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Transcatheter Aortic Valve Replacement versus Sutureless Aortic Valve Replacement: A Single Center Retrospective Cohort Study

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Purpose: This study sought to compare clinical outcomes between transcatheter aortic valve replacement (TAVR) and sutureless aortic valve replacement (SU-AVR).

Materials and Methods: In total, 320 patients with symptomatic severe aortic stenosis who underwent TAVR (n=254) or SU-AVR (n=66) at Severance Cardiovascular Hospital between July 2011 and September 2019 were included for analysis. Propensity score matching and inverse probability weighted adjustment were performed to adjust for confounding baseline characteristics. Outcomes defined by the Valve Academic Research Consortium-2 in 62 patients pairs were compared.

Results: Device success (79.0% vs. 79.0%, p>0.999) and 30-day mortality (4.8% vs. 0.0%, p=0.244) did not differ between the TAVR and SU-AVR groups. The TAVR group developed more frequent mild or moderate paravalvular leakage (59.7% vs. 8.1%, p<0.001), whereas SU-AVR was associated with higher rates of major or life-threatening bleeding (9.7% vs. 22.6%, p=0.040), acute kidney injury (8.1% vs. 21.0%, p=0.041), and new-onset atrial fibrillation (4.8% vs. 32.3%. p<0.001) at 30 days, along with longer stays in the intensive care unit (ICU) (1.9±1.6 days vs. 5.9±9.2 days, p=0.009) and hospital (7.1±7.9 days vs. 13.1±8.8 days, p<0.001). The TAVR group showed a trend towards a higher 1-year all-cause mortality, compared with the SU-AVR group (7.0% vs 1.7%, p=0.149). Cardiovascular mortality, however, did not differ significantly (1.6% vs 1.7%, p=0.960).

Conclusion: TAVR achieved a similar 1-year survival rate free from cardiovascular mortality as SU-AVR and was associated with a lower incidence of complications, except for paravalvular leakage, and shorter stays in the ICU and hospital.

Key Words: Aortic stenosis, transcatheter aortic valve replacement, sutureless aortic valve replacement, severe aortic stenosis

INTRODUCTION

Aortic stenosis (AS) is the most common degenerative heart valve disease in older adults.[1] Conventional surgical aortic valve replacement (SAVR) has been the gold standard for treating symptomatic severe AS.[2] However, a fair proportion (30%–40%) of AS patients are considered unsuitable or high risk for conventional SAVR because of comorbidities or frailty.[3] With population aging, there has been an increasing demand for less invasive treatment options replacing conventional SAVR.[4] In recent years, transcatheter aortic valve replacement (TAVR) and sutureless aortic valve replacement (SU-AVR) have emerged as alternative treatment options.[5] Randomized controlled trials have shown that TAVR is an effective treatment in inoperable patients and equal or superior to conventional SAVR in high-risk patients in regards to clinical outcomes.[6,7] Further clinical trials have also demonstrated favorable outcomes for TAVR in

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intermediate or low-risk patients.[8-10] SU-AVR was developed to minimize cardiopulmonary bypass (CPB) and aortic cross-clamp (ACC) times during valve surgery: CPB and ACC times are known to be correlated with risk of morbidity and mortality.[11] After removal of a degenerated and calcified valve, SU-AVR allows for rapid deployment of a valve under direct vision that requires no or minimal suturing.[12] While SU-AVR successfully reduces operation times, there is limited evidence supporting improved clinical outcomes with this surgical technique.[4] Furthermore, few studies have directly compared TAVR versus SU-AVR for severe AS.[13] Therefore, this study sought to compare early and late outcomes of TAVR versus SU-AVR for symptomatic severe AS in a single-center cohort.

MATERIALS AND METHODS

Study design and subjects

In total, 433 patients who underwent aortic valve (AV) replacement were screened, and after exclusion of patients treated for combined coronary artery disease and valvular heart disease, 320 patients with symptomatic severe AS who underwent TAVR (n=254) or SU-AVR (n=66) were included in the current analysis (Fig. 1). Decisions regarding the treatment modality were made by the heart team, a multidisciplinary team of interventional and noninterventional cardiologists, cardiac surgeons, anesthesiologists, and imaging specialists based on clinical assessment of each patient's daily performance and information acquired from pre-treatment transthoracic echocardiography, transesophageal echocardiography, and cardiac computed tomography. Surgical risk was estimated using the European System for Cardiac Operative Risk Evaluation (EuroSCORE) II. The Institutional Review Board of Yonsei University Severance Hospital approved this study (approval no. 4-2020-0813) and waived the requirements for informed consent for this retrospective analysis.

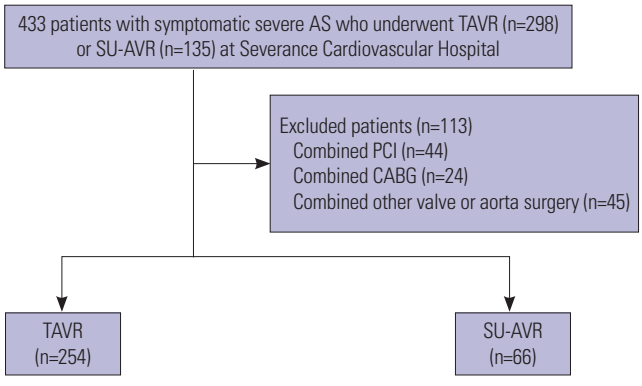

Fig. 1. Flowchart of this retrospective cohort study to compare TAVR vs. SU-AVR for severe AS at Severance Cardiovascular Hospital between July 2011 and September 2019. AS, aortic stenosis; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; SU-AVR, sutureless aortic valve replacement; TAVR, transcatheter aortic valve replacement.

