Original Article

Ten Years' Experience of Transcatheter Aortic Valve Replacement at the Faculty of Medicine Siriraj Hospital: Transapical vs. Transfemoral Approach

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Objective: To compare 30 days mortality and clinical outcomes between transapical transcatheter aortic valve replacement (TA-TAVR) and transfemoral transcatheter aortic valve replacement (TF-TAVR) in Thai patients who underwent transcatheter aortic valve replacement (TAVR).

Materials and Methods: The observational study included 83 consecutive patients that attended the authors' center for TAVR between January 2009 and December 2019. The patients' baseline demographic data and surgical risks were recorded. The clinical outcomes at 30 days and one year were prespecified targets.

Results: Eighty-three patients underwent TAVR at the authors' center between 2009 and 2019, with 77% of them considered inoperable or at high surgical risk by the authors' heart team. Of the 83 patients, 40 had a porcelain aorta (48.2%). The median Society of Thoracic Surgeons (STS) score and logistic EuroSCORE were 5.7 (4.6, 8.3) and 21.7 (15.2, 31.2), respectively. Twenty-two patients had a transapical approach (26.5%). The cardiovascular (CV) mortality rate was 2.4% at 30 days. The all-cause mortality 30-day rate and 1-year rate were 3.6% and 12.0%, respectively. Comparing between TA-TAVR and TF-TAVR, TA-TAVR had a significantly lower incidence of new permanent pacemaker placement after TAVR (p=0.032), but a longer length of hospital stay (p=0.087). There was a trend for a higher incidence of new onset atrial fibrillation in TA-TAVR. The all-cause mortality 30-day rate and 1-year rate were similar between TA-TAVR and TF-TAVR.

Conclusion: In Thai symptomatic severe aortic stenosis patients, of whom most patients were considered inoperable or at high surgical risk, both TA-TAVR and TF-TAVR showed acceptable short- and long-term clinical outcomes.

Keywords: Severe aortic stenosis (severe AS), Transcatheter aortic valve replacement (TAVR), Transfemoral (TF), Transapical (TA)

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Aortic stenosis (AS) is commonly found in aging populations. AS affects nearly 4% of adults over 75 years old. The presenting symptoms include angina, syncope, and congestive heart failure. The mortality rate is 50% once the patients have developed symptoms. Surgical aortic valve replacement (SAVR) is the treatment of choice for symptomatic severe AS. However, nearly one-third of patients cannot undergo SAVR due to co-morbidities, chronic obstructive pulmonary disease (COPD), prior chest radiation or surgery, or a porcelain aorta. Transcatheter aortic valve replacement (TAVR) is the common alternative treatment for symptomatic severe AS. Even though the 30-day mortality rate was 5% in the PARTNER Cohort B trial of inoperable patients, still, one life was saved for every five patients treated (number needing to be treated: NNT=5 for all-cause mortality). Furthermore, for high-risk SAVR patients,

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TAVR was found to be non-inferior to SAVR with a 30-day all-cause mortality rate of 3.4%, and a 1-year mortality rate of 24.2%[1,2]. TAVR is a class I indication for patients who are not suitable for SAVR. TAVR is often favored in elderly patients who have an increased surgical risk based on the Society of Thoracic Surgeons (STS) score greater than 4%, and the logistic European System for Cardiac Operative Risk Evaluation I (EuroSCORE I) score greater than 10%[3]. Siriraj Hospital was the first to launch a TAVR program in Thailand in 2009. The authors herein reported the authors' experiences and the clinical outcomes of TAVR between 2009 and 2019. The authors aimed to compare 30 days mortality and clinical outcomes between transapical (TA)-TAVR and transfemoral (TF)-TAVR in Thai patients that underwent TAVR.

Materials and Methods

The Siriraj Institutional Review Board approved the study (COA No. Si 438/2018). Investigations were performed in accordance with the Declaration of Helsinki. The present study was a retrospective prospective cohort study that enrolled 83 consecutive symptomatic severe AS patients who underwent TAVR in the authors' center between January 2009 and December 2019. The patients' baseline clinical characteristics, surgical risk, and clinical outcome intraoperatively at 30-day and 1-year follow-up were obtained.

