Transcarotid versus transaxillary access for transcatheter aortic valve replacement with a self-expanding valve: A propensity-matched analysis

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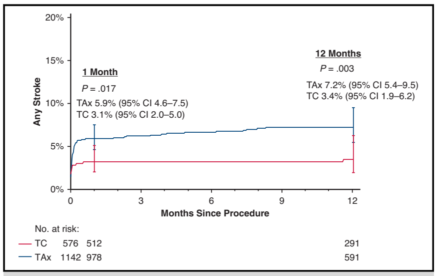
ABSTRACT

Transaxillary access has been the most frequently used nonfemoral access route for transcatheter aortic valve replacement (TAVR) with a self-expanding valve. Use of transcarotid TAVR is increasing; however, comparative data on these methods are limited. We compared outcomes following transcarotid or transaxillary TAVR with a self-expanding, supra-annular valve.

Methods: The Transcatheter Valve Therapy Registry was queried for TAVR procedures using transaxillary and transcarotid access between July 2015 and June 2021. Patients received a self-expanding Evolut R, PRO, or PRO + valve (Medtronic) and had 1-year follow-up. Thirty-day and 1-year outcomes were compared in transcarotid and transaxillary groups after 1:2 propensity score-matching. Multivariable regression models were fitted to identify predictors of key end points.

Results: The propensity score–matched cohort included 576 patients receiving transcarotid and 1142 receiving transaxillary access. Median procedure time (99 vs 118 minutes; $P < .001$) and hospital stay (2 vs 3 days; $P < .001$) were shorter with transcarotid versus transaxillary access. At 30 days, patients with transcarotid access had similar mortality (Kaplan–Meier estimates 3.7% vs 4.3%, $P = .57$) but significantly lower stroke (3.1% vs 5.9%; $P = .017$) and mortality or stroke (6.0% vs 8.9%; $P = .033$) compared with patients receiving transaxillary access. Similar differences were observed at 1 year. Transaxillary access was associated with increased risk of 30-day stroke (hazard ratio, 2.14; 95% confidence interval, 1.27-3.58) by multivariable regression analysis.

Conclusions: Transcarotid versus transaxillary access for TAVR using a self-expanding valve is associated with procedural benefits and significantly lower stroke and mortality or stroke at 30 days. In patients with unsuitable femoral anatomy, transcarotid access may be the preferred delivery route for self-expanding valves. (JTCVS Techniques 2023;21:45-55)



Significantly lower stroke in TAVR patients with transcarotid versus transaxillary access.

CENTRAL MESSAGE

Clinical and procedural advantages were observed with transcarotid compared with transaxillary access in TAVR patients with a self-expanding supra-annular valve.

PERSPECTIVE

In patients undergoing transcatheter aortic valve replacement (TAVR) with a self-expanding, supra-annular bioprosthesis, valve delivery by transcarotid access was associated with a significantly lower stroke rate and more favorable procedural outcomes compared with transaxillary access, suggesting that transcarotid access may be the preferred delivery route for patients with unsuitable femoral anatomy.

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Abbreviations and Acronyms

ACC	= American College of Cardiology
CI	= confidence interval
HR	= hazard ratio
KCCQ-OS	= Kansas City Cardiomyopathy Questionnaire Overall Summary
STS	= Society of Thoracic Surgeons
TAVR	= transcatheter aortic valve replacement
TAx	= transaxillary/subclavian
TC	= transcarotid
THV	= transcatheter heart valve
TVT	= transcatheter valve therapy

▶ Video clip is available online.

Transcatheter aortic valve replacement (TAVR) is currently the dominant technique for treating severe aortic stenosis and is approved for a broad range of patients regardless of surgical risk.[1-6] Although the vast majority of patients have suitable iliofemoral anatomy for transfemoral delivery of the transcatheter heart valve (THV),[7] the ability for the heart team to perform TAVR using alternate nonfemoral access remains relevant.[8] In the early TAVR experience, alternate nonfemoral access was confined to transthoracic routes, first using transapical and then direct aortic access.[7,9] The invasiveness of transapical/direct aortic and the evolution of TAVR away from large-bore sheaths to lower-profile delivery systems encouraged the consideration of nonfemoral options that did not violate the thoracic cavity, such as transaxillary/subclavian (TAx),[10-12] transcarotid (TC),[13-17] and transcaval access.[18,19]

Based on extensive study in the CoreValve (Medtronic) self-expanding THV pivotal trials,[11,20] TAx access emerged early as the most frequently used nonfemoral access site; however, the recent positive outcomes using TC access have elevated it to the preferred nonfemoral access site of choice at many centers. Although multiple reports have demonstrated TC or TAx access to be superior to transthoracic access,[15,17,21,22] randomized comparisons between TC and TAx are lacking. In a propensity score–matched analysis using the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry, TC appeared to be superior to TAx access when using a balloon-expandable THV[16]; however, no such comparison has been performed with a self-expanding THV. The aim of our study was to evaluate contemporary outcomes collected from the TVT Registry comparing TAVR using TC or TAx access in patients treated with a supra-annular, self-expanding THV.

METHODS

The STS/ACC TVT Registry is a national registry of safety, efficacy, and procedural outcomes with mandated participation from all US TAVR centers. The STS/ACC TVT Registry uses standardized definitions and collects participant-reported data, which includes demographics, comorbidities, procedural details, and outcomes from consecutive patients undergoing TAVR using commercially approved devices. The STS/ACC TVT Registry was granted a waiver of written informed consent, and authorization of this study was granted by Advarra (institutional review board #Pro00007280; approved August 25, 2022). The authors requested data analyses from Medtronic, who has obtained Medtronic TAVR product-specific data from the TVT Registry. The authors had control of the analyses proposed, full access to the analysis results, and authority to decide whether and where to submit the manuscript for publication.

