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Transcarotid versus transfemoral access in patients undergoing transcatheter aortic valve replacement with complex aortofemoral anatomy

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Abstract

Aims: While major vascular complications (MVC) remains an issue after Transfemoral (TF) transcatheter aortic valve replacement (TAVR), we compared outcomes in TF versus transcarotid (TC) approaches in patients with complex vascular anatomy.

Methods and results: Among patients undergoing TAVR in our center between 2015 and 2018, we evaluated patients with complex vascular anatomy defined on CT scan as: (a) iliofemoral diameter between 5.5 and 6 mm or <6.5 mm with severe calcifications or tortuosity AND/OR (b) abdominal aorta pathology. The primary endpoint included access failure, mortality, MVC, major bleeding and stroke at 1-month. Among 483 patients, 131 (31.2%) with complex vascular anatomy underwent TF ($n = 51$; 39.2%) or TC ($n = 80$; 60.8%) TAVR. The mean age was 81.7 ± 6.9 . TC group had higher STS score ($p = .01$), higher incidence of coronary artery disease ($p = .04$) and lower left ventricular ejection fraction ($p < .001$). In TC group, primary endpoint occurred twice less without reaching significance compared to TF group ($n = 8$; 10.0% vs. $n = 10$; 19.6% respectively; $p = .1$). Incidence of MVC was higher in TF group (11.8 vs. 1.3% in the TC group; $p = .01$) with similar incidence of stroke between groups ($p = .8$).

Conclusions: Despite higher patient risk profile, TC approach in complex aortofemoral anatomy provides similar favorable outcomes with less MVC compared to TF approach.

KEYWORDS

complex anatomy, TAVR, transcarotid, transfemoral, vascular complication

Abbreviations: ICU, intensive care unit; LVEF, left ventricular ejection fraction; MSCT, multislice computerized tomographic angiography; STS, society of thoracic surgeons; TAVR, transcatheter aortic valve replacement; TC, transcarotid; TF, transfemoral; VASC-2, valve academic research consortium-2; MVC, major vascular complication.

1 | INTRODUCTION

European guidelines recommend transfemoral (TF) approach as the first line access for transcatheter aortic valve replacement (TAVR)

when vessels anatomy is favorable.¹ However, some anatomic challenges as low vessel diameter, vascular tortuosity, calcifications or aortoiliac vascular pathology may increase the risk of procedural complications and failure leading to consider alternative access sites.²⁻⁶ Transaortic and transapical accesses are invasive hybrid approaches and are associated with less favorable results than TF approach.⁴⁻⁶ Subclavian access may be difficult in case of obesity, small artery diameter or important calcifications, and may be avoided in case of patent mammary artery bypass.⁷ More recently, the transcatheter (TC) approach initially developed by Modine et al. in 2010⁸ showed encouraging results in terms of feasibility and safety.^{9,10}

The purpose of this study was to compare outcomes between TF and TC access in patients undergoing TAVR when ilio-femoral or aortic anatomy is possible but complex regarding vessel diameters, calcifications and/or tortuosity.

2 | METHODS

2.1 | Study design and patients

Among patients undergoing TAVR in Montpellier University Hospital between 2015 and 2018, we included all patients undergoing TF or TC procedure with complex ilio-femoral and/or complex aortic anatomy according to multislice computerized tomographic (MSCT) analysis. All patients provided written informed consent. The protocol was approved by the local ethics committee (Comité de Protection des Personnes Sud Méditerranée, Montpellier, France), the institutional regulatory authorities (Institut Review Board [IRB]) of Montpellier University Hospital and was conducted according to the principals of the Declaration of Helsinki.

2.2 | MSCT analysis

Before the procedure, a MSCT analysis of the aortic valve, the entire aorta, iliofemoral and supra-aortic vessels using vascular windows settings was performed in all patients (General Electric LightSpeed VCT). After 3-dimensions reconstruction of the iliofemoral vessels and the aorta using OsiriX DICOM viewer (Pixmeo company, Geneva, Swiss), diameter, calcifications and tortuosity were determined by three different physicians, including a radiologist, an interventional cardiologist and a cardiac surgeon. Minimal luminal diameter measurements were performed perpendicular to the vessel axis. Evaluation of tortuosity was based on the most severe angulation of the iliofemoral system or abdominal aorta in anterior/posterior or medial/lateral directions. Vessels calcifications were graded as none, mild, moderate or severe.¹¹ Anatomy and calcifications of the carotid vessels were also evaluated according to same rules. Common carotid arteries diameter and calcifications were systematically analyzed using vascular Doppler ultrasonography.

