

Comparison of transcatheter aortic valve implantation outcomes in patients with severe aortic stenosis and contraindications for transfemoral access

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Abstract

Background: *The purpose of this study was to compare the safety and clinical outcomes of transcatheter aortic valve implantation (TAVI) patients whom the transfemoral approach (TF) was not feasible.*

Methods: *The analysis included consecutive patients with severe symptomatic aortic stenosis treated from 2017 to 2020 with TC-TAVI or TA-TAVI in two high-volume TAVI centers. The approach was selected by multidisciplinary heart teams after analyzing multislice computed tomography of the heart, aorta and peripheral arteries, transthoracic echocardiography and coronary angiography.*

Results: *One hundred and two patients were treated with alternative TAVI accesses (TC; n = 49 and TA; n = 53) in our centers. The groups were similar regarding age, gender, New York Heart Association class, and echocardiography parameters. Patients treated with TC-TAVI had significantly higher surgical risk. The procedural success rate was similar in both groups (TC-TAVI 98%; TA-TAVI 98.1%; p = 0.95). The rate of Valve Academic Research Consortium-2 defined clinical events was low in both groups. The percentage of new-onset rhythm disturbances and permanent pacemaker implantation was similar in TC and TA TAVI (4.1% vs. 11.3%; p = 0.17 and 10.2% vs. 5.7%; p = 0.39, respectively). In the TA-TAVI group, significantly more cases of pneumonia and blood transfusions were observed (11% vs. 0%; p = 0.01 and 30.2% vs. 12.2%; p = 0.03). The 30-day mortality was similar in TC and TA groups (4.1% vs. 5.7%; p = 0.71, respectively).*

Conclusions: *Both TC and TA TAVI are safe procedures in appropriately selected patients and are associated with a low risk of complications. (Cardiol J 2023; 30, 2: 188–195)*

Key words: aortic stenosis, transcatheter aortic valve implantation (TAVI)

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Introduction

The first transcatheter aortic valve implantation (TAVI) described in 2002 by Cribier et al. [1] opened a new era of treatment of severe, symptomatic aortic stenosis in high-risk or inoperable patients. Transfemoral (TF) is a well-known, minimally invasive, and safe access route for TAVI procedures recommended not only for high and intermediate-risk patients, but also for selected older low-risk patients [2–4]. Due to peripheral arterial disease, unfavorable aortoiliac anatomy, or diseases of the thoracoabdominal aorta, TF access is unavailable for approximately 15% of all TAVI candidates [5, 6]. The surgical antegrade transapical (TA) access, as described in 2006 by Ye et al., is the first-choice alternative approach in many centers, in case of an inability to use the TF route [7–9]. In 2010, Modine et al. [10] described the first TAVI performed via the left common carotid artery (CCA). Transcarotid (TC) TAVI seems to be a safe alternative for patients disqualified from TF-TAVI [11–13]. The present study aimed to compare the safety, and short-term efficacy outcome of consecutive patients treated TC-TAVI and TA-TAVI in two high-volume TAVI centers in Poland.

Methods

This retrospective analysis included consecutive patients with severe symptomatic aortic stenosis treated between 2017 and 2019 with TC-TAVI or TA-TAVI in two high-volume TAVI centers. The retrospective registry did not require the approval of an institutional review board or ethics committee. The database contained anonymized datasets. Written informed consent for the TAVI procedure according to the qualification was obtained from all patients. The study outcomes were defined according to the Valve Academic Research Consortium-2 (VARC-2) consensus [14]. The choice of access (TF vs. alternative) site was made by The Heart Team based on results from multislice computed tomography (MSCT) of the heart, aorta, and peripheral arteries, transthoracic echocardiography (TTE), and coronary angiography. For the analysis and reconstruction of the MSCT images, the 3Mensio (Pie Medical Imaging, Bilthoven The Netherlands) software was used. Patients with peripheral artery disease, including significant stenosis, extreme tortuosity, heavy calcifications, and small iliofemoral artery diameter (< 6 mm) were considered to have contraindications for TF-TAVI. Also, the thoracoabdominal aorta significant diseases includ-

