The Carotid Artery as a Preferred Alternative Access Route for Transcatheter Aortic Valve Replacement

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Background. In high-risk patients with severe aortic stenosis, transfemoral (TF) access for transcatheter aortic valve replacement (TAVR) is the preferred access route but is not always feasible. Compared with other alternative access routes, transcarotid (TC) access is often overlooked by many valvular heart teams.

Methods. We report our single-center experience of all patients undergoing TC (n = 25), transapical (TA) (n = 12), or TF (n = 100; limited to most recent cases) TAVR over a 1.5 year period. In-hospital and 30-day outcomes were retrospectively compared between groups using the Kruskal-Wallis and Wilcoxon rank sum tests.

Results. TAVR was successfully performed through the left or right carotid artery in all 25 patients. Procedurally, TC and TF procedures were faster than TA procedures ($p < 0.001$), and patients who underwent TC and TF procedures had shorter intensive care unit (ICU) hours ($p = 0.05$), ventilator hours ($p < 0.001$), and length of stay (LOS) ($p = 0.01$) compared to patients who underwent a TA procedure. No patients who underwent a TC procedure had in-hospital stroke, transient ischemic attack (TIA), or myocardial infarction (MI). One patient who underwent a TC procedure had a TIA by 30-day follow-up, which was not significantly different from the TF (2 patients) or TA groups (0 patients; $p = 0.75$). In-hospital mortality rates were the same between TC (1 patient) and TF (1 patient) procedures but were significantly greater for TA procedures (2 patients; $p = 0.009$). Thirty-day mortality rates were low and did not differ between the groups.

Conclusions. In our US community hospital setting, TC-TAVR is a safe alternative to TF-TAVR in appropriate patients and has evolved to be our alternative access route of choice if TF access is not feasible.

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In high-risk patients with severe symptomatic aortic stenosis, transcatheter aortic valve replacement (TAVR) is a safe and effective alternative to surgical aortic valve replacement [1, 2]. Recent evidence showing excellent 2-year safety outcomes in intermediate-risk patients indicate that TAVR may supplant surgical intervention for a much larger patient population in the future [3].

Transfemoral (TF) access through the femoral artery remains the safest and preferred option for TAVR [4]. Despite advances in device size and improvements in device deliverability, femoral access remains unfeasible in a significant number of patients because of iliofemoral tortuosity, calcification, or vessel diameter. Alternative access routes include transapical (TA) or transaortic, or access through the subclavian, axillary, or carotid artery. Previous studies have reported acceptable safety and outcome data with transcarotid (TC) access, with some surgery teams using an intraprocedural carotid shunt to ensure proper cerebral perfusion during the procedure [5–8]. In many centers, a TC approach is regarded as the last resort for TAVR access.

The French Transcarotid TAVR Registry, comprising 3 large European hospitals, recently reported excellent 30-day and 1-year outcomes in 96 patients who had undergone TC-TAVR [9]. In this report, we describe our single-center experience with TC-TAVR in a high-volume US community hospital setting. Under the auspices of a multidisciplinary valve center with the involvement of vascular and endovascular specialists, our approach has evolved to favor TC-TAVR without shunting as the preferred alternative access strategy for TAVR over TA, subclavian, axillary, or other approaches. Comparing outcomes between patients who underwent TA-TAVR, TC-TAVR, and TF-TAVR, our results show faster procedure times, shorter length of stay (LOS), and comparable or better 30-day outcomes for TC-TAVR.

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Abbreviations and Acronyms

EF	=	ejection fraction
ICU	=	intensive care unit
IQR	=	interquartile range
LOS	=	length of stay
MI	=	myocardial infarction
STS	=	The Society of Thoracic Surgeons
TA	=	transapical
TAVR	=	transcatheter aortic valve replacement
TC	=	transcarotid
TF	=	transfemoral
TIA	=	transient ischemic attack

Patients and Methods

Patients

Patient data were retrospectively collected from the National Cardiovascular Data Registry Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry and a local transcatheter valve registry. This study included all nonresearch patients who underwent TC- TAVR or TA-TAVR in our center between June 2014 and February 2016, and the 100 most recent nonresearch TF cases during a similar time frame. We restricted the number of patients undergoing TF procedures to allow for statistical testing between the 3 groups, because our total number of TF cases during that period (242 cases) would have skewed the statistics. All patients who underwent TAVR met criteria for severe aortic stenosis by peak flow velocity, mean gradient, and aortic valve area or criteria for low-flow, low-gradient severe aortic stenosis. Access route was determined using the algorithm presented in Figure 1. Outcomes and adverse events were defined using Transcatheter Valve Registry, version 2.0 and Valve Academic Research Consortium 2 definitions. This study was reviewed and considered exempt by the Providence Institutional Review Board, with waiver of patient consent (study No. 15-168EX).

Preoperatively, all patients received standard computed tomographic angiography of the chest, abdomen, and pelvis, which included the lower cervical common carotid artery. Carotid duplex ultrasonography was performed in all patients. The smallest carotid diameter allowed was 6.5 mm to accommodate the femoral delivery sheaths that were available at the time of the procedure. Sizing criteria for different valves for carotid access followed femoral sizing criteria provided by the manufacturer. When carotid stenoses greater than 50% were detected by duplex ultrasonography, the stenotic side was given preference for the common carotid access to maximize cerebral blood flow from the contralateral side. Patency of the contralateral carotid artery was required as documented by carotid duplex ultrasonography. Stenosis in the vertebral arteries was permitted, and occlusion of 1 of the vertebral arteries was also allowable. Retrograde flow consistent with steal in the contralateral vertebral artery at rest was considered to be a contraindication. If there was no steal at rest, contralateral carotid TAVR was still feasible. Ipsilateral steal was noted but considered permissible, with close attention to carotid stump pressures and cerebral saturation during test clamping.

