

Sutureless aortic valve implantation: first experience in Asia

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ABSTRACT Age-related degenerative calcification is currently the most common cause of aortic stenosis (AS) in adults and the most frequent reason for aortic valve replacement in patients with AS. With the increased life expectancy, a large proportion of elderly patients with AS is undergoing cardiac surgery, although many are not offered conventional aortic valve replacement due to the risks involved. However, sutureless aortic valve replacement provides an alternative for this group of elderly patients. This case series reports the first experience in Asia of sutureless aortic valve implantation in seven patients at our institution.

Keywords: aortic stenosis, aortic valve, sutureless

INTRODUCTION

Aortic stenosis (AS) is the most frequent heart valve disease in Western societies and its prevalence increases with age.⁽¹⁾ With the increase in life expectancy and the rising population in Singapore, the number of elderly patients with AS is expected to increase. The selection of the best definitive management among medical, interventional and surgical therapies for patients with aortic valve disease has become an important issue.⁽²⁾ The National University Hospital Heart Centre implanted the first non-TAVI sutureless aortic valve in Singapore. We report a series of seven patients who underwent implantation of the sutureless Perceval S aortic valve and describe the postoperative results.

CASE SERIES

All seven patients underwent aortic valve replacement using the sutureless Perceval S aortic valve. Five patients underwent isolated aortic valve replacement (AVR), while two patients underwent combined AVR and coronary artery bypass graft. Of the five patients who underwent isolated AVR, one case was a redo-AVR. Four patients were male and three were female. The mean age of our patients was 69.0 ± 11.3 years. All patients had severe AS with a mean aortic valve area of 0.88 ± 0.42 cm², an average mean pressure gradient (MPG) of 39.9 ± 12.0 mmHg and a mean peak pressure gradient (PPG) of 67.7 ± 20.8 mmHg. The patients had a mean preoperative left ventricular ejection fraction of $58.6\% \pm 3.8\%$.

Access to the aortic valve was achieved via median sternotomy in five patients. In two patients, a minimally invasive approach (via mini-sternotomy) was used. In all patients, the sutureless Perceval S aortic valve was implanted using three Prolene 4-0 guiding sutures. Positioning was then confirmed by inspection before removal of the guiding sutures. Subsequently, the basal annulus was dilated using the Perceval S large balloon inflated to 4 atm for 30 s. The mean cardiopulmonary bypass time and mean aortic cross-clamp time were 99.4 ± 37.8 min and 84.1 ± 42.3 min, respectively. The sizes of the Perceval



Fig. 1 Photograph shows the Sorin Perceval S (reproduced with permission of Sorin Group Asia Pte Ltd).

aortic valves implanted were large in four patients, medium in two patients and small in one patient.

Postoperatively, satisfactory results were achieved in all the patients. Transthoracic echocardiography was routinely performed 3–4 days postoperatively in all seven patients. There was a $3.0\% \pm 5.6\%$ improvement in left ventricular ejection fraction. Improvements in MPG and PPG by 26.3 ± 13.7 mmHg and 47.4 ± 29.7 mmHg, respectively, were achieved using the sutureless Perceval S aortic valve. None of the valves experienced paravalvular leak. The mean length of postoperative hospital stay was 12.6 ± 3.8 days, whereas the mean length of hospital stay for postoperative cardiac surgical patients

