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Comparing Outcomes of Transfemoral Versus Transbrachial or Transradial Approach in Carotid Artery Stenting (CAS)

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Background: While Transfemoral Carotid Artery Stenting (TFCAS) is a valid minimally invasive option for patients who also might be suitable for carotid endarterectomy (CEA) or transcarotid artery revascularization (TCAR), alternative access sites such as transbrachial (TB) or transradial (TR) are only utilized when anatomic factors preclude direct carotid or transfemoral access. In this study, we aimed to evaluate the outcomes of TR/TB access in comparison to TF for percutaneous carotid artery revascularization.

Methods: All patients undergoing non-TCAR carotid artery stenting (CAS) from January 2012 to June 2021 in the Vascular Quality Initiative (VQI) Database were included. Patients were divided into 2 groups based on the access site for CAS: TF or TR/TB. Primary outcomes included stroke/death, technical failure and access site complications (hematoma, stenosis, infection, pseudoaneurysm and AV fistula). Secondary outcomes included stroke, TIA, MI, death, non−home discharge, extended length of postoperative stay (LOS) (>1 day), and composite endpoints of stroke/MI and stroke/death/MI. Univariable and multivariable logistic regression models were used to assess postoperative outcomes, and results were adjusted for relevant potential confounders including age, gender, race, degree of stenosis, symptomatic status, anesthesia, comorbidities, and preoperative medications.

Results: Out of the 23,965 patients, TR/TB approach was employed in 819 (3.4%) while TF was used in 23,146 (96.6%). Baseline characteristics found men were more likely to undergo revascularization using TR/TB approach (69.4% vs. 64.9%, $P = 0.009$). Patients undergoing TR/TB approach were also more likely to be symptomatic (49.9% vs. 28.6%, $P < 0.001$). Guideline directed medications were more frequently used with TR/TB including P2Y12 inhibitor (80.3% vs. 74.7%, $P < 0.01$), statin (83.8% vs. 80.6%), and aspirin (88.3% vs. 84.5%, $P = 0.003$) preoperatively. On univariate analysis, patients with TB/TR approach experienced higher rates of adverse outcomes. After adjusting for potential confounders, TR/TB patients had no significant increase in the risk of stroke/death [aOR 1.10 (0.69−1.76), $P = 0.675$]; however, the use of TR/TB access was associated with a more than 2-fold increase in risk for in-hospital MI [aOR 2.39 (1.32−4.30), $P = 0.004$] and 2-fold increase in risk of technical failure [aOR 2.21 (1.31−3.73) $P = 0.003$]. The use of TR/TB access was also associated with a 50% reduction in the risk of access site complications [aOR 0.53 (0.32−0.85), $P = 0.009$].

Conclusions: This study confirms that although technically more challenging, TR or TB approach serves as a reasonable alternative with lower access site complications for CAS

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particularly in patients where anatomic factors preclude revascularization by TFCAS or TCAR. However, TR/TB is associated with an increased risk of technical failure and myocardial infarction, which requires further study.

INTRODUCTION

The approaches to carotid artery revascularization have significantly evolved over the past 3 decades. While carotid endarterectomy (CEA) remains the prevalent standard, the less invasive option of percutaneous carotid artery stenting (CAS) has become a viable option for patients who are unable to undergo surgery due to anatomical or medical contraindications.[1]

Traditionally, transfemoral (TF) arterial access is the preferred approach for CAS due to broad operator experience, ease of navigating the carotid vasculature from the aortic arch femorally and the larger vessel size allowing for a wide range of devices. However, aortic arch and supra-aortic vessel anatomic variations such as a bovine arch or type-III aortic arch, advanced atherosclerotic disease, severe iliac artery tortuosity or advanced peripheral arterial disease and morbid obesity can make selective catheterization of the carotid arteries via the femoral route challenging.[2] This can also lead to a higher risk of access site complications and prolonged multiple catheterization attempts of the carotid arteries, thereby potentially increasing the risk of cerebral embolization and stroke.[3]

In these situations, alternative carotid artery access sites such as transbrachial (TB) or transradial (TR) are important.[4,5] While these access sites are increasingly used for coronary interventions, carotid revascularization requires different technical systems which are associated with a steep learning curve.[6,7] Additionally, these access site options present their own unique challenges including limiting the use of larger sheath sizes (>7F), catheters in the radial artery, and difficult cannulation of the common carotid artery in a type-I aortic arch and left-sided lesions due to sharp angulation.[8,9] TB access has been associated with a higher risk of vessel thrombosis or pseudoaneurysm and increased fluoroscopic time has also dissuaded the use of TR or TB access.[10,11]

However, several studies have reported encouraging outcomes with alternative access sites in small patient populations.[8,12–14] A multicenter prospective randomized trial, RADCAR (RADial access for CARotid artery stenting) from Europe with 260 patients reported a higher radiation dose with TR approach in comparison to TF but no difference in major adverse events and a shorter length of hospital stay among the TR group.[11] Montorsi et al. showed an overall vascular complication rate of 1.87% with TR or TB CAS when used in conjunction with the proximal embolic protection balloon device and similar success in patients with left internal carotid artery (ICA) stenosis and bovine arch.[4,12]

Despite these outcomes, the TR/TB access sites are not routinely utilized and the data pertaining to their use are largely limited to small single-center studies which are inadequate to establish safety and feasibility. Therefore, we aimed to investigate the effect of the vascular access site on CAS outcomes using national real-world data from the Vascular Quality Initiative (VQI) encompassing heterogeneous patient populations across North America.