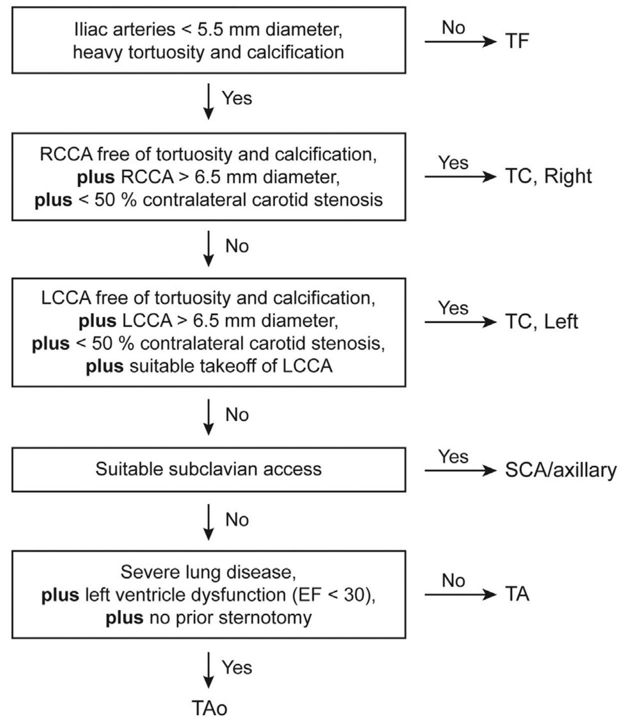

Fig 1. Algorithm for determining transcatheter aortic valve replacement (TAVR) access route. (EF = ejection fraction; LCCA = left common carotid artery; RCCA = right common carotid artery; SCA = subclavian artery; TA = transapical; TAo = transaortic; TC = transcarotid; TF = transfemoral.)

Intraoperative Technique

Before induction, patients had a radial arterial line placed and cerebral saturation monitoring instituted. All were placed using general endotracheal anesthesia and had contralateral internal jugular central venous access. The patients were prepared and draped with their necks extended and rotated away from the operative field. Femoral arterial and venous access was obtained for pigtail catheter and pacing, respectively. In select cases, radial artery access was used as an alternative for pigtail catheter placement.

An approximately 4-cm–long incision was made along the anterior sternocleidomastoid border, just above the clavicle (inferior to a typical carotid endarterectomy incision). Dissection was made down through the platysma exposing the omohyoid strap muscle. This was typically retracted caudally to expose the carotid sheath. The common carotid artery was dissected out sharply to avoid thermal injury to the vagus nerve. Polymeric silicone vessel loops were placed around the artery

proximally and distally. At this point, heparin was administered at 100 units per kilogram.

Systolic blood pressure was maintained at no lower than 120 mm Hg, with administration of pressors when necessary. The proximal common carotid artery was clamped, and a small needle was introduced just distal to the clamp (Fig 2A) to record pressure distal to the clamp. This stump pressure was registered, and a mean arterial pressure greater than 32 mm Hg was accepted. In all cases, this goal was easily attained. If a minimum stump pressure of 32 to 38 mm Hg was not attained, our protocol would be to immediately perform chemical hemodynamic maneuvers to increase the stump mean arterial pressure. In the event of an inadequate stump pressure, a 5-minute test clamp with cerebral saturation monitoring would be attempted. If the cerebral saturation declined by more than 20%, the procedure would be aborted. Throughout all TC cases, cerebral saturation was continuously monitored for a decline of more than 20%, which did not occur in any cases.

The clamp was then released and a micropuncture needle was used to enter the carotid artery. The wire was threaded down into the aorta and was exchanged through the Seldinger technique up to a short 6F sheath (Fig 2). A straight wire with a short 5F angled Kumpe catheter with a 65-cm tip was used to cross the aortic valve. This differs from standard femoral or subclavian cases, because the valve was crossed before placement of the large sheath to minimize the time of carotid occlusion from the sheath. A pigtail was then placed in the ventricle, and pressures were recorded. The pigtail was then used to place a stiff delivery wire into the ventricle.

Next, the loops were tightened above and below the 6F sheath. At this point, the distal common carotid artery was clamped to prevent distal embolization during valve delivery sheath placement and valve deployment. The 6F sheath was removed, maintaining a stiff wire position in the ventricle. An No. 11 blade was then used to perform a transverse arteriotomy at the level of the wire entry to prevent tearing of the artery on sheath placement. No dilation was performed. The delivery sheath with the dilator was then delivered over the wire. If the valve was judged to be exceptionally stenotic, balloon aortic valvuloplasty was performed. In addition, the dilator itself was sometimes used to cross the valve, taking care not to cross excessively into the ventricle.

