Transfemoral versus transcarotid access for transcatheter aortic valve

The Reims Heart Team

2022-10

The Reims Heart Team , Olivier , M-E , Di Cesare , A , Poncet , A , Biancari , F & Ruggieri , V G 2022 , ' Transfemoral versus transcarotid access for transcatheter aortic valve ' , Jtcvs Techniques , vol. 15 , pp. 46-53 . https://doi.org/10.1016/j.xjtc.2022.05.019

http://hdl.handle.net/10138/351250
https://doi.org/10.1016/j.xjtc.2022.05.019

Transfemoral versus transcarotid access for transcatheter aortic valve replacement

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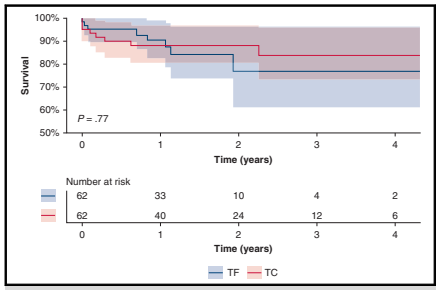
ABSTRACT

Objectives: To compare the outcomes after transcatheter aortic valve replacement (TAVR) through a transfemoral (TF) and transcarotid (TC) access at our institution.

Methods: From January 2014 to January 2020, 62 TC-TAVR and 449 TF-TAVR were performed using 2 prosthesis devices (Edwards SAPIEN 3, n = 369; Medtronic Evolut R, n = 142). Propensity score matching was used to adjust for imbalance in the baseline characteristics of the study groups.

Results: Propensity score matching provided 62 matched pairs with comparable operative risk (mean European System for Cardiac Operative Risk Evaluation II, TC-TAVR 7.6% vs TF-TAVR 6.6%, $P = .17$). Thirty-day mortality (4.8% vs 3.2%, $P = 1.00$) and 2-year mortality (11.3% vs 12.9%, $P = .64$) after TC-TAVR were comparable with TF-TAVR. Strokes were numerically more frequent after TC-TAVR compared with TF-TAVR (3.2% vs 0%, $P = .23$), but the difference did not reach statistical significance. TF-TAVR was associated with a significantly greater risk of permanent pacemaker implantation (29.0% vs 12.9%, $P = .04$) compared with TC-TAVR. Other complications were not frequent and were similarly distributed between the matched groups.

Conclusions: TC access for TAVR was associated with satisfactory results compared to the femoral access. TC-TAVR could be considered a valid and safe alternative to TF-TAVR when femoral access is contraindicated. (JTCVS Techniques 2022;15:46-53)



Survival of the propensity score matched groups.

CENTRAL MESSAGE

Transcarotid access for TAVR was associated with satisfactory results compared with femoral access.

PERSPECTIVE

TC-TAVR could be considered a valid and safe alternative to TF-TAVR when femoral access is contraindicated.

Video clip is available online.

Transcatheter aortic valve replacement (TAVR) is an effective and durable treatment for severe aortic stenosis.[1-3] Neurologic and vascular complications[4,5] remain the main complications of TAVR regardless of the type of prosthesis used. The transfemoral (TF) approach is privileged because the common femoral artery is easy to access, the procedure can be performed with the patient under local anesthesia, and the access site can be safely closed with vascular closure devices.

Still, TF-TAVR is contraindicated in a significant number of patients and in these cases transapical, transaortic, transsubclavian, transbrachiocephalic arterial, and transcarotid (TC) approaches are used as alternative access sites.[4,6-8] However, most of these approaches require general anesthesia, whereas transthoracic accesses can be associated with increased morbidities and mortality. Therefore, nowadays, the transsubclavian and TC access sites are favored when TF-TAVR is not feasible.[9-12]

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Received for publication Oct 20, 2020; revisions received Feb 9, 2022; accepted for publication March 3, 2022; available ahead of print July 20, 2022.

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2666-2507

https://doi.org/10.1016/j.xjtc.2022.05.019

Abbreviations and Acronyms

EuroSCORE II = European System for Cardiac Operative Risk Evaluation II
Fr = French
TAVR = transcatheter aortic valve replacement
TC = transcarotid
TF = transfemoral

TC-TAVR seems to be a promising procedure because it allows direct access to the aortic valve and the procedure is feasible under local anesthesia. Still, data on the efficacy of TC-TAVR compared with TF-TAVR are scarce. In this study, we sought to compare the outcomes of TC-TAVR and TF-TAVR in an institutional series.

