Transcatheter Aortic Valve Implantation Using the Transcervical Vascular Access (from a 7-Year Experience from a Swiss Tertiary Center)

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The gold-standard transfemoral (TF) access for transcatheter aortic valve implantation (TAVI) is not suitable in 10% to 15% of patients, and alternative accesses are needed. Studies have suggested that the transcervical (TC) access might yield outcomes comparable to the TF access. In our center, TC-TAVI is the first-line alternative to TF-TAVI. We herein present our 7-year experience regarding the use of the TC access in TAVI. We included all consecutive patients referred for TC-TAVI between January 1, 2016 and December 31, 2022. Data regarding the patients' characteristics,perioperative and 30-day outcomes were prospectively collected. Patients were separated into 2 temporal groups (group 1: January 1, 2016 to June 30, 2019; group 2: July 1, 2019 to December 31, 2022) to assess the changes of their characteristics and outcomes over time. A total of 95 patients were included, with more belonging to group 2 (n = 56 vs n = 39 in group 1). Patients in group 2 were significantly younger (81.0 [interquartile range 77.0 to 87.0] vs 89.0 [interquartile range 83.0 to 92.0] years, p <0.001) and had a higher prevalence of hypertension (87.5% vs 66.7%, p = 0.028) and chronic pulmonary disease (35.7% vs 15.4%, p = 0.029). There was no significant difference regarding other co-morbidities or surgical scores. All-cause mortality and the risk of stroke at 30 days were low and similar (group 2 vs group 1, 3.6% vs 2.5%, p = 0.787 and 1.8% vs 0%, p = 0.397, respectively), as were the risks of permanent pacemaker implantation, postoperative acute kidney injury, cardiac tamponade, life-threatening bleeding, and major vascular complications. In conclusion, the use of the TC access increased over time. The rates of adverse events did not change, despite patients from mid-2019 onward having slightly more co-morbidities. **(Am J Cardiol 2023;201:86−91)**

During the past 2 decades, transcatheter aortic valve implantation (TAVI) has developed into the first-line interventional treatment of symptomatic severe aortic stenosis in patients aged ≥75 years or those with a high surgical risk.[1] Hence, the volume of TAVI procedures has considerably increased, and this trend is expected to continue in the coming years.[2,3]

The transfemoral (TF) access is considered the gold-standard vascular pathway for TAVI. However, it is not suitable for up to 15% of patients, mainly because of anatomical contraindications, such as small or heavily calcified iliofemoral vessels or extreme vessel tortuosity.[3] Several vascular alternatives have been developed for these particular settings, among which figures the transcervical (TC) access.[4] Many studies and registries have suggested that the latter might yield better periprocedural and 30-day outcomes than the "transthoracic" ones (transapical or transaortic, which require a surgical cutdown of the thoracic wall)[5−7] and with outcomes comparable to the TF access.[8,9] As such, many teams consider TC-TAVI as the first alternative to TF-TAVI in patients with a challenging iliofemoral anatomy. In our center, the TC-TAVI program started in January 2016 as a collaborative effort between cardiac surgeons, cardiologists, and anesthesiologists, among others, and has since thrived. We hereby present a descriptive study of our 7-year experience regarding the use of the TC access for TAVI.

Methods

We included all patients who underwent TC-TAVI from January 1, 2016 to December 31, 2022 at Lausanne University Hospital (*Centre hospitalier universitaire vaudois*). The diagnosis of severe aortic stenosis was based on the clinical, echocardiographic, and hemodynamic criteria of the European Society of Cardiology guidelines.[1,10] All candidates for TAVI underwent cardiac catheterization to assess coronary artery status as well as cardiac and vascular assessment with multislice computed tomography

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See page 90 for Declaration of Conflict of Interest.