2.3 | Definition of complex femoral and aortic anatomy

TF access was considered as favorable when iliofemoral artery diameter was >6.5 mm, and complex when ilio femoral artery diameter was between 5.5 and 6 mm or between 6 and 6.5 mm AND associated with severe calcifications and/or severe tortuosity. According to guidelines of the Society of Vascular surgery, severe iliofemoral tortuosity was defined by more than one angulation <90° and severe calcification when more than 50% of the vessel segment length calcified or heavily circumferential calcified.¹¹ Complex aortic anatomy included abdominal aortic aneurysm, chronic aortic dissection, tortuosity >45° or penetrating aortic ulcer (Figure 1). TF approach was contra-indicated in case of ilio femoral artery <5.5 mm, severe stenosis, circumferential aortic thrombus or shaggy aorta. Only carotid diameter ≥5.5 mm with none or mild calcifications was considered as acceptable for TC TAVR procedure. Severe calcifications in the aortic arch, contralateral carotid stenosis or occlusion contra-indicated TC access.

2.4 | TAVR procedure

Access site was left to the operators' discretion. For TF access, a surgical "preclose technique" or a percutaneous access using double Proglide (Abott vascular) technique was used depending on the operator's choice.¹² For TC access, a surgical approach was systematically performed. The common carotid was approached between the two chiefs of the sternocleido-mastoïdian muscle and the omohyoid strap muscle was cut. The carotid artery was carefully dissected to avoid injury of the vagus nerve. One vessel-loop was set up on the carotid which was punctured before the insertion of a 6F introducer. The sheath (Ascendra certitude delivery, commander delivery and EnVeo Medtronic according to the selected valve) was introduced via a counter-incision made just above the neck incision to provide more stability to the procedure. We paid particular attention to reduce the duration of carotid occlusion during the procedure. Predilatation when indicated was performed through a small diameter sheath. A fast surgical closure was chosen using a running suture. A 6F catheter secondary arterial access was inserted through the radial or femoral artery and another 6F catheter was positioned in the femoral vein for right ventricular pacing for balloon-expandable valve implantation. All patients received 0.5 mg/kg of heparin at the time of introducing the sheath. An association of clopidogrel 75 mg and aspirin 75 mg was prescribed for all patients after TAVR, except those with indication for long term anti-coagulant therapy, in whom only aspirin 75 mg was added.

2.5 | Study end-points

The primary endpoint was a combined endpoint of safety and efficacy at 1-month including access failure, all-cause mortality, major vascular complications (MVC), major bleeding and stroke according to Valve academic research consortium-2 (VARC-2) criteria.¹³ The TC or TF

