Original Article

Sutureless aortic bioprosthesis replacement in elderly Asian patients with aortic stenosis: Experience in a single institution

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ABSTRACT

Background: Sutureless aortic valve replacement (SU-AVR) has emerged as a promising alternative for the treatment of patients with aortic valve stenosis. This study aims to assess the safety and efficacy of SU-AVR in an elderly Asian population.

Methods: From June 2015 to May 2016, 15 adults with severe aortic stenosis (9 females) with a median age of 79 years underwent Perceval sutureless bioprosthesis (LivaNova, UK) implantation in a single Taiwanese institution; peri-operative recovery, clinical improvement, and valve performance were analyzed.

Results: Three (20%) patients underwent concomitant procedures (coronary artery bypass grafting, 1 patient; maze, 2 patients) and 6/12 (50%) patients underwent J-ministernotomy for isolated SU-AVR. Median cardiopulmonary bypass and cross-clamp time were 105 min and 69 min, respectively. All sutureless bioprosthesis were implanted successfully without conversion to a traditional valve, but 2 patients (13.3%) need intraoperative valve repositioning because of paravalvular leakage. Median extubation time and intensive care unit stay were 5 h and 2 days, respectively. One patient experienced in-hospital mortality due to sudden collapse thought secondary to high degree atrioventricular block. Serial echocardiographic evaluations were performed preoperatively and at 1, 3, and 6 months postoperatively. The final echocardiographic exams showed nothing greater than mild aortic insufficiency and the median mean trans-valvular gradient was 13.2 (range, 6.0–26.3) mmHg.

Conclusions: By simplified procedure and improved hemodynamics, SU-AVR can be implanted safely in elderly Asian population with excellent valvular performance.

At a glance of commentary

Scientific background on the subject

Though transcatheter aortic valve implant (TAVI) gains more popular in clinical practice, surgical aortic valve remains the gold standard of treatment. We aim to assess the safety and efficacy of most advanced surgical valve, Perceval sutureless bioprothesis, in elderly population.

What this study adds to the field

Sutureless valve provides feasibility of minimal access and superior hemodynamics of valve performance in elderly patients. This will serve as a bench mark for TAVI comparisons with contemporary surgical valve operation, especially in low and intermediate risk population.

There has been a worldwide increase in the number of patients with aortic stenosis requiring aortic valve replacement (AVR) surgery [1]. However, these patients are often of advanced age and have multiple comorbidities which increase the surgical risk. Ultimately, only one third of these patients undergo surgery. A transcatheter aortic valve implantation (TAVI) procedure has been developed and has been extensively used with acceptable outcomes in patients considered to be ineligible for standard surgery [2—4]. However, the high cost of TAVI and the relatively high incidence of complications, such as stroke, paravalvular leak, pacemaker implantation, and peripheral vascular injury has limited the use of this technique to only intermediate and high risk patients [4,5]. Recent technological developments have led to an alternative minimally invasive option, known as sutureless aortic valve replacement (SU-AVR), which avoids the need for the placement and tying of sutures [6,7]. SU-AVR, in which the replacement valve is implanted surgically after removal of the native valve, has been reported to have comparable outcomes and durability compared to conventional AVR and TAVI in European multi-center studies [8,9]. Our goal was to evaluate the safety and efficacy of SU-AVR in elderly Asian patients with aortic stenosis.

Patients and methods

Study approval and patient consent

This prospective study was conducted with the approval of the Institutional Ethics Committee (No. 103-5141A). After a thorough discussion and explanation, all enrolled patients signed informed consent for accepting this experimental procedure with fully understanding the potential risk and associated complications, as well as the use of personal data and follow-up data.