The TVT Registry was queried for patients undergoing TAVR with a self-expanding Evolut R, PRO, or PRO + transcatheter valve (Medtronic) using TC or TAx access from July 2015 to June 2021. The analysis included procedures eligible for 1-year follow-up. Patients had tricuspid aortic valve morphology and primary aortic stenosis or mixed stenosis/insufficiency; bicuspid aortic valve morphology, valve-in-valve procedures, and those with an indication of a failed bioprosthesis were excluded.

The primary end points of this retrospective analysis included 30-day rates of all-cause mortality, any stroke, and the composite end point of all-cause mortality or any stroke. Secondary end points included procedural outcomes, safety events at 30 days and 1 year, and quality of life as measured by the Kansas City Cardiomyopathy Questionnaire Overall Summary (KCCQ-OS) score at 30 days and 1 year. All primary and secondary outcomes were site-reported using standard definitions from the TVT Registry.

Statistical Analyses

Categorical variables were reported as counts and percentages, and continuous variables were summarized as mean ± standard deviation or median (first quartile, third quartile). Between-group differences for TAx versus TC access were compared using the independent samples *t*-test or Wilcoxon rank-sum test for continuous variables, and the χ^2 or Fisher exact test for categorical variables, as appropriate. Clinical outcomes were reported using the Kaplan–Meier estimator and compared between groups using the log-rank test. Within each access group, change in KCCQ-OS score from baseline to 30 days or 1 year was evaluated by paired *t*-test.

Propensity score matching was performed in the TAx and TC groups to address confounding due to differences in baseline characteristics. Propensity scores were estimated using a multivariable logistic regression model based on baseline patient characteristics that included age, male, body mass index (kg/m^2), STS-Predicted Risk of Mortality, New York Heart Association class III/IV (vs I/II), history of previous percutaneous coronary intervention, previous coronary artery bypass surgery, previous stroke, carotid stenosis, peripheral vascular disease, hypertension, diabetes mellitus, moderate/severe chronic lung disease, porcelain aorta, atrial fibrillation/atrial flutter, glomerular filtration rate, left ventricular ejection fraction, and KCCQ-OS score. Access site (TC vs TAx) was the dependent variable. Propensity scores were used to match (without replacement) patients with TC to patients with TAx 1:2 using a greedy nearest neighbor matching algorithm with a caliper of 0.2 times the common standard deviation of the logit-transformed propensity scores. Groups were considered well balanced if the absolute standardized difference for each covariate was <0.1. A single imputation method using fully conditional specification was applied to assign values for missing covariate data, and the imputed data set was used to generate propensity scores and perform the matching. Postmatching analyses were carried out on the observed (nonimputed) data.

Predictors of stroke, all-cause mortality, and the composite of all-cause mortality or stroke at 30 days were examined in the unmatched cohort using multivariable Cox proportional hazards regression models and the same baseline covariates used in the propensity score model. Univariable prescreening was first applied, selecting covariates with a P value $< .15$ and $\leq 15\%$ missing data. Stepwise selection was then employed with thresholds for entry and exit of $P = .10$. Access site was forced into each multivariable model. The proportional hazards assumption was evaluated using the Grambsch–Therneau test, with no gross deviations from the assumption detected.[23] All P values reported were 2-sided. No adjustment for multiple testing was undertaken. All statistical analyses were performed using SAS, version 9.4 (SAS Institute).

RESULTS

Of the 65,510 native tricuspid patients who underwent TAVR with the Evolut R, PRO, or PRO + transcatheter valve between July 2015 and June 2021, TF access was used in 94.1% (61,671/65,510), TAx in 4.0% (2602/65,510), and TC in 0.9% (576/65,510) of cases. The overall percentage of TC procedures (Figure 1, *A*) and the percentage of sites performing ≥1 TC case (Figure 1, *B*) increased each year over the course of the analysis, whereas the percentage of TAx procedures and sites performing TAx procedures declined over the same period.

Baseline characteristics used for propensity score matching in the TC and TAx groups are represented in Table 1. Before matching, patients who received TC were less often male (46.0% vs 53.7%, $P < .001$) with greater rates of peripheral vascular disease (66.3% vs 60.7%, $P = .013$), previous coronary artery bypass (33.2% vs 23.4%, $P < .001$), and carotid stenosis (49.0% vs 41.5%, $P = .003$) compared with patients who received TAx. After 1:2 propensity-score matching, baseline characteristics in the TC (n = 576) and TAx (n = 1142) groups were well balanced (absolute standardized difference < 0.1 for all variables; Table 1 and Figure E1).

Propensity score–adjusted procedural and clinical outcomes overall favored TC over TAx access and are summarized in Table 2. Median total procedure time (99.0 vs 118.0 minutes; $P < .001$), fluoroscopy time (18.0 vs 18.8 minutes; $P = .021$), and hospital length of stay (2 vs 3 days; $P < .001$) were shorter with TC versus TAx access, and a significantly greater percentage of patients who received TC were discharged to home (88.4% vs 80.7%, $P < .001$). The percentage of devices successfully implanted was similar (TC 94.9%; TAx 96.4%; $P = .17$). TAx access was performed using a percutaneous method in 14.7% (167/1139) and by cutdown in 83.6% (952/1139) of patients in the TAx group.

The proportion of patients with in-hospital stroke was 3.0% (17/576) for the TC group and 5.2% (59/1142) for the TAx group ($P = .035$). At 30 days, patients with TC and TAx access had similar mortality (3.7% vs 4.3%, $P = .57$; Table 2), but patients with TC had statistically significantly lower rates of any stroke (3.1% vs 5.9%, $P = .017$) and the composite of mortality or any stroke (6.0% vs 8.9%, $P = .033$). Similar findings were observed at 1 year (Figure 2, *A-C*). Rates of life-threatening/major bleeding, major vascular complications, new pacemaker implantation, or any hospital readmission at 30 days or 1 year were not significantly different. Quality of life as measured by KCCQ-OS scores was similar across groups at 30 days (TC 71.4; TAx 71.7, $P = .86$) and 1 year (TC 76.2; TAx 76.1, $P = .95$; Table 2). The 30-day echocardiography data for the propensity score-matched cohort are provided in Table E1. There was no significant difference between groups for aortic valve mean gradient or paravalvular regurgitation moderate or greater at 30 days. A greater proportion of patients in the TC group had none or mild paravalvular regurgitation at 30 days compared with the TAx group.

