.5
Risk factors*		
Systemic hypertension	24	46.2
Hyperlipidaemia	21	40.4
Diabetes	12	23.1
Renal insufficiency	4	7.7
Smokers	13	25.0
Ex-smokers	12	23.1
Obesity	5	9.6
Cerebrovascular disease	3	5.8
Cardiac rhythm		
Sinus	35	67.3
Atrial arrhythmia	15	28.8
Ventricular arrhythmia	1	1.9
Heart block	1	1.9
Other	1	1.9
Pacemaker in place prior to surgery	2	3.8

*Information presented was subject to availability per patient.

Table 2 Operative details.

Patients	n = 52	%
Surgical priority		
Elective	42	80.8
Urgent	9	17.3
Emergency	1	1.9
Prosthesis size		
S	3	5.8
M	13	25.0
L	19	36.5
XL	17	32.7
Concomitant procedures		
None (isolated SU-AVR)	24	46.2
CABG	26	50.0
Septal myomectomy	2	3.8
Maze	2	3.8
Other	11	21.2

Abbreviations: SU-AVR, sutureless aortic valve replacement; CABG, coronary artery bypass graft.

Table 3 Procedure times.

Procedure	ACC time (minutes)	CPB time (minutes)
Isolated SU-AVR (n = 24) (Mean ± SD)	48.8 ± 14.9	67.8 ± 21.2
SU-AVR with concomitant procedures (n = 28) (Mean ± SD)	89.6 ± 41.7	115.6 ± 49.7
Overall (n = 52) (Mean ± SD)	70.7 ± 38.0	93.5 ± 45.7

Abbreviations: ACC, aortic cross-clamp; CPB, cardiopulmonary bypass; SU-AVR, sutureless aortic valve replacement.

gradients at different times. At follow-up, the position and function of the prosthesis were satisfactory in all patients. There was no incidence of prosthesis migration or dislodgement. Lastly, central or paravalvular aortic regurgitation was either absent or trivial across the entire study population.

Discussion

The Perceval S bioprosthesis was designed to facilitate safe and rapid implantation, and has become a popular alternative to traditional sutured prostheses. The objective of this retrospective study was to assess the early experience in SU-AVR with the Perceval S valve at Monash Medical Centre.

Among the 52 patients who successfully underwent SU-AVR, there was no early mortality. The mean preoperative EuroSCORE II was 4.7 ± 6.1%, meaning that the overall operative risk was moderate, which may have contributed to this operative outcome. Successful implantation with correct annular sizing and optimal seating of the prosthesis may have also contributed to this result. The absence of early mortality in this study compares favourably with that of other studies. A meta-analysis by Phan et al. [3] reported a 30-day mortality rate of 2.1%, whilst another recent meta-analysis reported a similar rate of 2.34% [9]. In contrast, most studies which focus on traditional sutured AVR report early mortality rates ranging from 6.9% to 16.7% [10–14], which are noticeably higher than the rates described in the current study and three other SU-AVR meta-analyses [3,9,15]. Therefore, the risk of early mortality appears to be lower for

Table 4 Post-operative outcomes within 30 days after surgery.

Outcomes	Isolated SU-AVR (n = 24), *n* (%)	SU-AVR with concomitant procedures (n = 28), *n* (%)	Overall (n = 52), *n* (%)
Death	0 (0)	0 (0)	0 (0)
Valve-related complications			
Prosthesis dysfunction	0 (0)	0 (0)	0 (0)
New conduction disorder	14 (26.9)	12 (23.1)	26 (50.0)
Heart block	3 (5.8)	2 (3.8)	5 (9.6)
Bradycardia	1 (1.9)	0 (0)	1 (1.9)
Atrial fibrillation	8 (15.4)	9 (17.3)	17 (32.7)
Ventricular tachycardia	1 (1.9)	0 (0)	1 (1.9)
Cardiac arrest	1 (1.9)	1 (1.9)	2 (3.8)
Other cardiac-related complications			
Myocardial infarction	0 (0)	3 (5.8)	3 (5.8)
Cardiogenic shock	1 (1.9)	2 (3.8)	3 (5.8)
Non-cardiac related complications			
Renal insufficiency	3 (5.8)	3 (5.8)	6 (11.5)
Stroke	0 (0)	3 (5.8)	3 (5.8)
Pneumonia	0 (0)	4 (7.7)	4 (7.7)
Gastrointestinal	0 (0)	1 (1.9)	1 (1.9)
Sternal infection	0 (0)	2 (3.8)	2 (3.8)
Other	2 (3.8)	5 (9.6)	7 (13.5)
Return to theatre during hospital stay			
Pacemaker implantation	0 (0)	1 (1.9)	1 (1.9)
Bleeding or tamponade	0 (0)	1 (1.9)	1 (1.9)
Septicaemia	0 (0)	3 (5.8)	3 (5.8)
Other	1 (1.9)	1 (1.9)	2 (3.8)
Pacemaker implantation			
Return to theatre	1 (1.9)	0 (0)	1 (1.9)
Cardiac catheterisation laboratory	3 (5.8)	2 (3.8)	5 (11.5)

Abbreviations: SU-AVR, sutureless aortic valve replacement.

