Valve Hemodynamics and Clinical Outcomes After Transcatheter Aortic Valve Replacement for a Small Aortic Annulus

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Summary

The hemodynamics and outcomes in patients with a small aortic annulus (SAA) after transcatheter aortic valve replacement (TAVR) with a second-generation transcatheter heart valve remain unclear. We investigated whether TAVR with a Sapien XT (Edwards Lifesciences, Irvine, California) influences postprocedural valve hemodynamics and long-term outcome in high-risk SAA patients compared with surgical aortic valve replacement (SAVR).

We retrospectively identified 94 SAA patients who underwent aortic valve replacement (TAVR = 35 and SAVR = 59). SAA was defined as an aortic annulus diameter ≤ 20 mm, measured by preprocedural transesophageal echocardiography.

The mean age was 80.2 years. The mean Society of Thoracic Surgeons-Predicted Risk of Mortality was 6.8%. The post-procedural peak transvalvular velocity and mean pressure gradient were significantly lower in the TAVR cohort than in the SAVR cohort, whereas the postprocedural aortic valve area was significantly higher in the TAVR cohort. Severe prosthesis-patient mismatch (PPM) occurred less frequently after TAVR than SAVR (TAVR 2.9% versus SAVR 22.0%, $P = 0.01$). The two-year mortality in SAA patients was similar between the two groups.

TAVR with a Sapien XT in SAA patients improved the valve hemodynamics and reduced the incidence of PPM compared with SAVR. TAVR patients had a similar 2-year mortality despite higher risk baseline characteristics. To avoid PPM and the consequent poor outcomes, TAVR can be considered an alternative option to SAVR in high surgical risk patients with SAA.

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Key words: Balloon-expandable valve, TAVR, TAVI, SAVR, Prosthesis-patient mismatch

A small aortic annulus (SAA) has been reported to not only increase the incidence of prosthesis-patient mismatch (PPM) but also contribute to worse procedural and clinical outcomes following surgical aortic valve replacement (SAVR).¹⁻³ Transcatheter aortic valve replacement (TAVR) using a first-generation transcatheter heart valve (THV) was reported to improve hemodynamics, reduce PPM, and improve clinical outcomes compared with SAVR, even in patients with SAA.⁴⁻⁷ However, the hemodynamics and outcomes in SAA patients after TAVR with a second-generation THV remain unclear. Therefore, we investigated whether TAVR with a second-generation THV influences valve hemodynamics and long-term clinical outcomes in high-risk SAA patients compared with SAVR.

Methods

From January 2013 to December 2014, 291 consecutive patients who underwent their first aortic valve replacement for severe aortic stenosis at our institution were retrospectively enrolled. All patients were reviewed by our local multidisciplinary heart team who determined the appropriate procedure for each patient as per their preprocedural risk. All patients who were assigned with TAVR were deemed as high surgical risk due to high STS risk score, advanced age, frailty, and severe comorbidity. From this cohort, 165 cases were excluded as their aortic annulus was > 20 mm by preprocedural transesophageal echocardiography (TEE). Of the remaining 126 cases, we included patients with a preprocedural peak transvalvular velocity (PV) ≥ 4.0 m/second or a mean pressure gradient (MPG) ≥ 40 mmHg who then received a bioprosthetic valve by TAVR or SAVR. In the SAVR group, we also

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excluded 4 patients who received a mechanical prosthetic valve: a Regent aortic valve ($n = 3$) (St. Jude Medical, St. Paul, Minnesota) and a Carbomedics aortic valve ($n = 1$) (Sorin, Milan, Italy). All the patients agreed to participate in this study and provided written informed consent. This study was approved by the local institutional review board.

All TAVR procedures were performed in accordance with the standard procedure of TAVR under general anesthesia in a hybrid operating room.⁸⁾ The access route and size of a prosthetic valve were determined in each patient based on a preprocedural assessment, including multidetector computed tomography, echocardiography, Doppler ultrasound of the peripheral vessels, and angiography. The transapical approach was selected because of small lumen size, significant calcification, or extensive tortuosity of the iliofemoral arterial access. All the TAVR procedures were performed using a second-generation THV device, a Sapien XT valve system (Edwards Lifesciences, Irvine, California).

