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Clinical Research

Clinical Midterm Results of Surgical Aortic Valve Replacement with Sutureless Valves

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Background: Sutureless aortic valves may enable shorter procedure times, which benefits patients with elevated surgical risk. We describe the outcomes of patients with aortic stenosis who underwent aortic valve replacement (AVR) using the sutureless Perceval aortic bioprosthesis.
Methods: Data from a retrospective cohort were obtained from a clinical database. The study enrolled patients with symptomatic severe aortic stenosis who underwent surgical AVR with a sutureless bioprosthesis between August 2015 and December 2020. In total, 113 patients were included (mean age, 75.3±8.4 years; 57.5% women; median Society of Thoracic Surgeons score, 9.7%; mean follow-up period, 51.19±20.6 months). Of these patients, 41 were octogenarians (36.2%) and 3 were nonagenarians (2.6%). Transthoracic echocardiography was employed to assess changes in ejection fraction (EF), left ventricular mass index (LVMI), and mean pressure gradient (MPG).
Results: The in-hospital mortality rate was 2.6%, and 13 patients developed new-onset atrial fibrillation. A permanent pacemaker was implanted in 3 patients (2.6%). The median intensive care unit stay was 1 day (interquartile range [IQR], 1–2 days), and the median hospital stay was 12 days (IQR, 9.5–15 days). The overall survival rate at 5 years was 95.9%. LVMI and MPG were reduced postoperatively, while EF increased over the follow-up period. No structural valve deterioration was observed, and no meaningful paravalvular leakage developed during follow-up.
Conclusion: The use of a sutureless valve in the aortic position is safe and feasible, even for high-risk elderly patients requiring surgical AVR. LVMI and MPG decreased postoperatively, while EF increased over the follow-up period.

Keywords: Aortic stenosis, Aortic valve replacement, Thoracic surgery, Adult, Heart valve disease

Introduction

Sutureless bioprostheses have recently been introduced into clinical practice, expanding the options for aortic valve substitutes available to patients undergoing surgical aortic valve replacement (AVR) for severe aortic valve stenosis. Following removal of the calcified valve, a sutureless aortic valve can be implanted without suturing; this can reduce aortic cross-clamp and cardiopulmonary bypass times [1]. Furthermore, the absence of a sewing ring in sutureless valves may enable improved hemodynamics compared to other valve types [2]. A recent study comparing sutureless valves with transcatheter aortic valve implantation (TAVI) found a higher prevalence of paravalvular leak in the TAVI group [3]. The primary purpose of this study was to review the clinical experiences of patients with aortic stenosis who underwent surgical AVR with a sutureless valve.

Methods

Patients

In this retrospective study, we analyzed prospectively collected data from 113 consecutive patients with aortic valve disease who underwent implantation of the Perceval sutureless valve (Corcym, London, UK). We enrolled pa-

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tients with symptomatic severe aortic stenosis who underwent surgical AVR with a sutureless bioprosthesis between August 2015 and December 2020. Patients were excluded if less than 2 years had passed since sutureless valve implantation. The inclusion criteria were as follows: (1) an indication for AVR using a tissue valve for a diseased native aortic valve or a malfunctioning prosthetic aortic valve in patients over 65 years of age, (2) a preference for a tissue valve due to anticoagulation considerations, and (3) the absence of contraindications for a sutureless valve. Initially, we utilized the sutureless valve for elderly patients ranging from 65 to 70 years old, combined cases, and patients with substantial comorbidities. More recently, we have used the sutureless valve in patients with lower risk profiles; however, the application of the Perceval valve in patients younger than 60 years has been limited at our center to date. The demographic and clinical characteristics of the patients are detailed in Table 1. This study received approval from the