Table 5 Changes in mean and peak trans-aortic gradient (mean ± SD) over 12 months following SU-AVR.

Trans-aortic gradient	Pre-operative	<1 month	1-3 months	3-6 months	7-9 months	10-12 months	Overall (<1-12 months)
Available TTE reports *n* (%)	48 (92.3)	9 (17.3)	6 (11.5)	7 (13.5)	5 (9.6)	3 (5.8)	26 (50.0)
Mean gradient (mmHg)	46.2 ± 14.4	15.2 ± 6.5	11.2 ± 1.7	12.3 ± 5.3	12.4 ± 5.6	10.7 ± 2.1	12.6 ± 5.3
Peak gradient (mmHg)	77.9 ± 24.1	28.9 ± 14.4	21.8 ± 6.9	23.0 ± 9.4	22.0 ± 8.9	19.7 ± 2.1	23.7 ± 10.6

Abbreviations: SU-AVR, sutureless aortic valve replacement, TTE, transthoracic echocardiograph.

patients receiving sutureless valves rather than traditional valves.

Unlike other studies, in which various valve-related complications were found [16–20], postoperative valve-related complications in the present study only occurred in the form of new rhythm disturbances. Within the current study population, a large proportion of patients (46.2%) developed a rhythm disturbance postoperatively, which is consistent with previous research. In this study, atrial fibrillation—albeit a common occurrence after cardiac surgery [21] —developed in 32.7% of patients, whilst other studies report rates between 16.7% to as high as 41% [22–24]. Interestingly, the incidence of heart block (9.6%) was quite low compared to other studies which have reported rates between 37% to 51% for AV block alone [22–25]. The pacemaker implantation rate was 11.5% in this study, which was comparable to a large study (n = 658) with a rate of 11.6%

[26]. Nonetheless, some studies have reported pacemaker implantation rates as low as 3.1% and 3.3% [27,28], whereas others have described rates as high as 17% to 28.6% [23,25,29].

Despite all the observed variation, the risk of heart block following SU-AVR is higher compared to traditional AVR, which is accompanied by an increased rate of permanent pacemaker implantation [22,30]. This could be attributable to the sutureless valves relying on radial forces exerted by its self-expandable frame for stabilisation, which may result in compression of specific components of the conduction pathway [25]. Similarly, the rate of rhythm disturbances may also be augmented by balloon expansion of the sutureless prosthesis.

The risk of causing damage may be much higher when the annulus is over-sized, which highlights the importance of accurately sizing the annulus. This is supported by one study which found that there was an incremental increase in the pacemaker implantation rate with increasing prosthesis size [23]. The pacemaker implantation rates for patients in this series who received a small, medium, large and extra-large prosthesis were 9%, 12%, 24% and 50%, respectively. Interestingly, another study found that membranous septum length—an anatomic surrogate of the distance between the annulus and bundle of His—was independently associated with the incidence of high-degree AV block and pacemaker implantation [31]. The authors found that membranous septum length was significantly shorter in patients who required postoperative pacemaker implantation compared to patients who did not. Hence, taking measurements of membranous septum length to predict the risk of developing rhythm disturbances may be helpful in determining whether a sutureless or traditional prosthetic valve should be implanted.

Furthermore, variation in pacemaker implantation rates across studies may be attributable to differences in each hospital's approach to pacemaker implantation. Bouhout et al. [25] suggested that the high rate (51%) of pacemaker implantation at their centre may be due to an aggressive early approach compared to other hospitals. A potentially effective strategy that could be used to reduce the incidence of rhythm disturbances and subsequent pacemaker implantation was recently suggested by Yanagawa et al. [32]. The authors found that by placing the guiding sutures at the leaflet insertion line, instead of 2–3 mm below as is currently recommended by LivaNova, the incidence of heart block substantially reduced from 28% (7/25 patients) to 0% (0/18 patients). Whilst these results are promising, further research using large-cohort, multicentre samples are required to confirm the safety and efficacy of this strategy.

The success rate of prosthesis implantation was high (96.2%), meaning that the first attempt at implanting the prosthesis was successful in the majority of patients. Failure to implant the prosthesis successfully on the first attempt occurred in two patients. In one patient, a paravalvular leak was detected with intraoperative transoesophageal echocardiography following implantation of a large prosthesis. It was determined that the annulus had been under-sized, and the large prosthesis was subsequently replaced with an extra-large prosthesis. The patient experienced a normal postoperative recovery. In another patient, following implantation of a medium Perceval S valve, the surgeon noticed that the annulus was clearly distorted and reported that this was indicative of over-sizing. The medium prosthesis was removed and replaced with a small prosthesis, which showed better coaptation of the leaflets. Following surgery, however, the patient developed atrial fibrillation which was treated with medication. The difficulty experienced in selecting the most appropriate prosthesis size for these two patients may also be a result of the learning curve faced by the surgeons, as the Perceval S valve was only recently introduced to Monash Medical Centre in mid-2015. Nonetheless, the success rate of prosthesis implantation reported in the present study is comparable to other studies which report success rates of 95.0% (n = 208) [20] and 95.4% (n = 658) [16,26]. These high success rates further demonstrate the ease of implantation associated with sutureless prostheses.