The SAVR procedures were performed via standard median sternotomy with a cardiopulmonary bypass. In this study, we used two types of surgical bioprostheses: a Carpentier-Edwards prosthesis Magna Ease valve (Edwards Lifesciences) and a Mosaic Ultra valve (Medtronic, Minneapolis, Minnesota). Operators determined the valve type prior to the procedure. Native aortic valve and perivalvular calcification were carefully resected in all the SAVR cases before implantation of the prosthesis. The size of the bioprosthesis was determined by calibrating to proprietary valve sizers. Fifty-seven of the valves were implanted in the supra-annular position. The remaining two valves were implanted in the intra-annular position. No patients underwent an aortic annular enlargement or an aortic root replacement despite SAA.

The aortic annulus diameter was measured preoperatively between the hinge points of the leaflet in midsystole from the long-axis view using TEE, according to the guidelines of the American Society of Echocardiography.⁹⁾ The left ventricular and valvular functions were assessed pre- and postprocedure with transthoracic echocardiography according to the established guidelines.⁹⁻¹¹⁾ The aortic valve area (AVA) postprocedure was calculated according to the guideline and indexed for the patient's body surface area.¹¹⁾ PPM was defined as an indexed AVA $< 0.65 \text{ cm}^2/\text{m}^2$.²⁾

The aim of this study was to compare the valve hemodynamics and clinical outcomes of SAA patients after TAVR using a Sapien XT valve with those after SAVR using a conventional stented bioprosthesis. We first compared valve hemodynamics, including the incidence of PPM, and then compared postprocedure outcomes between the two groups. The primary endpoint was 2-year mortality, and the secondary endpoint was 30-day mortality.

The patients' baseline characteristics were included in our assessment. Coronary artery disease was defined as any of the following: angina pectoris with documented coronary artery stenosis, previous myocardial infarction, or previous coronary artery revascularization. Cerebrovascular disease was defined as transient ischemic attack or

ischemic stroke. Renal failure was defined as a serum creatinine level $> 1.5 \text{ mg/dL}$. Outcomes and complications were reported in accordance with the definition by the valve academic research consortium (VARC)-2 criteria.¹²⁾

Clinical status and valve hemodynamics were evaluated at baseline, at discharge, at 1, 3, and 6 months, and annually thereafter. All the information was collected from the medical record or direct phone contact with patients or their families.

Statistical analyses were performed using JMP version 10.0.2 (SAS Institute, Cary, North Carolina). Quantitative values are reported as the mean $\pm$ standard deviation, and qualitative values are reported as numbers and percentages. Continuous variables were examined using the unpaired *t*-test or nonparametric analysis by the Wilcoxon rank sum test. Categorical variables were compared using the chi-square test or Fisher's exact test. Survival curves were analyzed using the Kaplan-Meier method and compared with the log-rank test. *P*-values less than 0.05 were considered to be statistically significant.

Results

We identified 94 patients (TAVR = 35 and SAVR = 59) who met our inclusion criteria. Sapien XT 23-mm valves were used for all TAVRs. The median-adjusted contrast volume to deploy a valve was -1.0 mL (interquartile range: -1.0 to 0.0 mL). In the SAVR group, 35 Mosaic ultravalves (19-mm valve = 32 and 21-mm valve = 3) and 24 Carpentier-Edwards prosthesis Magna ease valves (19-mm valve = 15 and 21-mm valve = 9) were used. The mean age and mean Society of Thoracic Surgeons-Predicted Risk of Mortality of the entire cohort were 80.2 years and 6.8%, respectively. Unsurprisingly, TAVR patients were older and were more likely to have a history of coronary artery bypass grafting or balloon aortic valvuloplasty than SAVR patients (Table I). Additionally, TAVR patients exhibited more severe symptoms of heart failure and higher logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE). SAVR patients were more likely to have diabetes mellitus. The baseline valve hemodynamics were similar for the PV, MPG, and AVA between the two groups (Table II). Some of the SAVR patients underwent planned concomitant procedures: coronary artery bypass grafting (17 cases), mitral valve replacement (4 cases), and combined mitral and tricuspid valve replacement (1 case).

The postprocedural PV and MPG were significantly lower in the TAVR cohort than in the SAVR cohort, and the postprocedural AVA was significantly larger in the TAVR cohort. PPM was observed in only 1 case (2.9%) post-TAVR, whereas it occurred in 13 cases (22.0%, $P = 0.01$) post-SAVR (Figure 1). Significant paravalvular leakage (PVL) was observed in 4 patients post-TAVR (Table III). The superiority in valve hemodynamics after TAVR with a Sapien XT was maintained 6 months after the procedure (Figure 1A-C).