Table 1. Baseline characteristics of the study population

Characteristic	Value
Female sex	65 (57.5)
Age (yr)	75.3±8.4 (59–95)
≥90	3 (2.6)
80–90	41 (36.2)
<80	69 (61.2)
New York Heart Association class	
I	14 (12.5)
II	58 (51.3)
III	33 (28.7)
IV	8 (7.5)
Hypertension	81 (71.6)
Obesity (body mass index ≥30 kg/m^2)	29 (25.6)
Diabetes	40 (35.4)
Dyslipidemia	47 (41.6)
Atrial fibrillation	17 (15.0)
Pacemaker	3 (2.6)
Bicuspid aortic valve	13 (11.5)
Cerebrovascular disease	13 (11.5)
Chronic kidney disease (stage ≥3b)	68 (60.1)
End-stage renal failure (dialysis)	12 (10.6)
Chronic obstructive pulmonary disease (FEV1 <80%)	76 (67.2)
Peripheral artery obstructive disease	64 (56.6)
Aortic valve disease	
Aortic valve stenosis	86 (76.1)
Mixed aortic valve disease	27 (23.8)
Left ventricular ejection fraction (%)	61 (47.5–67.0)
>50%	70 (61.9)
30%–50%	32 (28.4)
<30%	11 (9.7)
Aortic valve area (cm^2)	0.72±0.20 (0.25–1.12)
Peak aortic valve gradient (mm Hg)	90.86±21.42 (65–146)
Mean aortic valve gradient (mm Hg)	65.2±7.5 (55–83)
Previous cardiac surgery	
Aortic valve replacement	6 (5.3)
Coronary artery bypass graft	2 (1.8)
Mitral/tricuspid surgery	4 (3.5)
STS score (%)	9.7 (4.4–18.0)
Low (<4)	20 (17.6)
Intermediate (4–8)	28 (24.9
High (≥8)	65 (57.5)

Values are presented as number (%), mean±standard deviation (range), or median (interquartile range).
FEV1, forced expiratory volume in the first second; STS, Society of Thoracic Surgeons.

Ethics Committee at Yonsei University Wonju College of Medicine (approval no., CR 318147), and the requirement for individual informed consent was waived due to the retrospective nature of the research.

Surgical procedure

AVR was performed through either a standard median sternotomy or a minimally invasive approach. Access to the aortic root was gained through a high aortotomy at or immediately below the level of the aortic fat pad. The aortic valve leaflets were resected, and the annulus was meticulously decalcified to achieve an orifice that was as circular as possible. The annulus was measured using preoperative evaluation and designated sizers. To ensure accurate placement of the prosthesis, 3 guiding sutures were employed to align the inflow section of the prosthesis with the insertion plane of the native leaflets. In early use, these sutures were positioned 2–3 mm below the nadir of the native leaflet insertion line of each valve sinus and then threaded through the corresponding eyelets on the prosthetic inflow ring. In elderly patients with a small body surface area and a narrow left ventricular outflow tract, the guiding sutures were positioned 1–2 mm below the nadir of the native leaflet to prevent heart block. It is critical to avoid placing the guiding suture more than 2–3 mm below the annulus, ensuring that the collar of the Perceval inflow is seated above the annulus. Recently, we have placed a guiding suture in each valve sinus 1–2 mm beneath the leaflet hinge point. The valve prosthesis was loaded onto the delivery device using a proprietary collapsing mechanism. Following implantation and release of the prosthetic valve, to optimize the area of contact between the prosthesis and the aortic annulus, dilation was performed with a specially designed balloon catheter at 4 atmospheres of pressure for 30 seconds while warm water was applied to the valve. Once the prosthesis was fully deployed, the guiding sutures were removed. After weaning from cardiopulmonary bypass, valve function was assessed in all patients using transesophageal echocardiography (TEE). Postoperatively, patients were placed on anticoagulation therapy for 3 months. Warfarin was the first-choice agent, with a target international normalized ratio of approximately 2.0. All surgical procedures were performed by a single surgeon.