In the multivariable regression model summarized in Table 3, TAx (vs TC) access was associated with increased

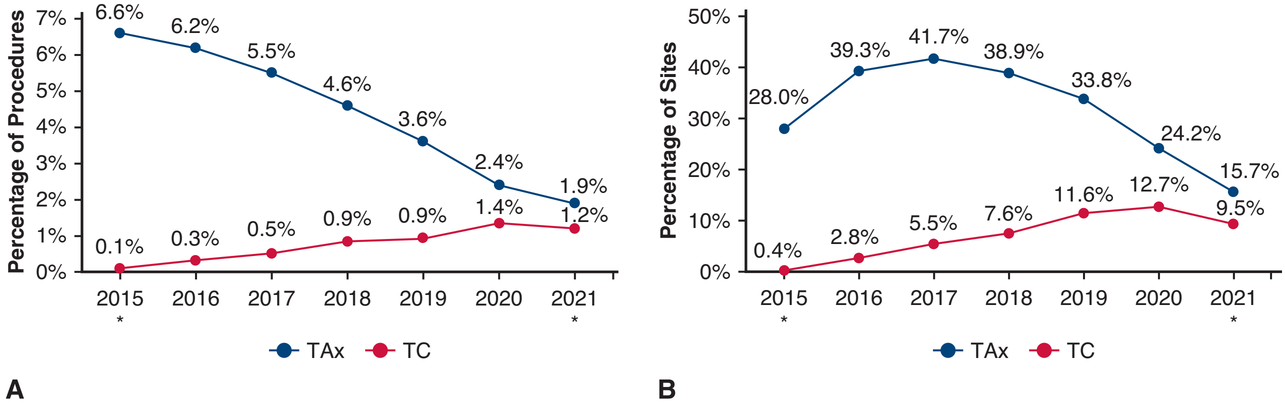

FIGURE 1. Percentage of TAx and TC procedures and procedure sites in the United States. The percentage of TAx and TC access procedures (A) and percentage of clinical sites performing at least 1 TAx or TC case (B) are reported in yearly intervals. The number TC procedures and clinical sites performing TC procedures increased over the study period, whereas the corresponding percentages for TAx procedures decreased over the same period. Percentages were calculated from among all TVT Registry patients who received a self-expanding Evolut R, PRO, or PRO + valve from July 2015 through June 2021. *Incomplete yearly data. *TAx*, Transaxillary; *TC*, transcarotid; *CI*, confidence interval; *TVT*, transcatheter valve therapy.

TABLE 1. Baseline characteristics in the TAx and TC groups before and after propensity score matching

	Before propensity score matching				After propensity score matching		
Demographics	TC (n = 576)	TAx (n = 2602)	*P* value	ASD	TC (n = 576)	TAx (n = 1142)	ASD
Age,* y	78.4 ± 7.7 (576)	79.6 ± 8.0 (2602)	.001	0.153	78.4 ± 7.7 (576)	78.4 ± 8.1 (1142)	0.006
Male	265 (46.0%)	1396 (53.7%)	<.001	0.153	265 (46.0%)	529 (46.3%)	0.006
BMI, kg/m^2	28.4 ± 11.7 (575)	28.9 ± 16.1 (2600)	.39	0.036	28.4 ± 11.7 (575)	28.4 ± 8.0 (1140)	0.001
STS PROM score, %	7.1 ± 5.2 (548)	7.1 ± 5.1 (2545)	.88	0.007	7.1 ± 5.2 (548)	7.0 ± 4.9 (1119)	0.005
NYHA class III/IV	427/567 (75.3%)	1950/2578 (75.6%)	.87	0.008	427/567 (75.3%)	851/1129 (75.4%)	0.002
PCI	243 (42.2%)	1076/2597 (41.4%)	.74	0.015	243 (42.2%)	485/1139 (42.6%)	0.008
CABG	191 (33.2%)	609/2600 (23.4%)	<.001	0.217	191 (33.2%)	378/1140 (33.2%)	0.000
Previous stroke	80/574 (13.9%)	358/2599 (13.8%)	.92	0.005	80/574 (13.9%)	151/1139 (13.3%)	0.020
Carotid stenosis	234/478 (49.0%)	898/2163 (41.5%)	.003	0.150	234/478 (49.0%)	451/944 (47.8%)	0.024
Peripheral vascular disease	382 (66.3%)	1578/2598 (60.7%)	.013	0.116	382 (66.3%)	749/1139 (65.8%)	0.012
Hypertension	546 (94.8%)	2420 (93.0%)	.12	0.075	546 (94.8%)	1080/1142 (94.6%)	0.010
Diabetes mellitus	241 (41.8%)	1077/2600 (41.4%)	.85	0.009	241 (41.8%)	484/1140 (42.5%)	0.013
Chronic lung disease moderate/severe	189/560 (33.8%)	911/2574 (35.4%)	.46	0.035	189/560 (33.8%)	386/1132 (34.1%)	0.007
Porcelain aorta	30 (5.2%)	121/2596 (4.7%)	.58	0.025	30 (5.2%)	63/1139 (5.5%)	0.014
Atrial fibrillation/atrial flutter	209/575 (36.3%)	957/2599 (36.8%)	.83	0.010	209/575 (36.3%)	419/1141 (36.7%)	0.008
GFR, mL/min/1.73 m^2	58.4 ± 25.1 (571)	58.8 ± 25.7 (2520)	.71	0.017	58.4 ± 25.1 (571)	58.7 ± 26.4 (1115)	0.012
Baseline LVEF, %	54.5 ± 13.2 (575)	55.2 ± 13.2 (2592)	.23	0.055	54.5 ± 13.2 (575)	54.6 ± 13.4 (1137)	0.006
Baseline KCCQ overall score	42.0 ± 25.4 (541)	44.2 ± 24.3 (2434)	.059	0.089	42.0 ± 25.4 (541)	42.4 ± 24.2 (1068)	0.019

