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ORIGINAL ARTICLE
Surgery

Clinical and Hemodynamic Outcomes in 121 Patients Who Underwent Perceval Sutureless Aortic Valve Implantation

— Early Results From a Single Korean Institution —

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Background: This study aimed to evaluate the early outcomes of Perceval sutureless valves in the Korean population and to introduce a modified technique of guiding suture placement during valve deployment.

Methods and Results: From December 2014 to April 2019, 121 patients (mean age: 74.7±6.2 years; 53.7% female) received a Perceval sutureless aortic valve replacement. To prevent conduction system injury, the depth of guiding suture placement (1 mm below the nadir of the annulus) was modified. All patients underwent echocardiographic evaluation at discharge and 6–12 months postoperatively, with a mean follow up of 13.7±11.2 months. Concomitant surgeries, such as coronary artery bypass grafting, and other valvular surgeries, were performed in 45.5% of cases. The mean aortic cross-clamp times for isolated and minimal procedures were 32.8±7.9, and 41.2±8.0 min, respectively. The overall transvalvular mean gradients were 13.1±3.8 mmHg at discharge and 11.5±4.7 mmHg at the last follow up. After modifying the guiding suture placement, permanent pacemaker implantation risk decreased from 9.9% to 2.5%. Cardiac-related mortality was 0.8%, with no patient developing valvular or paravalvular aortic regurgitation, valve thrombosis, or endocarditis.

Conclusions: Perceval valve implantation provided a significant cardiac-related survival benefit with excellent early hemodynamic and clinical outcomes. Further research is needed to determine whether adjusting the implantation depth, such as modification of the guiding suture technique, can reduce the risk of permanent pacemaker implantation.

Key Words: Aortic valve; Pacemaker implantation; Perceval valve; Sutureless aortic valve replacement

Various new technical approaches have emerged as promising alternatives to conventional aortic valve replacement (AVR) for severe aortic stenosis in the elderly and high-risk patients with multiple comorbidities. Transcatheter aortic valve implantation (TAVI) and rapid deployment or sutureless AVR (SU-AVR) are among the most promising approaches.

Several studies on SU-AVR reported that this method could reduce the time of aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB). Moreover, SU-AVR facilitates the use of a minimally invasive approach and concomitant cardiac surgery, and it is associated with excellent hemodynamic and clinical outcomes.[1–6] However, SU-AVR is also associated with a considerably higher rate of permanent pacemaker implantation (PPI) than conventional AVR. Recent studies have proposed several surgical precautions and recommendations, including precise positioning of the guiding sutures or holder angle, evaluation of the extent of annular decalcification required, and reduction in inflation pressure, to avoid conduction disturbance.[7,8] Therefore, our study aimed to assess the early clinical and hemodynamic outcomes in 121 Korean single-institution patients with severe aortic stenosis who underwent Perceval SU-AVR and to introduce a modified guiding suture technique for reducing PPI after SU-AVR.

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Methods

Study Population

Between December 2014 and April 2019, 121 consecutive patients presenting with symptomatic severe aortic valve

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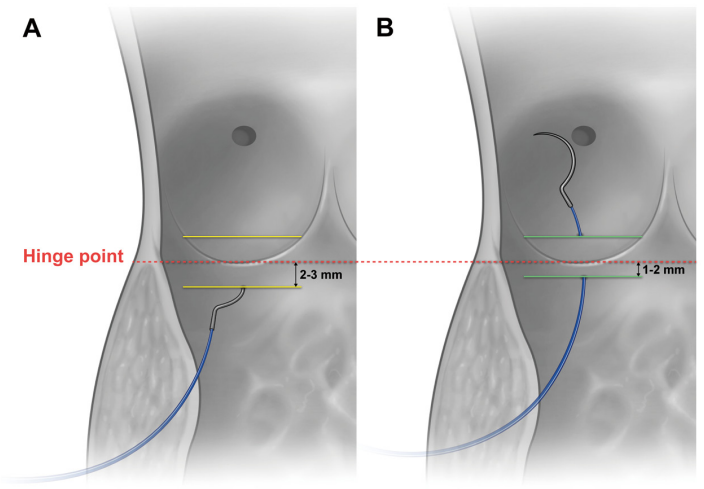

Figure 1. Guiding suture technique. (**A**) The general guiding sutures supported by Perceval user's guidelines were placed 2–3 mm below the nadir of the annulus (hinge point). (**B**) Our institution used the new technique placing the guiding sutures 1–2 mm below the annulus.