Perioperative study and hemodynamic assessment

All patients underwent a transthoracic echocardiogram (TTE) or TEE. Conventional echocardiography was conducted using a commercially available system (Vivid-E9; Vingmed-General Electric, Horten, Norway). Echocardiographic views were obtained in accordance with the recommendations of the American Society of Echocardiography [3]. Left ventricular ejection fraction (EF) was measured from the apical 4- and 2-chamber views using the Simpson biplane method. The left atrial volume index and left ventricular mass index (LVMI) were calculated using the formula recommended by the American Society of Echocardiography [4]. Electrocardiography was performed in the hospital following surgery and at 1-year intervals after discharge to analyze postoperative changes. In all patients except those with severe chronic kidney disease, preoperative aortic computed tomography was routinely performed to evaluate the size and shape of the aortic root and ascending aorta, as well as to determine the vascular structure. Non-contrast chest computed tomography was performed in 30 patients to evaluate the size and shape of the aortic root using non-contrast imaging and TTE. The operative risk for each patient was calculated according to the Society of Thoracic Surgeons (STS) score classification system. TTE was repeated before discharge and annually after the operation. Hemodynamic parameters were assessed via TTE using 2-dimensional, M-mode, pulsed-wave, and color flow imaging. A cardiologist calculated the EF, LVMI, mean pressure gradient (MPG), and peak pressure gradient to compare the changes in reverse remodeling after the procedures.

Statistical analyses

All statistical analyses were performed using IBM SPSS for Windows ver. 23.0 (IBM Corp., Armonk, NY, USA), along with R Studio and R ver. 3.5.1 (R Studio, Boston, MA, USA). Continuous variables were expressed as means± standard deviations, while categorical variables were presented as absolute numbers and percentages. To adjust for significant covariates, multivariable models were developed to analyze all-cause mortality. The log-rank test was employed to assess differences in unadjusted survival curves. A 2-sided p-value of less than 0.05 was considered to indicate statistical significance. A linear mixed model was used to evaluate differences in hemodynamic variables across time points and groups, with post hoc analysis conducted using the Bonferroni method.

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Results

Clinical results

A total of 113 patients were enrolled in the study, with a mean age of 75.3±8.4 years. Among these patients, 41 were octogenarians (36.2%) and 3 were nonagenarians (2.6%). Regarding sex, 65 patients were female (57.5%). The median STS score was 9.7% (interquartile range [IQR], 4.4%–18.0%). The high-risk category, defined as an STS score of 8 or above, included 65 patients (57.5%), while 28 patients (24.9%) were categorized as intermediate risk, with STS scores ranging from 4 to less than 8. Previous cardiac surgical procedures among the patients included isolated AVR in 5.3%, mitral/tricuspid valve surgery in 3.5%, and coronary artery bypass graft (CABG) in 1.8%. Primary isolated surgery was conducted in 66 patients (58.4%), with a minimally invasive technique employed in 27 of these cases (23.9%) (Table 2). Combined procedures were performed in 40 patients (35.3%). Specifically, CABG was done in 18 patients, aortic surgery in 6, mitral valve surgery in 6, triple valve surgery in 3, and myectomy in 5, while 1 patient underwent hemi-arch surgery and CABG under circulatory arrest. Medium or large valves were implanted in 71% of patients, while small valves were used in 13.4%. For isolated surgical cases, the mean aortic cross-clamp time was 35.2±3.9 minutes, and the mean cardiopulmonary bypass time was 82.7±9.5 minutes. In contrast, for combined surgical cases, these times were 77.6±31.7 minutes for aortic cross-clamp and 119.1±40.5 minutes for cardiopulmonary bypass time.

In-hospital mortality occurred in 3 patients (2.6%). We noted no cerebrovascular accidents, including transient ischemic attack or any other thromboembolic event. New-onset atrial fibrillation was observed in 13 patients (11.5%). A permanent pacemaker was implanted in 3 patients (2.6%). No cases required reoperation due to postoperative bleeding, and no patient exhibited more than trivial paravalvular leakage on TTE. The median stay in the intensive care unit was 1 day (IQR, 1–2 days). A total of 62 patients (77.5%) were transferred to the general ward on the first postoperative day, and the median length of hospitalization was 12 days (IQR, 9.5–15 days). The postoperative events and echocardiographic parameters are detailed in Table 3.