Transcatheter aortic valve replacement

TAVR was performed either under general anesthesia or local anesthesia combined with sedation. A transfemoral approach was the first-line strategy. However, a transsubclavian or transaortic approach was chosen when the transfemoral approach was considered ineligible. Valves used for TAVR included CoreValve, Evolut R, Evolut Pro (Medtronic, Minneapolis, MN, USA), Sapien 3 (Edwards Lifesciences, Irvine, CA, USA), and Lotus (Boston Scientific, Marlborough, MA, USA). The choice of device and size thereof was determined by the heart team based on the access route lumen diameter and the morphology and dimensions of the AV and adjacent structures according to the manufacturer's instructions. Generally, we chose a valve size that allowed for 0%–10% oversizing for balloon expandable valves and 10%–25% oversizing for self-expandable valves. Predilation of the AV was selectively carried out using a balloon catheter with a diameter smaller than the minimum annulus diameter when the AV area was smaller than 0.6 cm^2 or when the AV was severely calcified. The delivery and deployment of the valve was performed according to the instructions for use provided by the device companies. Postdilation was required when moderate to severe paravalvular leakage (PVL) was noted after valve deployment. After successful deployment of the valve, hemostasis of the access site was achieved using two 6-F ProGlide (Abbott Vascular, Santa Clara, CA, USA) via the preclosure method.

Sutureless aortic valve replacement

The implantation of a sutureless bioprosthesis was considered feasible if the mean aortic annulus diameter was 19 to 27 mm. Valves used for SU-AVR included Perceval (Sorin, Saluggia, Italy; true sutureless type) or Intuity (Edwards Lifesciences, rapid deployment type) valves. We made a transverse aortotomy 3.5 cm above the annulus or 0.5 cm above the sinotubular junction (STJ), approximating the epiaortic fat pad for Perceval valves and a classic aortotomy 1 cm above the STJ for Intuity valves. The diseased AV was completely removed, and aortic annulus calcium was clearly removed. The appropriate valve size was selected using the manufacturer sizing tool. Three 4/0 polypropylene guiding sutures were placed at the nadir point of each valve sinus. Simultaneously, an appropriate-size prosthesis was collapsed on a separate table and firmed into the manufacturer holder. Three guiding sutures were passed through the three eyelets at the inflow ring of the prosthesis, which was consequently positioned into the aortic annulus. The AV was released, and the holder was removed. The prosthesis was dilated with a balloon at 4 atmospheres for 30 seconds while the field was rinsed with warm saline. Afterwards, the three guiding sutures were removed, and the aorta was closed using running sutures in a standard fashion.

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Follow-up and data collection

All patients who underwent TAVR and SU-AVR were clinically followed at 3- or 6-month intervals after the procedure. Follow-up transthoracic echocardiography was performed within 7 days, at 1 year, and thereafter annually after the AV replacement. Information on mortality, cause of death, and the incidences of myocardial infarction, stroke, permanent pacemaker implantation, major or life-threatening bleeding, hospitalization for heart failure, endocarditis, and valve thrombosis were collected during the follow-up period.

Study endpoints and definitions

The primary end point was defined as 30-day mortality. Secondary end points were 1-year mortality and postoperative complications that may arise following a procedure. Postoperative outcomes were defined based on the Valve Academic Research Consortium-2 definitions.[14] Before discharge, transthoracic echocardiography was performed for all patients. PVL with aortic regurgitation was determined based on color Doppler imaging outcomes. All-cause mortality was defined as that involving both cardiovascular and non-cardiovascular mortality. Cardiovascular mortality was defined as death due to proximate cardiac cause (e.g., myocardial infarction, cardiac tamponade, worsening heart failure), death caused by noncoronary vascular conditions (e.g., neurological events, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular disease), all procedure-related deaths (including those related to a complication of the procedure or treatment for a complication of the procedure), all valve-related deaths (including structural or nonstructural valve dysfunction or other valve-related adverse events), sudden or unwitnessed death, or death from unknown causes. Non-cardiovascular mortality was defined as one wherein the primary cause of death is clearly related to another condition (e.g., infection, trauma, cancer, suicide). 30-day mortality consisted of all-cause mortality within 30 days of the index procedure. 1-year mortality was defined as mortality occurring within 1 year after the index procedure. Device success was defined as the absence of procedural mortality and correct positioning of a single prosthetic heart valve into the proper anatomical location and intended performance of the prosthetic heart valve with absence of prosthesis-patient mismatch, mean AV gradient ≥20 mm Hg or peak velocity ≥3 m/s, or moderate/severe prosthetic valve regurgitation. Life-threatening bleeding was defined as fatal bleeding [Bleeding Academic Research Consortium (BARC) type 5]; bleeding in a critical organ, such as intracranial, intraspinal, intraocular, or pericardial necessitating pericardiocentesis, or intramuscular with compartment syndrome (BARC type 3b and 3c); bleeding causing hypovolemic shock or severe hypotension requiring vasopressors or surgery (BARC type 3b); overt source of bleeding with drop in hemoglobin ≥5 g/dL or whole blood or packed red blood cells (RBC) transfusion ≥4 units (BARC type 3b). Major bleeding was defined as overt bleeding associated with either a drop in hemoglobin level of at least 3.0 g/dL or requiring transfusion of two or three units of whole blood/RBC, or causing hospitalization or permanent injury, or requiring surgery (BARC type 3a).[15] Acute kidney injury (AKI) was defined as an increase in serum creatinine by ≥0.3 mg/dL (≥26.5 micromol/L) within 48 hours, an increase in serum creatinine to ≥1.5 times baseline, or urine volume <0.5 mL/kg/hour for 6 hours.[16]