Table 1. Baseline Patient Characteristics

Variables	All (n=121)
Age (years)	74.7±6.2
Female	65 (53.7)
Body mass index (kg/m^2)	24.8±4.5
Body surface area (m^2)	1.63±0.19
EuroSCORE II (%)	3.0±4.3
STS risk score (%)	4.1±3.6
Smoking	24 (19.8)
Hypertension	99 (81.8)
Diabetes mellitus	43 (35.5)
Chronic renal failure	19 (15.7)
Cerebrovascular accidents	17 (14.0)
Chronic obstructive pulmonary disease	10 (8.3)
Coronary artery disease	54 (43.8)
Previous percutaneous coronary intervention	25 (20.7)
Peripheral arterial disease	7 (5.8)
Previous cardiac surgery	12 (9.1)
NYHA class III–IV	77 (63.6)
Sinus rhythm	99 (81.8)
Atrial fibrillation/flutter	17 (14.0)
Left bundle branch block	2 (1.7)
Right bundle branch block	9 (7.4)
Paced rhythm	4 (3.3)
Aortic valve etiology	
Degenerative	101 (83.5)
Congenital bicuspid	11 (9.1)
Rheumatic	7 (5.8)
Prosthetic valve failure	2 (1.7)

Values are presented as mean±standard deviation or n (%). EuroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; STS, Society of Thoracic Surgery Risk Score.

stenosis or steno-insufficiency underwent SU-AVR using Perceval bioprosthesis (LivaNova, Saluggia, Italy). The patients were retrospectively reviewed at the Severance Cardiovascular Hospital, Yonsei University College of Medicine. Patients with active endocarditis, dilated aortic annulus (>28 mm), or true bicuspid aortic valve (type 0) were excluded from undergoing Perceval aortic implantation. This study was approved by the institutional review board of Yonsei University College of Medicine (IRB number: 4-2020-0287). The requirement for informed patient consent was waived due to the retrospective nature of the study.

Surgical Technique

After median or partial upper sternotomy, CPB was performed under mild hypothermia (32.0°C). Transverse aortotomy was performed approximately 3.5 cm above the annulus in all patients. After excision of the aortic valve leaflet and decalcification of the annulus, we inserted 3 guiding sutures into the midpoint of each intercommissural zone (the nadir portion of each annulus). The guiding sutures were placed 2–3 mm below the nadir of the annulus. We speculate that by using this general guiding suture technique, the implantation depth (the distance from the annulus to the bottom of the sealing collar) may exceed 6 mm, which may cause conduction disturbance, thus requiring PPI. Although not currently supported by Perceval implantation user guidelines, modified guiding sutures (placement 1–2 mm below the annulus) have been used consistently at our institution since September 2018 (**Figure 1**). We determined the prosthesis size by measuring the aortic annulus using manufacturer-specific annular valve sizers. Once the prosthesis was accurately placed, the guiding sutures were removed, and the valve was dilated with a low-pressure balloon catheter for 30 s under 4 atmospheric pressure with warm saline irrigation. After confirmation of proper implantation, the aortotomy was closed. After weaning from CPB, intraoperative transesophageal echocardiography was performed to confirm the correct positioning of the bioprosthesis and to assess for the presence of paravalvular leakage (PVL).