Values are reported as n (%) or mean ± standard deviation (n). *TC*, Transcarotid; *TAx*, transaxillary/subclavian; *ASD*, absolute standardized difference; *BMI*, body mass index; *STS-PROM*, Society of Thoracic Surgeons Predicted Risk of Mortality; *NYHA*, New York Heart Association; *PCI*, percutaneous coronary intervention; *CABG*, coronary artery bypass surgery; *GFR*, glomerular filtration rate; *LVEF*, left ventricular ejection fraction; *KCCQ*, Kansas City Cardiomyopathy Questionnaire. *Patients age >90 y are reported as "90 plus" in the database and for calculation are set to 90.

risk of stroke at 30 days (hazard ratio [HR], 2.14; 95% confidence interval [CI], 1.27-3.58; *P* = .004). Additional risk factors for 30-day stroke included previous stroke (HR, 2.14; 95% CI, 1.50-3.05; *P* < .001) and age (HR, 1.02 per patient year; 95% CI, 1.00-1.04; *P* = .033), whereas male sex (HR, 0.56; 95% CI, 0.41-0.77; *P* < .001) and body mass index (HR, 0.97; 95% CI, 0.94-0.99; *P* = .004) were protective. TAx access (vs TC) was also associated with mortality or any stroke at 30 days (HR, 1.63; 95% CI, 1.11-2.42; *P* = .014) but not mortality alone (HR, 1.07; 95% CI, 0.64-1.77; *P* = .81).

DISCUSSION

Although both TC and TAx TAVR can be performed efficiently and with a high degree of procedural success using a self-expanding Evolut valve, this propensity score–matched comparison using TVT Registry data demonstrates some distinct clinical and procedural advantages of TC compared with TAx access. At 30 days, TC access was associated with a significantly lower rate of stroke (Kaplan-Meier rates 3.1% vs 5.9%; *P* = .017), with this observed difference persisting through 1 year (3.4% vs 7.2%; *P* = .003). In addition, in a multivariable regression model, TAx access remained significantly associated with greater risk of stroke at 30 days. Although 30-day mortality was similar (TC 3.7% vs TAx 4.3%; *P* = .57), the composite end point of mortality or stroke at 30 days favored TC access (TC 6.0% vs TAx 8.9%; *P* = .033). TC access was also associated with a significantly shorter total procedure time, less fluoroscopy time, shorter hospital length of stay (median 2 vs 3 days; *P* < .001), and a greater likelihood of being discharged directly to home (88.4% vs 80.7%; *P* < .001; Figure 3), which may have positive financial benefits for hospitals performing alternate access TAVR in light of Medicare transfer rules and their negative impact on hospital reimbursement.[24]

The 30-day stroke rate of 5.9% with TAx access using a self-expanding THV observed in the current study is similar to that observed with TAx access in the CoreValve Extreme Risk U.S. Pivotal Trial[20] and in an analysis of patients from the CoreValve Extreme Risk and High Risk Pivotal Trials and Continued Access Study,[11] with 30-day stroke rates of 7.5% and 6.5%, respectively. In addition, the increased stroke signal with TAx compared with TC access appears with both self-expanding and balloon-expandable TAVR. In a previous TVT Registry analysis, among 1249 patients who underwent TAx TAVR using the SAPIEN 3 THV, the 30-day stroke rate was 6.1%.[12] Furthermore, in a previous

TABLE 2. Procedural and clinical outcomes in the TAx and TC groups after propensity score matching

Demographics	TC (n = 576)	TAx (n = 1142)	*P* value
Procedural outcomes			
Total procedure time, min	99.0 (80.0, 126.0)	118.0 (88.0, 156.0)	<.001
Fluoroscopy time, min	18.0 (14.0, 23.0)	18.8 (14.0, 26.0)	.021
Hospital length of stay, d	2.0 (2.0, 4.0)	3.0 (2.0, 4.0)	<.001
ICU length of stay, h	24.0 (6.7, 39.1)	24.0 (8.0, 45.0)	.20
Contrast volume, mL	85.5 (60.0, 120.0)	95.0 (60.0, 140.0)	<.001
Device implanted successfully	443/467 (94.9%)	1031/1070 (96.4%)	.17
Conversion to open heart surgery	4/576 (0.7%)	7/1140 (0.6%)	>.99
Discharged to home	497/562 (88.4%)	893/1106 (80.7%)	<.001
30-d outcomes			
Any stroke	18 (3.1%)	66 (5.9%)	.017
Ischemic	17 (3.0%)	58 (5.1%)	.044
Hemorrhagic	1 (0.2%)	7 (0.6%)	.20
Undetermined	0 (0.0%)	2 (0.2%)	.31
All-cause mortality or any stroke	34 (6.0%)	101 (8.9%)	.033
All-cause mortality	21 (3.7%)	48 (4.3%)	.57
Life-threatening/major bleed	47 (8.3%)	120 (10.6%)	.12
Major vascular complication	12 (2.1%)	28 (2.5%)	.63
Myocardial infarction	2 (0.4%)	4 (0.4%)	.99
New pacemaker implantation*	60 (12.4%)	128 (13.1%)	.66
Any readmission	51 (9.3%)	103 (9.6%)	.93
KCCQ-OS score	71.4 ± 23.1 (427)	71.7 ± 23.7 (836)	.86
Change from baseline	28.7 ± 27.5	29.1 ± 27.9	.80
P value change from baseline, paired t-test	<.001	<.001	
1-y outcomes			
Any stroke	19 (3.4%)	78 (7.2%)	.003
Ischemic	18 (3.3%)	67 (6.1%)	.015
Hemorrhagic	1 (0.2%)	10 (1.0%)	.088
Undetermined	0 (0.0%)	3 (0.3%)	.22
All-cause mortality or any stroke	88 (17.2%)	223 (21.4%)	.048
All-cause mortality	77 (15.4%)	174 (17.1%)	.45
Myocardial infarction	10 (2.2%)	15 (1.7%)	.44
New pacemaker implantation*	66 (14.0%)	143 (15.1%)	.59
Any readmission	183 (38.8%)	341 (35.7%)	.32
KCCQ-OS score	76.2 ± 22.3 (269)	76.1 ± 22.2 (560)	.95
Change from baseline	32.0 ± 27.6	31.5 ± 27.2	.81
P value change from baseline, paired t-test	<.001	<.001	