In 2009, the initial criterion for TAVR was only symptomatic severe AS patients who were not suitable for open surgery. The authors later allowed high-surgical-risk patients to undergo TAVR evaluation. In 2017, two years after the NOTION trial was published. Patients with an intermediate surgical risk and who were over 80 years old and who could afford the device needed for TAVR evaluation by the heart team were also considered for TAVR. The initial surgical access for TAVR in the authors' center was mainly via a TA approach because the sheath for the first generation SAPIEN device was 22 to 24F. Once the second generation SAPIEN XT TAVR device sheath size was dropped down to 18F, the TF approach was applied in 50% of the cases. In 2017, the third generation SAPIEN 3 device became commercially available in Thailand. Here, the TAVR sheath size was dropped down to 14 to 16F. The TF approach was adopted for most patients. The authors also acquired a self-expandable TAVR device from Abbott Portico in 2017.

For access site selection (TA-TAVR versus TF-TAVR), patients were selected for TA-TAVR if the smallest femoral diameter was 7 mm or smaller (sheath size 22F), 8 mm or smaller (sheath size 24F) for first generation SAPIEN, 6 mm or smaller (sheath size 16F), 5 mm or smaller (sheath size 18F), and 7 mm or smaller (sheath size 20F) for SAPIEN XT or Abbott Portico, and 5 mm or smaller (sheath size 14F), 5.5 mm or smaller (sheath size 14F), and 6 mm or smaller (sheath size 16F) for SAPIEN 3.

At the beginning, the heart team met on the day of the TAVR surgery. Subsequently, the heart team meetings were arranged in two consecutive sessions to review patients before and on the day of the TAVR surgery. In 2015, an annular rupture occurred in one patient, causing intra-operative mortality. A retrospective review of the case reported that several findings from the echocardiographic assessment and computerized tomography (CT) image would have been helpful in risk prediction. Consequently, the heart team came up with the plan that during the initial assessment of a patient's CT image, they would obtain an echocardiogram to gain an anatomical perspective to look for things of concern, such a coronary obstruction, annular rupture, or vascular access complications. The authors, then tailor-made a pre-TAVR plan to include the size of balloon post-dilatation, volume of contrast added in the balloon, degree of acceptance of paravalvular leakages, and pre and post angiographic surveillance of the access side in accordance with their anatomical perspective.

Heart team evaluation protocol. Once a patient is referred for TAVR evaluation, the nurse coordinator will arrange for the pre-TAVR investigations. All patients undergo a coronary angiogram, echocardiogram, and CT angiogram of the whole aorta. The patient is then seen by the interventional cardiologist and cardiothoracic surgeon to evaluate their clinical status, co-morbidities, and frailty. The heart team will then have their first meeting to evaluate the patient's clinical status, frailty, coronary angiogram, echocardiogram, and CT image. The patient is then assigned as a low, intermediate, high, or inoperable SAVR risk. Patients will be scheduled for TAVR if their SAVR risk were high or inoperable. Patients with an intermediate SAVR risk who are aged over 80 years old and who prefer TAVR and who can afford to pay for their device are also included in the TAVR program. Because SAVR is the gold standard treatment for symptomatic severe AS at the time of the present study, patients with a low surgical SAVR risk and intermediate SAVR risk and who are aged less than 80 years old will be arranged for SAVR. The

second heart team conference is scheduled again to be held at the date of the TAVR surgery to finalize the TAVR plan.

The patients' baseline demographic data, such as age, gender, body weight, height, underlying disease, previous surgery, previous radiation, and electrocardiogram, are recorded. The patients' clinical presentation, STS score, EuroSCORE, laboratory value, echocardiogram, CT angiogram, and coronary angiogram data are recorded. The TAVR device information, model, and size are recorded. Intra-operative clinical findings, such as post-TAVR paravalvular leakage, device embolization, device thrombosis, vascular injury, access site complications, are also recorded. In-hospital, 30-day, and 1-year clinical events of death, acute kidney injury (AKI), major bleeding, vascular complications, stroke, congestive heart failure, and myocardial infarction are prespecified. Definitions of TAVR clinical endpoints is based on the Valve Academic Research Consortium (VARC)-2[4].

Statistical analysis

Categorical data were presented as the frequency and percentage. Continuous variables were reported as the mean ± standard deviation or median (interquartile range 25%, 75%) depending on the distribution of the data. Categorical data were compared using the chi-square test or Fisher's exact test, and continuous data were compared using the Student's t-test (normality) or Mann-Whitney U test (non-normality). A p-value of less than 0.05 is considered statistically significant. All the statistical analyses were performed using IBM SPSS Statistics, version 22.0 (IBM Corp., Armonk, NY, USA).