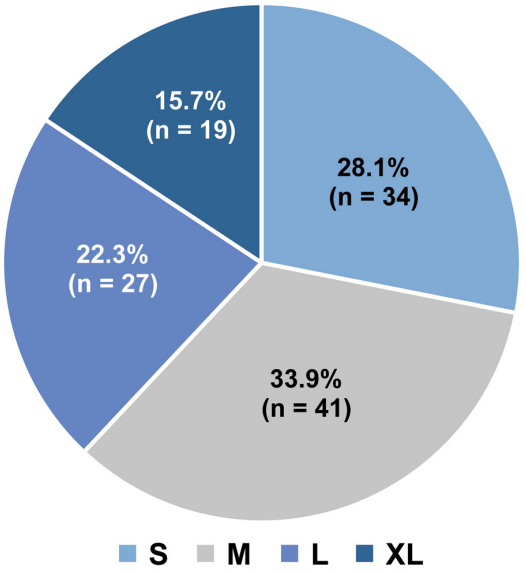

Figure 2. Number of patients per implanted valve size. S, small; M, medium; L, large; XL, extra-large.

Table 2. Perioperative Characteristics

Variables	All (n=121)
Isolated AVR	66 (54.5)
Minimal invasive approach	27 (22.3)
Concomitant procedures	
Coronary artery bypass	30 (24.8)
Mitral surgery	11 (9.1)
Tricuspid surgery	13 (10.7)
Ascending aorta	4 (3.3)
Surgical ablation	2 (1.7)
Miscellaneous procedures	7 (8.6)
Cardiopulmonary bypass time (min)	91.4±42.8
Isolated AVR	64.2±13.0
Full-sternotomy, isolated	59.4±12.2
Mini-sternotomy, isolated	70.5±11.3
Aortic cross-clamp time (min)	57.4±37.9
Isolated AVR	36.4±8.9
Full-sternotomy, isolated	32.8±7.8
Mini-sternotomy, isolated	41.2±8.0

Values are presented as mean±standard deviation or n (%). AVR, aortic valve replacement.

Follow up

Transthoracic echocardiography was performed preoperatively, immediate postoperatively, and at the last follow up (postoperatively between 6 and 12 months). Hemodynamic parameters were assessed by 2-dimensional M-mode. Transvalvular pressure gradients (TVPG) were calculated using the modified Bernoulli equation.[9] Prosthetic valve regurgitation was assessed by using color flow Doppler, and the severity was classified as mild, moderate, moderately severe, or severe, as previously described.[10] Outpatient clinic examinations were performed along with each echocardiographic assessment. We retrospectively collected follow-up data from the cardiac and heart valve research database of the institution, as well as from surviving patients' interviews regarding their adverse postoperative events.

Statistical Analysis

Continuous variables are expressed as mean±standard deviation. Categorical variables are presented as numbers with percentages. Survival analyses were performed by using the Kaplan-Meier method, with 95% confidence intervals. The Wilcoxon signed-rank test was used to compare echocardiographic data based on TVPG and left ventricular mass index (LVMI). Additionally, we compared the 2 subgroups with or without the new guiding suture technique and performed logistic regression analysis to identify the risk factors for PPI within 30 days post-surgery. Variables for the multivariate regression model were required to have clinical relevance, including patient characteristics (**Table 1**), and surgical factors (combined procedures, ACC and CPB time, modified guiding sutures, type of surgeon, valve size, and learning curve), and a P value <0.2 upon univariate analysis. A P value of <0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp, Armonk, NY, USA).

Results

Patient Characteristics

Detailed baseline characteristics of the patients are presented in **Table 1**. The mean age was 74.7±6.2 years (range, 64–86 years); 28.9% (n=35) of patients were octogenarians, and 53.7% were female. The mean Society of Thoracic Surgeons (STS) score and EuroSCORE II-predicted mortality rates were 4.1±3.6% and 3.0±4.3%, respectively. Twelve patients (9.1%) had previously undergone cardiac surgery. Moreover, subgroups were divides into G group with the general guiding sutures (n=81) and N group with new guiding sutures (n=40). The patients who received the general guiding suture technique tended to have a higher prevalence of coronary artery disease (P=0.078), smoking (P=0.057), and older age (P=0.059) than the patients who received the new guiding suture technique. The STS score and New York Heart Association functional class III–IV were higher in the G group (**Supplementary Table 1**).

