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Article

Early Outcomes of Aortic Valve Replacement with Sutureless and Rapid Deployment Prostheses in Dialysis Patients

Hiroo Uehara[1], Naomi Ozawa[1,*], Masateru Uchiyama[1], Tomohiro Iwakura[2], Tomohiro Imazuru[1], Tomoki Shimokawa[1]

[1]Department of Cardiovascular Surgery, Teikyo University Hospital, 173-8605 Tokyo, Japan
[2]Department of Cardiovascular Surgery, Sakakibara Institute, 183-0003 Tokyo, Japan
*Correspondence: naozawa@med.teikyo-u.ac.jp (Naomi Ozawa)

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Abstract

Background: Although sutureless aortic valve replacement is rising in popularity, there are few reports on its use in patients on dialysis. This study aimed to investigate the early and mid-term surgical outcomes of the procedure in these patients. **Methods**: Twenty-one dialysis (mean age, 77.4 ± 5.2 years) patients with aortic stenosis who underwent aortic valve replacement with sutureless and rapid deployment prostheses between May 2019 and March 2021 were enrolled. We retrospectively reviewed and analyzed the clinical courses of all dialysis patients. Data on patient characteristics, surgical procedures, and postoperative outcomes (survival times and major adverse cardiac and cerebrovascular events) were collected. The mean follow-up duration was 371 days (interquartile range (IQR) 364–399). **Results**: Two (9.5%) operative deaths occurred within 30 days of surgery. The 1-year survival was 85.7%, and the rates of freedom from cardiac death, myocardial infarction, and stroke were 95.0%, 89.7%, and 95.0%, respectively. 1 year freedom from major adverse cardiac and cerebrovascular events was 67.8%. There was one (5.5%) permanent pacemaker implantation 9 months after surgery. No reoperations were performed for any cause. Three patients had moderate prosthesis-patient mismatch 4–7 days after surgery. Effective orifice area index improved from 0.74 cm^2/m^2 to 0.87 cm^2/m^2 in one patient 1 year after surgery. No cases of structural valve deterioration or a paravalvular leak were observed. **Conclusions**: Sutureless aortic valve replacement in dialysis patients may be a novel treatment strategy with lower early mortality rates comparable to those of conventional treatments, increased freedom from pacemaker implantation, and good valve function.

Keywords

aortic valve replacement; sutureless bioprosthetic valves; dialysis

Introduction

Currently, two main surgical treatments are available for patients with aortic stenosis (AS): surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR). AS is one of the most common valve diseases in dialysis patients. SAVR has become the standard of care for severe calcific aortic stenosis. However, many suffer from high surgical morbidity and mortality. TAVR is regarded as a less invasive procedure; however, the patient criteria used are controversial in terms of superior hemodynamics and durability [1]. Both SAVR and TAVR are now becoming feasible in dialysis patients. Conversely, SAVR is more invasive than TAVR with respect to operation time and bleeding; however, it results in less paravalvular leakage and has fewer requirements for permanent pacemaker implantation [2]. Additionally, SAVR may have an added advantage as a less invasive surgical procedure for high-risk patients, including those on dialysis, if the associated operation time is shortened [3,4]. Recently, sutureless bioprosthetic valves that eliminate the need for sutures in the aortic annulus (AA, except for three guiding stitches) in aortic valve replacement (AVR) have been developed to reduce cardiopulmonary bypass (CPB) time and complications, particularly in high-risk patients [5]. Several studies have reported the clinical outcomes of sutureless aortic valve replacement (SUAVR) in older patients [6–8]. However, few studies have focused on the outcomes of AVR with sutureless valves in patients on dialysis. Therefore, this study aimed to investigate the early and mid-term surgical outcomes of SUAVR in patients on dialysis.

Subjects

In total, 136 patients with moderate or severe AS underwent AVR with sutureless bioprosthetic valves at Teikyo University Hospital and Sakakibara Heart Institute, Japan between April 2019 and March 2021. Sutureless bioprostheses included the Perceval (LivaNova, Saluggia, Italy) and INTUITY Elite (Edwards Life Sciences, Irvine, CA,

Table 1. Definition of prosthetic valve dysfunction.