ing aneurysm, chronic dissection, large thrombus, extreme tortuosity, previous vascular surgery, or presence of an aortic stent graft was an indication for the use of alternative access routes (TC or TA). The choice depended on the operator's experience and preferences. The criteria for consideration of TC-TAVI were as follows: diameter of the CCA > 5.5 mm with no significant calcifications and no ipsi- and contralateral CCA stenosis (> 50%). The exclusion criteria for TA access were frailty syndrome, cachexia, significant coagulopathies, and severe lung diseases. All procedures were done by an experienced Heart Team in a hybrid operating room under general or in some cases of TC-TAVI under local anesthesia. The detailed protocol of transcarotid access was described in earlier publications [11, 15]. In TA-TAVI, access to the pericardium was achieved through the left anterior mini-thoracotomy. The decision on the location of the incision was made under angiographic and TTE guidance. Typically, a 4–5 cm long incision was made at the 7th intercostal space. Then the pericardium was visualized and opened. An apical two U pledged sutures were placed slightly lateral and above the true apex. The heart was punctured with a needle, and after the introduction of 6 F vascular sheath, the J-tipped wire crossed the aortic valve and was positioned in the descending aorta. Following that, the right Judkins or pigtail catheter was positioned, and the soft wire was exchanged for a stiff wire. Over the stiff wire, the Certitude sheath was inserted into the left ventricle. The valve was placed at the target position, as confirmed by root contrast injection. Valves were expanded during the rapid pacing 160–180 bpm to achieve systolic blood pressure below 50 mmHg. After implantation position of the valve and grade of paravalvular leak was controlled by contrast injection. All patients were given antibiotics (1.5 g cephazolin) as infectious endocarditis prophylaxis. The heparin (100 U/kg, target activated clotting time > 250 s) was administered after placement of a vascular access catheter (6 F) into the carotid artery in TC-TAVI and before cardiac puncture in TA-TAVI. Patient monitoring during both types of procedure included: continuous intraarterial blood pressure, arterial blood saturation, electrocardiography, and additionally cerebral oximetry (Covidien, Medtronic plc, Ireland) in cases of the TC-TAVI cases. TTE was used during TC-TAVI, and transesophageal echocardiography was performed in TA-TAVI. The electrode for rapid pacing was placed through the 6 F sheath through an internal jugular vein or femoral vein. External defibrillator pads were

Table 1. Baseline and demographic data.

Variables	TC-TAVI (n = 49)	TA-TAVI (n = 53)	P
Age [years]	78 (72–85)	78 (71–81)	0.30
Male	26 (53.1)	30 (56.6)	0.72
Body mass index [kg/m ²]	28 (24.8–31.2)	27 (24.7–29.2)	0.45
NYHA class	3 (3–3)	3 (3–3)	0.12
EuroSCORE II [%]	8.0 (4.8–10.9)	5.7 (2.9–8.2)	0.009
Cardiac comorbidities			
Prior myocardial infarction	17 (34.7)	20 (37.7)	0.75
Prior cardiac operation	13 (26.5)	24 (45.3)	0.05
Prior PCI	25 (51)	18 (34)	0.08
Hypertension	48 (98)	47 (88.7)	0.06
Bicuspid aortic valve	11 (22.4)	8 (15.1)	0.34
Other comorbidities			
Diabetes mellitus	22 (44.9)	23 (43.4)	0.88
COPD	13 (26.5)	10 (18.9)	0.36
Peripheral arterial disease	22 (44.9)	27 (50.9)	0.54
Abdominal aortic aneurysm	8 (16.3)	2 (3.8)	0.03
Atrial fibrillation	16 (32.7)	15 (28.3)	0.63
Hypertension	48 (98)	47 (88.7)	0.06
Thrombus in aorta	18 (36.7)	10 (18.9)	0.04
Blood test results			
GFR [mL/min/1.73 m ²]	61.0 (48.5–70.2)	56 (43.7–66.7)	0.21
Hemoglobin level [g/L]	12.9 (11.8–14.2)	12.5 (10.9–13.4)	0.03
Hematocrit [%]	39.7 (35.5–42.1)	37.3 (32.9–39.8)	0.01
Platelet level × 10 ³ /μL	173 (153–224.5)	207 (162.2–257.7)	0.04
WBC level × 10 ³ /μL	7.1 (6.0–8.6)	7.2 (6.0–8.6)	1.00

Data are given as the median (interquartile range) or as number (%); COPD — chronic obstructive pulmonary disease; GFR — glomerular filtration rate; NYHA — New York Heart Association; PCI — percutaneous coronary intervention; TAVI — transcatheter aortic valve implantation; TA — transapical access; TC — transcarotid access; WBC — white blood cells

also placed. Post dilatation was performed if the angiographic and echocardiographic evaluation of paravalvular leak was moderate or larger. Protamine was given after removing the instruments and tightening sutures. After TC-TAVI, the selective arteriography was performed for control of CCA patency. The eligibility criteria, methods, and techniques of TA-TAVI and TC-TAVI procedures did not differ at both centers.