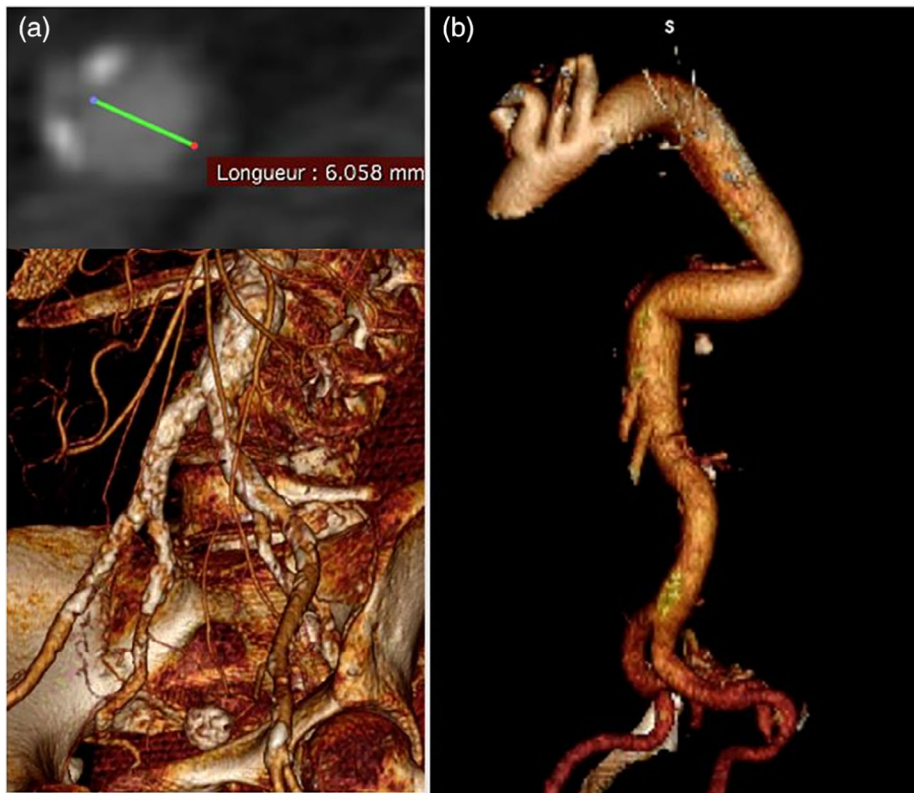


FIGURE 1 A: complex femoral anatomy B: Aortic tortuosity [Color figure can be viewed at wileyonlinelibrary.com]

access failure was defined by the need of a surgical conversion by sternotomy or conversion for another access. Each patient with suspected stroke had an emergency brain magnetic resonance imaging (MRI) or an injected brain scanner in case of contraindication to MRI. The diagnosis was confirmed by a neurologist.

Secondary endpoints included major outcomes at 1-month follow-up including more than mild aortic regurgitation, pacemaker implantation, new hospitalization for cardiac causes. Evaluation of procedural factors included procedure length, radiation dose, contrast amount, post dilatation rate, and hospital length of stay.

Data on baseline characteristics, procedural results and in-hospital outcomes were collected from medical records. The 1-month outcomes were collected through the usual follow-up consultations with the cardiologist or by phone interview with the patient.

2.6 | Statistical consideration

Characteristics of the study participants were described with mean (SD) for continuous variables and number (%) for categorical variables. We used the Student t test and Chi-square test to compare groups. An univariate logistic regression was performed to assess the risk of complications. The combined endpoint was verified if at least one of the major endpoints (*access failure, all-cause mortality, MVC, major bleeding and stroke*) occurred. Statistical significance was set at $p < .05$. SAS Enterprise Guide 7.1 was used for data analysis.

3 | RESULTS

3.1 | Study population

Among a cohort of 483 patients included within the study period, 131 (31.2%) patients with complex access vascular anatomy underwent TF ($n = 51$ (39.2%)) or TC ($n = 80$ (60.8%)) TAVR (Figure 2). Baseline characteristics of the population are presented in Table 1. Patients from TC group were at higher risk profile. Women were more frequently encountered in TF group ($p < .001$). Aortic complex anatomy was more frequent in TC group ($p = .03$). Detailed characteristics of vascular complex anatomy in both groups are depicted Table 2.

3.2 | Procedural characteristics

In the TF group, the procedure was performed by the left side in 31 patients (60.8%), and a percutaneous technique was used in 31 patients (60.8%). In the TC group, the main access was the left carotid ($n = 61$ (76%)). A balloon expandable valve was used in 93 patients (71%) without significant difference between the two groups. Pre and post dilatation rates did not differ between the TC and the TF patients. No patient required a second valve implantation or a conversion by sternotomy. Procedural characteristics are presented in Table 3.

FIGURE 2 Study flow chart
[Color figure can be viewed at
wileyonlinelibrary.com]