Structural valve deterioration	
Moderate hemodynamic SVD (any of the following)	
1. Mean transprosthetic gradient ≥20 mmHg and <40 mmHg	
2. Mean transprosthetic gradient ≥10 and <20 mmHg change from baseline	
3. Moderate intra-prosthetic aortic regurgitation, new or worsening (>1+/4+) from baseline	
Severe hemodynamic SVD (any of the following)	
1. Mean transprosthetic gradient ≥40 mmHg	
2. Mean transprosthetic gradient ≥20 mmHg change from baseline	
3. Severe intra-prosthetic aortic regurgitation, new or worsening (>2+/4+) from baseline	
Morphological SVD (any of the following)	
1. Leaflet integrity abnormality (i.e., torn or flail causing intra-frame regurgitation)	
2. Leaflet structure abnormality (i.e., pathological thickening and/or calcification causing valvular stenosis or central regurgitation)	
3. Leaflet function abnormality (i.e., impaired mobility resulting in stenosis and/or central regurgitation)	
4. Strut/frame abnormality (i.e., fracture)	
Prosthesis–patient mismatch	
Severe	Indexed effective orifice area (cm^2/m^2) <0.65
Moderate	0.85 > Indexed effective orifice area (cm^2/m^2) ≥0.65

Abbreviations: SVD, structural valve deterioration; BMI, body mass index; PG, pressure gradient.

USA). Among 136 patients, 21 were on dialysis and enrolled in this study. We retrospectively analyzed their clinical course. All patients with SUAVR were assessed using diagnostic imaging modalities such as contrast-enhanced computed tomography to measure the diameters of the AA, sinuses of Valsalva, and sinotubular junction (STJ).

Methods

Surgical Procedures

All cardiac procedures were performed by trained surgeons with certifications in the implantation of sutureless prosthetic valves. The typical surgical procedure was as follows. All procedures were performed via total median sternotomy or right anterior mini-thoracotomy at the level of the second intercostal space. Standard CPB was performed using ascending aortic and right atrial cannulations. In the case of right anterior mini-thoracotomy, CPB was established with cannulation of the ascending aorta and right femoral vein. Myocardial protection was achieved using intermittent retrograde blood cardioplegia. The native aortic valve was excised after clamping and transecting the ascending aorta. Calcification of the AA was removed as much as possible using a Cavitron ultrasonic surgical aspirator (CUSA® Excel plus system; Integra Life Sciences, NJ, USA) and rongeur, and the AA was sized using sizers provided by the manufacturers. Three guiding sutures were placed equidistantly at the nadir of each sinus at 120° and passed through the sewing ring (INTUITY Elite) or suture eyelet (Perceval). The choice of sutureless valves was primarily dependent on patient-specific characteristics (i.e., Perceval for cases with a STJ diameter <1.3 times the diameter of the AA).

Study Variables, Operative Outcomes, and Clinical Endpoints

Data on patient characteristics, surgical procedures, and postoperative outcomes were collected. Follow-up data were obtained from clinical records at each institution. Study variables included operation, CPB, and aortic cross-clamp time, concomitant surgical procedures, blood transfusion requirements, length of stay on the intensive care unit, length of hospital stay, 30-day mortality, and long-term survival rates.

Postoperative follow-up with transthoracic echocardiography was routinely performed 4–7 days, 1 year after surgery, and yearly thereafter. The peak and mean pressure gradients (PGs), peak flow velocity, effective orifice area (EOA), EOA index (EOAI), left ventricular ejection fraction (LVEF), valve dysfunction (structural valve deterioration [SVD] and prosthesis-patient mismatch [PPM] shown in Table 1) [1,9], and presence of paravalvular leak (PVL) were recorded.

Surgical complications, such as cardiovascular mortality, cerebral infarction, and valve dysfunction, were classified according to a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) [9].

The primary endpoint was all-cause death. Secondary endpoints included major adverse cardiovascular and cerebrovascular event (MACCE), prosthetic valve dysfunction, and non-occlusive mesenteric ischemia. MACCE was defined as a composite outcome of all-cause death, myocardial infarction (MI), stroke, permanent pacemaker implantation, and heart failure.

Statistical Analyses

Continuous data are presented as means ± standard deviations, while categorical variables are presented as numbers and percentages. The survival and event-free rates were analyzed using the Kaplan-Meier method. Bivariate differences were compared using the Mann-Whitney U test for continuous variables. Statistical significance was set at p values < 0.05. All statistical analyses were performed using GraphPad Prism version 5 (GraphPad Software Inc., San Diego, CA, USA).