Statistical analysis

Categorical data were presented as numbers (%). The Kolmogorov-Smirnov test was used to assess the data distribution. Normally distributed values were presented as mean with standard deviation. Non-normally distributed values were presented as median with 25th and 75th percentile (interquartile range [IQR]). Continuous data were compared by the Student t-test or by the Mann-

-Whitney U test, depending on the distribution. Categorical data were analyzed with the χ^2 or the Fisher exact test. P values of < 0.05 were considered statistically significant. The statistical analysis was performed using Medcalc 17.9.2 (Medcalc software).

Results

Patient characteristics

Between 2017–2020, 882 TAVI procedures were performed in the Upper-Silesian Medical Center of the Medical University of Silesia in Katowice and the Medical University of Gdansk. Most of them (88%) were TF-TAVI. This retrospective study enrolled 102 patients treated with alternative TAVI accesses (TC; n = 49 and TA; n = 53). The baseline characteristics of the patients are presented in Tables 1 and 2. The groups were

Table 2. Perioperative and postoperative outcomes.

Variables	TC-TAVI (n = 49)	TA-TAVI (n = 53)	P
Perioperative			
Procedural success	48 (98.0)	52 (98.1)	0.95
Procedural time [min]	65 (60.0–76.2)	110 (80.0–120.0)	< 0.0001
General anesthesia	47 (95.9)	53 (100)	0.39
Valve prosthesis size	29.0 (26.0–29.0)	26.0 (23.0–26.0)	< 0.0001
Balloon aortic predilatation	5 (10.2)	0 (0)	0.01
Balloon aortic postdilatation	10 (20.4)	5 (9.4)	0.12
Coronary occlusion	0 (0)	1 (1.9)	0.33
Intraoperatively inotropic drugs	11 (22.4)	15 (28.3)	0.50
Temporary pacemaker > 24 hours	9 (18.4)	8 (15.1)	0.66
Postoperative			
Myocardial infarction	1 (2.0)	2 (3.8)	0.60
Life-threatening bleeding	0 (0)	1 (1.9)	0.33
Blood transfusion	6 (12.2)	16 (30.2)	0.03
Transient ischemic attack	3 (6.1)	1 (1.9)	0.23
Stroke	0 (0)	1 (1.9)	0.86
Tamponade	1 (2.0)	2 (3.8)	0.60
Minor vascular complication	2 (4.1)	2 (3.8)	0.93
Mechanical ventilation time [min]	160.0 (92.5–360)	200 (160.0–315)	0.07
ICU stay [days]	2 (2–3)	3 (2–4)	0.21
Hospital stay [days]	6 (6–7)	7 (5–8)	0.03
NYHA class on discharge	1 (1–2)	2 (1–2)	0.003
Pneumonia	0	6 (11.5)	0.01
New-onset atrial fibrillation	2 (4.1)	6 (11.3)	0.17
Permanent pacemaker implantation	5 (10.2)	3 (5.7)	0.39
In-hospital mortality	1 (2.0)	2 (3.8)	0.60
Short-term follow-up mortality	2 (4.1)	3 (5.7)	0.35
Blood test results			
GFR [mL/min/1.73 m ²]	62.5 (48–79.5)	60 (47–72)	0.27
Hemoglobin level [g/L]	11.2 (9.9–11.9)	10.7 (9.6–11.7)	0.17
Hematocrit [%]	33.4 (30.1–35.4)	33.0 (28.8–35.1)	0.47
Platelet level × 10 ³ /μL	139 (116–162)	157 (123.5–192.7)	0.04
WBC level × 10 ³ /μL	6.8 (5–8.8)	9 (6.8–11.4)	0.0002