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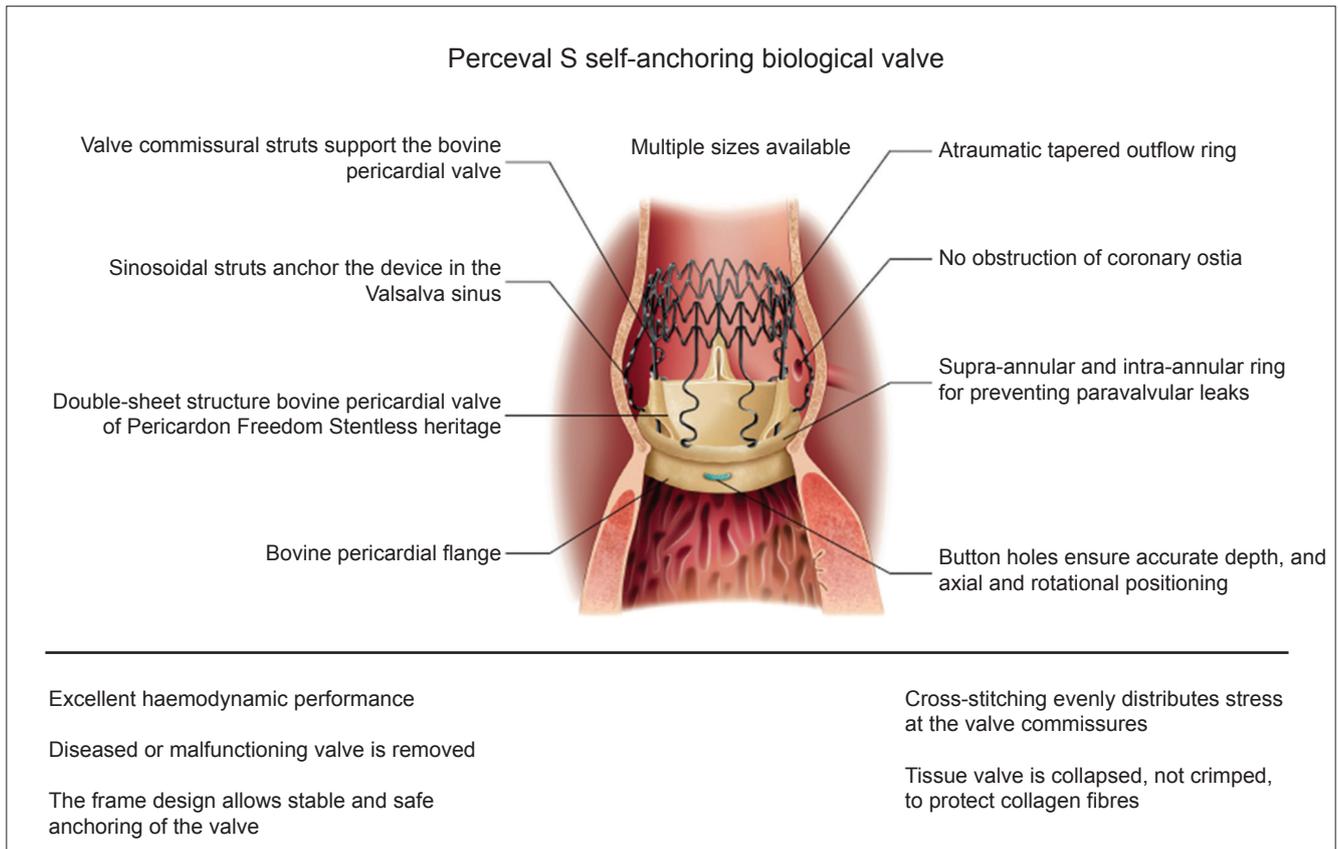


Fig. 2 Photograph shows the features of the Sorin Perceval S (reproduced with permission of Sorin Group Asia Pte Ltd).

during the same period was 14 days. This slight difference in postoperative length of stay is likely an underestimation, in view of the administrative throughput of the cardiac surgical patients; in particular, the discharging process typically factors in other social issues.

DISCUSSION

Valvular AS without accompanying mitral valve disease is more common in men than women, and is rarely rheumatic in aetiology. Age-related degenerative calcification is currently the most common cause of AS in adults and is the most frequent reason for AVR in these patients.⁽³⁾ The prevalence of aortic valve abnormalities detected by population-based echocardiographic study increases with age. It has been reported that 2% of individuals above 65 years of age have isolated calcific AS, while 29% exhibit age-related aortic valve sclerosis without stenosis.⁽³⁾

Increasing life expectancy in developed countries has led to a steady increase in the number of octogenarians undergoing cardiac surgery. More than 25% of octogenarians are functionally limited by cardiovascular disease.⁽⁴⁾ Furthermore, aortic valve disease is the most commonly acquired heart valve lesion in this age group, being present in approximately 4% of octogenarians.⁽⁵⁾ Despite the frequency of this disease process, AS is under-treated in elderly patients.⁽⁶⁾ The Euro Heart Survey published in 2003 reported that nearly one-third of patients aged ≥ 80 years with symptomatic severe aortic valve stenosis denied standard care, namely AVR.⁽¹⁾

Patients with AS who require surgical treatment typically present with a spectrum of risk profiles. Concomitant surgery, redo surgery or access via a minimally invasive approach (right mini-thoracotomy) may add to the complexity of surgery. For patients with symptomatic severe AS, the clear superiority of surgical intervention over medical therapy in terms of both quality of life and prognostic benefits are indisputable. As such, Perceval S and other sutureless valves that are currently being developed present an important alternative for surgeons who are exploring the safest and most effective operation for their patients. AVR in high-risk patients carry a significant risk of mortality and morbidity. The recently published PARTNER Trial (transcatheter vs. surgical AVR in high-risk patients) demonstrated favourable results for the use of sutureless aortic valves as a viable option in a high-risk patient population.⁽²⁾