Patient enrollment and surgical management

From June 2015 to May 2016, 15 adults (9 females) with severe aortic stenosis and a median age of 79 years underwent SU-AVR with Perceval sutureless bioprosthesis (LivaNova, UK) implantation in a single institution in Taiwan. After a discussion with the cardiologist and cardiac surgeon, patients >40 years of age with echocardiography-documented severe aortic stenosis, and with indications for AVR surgery according to the 2014 American College of Cardiology/American Heart Association guidelines for valvular heart disease [10], were included in the study. Patients were excluded from the study if the aortic annulus size was unsuitable for SU-AVR (<19 mm or >27 mm), if they required multiple valve procedures or a redo operation, or if they had active infective endocarditis, a congenital bicuspid aortic valve, or chronic renal impairment. All patients underwent general anesthesia and were place in the standard supine position. Through an approach with sternotomy or J-ministernotomy, cardiopulmonary bypass (CPB) was established via cannulation of the aorta and right atrium. Aortotomy was performed approximately 3.5 cm above the annulus, followed by the placement of suspension stitches on each commissure with careful inspection for valvular pathology. Then, the diseased native valve tissue was removed and the annulus was extensively decalcified. After measuring the annular width with a commercialized valve sizer, the sutureless valve was implanted using three 4-0 Prolene guiding sutures in the middle of annulus among each cusp. These guiding sutures were carried into the valvular eyelet to allow accurate valve orientation within the aortic annulus. All three Prolene guiding sutures were removed after deployment of the valve was completed. Then, a dedicated balloon was inserted into the valve and expanded for 30 s at 4 atm of pressure to fit the prosthetic valve tightly against the aortic wall. Before closing the aortotomy, final confirmation of coronary artery patency, proper orientation of the prosthetic valve, and good coaptation over the three leaflets was done.

Data collection and statistical analysis

Clinical demographics including preoperative condition, valve hemodynamics, and surgical information are collected and analyzed. Echocardiography for the measurement of valve performance including aortic valve area, mean trans-valvular pressure gradient, maximum transvalvular velocity, and aortic regurgitation was performed preoperatively and at 1, 3, and 6 months postoperatively. The perioperative recovery, complications, and clinical improvement were also reviewed and analyzed. Data collection was performed weekly by one data-manager through the electronic medical records. Since this study includes a limited number of patients, data are

presented as medians and maximum/minimum values for continuous variables to reduce the impact of extreme values, and as percentages for categorical data. All statistical analyses were performed using SPSS for Windows (Version 22.0, SPSS Inc, Chicago, IL). The European system for cardiac operative risk evaluation score II (EuroSCORE II) was used to evaluate the surgical risk [11]. The generalized estimating equation (GEE) model was used to assess the improvement in clinical symptoms after SU-AVR.

Results

Clinical demographics and preoperative patient characteristics

As shown in Table 1, 60% of the patients were female, and the median age was 79 years. The most prevalent comorbidity was hypertension (46.7%), followed by diabetes mellitus and chronic obstructive lung disease. The preoperative median left ventricular ejection fraction (LVEF) was 70%, and 3 patients (20%) had poor heart function. The median EuroSCORE II-predicted mortality rate was 4.6%. Preoperative echocardiography revealed a small aortic valve area, a high maximum velocity, and a high pressure gradient in all patients. Two patients (13.3%) had a greater than mild degree of aortic regurgitation.

Surgical information

As shown in Table 2, 3 patients (20%) had concomitant procedures (coronary artery bypass grafting in 1 patient and maze in 2 patients) and 6/12 patients (50%) underwent J-ministernotomy for isolated SU-AVR. The median cross-clamp and CPB times were 69 min and 105 min, respectively. The sizes of the sutureless prosthesis were equally distributed. All sutureless bioprosthesis were implanted successfully without conversion to traditional valve replacement surgery, but 2 patients (13.3%) required intra-operative repositioning of the valve because of para-valvular leakage caused by improper positioning of the prosthetic valve. No mechanical support or pacemaker use was required in the operating room.