Data are given as the median (interquartile range) or as number (%); GFR — glomerular filtration rate; ICU — intensive care unit; TAVI — transcatheter aortic valve implantation; TA — transapical access; TC — transcarotid access; WBC — white blood cells

similar regarding age (78 [72–85] vs. 78 [71–81]; $p = 0.30$), gender (53.1% males vs. 56.6%; $p = 0.72$), baseline New York Heart Association (NYHA) class and echocardiography parameters (left ventricular ejection fraction; aortic valve area; aortic valve maximal gradient [PG_{max}], aortic valve mean gradient [PG_{mean}]; transaortic peak instantaneous velocity [V_{max}]). Patients treated with TC-TAVI more often had a pathology of the abdominal aorta (aneurysm, extreme tortuosity,

and thrombus) (16.3% vs. 3.8%; $p = 0.03$ and 36.7% vs. 18.9%; $p = 0.03$, respectively). Additionally, their surgical risk assessed by EuroSCORE II was significantly higher (8.0 [4.8–10.9] vs. 5.7 [2.9–8.2]; $p = 0.009$) than the TA group. In preoperative blood tests there were differences between the TC and TA group in the level of hemoglobin (12.9 [11.8–14.2] vs. 12.5 [10.9–13.4]; $p = 0.03$), hematocrit (39.7 [35.5–42.1] vs. 37.3 [32.9–39.8]; $p = 0.01$) and platelets (173 [153–224.5] vs. 207

Table 3. Pre- and postprocedural echocardiographic parameters.

	Preprocedural			Postprocedural		
	TC-TAVI (n = 49)	TA-TAVI (n = 53)	P	TC-TAVI (n = 48)	TA-TAVI (n = 51)	P
LVEF [%]	50 (41–60)	50 (40–55)	0.23	55 (50–60)	50(40–55)	0.03
PGmean [mmHg]	44 (36–54)	44 (38–51)	0.83	8 (6–11)*	10 (8–12)*	0.02
PGmax [mmHg]	73 (63–86)	73 (63–85)	0.91	15 (13–20)*	18 (15–21)*	0.03
Vmax [m/s]	4.1 (3.9–4.6)	4.3 (3.8–4.6)	0.57	2 (1.8–2.3)*	2 (1.9–2.3)*	0.27
Paravalvular leak > 2 grade	–	–	–	2 (4.2)	0 (0)	0.41

Data are presented as the median (interquartile range) or as number (%). *An asterisk indicated values statistically different from the preoperative values ($p < 0.001$); LVEF — left ventricular ejection fraction; PGmax — aortic valve maximal gradient; PGmean — aortic valve mean gradient; TAVI — transcatheter aortic valve implantation; TA — transapical access; TC — transcarotid access; Vmax — transaortic peak instantaneous velocity

[162.2–257.7]; $p = 0.04$), respectively. However, the number of patients with anemia by definition of the World Heart Organization was similar (TC: 15/49 [31%] vs. TA: 22/53 [41.5%]; $p = 0.25$). Both groups did not show statistically significant differences in terms of other blood test results and comorbidities.

Perioperative outcomes

All TA-TAVI and most TC-TAVI (95.9%) were made under general anesthesia ($p = 0.13$). There were differences in terms of type of prosthesis used. Balloon-expandable (BE) Sapien 3 aortic valve prosthesis (Edwards Lifesciences Corp., Irvine, CA, USA) were implanted in all procedures performed via TA access. In the TC-TAVI group both BE valves were used (Edwards-Sapien 3 Ultra in 26.5% of cases), as well as self-expandable (SE) valves (Evolute R [Medtronic, Minneapolis, MN, USA] and Portico [Abbott Vascular, Santa Clara, CA, USA] in 71.5% and 2% of cases, respectively). In patients treated with TC-TAVI, significantly larger valve sizes were used (29 [26–29] mm vs. 26 [23–26] mm; $p < 0.0001$). The median procedure time was significantly shorter in TC group (65 [60–76.2] min vs. 110 [80–120] min; $p < 0.0001$). In this group, there was a higher percentage of balloon predilatation (5% vs. 0%; $p = 0.01$) than in TA. No statistically significant differences in other procedural parameters were noted (Table 3).

The procedural success rate was high and were similar in both groups: TC-TAVI 98%; TA-TAVI 98.1% ($p = 0.95$). One patient died during TC-TAVI, and 2 patients died during TA-TAVI ($p = 0.60$). A low rate of neurological complications was observed in both groups (only 1 stroke in TA group [1.9%] vs. none in TC group; $p = 0.33$ and

1 transient ischemic attack [1.9%] vs. 3 [6.1%]; $p = 0.27$, respectively). The rate of other events was assessed according to VARC-2 was low and did not differ between groups (coronary artery occlusion [0% vs 1.9%; $p = 0.33$], myocardial infarction [2% vs. 3.8%; $p = 0.6$], life-threatening or disabling bleeding [0% vs. 1.9%; $p = 0.33$], major and minor vascular complications [4.1% vs. 3.8%; $p = 0.93$] and acute renal failure with need of dialysis [0% vs. 1.9%; $p = 0.33$]). None of the patients required conversion to surgical valve replacement due to prosthetic dislocation or dysfunction.