Results

Preoperative Characteristics

Among 21 patients included in this study, 11 (52.4%) were male, and the average patient age was 77.4 ± 5.2 years. Preoperative data are presented in Table 2. The mean Society of Thoracic Surgery (STS) score and European System for Cardiac Operative Risk Evaluation (EuroSCORE) II were 9.8% and 6.0%, respectively.

Intraoperative Characteristics

The average operative, CPB, and aortic cross-clamp times were 288.0 ± 84.8, 136.7 ± 48.2, 102.0 ± 47.7 min, respectively (Table 2). Median sternotomy was performed in 85.7% (18 of 21) of patients. Among 21 patients, 14 underwent concomitant surgery in addition to AVR, 14 underwent coronary artery bypass grafting, and 1 underwent mitral valve replacement (Table 2). The Perceval and INTUITY Elite were implanted in 16 (76.2%) and 5 (23.8%) patients, respectively.

Postoperative Clinical Outcomes

The median length of intensive care unit and hospital stay after surgery was 5 (IQR 4–11) and 17 (IQR 14–33) days, respectively (Table 3). In-hospital mortality occurred in 2 patients: 1 with acute MI complicated by nonocclusive mesenteric ischemia on postoperative day 5 and 1 with pneumonia. Among the 21 patients, 3 had pneumonia and 2 underwent re-exploration for bleeding. Follow-up was completed in all patients, with a mean follow-up time of 371 (IQR 364–399) days. The 30-day and 1-year survival rates were 90.5% and 85.7%, respectively (Fig. 1a). The 30-day and 1-year freedom from cardiovascular death were 95.0% and 95.0%, respectively (Fig. 1b). The 30-day and 1-year freedom from MI were 95.0% and 89.7%, respectively (Fig. 1c). The 30-day and 1-year freedom from MACCEs were 80.4% and 57.7%, respectively (Fig. 1d). Although no patient underwent permanent pacemaker implantation during hospitalization, one individual underwent permanent pacemaker implantation due to atrioventricular block 9 months after surgery (Table 3).

Table 2. Patient and intraoperative characteristics.

		n = 21*
Age, years		77.4 ± 5.2
Female sex		10 (47.6)
BSA, m^2		1.49 ± 0.16
BMI, kg/m^2		21.2 ± 2.8
Hypertension		15 (71.4)
Diabetes		8 (38.1)
Dyslipidemia		9 (42.9)
Antiplatelet therapy		11 (52.4)
Anticoagulant therapy		2 (9.5)
Previous PCI		6 (28.6)
Cerebral infarction		8 (38.1)
Carotid artery stenosis		9 (42.9)
STS score, %		9.8 ± 4.6
EuroSCORE II, %		6.0 ± 4.6
Operation time, min		288.0 ± 84.8
CPB time, min		136.7 ± 48.2
Aortic cross-clamp time, min		102.0 ± 47.7
Surgical approach	Median sternotomy	18 (85.7)
	Mini thoracotomy	3 (14.3)
Concomitant procedure	CABG	14 (66.7)
	MVR	1 (4.8)
	TAP	2 (9.5)
	PVI	2 (9.5)
Valve choice	Perceval S	7 (33.3)
	Perceval M	4 (19.0)
	Perceval L	2 (9.5)
	Perceval XL	3 (14.3)
	Intuity 21 mm	3 (14.3)
	Intuity 25 mm	2 (9.5)
Blood transfusion (intraoperative)	RBC	20 (95.2)
	Platelet	8 (38.1)

*Data are presented as means ± SDs or n (%) unless noted otherwise. Abbreviations: BMI, body mass index; BSA, body surface area; PCI, percutaneous coronary intervention; SD, standard deviation; STS, Society of Thoracic Surgery; CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass; MVR, mitral valve replacement; PVI, pulmonary vein isolation; RBC, red blood cell; SD, standard deviation; TAP, tricuspid annuloplasty.