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angiography studies. Furthermore, patients considered for TC-TAVI had a bilateral carotid Doppler ultrasound to screen for carotid artery (CA) stenosis. For all cases, the suitability for TAVI and the choice of vascular access (TF as the first choice, TC as the second choice) were assessed by a heart team, consisting of at least a senior interventional cardiologist, a senior cardiac surgeon, an echocardiographer, and an anesthesiologist. Patients were not considered for the TF approach if they had any of the following criteria: iliofemoral atherosclerosis precluding safe arterial puncture, small or heavily calcified vessels (diameter <6 mm), mural thrombus, extreme tortuosity, or abdominal aortic aneurysms. In those cases, TC-TAVI was chosen, unless 1 of the following contraindications was met: previous ipsilateral CA intervention, small vessel diameter (<6 mm), stenosis (>50%) or occlusion of the contralateral CA, and heavy CA calcification and tortuosity. Transthoracic approaches were finally considered as the last alternatives in case of nonfeasibility of the TF- and TC-TAVI.

All patients provided written informed consent for the use of their data for research purposes. Our study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was given by the Vaud Canton Ethics Committee (decision CER-VD 211/13, dated May 10, 2013).

The TC-TAVI procedures were usually performed in the catheterization laboratory either under general anesthesia (GA) or local anesthesia with procedural sedation (LPS), with placement of an arterial radial line and implementation of cerebral saturation monitoring. All patients were monitored by continuous near-infrared spectroscopy (INVOS, Somanetics, Minnesota or symmetrical bifrontal electrodes, Masimo, Irvine, CA) to detect perioperative cerebral desaturation. In addition, patients under GA received a propofol infusion aimed at maintaining a bispectral index between 40 and 60, minimizing the cumulative deep hypnotic time (bispectral index <40).

Femoral arterial and venous accesses were then obtained for the pigtail catheter and cardiac pacing, respectively. Among patients under GA, transesophageal echocardiography was performed to assess the valve positioning and paravalvular regurgitation. During the interventions, patients were given heparin, with a target of activated clotting time of at least 250 seconds.

From a surgical standpoint, a precise procedural description of TC-TAVI has been previously published.[11] Briefly, a 5- to 7-cm incision was performed along the anterior border of the sternocleidomastoid muscle, exposing the common CA (usually the right CA; Figure 1). The choice of the exact puncture site (common CA, brachiocephalic trunk, or subclavian artery) was made intraoperatively, depending on local anatomy (vessel diameters, calcification) and accessibility for repair. A common CA cross-clamping test was systematically performed for at least 30 seconds to evaluate the functional integrity of the arterial circle of Willis and patency of the contralateral CA. In case no significant decrease in cerebral oximetry parameters (>20%) was detected,[12] a purse-string suture was placed around the puncture site and a 6-Fr introducer sheath inserted through the artery, with a stiff wire positioned in the left ventricle. The introducer sheath was then changed into a delivery sheath after dilatation of the vascular puncture site. Finally,

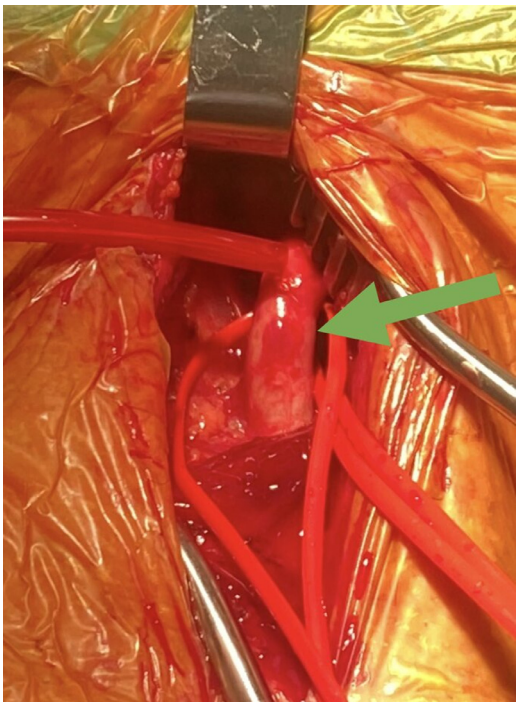

Figure 1. Surgical exposition of the right common carotid artery (green arrow). The patient's head is toward the bottom of the picture.

the transcatheter heart valve (THV) was brought into the field; once properly positioned, it was deployed under rapid right ventricular pacing. At the end of the procedure, the delivery catheter and wire were removed, and the artery was clamped distally to avoid any embolization of debris. Eventually, the artery was reconstructed using separate stitches, and a small drain was left in the incision closure site.