The tip of the delivery sheath was meticulously maintained at the ostia of the innominate artery. The valve was brought into the field and aligned on the balloon in the ascending aorta in the case of a SAPIEN XT or SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA). After valve deployment, standard transesophageal echocardiographic and pressure evaluations were briefly performed. The delivery catheter, wire, and delivery sheath were then removed, and the arteriotomy was back-bled to ensure that no air or particulate emboli were present. The carotid artery was then closed with a double running layer of 5-0 monofilament (Fig 3). The distal artery was monitored with a Doppler ultrasonographic probe to confirm triphasic flow. Heparin administration was then reversed, and the neck was closed without drains. The platysma and then the skin layers were closed with absorbable braided suture.

Statistical Analysis

χ^2 analysis was used to test for differences between TAVR approach groups for categorical variables. Numeric data were analyzed for normality using the Shapiro-Wilk test. Parametric data were analyzed using 1-way analysis of variance with Tukey's post hoc test, and nonparametric

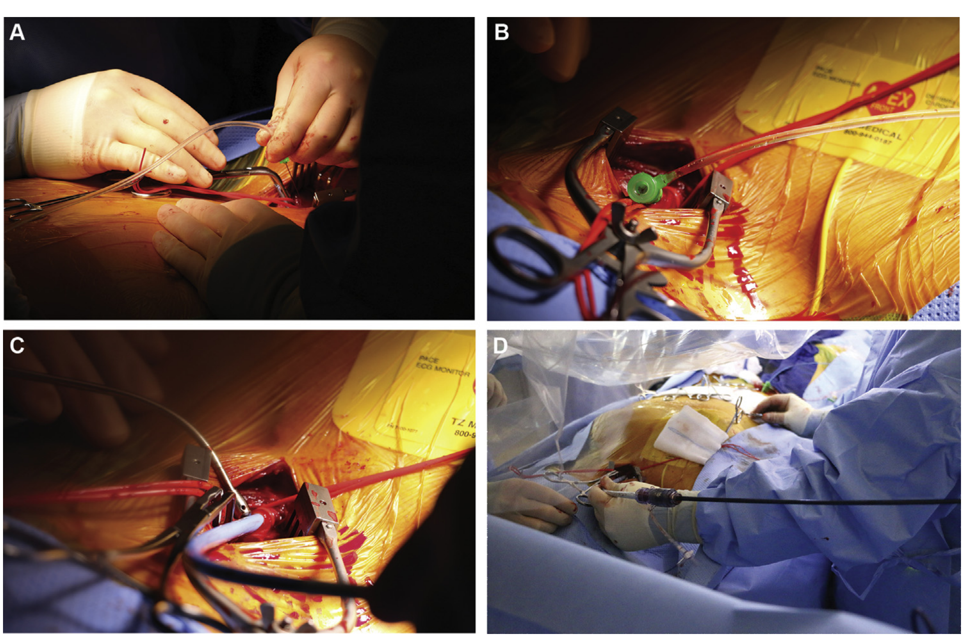

Fig 2. Surgical exposure and access to common carotid artery. (A) Carotid stump pressure distal to clamp was checked to ensure mean arterial pressure >32 mm Hg. (B) A micropuncture needle was used to enter carotid artery, followed by insertion of 6F sheath. (C) After aortic valve crossing, valve delivery sheath was placed. (D) Transcatheter aortic valve replacement (TAVR) valve was passed through delivery sheath into position.