Statistical analysis

Statistical analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA) and R package version 4.0.0 (http://www.R-project.org). Continuous data are presented as a mean ±standard deviation, and categorical data are presented as percentages or absolute numbers. The Shapiro-wilk test and Quantile-Quantile Plot were performed before analysis, and the data were confirmed to be normally distributed. Comparisons of continuous variables between patients treated with TAVR and patients treated with SU-AVR were made via the independent t-test, and comparisons of categorical variables were made via the chi-square test (Fisher's exact test). Propensity score matching (PSM) and inverse probability weighted (IPW) adjustment were performed to adjust for significant differences in baseline characteristics and to reduce the impact of potential confounding factors and selection bias. Propensity scores were calculated in a non-parsimonious way including all preoperative variables [age, sex, body mass index (BMI); history of hypertension, diabetes mellitus, dyslipidemia, chronic kidney disease, end-stage renal disease, smoking, coronary artery disease, previous cardiac surgery, stroke, atrial fibrillation (AF), peripheral artery disease, chronic lung disease and cancer; New York Heart Association classification, EuroSCORE II, AV type, left ventricular ejection fraction, AV area, and mean annulus diameter at baseline]. PSM was performed using the "MatchIt" package in R software. We performed PSM with the caliper set to 0.01 when matching. In the PSM, each patient in the TAVR group was matched to a patient in the SU-AVR group who had the closest propensity score, selected using the greedy algorithm. The analyses performed before the match were performed again after the match. Weights for patients treated with TAVR were the inverse of the propensity score, and weights for patients treated with SU-AVR were the inverse (1–propensity score). Finally, results using IPW adjustment with stabilization and trimming of weights were presented. Weights were set equal to 0.10 if the stabilized weight was less than 0.10 and set equal to 10 if the stabilized weight was greater than 10. Survival curves were compared with a stratified log-rank test for the unmatched, matched pairs, and IPW-adjusted pairs. All tests were two-tailed, and p values <0.05 were considered to indicate statistical significance.

RESULTS

Baseline clinical characteristics

The baseline clinical characteristics of study subjects are summarized in Table 1 and Supplementary Table 1 (only online). Patients in the TAVR group were older (81.3±5.8 years vs. 75.7±5.4 years, p<0.001) and had lower BMI (23.2±3.8 vs. 25.0±3.5, p<0.001), more frequent peripheral artery disease (29.5% vs. 7.6%, p<0.001), and higher EuroSCORE II (≥4%) (39.8% vs. 13.6%, p<0.001), compared with those in the SU-AVR group. After PSM, 62 matched patient groups showed no significant differences in baseline clinical variables (Table 1, Fig. 2).

Procedural data

The procedural data are summarized in Table 2. Among a total of 254 patients, 249 (98%) were treated with TAVR via a transfemoral approach, 3 (1.2%) via a transsubclavian approach, and 2 (0.8%) via a transaortic approach. CoreValve (Medtronic), Evolut R (Medtronic), Evolut Pro (Medtronic), Sapien 3 (Edwards Lifesciences), and Lotus (Boston Scientific) valves were used in 64 (25.2%), 101 (39.8%), 17 (6.7%), 61 (24.0%), and 11 (4.3%) patients, respectively. TAVR was performed as an emergent procedure in 7 (2.8%) patients. Among all 254 cases, 228 (89.8%) were performed under general anesthesia and 26 (10.2%) under local anesthesia combined with sedation. SU-

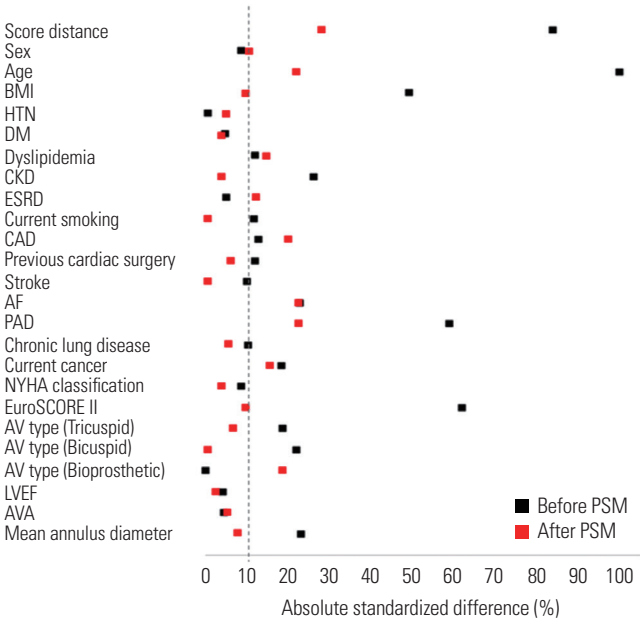

Fig. 2. Love plot. Difference in baseline characteristics between the two groups before and after PSM. Propensity score matched cohorts were well balanced. AF, atrial fibrillation; AV, Aortic valve; AVA, aortic valve area; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease; HTN, hypertension; LVEF, Left ventricular ejection fraction; NYHA, New York Heart Association; PAD, peripheral artery disease; PSM, propensity score matching; EuroSCORE, European System for Cardiac Operative Risk Evaluation.