Regarding blood pressure management, if cerebral desaturation was detected by near-infrared spectroscopy during the carotid clamping test or during the procedure, blood pressure was raised by 10% to 20% above the baseline value using vasopressors (i.e., phenylephrine or norepinephrine). During the hemostatic phase of surgery, blood pressure could be lowered to the baseline values (or by 10% to 20%) using vasodilators, such as nicardipine or nitrates.

After the intervention, patients who underwent GA were usually extubated on-table. All patients were transferred to the recovery room and then to the surgical intermediate care unit.

Data regarding the patients' clinical and echocardiographic characteristics as well as perioperative and 30-day outcomes were prospectively collected and reported according to the Valve Academic Research Consortium 2 definitions.[13] The more recent Valve Academic Research Consortium 3 criteria were not used because the data collection in our registry preceded the publication of the new criteria.[14]

Categorical variables were reported as percentages and were analyzed using the Pearson chi-square test. Continuous variables were assessed for normality through visual inspection of histograms and were expressed accordingly as means with SDs or medians with interquartile ranges

Table 1
Baseline clinical and echocardiographic characteristics of patients undergoing transcervical TAVI, according to year groups

	Overall (N=95)	01.2016-06.2019 (N=39)	07.2019-12.2022 (N=56)	*p* value
Clinical characteristics				
Age, years, median (IQR)	84.0 (80.0-90.0)	89.0 (83.0-92.0)	81.0 (77.0-87.0)	<0.001
Male	59 (62.1)	25 (64.1)	34 (60.7)	0.738
BMI, kg/m^2, mean ± SD	25.6±4.5	25.1±4.4	25.9±4.6	0.744
Euroscore, median (IQR)	4.1 (2.8-6.2)	4.0 (2.8-5.9)	4.1 (2.8-6.3)	0.644
STS score, median (IQR)	3.6 (2.4-5.2)	3.9 (2.3-5.2)	3.2 (2.5-5.2)	0.482
NYHA Functional class				
- I-II	35 (36.8)	13 (33.3)	22 (39.3)	0.554
- III-IV	60 (63.2)	26 (66.7)	34 (60.7)	
Lower extremity artery disease	34 (35.8)	15 (38.5)	19 (33.9)	0.650
Previous pacemaker	12 (12.6)	5 (12.8)	7 (12.5)	0.963
Chronic pulmonary disease	26 (27.4)	6 (15.4)	20 (35.7)	0.029
Diabetes mellitus	27 (28.4)	14 (35.9)	13 (22.2)	0.178
Dyslipidemia	63 (66.3)	26 (66.7)	37 (66.1)	0.952
Previous cardiac surgery	21 (22.1)	10 (25.6)	11 (19.6)	0.363
Previous PCI	29 (30.5)	9 (23.1)	20 (35.7)	0.273
Hypertension	75 (78.9)	26 (66.7)	49 (87.5)	0.028
Stroke or TIA	16 (16.8)	8 (20.5)	8 (14.3)	0.419
Moderate to severe CKD	52 (54.7)	18 (46.2)	34 (60.7)	0.161
Carotid stenosis	14 (14.7)	6 (15.4)	8 (14.3)	0.882
Bicuspid aortic valve	3 (3.1)	0 (0)	3 (5.4)	0.142
Preoperative creatinine, μmol/l, median (IQR)	101 (78-133)	93 (73-132)	103 (82-133)	0.365
Echocardiographic characteristics				
LVEF				
- <30%	5 (5.3)	2 (5.1)	3 (5.4)	0.999
- 30-50%	17(17.9)	7 (18.0)	10 (17.9)	
- >50%	73 (76.8)	30 (76.9)	43 (76.8)	

Values are expressed as n (%), unless specified otherwise.

BMI = body mass index; CABG = coronary artery bypass graft; CKD = chronic kidney disease; IQR = interquartile range; LVEF = left ventricle ejection fraction; NYHA = Hew York Heart Association; PCI = percutaneous coronary intervention; SD = standard deviation; STS score = Society of Thoracic Surgeons score; TAVI = transcatheter aortic valve implantation; TF = transfemoral; TIA = transient ischemic attack.