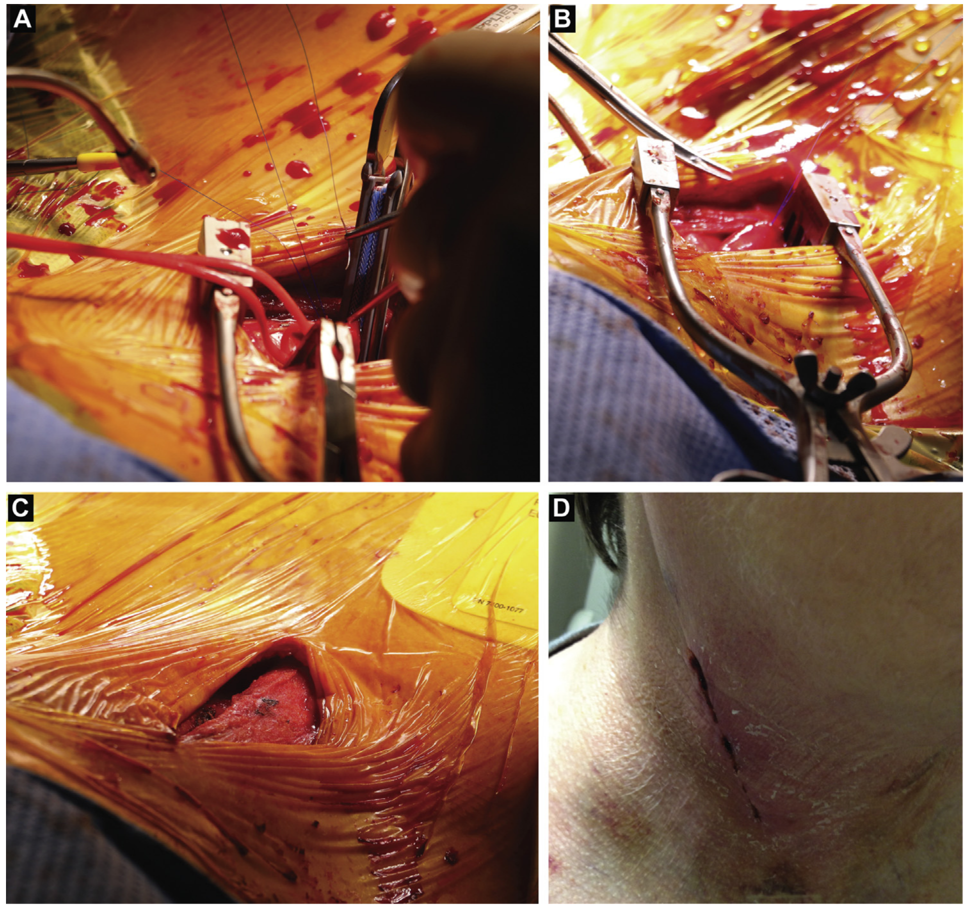

Fig 3. Surgical repair and recovery from transcarotid transcatheter aortic valve replacement (TC-TAVR). (A–C) Transverse repair of carotid artery, with distal and proximal clamps in place. (D) Small incision site and minimal scarring 7 days postoperatively.

data were analyzed using the Kruskal-Wallis test and the Wilcoxon rank sum post hoc test. Parametric data are presented as mean ± SD, and nonparametric data are presented as median and interquartile range (IQR). Analysis of covariance was used to test the effect of age on outcomes data.

Missing Data

Four patients had missing paravalvular leak data at the time of predischarge echocardiography because of technical issues (1 patient who underwent TA-TAVR, 2 patients who underwent TC-TAVR, and 1 patient who underwent TF-TAVR), and 4 additional patients were excluded because of in-hospital mortality.

Results

After careful evaluation of each patient, our multidisciplinary heart team performed TC-TAVR on 25 patients from June 2014 to February 2016. Our algorithm for deciding the access route is shown in Figure 1. To assess the safety and efficacy of TC access, we retrospectively compared these 25 carotid cases with all the TA cases during the same time frame (12 patients) and the most recent 100 TF cases (there were 242 TF cases over this time frame, which we limited to 100 to allow for statistical comparisons). Aside from 2 patients who underwent aortic TAVR and 4 patients who underwent subclavian/axillary TAVR, this analysis reflects all patients who underwent alternative-access procedures in our center during this time frame. We did not include patients who underwent aortic and axillary procedures in our analysis, because statistical testing would not be possible with such small sample sizes.

Patient demographics are presented in Table 1. Society of Thoracic Surgeons Predicted Risk of Mortality did not differ between groups. Compared with patients who underwent TF-TAVR, both TC-TAVR and TA-TAVR groups had higher rates of cerebrovascular disease, peripheral vascular disease, and porcelain aorta. Patients who underwent TA procedures had higher baseline ejection fractions (median, 69%; IQR, 64.5%–70%) than both patients who underwent TC-TAVR (median, 55%; IQR, 35%–60%; $p < 0.001$) and patients who underwent TF procedures (median, 60%; IQR, 45%–65%; $p = 0.003$). We did not consider age when deciding access route, yet we found retrospectively that patients who underwent TC procedures (median, 77.0 years; IQR, 72.0–83.0 years) trended younger than patients who underwent TA-TAVR (median, 82.5 years; IQR, 79.0–87.5 years; $p = 0.06$) and were significantly younger than patients who underwent TF procedures (median, 83.0 years; IQR, 79.0–88.0 years; $p = 0.004$). This finding was addressed in our outcomes analysis.

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Table 1. Patient Demographics and Preoperative Characteristics

Variable	TA (n = 12)	TC (n = 25)	TF (n = 100)	*p* Value	Pairwise Comparisons
Age, median (IQR)	82.5 (79.0–87.5)	77.0 (72.0–83.0)	83.0 (79.0–88.0)	0.01	TA vs TC $p = 0.06$; TC vs TF $p = 0.004$
Female sex, n (%)	7 (58.3)	12 (48.0)	49 (49.0)	0.82	. . .
BMI, median (IQR)	43.4 (41.8–49.1)	45.7 (40.3–51.9)	44.3 (38.0–52.0)	0.77	. . .
White race, n (%)	11 (91.7)	24 (96.0)	98 (98.0)	0.44	. . .
Diabetes, n (%)	6 (50.0)	12 (48.0)	34 (34.0)	0.29	. . .
Insulin dependence, n (%)	2 (33.3)	7 (58.3)	12 (36.4)	0.14	. . .
Moderate to severe chronic lung disease[a], n (%)	1 (8.3)	7 (28.0)	19 (19.0)	0.55	. . .
Hypertension, n (%)	11 (91.7)	22 (88.0)	85 (85.0)	0.78	. . .
Immunosuppression, n (%)	1 (8.3)	4 (16.0)	19 (19.0)	0.64	. . .
Last creatinine level, median (IQR)	1.33 (1.25–1.46)	1.20 (1.06–1.58)	1.19 (0.96–1.49)	0.32	. . .
Dialysis, n (%)	0 (0.0)	2 (8.0)	4 (4.0)	0.51	. . .
Cerebrovascular disease,[b] n (%)	8 (66.7)	12 (48.0)	31 (31.0)	0.005	TA vs TF $p = 0.003$; TC vs TF $p = 0.06$
Peripheral vascular disease, n (%)	10 (83.3)	20 (80.0)	39 (39.0)	<0.001	TA vs TF $p = 0.003$; TC vs TF $p < 0.001$
Previous stroke, n (%)	1 (8.3)	4 (16.0)	13 (13.0)	0.81	. . .
Previous CABG, n (%)	5 (41.7)	9 (36.0)	29 (29.0)	0.58	. . .
Previous valve procedure,[c] n (%)	1 (8.3)	2 (8.0)	8 (8.0)	0.99	. . .
Porcelain aorta, n (%)	4 (33.3)	6 (24.0)	9 (9.0)	0.02	TA vs TF $p = 0.01$; TC vs TF $p = 0.04$
NYHA, class 3 or 4, n (%)	4 (33.3)	10 (40.0)	53 (53.0)	0.48	. . .
Ejection fraction, median (IQR)	69 (64.5–70)	55 (35–60)	60 (45–65)	0.001	TA vs TF $p = 0.003$; TA vs TC $p < 0.001$
Inoperable patients, n (%)	4 (33.3)	8 (32.0)	15 (15.0)	0.14	. . .
STS-PROM, median (IQR)	7.9 (6.9–8.8)	6.1 (4.1–9.6)	6 (4.4–8.1)	0.15	. . .