Postoperative echocardiography demonstrated that the LVEF, peak/mean pressure gradient (PG), EOA, and EOAI 4–7 days and 1 year after surgery had no significant differences (55.1 ± 6.9% vs. 58.2 ± 8.1%, 25.2 ± 7.6 mmHg vs. 22.3 ± 7.5 mmHg, 12.5 ± 4.0 mmHg vs. 11.2 ± 5.3 mmHg, 1.73 ± 0.47 cm^2 vs. 1.72 ± 0.33 cm^2, and 1.17 ± 0.3 cm^2/m^2 vs. 11.7 ± 0.24 cm^2/m^2, respectively: Table 4). Three patients had moderate PPM 4–7 days after surgery (2 cases of Perceval S and 1 of Perceval M). Echocardiography 1 year after surgery performed in one patient showed an improvement in the EOAI from 0.74 cm^2/m^2 to 0.87 cm^2/m^2. No cases of SVD or PVL were observed (Table 4).

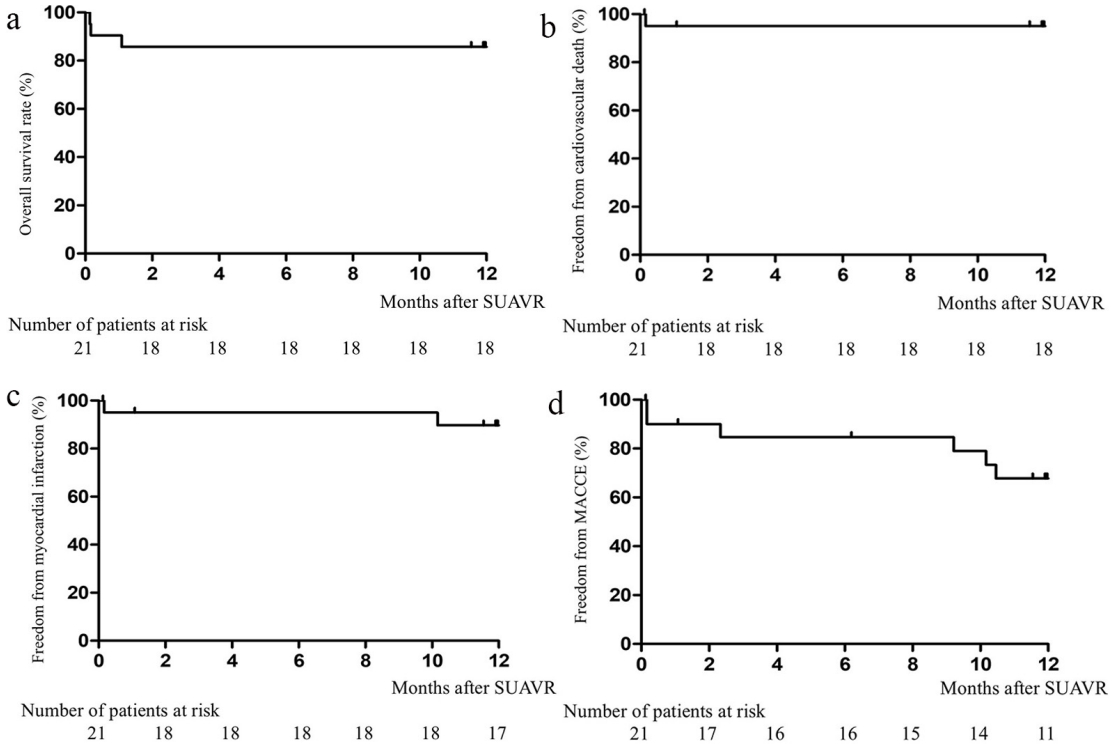

Fig. 1. Kaplan–Meier analysis of the surgical outcomes after sutureless aortic valve replacement. (a) overall survival rate; (b) freedom from cardiovascular death; (c) freedom from myocardial infarction; and (d) freedom from major adverse cardiac and cerebrovascular events. The overall survival rates at 30 days and 1 year after surgery were 90.5% and 85.7%, respectively. The rates of freedom from cardiovascular death at 30 days and 1 year were 95.0% and 95.0%, respectively. The rates of freedom from myocardial infarction at 30 days and 1 year were 95.0% and 89.7%, respectively. The rates of freedom from MACCE at 30 days and 1 year were 80.4% and 57.7%, respectively. SUAVR, sutureless aortic valve replacementt; MACCE, major adverse cardiovascular and cerebrovascular event.