The mean follow-up was 20.6 ± 9.3 months (range: 2.0-38.7 months). The main clinical outcomes are listed in Table III. Procedure success was achieved in all the cases. No procedure-related death was observed. Three patients

Table I. Baseline Clinical Characteristics

Variable	Overall (n = 94)	TAVR (n = 35)	SAVR (n = 59)	P value
Age (years)	80.2 ± 8.6	85.1 ± 6.0	77.4 ± 8.7	< 0.001
Female	88 (93.6%)	32 (91.4%)	56 (94.9%)	0.67
BMI (kg/m ²)	22.3 ± 3.8	21.6 ± 3.4	22.7 ± 4.0	0.16
BSA (m ²)	1.38 ± 0.14	1.37 ± 0.17	1.38 ± 0.13	0.64
NYHA class III/IV	37 (39.4%)	19 (54.3%)	18 (30.5%)	0.03
Logistic EuroSCORE (%)	14.3 ± 10.2	18.9 ± 12.8	11.6 ± 7.3	0.01
EuroSCORE II (%)	5.5 ± 5.7	6.4 ± 4.7	5.0 ± 6.1	0.23
STS-PROM (%)	6.8 ± 4.3	6.7 ± 3.0	6.8 ± 5.0	0.91
Hypertension	68 (72.3%)	26 (74.3%)	42 (71.2%)	0.81
Dyslipidemia	44 (46.8%)	16 (45.7%)	28 (47.5%)	1.00
Diabetes mellitus	33 (35.1%)	6 (17.1%)	27 (45.8%)	0.01
Renal failure*	10 (10.6%)	3 (8.6%)	7 (11.9%)	0.74
eGFR (mL/minute/1.73 m ²)	52.3 ± 23.7	50.9 ± 21.1	53.1 ± 25.2	0.50
Smoking habit	7 (7.5%)	1 (2.9%)	6 (10.2%)	0.25
Cerebrovascular disease	10 (10.6%)	1 (2.9%)	9 (15.3%)	0.08
Coronary artery disease	29 (30.9%)	14 (40.0%)	15 (25.4%)	0.17
History of CABG	4 (4.3%)	4 (11.4%)	0 (0.0%)	0.02
History of PCI	23 (24.5%)	10 (28.6%)	13 (22.0%)	0.62
History of heart failure	35 (37.2%)	10 (28.6%)	25 (42.4%)	0.20
History of BAV	23 (24.5%)	18 (51.4%)	5 (8.5%)	< 0.001

*Renal failure is defined as a serum-creatinine level more than 1.5 mg/dL. Values are expressed mean ± SD, median (interquartile range) or n (%). BAV indicates balloon aortic valvuloplasty; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; eGFR, estimated glomerular filtration rate; EuroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; SD, standard deviation; STS-PROM, Society of Thoracic Surgery-Predicted Risk of Mortality; and TAVR, transcatheter aortic valve replacement.

Table II. Baseline Echocardiographic Characteristics

Variable	Overall (n = 94)	TAVR (n = 35)	SAVR (n = 59)	P value
Peak velocity (m/second)	5.08 ± 0.71	5.21 ± 0.77	5.01 ± 0.68	0.19
Mean PG (mmHg)	60.9 ± 19.1	64.6 ± 20.1	58.7 ± 18.3	0.15
Aortic valve area (cm ²)	0.57 ± 0.13	0.56 ± 0.11	0.58 ± 0.13	0.34
Aortic annulus (mm) *	19.1 ± 0.6	19.1 ± 0.7	19.1 ± 0.6	0.77
AR (≥ moderate)	29 (30.1%)	14 (40.0%)	15 (25.4%)	0.14
MR (≥ moderate)	35 (37.2%)	10 (28.6%)	25 (42.4%)	0.20
TR (≥ moderate)	21 (22.3%)	8 (22.9%)	13 (22.0%)	0.93
LVEF (%)	60.8 ± 8.9	60.9 ± 7.8	60.6 ± 9.5	0.88
SV (mL)	71.2 ± 14.7	72.6 ± 13.2	70.4 ± 15.7	0.49
SI (mL/m ²)	52.1 ± 10.4	53.8 ± 9.6	51.1 ± 10.8	0.23
LV mass index (g/m ²)	137.0 ± 37.5	135.1 ± 39.1	138.1 ± 36.7	0.71

*Aortic annulus diameter was measured by transesophageal echocardiography. AR indicates aortic regurgitation; LV, left ventricle; LVEF, left ventricle ejection fraction; MR, mitral regurgitation; PG, pressure gradient; SAVR, surgical aortic valve replacement; SI, stroke volume index; SV, stroke volume; TAVR, transcatheter aortic valve replacement; and TR, tricuspid regurgitation.

had a stroke after TAVR. In addition to the complications listed in Table III, 1 patient suffered coronary obstruction immediately after TAVR and underwent percutaneous coronary intervention as a bail-out procedure. There was no 30-day mortality in either cohort. The Kaplan-Meier curve revealed similar mortality at 2 years in both groups (TAVR 19.4% versus SAVR 19.2%, $P = 0.95$, Figure 2).