[a] Includes chronic obstructive pulmonary disease, chronic bronchitis, or emphysema. [b] Includes carotid stenosis, carotid operation, or stent. [c] Includes aortic and nonaortic procedures.

Pairwise comparisons column includes only significant or nearly significant *p* values.

BMI = body mass index; CABG = coronary artery bypass grafting; IQR = interquartile range; NYHA = New York Heart Association; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; TA = transapical; TC = transcarotid; TF = transfemoral.

Successful deployment of the transcatheter heart valve was achieved in all patients who underwent TC procedures, and all commercially available valves were used (Fig 4). Intraoperatively, fluoroscopy dose was significantly lower in patients who underwent TC procedures compared to patients who underwent TF procedures (TC procedures: median, 310.0; IQR, 252.0–432.0; TF procedures: median, 432.5; IQR, 287.0–610.5; $p = 0.038$) (Table 2). Almost all patients in all groups had mild or better paravalvular leak (Table 2). Few patients in any of the groups required blood transfusion (2 patients who underwent TA procedures, 1 patient who underwent a TC procedure, 9 patients who underwent TF procedures; $p = 0.44$). The 1 patient in the TC group who did require transfusion had significant iliac artery disease that precluded TF-TAVR access but was adequate for 5F pigtail insertion. The groin access site appeared to have adequate hemostasis in the operating room but a hematoma developed later that day. The resultant retroperitoneal hematoma was managed nonoperatively.

Postoperative echocardiography showed that all patients had significant improvements in mean aortic gradient, velocity, and area ($p < 0.001$ for all preoperative to postoperative comparisons in all 3 groups) (Table 3). Patients who underwent TA procedures had lower postoperative valve gradients (median, 6.5; IQR, 4.75–7.5) compared with patients who underwent TF procedures (median, 9; IQR, 7–12; $p = 0.03$) and lower postoperative aortic valve velocities (median, 1.7; IQR, 1.5–1.8) compared with both TF procedures (median, 2.1; IQR, 1.8–2.4; $p = 0.001$) and TC procedures (median, 2; IQR, 1.8–2.4; $p = 0.01$). However, patients who underwent TA procedures also had significantly smaller aortic annular areas (median, 1.37; IQR, 1.24–1.58) compared with those who underwent TF procedures (median, 1.63; IQR, 1.4–1.8; $p = 0.03$) and those who underwent TC procedures (median, 1.88; IQR, 1.5–2.18; $p = 0.04$). Because of patient deaths and technical issues, sample sizes were smaller for all the postoperative echocardiography measures.

Postoperative and 30-day outcomes are presented in Table 4. Procedure time, ventilator use, intensive care unit (ICU) hours, and LOS were all significantly higher for patients who underwent TA procedures than for both

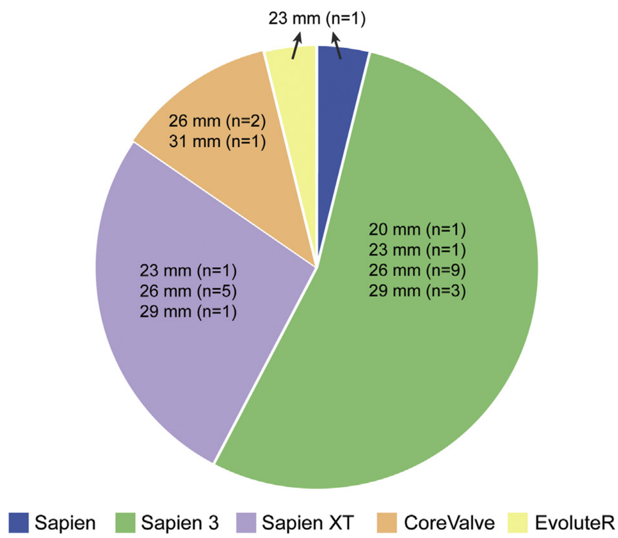

Fig 4. Valve types successfully deployed for transcarotid transcatheter aortic valve replacement (TC-TAVR). Measurements in each pie piece indicate different diameters used for each valve type, with number of patients included in parentheses.

patients who underwent TC-TAVR and those who underwent TF procedures (Fig 5). One patient (8.3%) who underwent TA-TAVR died in the operating room of massive hemoptysis after heparin administration. Another patient (8.3%) who underwent TA-TAVR died of complications arising from aspiration pneumonia and respiratory failure in the postoperative period. One patient who underwent TC-TAVR (4%) died in-house of hypotension and cardiac arrest, which was thought to result from underlying coronary artery disease that was unable to be revascularized. One patient who underwent TF-TAVR (1%) died in-house of complications from a large-volume retroperitoneal hematoma. There were no in-hospital cases of stroke, TIA, or MI in patients who underwent TC procedures.