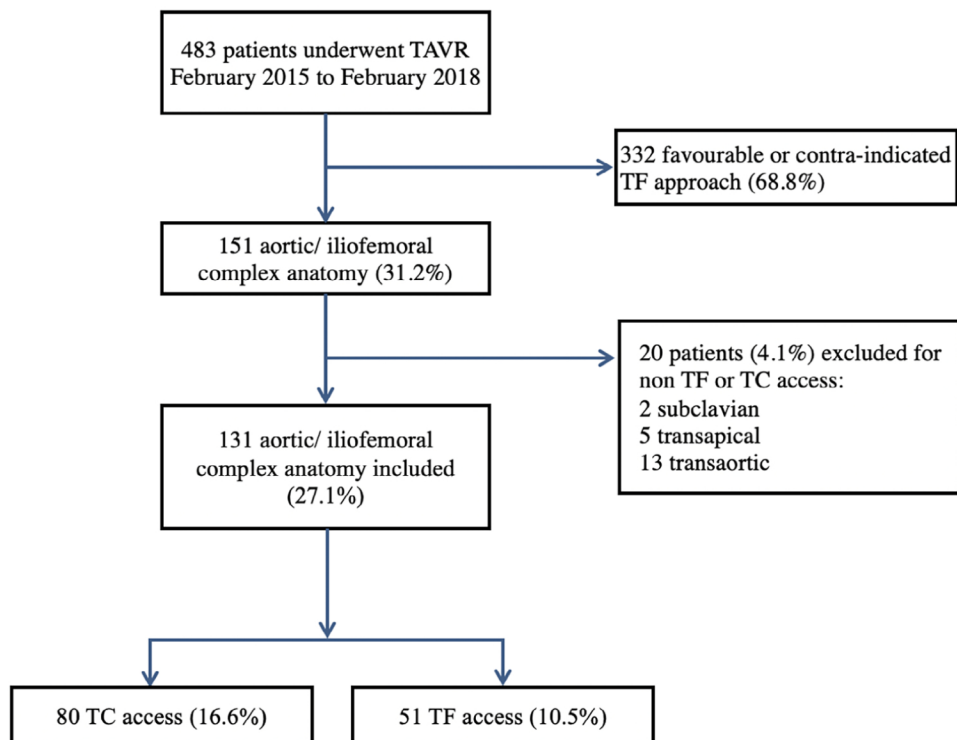


TABLE 1 Baseline characteristics of the population

	Total population (n = 131)	TF access (n = 51)	TC access (n = 80)	p
Age, mean ± SD (years)	81.7 ± 6.9	81.8 ± 6.3	81.6 ± 7.5	.4
Male gender, n (%)	72 (54.9)	17 (33.3)	55 (68.8)	<.001
BMI kg/m ² , mean ± SD	26.2 ± 6.2	25.9 ± 4.9	26.4 ± 7.4	.8
NYHA class ≥ III, n (%)	85 (64.9)	32 (62.7)	53 (66.3)	.5
Previous PCI, n (%)	59 (45.0)	17 (33.3)	42 (52.5)	.05
Previous CABG, n (%)	18 (13.7)	5 (9.8)	13 (16.3)	.3
Cardiac valve surgery, n (%)	10 (7.6)	5 (9.8)	5 (6.3)	.5
Pacemaker, n (%)	19 (14.5)	5 (9.8)	14 (17.5)	.2
Diabetes mellitus n (%)	50 (38.5)	21 (42)	29 (36.3)	.6
Stroke, n (%)	16 (12.2)	6 (11.8)	10 (12.5)	1
Respiratory failure, n (%)	41 (31.3)	15 (29.4)	26 (32.5)	.8
Atrial fibrillation, n (%)	49 (37.4)	19 (37.3)	27 (33.8)	.7
Oral anticoagulant, n (%)	44 (33.6)	15 (29.4)	29 (36.3)	.6
LVEF, mean ± SD	53.4 ± 10.2	57.9 ± 9.1	48.9 ± 11.2	<.001
Mean aortic gradient, mean ± SD	48.8 ± 14.4	53 ± 14.4	44.6 ± 13.4	.01
STS score, mean ± SD	5.9 ± 4.0	4.5 ± 2.5	7.3 ± 5.4	.01
Euroscore 2, mean ± SD	6.7 ± 6	5.5 ± 3.4	7.8 ± 8.6	.09

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; LVEF, left ventricular ejection fraction; NYHA, New York association functional classification; PCI, percutaneous coronary intervention; STS, society of Thoracic Surgeons; TC, transcarotid; TF, complex transfemoral.

3.3 | Primary endpoint

In TC group, primary endpoint occurred twice less without reaching significance, compared to TF group (n = 8 (10.0%) vs. n = 10 (19.6%) respectively); OR (95% confidence interval) = 0.5 (0.2–1.3), p = .1

(Table 4, Figure 3). A conversion from TF to TC access was necessary in one patient (2.0%) in the TF group due to crossing failure of calcified iliac artery (6 mm minimal diameter). At 1-month follow-up, two patients died in the TC group related to septic shock (n = 1, 1.3%) and heart failure (n = 1, 1.3%) versus one patient (1.9%) in the TF group