Table 1. Characteristics of TAVR and SU-AVR Patients Before and After Matching

Characteristics	Before matching			After matching		
	TAVR (n=254)	SU-AVR (n=66)	*p* value	TAVR (n=62)	SU-AVR (n=62)	*p* value
Sex			0.525			0.453
Male	115 (45.3)	27 (40.9)		20 (32.3)	24 (38.7)	
Female	139 (54.7)	39 (59.1)		42 (67.7)	38 (61.3)	
Age (yr)	81.3±5.8	75.7±5.4	<0.001	76.8±6.0	75.5±5.3	0.203
BMI (kg/m^2)	23.2±3.8	25.0±3.5	<0.001	24.9±3.4	24.9±3.3	0.986
HTN	211 (83.1)	55 (83.3)	0.960	54 (87.1)	52 (83.9)	0.610
DM	106 (41.7)	26 (39.4)	0.731	23 (37.1)	24 (38.7)	0.853
Dyslipidemia	175 (68.9)	49 (74.2)	0.399	43 (69.4)	46 (74.2)	0.550
CKD (stage≥III)	133 (52.4)	26 (39.4)	0.061	26 (41.9)	25 (40.3)	0.855
ESRD	23 (9.1)	5 (7.6)	0.705	7 (11.3)	4 (6.5)	0.343
Current smoking	9 (3.5)	4 (6.1)	0.316	0 (0)	0 (0)	>0.999
CAD	132 (52.0)	30 (45.5)	0.346	31 (50.0)	27 (43.6)	0.472
Previous cardiac surgery	28 (11.0)	5 (7.6)	0.412	4 (6.5)	5 (8.1)	>0.999
Stroke	51 (20.1)	16 (24.2)	0.459	14 (22.6)	15 (24.2)	0.832
AF	52 (20.5)	8 (12.1)	0.122	5 (8.1)	8 (12.9)	0.379
PAD	75 (29.5)	5 (7.6)	<0.001	7 (11.3)	4 (6.5)	0.343
Chronic lung disease	44 (17.3)	9 (13.6)	0.473	8 (12.9)	8 (12.9)	>0.999
Active malignancy	18 (7.1)	2 (3.0)	0.389	4 (6.5)	2 (3.2)	0.680
NYHA III/IV	155 (61.0)	43 (65.2)	0.539	37 (59.7)	39 (62.9)	0.712
EuroSCORE II (≥4%)	101(39.8)	9 (13.6)	<0.001	9 (14.5)	8 (12.9)	0.794

AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease; HTN, hypertension; NYHA, New York Heart Association; PAD, peripheral artery disease; EuroSCORE, European System for Cardiac Operative Risk Evaluation; SU-AVR, sutureless aortic valve replacement; TAVR, transcatheter aortic valve replacement.
Data are expressed as n (%) or mean±standard deviation.

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Table 2. Procedural Data of TAVR and SU-AVR Patients Before and After Matching

Variables	Before matching			After matching		
	TAVR (n=254)	SU-AVR (n=66)	*p* value	TAVR (n=62)	SU-AVR (n=62)	*p* value
Preprocedural						
AV type			0.139			0.440
Tricuspid	236 (96.3)	57 (91.9)		60 (96.8)	57 (91.9)	
Bicuspid	5 (2.0)	4 (6.5)		2 (3.2)	4 (6.5)	
Bioprosthetic	4 (1.6)	1 (1.6)		0 (0.0)	1 (1.6)	
AV area (cm^2)	0.73±0.18	0.72±0.19	0.741	0.72±0.17	0.72±0.19	0.901
Annulus diameter (mm)	23.2±2.4	22.7±2.2	0.106	22.8±2.7	22.6±2.2	0.771
Peak PG (mm Hg)	82.9±28.2	86.6±25.9	0.335	85.0±29.1	88.1±25.4	0.519
Mean PG (mm Hg)	50.5±18.7	53.2±17.4	0.296	52.0±19.4	54.0±17.3	0.552
LVEF (%)	61.3±14.9	60.7±13.9	0.762	62.2±14.6	60.8±13.8	0.605
TAVR valve type						
CoreValve	64 (25.2)			16 (25.8)		
Evolut R	101 (39.8)			25 (40.3)		
Evolut Pro	17 (6.7)			3 (4.8)		
Sapien 3	61 (24.0)			15 (24.2)		
Lotus	11 (4.3)			3 (4.8)		
TAVR valve diameter (mm)	25.1±2.3			23.8±2.2		
Access route						
Transfemoral	249 (98.0)			62 (100)		
Transsubclavian	3 (1.2)			0 (0.0)		
Transaortic	2 (0.8)			0 (0.0)		
SU-AVR prosthesis						
Perceval		64 (97.0)			60 (96.8)	
Intuity		2 (3.0)			2 (3.2)	
Pre-dilation	158 (62.2)			40 (64.5)		
Post-dilation	94 (37.0)			26 (41.9)		
ACC time (min)		40.1±13.9			39.9±14.2	
CPB time (min)		72.3±24.2			72.6± 24.8	

ACC, aortic cross-clamp; AV, aortic valve; CPB, cardiopulmonary bypass; LVEF, left ventricular ejection fraction; PG, pressure gradient; SU-AVR, sutureless aortic valve replacement; TAVR, transcatheter aortic valve replacement.
Data are expressed as n (%) or mean±standard deviation.

AVR was performed using two types of prostheses: Perceval S (Sorin) was implanted in 64 (97.0%), and Intuity (Edwards Lifesciences) was used in 2 (3.0%). SU-AVR was performed as an emergent surgery in 2 (3.0%). The mean CPB time was 72.3±24.2 minutes, and the mean ACC time was 40.1±13.9 minutes.