Post-operative recovery and morbidities

As shown in Table 3, the median extubation time and intensive care unit (ICU) stay was 5 h and 2 days, respectively. One patient experienced in-hospital mortality due to sudden hemodynamic collapse thought to be due to a high degree atrioventricular conduction block. In addition to the 1 patient death, a single patient developed hemorrhagic stroke and underwent decompression craniotomy on post-operative day 2 because of a sudden hypertensive crisis. No patients experienced acute renal failure or cerebral infarction, and none required operative re-exploration for hemostasis while hospitalized. Over a median follow-up period of 13 months, an 80 year old male patient died from a non-cardiac cause which suspected to be associated with aging organ failure, and an 86 year old female patient

Table 1 Clinical demographics, comorbidities, preoperative condition, and valve hemodynamics.

Variable	Patients (n = 15)
Clinical demographics	
Sex (female)	9 (60%)
Age (years)	79 (50−87)
Body mass index (kg/m^2)	24 (21−27)
Co-morbidities	
Diabetes mellitus	6 (40%)
Hypertension	7 (46.7%)
Atrial fibrillation	1 (6.7%)
COPD	3 (20%)
ESRD	0
Creatinine (mg/dL)	0.9 (0.5−1.9)
Preoperative condition	
LVEF (%)	70 (41−83)
LVEF <50%	3 (20%)
Ventilator support	0
IABP support	0
ECMO support	0
Redo operation	0
Emergent operation	0
EuroSCORE II (%)	4.6 (1.2−10.4)
NYHA FC ≧ 2	12 (80%)
Valve hemodynamics	
AVA (cm^2)	0.7 (0.4−1)
Vmax (m/s)	4.4 (3−6.1)
MPG (mmHg)	50.6 (24.1−96.9)
Aortic regurgitation[a]	2 (13.3%)

Abbreviations: AVA: aortic valve area; COPD: chronic obstructive lung disease; ECMO: extracorporeal membrane oxygenation; ESRD: end-stage renal disease; EuroSCORE II: European system for cardiac operative risk evaluation score II; IABP: intra-aortic balloon pump; LVEF: left ventricular ejection fraction; MPG: mean trans-valvular pressure gradient; NYHA FC: New York Heart Association functional classification; Vmax: maximum trans-valvular velocity.
[a] Indicated aortic regurgitation of more than a mild degree.

Table 2 Surgical information in patients undergo sutureless valve implantation.

Variable	Patients (n = 15)
Approach	
Full-sternotomy	9 (60%)
J-ministernotomy	6 (40%)
Isolated SU-AVR	12 (80%)
Combined CABG	1 (6.7%)
Combined maze	2 (13.3%)
Prosthesis size[a]	
S	4 (26.7%)
M	5 (33.3%)
L	3 (20%)
XL	3 (20%)
Cardiopulmonary bypass time (min)	105 (69−271)
Aortic clamping time (min)	69 (51−201)
Repeated implantation	2 (13.3%)
IABP in OR	0
ECMO in OR	0
Pacemaker in OR	0

Abbreviations: CABG: coronary artery bypass grafting; ECMO: extracorporeal membrane oxygenation; IABP: intra-aortic balloon pump; OR: operating room; SU-AVR: sutureless aortic valve replacement.
[a] S (19−21 mm); M (21−23 mm); L (23−25 mm); XL (25−27 mm).

Table 3 Post-operative recovery and morbidities.

Variable	Patients (n = 15)
In-hospital mortality	1 (6.7%)
Check bleeding	0
Wound infection	1 (6.7%)
Hemodialysis	0
Permanent pacemaker	0
Stroke	0
Intra-cranial hemorrhage	1 (6.7%)
Extubation time (hrs)	5 (3—248)
Ventilator > 7 days	1 (6.7%)
Hospital stay (days)	10 (5—42)
ICU stay (days)	2 (1—38)
ICU re-admission	1 (6.7%)

Abbreviation: ICU: intensive care unit.

required pacemaker implantation due to symptomatic bradycardia at 5 months post operation.