METHODS

TAVR was performed in 541 patients at the Reims University Hospital, France, between January 2014 and January 2020. Each patient provided written consent for data publication; institutional review board approval was not required. Data were retrospectively collected in an electronic datasheet with prespecified variables and definition criteria.

The Heart Team in all these patients decided the indication for TAVR and access site. Patients underwent preprocedural computed tomography and the images were analyzed using an imaging reconstruction software (OsiriX MD, 7.0; Pixmo) with a double reading. Contraindications to TF-TAVR were according to the current recommendations[1,2,13-15] and are herein summarized: a diameter of the common femoral artery <6 mm, severe iliacofemoral artery tortuosities, thrombosis, previous surgical procedure on the femoral arteries, or aortic bifurcation. In the case of contraindication to TF access, the choice of the alternative access was made on a collegial decision of the Heart-Team, with the left transubclavian access as first choice. When the transubclavian access was contraindicated due to previous coronary artery bypass grafting using the left internal mammary artery, calcifications, tortuosity or inappropriate diameter, then the Heart Team prioritized the TC access.

Procedural Methods

The TC access indication required a common carotid artery with a diameter >6 mm. Patency of the circle of Willis was routinely assessed with angiographic computed tomography. The following conditions contraindicated TC-TAVR: diameter of the common carotid artery <6 mm, significant tortuosity, presence of atherosclerotic plaques considered at risk of embolization, previous carotid surgery on the ipsilateral side, untreated significant stenosis of the contralateral common carotid artery, and/or lack of patency of the circle of Willis. All patients underwent preprocedural coronary angiography to assess and eventually treat any significant coronary stenosis according to the current recommendations.[1,2]

TF-TAVR and TC-TAVR were performed with the patient under local anesthesia in accordance with best practice guidelines.[16-19] The Edwards SAPIEN 3 balloon-expandable valve was implanted using the Certitude catheter (Edwards Lifesciences). The dedicated introducer had an internal diameter of 18 French (Fr) for valve sizes of 23 mm and 26 mm, whereas an introducer diameter of 21 Fr was used for a valve size of 29 mm. The Medtronic CoreValve Evolut R auto-expandable valve prosthesis was implanted using the EnVeo R (Medtronic) carrying catheter, requiring an introducer of 14 Fr for 26-mm and 29-mm prostheses or 16 Fr for the 34-mm prosthesis.

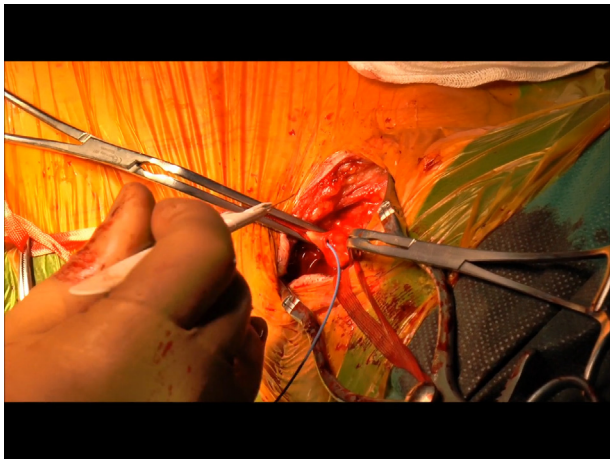
The procedural methods for TC-TAVR were according to previous recommendations.[20-22] The procedure (Video 1) was performed in a hybrid operating room with the patient under local anesthesia by cervical block with ropivacaine 2 mg/mL as recommended by the French Society of Anesthesia and Intensive Care Medicine.[23] In addition, remifentanil was used to allow a suitable level of sedation. Patients' neurologic conditions were monitored using near-infrared spectroscopy and bispectral index as well as by clinical monitoring. Heparin 100 UI/kg was administered intravenously to achieve an activated clotting time target >250 seconds. The common carotid artery was surgically prepared by a 3- to 4-cm long cervicotomy. Neurologic tolerance to a 3-minute carotid artery clamping was tested by clinical and near-infrared spectroscopy monitoring. Once the TAVR prosthesis was implanted, angiography control and transthoracic echocardiography were performed to detect any paravalvular regurgitation. The access site was surgically sutured.