Discussion

This study demonstrated two major findings: (1) the

valve hemodynamics were significantly better after TAVR with a Sapien XT than after SAVR with a conventional stented valve; (2) SAA patients after TAVR achieved similar long-term clinical outcomes compared with patients after SAVR despite the higher risk baseline characteristics in the TAVR cohort. Therefore, TAVR using a Sapien XT can be considered an alternative to SAVR in SAA patients with high surgical risk.

In this study, TAVR with a Sapien XT demonstrated superior valve hemodynamics and a lower incidence of PPM than SAVR, which was consistent with previous

A Peak velocity

B Mean pressure gradient

C Aortic valve area

D Prosthesis-Patient Mismatch

Figure 1. Valve hemodynamics. **A:** Change of peak velocity. **B:** Change of mean pressure gradient. **C:** Change of aortic valve area. **D:** Incidence of PPM. PPM was defined as an indexed AVA < 0.65 cm²/m². AVA indicates aortic valve area; MPG, mean pressure gradient; PPM, prosthesis-patient mismatch; SAVR, surgical aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

studies.^{4,6)} These hemodynamic findings were preserved until 6 months postprocedure. To avoid PPM and the consequent adverse long-term effects in SAA patients who underwent SAVR, supra-annular valve implantation was performed in most of our SAVR cohort.¹³⁾ Despite the use of this procedure, PPM was observed more frequently after SAVR in this study. Importantly, the incidence of severe PPM after SAVR in this study (22.0%) was lower than in previous studies (28.1-33.9%), and the incidence of severe PPM after TAVR was also lower in this study (2.2%) than in previous studies (7.0-19.7%).^{4,6,14)} The low incidence of PPM post-TAVR may be due to our unique procedural strategy. We implanted a 23-mm valve with underfilled volume for all the SAA patients because a 23-mm valve was the smallest valve available during the study period. Further investigation is required to determine the long-term impact of implanting a valve with underfilled volume in SAA.

In addition, the structural differences between the THV and the surgical bioprosthesis (i.e., the valvular membrane sewn in the thin strut stent [cobalt chrome metal] versus the thick stent frame [fabric-covered wire frame]) and the difference in the manner of implantation (i.e., hanging with dilatation of the aortic annulus [the oversizing concept] versus sewing inside of the aortic annulus) may affect the postprocedural AVA.¹⁵⁻¹⁷⁾ In SAA patients, our study demonstrates that the structure of THV

may contribute to a larger AVA than surgical valves at the time of the procedure. In addition, the structural difference between THVs and surgical valves may favor THVs when considering a valve-in-valve procedure for the degenerative valve in the future.¹⁷⁾ Such differences may influence the long-term outcomes and require further investigation.

SAA has been reported to contribute to a high incidence of PPM, leading to worse procedural and clinical outcomes following SAVR.^{1-3,18)} Prior randomized studies have also shown the impact of aortic annulus size on outcomes following TAVR, particularly in SAA patients.^{4,19)} However, this SAA study demonstrated similar long-term outcomes after both TAVR and SAVR. This difference could be attributed to higher age and higher surgical risk in the TAVR patients than in the SAVR patients. Moreover, previous reports revealed the impact of PPM in larger populations and at longer time periods than our study.²⁰⁻²²⁾ Therefore, further studies with larger populations and longer observational periods are required to investigate the impact of PPM on long-term outcome in SAA patients.