Valve performance and clinical improvement

Serial echocardiograms performed preoperatively and at 1, 3, and 6 months postoperatively revealed an improved LVEF [Fig. 1A] and good valve hemodynamics without early dysfunction [Figs. 1B and 2, respectively]. Furthermore, the GEE model revealed a significant improvement of the patients' clinical symptoms after SU-AVR operation based on their New York Heart Association functional classification ($p = 0.003$), and none had greater than mild aortic insufficiency [Fig. 3].
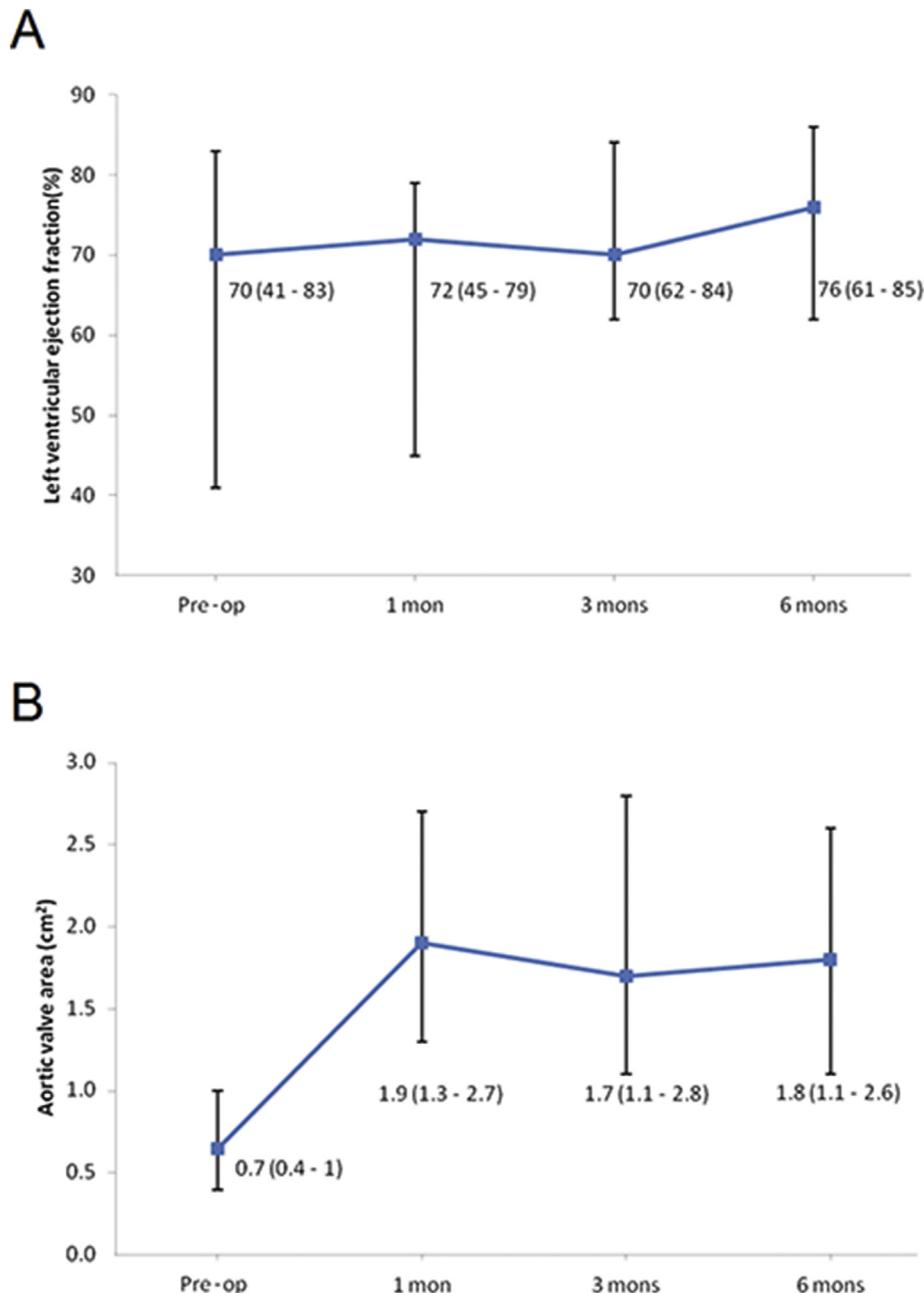

Fig. 1 Comparison of echocardiographic measurements of left ventricular performance (A) and aortic valve area (B) preoperatively and at 6 months post sutureless aortic valve replacement.