Operative Data

The implant sizes are shown in **Figure 2**. Valves size S (19–21 mm) or M (21–23 mm) were implanted in 62% of the patients (n=75). Isolated AVR was performed in 66 patients (54.5%), and concomitant procedures were performed in 55 patients (45.5%). Among patients who underwent isolated AVR, 27 patients had a partial upper sternotomy as a minimally invasive approach. The mean ACC time was 32.8±7.8 min for full sternotomy and 41.2±8.0 min for mini-sternotomy. In 55 patients who had SU-AVR with concomitant procedures, coronary bypass surgery was the most frequent. The perioperative characteristics are summarized in **Table 2**. All Perceval SU-AVR was conducted successfully without conversion to conventional AVR surgery; however, 2 patients required intraoperative repositioning of the valve due to PVL from mispositioning very early during surgery.

Table 3. Early Clinical Outcomes

Variables	All (n=121)
Reoperation for bleeding	3 (2.5)
Renal failure	6 (5.0)
Stroke	2 (1.7)
Thrombocytopenia (<50×10³/μL)	14 (11.6)
Postoperative atrial fibrillation	15 (12.4)
Permanent pacemaker implantation	9 (7.4)
Prosthesis-patient mismatch, moderate†	20 (16.5)
Paravalvular leakage	
Trivial-mild	2 (1.7)
Moderate-severe	0 (0)
Prosthetic-related thrombosis	0 (0)
In-hospital mortality	2 (1.7)
All-cause mortality	9 (7.4)
Cardiac mortality	1 (0.8)

Values are presented as n (%). †Moderate prosthesis-patient mismatch was defined as 0.65<indexed effective orifice area≤0.85 cm²/m².

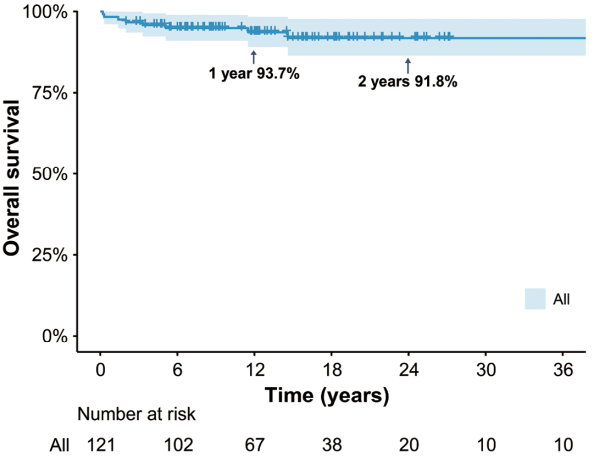

Figure 3. Kaplan-Meier survival analysis for the entire study population.

Table 4. Echocardiographic Data at Baseline, Discharge, and at Last Follow up

Variables	Baseline	Discharge	Last follow up	P value†	P value‡
Ejection fraction (%)	59.6±14.7	57.2±13.3	58.9±12.8	0.01	0.224
Effective orifice area (cm²)	0.76±0.22	1.87±0.48	1.84±0.51	<0.01	0.764
Indexed effective orifice area (cm²/m²)	0.47±0.14	1.15±0.29	1.14±0.28	<0.01	0.384
Aortic peak gradient (mmHg)	80.3±26.7	24.9±7.3	22.3±8.7	<0.01	0.006
Aortic mean gradient (mmHg)	48.8±17.5	13.1±3.8	11.5±4.7	<0.01	0.003
Left ventricular mass index (g/m²)	143.5±36.4	126.3±31.3	110.8±30.8	<0.01	<0.001

Values are presented as mean±standard deviation. †Baseline vs. Discharge, ‡Discharge vs. Last follow up.

