Heart Surgery Forum 2025; 28(4): E327–E334
doi: 10.59958/hsf.8325
https://journal.hsforum.com/

Article

Echocardiographic Evaluation of Aortic Valve Replacement for Small Aortic Annulus: Comparison Between Sutureless and Stented Valves

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Submitted: 16 December 2024 Revised: 9 February 2025 Accepted: 19 February 2025 Published: 26 April 2025

Abstract

Background: Sutureless valves are gaining interest for aortic valve replacement in patients with small annuli; however, their effectiveness compared to traditional valves remains unclear. This study aimed to explore the clinical outcomes and hemodynamic performance of sutureless versus stented valves. **Methods**: In total, 190 patients underwent aortic valve replacement (AVR) at two hospitals from May 2019 to March 2022; 60 patients underwent AVR with Perceval S sutureless aortic valves S size (P group), and 130 underwent AVR with INSPIRIS RESILIA 19 mm (I-19 group) or 21 mm valves (I-21 group). We retrospectively reviewed and analyzed the patient characteristics and intra- and postoperative outcomes. **Results**: The mean cardiopulmonary bypass (CPB) and aortic cross-clamp (ACC) times were significantly shorter in the P group than in the I group. There were no significant differences in intensive care unit length of stay, hospitalization, and 30-day mortality. The echocardiographic evaluation showed no significant differences in prosthesis performances between the P group and I-19 group 4–7 days after surgery. However, the performance in the I-21 group significantly differed from that in the P group. At the 1 year follow-up, prosthesis performance in the P group was equivalent to that in the I-21 group. **Conclusions**: Surgical intervention with S size Perceval S sutureless valves is a safe and effective treatment for patients with a small aortic annulus and demonstrates superior intermediate-term hemodynamic performance.

Keywords

aortic valve replacement; sutureless valve; stented valve; small aortic annulus

Introduction

Aortic valve replacement (AVR) is reported to be the standard surgical treatment for severe aortic valve stenosis (AS) with excellent long-term clinical outcomes [1,2]. Furthermore, the INSPIRIS RESILIA bioprosthetic valve used for AVR is quite common. However, prolonged cardiopulmonary bypass (CPB) and aortic cross-clamp (ACC) times are associated with high postoperative mortality and morbidity [3,4]. To address this, sutureless and rapid-deployment valves were introduced in 2016 (Japan in 2019) to reduce short operative times and minimize surgical access [5,6]. Importantly, sutureless valves in aortic valve replacement (SUAVR) enable easy and rapid implantation and reduce the CPB and ACC times [7,8]. Based on the long-term studies, the non-inferiority of SUAVR was shown in terms of survival rate and freedom from device-related complications, such as reoperation and structural valve deterioration, compared to conventional prosthetic valve replacement [9,10]. Additionally, several studies have demonstrated the long-term functionality of sutureless valves after surgery [10,11]. A narrow aortic annulus makes it difficult to minimize the residual intravalvular gradient, which is the goal of AVR. This is because implantation of a small aortic valve may result in a high residual gradient despite normal functioning of the prosthesis. Furthermore, patients with a small aortic annulus, especially those with a large body surface area, are at high risk of prosthesis–patient mismatch, leading to poor clinical outcomes and reduced survival [12]. Therefore, in addition to AVR with the INSPIRIS RESILIA bioprostheses, annular enlargement surgery is required for a narrow annulus. However, for older high-risk patients who are unable to tolerate annular enlargement, a viable option is to implant a small INSPIRIS RESILIA bioprosthetic. The usefulness of SUAVR in patients with a small aortic annulus has garnered interest [13,14]. Although some reports have compared SUAVR and various conventional stented valves for these patients [15,16], no study has directly compared SUAVR with a single type of traditional stented valves. Therefore, this study aimed to compare the clinical outcomes

and hemodynamic performance of the sutureless Perceval S valve (LivaNova, London, UK) with conventional stented valves in patients with a small aortic annulus (≤21 mm).