Early outcomes at 30 days

The early outcomes of TAVR and SU-AVR are presented in Table 3, Supplementary Table 2 (only online), and Supplementary Table 3 (only online), Fig. 3. The device success did not differ significantly between the two groups (79.0% vs. 79.0%, p>0.999). There was no significant difference in 30-day mortality between the TAVR and SU-AVR groups before PSM (4.7% vs. 1.5%, p=0.481). However, there was a trend toward a higher 30-day mortality with TAVR after PSM (4.8% vs. 0.0%, p=0.244).

From a hemodynamic standpoint, the incidence of any mild or moderate PVL was higher in the TAVR group than in the SU-AVR group (59.7% vs. 8.1%, p<0.001). However, there was no significant difference between the two groups in the incidence of moderate PVL (1.6% vs. 0.0%, p>0.999). There was no case of severe PVL in either patient group. The TAVR group showed significantly lower transaortic mean and peak gradients (11.2±5.7 mm Hg vs. 14.7±3.8 mm Hg, p<0.001 and 21.4±10.5 mm Hg vs. 27.5±7.0 mm Hg, p<0.001, respectively), but larger AV areas (1.8±0.4 cm^2 vs. 1.6±0.4 cm^2, p=0.009). Major or life-threatening bleeding (9.7% vs. 22.6%, p=0.040), AKI (8.1% vs. 21.0%, p=0.041), and new-onset AF (4.8% vs. 32.3%, p<0.001) were less frequent in the TAVR group than in the SU-AVR group. Furthermore, hospital stay from procedure to discharge (7.1±7.9 days vs. 13.1±8.8 days, p<0.001) and intensive care unit (ICU) stay (1.9±1.6 days vs. 5.9±9.2 days, p=0.009) were shorter in the TAVR group than in the SU-AVR group. However, there was a trend towards a higher incidence of permanent pacemaker implantation in the TAVR group (14.5% vs. 6.5%, p=0.143).

Table 3. Early Outcomes at 30 Days: TAVR and SU-AVR Before and After Matching

Variables	Before matching			After matching		
	TAVR (n=254)	SU-AVR (n=66)	*p* value	TAVR (n=62)	SU-AVR (n=62)	*p* value
30-day mortality	12 (4.7)	1 (1.5)	0.481	3 (4.8)	0 (0.0)	0.244
Major vascular complication	4 (1.6)	0 (0.0)	0.585	2 (3.2)	0 (0.0)	0.496
Major or life-threatening bleeding	18 (7.1)	15 (22.7)	<0.001	6 (9.7)	14 (22.6)	0.040
Surgical conversion	2 (0.8)	0 (0.0)	>0.999	0 (0.0)	0 (0.0)	>0.999
Myocardial infarction	1 (0.4)	0 (0.0)	>0.999	0 (0.0)	0 (0.0)	>0.999
Coronary obstruction	1 (0.4)	0 (0.0)	>0.999	1 (0.4)	0 (0.0)	>0.999
Stroke	11 (4.3)	3 (4.6)	>0.999	2 (3.2)	3 (4.8)	>0.999
New LBBB	71 (28.0)	16 (24.2)	0.546	21 (33.9)	15 (24.2)	0.235
Complete AV block	34 (13.4)	8 (12.1)	0.786	9 (14.5)	8 (12.9)	0.794
Permanent PM implantation	32 (12.6)	4 (6.1)	0.134	9 (14.5)	4 (6.5)	0.143
AKI	27 (10.6)	14 (21.2)	0.022	5 (8.1)	13 (21.0)	0.041
New hemodialysis	10 (3.9)	1 (1.5)	0.471	0 (0.0)	1 (1.6)	>0.999
New-onset AF	9 (3.5)	22 (33.3)	<0.001	3 (4.8)	20 (32.3)	<0.001
Hospital stay (day)	7.2±7.1	13.1±8.8	<0.001	7.1±7.9	13.1±8.8	<0.001
ICU stay (day)	2.7±4.5	5.6±9.0	0.037	1.9±1.6	5.9±9.2	0.009
Hemodynamic results						
AVA (cm^2)	1.9±0.5	1.6±0.4	<0.001	1.8±0.4	1.6±0.4	0.009
Peak gradient (mm Hg)	19.9±9.8	27.2±7.0	<0.001	21.4±10.5	27.5±7.0	<0.001
Mean gradient (mm Hg)	10.3±5.2	14.5±3.9	<0.001	11.2±5.7	14.7±3.8	<0.001
Device success	217 (85.4)	53 (80.3)	0.307	49 (79.0)	49 (79.0)	>0.999
Prosthesis-patient mismatch	12 (4.7)	8 (12.1)	0.042	6 (9.7)	8 (12.9)	0.570
Paravalvular leakage			<0.001			<0.001
Mild	141 (55.5)	5 (7.6)		36 (58.1)	5 (8.1)	
Moderate	12 (4.7)	0 (0.0)		1 (1.6)	0 (0.0)	
Severe	0 (0)	0 (0)		0 (0)	0 (0)	

AF, atrial fibrillation; AKI, acute kidney injury; AV, atrioventricular; AVA, aortic valve area; ICU, intensive care unit; LBBB, left bundle branch block; PM, pacemaker; SU-AVR, sutureless aortic valve replacement; TAVR, transcatheter aortic valve replacement.
Early outcomes are defined as 30-day outcomes. Data are expressed as n (%) or mean±standard deviation.