Results

Eighty-four patients were initially scheduled for TAVR. One patient was excluded as she was found to have unstable arrhythmia while accessing the site and so the TAVR procedure was terminated without any device deployment. Consequently, 83 patients were enrolled in the present study, of whom 64 (77%) were concluded by the heart team as having a high SAVR risk or as being inoperable for open surgery. The mean patient age was 83.8±6.6 years old. The oldest patient who underwent TAVR was 103 years old. The median STS score, logistic EuroSCORE, and EuroSCORE II were 5.7 (4.6, 8.3), 21.7 (15.2, 31.2), and 4.8 (3.3, 8.6), respectively. In addition, 40 patients (48.2%) had a porcelain aorta. Prior chest radiation, COPD, and end-stage renal disease on hemodialysis occurred in two (2.4%), six (7.2%), and six (7.2%) patients, respectively. Previous cardiothoracic surgery occurred in 16 patients. Forty-one patients were classed as Baseline New York Heart Association (NYHA) classes III to IV (49.4%). The mean creatinine clearance was 31.1±13.8. The major presenting symptom indication for TAVR was heart failure (59%). The baseline demographic data are summarized in Table 1. The baseline ejection fraction (EF) was 65.0±14.7%. The mean aortic valve area was 74.8±24.8 mm^2. The mean aortic valve gradient was 51.4±16.7 mmHg. The average annulus diameter by echocardiogram was 21.5±1.8 mm. The average annulus diameter measured by computed tomography angiography (CTA) was 22.0±4.4 mm. The mean height of the left coronary ostium from the aortic annulus was 13.4±2.5 mm. The mean height of the right coronary ostium from the aortic annulus was 14.8±3.1 mm. The mean minimal femoral access diameter was 6.5±1.3 mm. The baseline echocardiogram and CTA results are demonstrated in Table 2. The transcatheter aortic value size and type are demonstrated in Table 3.

Clinical outcomes

Intra-operative mortality occurred in one patient (1.2%) due to annular rupture. The cardiovascular (CV) mortality rate at 30 days was 2.4%. The all-cause mortality rate at 30 days was 3.6%. Two additional patients died due to sepsis, which included aspiration pneumonia and sepsis related to vascular complications.

The one-year mortality rate was 12.0%. Major vascular complications occurred in nine patients (10.8%), while stroke occurred in two patients (2.4%), and eleven patients (13.3%) had permanent pacemaker placement after TAVR. The clinical outcomes are shown in Table 4.

TA-TAVR versus TF-TAVR

Twenty-two patients had TA-TAVR, while 61 patients had TF-TAVR. Comparing between TA-TAVR and TF-TAVR, the median STS score was higher [8.4 (4.3, 13.3) versus 5.4 (4.7, 6.7)] in the TA-TAVR patients. The mean minimal femoral access diameter was smaller in the TA-TAVR patients (5.4±1.3 versus 6.6±1.2 mm). A comparison of the baseline demographic characteristics between the TA-TAVR and TF-TAVR patients is shown in Table 1. Comparing between TA-TAVR and TF-TAVR, there was a similar all-cause mortality at 30 days and one year. TA-TAVR had a significantly lower incidence