TF-TAVR procedure was performed under local anesthesia by iliacoinguinal and iliacohypogastric block with ropivacaine 7.5 mg/mL and 2 mg/mL,[14,24] if necessary supplemented by a slight sedation with remifentanil (0.1-0.15 μ/kg/min). Upon removal of the introducer, hemostasis was ensured by the use of 2 previously installed ProStar percutaneous closure systems (Abbott Vascular). Vascular complications at the access site were excluded by control angiography of the iliacofemoral arteries.

Aspirin (75 mg) was administered preoperatively to all patients. Cefazoline (2 g) or vancomycin (30 mg/kg) was administered for antibiotic prophylaxis. For patients on oral anticoagulant therapy, it was suspended in preoperative with the installation of a relay maintained in immediate postoperative. After the procedure, dual therapy with aspirin and clopidogrel was given for 3 months. Resumption of oral anticoagulation associated with aspirin was made in patients on oral anticoagulation according to current recommendations.[16-18]

Outcomes

The primary outcomes of this study were 30-day and 2-year all-cause mortality as well as stroke or transient ischemic attack during the index hospitalization. The secondary outcomes of this study were myocardial infarction, major bleeding, vascular access complications, acute kidney



VIDEO 1. This video shows the transcarotid TAVR conducted in a hybrid operating room by our multidisciplinary team with the patient under locoregional anesthesia by cervical block. Neurologic monitoring was clinical associated to NIRS (near-infrared spectroscopy) after a 3-minute carotid clamping test. The eSheath to introduce the prosthesis delivery system was placed through the carotid artery after a partial transverse section of approximately 3 to 4 mm of the vessel. Video available at: https://www.jtcvs.org/article/S2666-2507(22)00372-8/fulltext.

injury, permanent pacemaker implantation, valve-related complications, sepsis, and paravalvular regurgitation.

The outcomes were defined according to the Valve Academic Research Consortium 2 criteria.[24] Data on survival status were retrieved from patients' records and from the National Institute of Statistics and Economic Studies National Compendium of Deaths with a follow-up ending on January 1, 2020.

Statistical Analysis

Continuous variables were reported as the mean and standard deviation and categorical variables as counts and percentages. The normal distribution of continuous variables was verified by the Shapiro–Wilk test. Differences between the study groups were evaluated using the Wilcoxon signed rank test and the Fisher exact test. Because of the imbalance in the baseline variables of the TF-TAVR group and TC-TAVR group, propensity score matching was performed to obtain 2 comparable groups. A propensity score by logistic regression of the following variables considered as confounding factors: age, sex, body mass index, chronic obstructive pulmonary disease, diabetes, New York Heart Association classes, estimated glomerular filtration rate, peripheral artery disease, European System for Cardiac Operative Risk Evaluation II (EuroSCORE II), atrial fibrillation, coronary artery disease, previous percutaneous coronary intervention, previous coronary artery bypass grafting, left ventricular ejection fraction, systolic pulmonary artery pressure, and mitral valve regurgitation. One-to-one propensity score matching was performed using the nearest neighbor method. A tolerance threshold was not established. Matching was made without a replacement. Balance in the preoperative variables between the study groups before and after matching was verified by evaluation of the standardized differences. A standardized difference <0.25 was considered as a negligible difference. Survival was assessed using the Kaplan–Meier method with the log-rank test. Statistical analyses were performed using R 3.6.0 (R Foundation for Statistical Computing).

RESULTS

Characteristics and Results in the Overall Series

TF-TAVR was performed in 449 consecutive patients and TC-TAVR in 62 consecutive patients, whose characteristics are summarized in Table 1. Significant differences between the study groups were observed in some of baseline characteristics, which resulted in an increased operative risk in patients undergoing TC-TAVR compared with those undergoing TF-TAVR (mean EuroSCORE II, 7.6% vs 6.1%, $P < .01$) (Table 1).