Discussion

Sutureless aortic valve replacement

Though conventional midline sternotomy for AVR is an effective therapy, the development of minimally invasive procedures to decrease surgical risk and improve patient acceptance is particularly important for the elderly high-risk population. Perceval S is a sutureless prosthetic valve comprised of a tissue component valve made from bovine pericardium attached to a self-expanding anchoring device [12]. The anchoring device design is made by dual-ring segments, three commissural elements supporting the valve, and six sinusoidal elements enhancing fixation in the aortic root, sinotubular junction, and sinuses of valsalva. With the sturdy anchoring device, this sutureless device can ensure good stability with a low risk of coronary compromise and valve migration. Using a sutureless bioprosthetic valve for minimally invasive AVR has become a commonly preferable procedure for patients with aortic stenosis in some European countries [8].

Reduction in cross-clamp and cardiopulmonary bypass time

It is well established in the cardiothoracic surgical literature that extended CPB and aortic cross-clamping times are
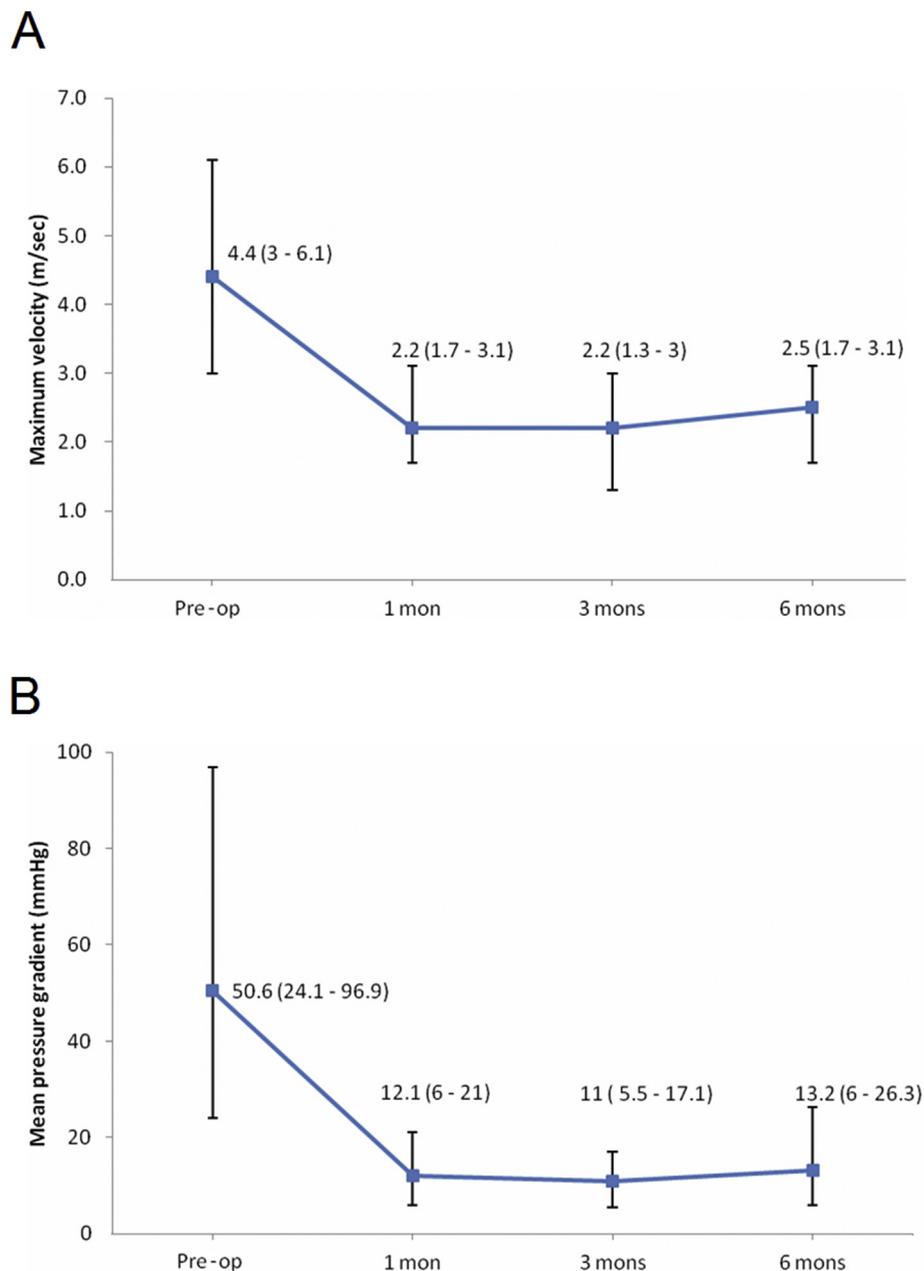