Thirty-day outcomes showed few cerebrovascular or cardiovascular events. One patient who underwent TC-TAVR (4.2%) and 2 patients who underwent TF procedures (2.2%) had outpatient TIAs by 30 days ($p = 0.75$). Two additional patients in the TF group (3.0%) had died by the 30-day follow-up appointment, 1 because of progressive heart failure resulting in electing for hospice care and 1 because of complications from outpatient pacemaker placement at an outside institution. Observed 30-day mortality was higher for patients who underwent TA procedures (2 patients [16.7%]) compared with TF procedures (3 patients [3%]; $p = 0.001$). Overall, patients who underwent TA procedures had an observed/expected mortality ratio of 2.1, whereas in patients who underwent TC procedures and in those who underwent TF-TAVR, ratios were both less than 1.

Because patients who underwent TC procedures were younger than patients who underwent TA and TF procedures (Table 1), we tested whether age had a significant impact on outcomes using analysis of covariance, with age as a covariate. We found no significant effects of age on the TC/TF comparison for any of the outcomes.

Comment

Our data indicate that at our institution, TC-TAVR is faster and safer than TA-TAVR, with outcomes

Table 2. Perioperative Outcomes

Variable	TA (n = 12)	TC (n = 25)	TF (n = 100)	*p* Value	Pairwise Comparisons
Successful valve deployment, n (%)	12 (100)	25 (100)	98 (98)	0.69	. . .
Valve-in-valve, n (%)	0 (0.0)	2 (8.0)	5 (5.0)	0.58	. . .
Fluoroscopy time, median (IQR), min	9.95 (7.75–15.98)	10.7 (8.60–12.80)	11.9 (8.425–17.220)	0.8	. . .
Fluoroscopy dose/cumulative AK, mGy, median (IQR)	310.0 (218.5–524.0)	310.0 (252.0–432.0)	432.5 (287.0–610.5)	0.07	TC vs TF $p = 0.038$
Fluoroscopy DAP, median (IQR), cGy/cm^2	7024 (5260–8466)	5775 (4406–14630)	7566 (5304–11960)	0.7	. . .
PRBC use, n (%)	2 (16.7)	1 (4.0)	9 (9.0)	0.44	. . .
PRBC units transfused, median (IQR)[a]	2 (0)	4 (0)	2 (2–7)	. . .	. . .
Paravalvular leak,[b] n (%)					
None	6 (66.6)	10 (45.5)	27 (27.6)	0.02	TA vs TF $p = 0.02$
Trace	3 (33.3)	9 (40.9)	41 (41.8)	0.88	. . .
Mild	0 (0.0)	3 (13.6)	26 (26.5)	0.1	. . .
Moderate	0 (0.0)	0 (0.0)	4 (4.1)	0.52	. . .
Severe	0 (0.0)	0 (0.0)	0 (0.0)	. . .	. . .
Carotid access, right side, n (%)	. . .	22 (85)	. . .	. . .	. . .

[a] Not enough data for statistical analysis. [b] Missing data for some patients (see Methods section).

Pairwise comparisons column includes only significant or nearly significant *p* values.

AK = air kerma; DAP = dose area product; IQR = interquartile range; PRBC = packed red blood cells; TA = transapical; TC = transcarotid; TF = transfemoral.

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Table 3. Preoperative and Postoperative Echocardiographic Results

Variable	TA (Postoperative[a] n = 9)	TC (Postoperative[a] n = 22)	TF (Postoperative[a] n = 98)	p Value	Pairwise Comparisons
Preoperative mean AV gradient (mm Hg)	43 (35.25–53.25)	32 (27.5–39.25)	37 (28–48.5)	0.06	. . .
Preoperative max AV velocity (m/s)[b]	4.3 ± 0.7	3.8 ± 0.6	4.0 ± 0.7	0.11	. . .
Preoperative aortic annular area (cm^2)	0.65 (0.47–0.82)	0.7 (0.52–0.79)	0.7 (0.6–0.84)	0.57	. . .
Postoperative mean AV gradient (mm Hg)	6.5 (4.75–7.5)	9 (7–12)	9 (7–12)	0.09	TA vs TF $p = 0.03$
Postoperative max AV velocity (m/s)	1.7 (1.5–1.8)	2 (1.8–2.4)	2.1 (1.8–2.4)	0.005	TA vs TF $p = 0.001$; TA vs TC $p = 0.01$
Postoperative aortic annular area (cm^2)	1.37 (1.24–1.58)	1.88 (1.5–2.18)	1.63 (1.4–1.8)	0.04	TA vs TF $p = 0.03$; TA vs TC $p = 0.04$

[a] Missing postoperative data for 3 patients who underwent TA procedures, 3 patients who underwent TC procedures, and 2 patients who underwent TF procedures (see Methods section). [b] Mean ± SD.

Pairwise comparisons column includes only significant or nearly significant p values. Data presented as median (IQR) or mean ± SD.