Values are reported as n (%), median (first-third quartile), or mean ± standard deviation (n). For clinical outcomes, % is the Kaplan–Meier event rate. *TC*, Transcarotid; *TAx*, transaxillary/subclavian; *ICU*, intensive care unit; *KCCQ-OS*, Kansas City Cardiomyopathy Questionnaire Overall Summary; *ICD*, implantable cardioverter defibrillator. *Patients with pacemaker or ICD at baseline are not included.

TVT Registry analysis comparing TC with TAx access with the SAPIEN 3 THV using similar methodology as the current study, Kirker and colleagues[16] demonstrated that TC TAVR with a balloon-expandable THV was associated with similar 30-day mortality (4.3% vs 5.2%, $P = .34$) but significantly lower risk of stroke (4.2% vs 7.4%, HR, 0.56; 95% CI, 0.38-0.83; $P = .003$) compared with TAx access. As in the present study, TC access was also associated with a shorter procedure time (117.0 vs 132.4 minutes; $P < .001$), reduced fluoroscopy time (16.6 vs 21.6 minutes; $P < .001$), lower contrast volume (78.5 vs 96.7 mL; $P < .001$), shorter hospital stay (2.0 vs 3.0 days; $P = .002$), and increased likelihood of discharge to home (82.9% vs 74.6%; $P < .001$). Taken in total, improved outcomes associated with TC compared with TAx access appear agnostic of THV type and suggest that TC access should be the alternate nonfemoral access site of choice when iliofemoral anatomy is prohibitive.

Although the reduced stroke rate observed with TC compared with TAx access may seem counterintuitive, there are a number of potential explanations for this observation. TC access is inexpensive embolic protection to the ipsilateral cerebral hemisphere, since the distal common carotid artery is typically clamped during the procedure and potential embolic material can be flushed before re-establishing blood flow in the carotid artery; in addition,

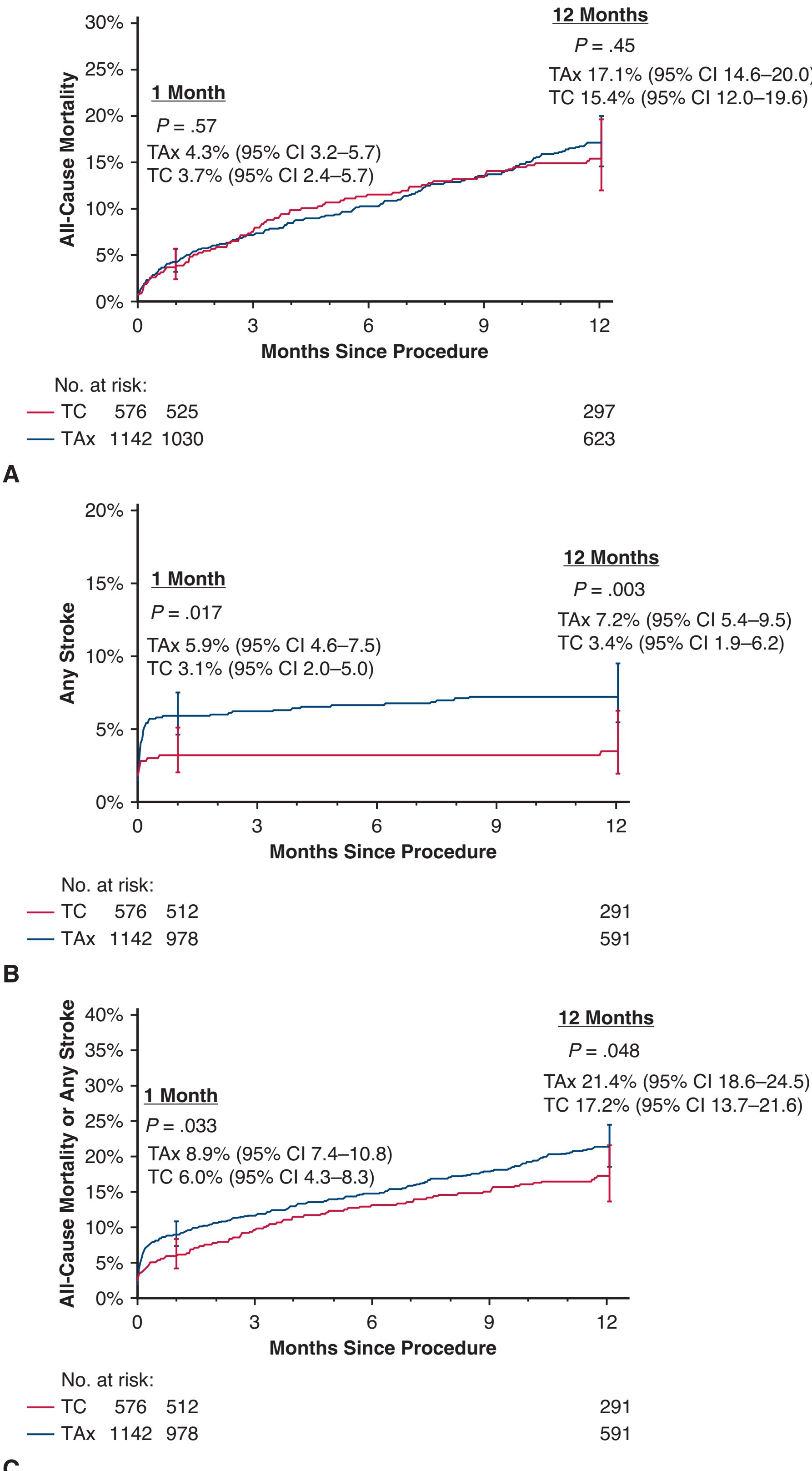

FIGURE 2. Time-to-event curves. Kaplan–Meier estimates with 95% CIs and log-rank *P* values for all-cause mortality (A), any stroke (B), and the composite of all-cause mortality or any stroke (C) through 1 year in the propensity score–matched patients. Rates of mortality were similar between groups, but patients with TC access had significantly lower rates of stroke and mortality or stroke at 1 year compared with TAx access. *TAx*, Transaxillary; *CI*, confidence interval; *TC*, transcarotid.