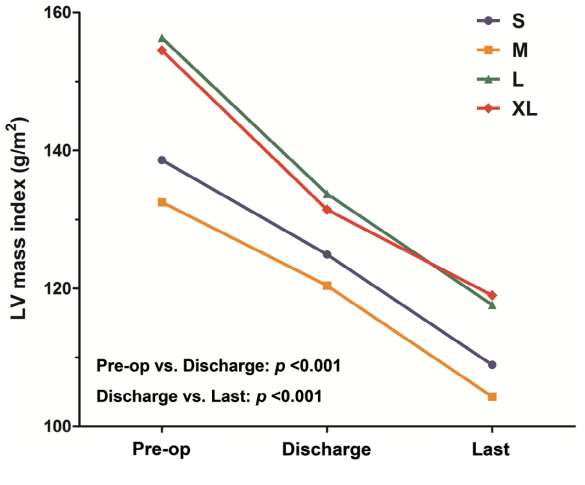

Figure 4. Left ventricular mass index (LVMI) preoperatively (pre-op), at discharge, and at last follow up. Overall, LVMI (g/m²) decreased from 143.5±36.4 before surgery to 110.8±30.8 at the last follow up (P<0.001). S, small; M, medium; L, large; XL, extra-large.

Clinical Outcomes

As shown in **Table 3**, in-hospital mortality was observed in 2 patients who died of aspiration pneumonia and an ischemic limb complication. Patients were followed for 13.7±11.2 months (maximum of 4 years). During follow up, 7 late deaths were reported due to gastrointestinal bleeding, pneumonia, or sepsis, and cardiac-related deaths occurred in 0.8% of patients. The overall postoperative survival rates were 93.7±3.1% at 1 year and 91.8±4.2% at 2 years (**Figure 3**).

Postoperative PPI was required in 9 patients (7.4%) following SU-AVR because of newly developed arrhythmia, including atrioventricular block. Since September 2018, the changes in our guiding suture technique (change of guiding suture site on the left ventricle side depth from 2–3 mm to 1–2 mm) have shown a tendency to decrease the PPI rate, but no significant difference was seen between the subgroups (G group, 9.9% vs. N group, 2.5%, P=0.146). On multivariate analysis, the presence of a preoperative right bundle branch block and age >80 years were independently associated with postoperative PPI (odds ratio [OR] 7.810, P=0.039 and OR 4.754, P=0.048), whereas the new guiding suture technique and the type of surgeon were not related to PPI (**Supplementary Table 2**).

Furthermore, only 1.7% of patients had mild aortic regurgitation. Until the last follow up, no patient developed moderately severe aortic regurgitation. Thrombocy-

topenia (platelet count less than $50\times10^3/\mu L$) was observed in 14 patients (11.6%), and platelet count in most patients had spontaneously recovered by the time of discharge; however, 3 patients required platelet transfusions because of the postoperative decrease in platelet count until the third day. None of the patients developed valve thrombosis or endocarditis.

Hemodynamic Outcomes

At the last follow up, echocardiography was performed for 89.3% of the enrolled patients. Hemodynamic outcomes are listed in **Table 4**. The peak and mean TVPG decreased from 24.9±7.3 mmHg and 13.1±3.8 mmHg at discharge to 22.3±8.7 mmHg and 11.5±4.7 mmHg at the last follow up, respectively. Paired comparisons of TVPG for each valve size are presented in **Supplementary Figure**. Additionally, the effective orifice area (EOA) was 1.87 cm^2/m^2 at discharge. There was no patient with severe prosthesis patient mismatch (PPM), whereas moderate PPM occurred in 16.5%. LVMI also decreased from a preoperative value of 143.5 g/m^2 to 110.8 g/m^2 at the last follow up (**Figure 4**). TVPG and LVMI exhibited significant changes from baseline to discharge and at the last follow up ($P<0.05$ for all).