In-hospital outcomes

The median time patients spent in the intensive care unit was similar (2 [2–3] vs. 2 [2–3]; $p = 0.66$) while the median hospitalization time was shorter in TC group (6 [5–7] vs. 7 [5–8]; $p = 0.03$). The percentage of new-onset atrial fibrillation and permanent pacemaker implantation was similar in TC and TA TAVI (4.1% vs. 11.3%; $p = 0.17$ and 10.2% vs. 5.7%; $p = 0.39$, respectively). Prolonged postoperative temporary pacing was required in 18.4% of patients with the TC approach and 15.1% with TA ($p = 0.65$). In the TA-TAVI group, significantly more cases of pneumonia and blood transfusions were observed (11% vs. 0%; $p = 0.01$ and 30.2% vs. 12.2%; $p = 0.03$). Total postoperative drainage was small 330.0 mL (220.5–482.5 mL) in TA patients. Local complications were rare and only related to wound hematoma (TC 4.1%, TA 1.9%; $p = 0.51$). There was no wound infection or pneumothorax in any of the groups. In the control TTE similar ejection fraction was observed as well as a significant reduction in aortic stenosis parameters (PGmax, PGmean, and Vmax). The median NYHA functional class significantly decreased as

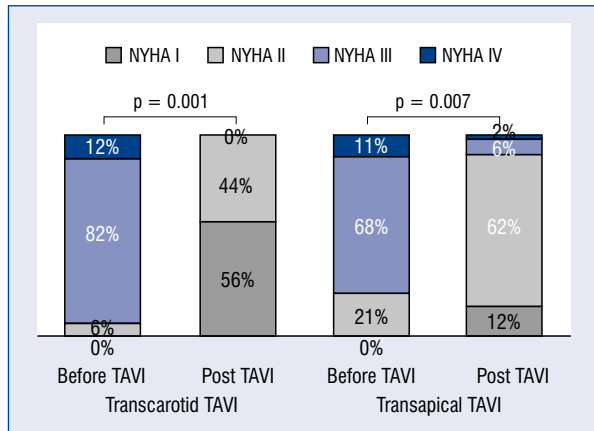


Figure 1. Changes in the New York Heart Association (NYHA) class before and after transcatheter aortic valve implantation (TAVI) — a comparison of transcatheter and transapical TAVI.

compared to the initial values (Table 2, Fig. 1). Postprocedural echocardiography results were showed slightly lower transvalvular gradients in the TC group (PG_{max} 15.5 [13–20.5] vs. 18.5 [15.5–21]; $p = 0.03$), PG_{mean} 8.5 [6–11] vs. 10 [8–12]; $p = 0.02$), ejection fraction 55 [50–60] vs. 50 [40–57.5]; $p = 0.03$). In the control laboratory test results had differences between the TC and TA group in the white blood cells level (6.8 [5–8.8] vs. 9 [6.8–11.4]; $p = 0.0002$) and platelets (139 [116–162] vs. 157 [123.5–192.70]; $p = 0.04$).

Short-term outcomes

The final NYHA class was lower in TC group (1 [1–2] vs. 2 [1–2]; $p = 0.003$). The 30-day mortality was similar in TC and TA groups (4.1% vs. 5.7%; $p = 0.71$, respectively).

Discussion

Selection of the alternative access

Data herein, shows that the use of an alternative to TF access routes pertains to a relatively small population of approximately 12% of TAVI-eligible patients. The registry evaluated the data of 102 consecutive patients treated with non-TF TAVI accesses. Both groups were comparable in sample size, age, gender, heart failure class, and baseline echocardiographic parameters. The differences between groups are mainly related to the operative EuroSCORE II risk and the frequency of aortic pathology (aneurysm, thrombus) which were significantly higher in the TC group. On the other hand, the patients treated with the TA approach

more often had a history of cardiac surgery. There were some differences in the baseline hemoglobin levels; however, they were not marked, and the frequency of anemia was similar. Patient selection is crucial because TF access provides the lowest risk of complications, and the decision to switch to an alternative access should be based on thorough Heart Team discussion [16, 17]. TA access, as the more invasive, is currently used less across Europe and the United States of America than in the early era of TAVI (a decline from 17% to 4% in French registries) as seen in the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry [5, 18].