Changes in platelet counts by postoperative day are depicted in Fig. 1. A reduction in platelet count was observed between the immediate postoperative period and postoperative days 2 to 3. Patients with underlying conditions (n=13, 16.2%), including liver cirrhosis and immune thrombocytopenic purpura, experienced a significant reduction in platelet count ($p<0.05$), as shown in Fig. 2. No bleeding complications associated with thrombocytopenia were ob-

Table 2. Operative data

Variable	Value
Primary isolated aortic valve replacement	66 (58.4)
Midsternotomy	39 (34.5)
Minimally invasive technique	27 (23.9)
Upper sternotomy/right mini-thoracotmy	25/2 (22.1/1.8)
Combined procedures	
Mitral valve surgery	6 (5.3)
Mitral and tricuspid valve (triple valve surgery)	3 (2.6)
Myectomy	5 (4.4)
Aortic surgery	6 (5.3)
CABG	18 (15.9)
Aortic surgery+CABG	1 (0.9)
MAZE IV	1 (0.9)
Perceval size	
Small	15 (13.4)
Medium	44 (38.9)
Large	37 (32.7)
Extra-large	17 (15.0)
Cardiopulmonary bypass time (min)	
Primary isolated surgery	82.7±9.5
Combined	119.1±40.5
Clamp time (min)	
Primary isolated surgery	35.2±3.9
Combined surgery	77.6±31.7

Values are presented as number (%) or mean±standard deviation.
CABG, coronary artery bypass graft.

Table 3. Postoperative in-hospital outcomes

Outcomes	Value
In-hospital mortality	3 (2.6)
Left ventricular ejection fraction (%)	57.6±11.5
Cerebrovascular accident (including transient ischemic attack)	0
Other thromboembolic events	0
Ventilator support >24 hr	9 (7.9)
New-onset atrial fibrillation	13 (11.5)
New atrioventricular block requiring pacemaker	3 (2.6)
Paravalvular leakage (more than trivial)	0
Mean pressure gradient (mm Hg)	10.5±1.1
Bleeding requiring revision surgery	2 (1.7)
Acute kidney injury requiring renal replacement	2 (1.7)
Deep sternal wound infection	1 (0.9)
Intensive care unit stay (day)	1 (1–2)
Hospital stay (day)	12 (9.5–15)
Thrombocytopenia requiring transfusion	21 (26.5)

Values are presented as number (%), mean±standard deviation, or median (interquartile range).

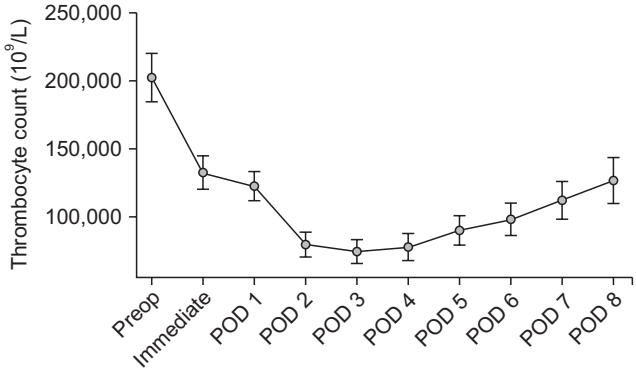

Fig. 1. Changes in platelet count by postoperative day (POD). Preop, preoperative.

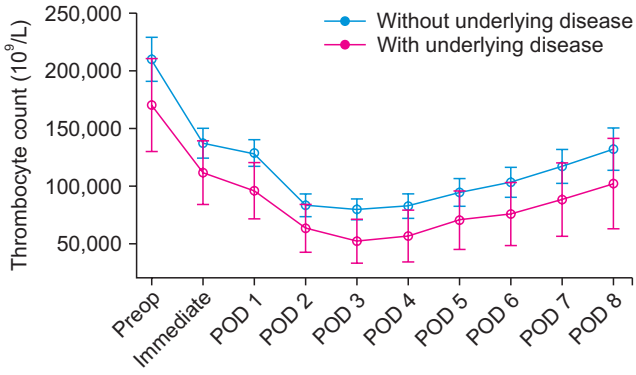

Fig. 2. Changes in platelet count according to the presence of underlying disease. Preop, preoperative; POD, postoperative day.

served.