Discussion

We made 3 crucial observations in our single-center study. First, the implantation of the Perceval valve reduced the ACC and CPB times significantly. Second, the Perceval SU-AVR provided favorable short-term outcomes in terms of hemodynamic characteristics and reversed left ventricular (LV) remodeling. Third, the incidence of PPI tended to decrease dramatically after using the modified guiding suture technique.

Recent studies[4–6] demonstrated that Perceval SU-AVR could shorten the procedure times, which could lead to decreased mortality and morbidity, especially in high-risk patients with advanced age and multiple comorbidities. Because increased ACC time is a significant independent predictor of cardiovascular morbidity,[11] the reduction in ACC time during minimally invasive surgery[12] or combined multiple valvular surgery[1] makes Perceval SU-AVR an attractive therapeutic option to conventional AVR. In our study, the ACC time was 32.8 min. In addition, mitral and/or tricuspid valve surgery was performed in 32.7% of the patients undergoing concomitant cardiac procedures, with a mean ACC time of 79.2 min. These ACC times are similar to the ACC times reported by previous studies.[3,6,13] It is likely that shortened ACC and CPB times reduced the surgical stress in high-risk elderly patients and resulted in favorable early hazard outcomes as shown by acceptable cardiac-related mortality in our study.

Perceval SU-AVR has been designed to enable faster and easier implantation and to provide better hemodynamic performance, with a stable reduction in TVPG in all valve sizes and better regression in LV mass. We found that the postoperative TVPG and LVMI were notably reduced, even in patients with a small aortic annulus. Similarly, Shrestha et al[5] showed that patients who underwent SU-AVR with small Perceval valves had low postoperative TVPG that remained stable up to the 5-year follow up. They also recorded an EOA of 1.49 cm^2/m^2 at discharge or after 1 month, 1.55 cm^2/m^2 at 12 months, up to 1.80 cm^2/m^2 at 5 years. Greater EOA may potentially result in better hemodynamics even without aortic root enlargement. Furthermore, Villa et al[14] have reported that early and late hemodynamic gradients were similar between the small- and large-sized sutureless valves. Therefore, Perceval SU-AVR might maximize the blood flow regardless of the valve size, which is probably due to the absence of bulky sutures and the fact that they rely on a self-anchoring system that fits precisely in the annulus. This indicates that the Perceval SU-AVR can be expected to perform well even in Asian patients with a small body surface area.

However, the frequency of PPI remains high after SU-AVR. The self-expanding Nitinol frame of Perceval valves compresses the LV outflow tract, potentially damaging the atrioventricular conduction tissue. The overall incidence of PPI in our study was 7.4%, slightly lower than that reported in the multicenter German Aortic Valve Registry.[15] The reported incidence of PPI in the rapid deployment valve group was 8.8% and 3.7% in the conventional AVR group. The valve size, age, annular calcification, and preoperative rhythm disturbance (right or left bundle branch block and first-degree atrioventricular block) are well-demonstrated risk factors for PPI after AVR.[16,17] A recent study by Vogt et al[18] showed that improved implantation strategies, including appropriate annular decalcification, precise positioning of guiding sutures, and reduced balloon insufflation pressure, resulted in lower PPI rates after SU-AVR.