AVR with biologic heart valves is the treatment of choice for symptomatic or severe AS in patients above 65 years old. Pericardial and porcine valves have been shown to produce excellent results with very low gradient and improved long-term durability, up to 20 years. However, these valves are mounted on a stent with a Dacron cuff, which allows the prosthesis to be sutured to the aortic annulus. This is technically challenging in patients with a small and calcified aortic annulus, with less favourable results seen. Stentless valves have been designed to overcome some of the disadvantages of stented valves. By removing the stent, these bioprostheses provide a greater orifice area as well as preserve the distensibility of the annulus and the expansibility of the sinotubular junction. They offer a

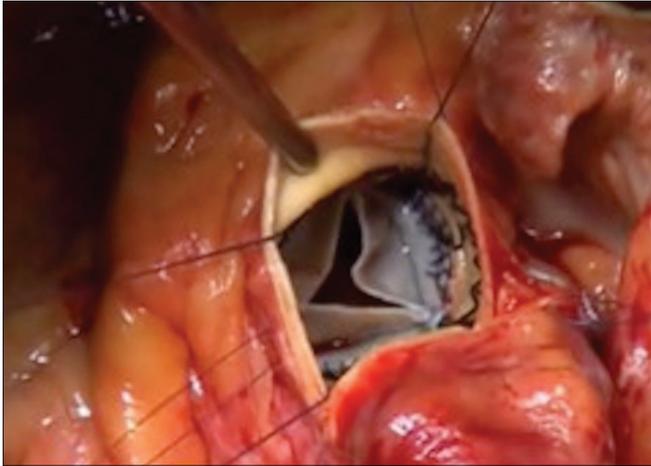


Fig. 3 Photograph shows the implanted Sorin Perceval S (reproduced with permission of Sorin Group Asia Pte Ltd).

greater effective orifice area and lower haemodynamic gradients compared to their stented counterpart. However, they are more difficult to insert, with increased cross-clamp time, and their immediate results do not translate into improved long-term results.⁽⁷⁾ In addition, some bioprostheses exhibit late structural valve failure, with wear and tear at the commissures. Hence, the sutureless Perceval bioprosthesis was designed in order to obtain the haemodynamic benefits of stentless valves without the increased difficulty in surgical implantation.

Sorin Perceval S (Figs. 1-3) is a self-anchoring, self-expanding, sutureless, biological aortic valve designed to preserve the aortic sinuses and sinotubular junction. It is made of a trileaflet bovine pericardial valve mounted on an expandable metal frame in nitinol, and has a unique characteristic of allowing sutureless positioning and anchoring at the implantation site. This prosthesis can also be implanted through a partial sternotomy or right mini-thoracotomy, hence rendering the procedure less invasive compared to conventional AVR. This innovative treatment has revolutionised surgical AVR, optimising both operating time and clinical outcomes.

The design of the Perceval S prosthesis stems from the intention to offer an alternative to traditional flexible prosthesis (stented and stentless biologic valves). As a result of this sutureless technology, patients can benefit from a reduction in aortic cross-clamp times, with subsequent overall reduction in surgical timing, and therefore, a reduction in related risks, as the need to pass the stitches through the annulus and sutures knotting is avoided.⁽⁸⁾ Consequently, there are reduced risks of

tearing of the aortic annulus and wall, damage to the bundle of His, or embolisation of foreign material in the vascular system.

In a four-year follow-up of 208 high-risk patients in two European centres,⁽⁸⁾ implantation of the Perceval S prosthesis resulted in significant improvement of patients' symptoms, as well as in echocardiographic findings. Mean preoperative and postoperative gradients were 48.6 ± 18.6 mm Hg and 10.4 ± 4.3 mm Hg, respectively, and mean effective orifice areas were 0.7 ± 0.2 cm² preoperatively and 1.4 ± 0.4 cm² postoperatively. Intraoperatively, the mean cross-clamp time and cardiopulmonary bypass time were 33 ± 14 min and 54 ± 24 min, respectively; this included 45 patients who underwent surgery through mini-sternotomy without conversion.

AVR remains the gold standard for treatment of aortic valve stenosis. Conventional surgery has excellent outcomes in low-risk patients and acceptable outcomes in medium- and high-risk patients. For some patients, the traditional sutured AVR (whether stented or stentless) is the best option, whereas for others, the sutureless AVR is a better alternative. With new innovations in surgical treatment, it is important to tailor the operation for different subsets of patients. AVR using sutureless bioprosthesis has the potential to benefit moderate- and high-risk patients, and should thus be considered for such individuals on a case-by-case basis, particularly when a minimally invasive approach is considered.

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