Clinical outcomes at 1-year follow-up

Patients were followed for a median duration of 12.9 (interquartile range: 4.1–26.5) months. The clinical outcomes during the follow-up are presented in Table 4 and Supplementary Table 4 (only online), Figs. 3 and 4. Before PSM, there was a trend toward a higher all-cause mortality in the TAVR group than in the SU-AVR group (11.2% vs. 3.1%, *p*=0.068). Among the 24 patients who died in the TAVR group during the follow-up period, 11 (45.8%) died due to sepsis, 3 (12.5%) died due to the progression or worsening of an underlying disease, 3 (12.5%) died due to gastrointestinal bleeding, 3 (12.5%) died due to respiratory failure caused by an aspiration, and 4 (16.7%) died due to traumatic subdural hemorrhage. In the SU-AVR group, two patients died during follow up: one died due to respiratory failure caused by aspiration, and another patient died due to sepsis. However, cardiovascular mortality did not differ between the TAVR group and the SU-AVR group (2.4% vs. 1.6%, *p*=0.656). After PSM, all-cause mortality did not differ significantly. However, there was still a trend toward higher all-cause mortality in the TAVR group (7.0% vs. 1.7%, *p*=0.149). Cardiovascular mortality did not differ between the TAVR group and SU-AVR group (1.6% vs. 1.7%, *p*=0.960). Major or life-threatening bleeding was significantly lower in the TAVR group than in the SU-AVR group (10.9% vs. 25.8%, *p*=0.023). However, there were no significant differences between the two groups in the incidences of myocardial infarction, stroke, permanent pacemaker implantation, hospitalization for heart failure, endocarditis, and valve thrombosis.

DISCUSSION

In this retrospective single cohort study, TAVR and SU-AVR showed no significant differences in 30-day and 1-year mortality rates after adjustment for confounding factors using PSM and IPW adjustment. SU-AVR showed higher incidences of major or life-threatening bleeding, AKI, and new-onset AF, compared with TAVR, whereas TAVR was associated with a higher incidence of PVL and a trend towards a higher risk of permanent pacemaker implantation.

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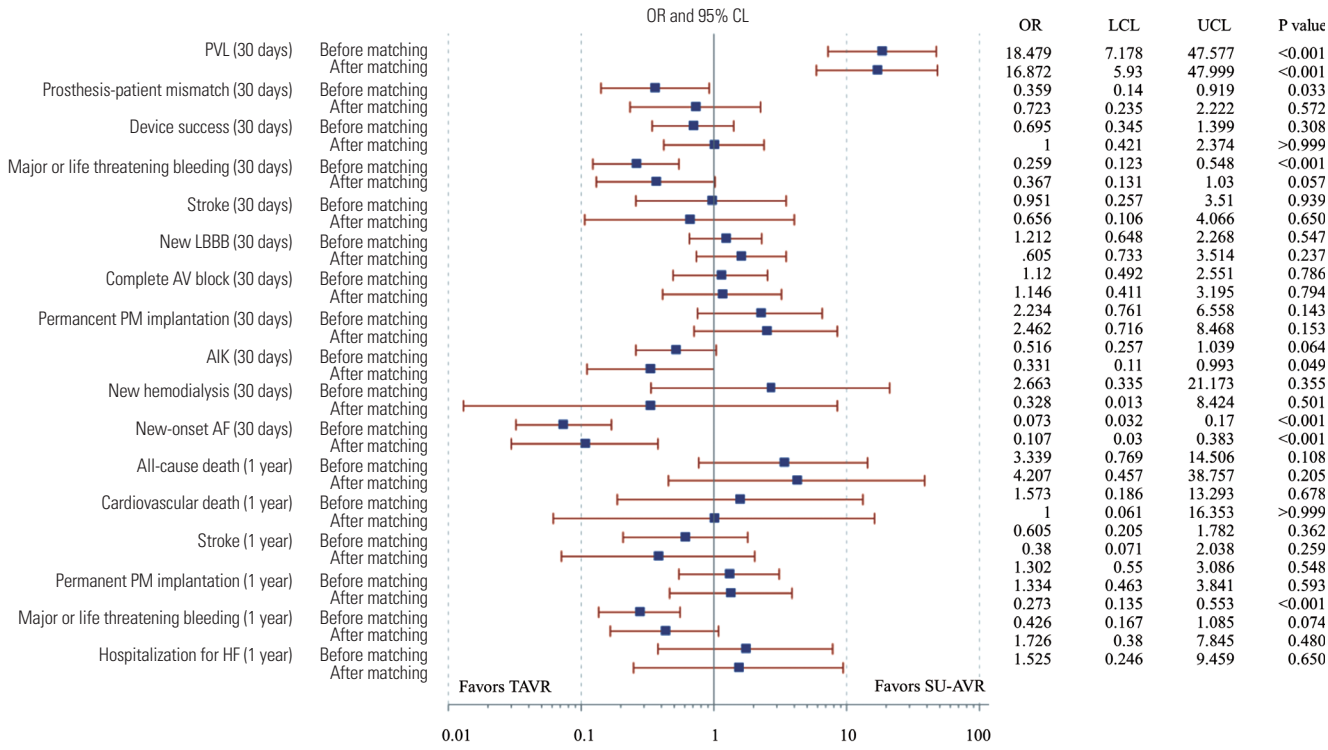

Fig. 3. Clinical outcomes according to procedure. Impact on clinical outcomes of the two procedures at 30-day or 1-year follow up. TAVR was associated with increased PVL, whereas SU-AVR was associated with increased major or life threatening bleeding, AKI, and new-onset AF. AF, atrial fibrillation; AKI, acute kidney injury; AV, atrioventricular; CL, confidence limit; HF, heart failure; LBBB, left bundle branch block; LCL, lower confidence limit; OR, odds ratio; PM, pacemaker; PVL, paravalvular leakage; SU-AVR, sutureless aortic valve replacement; TAVR, transcatheter aortic valve replacement; UCL, upper confidence limit.