(IQRs). Student's *t* test was used to compare the normally distributed variables, whereas the Mann−Whitney test was used to compare non-normally distributed ones. The mortality rates at 30 days were compared using a log-rank test. A p <0.05 was considered statistically significant.

Patients were separated into 2 temporal groups (group 1: January 1, 2016 to June 30, 2019; group 2: July 1, 2019 to December 31, 2022) to assess the changes of their characteristics and outcomes over time.

All analyses were performed using the Stata software, version 16.0 (StataCorp LLC, College Station, Texas).

Results

Between January 1, 2016 and December 31, 2022, a total of 750 patients underwent TAVI in our institution. Among these, 119 patients (15.9%) were not eligible for TF-TAVI: 95 (12.7%) underwent TC-TAVI, whereas 24 patients (3.2%) underwent TAVI using a transthoracic pathway (transaortic or transapical). The use of the TC access increased over time, with more patients in group 2 (n = 56 vs n = 39 in group 1). The number of patients by year is shown in Supplementary Figure 1. Patients' baseline clinical and echocardiographic characteristics are presented in Table 1. Overall, the patients were predominantly male (62.1%) and presented with a high co-morbidity burden (28.4% had diabetes mellitus, 78.9% had hypertension, and 54.7% had moderate to severe chronic kidney disease). The prevalence of cardiovascular disease at baseline was also high (history of lower extremity artery disease: 35.8%, previous percutaneous coronary intervention: 30.5%). Compared with patients in group 1, those in group 2 were younger (81.0 [IQR 77.0 to 87.0] vs 89.0 [IQR 83.0 to 92.0] years, p <0.001) and presented with a higher prevalence of hypertension (87.5% vs 66.7%, p = 0.028) and chronic pulmonary disease (35.7% vs 15.4%; p = 0.029). There was no significant difference regarding the other co-morbidities or surgical risk scores (EuroSCORE and Society of Thoracic Surgeons score).

The periprocedural details are listed in Table 2. All patients benefited from the implantation of balloon-expandable THVs of the Edwards SAPIEN family (Edwards Lifesciences, Irvine, California). Overall, the right common CA was used in 95.8% of cases, and most interventions (97.9%) were performed under GA. There was no significant difference regarding the periprocedural details and outcomes between groups 1 and 2.

The 30-day outcomes are listed in Table 3. Overall, the rate of 30-day all-cause mortality was 3.2%, with no difference between groups 1 and 2 (2.5% vs 3.6%, p = 0.787,

Table 2
Perioperative characteristics of patients undergoing transcervical TAVI, according to year groups

	Overall (N=95)	01.2016-06.2019 (N=39)	07.2019-12.2022 (N=56)	*p* value
THV				
- Edwards Sapien 3	96 (100.0)	39 (100.0)	56 (100.0)	
Prosthesis size, mm				
- 20	4 (4.2)	2 (5.1)	2 (3.6)	0.974
- 23	27 (28.4)	11 (28.2)	16 (28.6)	
- 26	48 (50.5)	20 (51.3)	28 (50.0)	
- 29	16 (16.8)	6 (15.4)	10 (17.9)	
Right side	91 (95.8)	37 (94.9)	54 (96.4)	0.710
Puncture location				
- Transcarotid	56 (59.0)	26 (66.7)	30 (53.6)	0.433
- Brachiocephalic trunk	19 (20.0)	6 (15.4)	13 (23.2)	
- Subclavian	20 (21.1)	7 (18.0)	13 (23.2)	
Valve-in-valve TAVI	4 (4.2)	1 (2.6)	3 (5.4)	0.505
General anesthesia	93 (97.9)	37 (94.9)	56 (100.0)	0.087
Valve malposition	4 (4.2)	2 (5.1)	2 (3.7)	0.710
Procedure duration, min, median (IQR)	74 (57-98)	71 (52-98)	77 (58-96)	0.444
Contrast volume, ml, median (IQR)	100 (80-140)	100 (80-137)	100 (90-140)	0.682

Values are expressed as n (%), unless specified otherwise.
IQR = interquartile range; TAVI = transcatheter aortic valve implantation; THV = transcatheter heart valve.

respectively). Regarding procedure-related death, there was 1 case in each group; group 1, the death was related to valve malposition with cardiogenic shock and in group 2, the death was related to cardiac tamponade. In addition, there was 1 case of noncardiovascular death (digestive septic shock) in group 2.