Table 3. Postoperative clinical outcomes.

Early outcomes		n = 21*
ICU length of stay, day		5 (4–11)
Hospitalization, day		17 (14–33)
30-day mortality		2 (9.5)
Complications	Re-exploration for bleeding	2 (9.5)
	Stroke	1 (4.8)
	Myocardial infarction	1 (4.8)
	NOMI	1 (4.8)
	Permanent pacemaker	0 (0)
	Pneumonia	3 (14.3)
Postoperative 1-year outcomes		n = 18*
MACCE	Stroke	0 (0)
	AMI	1 (5.5)
	Permanent pacemaker	1 (5.5)
	Heart failure	2 (11.1)

*Data are presented as median (interquartile range) or n (%) unless noted otherwise.

Abbreviations: ICU, intensive care unit; NOMI, non-occlusive mesenteric ischemia.SD, standard deviation; AMI, acute myocardial infarction; MACCE, major adverse cardiovascular and cerebrovascular event; SD, standard deviation.

Discussion

To the best of our knowledge, this is the first report of surgical outcomes of SUAVR in patients on dialysis. The major findings of the present study were as follows: the operative mortality rate was similar to that observed in conventional AVR and TAVR among dialysis patients, no permanent pacemaker implantation was required within 30-days after surgery, and valve function at 1 year after surgery was good.

Generally, the mortality rates following cardiovascular surgery in patients on dialysis is believed to be higher than those in patients not on dialysis when evaluated using the STS score, JapanSCORE, and EuroSCORE II. Improvements in surgical procedures for patients on dialysis are required. Importantly, regarding mortality after AVR, the early mortality of conventional AVR is reported to be 1.8–5.0% [9], while that of conventional AVR in patients on dialysis is 5.1–11.8% [3,4,10]. Various studies have investigated factors to potentially improve the outcomes of patients on dialysis who underwent AVR [3,11]. Given that patients on dialysis have cardiovascular diseases other than aortic valve disease and require concomitant cardiovascular

Table 4. Echocardiographic evaluation 4–7 days and 1 year after surgery.

		POD 4–7 (n = 19)*	1 year (n = 13)*	*p* value
Peak pressure gradient, mmHg		25.2 ± 7.6	22.3 ± 7.5	0.2496
Mean pressure gradient, mmHg		12.5 ± 4.0	11.2 ± 5.3	0.1789
Peak flow velocity, cm/s		248.5 ± 38.0	233.3 ± 39.6	0.2407
Effective orifice area, cm^2		1.73 ± 0.47	1.72 ± 0.33	0.9693
Effective orifice area index, cm^2/m^2		1.17 ± 0.3	1.17 ± 0.24	0.7823
LVEF, %		55.1 ± 6.9	58.2 ± 8.1	0.1129
PPM	Moderate	3 (15.8)	1 (7.3)	0.6291
	Severe	0 (0)	0 (0)	-
SVD	Moderate hemodynamic	1 (5.3)	1 (7.3)	1.0000
	Severe hemodynamic	0 (0)	0 (0)	-
	Morphological	0 (0)	0 (0)	-
Endocarditis		0 (0)	0 (0)	-
Paravalvular leak		0 (0)	0 (0)	-

*Data are presented as means ± SDs or n (%) unless noted otherwise.

Abbreviations: LVEF, left ventricular ejection fraction; POD, postoperative day; PPM, prosthetic-patient mismatch; SD, standard deviation; SVD, structural valve deterioration.

surgery, we should discuss whether AVR complications can be reduced. Early mortality reported in this study (9.5%) was within the range shown in previous studies on conventional AVR and TAVR in patients on dialysis [3,4,12,13]. Additionally, the 1-year mortality rate (14.3%) was acceptable compared with that reported in a previous trial (20.0–36.4%) [14–16].

Moreover, regarding pacemaker implantation, several studies have shown that a high rate of pacemaker implantation may result from mechanical stress on the atrioventricular septum due to valve deployment and conduction disturbance due to localized septal hematoma (10.5–11.6%) [4,17,18], while no in-hospital pacemaker implantation occurred in this study. Additionally, compared with the proportion of pacemaker implantation in trials on TAVR (5.9–25.8%) [19–21], our results showed a lower value. We minimized decalcification under the aortic valve to avoid affecting the membranous septum involved in conduction disturbance [22] and placed the guide suture on the leaflet insertion line [23], which may have resulted in a reduction in the incidence of conduction disturbance. Indeed, 1 patient had a new-onset complete atrioventricular block 1 year after the surgery, suggesting that long-term follow-up in all patients was required.