TABLE 3. Multivariable predictors of 30-d outcomes in TAx and TC patients

Unadjusted cohort, N = 3178	HR (95% CI)	*P* value
Any stroke at 30 d		
TAx (vs TC)	2.14 (1.27-3.58)	.004
Age, y	1.02 (1.00-1.04)	.033
Male	0.56 (0.41-0.77)	<.001
BMI, kg/m^2	0.97 (0.94-0.99)	.004
Previous stroke	2.14 (1.50-3.05)	<.001
All-cause mortality at 30 d		
TAx (vs TC)	1.07 (0.64-1.77)	.81
Age, y	1.04 (1.01-1.07)	.003
STS PROM score, %	1.04 (1.01-1.06)	.009
Peripheral vascular disease	1.58 (1.03-2.41)	.035
GFR	0.99 (0.98-0.99)	.001
Baseline KCCQ score	0.99 (0.98-0.99)	.001
All-cause mortality or any stroke at 30 d		
TAx (vs TC)	1.63 (1.11-2.42)	.014
Age, y	1.02 (1.01-1.04)	.009
Male	0.68 (0.52-0.89)	.004
BMI, kg/m^2	0.97 (0.95-0.99)	.004
STS PROM score, %	1.02 (1.00-1.05)	.050
Peripheral vascular disease	1.35 (1.02-1.79)	.038
Previous stroke	1.54 (1.11-2.12)	.009
GFR	0.99 (0.99-1.00)	.005
Baseline KCCQ score	0.99 (0.99-1.00)	.043

Multivariable Cox models were conducted in the unadjusted cohort of TAx and TC patients (n = 3178). Variables were selected from univariable predictors with a *P* value ≤ .15 and with ≤15% missing values. The stepwise selection method was used with thresholds for entry and exit of *P* = .10. Access site (TAx vs TC) was forced into the model. *HR*, Hazard ratio; *CI*, confidence interval; *TAx*, transaxillary/subclavian; *TC*, transcarotid; *BMI*, body mass index; *STS PROM*, Society of Thoracic Surgeons Predicted Risk of Mortality; *GFR*, glomerular filtration rate; *KCCQ*, Kansas City Cardiomyopathy Questionnaire.

the origin of the vertebral arteries is not traversed as in TAx access. Finally, unlike TAx access, during which wire interaction with the aorta can be more extreme, TC access often provides a direct path into the ascending aorta, thus reducing wire and device interaction with the aortic arch. The evolution of the TC TAVR technique has also likely played an important role in mitigating the risk of stroke. The initial stroke rate using TC access in the first 96 patients in the French Transcarotid TAVR Registry was 6.3%, similar to the rate of stroke with TAx access in the present study.[25] The French technique described by Mylotte and colleagues[25] in this early experience was to access the carotid artery using a modified Seldinger technique after surgically exposing the carotid artery, sequentially dilating the artery before introducing the delivery sheath and not clamping the distal common carotid artery during the procedure. In contrast to the early French technique, a more contemporary TC access technique has evolved (Video 1), which includes clamping the distal common carotid artery and using a transverse arteriotomy rather than purse string sutures without serial dilation. After valve delivery, the carotid artery is flushed of potential embolic material and the arteriotomy is repaired primarily before removing the carotid clamp. This technique has been associated with stroke rates as low as 0% to 2.4% in single-center series.[15,26] In an updated report involving TC access in 314 patients, the French Transcarotid Registry reported an evolution in their technique to using a transverse carotid arteriotomy with carotid clamping and showed a significantly lower 30-day neurologic event rate of 1.6%, significantly lower than that reported in the first 96 patients.[13] The TVT Registry, unfortunately, does not track procedural details that could drive best surgical practice; thus, single-center experiences that report low stroke rates using this technique are valuable.[15,26]

Streamlining the preoperative evaluation of patients being screened for TAVR requires efficient imaging without the need for additional testing. Routine computed tomographic angiography (which includes the lower cervical common carotid artery) used for TAVR and carotid duplex ultrasonography are the only imaging needed to evaluate a patient for TC access.[15,17,26] The right or left carotid artery can be used with choice based on TF sizing criteria, tortuosity, and angle into the ascending aorta. Preference should be given to the carotid artery with *worse* internal carotid artery stenosis on duplex, since this carotid will be occluded during the procedure, thus allowing the contralateral, less-diseased carotid to provide cerebral perfusion. It is