During the follow-up period, we noted no instances of reoperation or other adverse events, including thromboembolic complications, endocarditis, or structural valve failure. Furthermore, no prosthetic migration or dislodgement occurred. At 5 years postoperatively, the overall survival rate was 95.9% (Fig. 3).

Hemodynamic results

Hemodynamic changes were observed over the follow-up period, during which EF, LVMI, and MPG were assessed. Specifically, MPG decreased from preoperative levels to a mean value of 10.5±1.1 mm Hg after surgery. EF exhibited a marked change after 6 months, whereas LVMI and MPG exhibited declines in the immediate postoperative period (Fig. 4).

The change in LVMI, which was not significant immediately after surgery, is indicative of reverse remodeling. We therefore present the LVMI data across the entire follow-up

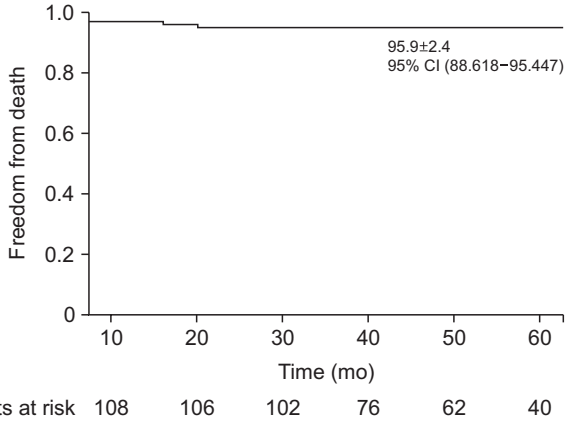

Fig. 3. Overall survival after surgical aortic valve replacement using a sutureless valve. CI, confidence interval.

period. Six months after surgery, the decrease in LVMI became significant, with the peak reduction occurring at 1 year or later. No significant difference was observed in the change of MPG when analyzed according to Perceval size (Fig. 4).

Discussion

This study presents the midterm clinical and hemodynamic outcomes of patients who underwent AVR with a sutureless valve. The study had several distinctive features. First, in the analysis of the midterm results, patients at less than 2 years post-operation were excluded. Second, a considerable proportion of the study population consisted of elderly patients: 3 were nonagenarians and 41 were octogenarians, corresponding to approximately 40% of the entire cohort being over 80 years old. Third, 57% of the patients were considered high-risk surgical candidates, with an STS score of 8% or higher; only 20 patients (17.6%) were categorized as low-risk. Fourth, primary isolated surgery was performed in only 58% of the patients, while the remainder underwent combined cardiac surgery or redo cardiac surgery. These findings suggest that sutureless valves were predominantly implanted in elderly and/or high-risk patients or in those requiring complex operations. In a study by Villa et al. [5], the use of a sutureless valve was found to be advantageous in high-risk patients, with cost savings that were particularly notable in older patients and those with elevated risk [6]. Despite a substantial number of patients in the present study being considered high-risk, the in-hospital mortality rate was approximately 2%, and the midterm survival rate was 95.9%. In recent years, TAVI has emerged as a minimally invasive option for patients at high