The most remarkable finding of this study was the postoperative echocardiographic evaluation results of SUAVR. Several studies on echocardiographic evaluation 1 year after conventional AVR demonstrated that the mean PG, EOA, and incidence of severe PPM were 10.5–10.9 mmHg, 1.5–2.0 cm^2, and 4.4%, respectively [24,25]. Remarkably, our current data showed that the mean PG and EOA were 12.5 ± 4.0 mmHg and 1.73 ± 0.47 cm^2 immediately after surgery. At 1 year, the mean PG and EOA were 11.2 ± 5.3 mmHg and 1.72 ± 0.33 cm^2, respectively, with no severe PPM and PVL noted. Consistent with previous reports investigating the clinical outcomes of patients who underwent AVR with Perceval [7,8], our study showed that the prosthetic valve function was preserved. Furthermore, our results may be comparable to those with trials on TAVR [24,25]. Moderate PPM was observed in three cases immediately after surgery, but all of them had Perceval S size inserted. This may be due to the small annulus diameter relative to the patient's body size. However, there was only one moderate PPM at one year, and this was due to the fact that Perceval, a self-expanding valve, was able to gradually expand and fit into the AA after AVR. On the other hand, the Intuity ELITE, with a subvalvular stent-frame that kept the left ventricular outflow tract, could preserve good hemodynamics with little PG through the prosthetic valve [26], which could result in the maintenance of valve function 1 year after SUAVR. Interestingly, the outcome of postoperative PVL (0%) in this study was satisfactory compared with that of conventional AVR (0.8–3.4%) and TAVR (mild PVL, 13.5–36.0%; moderate-severe PVL, 3.5–3.7%) shown in several studies [24,25,27,28]. In many studies on TAVR for patients on dialysis, TAVR was often performed for those with severe calcification of the leaflets and AA [12,24,29], whereas SUAVR was performed after complete resection of all leaflets and careful removal of calcification on the annulus using the CUSA® system, which could prevent PVL occurrence. However, considering that moderate PPM and SVD occurred in approximately 7% of patients 1 year after SUAVR, we should continue to improve surgical techniques and size evaluation. Considering these findings, although a direct comparison cannot be made, our data suggest that SUAVR for patients on dialysis is a novel treatment strategy.

Study Limitations

The study has several limitations that should be considered when interpreting its findings. Firstly, the sample size is notably small, with only 21 patients included over two years. This limited number of participants reduces the statistical power of the study and may not provide a comprehensive representation of the broader population of dialysis patients undergoing aortic valve replacement. Secondly, the retrospective design of the study introduces several potential biases, such as selection bias and information bias, which can affect the validity of the outcomes. Additionally, the fact that all surgeries were performed by a single surgeon at two institutions may limit the generalizability of the findings, as the outcomes may be influenced by the specific techniques and expertise of that surgeon. Finally, the absence of a comparative cohort may restrict the ability to draw definitive conclusions regarding the relative efficacy and safety of sutureless and rapid deployment bioprosthetic valves compared to other valve replacement options. However, despite these well-acknowledged limitations, this study is one of the few studies focused on this specific valve-related topic. It contributes initial evidence in the field and highlights key areas for further investigation.

Conclusions

SUAVR in patients on dialysis may be a novel treatment strategy with lower early mortality rates comparable to those of conventional treatments, with limited major complications, including pacemaker implantation and good valve function.

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, NO, MU, TIwa, TIma and TS designed the study, analyzed the data, and wrote the manuscript. HU, NO, MU, and TIwa helped gather patient information and analyzed the data. TIwa, TIma, and TS revised critically for important intellectual content. 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

All patients provided informed consent in the form of opt-out on the website. The study protocol was conducted in accordance with the Declaration of Helsinki, and was approved by the Ethics Committee of Teikyo University and Sakakibara Heart Institute (Approval number: 20-182, 2020/11/6; 24-022, 2024/7/23).

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Conflict of Interest

The authors declare no conflict of interest.

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