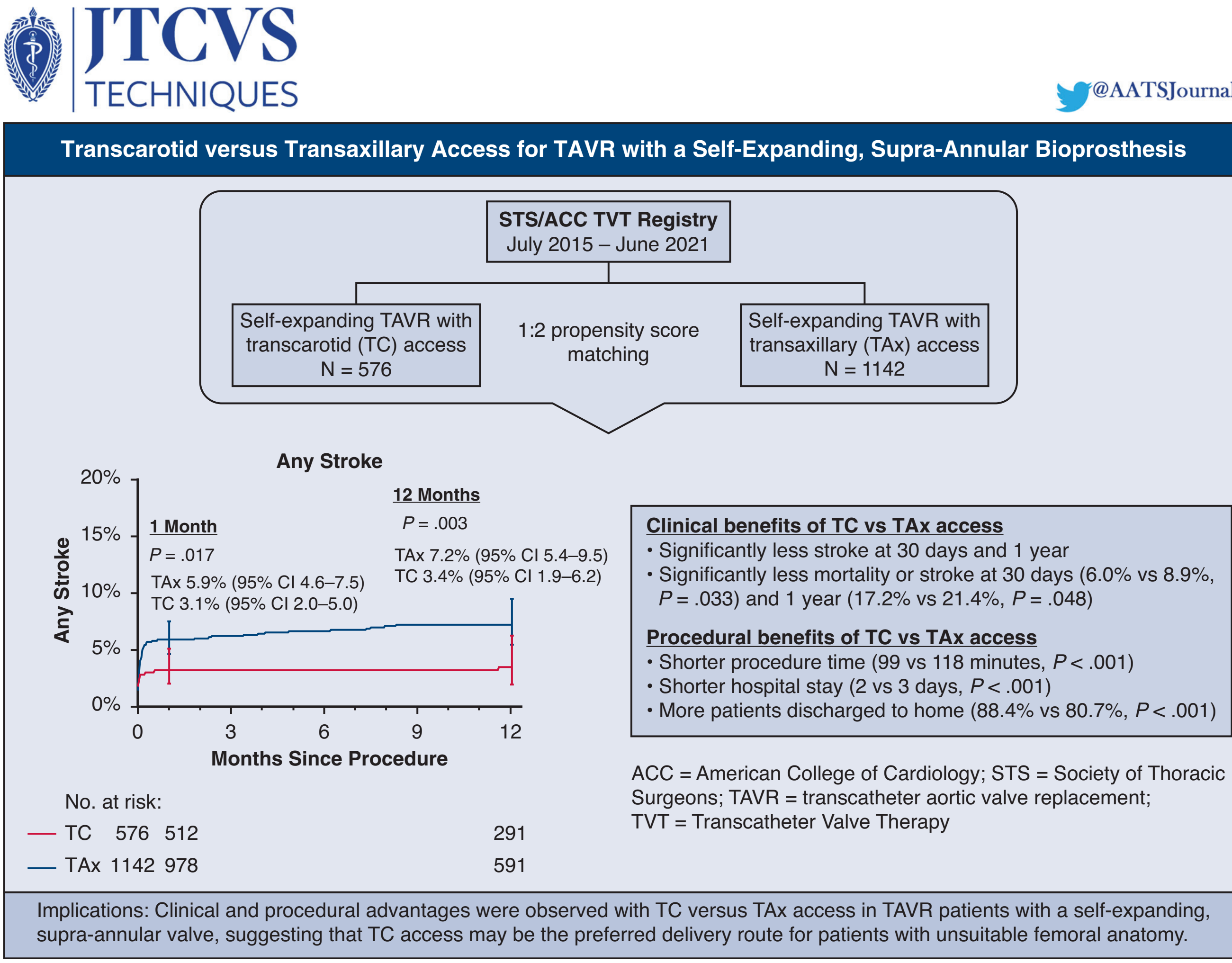

FIGURE 3. Procedural and clinical outcomes following TAVR with a self-expanding valve using transcarotid versus transaxillary access. *TAVR*, Transcatheter aortic valve replacement; *STS/ACC*, Society of Thoracic Surgeons/American College of Cardiology; *TVT*, transcatheter valve therapy; *CI*, confidence interval.

recommended that systolic blood pressures be maintained >150 mm Hg during carotid clamping to optimize cerebral perfusion.

Although the use of nonfemoral alternative access will undoubtably continue to decline, the heart team should be familiar with at least one nonintrathoracic option. The lower stroke signal and more favorable procedural and clinical outcomes with TC compared with TAx TAVR suggest that TC access should be the first consideration when iliofemoral access is inadequate for TAVR.

Limitations

This is a nonrandomized, retrospective, observational study using registry procedural and outcome data that have not been independently adjudicated. Although propensity score–matched variables such as selection criteria and institutional or heart team bias toward TC or TAx access cannot be accounted for, this analysis also cannot account for improvements in valve technology and implanter expertise over the 6-year analysis period, which may result in temporal bias. Furthermore, the TVT Registry lacks procedural granularity that prevents leveraging these results to establish best practice that might include recommending right versus left carotid access or a specific surgical technique. Finally, this analysis involves only Medtronic self-expanding THVs and cannot be extrapolated to other self-expanding prostheses.

CONCLUSIONS

In this propensity score–matched comparison of TC versus TAx access in patients who underwent TAVR from the TVT Registry who received a self-expanding Evolut transcatheter valve, mortality rates were similar between groups, but patients with TC access had a significantly

VIDEO 1. Technique for delivery of a self-expanding transcatheter heart valve using transcarotid access. Patient evaluation for transcarotid suitability, selection of the right versus left carotid artery, and method for artery exposure, sheath insertion, and device delivery using a self-expanding, supra-annular transcatheter aortic valve. Video available at: https://www.jtcvs.org/article/S2666-2507(23)00267-5/fulltext.

lower rate of stroke at 30 days and 1 year compared with those with TAx access. Multivariable regression analysis identified TAx (vs TC) access as a predictor of 30-day stroke. TC access was also associated with more favorable procedural outcomes compared with TAx access. Combined, these data suggest TC access may be the preferred delivery route for patients with unsuitable iliofemoral anatomy.