Table 1. Comparison of baseline characteristics between TA and TF cohorts

Baseline characteristics	Total (n=83); n (%)	TA (n=22); n (%)	TF (n=61); n (%)	p-value
Age (years); mean±SD	83.8±6.6	81.7±8.9	84.6±5.4	0.164
Sex: male	32 (38.6)	7 (31.8)	25 (41.0)	0.449
BMI (kg/m^2); mean±SD	22.8±4.1	21.6±4.5	23.2±3.9	0.140
DM	32 (38.6)	9 (40.9)	23 (37.7)	0.791
CrCl; mean±SD	31.1±13.8	27.4±15.1	33.3±12.7	0.136
PAD	19 (22.9)	9 (40.9)	10 (16.4)	0.019
CAD	57 (68.7)	19 (86.4)	38 (62.3)	0.037
Cancer	10 (12.0)	4 (18.2)	6 (9.8)	0.444
Previous MI	26 (31.3)	10 (45.5)	16 (26.2)	0.096
Previous PCI	37 (44.6)	13 (59.1)	24 (39.3)	0.110
Previous CABG	16 (19.3)	7 (31.8)	9 (14.8)	0.114
Existing atrial fibrillation	21 (25.3)	4 (18.2)	17 (27.9)	0.370
Angina	17 (20.5)	4 (18.2)	13 (21.3)	1.000
Syncope	19 (22.9)	5 (22.7)	14 (23.0)	0.983
DOE	56 (67.5)	14 (63.6)	42 (68.9)	0.654
HF	49 (59.0)	17 (77.3)	32 (52.5)	0.042
STS; median (IQR)	5.7 (4.6, 8.3)	8.4 (4.3, 13.3)	5.4 (4.7, 6.7)	0.097
EuroScore II; median (IQR)	4.8 (3.3, 8.6)	5.6 (2.9, 10.3)	4.8 (3.5, 7.8)	0.937
Logistic EuroSCORE; median (IQR)	21.7 (15.2, 31.2)	21.7 (13.4, 28.9)	21.7 (16.6, 31.2)	0.887
Porcelain Aorta	40 (48.2)	14 (63.6)	26 (42.6)	0.091
Heart team conclude				0.105
Inoperable	7 (8.4)	2 (9.1)	5 (8.2)	
High risk	57 (68.7)	19 (86.4)	38 (62.3)	
Intermediate risk	17 (20.5)	1 (4.5)	16 (26.2)	
Low risk	2 (2.4)	0 (0.0)	2 (3.3)	

SD=standard deviation; IQR=interquartile range; TA=transapical; TF=transfemoral; BMI=body mass index; DM=diabetes mellitus; CrCl=creatinine clearance; PAD=peripheral arterial disease; CAD=coronary artery disease; MI=myocardial infarction; PCI=percutaneous coronary intervention; CABG=coronary artery bypass grafting; DOE=dyspnea on exertion; HF=heart failure; STS=Society of Thoracic Surgeons

A p<0.05 indicates statistical significance

of new permanent pacemaker placement after TAVR (p=0.032). However, the trend for AKI and new onset atrial fibrillation was higher in TA-TAVR. The length of hospital stay was also longer in TA-TAVR (p=0.087). A comparison of the clinical outcomes between TA-TAVR and TF-TAVR is shown in Table 4.

Discussion

The authors' found that both TA-TAVR and TF-TAVR had acceptable short- and long-term outcomes in Thai patients with symptomatic severe AS, in which most patients were not candidates for SAVR or were considered a high surgical risk for SAVR. TA-TAVR had a higher incidence of new onset atrial fibrillation and a longer length of hospital stay, but a lower incidence of new permanent pacemaker placement when compared with TF-TAVR.

The present study is unique as it included the largest cohort of TA-TAVR patients in Thailand and Southeast Asia. TA-TAVR was perceived to have a worse prognosis based on the several registries[5-7]. Schymik et al demonstrated similar short- and long-term mortalities between TA-TAVR and TF-TAVR with their heart team experience[8]. In the present study, the long-term mortality was higher with TA-TAVR, and after propensity score matching, there was statistical difference. The initial higher long-term mortality risk could be due to the different risk profiles. In the present study, TA-TAVR had a higher prevalence of coronary and peripheral vascular disease. There was also a trend of a lower body mass index (BMI) and higher STS score in the present study TA-TAVR patients.

TA-TAVR in the present study had less

Table 2. Comparison of baseline echocardiography and CTA between TA and TF cohorts