In this series, 2 TAVR prosthesis devices were implanted (SAPIEN 3, n = 369; Evolut R, n = 142) The SAPIEN 3 prosthesis was implanted in 72.4% of patients who underwent TF-TAVR and in 71.0% of patients who underwent TC-TAVR (Table 2). No conversion to general anesthesia or to open surgery was required in this series. Stroke/transient ischemic attack were similar distributed between the study groups (TF-TAVR 3.5% vs TC-TAVR 3.2%, $P = 1.00$; only stroke: TF-TAVR 2.9% vs TC-TAVR 3.2%, $P = .76$). Nine (1.8%) patients died during the procedure, 3 (4.8%) in the TC-TAVR group and 6 (1.3%) in the TF-TAVR group ($P = .08$). None of these patients died of vascular access–related complications. Indeed, the causes of intraoperative deaths were in the TC-TAVR group annular rupture in 1 patient, myocardial infarction in 1 patient, and ventricle rupture in another patient. In the TF-TAVR group, intraoperative death was secondary to aortic annulus rupture in 3 patients, ventricle rupture in 1 patient, myocardial stunning in 1 patient, and myocardial infarction in another patient.

Propensity Score Matching Analysis

Propensity score matching provided 62 matched pairs with comparable operative risk (mean EuroSCORE II, TC-TAVR 7.6% vs TF-TAVR 6.6%, $P = .17$) (Table 3). Thirty-day (4.8% vs 3.2%, $P = 1.00$) and 2-year mortality (11.3% vs 12.9%, $P = .64$) after TC-TAVR were comparable with TF-TAVR (Figure 1). No transient ischemic attack was observed in this series. Stroke (n = 2) was numerically more frequent after TC-TAVR compared with TF-TAVR (3.2% vs 0%, $P = .23$), but the difference did not reach statistical significance (Table 4). Among patients undergoing TC-TAVR, stroke was ipsilateral to the access site in one case and occurred on the third postoperative day. Another patient suffered bilateral stroke on the 20th postoperative day.

TF-TAVR was associated with a significantly greater risk of permanent pacemaker implantation (29.0% vs 12.9%, $P = .04$) compared with TC-TAVR. Other complications were not frequent and were similarly distributed between the matched groups (Table 4). TC-TAVR and TF-TAVR resulted in a similar, significant decrease of transvalvular gradient after the procedure (both $P < .01$) (Table 5).

DISCUSSION

The main findings of this study are as follows: (1) TC access for TAVR was necessary in a limited number of patients (11.5%); (2) patients undergoing TC-TAVR had a significantly increased operative risk than those undergoing TF-TAVR; (3) when differences between the study groups were adjusted by propensity score matching, TC-TAVR presented an early- and mid-term mortality, stroke/transient ischemic attack not different than TF-TAVR; and (4) secondary adverse events were not frequent in this series and were not more significant in the TC-TAVI group.

Neurologic and vascular complications are key issues in patients in whom femoral access for TAVR is contraindicated.[25-27] Neurologic complications are of concern, particularly in patients undergoing TC-TAVR because of the transient clamping and manipulation of the common carotid artery.[28,29] Other potential mechanisms underlying the development of stroke/transient ischemic attack are embolization of debris during balloon valvuloplasty and the deployment of the prosthesis device, episodes of hypotension due to rapid ventricular stimulation, atrial fibrillation, and inadequate collateral cerebral vascularization through the circle of Willis.[10,11,30-32] This