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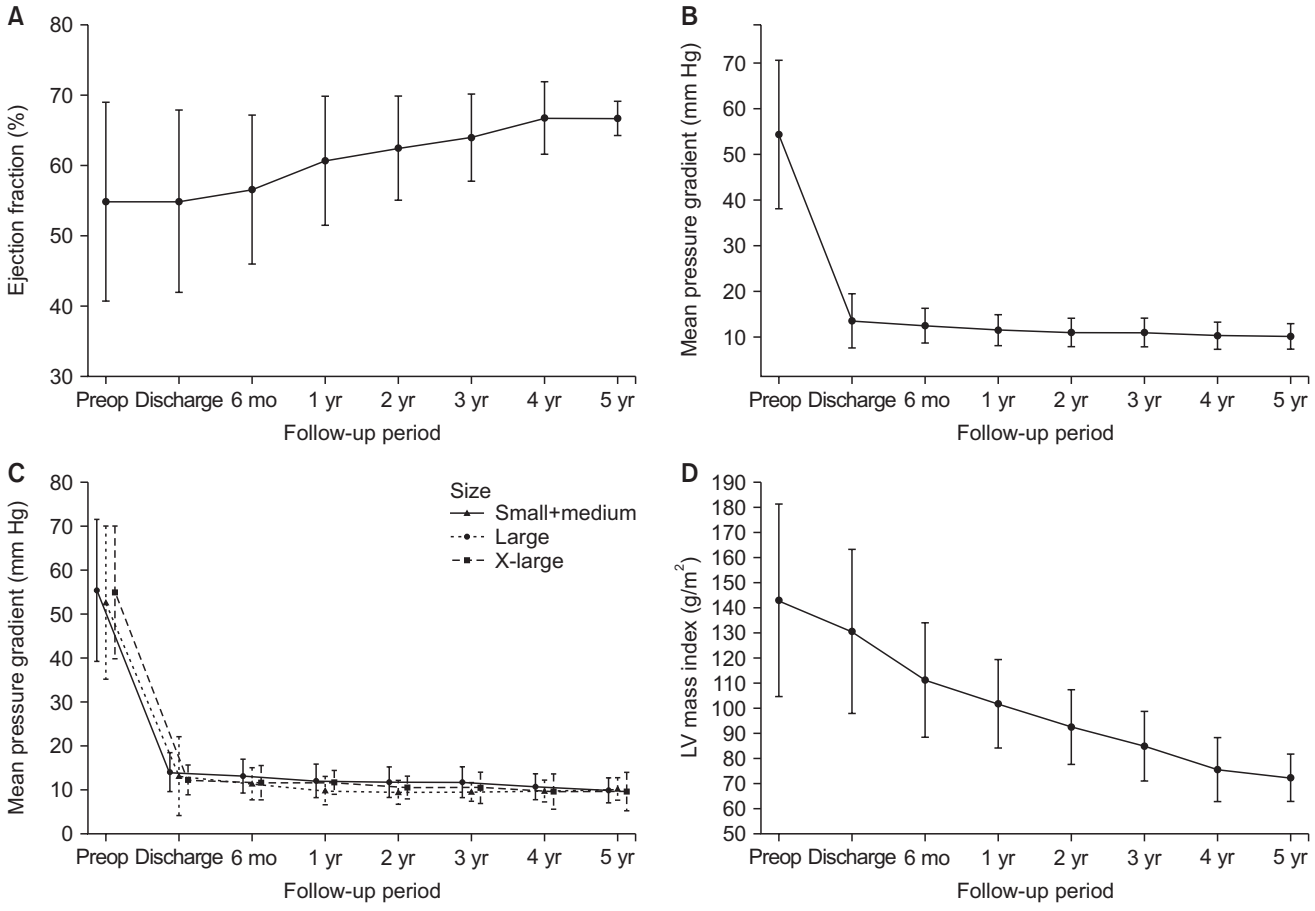

Fig. 4. Hemodynamic changes following surgery. (A) Ejection fraction. (B) Mean pressure gradient. (C) Mean pressure gradient according to Perceval size. (D) Left ventricular (LV) mass index. Preop, preoperative.

risk of intraoperative complications. The PARTNER 1 and 2 studies demonstrated the superiority of TAVI over medical therapy in patients deemed inoperable, while also showing TAVI to be non-inferior to surgical AVR in high- and intermediate-risk patients [7,8]. However, TAVI has been associated with elevated rates of paravalvular leaks, vascular complications, and concerns about leaflet thrombosis compared to conventional AVR [8-12]. In this study, we observed no instances of meaningful (greater than trivial) paravalvular leak, and we noted no cases of valve thrombosis or structural valve deterioration in the immediate postoperative interval or during the subsequent follow-up period.

The implantation of a permanent pacemaker is an important consideration in the context of sutureless valve procedures. In a study by Mugnai et al. [13], the number of permanent pacemaker implantations was approximately 4 times greater than that observed for conventional AVR. Erdogan et al. [14] reported a permanent pacemaker implantation rate of 4.1% with standard AVR, while Dawkins et al. [15] found a rate of 8.5%.