Of these factors, we focused on the optimal implantation depth (defined as a distance from annulus to the bottom of the sealing collar) of Perceval valves, and we speculate that deeper implantation depth (>6 mm) may cause damage to the conduction system. These assumptions are further supported by the recent study by Yanagawa et al.[8] They used the modified technique placing the guiding sutures at the nadir of each cusp, thus reducing their PPI rate from 28% to 0%. As the penetrating bundle of His emerges just below the membranous septum (MS) at the LV surface, MS length equals the distance between the aortic annulus and His bundle. Perceval valves contain a self-expanding Nitinol stent with a high radial force that interacts with the tissue a few millimeters below the aortic annulus. Therefore, the conduction system may be compromised due to high pressure at the MS level during implantation. Similarly, several studies demonstrated that the MS length and implantation depth were predictors of conduction disturbance in patients treated with TAVI procedures.[19–21]

When the guiding sutures are used below the annulus 1 mm (new guiding suture technique), the maximum implantation depth will be 4.9 mm (S), 5.2 mm (M), 5.5 mm (L), and 5.8 mm (XL). In this study, only 1 patient (2.5%) required PPI, although no significant association was observed between the new guiding suture technique and PPI. To assess the effect of shallow implantation depth (<6 mm) in preventing conduction injury, further large-scale studies with accurate monitoring should be conducted. Additionally, selecting the appropriate valve size according to a patient's annulus size could be vital in preventing the need for PPI. Because our institution used the same strategy for complete decalcification and debridement of the aortic annulus between the initial and latter populations, we believe that a modified suture technique and proper valve size may play an important role in preventing conduction disorders.

SU-AVR has been introduced to overcome the drawbacks of TAVI and conventional surgical AVR. Although the application of TAVI has been expanded to intermediate- and low-risk patients through Placement of Aortic

Transcatheter Valves trials, significant PVL, early thrombosis in the younger population, and a higher rate of PPI remain major drawbacks of TAVI to date. Previously published reports demonstrated the rare incidence of PVL after SU-AVR compared with TAVI, whereas the rates of PPI were comparable or slightly superior to those of TAVI.[22–24] We are convinced that SU-AVR ensures the complete removal of the calcified aortic annulus through direct vision, which may lead to a reduced risk of PVL. Nevertheless, studies regarding valve durability in TAVI are limited. Using an animal model, Kiefer et al[25] reported that the structural changes in the aortic valve leaflets caused by crimping might impact valve durability. In contrast to aggressive valve crimping required for TAVI, Perceval sutureless valves only require collapsing, which does not affect the pericardial leaflets on their own. Therefore, we believe that the Perceval SU-AVR could provide superior durability. Recently, the clinical outcome of Perceval SU-AVR after 12 years was presented at the 2019 American Association for Thoracic Surgery meeting.[26] It was found to have excellent longevity, and no structural deterioration was observed.

Our study has several limitations. Most significantly, it was a non-randomized, single-center retrospective analysis. Because the patient cohorts were relatively small, certain confounding factors associated with postoperative morbidity or mortality might have been overlooked. Furthermore, the study lacked a control group, which could have allowed for assessing the benefits of the Perceval SU-AVR compared with the conventional AVR or TAVI. Not only was the number of patients low, but also the study had a relatively low occurrence of PPI (in only 9 patients). For these reasons, a multivariable logistic model was too unstable to identify predictors for PPI; hence, we could not account for multiple factors, such as the implantation depth, valve size, type of surgeon, and learning curve, related to the incidence of PPI. Therefore, further studies with larger patient cohorts are required to evaluate the impact of hemodynamic performance and long-term outcomes of Perceval SU-AVR in the Asian population and to identify the predictors for PPI.

The Perceval SU-AVR in Korean patients provided excellent early clinical and hemodynamic outcomes in all valve sizes. Even in patients requiring AVR with minimally invasive approaches or concomitant cardiac procedures, the use of SU-AVR allowed for shorter ACC times, which could reduce the rate of cardiac-related mortality. Additionally, because various implantation strategies are being used to prevent damage to the conduction system, further large-scale research is needed to prove the relation between implantation depth and PPI occurrence.

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Disclosures

The authors declare that there are no conflicts of interest. They received no funding or grants for this study.

IRB Information

This study was approved by the Institutional Review Board of Yonsei University College of Medicine (Reference number: 4-2020-0287).

Data Availability

We do not wish to share the de-identified participant data.

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Supplementary Files

Please find supplementary file(s);
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