It is well recognised that the main advantage of SU-AVR is the short ACC and CPB times. In the present study, the mean ACC and CPB times for patients undergoing isolated SU-AVR were 48.8 ± 14.9 and 67.8 ± 21.2 minutes, respectively. In comparison, other studies have reported mean ACC times ranging from as short as 17.8 ± 6.2 to 48.9 ± 19.4 minutes, whereas mean CPB times range from 50.8 ± 19.5 to 69 ± 26 minutes [20,28,33,34]. Currently, the most comprehensive and recent study, performed by Shrestha et al. [1] —involving 700 patients from 25 different European centres—reported mean ACC and CPB times of 33 and 56 minutes, respectively, which is virtually half that of traditional AVR surgery [35]. However, as shown, mean ACC and CPB times for isolated SU-AVR vary across studies and are often influenced by various patient characteristics, surgical experience and the learning curve [33], making it difficult to compare these outcomes between studies. Nevertheless, the findings reported in the literature and the current study, demonstrate significant reductions in ACC and CPB times for SU-AVR, compared to traditional AVR. These shortened operative times are achieved by avoiding the insertion and tying of sutures in the aortic ring and prosthesis. With ACC and CPB times considered as independent predictors of morbidity and mortality [36,37], the reduction in operative times are particularly beneficial for patients with a high operative risk and for those in the 'grey zone' of intermediate to high risk [6,38].

Haemodynamic performance of the Perceval S valve, in this study, was satisfactory. Within 30 days after surgery, the mean and peak transaortic gradients had reduced considerably and continued to improve steadily up to 12 months after surgery. These findings were, again, very similar to those described in other studies. In a study conducted by Laborde et al. [26] (n = 658), mean and peak gradients declined substantially from 44.8 and 73.24 mmHg prior to surgery, to 10.24 and 19.27 mmHg at discharge, respectively. In other studies, mean transaortic gradient at discharge ranged from 9.0 ± 3.4 to 14.6 ± 6.0 mmHg [39–42], 8.9 ± 3.2 to 12.8 ± 4.9 mmHg at 6 months [8,20,28,43,44], 8.9 ± 4.6 to 12.5 ± 4.5 mmHg [8,27,28,44] at 1 year, and 8.0 ± 3.4 to 11.8 ± 4.7 mmHg at 2 years [8,27,44]. Altogether, a transaortic gradient of approximately 10 mmHg is usually maintained over several years following SU-AVR, which is not only lower than those

achieved with traditional AVR, but also TAVI [35,45]. These excellent haemodynamic outcomes could be attributed to the complete annular decalcification to create a smooth annulus, which is vital in preventing paravalvular leaks by facilitating proper fitting of the prosthesis into the annulus. This would allow the prosthesis to expand as much as possible which helps to increase the effective orifice area. Moreover, the balloon-deployable frame, the lack of annular suture material and the ability of the prosthesis to adapt to the anatomy of the aorta ensure proper fixation of the prosthesis without any valve dislodgement over time, which facilitates optimal haemodynamic performance of the Perceval S valve [27].

Limitations

This study has several limitations. These include the small sample size, lack of randomisation and the absence of a control group of patients undergoing traditional AVR. The patients were also only treated at one centre which consequently reduces the generalisability of these findings. The retrospective nature of this study is another limitation, as this meant that not all the data relating to the performance of the Perceval S valve was available for analysis.

Future Directions

The long-term durability and performance of the Perceval S prosthesis remains unclear. Studies with long-term follow-up data beyond 5 years after surgery, large multicentre cohorts and a randomised study design are required to adequately assess the durability and long-term performance of sutureless valves. Further studies are also required to investigate methods of reducing the risk of rhythm disturbances following SU-AVR. In particular, the promising method of placing the guiding sutures at the leaflet insertion line, as described by Yanagawa et al. [32], should be further investigated to confirm its safety and efficacy.

Conclusion

This study examined the early outcomes of SU-AVR with the Perceval S bioprosthesis. The early outcomes included a high success rate of implantation, satisfactory haemodynamic performance of the prosthesis, low rates of mortality and morbidity, and ACC and CPB times which compare favourably to those of traditional AVR reported in other studies. However, the high incidence of rhythm disturbances, particularly heart block, demonstrates an ongoing concern with SU-AVR surgery. Methods of reducing the risk of these rhythm disturbances should be investigated in future research. Randomised studies with a long-term follow-up period and large sample size are also required to assess the durability and long-term performance of this prosthesis.

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Conflict of Interest

Aubrey Almeida is a proctor for LivaNova.

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