TABLE 1. Clinical characteristics of in unmatched study groups

Clinical variables	Overall series n = 511	Femoral access n = 449	Carotid access n = 62	Standardized difference	*P* value
Age, y	84 (6)*	84 (6)*	83 (10.75)*	0.247	.13†
Male	244 (47.7)	211 (47.0)	33 (53.2)	0.125	.42‡
Body mass index	26 (7)*	27 (6)*	25 (7.75)*	0.181	.11†
COPD	157 (30.7)	134 (29.8)	23 (37.1)	0.154	.24‡
NYHA class				0.157	.30‡
2	179 (35)	160 (35.6)	19 (30.6)		
3	324 (63.4)	283 (63.0)	41 (66.1)		
4	8 (1.6)	6 (1.3)	2 (3.2)		
Diabetes	157 (30.7)	138 (30.7)	19 (30.6)	0.002	1.00‡
eGFR, mL/min/1.73 m^2				0.140	.90‡
>90	7 (1.4)	6 (1.3)	1 (1.6)		
>60-90	200 (39.1)	178 (39.6)	22 (35.5)		
>30-60	197 (38.6)	173 (38.5)	24 (38.7)		
>15-30	83 (16.2)	71 (15.8)	12 (19.4)		
<15	12 (2.3)	10 (2.2)	2 (3.2)		
Dialysis	12 (2.3)	11 (2.4)	1 (1.6)		
Peripheral artery disease	88 (17.2)	60 (13.4)	28 (45.2)	0.746	<.01‡
Atrial fibrillation	196 (38.4)	169 (37.6)	27 (43.5)	0.121	.41‡
Previous pacemaker	62 (12.1)	55 (12.2)	7 (11.3)	0.030	1.00‡
Coronary artery disease	263 (51.5)	234 (52.1)	29 (46.8)	0.107	.50‡
Previous PCI	173 (33.9)	152 (33.9)	21 (33.9)	<0.001	1.00‡
Previous CABG	31 (6.1)	21 (4.7)	10 (16.1)	0.382	<.01‡
SPAP, mm Hg				0.321	.15‡
<25	220 (43)	192 (42.8)	28 (45.2)		
25-31	82 (16)	67 (14.9)	15 (24.2)		
31-55	146 (28.6)	131 (29.2)	15 (24.2)		
>55	63 (12.3)	59 (13.1)	4 (6.5)		
Mitral valve insufficiency	126 (24.7)	113 (25.2)	13 (21.0)	0.100	.53‡
LVEF, %	56 (15)*	57 (15)*	55 (10)*	0.146	.22†
EuroSCORE II, %	4.5 (4.68)*	4.3 (4.4)*	5.55 (6.18)*	0.264	<.01†

Values are reported as counts and percentages or mean and standard deviation. *COPD*, Chronic obstructive pulmonary disease; *NYHA*, New York Heart Association; *eGFR*, estimated glomerular filtration rate; *PCI*, percutaneous coronary intervention; *CABG*, coronary artery bypass grafting; *SPAP*, systolic pulmonary artery pressure; *LVEF*, left ventricular ejection fraction; *EuroSCORE II*, European System for Cardiac Operative Risk Evaluation II. *Median (interquartile ranges). †Unpaired Wilcoxon test. ‡Fisher exact test.

study showed that the incidence of stroke in patients undergoing a TC access occurred late after the procedure (on the third and twentieth postoperative day). Similarly, in the overall series, there was not a significant different rate of stroke/transient ischemic attack in the study groups (TF-TAVR 3.5% vs TC-TAVR 3.2%, $P = 1.00$; only stroke:

TABLE 2. Characteristics of valve prostheses

Type of device and its size	Overall series n = 511	Femoral access n = 449	Carotid access n = 62
Evolut R	142 (27.8)	123 (27.4)	18 (29)
23 mm	10 (1.9)	10 (2.2)	0 (0)
26 mm	53 (10.4)	48 (10.7)	5 (8.0)
29 mm	51 (10.0)	45 (10.0)	6 (9.7)
31 mm	5 (1.0)	4 (0.8)	1 (1.6)
34 mm	23 (4.5)	17 (3.8)	6 (9.7)
SAPIEN 3	369 (72.2)	325 (72.4)	44 (71)
23 mm	157 (30.7)	140 (31.2)	17 (27.5)
26 mm	160 (31.3)	136 (30.3)	24 (38.7)
29 mm	52 (10.2)	49 (10.9)	3 (4.8)

Values are reported as counts and percentages.