Subjects

We retrospectively reviewed 190 patients who underwent AVR at Teikyo University Hospital and Sakakibara Heart Institute between May 2019 and March 2022. Of these, 60 underwent SUAVR with the Perceval prosthesis S size (P group), and 130 underwent AVR with INSPIRIS RESILIA 19 mm or 21 mm (Edwards Lifesciences, Irvine, CA, USA) (I group). In the I group, a 19 mm implant was used in 33 patients (25.4%) (I-19 group), and a 21 mm implant was used in 97 patients (74.6%) (I-21 group). The preoperative data are summarized in Table 1. The operative risk was estimated according to the Society of Thoracic Surgeons (STS) score (http://riskcalc.sts.org/stswebriskcalc/calculate) and the European System for Cardiac Operative Risk Evaluation II (EuroScore II https://www.euroscore.org/). All subjects enrolled in this research provided informed consent, which, alongside the study design, was approved by the Institutional Committees on Human Research at Teikyo University and Sakakibara Heart Institute (Approval number: 20-182 2020/11/6, 24-022 2024/7/23).

Table 1. Characteristics of baseline patients.

	P group (n = 60)	I group (n = 130)	*p*-value
Age, y	77.4 ± 4.5	75.3 ± 8.1	0.065
Female gender	54 (90.0)	117 (90.0)	1.000
BSA, m^2	1.43 ± 0.12	1.45 ± 0.13	0.268
BMI, kg/m^2	23.1 ± 4.2	21.9 ± 3.6	0.053
Hypertension	50 (83.3)	99 (77.3)	0.345
Diabetes	18 (30.0)	17 (13.3)	0.008
Dyslipidemia	41 (68.3)	62 (48.4)	0.457
Chronic kidney disease	33 (55.0)	42 (36.8)	0.004
Antiplatelet therapy	22 (36.7)	21 (16.5)	0.003
Anticoagulant therapy	6 (10.0)	20 (15.8)	0.371
Previous PCI	11 (18.3)	6 (4.7)	0.005
Cerebral infarction	24 (41.4)	35 (31.0)	0.091
Carotid artery stenosis	15 (25.4)	5 (4.5)	<0.001
STS score, %	3.95 (2.78–6.33)	3.40 (2.43–5.95)	0.147
EuroSCORE II, %	2.39 (1.49–4.33)	3.16 (1.49–6.21)	0.214

Unless noted otherwise, data are the mean ± SD or n (%). Abbreviations: BMI, body mass index; BSA, body surface area; PCI, percutaneous coronary intervention; SD, standard deviation; STS, Society of Thoracic Surgery.

Methods

Surgical Technique

The operation was performed under general anesthesia. The typical surgical procedures are described as follows. Patients with isolated AVR underwent right anterior thoracotomy (RAT) or three-dimensional-endoscopic minimally invasive cardiac surgery (3D-MICS). Patients who underwent concomitant surgical procedures, including aortic surgery, coronary artery bypass grafting (CABG), other valve surgery, and arrhythmia surgery, underwent total median sternotomy. Patients with Sievers type 0, patients whose ST junction is 1.4 times larger than the aortic annulus, and patients with concomitant aortic surgery were implanted with an INSPIRIS RESILIA valve. In addition, INSPIRIS RESILIA valves were often used for multiple valve procedures. Perceval S prosthesis valves were usually used for patients aged 75 years or older. Patients who underwent RAT and 3D-MICS were mainly implanted with Perceval S prostheses valves. After removing the valve and decalcifying the annulus using a Cavitron Ultrasonic Surgical Aspirator (CUSA: Integra Lifesciences Corporation, NJ, USA) and a rongeur, sizing was performed using dedicated sizers, as dictated by the manufacturer. Implantation of the Perceval S prosthesis was aided by three guiding sutures placed at the nadir of each sinus. After device deployment and verification of the correct intra-annular position of the prosthesis, balloon inflation was performed for 30 seconds. Correct prosthesis implantation was confirmed using intraoperative transesophageal echocardiography. SUAVR was performed after concomitant cardiac surgery.

Study Variables, Operative Outcomes, and Clinical Endpoints

Patient characteristics, surgical procedures, and intra- and postoperative outcomes were recorded. Follow-up data were obtained from the clinical records at our institutions. All data and variables were compared, including operation time, CPB time, ACC time, and concomitant procedures. Additionally, parameters such as peak pressure gradient (pPG), mean pressure gradient (mPG), peak flow velocity (Vmax), effective orifice area (EOA), effective orifice area index (EOAi), ejection fraction (EF), prosthetic patient mismatch (PPM) and paravalvular leak (PVL) (as shown in Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research [17]) were evaluated using transthoracic echocardiography on postoperative days 4–7 (early after surgery) and 1 year after surgery.