The hospital lengths of stay and 30-day risks of stroke or transient ischemic attack were similar (group 1 vs group 2; 8.0 [IQR 6.0 to 11.0] vs 7.0 [IQR 5.0 to 9.0] days, p = 0.337, 0% vs 1.8%, p = 0.397, respectively), as were the risks of permanent pacemaker implantation, postoperative acute kidney injury, cardiac tamponade, life-threatening bleeding, and major vascular complications.

The only case of stroke took place in group 2 <24 hours after the TAVI intervention, with a diagnosis of left cerebellum ischemic stroke based on brain magnetic resonance imaging. In this specific case, because the punctured artery was the right common CA, it was considered unlikely that the stroke was caused by the TC procedure; instead, an embolic etiology was considered more plausible. The patient subsequently completely recovered, with no neurological sequelae. All cases of major vascular complications

Table 3
Postoperative endpoints of patients undergoing transcervical TAVI, according to year groups

	Overall (N=95)	01.2016-06.2019 (N=39)	07.2019-12.2022 (N=56)	*p* value
30-day all-cause mortality	3 (3.2)	1 (2.5)	2 (3.6)	0.787
- Procedure related	2 (2.1)	1 (2.5)	1 (1.8)	
- Non-CV death	1 (1.1)	0 (0.0)	1 (1.8)	
Hospital LOS, days, median (IQR)	7.0 (5.0-10.0)	8.0 (6.0-11.0)	7.0 (5.0-9.0)	0.337
Place of discharge				
- Home	65 (68.4)	25 (64.1)	40 (71.4)	0.529
- Rehabilitation center	16 (16.8)	9 (23.1)	7 (12.5)	
- Other hospital	10 (10.6)	4 (10.3)	6 (10.7)	
Stroke or TIA at 30 days	1 (1.1)	0 (0)	1 (1.8)	0.397
Permanent pacemaker implantation	10 (10.6)	4 (10.3)	6 (10.9)	0.919
Postoperative acute kidney injury	4 (4.2)	1 (2.6)	3 (5.4)	0.505
Cardiac tamponade	5 (5.3)	3 (7.7)	2 (3.6)	0.376
Life-threatening bleeding	2 (2.1)	1 (2.6)	1 (1.8)	0.795
Major vascular complications	3 (3.2)	1 (2.6)	2 (3.6)	0.782
Echocardiographic variables				
Mean transvalvular gradient, mmHg, median (IQR)	11.1±4.1	10.9±4.2	11.2±4.0	0.654
Aortic regurgitation				
- I-II	94 (99.0)	38 (97.4)	56 (100.0)	0.228
- III-IV	1 (1.1)	1 (2.6)	0 (0.0)	

Values are expressed as n (%) unless specified otherwise.
IQR = interquartile range; LOS = length of stay; TAVI = transcatheter aortic valve implantation; TIA = transient ischemic attack.

(3 in total) were internal or common CA dissections, treated either with on-site artery stenting (2 cases) or surgical repair (1 case); none of which resulted in neurovascular complications. There was no significant difference regarding the postoperative echocardiographic characteristics.

Discussion

Our results can be summarized as follows: in our single-center cohort, (1) the use of the TC access increased over time, (2) the overall TC-TAVI population had a high co-morbidity burden, (3) the periprocedural and 30-day outcomes were reassuring, including 30-day all-cause mortality and neurovascular complications that remained low and comparable to rates reported in previous studies, and (4) there was no significant difference regarding outcomes over time, despite having a more co-morbid population.