Table 4. Clinical Outcomes at 1 Year: TAVR and SU-AVR Before and After Matching

Variables	Before matching			After matching		
	TAVR (n=254)	SU-AVR (n=66)	*p* value	TAVR (n=62)	SU-AVR (n=62)	*p* value
All-cause mortality	24 (11.2)	2 (3.1)	0.068	4 (7.0)	1 (1.7)	0.149
Cardiovascular mortality	6 (2.4)	1 (1.6)	0.656	1 (1.6)	1 (1.7)	0.960
Myocardial infarction	1 (0.4)	0 (0)	0.610	0 (0)	0 (0)	>0.999
Stroke	12 (5.0)	5 (7.9)	0.400	2 (3.2)	5 (8.3)	0.270
Permanent PM implantation	34 (14.1)	7 (11.1)	0.488	9 (14.5)	7 (11.7)	0.544
Major or life-threatening bleeding	22 (9.6)	17 (25.8)	<0.001	6 (10.9)	16 (25.8)	0.023
Hospitalization for HF	13 (6.4)	2 (3.1)	0.356	3 (5.1)	2 (3.3)	0.584
Endocarditis	1 (0.6)	1 (1.7)	0.385	0 (0)	1 (1.8)	0.344
Valve thrombosis	1 (0.6)	2 (4.4)	0.101	0 (0)	2 (4.8)	0.179
Hemodynamic results						
AVA (cm^2)	1.8±0.4	1.5±0.3	0.021	1.7±0.4	1.5±0.3	0.218
Peak gradient (mm Hg)	19.8±8.8	23.2±8.9	0.019	23.6±11.8	23.8±8.8	0.912
Mean gradient (mm Hg)	10.1±4.6	12.1±5.3	0.011	12.1±6.1	12.4±5.3	0.788

AVA, aortic valve area; HF, heart failure; PM, pacemaker; SU-AVR, sutureless aortic valve replacement; TAVR, transcatheter aortic valve replacement.
Data are expressed as n (%) or mean±standard deviation.

Recently, a meta-analysis of seven randomized controlled clinical trials demonstrated that TAVR was associated with a reduction in all-cause mortality and stroke up to 2 years, irrespective of the baseline surgical risk and type of transcatheter heart valve system, compared with conventional SAVR. Furthermore, patients treated with TAVR experienced a reduction in the risk of new-onset AF, AKI, and major bleeding.[17] Sutureless valves offer faster implantation with significantly reduced CPB and ACC times, compared with conventional SAVR, and the absence of a sewing ring may also result in improved hemodynamics.[11] A network meta-analysis of 16432 patients from seven randomized controlled trials and 25 propensity score-