TABLE 3. Clinical characteristics of the study groups after propensity score matching

Clinical variables	Femoral access n = 62	Carotid access n = 62	Standardized difference	*P* value
Age, y	83.5 (5.75)*	83 (10.75)*	0.034	.97†
Male	26 (41.9)	33 (53.2)	0.228	.28‡
Body mass index	25 (4)*	25 (7.75)*	0.072	.48†
COPD	19 (30.6)	23 (37.1)	0.137	.57‡
NYHA class			0.108	.80‡
2	16 (25.8)	19 (30.6)		
3	44 (71.0)	41 (66.1)		
4	2 (3.2)	2 (3.2)		
Diabetes	22 (35.5)	19 (30.6)	0.103	.70‡
eGFR, mL/min/1.73 m^2			0.203	.98‡
>90	0 (0.0)	1 (1.6)		
>60-90	20 (32.3)	22 (35.5)		
>30-60	25 (40.3)	24 (38.7)		
>15-30	14 (22.6)	12 (19.4)		
<15	2 (3.2)	2 (3.2)		
Dialysis	1 (1.6)	1 (1.6)		
Peripheral artery disease	26 (41.9)	28 (45.2)	0.065	.86‡
Atrial fibrillation	29 (46.8)	27 (43.5)	0.065	.86‡
Previous pacemaker	11 (17.7)	7 (11.3)	0.184	.45‡
Coronary artery disease	30 (48.4)	29 (46.8)	0.032	1.00‡
Previous PCI	20 (32.3)	21 (33.9)	0.034	1.00‡
Previous CABG	8 (12.9)	10 (16.1)	0.092	.80‡
SPAP, mm Hg			0.250	.66‡
<25	30 (48.4)	28 (45.2)		
25-31	15 (24.2)	15 (24.2)		
31-55	16 (25.8)	15 (24.2)		
>55	1 (1.6)	4 (6.5)		
Mitral valve insufficiency	14 (22.6)	13 (21.0)	0.039	1.00‡
LVEF (%)	58.5 (10.75)*	55 (10)*	0.077	.40†
EuroSCORE II (%)	4.95 (5.53)*	5.55 (6.18)*	0.171	.17†

Values are reported as counts and percentages or mean and standard deviation. *COPD*, Chronic obstructive pulmonary disease; *NYHA*, New York Heart Association; *eGFR*, estimated glomerular filtration rate; *PCI*, percutaneous coronary intervention; *CABG*, coronary artery bypass grafting; *SPAP*, systolic pulmonary artery pressure; *LVEF*, left ventricular ejection fraction; *EuroSCORE II*, European System for Cardiac Operative Risk Evaluation II. *Median (interquartile ranges). †Unpaired Wilcoxon test. ‡Fisher exact test.

TF-TAVR 2.9% vs TC-TAVR 3.2%, $P = .76$). These findings could suggest the non-dangerousness of TC access for TAVR. However, the preoperative assessment of the patency of circle of Willis and the absence of significant atherosclerotic changes in the carotid arteries are key issues with this approach and have contributed to the low incidence of neurologic complications in patients undergoing TC-TAVR.

The absence of significant differences in terms of vascular complications and other early outcomes further can demonstrate the nondifference of safety and efficacy of the TC-TAVR than TF-TAVR, as documented by previous institutional and multicenter studies.[12,15,33,34] In fact, the access to the common carotid artery can be achieved easily, and this makes bleeding and infectious complications quite uncommon.[30-32,34,35] The minimal distance between the vascular-site access and the valve plane also allows the stability of the introduction system with greater precision during the deployment of the valve.

Limitations

The retrospective nature of this study is the main limitation of this analysis. However, this study relies on the quality and completeness of data gathered from our institutional and rehabilitation centers. Data on mortality were obtained from a national statistical registry, which guarantees information on the survival status of all these patients.