Procedural data

There are obvious differences in procedural setup for both procedures because all patients treated with TF were under general anesthesia while some of the TC were operated under deep conscious sedation. Also, the TC patients were monitored uniformly by cerebral oximetry. It was shown that this approach leads to a low risk of cerebrovascular complications and has favorable outcomes [11].

Because of the prosthetic valve design, only BE Sapien 3 valves were implanted in patients with TA access. For TC access, the choice of the valves was broader and included both BE and SE (Evolute R and Portico). Interestingly, in patients treated with TC-TAVI, significantly larger valve sizes were used (29 vs. 26 mm), which might have influenced the residual gradients in favor of SE valves. However, for both types of valves, the final gradients were acceptable. Use of SE valves is required more often than in TA group balloon predilatation. The median procedure time was significantly shorter in the TC group. In our opinion, the choice of valve for TC TAVI should be based on the same criteria as in the planning of TF procedures. Both BE, and two types of SE valves (Evolute or Portico) can be used through TC access. In the case of BE valve, we use a standard delivery sheath, and for SE valves, we prefer to deliver them sheathless. For patients with a smaller body size and narrower CCA, the sheathless SE valves may be preferable.

Procedural outcomes

The procedural success rate was high and comparable in both groups. There were 3 periprocedural deaths (1 in TC and 2 in TA group) which corresponds to the high procedural risk, more diffuse atherosclerosis in this group. Reassuringly, there was a low rate of neurological complications

in both groups (only 1 stroke). The rate of other events assessed according to VARC-2 was low and did not differ between groups, and no patients required conversion to surgical valve replacement due to prosthetic dislocation or dysfunction.

Despite the fact that in experienced hands, TA access is a safe treatment option, periprocedural mortality is higher than for patients treated through the TF approach. Registries show a difference in 30-day mortality of 5% vs. 1.6% in favor of TF [19]. Most likely, a patient's anatomy and comorbidities are key factors in this difference. Also, in some patients with frailty syndrome and left ventricle scar related to a history of myocardial infarction, a surgical procedure using the 24 F delivery system has inherent limitations, and rehabilitation is prolonged [20].

In-hospital outcomes

The median time patients spent in the intensive care unit was similar, while the median hospitalization time was shorter in the TC group. No differences were noted with regard to new-onset rhythm and conduction disturbances. The need for permanent pacemaker implantation was 10.2% vs. 5.7% in TC vs. TA and is consistent with higher use of SE valves in the TC group. TA-TAVI was associated with more cases of pneumonia and blood transfusions. Local complications were rare and were only related to a wound hematoma but without infections. In the control TTE, similar ejection fraction was observed and a significant reduction in aortic stenosis parameters. There were slightly lower transvalvular gradients in the TC group which is consistent with the use of larger devices.

Short-term outcomes

The median NYHA functional class significantly decreased as compared to initial values, and the NYHA class 1 was more frequent in TC group, which can be related to more rapid ambulation and rehabilitation after this artery-based approach. The 30-day mortality was similar in TC and TA groups despite the fact that surgical risk was significantly higher in the TC group. In comparison to the recent meta-analysis of Wee et al. [21], which reported 6.5% 30-day mortality and 3.8% of cerebrovascular complications, the present study outcomes tend to be more favorable. In particular, the rate of vascular complications and bleeding reported by Wee et al. [21] was as high as 7.7% and 14.3%, which are much higher than the current experience.

Limitations of the study

This is a retrospective registry, and the number of cases in both groups is limited; it does however, reflect current practice with a very high use of TF access. The selection of patients was for a particular type of alternative access was based on the local experience and protocols in both centers. In addition, the results may be slightly biased because, compared to the TC-TAVI group, only BE aortic valve prosthesis were used in the TA-TAVI group. On the other hand, such an approach allows the operators to master the operational technique of alternative access and provides consistent results. Also, it is highly unlikely that the randomized trial would be feasible in these patient populations. The strength of this registry is a complete follow-up and adheres to consistent institutional protocols.

Conclusions

In conclusion, alternative access for TAVI is required in approximately 10% of patients. The choice of access should be based on the anatomy and an operator's experience. Both TC and TA are safe procedures in appropriately selected patients, and procedures are associated with a low risk of complications.

Conflict of interest: None declared

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