Statistical Analysis

Our data were summarized by the calculation of means and standard deviations for normally distributed variables, medians and interquartile ranges for non-normally distributed variables, and frequency and percentage for categorical variables. The Shapiro-Wilk test was used to assess the normal distribution of continuous variables. Differences between the two groups were examined using unpaired *t*-

Table 2. Intraoperative characteristics.

		P group (n = 60)	I group (n = 130)	*p*-value
Operation time, min		234 (182–300)	230 (182–310)	0.803
CPB time, min		112 (81–165)	132 (107–181)	0.009
ACC time, min		78 (53–119)	100 (77–130)	0.007
Surgical approach	Median sternotomy	40 (66.7)	113 (86.9)	0.002
	Mini thoracotomy	20 (33.3)	17 (13.1)	
Concomitant procedure	All	31 (51.7)	89 (68.5)	0.035
	CABG	25 (41.7)	27 (20.8)	0.005
	Multiple valve procedure	8 (13.3)	35 (26.9)	0.041
	Aortic surgery	0 (0)	30 (23.1)	<0.001
	Others	7 (11.7)	30 (23.1)	0.077

Unless noted otherwise, data are the mean ± SD or n (%). Abbreviations: ACC, aortic cross-clamp; CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass time.

test or the Mann–Whitney U test for continuous variables and chi-square test for categorical variables. A *p*-value of less than 0.05 was regarded as significant. All statistical analyses were performed using JMP Pro 17.0 for Windows (SAS Institute, Cary, NC, USA).

Results

Preoperative Characteristics

Table 1 summarizes the baseline characteristics of the P and I groups (average age, 77.4 ± 4.5 and 75.3 ± 8.1 years old [$p = 0.065$], respectively; Table 1). The mean STS score and EuroSCORE II were 3.95% (2.78–6.33) and 2.39% (1.49–4.33) in the P group, respectively, and 3.40% (2.43–5.95) [$p = 0.147$] and 3.16% (1.49–6.21) [$p = 0.214$] in the I group, respectively. The P group had significantly more cases of diabetes, dyslipidemia, chronic kidney disease, antiplatelet therapy, and previous percutaneous coronary intervention [$p < 0.05$].

Intraoperative Characteristics

Intraoperative characteristics are reported in Table 2. There was no significant difference in the operation time [$p = 0.803$]. Importantly, average CPB time and ACC time were significantly shorter in the P group than those in the I group (112 (81–165) min versus 132 (107–181) min [$p = 0.009$] and 78 (53–119) min versus 100 (77–130) min [$p = 0.007$], respectively; Table 2). Regarding the surgical approach, median sternotomy was performed in 40 (66.7%) and 113 (86.9%) of the patients in the P and I groups [$p = 0.002$], respectively. The overall rate of concomitant procedures was lower in the P group than in the I group (31 patients (51.7%) in the P group versus 89 patients (68.5%) in the I groups [$p = 0.035$]), and the number of patients who underwent multiple valve procedures was higher in the P group (8 patients (13.3%) in the P group versus 35 patients (26.9%) in the I groups [$p = 0.041$]). However, the rate of CABG as a concomitant procedure significantly differed between the groups (25 patients (41.7%) in the P group and 27 patients (20.8%) in the I group [$p = 0.005$]).

Early and Midterm Clinical Outcomes

The postoperative early clinical outcomes are reported in Table 3. There were no significant differences in intensive care unit length of stay, hospitalization, and 30-day mortality between the P and the I group (2 (1–3.5) days versus 3 (2–4.3) days [$p = 0.107$]; 15 (11–24) days versus 15 (11–21) days [$p = 0.310$]; 0% and 4.6% [$p = 0.179$], respectively; Table 3).

Additionally, no operative complications such as revisions for bleeding, valve thrombosis, prosthetic valve dysfunction, and infective endocarditis occurred in the P and I groups during the 1 year post-surgery. One patient (1.9%) in the P group required permanent pacemaker implantation (PMI) during the follow-up.