	TF access n = 51	TC access n = 80	p value
Complex femoral access (5.5–6.5 mm)	48 (94.1)	68 (85.0)	.1
Iliofemoral diameter 5.5–6 mm	24 (50.0)	35 (51.5)	.7
Iliofemoral diameter 6–6.5 mm AND:	24 (50.0)	33 (48.5)	.5
Severe tortuosity	16 (66.7)	26 (78.8)	.8
Severe calcifications	17 (70.8)	31 (93.4)	.5
Complex aortic access	6 (11.8)	22 (27.5)	.03
Aneurysm	2 (33.3)	12 (54.5)	
Dissection	1 (16.7)	3 (13.6)	
Penetrating ulcer	2 (33.3)	5 (22.7)	
Tortuosity	2 (33.3)	2 (9.1)	
Complex femoral and aortic access	4 (7.8)	12 (1.0)	.2

TABLE 2 characteristics of the complex ilio-femoral vascular access in the two study groups

Note: Values are expressed as proportion n (%).

Abbreviations: TC, transcarotid; TF, complex transfemoral.

TABLE 3 Procedural characteristics

	Total (n = 131)	TF (n = 51)	TC (n = 80)	p
General anesthesia, n (%)	129 (98)	50 (98.0)	79 (98.7)	1
Prosthesis, n (%)				
Edwards S3	93 (71)	28 (54.9)	65 (81.3)	.2
23 mm	31 (23.7)	14 (27.5)	17 (21.3)	
26 mm	43 (32.8)	10 (19.6)	33 (41.3)	
29 mm	19 (14.5)	4 (7.8)	15 (18.8)	
Corevalve Evolut R	35 (26.7)	20 (39.2)	15 (18.8)	.057
23 mm	3 (2.3)	2 (3.9)	1 (1.3)	
26 mm	19 (14.5)	13 (25.5)	6 (7.5)	
29 mm	10 (7.6)	4 (7.8)	6 (7.5)	
34 mm	3 (2.3)	1 (1.9)	2 (2.5)	
Corevalve Evolut PRO	3 (2.3)	3 (5.9)	0	.06
26 mm	3 (2.3)	3 (5.9)		
Catheter, n (%)				
Ascendra certitude delivery	59 (45.0)	-	59 (73.8)	1
Commander delivery	34 (26.0)	28 (54.9)	6 (7.5)	.09
EnVeo Medtronic	38 (29.0)	23 (45.1)	15 (18.8)	.03
Predilatation, n (%)	61 (46.6)	23 (45.1)	38 (47.5)	1
Posdilatation, n (%)	11 (8.3)	8 (15.7)	3 (3.8)	.052
Radiation dose cGy.cm ² , mean ± SD	3,087 ± 2,528	3,055 ± 2089	3,118 ± 2,966	.89
Procedure length, mean ± SD	67.5 ± 21.5	64 ± 18	71 ± 25	.051
Contrast amount (ml), mean ± SD	71 ± 24	71 ± 25	71 ± 23	.96
Radiation length (min), mean ± SD	10.5 ± 5	11 ± 5	10 ± 5	.30

Abbreviations: cGy cm², centigray/centimeter; ml, milliliter; SD, standard deviation.

due to heart failure ($p = .8$). MVC were more frequent in the TF group ($p = .01$), all requiring surgical revision. Transfusion was required in 13 patients (9.9%) and 8, (61.5%) needed only 2 unit of red blood cells without difference between the two groups. Ischemic stroke occurred

in 1 (2.0%) patient in the TF group versus 2 (2.5%) in the TC group (1 contralateral to the carotid access and 1 related to the procedure induced carotid occlusion with ipsilateral vertebral artery occlusion on CT scan), $p = .8$.