The incidence of stroke was reported to be similar after SAVR and TAVR, although potential sources of embolization differ between the two procedures.^{23,24)} In this study, three patients experienced stroke symptoms after TAVR using a Sapien XT, although all the symptoms

Table III. Clinical Outcomes

	Overall (n = 94)	TAVR (n = 35)	SAVR (n = 59)	P value
In-hospital outcomes				
All vascular complication	7 (7.5%)	4 (11.4%)	3 (5.1%)	0.42
Major vascular complication	3 (3.2%)	1 (2.9%)	2 (3.4%)	1.00
All bleeding	59 (62.3%)	23 (65.7%)	36 (61.0%)	0.65
LT bleeding	25 (26.6%)	1 (2.9%)	24 (40.7%)	< 0.001
Major bleeding	25 (26.6%)	15 (42.9%)	10 (17.0%)	0.01
LT and major bleeding	50 (53.2%)	16 (45.7%)	34 (57.6%)	0.26
Stroke	3 (3.2%)	3 (8.6%)	0 (0.0%)	0.05
All AKI	10 (9.6%)	3 (8.6%)	7 (11.9%)	0.74
AKI $\geq$ stage 2	3 (3.2%)	1 (2.9%)	2 (3.4%)	1.00
New PM implantation	4 (4.3%)	2 (5.7%)	2 (3.4%)	0.63
Echocardiographic outcomes				
Mean APG < 20 mmHg	76 (80.6%)	32 (91.4%)	44 (74.6%)	0.04
Moderate/severe PVL	4 (4.3%)	4 (4.3%)	0 (0.0%)	0.02
LVEF (%)	60.8 $\pm$ 8.9	60.9 $\pm$ 7.8	60.6 $\pm$ 9.5	0.88
Short- and long-term outcomes				
30-day mortality	0	0	0	-
1-year mortality	8 (8.5%)	4 (11.4%)	4 (6.8%)	0.43
2-year mortality	15 (16.0%)	6 (17.1%)	9 (15.3%)	0.81

AKI indicates acute kidney injury; APG, aortic pressure gradient; LT, life-threatening; LVEF, left ventricular ejection fraction; PM, pacemaker; PVL, paravalvular leakage; SAVR, surgical aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

	Months	0	6	12	18	24
TAVR	No. at risk	35	35	29	25	20
	%	0	2.8	11.7	11.7	19.4
	SE	0	0.03	0.06	0.06	0.07
SAVR	No. at risk	59	56	45	35	16
	%	0	5.1	7.1	14.1	19.2
	SE	0	0.03	0.03	0.05	0.06

Figure 2. Kaplan-Meier curve of mortality. SAVR indicates surgical aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

were not severe (dizziness, double vision, and visual field defect, respectively). Next-generation valves (i.e., Sapien 3) and utilization of stroke prevention devices may help to prevent stroke.²⁵⁻²⁷⁾

Several limitations could affect our outcomes. First, this was a single-center, retrospective analysis. Therefore, the small sample size may affect our results. Second, we hired the SAA criteria defined by two-dimensional TEE findings according to the report which revealed efficacy of

a first-generation THV in SAA patients.⁵⁾ Aortic annulus diameters measured by multidetector computed tomography or magnetic resonance imaging would have provided more precise information as we commonly use multimodal imaging for the preprocedural planning of structural heart disease. Although the most convenient and reliable way of measuring an aortic annulus diameter remains unclear, the most acceptable SAA definition would be preferred to determine the influence of SAA on the very

long-term outcomes. Third, a Sapien XT 23-mm valve was used in all the TAVR procedures because it was the smallest commercially available THV during the study period. Nevertheless, no aortic annulus rupture was observed, demonstrating the procedural safety of TAVR with a Sapien XT for SAA patients. In the SAVR group, we used two types of stented bioprostheses. Other newer bioprostheses, such as stentless valves or sutureless valves, may affect the outcomes.²⁸⁾ The difference in bleeding following TAVR and SAVR was not assessed.^{29,31)} Fourth, aortic annular enlargement or root replacement was not performed in our elderly cohort, although some reports have demonstrated efficacy in young patients.^{3,32,33)} The indication of these procedures should be discussed on a case-by-case basis as the adjunctive procedure could make the surgery more complex.³⁴⁾ Finally, the influence of PVL was not considered because its incidence was relatively low in this study, although PVL has been reported to be associated with poor outcome.³⁵⁻³⁷⁾

Conclusion

In SAA patients with high surgical risk, TAVR with a Sapien XT exhibited better valve hemodynamics and a lower incidence of PPM than SAVR. In addition, the long-term mortality in SAA patients was similar between the two groups despite the increased age and higher surgical risk in the TAVR population. TAVR can be considered as an alternative to SAVR in high surgical risk SAA patients who are susceptible to PPM and consequent poor clinical outcomes.

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Disclosures

Conflicts of interest: Shinichi Shirai, MD is a proctor for transfemoral-TAVR for Edwards Lifesciences. Yoshio Arai, MD is a proctor for transapical-TAVR for Edwards Lifesciences. The other authors have stated that they have no relationships relevant to the contents of this paper to disclose.

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