Hemodynamic Outcomes

The hemodynamic results are reported in Tables 4-1,4-2,4-3. In Table 4-2, the number of patients in the first year following surgery decreased because some patients did not visit the clinic. The echocardiographic evaluation showed that the mPG of the P and I groups early after surgery were 14.7 ± 5.3 mmHg and 11.8 ± 3.8 mmHg [$p < 0.001$], respectively (Table 4-1). However, no significant differences were observed in the mPG between the P and I-19 groups (14.7 ± 5.3 mmHg and 14.0 ± 4.0 mmHg [$p = 0.456$], respectively). This trend was similar for pPG, Vmax, EOA, and EOAi. At the 1-year follow-up, the echocardiographic evaluation showed the mPG of the P group and I group was 12.2 ± 4.6 mmHg and 12.7 ± 4.7 mmHg [$p = 0.577$], respectively (Table 4-2). However, mPG showed a significant difference between the P group and I-19 group (12.2 ± 4.6 mmHg versus 15.0 ± 6.2 mmHg [$p = 0.014$], respectively) but showed no significant difference between the P

Table 3. Postoperative early clinical outcomes.

		P group (n = 60)	I group (n = 130)	*p*-value
ICU length of stay, day		2 (1–3.5)	3 (2–4.3)	0.107
Hospitalization, day		15 (11–24)	15 (11–21)	0.310
30-day mortality		0 (0)	6 (4.6)	0.179
Complications	Revision for bleeding	1 (1.7)	6 (4.6)	0.435
	Stroke	0 (0)	5 (3.8)	0.182
	Myocardial infarction	0 (0)	1 (0.8)	1.000
	Vascular events	2 (3.3)	3 (2.3)	0.652
	Permanent pacemaker	4 (6.7)	4 (3.1)	0.264
	NOMI	0 (0)	1 (0.8)	1.000
	Deep wound infection	1 (1.7)	1 (0.8)	0.533
	Pneumonia	1 (1.7)	3 (2.3)	1.000

Unless noted otherwise, data are the mean ± SD or n (%). Abbreviations: ICU, intensive care unit; NOMI, non-occlusive mesenteric ischemia.

Table 4-1. Echocardiographic evaluation early after surgery.

		P group (n = 60)	I group (n = 124)	*p*-value	I group (19 mm) (n = 30)	*p*-value	I group (21 mm) (n = 94)	*p*-value
Peak pressure gradient, mmHg		29.6 ± 10.6	23.9 ± 7.2	<0.001	27.6 ± 7.4	0.390	22.7 ± 7.6	<0.001
Mean pressure gradient, mmHg		14.7 ± 5.3	11.8 ± 3.8	<0.001	14.0 ± 4.0	0.456	11.1 ± 3.4	<0.001
Peak flow velocity, cm/s		268.5 ± 46.2	241.4 ± 35.9	<0.001	259.3 ± 34.4	0.343	235.5 ± 34.6	<0.001
Effective orifice area, cm^2		1.50 ± 0.28	1.68 ± 0.32	0.001	1.54 ± 0.31	0.733	1.73 ± 0.30	<0.001
Effective orifice area index, cm^2/m^2		1.06 ± 0.21	1.17 ± 0.24	0.003	1.10 ± 0.24	0.717	1.19 ± 0.23	0.001
LVEF, %		58.7 ± 7.8	58.4 ± 7.6	0.804	58.8 ± 6.9	0.953	58.2 ± 7.9	0.701
PPM	Moderate	10 (16.7)	5 (4.0)	0.007	2 (6.7)	0.324	3 (3.2)	0.006
	Severe	0 (0)	0 (0)	-	0 (0)	-	0 (0)	-
PVE		1 (1.7)	1 (0.8)	0.547	0 (0)	1.000	1 (1.1)	1.000
PVL	Mild	1 (1.7)	13 (10.5)	0.038	2 (6.7)	0.257	11 (11.7)	0.029
	Moderate	0 (0)	0 (0)	-	0 (0)	-	0 (0)	-
	Severe	0 (0)	0 (0)	-	0 (0)	-	0 (0)	-

Unless noted otherwise, data are the mean ± SD or n (%). Abbreviations: LVEF, left ventricular ejection fraction; PPM, prosthetic–patient mismatch; PVE, prosthetic valve endocarditis; PVL, paravalvular leakage.

group and I-21 group (12.2 ± 4.6 mmHg versus 12.0 ± 4.0 mmHg [$p = 0.814$], respectively). This trend was similar for pPG and Vmax. Importantly, variables such as mPG, pPG, and Vmax in the P group during hospitalization were comparable to those in the I-19 group. One year after surgery, these variables in the P group were similar to those in the I-21 group.