	Total (n=83); mean±SD	TA (n=22); mean±SD	TF (n=61); mean±SD	p-value
Baseline echocardiograph				
LVEF (%)	65.0±14.7	64.9±13.5	65.1±15.2	0.957
LVEDV (mL)	62.8±25.8	62.1±21.6	63.1±27.2	0.878
LV mass Index (g/m^2)	160.5±44.1	150.6±37.2	162.5±45.3	0.397
AVA (mm^2)	74.8±24.8	70.9±17.7	76.1±26.9	0.415
Mean AVG (mmHg)	51.4±16.7	48.9±15.9	52.4±16.9	0.403
PHT; n (%)	64/78 (82.1)	14/18 (77.7)	50/60 (83.3)	0.030
sPAP (mmHg)	50.7±14.2	48.7±15.9	51.3±13.8	0.509
Aortic annulus (mm)	21.5±1.8	21.1±2.1	21.7±1.7	0.167
Aortic sinus (mm)	32.5±4.2	30.3±4.0	33.4±4.0	0.004
Aortic sinotubular (mm)	23.1±3.6	20.6±3.1	23.9±3.4	<0.001
Aortic tubular (mm)	33.2±4.7	30.5±5.0	34.1±4.2	0.003
Baseline CTA				
Annulus perimeter (mm)	72.1±8.7	71.9±5.9	72.1±9.1	0.977
Average diameter (mm)	22.0±4.4	22.8±2.2	21.9±4.7	0.602
Annulus area (mm^2)	398.9±63.6	388.8±64.4	400.4±63.9	0.631
Sinus (mm)	29.1±6.2	29.8±2.7	28.9±6.7	0.710
Sinotubular junction (mm)	26.8±3.9	24.6±4.1	27.1±3.8	0.113
Ascending aorta (mm)	32.8±7.3	31.9±1.6	32.9±7.9	0.678
Left coronary height (mm)	13.4±2.5	12.6±1.5	13.5±2.6	0.349
Right coronary height (mm)	14.8±3.1	14.4±2.8	14.9±3.2	0.690
Left leaflet length (mm)	12.7±1.9	12.10±0.8	12.8±2.0	0.399
Right leaflet length (mm)	12.8±2.1	12.7±2.3	12.9±2.1	0.831
Smallest access vessel diameter (mm)	6.5±1.3	5.4±1.3	6.6±1.2	0.021

SD=standard deviation; TA=transapical; TF=transfemoral; LVEF=left ventricular ejection fraction; LVEDV=left ventricular end diastolic volume; LV=left ventricle; AVA=aortic valve area; AVG=aortic valve gradient; PHT=pulmonary hypertension; sPAP=systolic pulmonary artery pressure; CTA=computed tomography angiography

A p<0.05 indicates statistical significance

Table 3. Comparison of device between TA and TF cohorts

Device	Total (n=83); n (%)	TA (n=22); n (%)	TF (n=61); n (%)	p-value
SapienTHV	9 (10.8)	7 (31.8)	2 (3.3)	0.001
Valve no. 23	5 (55.6)	4 (57.1)	1 (50.0)	1.000
Valve no. 26	4 (44.4)	3 (42.9)	1 (50.0)	
SapienXT	19 (22.9)	11 (50.0)	8 (13.1)	<0.001
Valve no. 23	13 (68.4)	9 (81.8)	4 (50.0)	0.319
Valve no. 26	6 (31.6)	2 (18.2)	4 (50.0)	
Sapien3	36 (43.4)	4 (18.2)	32 (52.5)	0.005
Valve no. 20	6 (16.7)	1 (25.0)	5 (15.6)	0.356
Valve no. 23	25 (69.4)	2 (50.0)	23 (71.9)	
Valve no. 26	5 (13.9)	1 (25.0)	4 (12.5)	
Portico	19 (22.9)	0 (0.0)	19 (31.1)	0.003
Valve no. 23	2 (10.5)	0 (0.0)	2 (10.5)	-
Valve no. 25	9 (47.4)	0 (0.0)	9 (47.4)	
Valve no. 27	5 (26.3)	0 (0.0)	5 (26.3)	
Valve no. 29	3 (15.8)	0 (0.0)	3 (15.8)	

TA=transapical; TF=transfemoral

A p<0.05 indicates statistical significance

paravalvular aortic regurgitation (AR), which is similar to the prior published literature[8,9]. TA access to the aortic valve is more direct, which allows more accurate positioning and less tilting of the device. TA-TAVR has a longer post-procedural hospital stay and a higher incidence of new onset atrial fibrillation. Even though TA-TAVR is a less invasive procedure compared to SAVR, it is still the required route on the left ventricle. This could create inflammation to the left ventricle and pericardium, leading to an increased incidence of atrial fibrillation. TF-TAVR has a route via femoral access without injuring the left ventricle. In the current practice, the surgeon ambulated and discharged the uncomplicated TF-TAVR patients the next day after the procedure.

TA-TAVR also has an increased incidence of AKI. TA access is a well-known independent predictor for AKI[10,11].