Fig. 2 Comparison of echocardiographic measurements of trans-valvular velocity (A) and mean pressure gradient (B) preoperatively and at 6 months post sutureless aortic valve replacement.
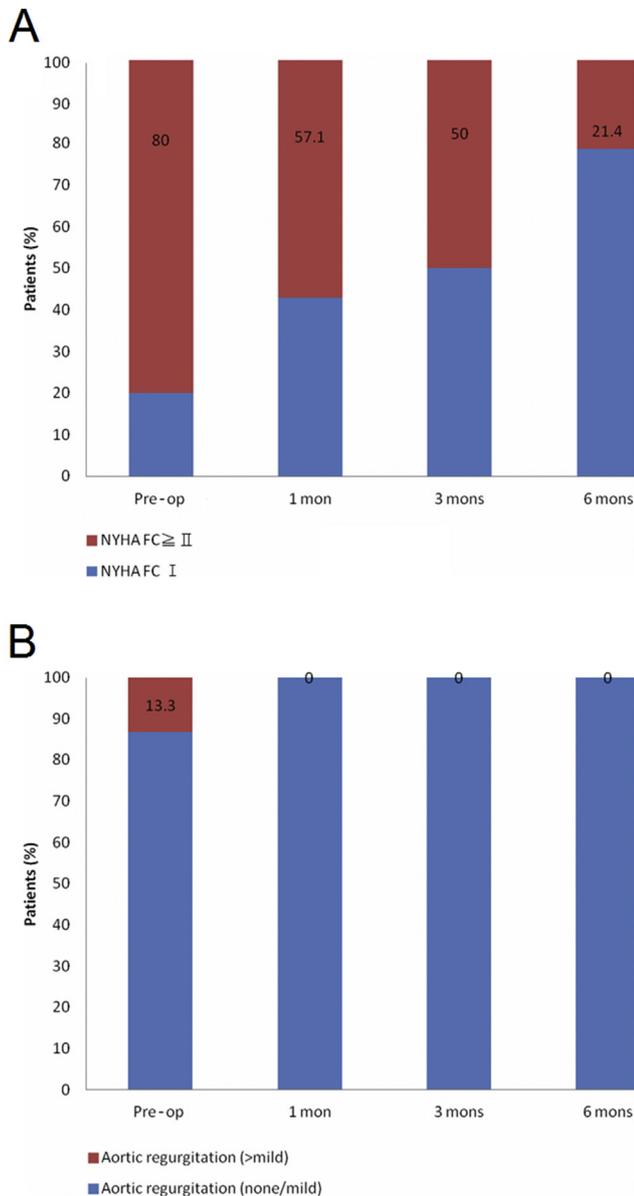
A

B

Fig. 3 Pre and postoperative clinical symptoms based on the New York Heart Association functional classification (A) and valve regurgitation severity (B) among 15 patients undergoing sutureless aortic valve replacement.

significant, independent risk factors for mortality and morbidity in patients undergoing cardiac surgery [13,14]. A retrospective analysis of patients with aortic valve stenosis demonstrated that aortic cross-clamp time was a significant, independent predictor of cardiovascular morbidity [15]. Therefore, any technique that shortens cross-clamp or CPB time has the potential to decrease the risk of complications and improve long-term survival.