No severe prosthetic–patient mismatch was noted in either group. Moderate PPMs were more common in the P group than in the I group early after surgery (10 patients (16.7%) versus five patients (4.0%) [$p = 0.007$], respectively), although, at the 1-year follow-up, the rate decreased to seven patients (13.0%) in the P group and increased to six patients (5.8%) in the I group [$p = 0.135$], respectively. Additionally, only one patient (1.7%) in the P group presented with PVL throughout the study period, whereas 13 patients (10.5%) [$p = 0.038$] and 11 patients (10.7%) [$p = 0.017$] presented with PVL at early and 1 year postoperatively, respectively, in the I group.

Discussion

We analyzed a two-center retrospective cohort study, including clinical and echocardiographic results of 190 patients undergoing AVR with the Perceval S sutureless aortic valve or conventional stented valve prosthesis. The main findings of the present study were that the hemodynamic performance early after surgery was comparable between the Perceval S prosthesis and INSPIRIS RESILIA 19 mm groups; however, SUAVR with Perceval S shows promise for better intermediate-term hemodynamics compared to 19 mm INSPIRIS RESILIA, achieving performance closer to the 21 mm INSPIRIS RESILIA valve. Additionally, as shown in Table 4-3, the Percival S valve significantly improved hemodynamic indicators of mPG and Vmax compared to those early after surgery. However, no such findings were observed with INSPIRIS RESILIA.

Table 4-2. Echocardiographic evaluation at postoperative 1 year.

		P group (n = 54)	I group (n = 103)	*p*-value	I group (19 mm) (n = 23)	*p*-value	I group (21 mm) (n = 80)	*p*-value
Peak pressure gradient, mmHg		24.5 ± 8.3	25.3 ± 9.0	0.589	29.5 ± 12.1	0.046	24.1 ± 7.6	0.744
Mean pressure gradient, mmHg		12.2 ± 4.6	12.7 ± 4.7	0.577	15.0 ± 6.2	0.014	12.0 ± 4.0	0.814
Peak flow velocity, cm/s		243.7 ± 41.4	248.3 ± 41.9	0.507	267.7 ± 49.4	0.043	242.8 ± 38.1	0.865
Effective orifice area, cm^2		1.52 ± 0.23	1.62 ± 0.28	0.032	1.39 ± 0.17	0.020	1.68 ± 0.28	0.001
Effective orifice area index, cm^2/m^2		1.07 ± 0.20	1.12 ± 0.22	0.124	1.00 ± 0.15	0.190	1.16 ± 0.22	0.010
LVEF, %		62.9 ± 3.6	62.0 ± 6.2	0.329	63.9 ± 3.8	0.364	61.5 ± 6.6	0.520
PPM	Moderate	7 (13.0)	6 (5.8)	0.135	2 (8.7)	0.710	4 (5.0)	0.118
	Severe	0 (0)	0 (0)	-	0 (0)	-	0 (0)	-
PVE		0 (0)	0 (0)	-	0 (0)	-	0 (0)	-
PVL	Mild	0 (0)	11 (10.7)	0.017	2 (8.7)	0.091	9 (11.3)	0.011
	Moderate	0 (0)	0 (0)	-	0 (0)	-	0 (0)	-
	Severe	0 (0)	0 (0)	-	0 (0)	-	0 (0)	-

Unless noted otherwise, data are the mean ± SD or n (%).

Table 4-3. Comparisons of echocardiographic evaluation between early post- and 1 year after surgery.

	P group	P group	*p*-value	I group (19 mm)	I group (19 mm)	*p*-value	I group (21 mm)	I group (21 mm)	*p*-value
	early post-surgery (n = 60)	1 year after surgery (n = 54)		early post-surgery (n = 30)	1 year after surgery (n = 23)		early post-surgery (n = 94)	1 year after surgery (n = 80)	
Mean pressure gradient, mmHg	14.7 ± 5.3	12.2 ± 4.6	0.009	14.0 ± 4.0	15.0 ± 6.2	0.554	11.1 ± 3.4	12.0 ± 4.0	0.185
Peak flow velocity, cm/s	268.5 ± 46.2	243.7 ± 41.4	0.003	259.3 ± 34.4	267.7 ± 49.4	0.477	235.5 ± 34.6	242.8 ± 38.1	0.272
Effective orifice area, cm^2	1.50 ± 0.28	1.52 ± 0.23	0.716	1.54 ± 0.31	1.39 ± 0.17	0.107	1.73 ± 0.30	1.68 ± 0.28	0.307

Unless noted otherwise, data are the mean ± SD or n (%).