AV = aortic valve; TA = transapical; TC = transcarotid; TF = transfemoral.

comparable to the gold standard of TF-TAVR. Compared with patients who underwent TA-TAVR, patients who underwent TC-TAVR had shorter procedure times, shorter LOS, and fewer ventilator hours. In contrast to other reports of TC-TAVR, we did not use carotid bypass or shunting, which we believe adds time and increases the potential for complications [5, 6]. The recent report of 96 patients from the French Transcarotid TAVR Registry also did not use shunting but did perform more extensive preoperative evaluation of cerebral circulation [9]. Our experience demonstrates that clamping of the distal carotid artery can be performed safely during TC-TAVR,

Table 4. Postoperative and 30-Day Outcomes

Variable	TA (n = 12)	TC (n = 25)	TF (n = 100)	p Value	Pairwise Comparisons
Procedure time, median (IQR), min	101.5 (93–124.2)	75 (61–89)	71.5 (60.75–85.75)	<0.001	TA vs TF $p < 0.001$; TA vs TC $p < 0.001$
ICU, median (IQR), h	47.7 (26.6–73.5)	27.8 (24.2–42.1)	25.9 (23.4–30.4)	0.05	TA vs TF $p = 0.02$; TA vs TC $p = 0.06$
Ventilator, median (IQR), min	361.5 (271.8–425.2)	115 (101–233)	83.5 (73.75–105)	<0.001	TA vs TF $p < 0.001$; TC vs TF $p < 0.001$; TA vs TC $p < 0.001$
Postoperative LOS, median (IQR), d	5 (4–7)	3 (2–3)	3 (2–5)	0.01	TA vs TF $p = 0.006$; TA vs TC $p = 0.001$
Life-threatening bleeding, n (%)	1 (8.3)	1 (4.0)	4 (4.0)	0.78	. . .
Major bleeding, n (%)	1 (8.3)	0 (0.0)	6 (6.0)	0.41	. . .
Nonbleeding major vascular complication, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	. . .	. . .
New dialysis, n (%)	0 (0.0)	0 (0.0)	1 (1.0)	0.83	. . .
MI, in-hospital, n (%)	0 (0.0)	0 (0.0)	1 (1.0)	0.83	. . .
Stroke, in-hospital, n (%)	1 (8.0)	0 (0.0)	0 (0.0)	0.005	TA vs TF $p = 0.004$
TIA, in-hospital, n (%)	0 (0.0)	0 (0.0)	2 (2.0)	0.69	. . .
Observed in-hospital mortality, n (%)	2 (16.7)	1 (4.0)	1 (1.0)	0.009	TA vs TF $p = 0.001$
Ejection fraction at 30 d, median (IQR)	65 (56.25–68.75)	64 (45–68)	60 (45–65)	0.34	. . .
Major bleeding at 30 d, n (%)	0 (0.0)	0 (0.0)	1 (1.1)	0.83	. . .
MI at 30 d, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	. . .	. . .
Stroke at 30 d, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	. . .	. . .
TIA at 30 d, n (%)	0 (0.0)	1 (4.2)	2 (2.2)	0.75	. . .
Observed 30-d mortality, n (%)	2 (16.7)	1 (4.0)	3 (3.0)	0.09	TA vs TF $p = 0.001$
Observed/expected mortality (95% CI)	2.1 (0.2–3.9)	0.54 (0.0–1.9)	0.15 (0.0–0.87)	. . .	. . .

Pairwise comparisons column includes only significant or nearly significant p values.

CI = confidence interval; ICU = intensive care unit; IQR = interquartile range; LOS = length of stay; MI = myocardial infarction; TA = transapical; TC = transcarotid; TF = transfemoral; TIA = transient ischemic attack.

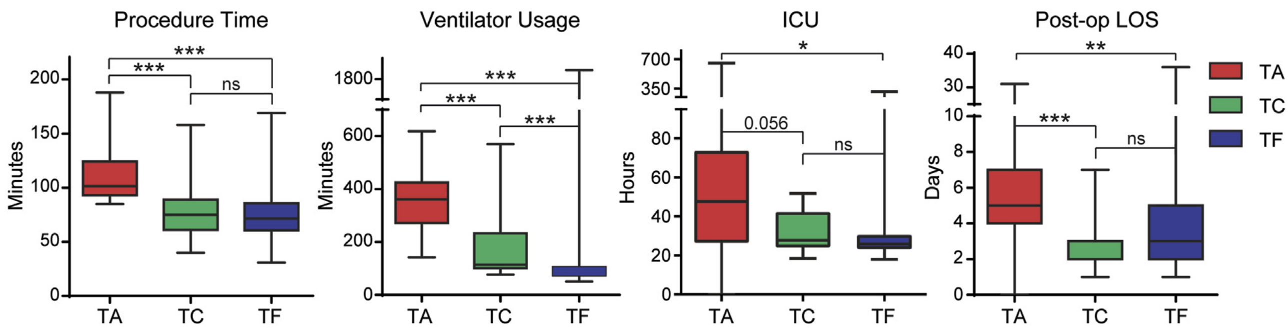

*Fig 5. Procedural outcomes were better for patients who underwent transcarotid (TC) and transfemoral (TF) procedures compared to patients who underwent transapical (TA) procedures. All data were nonparametric and were analyzed using Wilcoxon rank sum tests (*p < 0.05; **p < 0.01; ***p < 0.001). (ICU = intensive care unit; LOS = length of stay; ns = not significant; Post-op = postoperative.)*

with careful attention to minimizing occlusion time combined with continuous monitoring of cerebral oxygen saturation throughout the procedure. Using this approach, no patients who underwent TC procedures had in-hospital stroke or TIA. Incidents of stroke and TIA at 30 days were low and did not differ between groups. Our methods of ensuring sufficient carotid stump pressure and monitoring cerebral oxygen saturation were recently validated by another group for successful TC-TAVR placement in 5 patients [10].