TF-TAVR had a higher incidence of new permanent pacemaker placement in the present study.

Table 4. Comparison of clinical outcomes between TA and TF cohorts

Clinical outcomes	Total (n=83); n (%)	TA (n=22); n (%)	TF (n=61); n (%)	p-value
All-cause intra-operative mortality	1 (1.2)	0 (0.0)	1 (1.6)	1.000
All-cause 30 days mortality	3 (3.6)	1 (4.5)	2 (3.3)	1.000
CV death at 30 days	2 (2.40)	0 (0.0)	2 (3.3)	1.000
All-cause 1-year mortality	10 (12.0)	2 (9.1)	8 (13.1)	1.000
CV death at 1-year	2 (2.4)	0 (0.0)	2 (3.3)	1.000
Stroke	2 (2.4)	0 (0.0)	2 (3.3)	1.000
Acute kidney injury	20 (24.1)	8 (36.4)	12 (19.7)	0.117
Life threatening bleeding	10 (12.0)	4 (18.2)	6 (9.8)	0.444
Moderate to severe PVL	8 (9.6)	1 (4.5)	7 (11.5)	0.675
Myocardial infarction	4 (4.8)	2 (9.1)	2 (3.3)	0.285
Chronic heart failure	8 (9.6)	3 (13.6)	5 (8.2)	0.431
Major vascular complications	9 (10.8)	2 (9.1)	7 (11.5)	1.000
New atrial fibrillation	7 (8.4)	4 (18.2)	3 (4.9)	0.076
New permeant pacemaker	11 (13.3)	0 (0.0)	11 (18.0)	0.032
Infection	25 (30.1)	8 (36.4)	17 (27.9)	0.457
Shock	11 (13.3)	2 (9.1)	9 (14.8)	0.719
Length of stay (days); mean±SD	11.8±17.5	19.8±27.9	8.9±10.6	0.087
CCU LOS (days); mean±SD	2.1±1.9	2.2±2.2	2.1±1.8	0.756
30-day re-hospitalization	10/82 (12.2)	4/22 (18.2)	6/60 (1.0)	0.446

SD=standard deviation; TA=transapical; TF=transfemoral; CV=cardiovascular; PVL=paravalvular leak; CCU=cardiac care unit; LOS=length of stay

A $p<0.05$ indicates statistical significance

This was due to device-specific reasons. TF-TAVR involves both a balloon and a self-expandable TAVR device in the present study center, whereas TA-TAVR only involves a balloon expandable TAVR device. Because of the specific design of self-expandable TAVR devices, they more often protrude into the left ventricular outflow tract (LVOT) where the conduction system is located. Self-expandable TAVR devices are known for a higher incidence of permanent pacemakers[12,13].

Limitation

The authors did not directly compare between TA-TAVR and TF-TAVR using a prospective randomized trial design but used the procedural entity to separate the group. Common femoral vessel diameter from CTA was used as the access site selection. Selection bias cannot be excluded. The number of patients that underwent TAVR via both access sites was limited and may have lacked sufficient statistical power to identify significant differences between groups.

Conclusion

In symptomatic severe AS, both TA-TAVR and TF-TAVR showed acceptable short- and long-term outcomes even in the patient population who are not usually candidates or who are considered high surgical risk for AVR. Due to differences in the access site, there are pros and cons in each different endpoint. From a practical point of view, in the authors' center, we choose TF-TAVR as the default access. However, in patients for whom the access site is not suitable for TF-TAVR, TA-TAVR could be performed with similar short- and long-term outcomes.

What is already known on this topic?

TAVR is preferred over SAVR in patients who are not suitable for SAVR and who are considered a high surgical risk for SAVR. The TF approach is preferred in those cases. However, in cases with an inappropriate access site, the TA approach can be used.

What this study adds?

This study contributes data on the 30-day and 1-year clinical outcomes of symptomatic severe AS Thai patients who underwent TAVR. TAVR has acceptable short- and long-term outcomes in treating symptomatic severe AS that is inoperable or that carries a high surgical risk. In patients for whom the

access site is not suitable for TF-TAVR, TA-TAVR could be performed with similar short- and long-term outcomes.

Conflicts of interest

All the authors declare that they had no personal or professional conflicts of interest and received no financial support from the companies that produce or distribute the drugs, devices, or materials described in this report.

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