The first finding of this study on the advantages of Perceval S implantation is that the mean CPB and ACC times in the P group with the Perceval bioprostheses were shorter than those in the I group with INSPIRIS RESILIA. As shown in Table 2, this finding could certainly be related to the larger proportion of mini-thoracotomy in the P group than in the I group (20 patients (33.3%) versus 17 patients (13.1%) [$p = 0.002$] respectively). Additionally, the ACC time was reported to be an independent predictor of severe cardiovascular morbidity with an increased risk of 1.4% per 1-minute increase [18]. The present study observed no 30-day mortality or significantly increased surgical complications in the P group. Although a direct comparison cannot be made, AVR with the Perceval S valve may be a sufficiently safe and effective treatment, considering that the P group included more patients with pre-existing diseases such as diabetes, dyslipidemia, and chronic kidney disease.

New-onset complete atrioventricular block (AVB) is a common post-AVR complication, with postoperative PMI required in 2–4% of patients following conventional AVR [19] and 10.5–12.1% after isolated sutureless AVR [10,20–22]. High pressure at the level of the membranous septum caused during valve deployment is reported to be the primary trigger [21,22]. This study found that the rate of PMI in the P group tended to be lower than in previous studies. Minimal annulus decalcification and placing the guiding sutures at the leaflet insertion line rather than at the cusp nadir may reduce PMI incidence [20,23]. However, further investigation is needed as one patient who underwent a PMI experienced new-onset complete AVB at the 1-year follow-up.

Our study is among the few that have focused on postoperative hemodynamic performance following sutureless AVR in patients with a small aortic annulus. As a comparison of postoperative hemodynamic performance, no significant differences were observed in prosthesis performance, such as pPG, mPG, Vmax, EOA, and EOAi, between the P group and I-19 group early after surgery. However, those in the I-21 group significantly differed from those in the P group. At the 1-year follow-up, pPG, mPG, and Vmax in the P group were equivalent to the I-21 group and better than the I-19 group. Judging from the result of the maintained EOA in our series, the Perceval S valve had a larger internal diameter of valve prosthesis due to the absence of a sewing ring and stent posts and gradually fitted the aortic annulus after surgery by exerting a self-expanding nature, which may have resulted in the suppression of deterioration in valve performance [10,11]. PPM in the P group decreased from 10 patients (16.7%) to seven patients (13.0%) at the 1-year follow-up and showed no significant difference from the I-21 group, suggesting that maintaining EOA could affect the incidence of PPM [13]. EOAi in the P group did not deteriorate despite the reduction in EOAi in the I group during follow-up, suggesting that the self-expanding nature of the Perceval S valve may reduce moderate PPM. A PVL incidence occurred in one patient (1.7%) early postoperatively and in 0% at the 1-year follow-up, consistent with previous studies [10,24]. The PVL of sutureless valves, caused by a slight gap due to the absence of a sewing ring, was mitigated by sufficient leaflet resection and annulus decalcification. Considering the previous studies and our study, these data suggest that using Perceval S in patients with a small aortic annulus may reduce the risk of PPM and PVL, leading to better long-term hemodynamic performance with a larger EOA, although further evidence is necessary.

Study Limitations

Our study had several limitations. First, this report consisted of a non-randomized and retrospective analysis of existing data with significant differences in preoperative characteristics, such as pre-existing diseases, shown to be independent predictors of cardiac and overall mortality. This is one of the most significant limitations of this study. Second, the sample size was relatively small. Finally, the follow-up period was relatively short. Further investigation of patients will provide assessments of the long-term valve performance.

Conclusions

The Perceval S sutureless valve is a safe and effective treatment option for patients with a small aortic annulus, demonstrating superior intermediate-term hemodynamic performance compared to conventional stented bioprostheses. The improved hemodynamics of the Perceval S valve make it a favorable alternative for achieving better patient outcomes.

Availability of Data and Materials

Data used to support the findings of this study are available from the corresponding author upon request.

Author Contributions

HU, MU, YM, NO, TIm, TIw, and TS designed the study, analyzed the data, and wrote the manuscript. HU, MU, YM, NO, and TIw helped gather patient information and analyzed the data. All authors have participated sufficiently in the work. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

The study was carried out in accordance with the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of the institutional committees on human research of Teikyo University and Sakakibara Heart Institute (Protocol No. 20-182 2020/11/6, 24-022 2024/7/23). All subjects enrolled in this research gave their informed consent.

Acknowledgment

We would like to thank Editage (https://www.editage.com) for the English language editing.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

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