In our study, 3 patients (2.6%) required the implantation of a permanent pacemaker. The first patient had a pacemaker implanted on the eighth postoperative day, although the atrioventricular block resolved on postoperative day 10. The second case involved an 82-year-old patient with a right bundle branch block. The third patient, who was 81 years old, underwent AVR with myectomy. In the Cavalier Trial, a prospective multicenter study involving 658 patients, the rate of pacemaker implantation was 11.6% [16]. While the 2.6% value is not high compared to conventional AVR, pacemaker implantation rates may also be elevated in high-risk groups, such as the elderly or those undergoing combined surgery. In our study, the first patient to receive a pacemaker recovered sinus rhythm. Some centers opt to monitor patients for 7–10 days after surgery before deciding to implant a permanent pacemaker. Others advocate for immediate pacemaker implantation if normal car-

diac rhythm is not restored in the operating room. At our center, we typically wait for 2 weeks before proceeding with pacemaker implantation. Additionally, the lower rate of pacemaker implantation in our study may be attributable to the learning curve associated with proper annulus decalcification, the precise placement of guiding sutures, and the careful release of traction sutures applied to the 3 valve commissures to prevent excessively low deployment in the left ventricular outflow tract [17,18].

Consistent with our findings, a significant reduction in postoperative platelet count has been previously reported [19]. In our study, a reduction in platelet count occurred between the immediate postoperative period and postoperative days 2 and 3. Another investigation similarly suggested that transient thrombocytopenia could occur during this timeframe following cardiac surgery [20]. In the present study, patients with underlying diseases exhibited more severe reductions in platelet count. Several factors may influence platelet function. In our study, platelet counts in 3 patients recovered after the discontinuation of antibiotics, and 3 patients were diagnosed with idiopathic thrombocytopenic purpura (ITP) following bone marrow biopsy, although thrombocytopenia did not lead to clinical complications. As shown in Table 3, a total of 21 patients received platelet transfusions. Initially, we typically administered 1 pack of apheresis per patient at a time. Three patients diagnosed with ITP received 3–4 packs of apheresis. Some patients showed no change in thrombocytopenia after transfusion. The causes in these patients were cited as ITP, antibiotics, or underlying disease. Based on these experiences, we no longer routinely transfuse platelets. Relative to conventional AVR, the decrease in platelet count may be greater with sutureless valves [21]; however, no studies have demonstrated a clinical difference. More than 40% of patients in our study underwent combined surgery or redo cardiac surgery, such as double or triple valve surgery, CABG, aortic surgery, or septal myectomy in combination with AVR. This demonstrates the safety and efficacy of the sutureless aortic valve in complex aortic valve disease and additional cardiac procedures, particularly in elderly patients. A previous study reported that aortic cross-clamp time was an independent predictor of severe cardiovascular morbidity, with an increased risk of 1.4% per 1-minute increase. Therefore, the use of sutureless valves may have been advantageous in these cases due to the potential reduction in total cross-clamp time [22,23]. Based on our hemodynamic data, a key element is postoperative reverse remodeling. All patients underwent TTE at scheduled intervals. MPG was found to be lowered immediately after surgery, but the changes in EF and LVMI were most notable approximately 6 months postoperatively. This suggests that reverse remodeling took place at least 6 months after the operation. Furthermore, these changes were evident from 6 months to 1 year following surgery. Reverse myocardial remodeling after surgical AVR in patients with aortic stenosis has been shown on cardiac magnetic resonance at 1 year of follow-up [24].

In conclusion, our midterm results indicate that sutureless valves in the aortic position are a safe and feasible option for AVR in high-risk elderly patients. Furthermore, the postoperative hemodynamic changes observed in these patients are acceptable.

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Conceptualization: SH. Data curation: SH, YY. Investigation: JWS, YY. Formal analysis: JWS. Writing–original draft: SH. Writing–review & editing: SH. Supervision: JWS. Final approval of the manuscript: all authors.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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