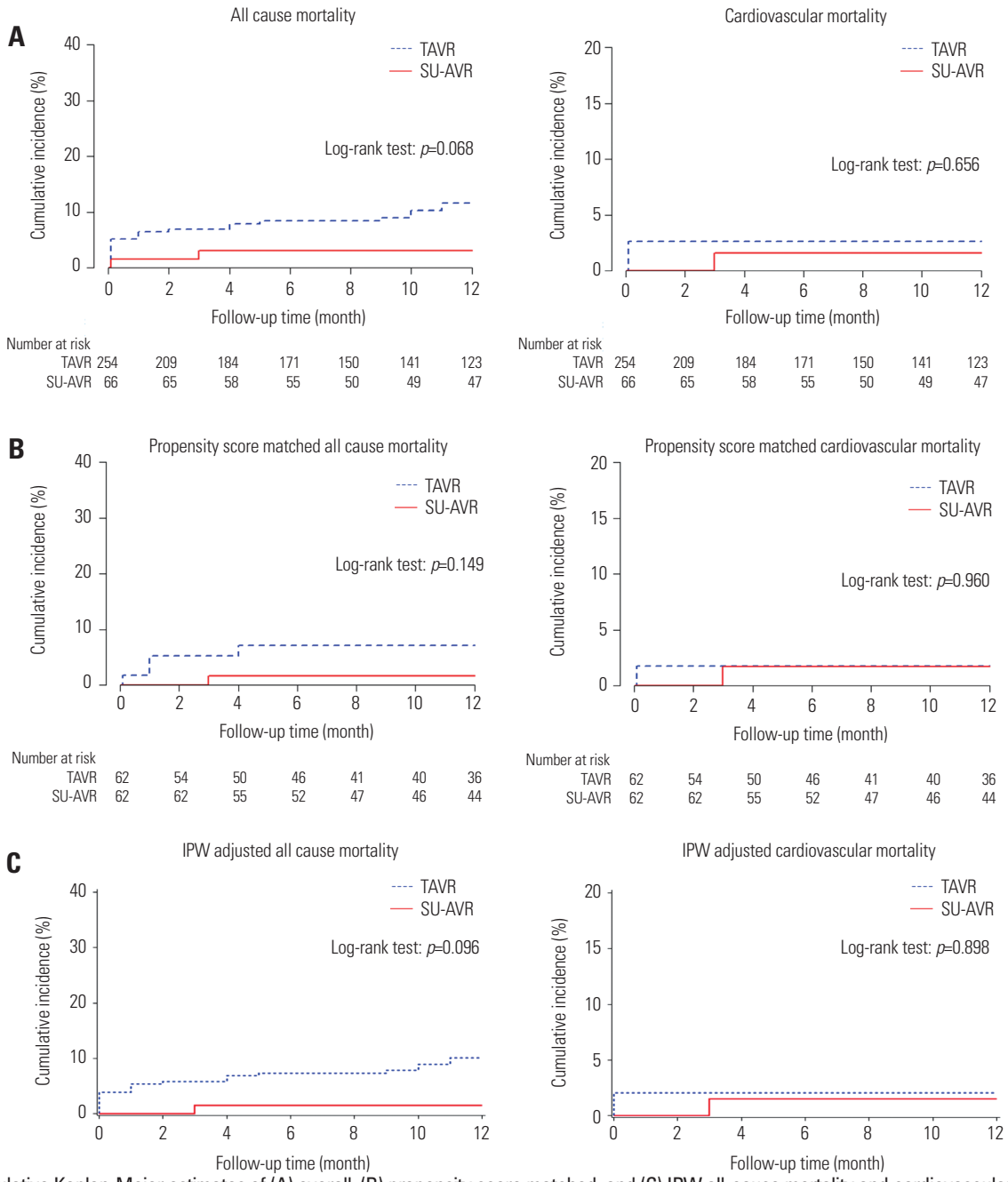

Fig. 4. Cumulative Kaplan-Meier estimates of (A) overall, (B) propensity score matched, and (C) IPW all-cause mortality and cardiovascular mortality between TAVR and SU-AVR groups during the 1-year follow-up period. Cardiovascular mortality did not differ between the TAVR and SU-AVR groups. IPW, inverse probability weighted; SU-AVR, sutureless aortic valve replacement; TAVR: transcatheter aortic valve replacement.

matched studies found that SU-AVR was associated with less major bleeding and AKI than conventional SAVR.[18] However, according to another study, SU-AVR showed higher incidences of PVL and permanent pacemaker implantation than conventional SAVR.[19] To date, there have been no randomized controlled trials comparing TAVR and SU-AVR. Thus, the current clinical evidence is based only on observational cohort studies or meta-analyses. Several meta-analyses reported higher post-procedural or 30-day mortality rates with TAVR group than with SU-AVR.[13,20,21] Similarly, in the present study, the TAVR group showed a trend towards a higher 30-day mortality than the SU-AVR group. However, there was no difference in cardiovascular mortality. Thus, the potentially higher mortality in the TAVR group may be explained by non-cardiovascular causes due to relatively older age and higher surgical risk profile expressed as in EuroSCORE II, although these differences were not statistically significant.

In this study, the incidence of mild or moderate PVL was higher for TAVR than SU-AVR, although the incidence of moderate PVL alone showed no difference between the two groups.

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There was no case of severe PVL in the TAVR group. These results are in line with the results of previously published studies.[18,22] It has been shown that the presence of PVL is a predictor of lower survival.[23] The surgical approach has an advantage of reducing the risk of PVL by removal of calcified AV tissues. However, adoption of a new generation TAVR device that was specially designed to improve sealing between the aortic annulus and the TAVR valve has greatly reduced the incidence of significant PVL after TAVR.[24,25] In the present study, TAVR demonstrated reduced incidences of major or life-threatening bleeding and AKI. These findings are also consistent with previous studies.[17] Postoperative new-onset AF occurred in about 30% of the patients treated with SU-AVR in our cohort, which is also compatible with other studies reporting AF incidences ranging from 16.7% to 41%.[26,27] Multiple acute transient factors, such as an increase in the circulating catecholamines, heightened sympathetic and parasympathetic tone, atrial stretch, transcellular fluid and electrolyte shifts, metabolic abnormalities, inflammation, and pericarditis, contribute to AF after cardiac surgery.[28]

TAVR showed shorter durations of hospitalization and ICU stay compared to SU-AVR owing to the less invasive nature and lack of extracorporeal circulation. However, the length of hospital or ICU stay can differ between centers due to differences in the policies of each center or clinician, regardless of each patient's postoperative course.

Previous studies reported no significant differences between SU-AVR and TAVR in terms of the incidence of atrioventricular block and permanent pacemaker implantation.[22,29] Similarly, in our study, there was no statistically significant difference between the two groups, although compared to patients treated with SU-AVR, there was a trend toward a higher risk of permanent pacemaker implantation in patients treated with TAVR. There is wide variability in terms of the postoperative need for pacemaker implantation among different TAVR devices because, with some prostheses, the incidence of pacemaker implantation is as high as 28% and the rate of new or worsened left bundle branch block is 78%.[30] SU-AVR or conventional SAVR may be a better choice for treatment of patients with anatomy precluding a good outcome from TAVR (e.g., short distance between coronary ostia and AV annulus, bicuspid AV, asymmetric calcification), concomitant conditions warranting surgery (e.g., aortic root aneurysm, complex coronary artery disease, severe mitral or tricuspid valve disease), inadequate vascular access condition, or active infective endocarditis. SU-AVR may be preferred to conventional SAVR in cases where shortening of CPB and ACC times are of great clinical importance. Therefore, a multidisciplinary heart team needs to evaluate the conditions of the patients and to guide the most appropriate treatment for each individual patient.

There are some limitations to this study. First, this study was conducted as a single-center retrospective analysis with a relatively small study population. We aimed to minimize selection bias using PSM. However, confounding factors may not have been sufficiently controlled as they would have been in a randomized controlled trial. Second, the follow-up duration was limited to assess the impact of the procedures on late clinical outcomes. Third, the impact of different TAVR or surgical valve types, valve sizes, and detailed native AV anatomy factors on the clinical outcomes could not be evaluated in this study due to the small study size.

In conclusion, TAVR was associated with increased PVL, whereas SU-AVR was associated with increased major or life-threatening bleeding, AKI, and new-onset AF, compared to TAVR, in this study. Therefore, compared to SU-AVR, TAVR appears to be a safer procedure for the treatment of patients with symptomatic severe AS.

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AUTHOR CONTRIBUTIONS

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