Because the carotid artery is clamped, we believe our surgical technique results in better control over distal embolization compared with other TAVR procedures. Although the incidence of stroke is low in TAVR procedures, debris embolization to the brain does occur [1, 11, 12]. Clinical trials using embolic protection devices are currently under way [13]. Our technique of distal carotid clamping with back-bleeding after valve deployment theoretically diminishes the risk of debris entry into the brain.

Compared with the cohort of patients included in the multicenter French Transcarotid TAVR Registry, our results show comparable outcomes regarding in-hospital and 30-day mortality, stroke, and TIA rates [9]. LOS in our study was shorter than what has been previously reported for TC-TAVR or TF-TAVR [2, 9]. We report data including procedure time, ventilator use, ICU hours, LOS, and in-hospital rates of stroke and mortality that demonstrate comparably less favorable outcomes for patients undergoing TA-TAVR. Postoperative hemodynamic data showed mixed results for patients who underwent TA procedures, with greater improvements in aortic valve velocity and gradient but the smallest improvement in valve area. These data are particularly hard to interpret given the small sample size for this patient group. However, other groups have shown that patients undergoing TA-TAVR have less favorable outcomes compared with those undergoing TF-TAVR, even when accounting for clinical differences between patients [14].

Our clinical experience has evolved to favor TC procedures over other alternative access routes for the following reasons: (1) TC-TAVR does not transgress the thoracic wall and does not require division of any major muscle groups and (2) compared with subclavian access, entry through the carotid artery gives operators a straighter pathway to the aortic valve with less vessel tortuosity, which is of particular importance in patients with horizontal hearts. Regarding right or left carotid access for TAVR, we prefer access through the right carotid artery because the room is set up similarly to that for transaortic TAVR.

The limitations of this study include the retrospective observational design and the small sample size of TA-TAVR and TC-TAVR groups. Furthermore, all patients were inherently high risk, with preexisting conditions that could contribute to outcomes. Sample sizes were not large enough to test the effect of preexisting clinical differences between patient groups. Our results reflect the expertise of our specialized heart surgery team—a vascular surgeon who is proficient with TAVR procedures is essential for safe, effective carotid operations and good outcomes for TC-TAVR. These promising results in support of TC-TAVR call for a larger multicenter study.

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References

1. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. The N Engl J Med 2010;363:1597–607.
2. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364:2187–98.
3. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 2016;374:1609–20.
4. Chandrasekhar J, Hibbert B, Ruel M, Lam BK, Labinaz M, Glover C. Transfemoral vs non-transfemoral access for transcatheter aortic valve implantation: a systematic review and meta-analysis. Can J Cardiol 2015;31:1427–38.
5. Thourani VH, Gunter RL, Neravetla S, et al. Use of transaortic, transapical, and transcarotid transcatheter aortic valve replacement in inoperable patients. Ann Thorac Surg 2013;96:1349–57.
6. Thourani VH, Li C, Devireddy C, et al. High-risk patients with inoperative aortic stenosis: use of transapical, transaortic, and transcarotid techniques. Ann Thorac Surg 2015;99:817–25.

7. Azmoun A, Amabile N, Ramadan R, et al. Transcatheter aortic valve implantation through carotid artery access under local anaesthesia. Eur J Cardiothorac Surg 2014;46:693–8; discussion 698.
8. Guyton RA, Block PC, Thourani VH, Lerakis S, Babaliaros V. Carotid artery access for transcatheter aortic valve replacement. Catheter Cardiovasc Interv 2013;82: E583–6.
9. Mylotte D, Sudre A, Teiger E, et al. Transcarotid transcatheter aortic valve replacement: Feasibility and safety. JACC Cardiovasc Interv 2016;9:472–80.
10. Campelo-Parada F, Rodes-Cabau J, Dumont E, et al. A novel transcarotid approach for implantation of balloon-expandable or self-expandable transcatheter aortic valves. Can J Cardiol 2016;32:1575.e12.
11. Van Mieghem NM, El Faquir N, Rahhab Z, et al. Incidence and predictors of debris embolizing to the brain during transcatheter aortic valve implantation. JACC Cardiovasc Interv 2015;8:718–24.
12. Holmes DR Jr, Brennan JM, Rumsfeld JS, et al. Clinical outcomes at 1 year following transcatheter aortic valve replacement. JAMA 2015;313:1019–28.
13. University of Leipzig. CLaret embolic protection and TAVI - trial (CLEAN-TAVI). Available at: https://clinicaltrials.gov/ct2/show/NCT01833052. Accessed June 1, 2016.
14. Blackstone EH, Suri RM, Rajeswaran J, et al. Propensity-matched comparisons of clinical outcomes after transapical or TF transcatheter aortic valve replacement: a placement of aortic transcatheter valves (PARTNER)-I trial substudy. Circulation 2015;131:1989–2000.

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