Conflict of Interest Statement

Dr Allen reports institutional research support, proctor fees, and consulting fees from Medtronic, Edwards, Abbott, with all payments to St Luke's Hospital. Dr Watson reports grant support/research contracts and consulting fees from Edwards Lifesciences and Medtronic. Dr Vora reports consulting fees for Medtronic. Dr Mahoney reports proctor and consultant fees from Boston Scientific, Edwards Lifesciences, and Medtronic. Dr Chhatriwalla reports speakers' bureau fees from Abbott Vascular, Edwards Lifesciences, and Medtronic Inc; proctor fees from Edwards Lifesciences, and Medtronic Inc; and research Support from Boston Scientific. Dr Schwartz reports proctor and consulting fees for Medtronic, Edwards Lifesciences, and Abbott, and consulting fees for Boston Scientific and Cordis. Dr Keller is a proctor for Medtronic and Edwards Lifesciences. Dr Sodhi reports consulting fees from Medtronic and Boston Scientific. Daniel Haugan is a full-time employee and shareholder in Medtronic. Dr Caskey reports proctor fees from Medtronic. The views or opinions presented in this document do not represent those of the American College of Cardiology (ACC) Foundation, The Society of Thoracic Surgeons (STS), or the STS/ACC Transcatheter Valve Therapy (TVT) Registry. The industry data file upon which the analysis was performed is a subset of the full STS/ACC TVT Registry data submissions.

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.

Susan Chow, PhD, CMPP, an employee of Medtronic, drafted the Methods, created figures and tables, and formatted the manuscript for journal style, all under the direction of the lead author.

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Key Words: transcarotid, transaxillary, TAVR, self-expanding, supra-annular, TVT registry

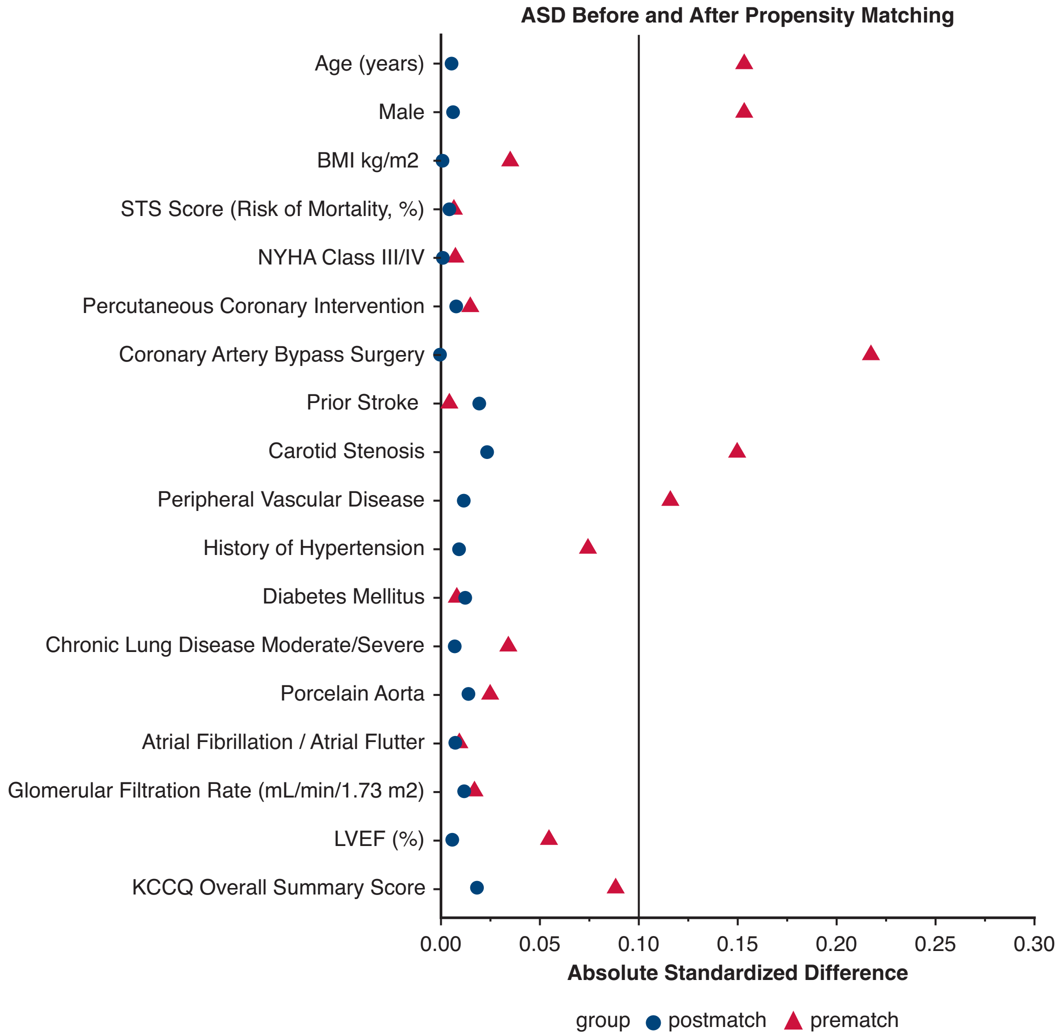

FIGURE E1. Love plot. Absolute standardized differences (*ASD*) before and after propensity score matching are shown for the TC and TAx groups. Groups were considered well balanced if the ASD for each covariate after matching was <0.1. *BMI*, Body mass index; *STS*, Society of Thoracic Surgeons; *NYHA*, New York Heart Association; *LVEF*, left ventricular ejection fraction; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *TC*, transcarotid; *TAx*, transaxillary.

TABLE E1. Echocardiographic data

Demographics	TAx (N = 1142)	TC (N = 576)	*P* value
Mean aortic valve gradient, mm Hg	7.2 ± 3.7 (792)	7.0 ± 3.7 (402)	.32
Paravalvular regurgitation grade			.002
None	69.2% (505/730)	78.1% (293/375)	
Mild	28.6% (209/730)	20.5% (77/375)	
Moderate	2.2% (16/730)	1.3% (5/375)	
Severe	0.0% (0/730)	0.0% (0/375)	
Moderate or greater	2.2% (16/730)	1.3% (5/375)	.32

Aortic valve mean gradient and paravalvular regurgitation at 30 days are shown in the propensity score–matched TC and TAx groups. There was no significant difference between groups for aortic valve mean gradient or paravalvular regurgitation moderate or greater at 30 days. A greater proportion of patients in the TC group had none or mild paravalvular regurgitation at 30 days compared with the TAx group. *TAx*, Transaxillary; *TC*, transcarotid.