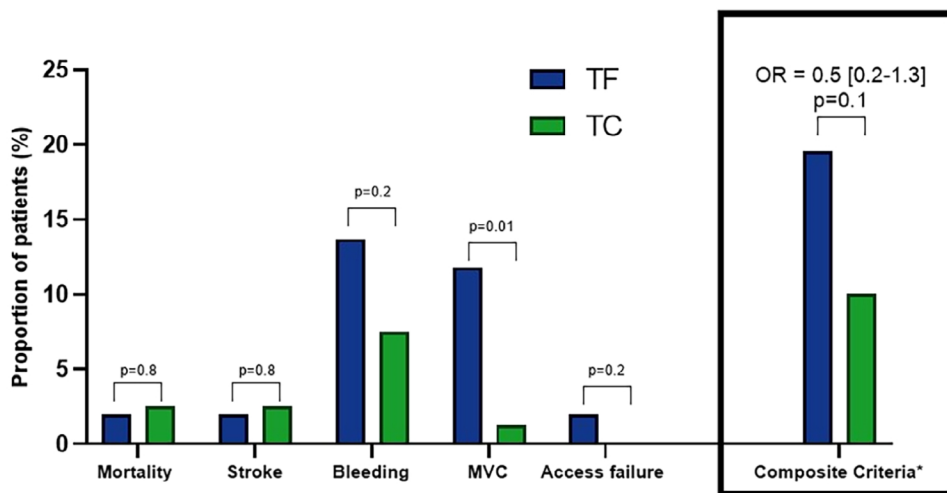
TABLE 4 Primary and secondary endpoint in the study population, TF, and TC groups

	Total population (n = 131)	TF group (n = 51)	TC group (n = 80)	p
Primary endpoint at 1-month	18 (13.8)	10 (19.6)	8 (10.0)	.1
Access failure, n (%)	1 (0.8)	1 (2.0)	0 (0)	.2
All-cause mortality, n (%)	3 (2.3)	1 (1.9)	2 (2.6)	.8
Major vascular complications, n (%)	7 (5.3)	6 (11.8)	1 (1.3)	.01
Major bleeding, n (%)	13 (9.9)	7 (13.7)	6 (7.5)	.2
Stroke, n (%)	3 (2.3)	1 (2.0)	2 (2.5)	.8
Secondary endpoints				
ICU monitoring, n (%)	108 (82.4)	28 (54.9)	80 (100)	.04
ICU length of stay, mean ± SD (days)	2.4 ± 1.4	2.3 ± 1.3	2.4 ± 1.4	.9
Pacemaker implantation, n (%)	33 (25.2)	12 (23.6)	21 (26.2)	.84
Minor VC, n (%)*	15 (11.5)	4 (8)	11 (11.8)	.39
Mean aortic gradient, mean ± SD	9.5 ± 3.7	9.7 ± 4.2	9.3 ± 3.2	.86
AR > grade 2, mean ± SD	10 (7.6)	5 (9.8)	5 (6.3)	.52
Hospitalization length of stay, mean ± SD (days)	6.9 ± 3.8	6.9 ± 3.2	6.8 ± 4.3	.89

Note: * according to the VARC-2criteria.

Abbreviations: AR, aortic regurgitation; ICU, intensive care unit; TF, complex transfemoral; TC, transcatheter; VC, vascular complications.

FIGURE 3 Primary endpoint: Proportion (%) of major complications in TF and TC groups at 1-month post-procedure. MVC, major vascular complication; TF, transfemoral; TC, transcatheter. *The composite criteria of complications was reached if at least one of the major complications (mortality, stroke, bleeding, MVC and access failure) occurred [Color figure can be viewed at wileyonlinelibrary.com]



3.4 | Secondary endpoints

According to our local monitoring protocol, all patients in the TC group and high risk patients (n = 28, 54.9%) in the TF group were monitored in ICU during at least 24 hr.¹⁴ Non compressive carotid hematoma was the most common minor VC in the TC Group (n = 8, 10%). In the TF group, three patients had a femoral hematoma (5.9%) and one patient had an arteriovenous fistula (1.9%). Both groups had similar procedure duration, radiation dose, amount of contrast and hospitalization duration. Detailed data on secondary endpoints are presented Table 4.

4 | DISCUSSION

This study compared both success rate and safety of TC versus TF access in patients undergoing TAVR with complex aorta/iliofemoral anatomy with three main findings:

1. Complex iliofemoral or aortic anatomy was observed in 1/3 of our TAVR cohort,
2. Despite higher risk profile of the patients in the TC group, we observed a two-fold reduction (p = 0.1) of the primary end point compared to the TF group with significantly less major VC and no access failure.
3. Similar radiation doses, contrast amount and hospitalization length were observed between the 2 strategies.