The overall high prevalence of cardiovascular diseases reported in our cohort was expected and aligns with previously published data. In fact, patients who underwent TC-TAVI have been shown to be more polymorbid than those benefiting from TF-TAVI.[9,15] This probably arises from the fact that patients referred for TC-TAVI present with, by definition, contraindications to TF-TAVI, of which advanced iliofemoral atherosclerotic disease is a typical example. Furthermore, the atherosclerotic process may preferentially affect the femoral arteries rather than the CAs,[16] and the TC vascular access often remains a practical option in patients presenting with a challenging iliofemoral anatomy for this reason. From mid-2019 onward, patients presented with slightly more co-morbidities; this was likely due to a higher co-morbidity burden in the whole population referred for TAVI because there was no change in the patient selection criteria for the TC access.

From a periprocedural standpoint, several important details are noteworthy. First, in our center, all TC-TAVI interventions were performed using balloon-expandable SAPIEN 3 THVs, although the use of both autoexpandable and balloon-expandable THVs has been reported in this setting.[17] Second, we performed 96% of all TC-TAVI interventions using the right-sided approach, in contrast to most other centers which favor the left-side approach.[15] The optimal side is subject to debate but in our experience, using the right common CA, brachiocephalic trunk, or subclavian artery provides an easier manipulation of the THV and its delivery system owing to the shorter distances between the access site and the aortic annulus, and a better alignment with the aortic root.[18] Finally, almost all procedures were performed under GA, in contrast to TF-TAVI, in which LPS is now commonly used. This observation is in line with data from other centers, despite some authors suggesting that LPS may be preferable in TC-TAVI by allowing "real-time" neurological monitoring.[19] The authors acknowledge that all these periprocedural details heavily depend on local experience and the operators' expertise.

Regarding the periprocedural or 30-day outcomes, it is interesting to note that despite a higher population co-morbidity burden, the rates of adverse events (including 30-day all-cause mortality) associated with TC-TAVI were in concordance with data reported for TF-TAVI,[15] as were the hospital lengths of stay (although only approximately 2/3 of patients were directly discharged home).[20] In particular, our rate of neurovascular complications (1%) was lower than the rates commonly reported for TF-TAVI.[17,21] This is all the more important because stroke remains one of the most feared complications after TAVI, especially TC-TAVI, because of the perceived risk associated with the direct manipulation of the precerebral arteries. Our lower rate of adverse neurological events might be partially explained by several factors: (1) all candidates for the TC access were carefully screened for CA atherosclerotic disease, (2) the functional integrity of the circle of Willis and patency of the contralateral CA were systematically preoperatively assessed, as described previously, and (3) at the end of the procedures, the punctured artery was reconstructed using interrupted sutures, thus allowing the purging of remaining intravascular debris by back-bleeding. It should, however, be emphasized that a significant part of neurovascular complications in TAVI reported in previous studies is caused by valvular debris embolization, and thus is independent of the vascular access itself.[22] Regarding the major vascular complications, the incidence found in our study was also lower than the rates usually reported for TF-TAVI and is in accordance with previous meta-analyses.[15,23] This may be explained by the fact that the access artery in our cohort was approached, cannulated, and reconstructed surgically, whereas most TF interventions are performed percutaneously without direct vascular control. Overall, no difference was observed between temporal groups 1 and 2 regarding the incidence of periprocedural and 30-day adverse events, despite the patients from mid-2019 onward presenting with slightly more co-morbidities.

This study has limitations. The authors acknowledge that our results are purely descriptive and based on the data of a single Swiss tertiary-care center. As such, they are not generalizable to other centers or settings. Furthermore, we did not include patients who underwent TF-TAVI, and all comparisons between TC-TAVI and TF-TAVI were extrapolated from a previous comparative study.[9] Finally, another factor that could not be considered is the increase of the operators' experience over time in performing TC-TAVI.

The use of the TC access increased over time. The rates of periprocedural success and adverse events remained stable, despite the patients from mid-2019 onward presenting with a slightly higher co-morbidity burden. Importantly, these rates are in the same ranges as those commonly reported in previous studies for TF-TAVI. Our results support the idea that a TC approach seems to be indeed a safe first-line alternative to the TF access in patients with contraindications to the latter. Other prospectively collected data are needed to confirm the safety and efficacy of TC-TAVI in patients ineligible for TF-TAVI.

Supplementary Figure 1. Number of transcatheter aortic valve implantation interventions using the transcervical access per year.

Declaration of Competing Interest

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Supplementary materials

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