Due to the efficient deployment system, SU-AVR can dramatically decrease cardiac ischemia time and total surgery duration compared to traditional open heart surgery. In a meta-analysis reported by Phan et al. [16], SU-AVR had shorter CPB and cross-clamp times with both conventional and minimally invasive approaches according to the Society of Thoracic Surgeons national database. Also, Pollari et al. reported that the shorter procedure time in SU-AVR was associated with a lower rate of postoperative complications, a shorter intubation time, a shorter ICU stay, and reduced hospital costs compared to conventional AVR [17]. In a previous study reported from this institute [18], the mean cross-clamp and CPB times were 123 ± 53.1 min and 157 ± 78.6 min respectively, and both longer then the data observed in the present study. Besides, it also revealed more extended ICU stay (4.9 ± 7.5 days) and hospital stay (24.1 ± 20.3 days) compared to the present study. In high-risk patients undergoing concomitant cardiac surgery with a prolonged surgical time as well as in patients undergoing reintervention, the use of the sutureless bioprosthesis is even more valuable. Additionally, sutureless implantation with the valve collapsed on a holder requires minimal manipulation of the aortic root and prosthetic valve, which may help avoid potential complications of the root or prosthetic valve endocarditis [19,20]. Furthermore, with good visibility of the annulus, SU-AVR facilitates a minimally invasive approach either through an upper J-ministernotomy or a right mini-thoracotomy requiring only a 6 cm surgical wound. These benefits decrease postoperative wound pain and hasten the patient's recovery.

Valve hemodynamics and paravalvular leakage

TAVI represents the least invasive approach to AVR because it can be performed percutaneously without requiring CPB. However, the main limitation of TAVI is that the native diseased valve tissue can not be removed. This may cause incomplete attachment of the prosthetic valve on the annulus and lead to a higher incidence of paravalvular leakage compared with that of conventional AVR [2,3]. Paravalvular leakage is an important complication that always has to be considered when assessing the outcomes of prosthetic valve implantation. Recent evidence from TAVI trials demonstrates a significant correlation between paravalvular leakage and a poorer mid-term survival [9,21]. The SU-AVR approach ensures a complete excision of the calcified valve in a manner as same as conventional AVR. Furthermore, with SU-AVR the prosthesis is implanted under direct visualization on a non beating heart, which also reduces the risk of misplacement and paravalvular leakage compared to the angiography-guided deployment used in TAVI. In a meta-analysis reported by Phan et al. [16], the incidence of paravalvular leakage in patients undergoing SU-AVR was only 3%. In the present study, follow-up echocardiography at 6 months postoperatively validated this finding.

In addition to a lower risk of a paravalvular leak, a prosthetic valve with a larger profile can be implanted because of the lack of a traditional bioprosthetic valve stent and sutured ring [22]. This results in improved valve hemodynamics compared to that seen with conventional AVR, and avoids a

patient/prosthesis mismatch. In the present study, all parameters measured by echocardiography indicated excellent valve hemodynamics [Figs. 1 and 2] and were associated with an improvement in clinical symptoms after SU-AVR.

Study limitations

Despite the promising results of this study, several important limitations must be considered. First, the study was an non-randomized trial without control group, and there may have been bias in the patient selection. Second, this study includes a limited number of patients, which might influence the complication rates and outcomes. Finally, since this was a prospective study, the follow-up period is short, and an extended follow-up is necessary to evaluate the long-term outcomes in this patient population.

Conclusions

In summary, by shortening surgery duration and completely removing diseased native valve, SU-AVR with Perceval sutureless bioprosthesis can be performed safely in an elderly Asian population and result in excellent valvular performance.

Conflicts of interest

All authors declare no conflicts of interest.

Acknowledgments

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.bj.2018.04.008.

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