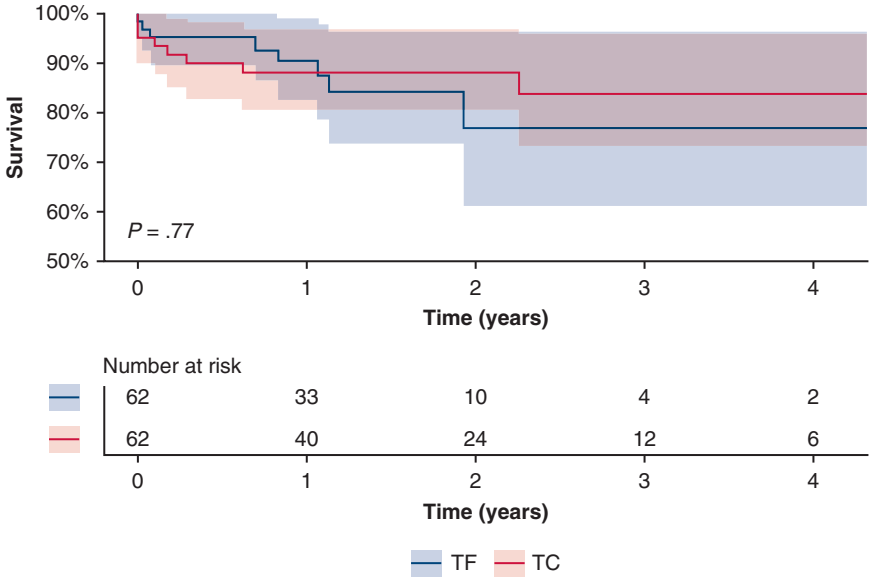


FIGURE 1. Survival of the propensity score–matched groups. *Curves* illustrate the survival rate in each group. It was more significant for the TF-TAVI group during the first year, but after 1 year, the survival was more significant in the TC-TAVI group and was stabilized at 2 years. All patients were informed and gave their written consent for publication of the study data. *TF*, Transfemoral; *TC*, transcarotid; *TAVR*, transcatheter aortic valve replacement.

Furthermore, neurologic complications were evaluated and confirmed by a neurologist. Second, this is not a randomized trial, and the results were adjusted for baseline differences using propensity score matching. However, the latter approach did not take into account of a selection bias and of other confounders. Finally, the limited size of this series may result in a type II error. Therefore, these results should be considered hypothesis-generating, and larger studies are needed to confirm the safety and efficacy of TC-TAVR.

TABLE 4. Postprocedural outcomes in the propensity score–matched pairs

Outcomes	Femoral access n = 62	Carotid access n = 62	*P* value
30-d mortality	2 (3.2)	3 (4.8)	1.00*
2-y mortality	8 (12.9)	7 (11.3)	.64*
Stroke/transient ischemic attack	0 (0)	2 (3.2)	.23*
Myocardial infarction	0 (0)	1 (1.6)	.32*
Major bleeding	2 (3.2)	1 (1.6)	.60*
Vascular access complications			
Hematoma not requiring surgery	7 (11.3)	2 (3.2)	.16†
Bleeding requiring surgery	1 (1.6)	2 (3.2)	1.00†
Infection	1 (1.6)	0 (0)	1.00†
MACCE	8 (12.9)	10 (16.1)	.12*
Acute kidney injury	0 (0)	0 (0)	1.00†
Postoperative pacemaker implantation	18 (29.0)	8 (12.9)	.04†
Valve–related complications	0 (0)	3 (4.8)	.09†
Sepsis	0 (0)	0 (0)	1.00†
Paravalvular regurgitation grade 1	0 (0)	1 (1.6)	1.00†
Paravalvular regurgitation grade 2 or greater	2 (3.2)	1 (1.6)	1.00†
Transvalvular pressure gradient, mm Hg	8.7 (4.0)	9.6 (4.1)	.10†
>20 mm Hg	0 (0)	1 (1.6)	1.00†

MACCE, Major adverse cardiac and cerebrovascular complications. *Log-rank test. †Fisher exact test.

TABLE 5. Transvalvular gradients before and after the procedure in the propensity score–matched pairs

	Femoral access	Carotid access	*P* value
Preoperative transvalvular gradient pressure, mm Hg	42.5 (13.3)	48.6 (13.5)	<.01
Postoperative transvalvular gradient pressure, mm Hg	8.7 (4.0)	9.6 (4.1)	<.01

Values are expressed as mean and standard deviation. *P* values are from the Wilcoxon test.

CONCLUSIONS

This institutional series demonstrated that TC-TAVR is a safe and effective procedure when compared with TF-TAVR. TC access allows a less-invasive and direct access to the aortic valve under local anesthesia. TC-TAVR should be considered a valid and safe alternative to TF-TAVR when the femoral access is contraindicated. The limited size of this series may result in a type II error. Therefore, these results should be considered hypothesis-generating and should be confirmed in larger studies.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: transcatheter aortic valve replacement, TAVR, TAVI, aortic stenosis, carotid artery