4.1 | Complex vascular anatomy in TAVR and alternative

Minimal iliofemoral artery diameter, presence of calcified iliofemoral arteries are predictive of complex TF access and correlated with increased risk of MVC during TAVR.^{2,4,15} In the Italian CoreValve

registry, the presence of major access site complication was a strong (OR 8.47) independent predictor of 30-day mortality.¹⁶ In our study, complex iliofemoral and/or aortic anatomy was observed in 31% of our TAVR cohort as previously reported.^{2,17,18} Regarding TAVR access, the common carotid artery is superficial, making the dissection easy and a relative excess of length facilitates its surgical closure.¹⁹⁻²¹ The direct access from the sheath to the ascending aorta provides a good control of the valve positioning and avoids multiple manipulations in the aortic arch. TC approach should however be performed by an experienced vascular surgeon due to the presence of important local structures, such as the vagus nerve and the respiratory system. The subclavian and axillary arteries are of the elastic type while the femoral is of the muscular type.⁷ Those characteristics predispose this access to vascular complications such as ruptures or dissections. Apical or direct aortic approaches are more invasive and furthermore, these techniques are limited by contraindications such as significant respiratory failure in case of transapical, and porcelain aorta, as well as previous heart surgery, in case of transaortic approach.²² TC approach was recently reported as safe and feasible in appropriately selected patients with a high rate of device success and similar outcomes to TF access.¹⁹⁻²¹

4.2 | Favorable primary outcomes after TC approach

In our study, despite higher risk profile of patients in the TC group, outcomes compared favorably with patients from the TF group. Moreover, the primary endpoint tended to be lower without reaching significance and MVC were significantly reduced in TC group ($p = .02$). While MVC remains one of the main complication of TF TAVR, our results argue to discuss a TC approach in patients with predictable challenging TF anatomy as recently pointed out in the FRANCE TAVI registry.³ TC group mortality rate in our study was low (2.6%) and comparable to the results observed in the French transcarotid multicenter registry.²⁰ Stroke is a major concern after TAVR and particularly for TC approach although randomized studies and registries did not find excess risk of neurologic events with this access.²⁰⁻²³ In our study, the stroke rate in the TC group was low (two patients) and only one of them could be attributed to the procedure induced carotid occlusion.

4.3 | TAVR procedure course according to the strategy

In our study, TC TAVR procedure was not associated with increased procedure duration, radiation dose or amount of contrast in comparison with TF approach as previously reported in registries.^{22,23} Post-operative care in TC access should include monitoring of signs of compressive hematoma (dysphonia, dysphagia, dyspnea) that may require emergency orotracheal intubation. However, no severe complication occurred in the TC patients in our study and the total

hospitalization length was similar between both groups with similar data from others experienced teams.^{23,24}

4.4 | Study limitations

The first limitation of this study is inherent to its monocentric nature with a relative small number of patients. Considering the favorable tendency of the primary endpoint for the TC group, a statistical difference might be observed for the primary endpoint between the two groups with a larger population. The relatively short follow-up at 1 month could be considered as another limitation but, occurrence of adverse events seems unlikely to be related to the vascular approach of TAVR beyond 1 month. Finally, a higher rate of women in the TF group, may have induced a bias regarding incidence of VC.

4.5 | Perspectives

Regarding favorable outcomes, TC approach has become the second-line access in many centers but only proposed in case of impossible TF access. Regarding the results of our study, extension of TC approach as first alternative in complex TF access may be considered. However, randomized studies would be necessary to validate this strategy.

5 | CONCLUSION

Despite a higher patients' risk profile in our study, TC approach was associated with similar success rate and numerically lower rate of major clinical endpoints in comparison to TF approach in patients with complex aortofemoral anatomy. As TC access was associated with a significant lower rate of MVC without increasing of stroke, this approach should be considered as the first alternative in case of challenging vascular anatomy in patients undergoing TAVR.

CONFLICT OF INTEREST

Florence Leclercq received research grants from Edwards, Medtronic, Boehringer; consultant fees from Boehringer; and lecture fees from Astra Zeneca and Bayer.

Guillaume Cayla received research grants/consultant fees/lectures fees from Amgen, AstraZeneca, Abbott, Bayer, Biotronik, Bristol-Myers Squibb, Pfizer, Sanofi-Aventis.

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Mariama Akodad received research grants from Edwards Lifescience and Medtronic.

Thomas Gandet received consultant fees from Medtronic.

Romuald Choteau, Chloé Chamard, Youcef Lounes, Jean-Christophe Macia, Delphine Delseny have no conflicts of interest to declare.

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