METHODS

Study Population and Database

A retrospective analysis of the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) CAS registry was performed. All patients undergoing CAS via TF, TR and TB approach from January 2012 to June 2021 in the Vascular Quality Initiative (VQI) Database were included. The VQI is a prospective data gathering program overseen by the Society of Vascular Surgery. This registry, which includes data from over 800 institutions from around North America, aims to improve the outcomes in vascular surgery. The database contains deidentified information on major vascular procedures including demographics, comorbidities, procedural details, and outcomes. To ensure data quality, the registry is subjected to stringent auditing method on a regular basis.

Patients were divided into 2 groups based on the access site utilized for CAS. Outcomes were compared between patients undergoing CAS via TF approach and those undergoing CAS via TB and/or TR approach. Patients undergoing revascularization for nonatherosclerotic lesions and for more than 1 lesion were excluded. Additionally, all patients undergoing transcarotid artery revascularization (TCAR) were excluded. A proposal for the project was approved by the VQI Committee which provided a deidentified database for the analysis, therefore the need for Institutional Review Board and individual patient informed consent was waived for this study.

Outcomes

Primary outcomes included stroke/death, technical failure, and access site complications (hematoma, stenosis, infection, pseudoaneurysm and arteriovenous (AV) fistula). Secondary outcomes included stroke, transient ischemic attack (TIA), myocardial infarction (MI), death, non−home discharge, extended length of postoperative stay (LOS) (>1 day), and composite endpoints of stroke/MI and stroke/death/MI.

TIA or stroke was defined as evidence of new cortical or ocular or vertebrobasilar TIA or stroke, or other neurologic symptoms judged to be cerebrovascular in etiology resulting from the procedure. TIA was defined as symptoms resolving within 24 hr of presentation and stroke was defined as focal neurologic deficits that persisted beyond 24 hr. Technical failure was defined as an inability to treat the lesion because either sheath or lesion access could not be obtained or the lesion could not be successfully crossed with the stent or balloon intended for treatment or any technical failure associated with failure of stent to deploy or deployment at incorrect location that could not be corrected and led to abandonment of procedure. Access site complications were defined as postoperative complications including hematoma, stenosis, infection, pseudoaneurysm and AV fistula which required medical, surgical or interventional treatment.

Other Covariates

Body mass index (BMI) was computed using height (meters) and weight (kilograms). Race was categorized as White, Black, and other. A history of coronary artery disease (CAD) included a history of asymptomatic CAD, MI, or unstable angina. A history of recent MI was defined as unstable angina or MI within the 6 months before CAS. The symptomatic condition was established depending on the operation indication, which comprised of ocular or cerebral TIA and stroke within the prior 6 months. The degree of stenosis at the treated lesion was assessed by either Duplex imaging, magnetic resonance angiography, computed tomography angiography, or digital angiogram, with the highest value chosen.

Statistical Analysis

Descriptive analysis was used to understand the characteristics of patients based on approach used. The chi-squared test was used for binary and categorical data to examine between-group differences, while the *t*-test was used for continuous variables. In order to ensure that the groups were well matched, the Standard Error of Mean was used for comparison. The association between approach and outcome was investigated using logistic regression. The adjusted odds ratios (aOR) were computed using multivariable logistic regression with possible confounder correction for age, gender, race, BMI, hypertension, diabetes, COPD, CHF, CAD, CKD, dialysis status, smoking status, American Society of Anesthesiologists (ASA) class, symptomatic status, degree of stenosis, urgency of case, anesthesia type, prior CEA, prior CAS, preoperative medication (P2Y12 inhibitor, statin, aspirin, beta-blocker, ACEI and anticoagulant), contrast volume, radiation time and procedure time. All covariates in the final model were chosen based on the stepwise backward selection with $P < 0.1$, past research, and clinically relevant factors. All analyses were clustered by centers to account for intragroup correlation, and all appropriate theory-based categorical-categorical interactions were tested. Hosmer-Lemeshow tests were used to assess the discrimination and area under the curve (AUC) for the calibration of the models. All analyses were carried out with Stata/SE 16.1 (Stata Corp LP, College Station, Texas) with the *P*-value less than 0.05 deemed as statistically significant.

RESULTS

Patient Characteristics

Among the 23,965 patients undergoing CAS during the study period, 819 (3.4%) underwent the procedure via TR/TB approach, whereas 23,146 (96.6%) underwent CAS via TF approach. Patients undergoing the procedure via TR/TB had a higher proportion of men (69.4% vs. 64.9%, $P = 0.009$), higher BMI (29.4 ± 7.1 vs. 28.7 ± 6.3, $P = 0.002$) and lower incidence of COPD (22.6% vs. 26.1%, $P = 0.024$). However, TR/TB was more likely to present with symptomatic disease (49.9% vs. 28.6%, $P < 0.001$) and undergo urgent/emergent procedure (39.3% vs. 26.0%, $P < 0.001$). Patients undergoing TR/TB CAS were more likely to be on guideline directed medical therapy including P2Y12 inhibitors (80.3% vs. 74.7%, $P < 0.001$), aspirin (88.3% vs. 84.5%, $P = 0.003$) and a statin (80.6% vs. 83.8%, $P = 0.020$). Intraoperatively, patients with TR/TB access had significantly higher procedure fluoroscopy time (median 18.2 vs. 15.9 min, $P < 0.001$) but a comparable contrast volume (mean 98.4 vs. 98.5 ml, $P = 0.954$) and total procedure time (mean 69.8 vs. 72.7 min, $P = 0.089$). Detailed baseline characteristics are shown in Table I.

Table I. Demographics

Variables	Femoral (TF) 23,146 (96.6)	Radial and brachial (TR/TB) 819 (3.4)	*P* Value
Age	69.8 ± 9.9	70.3 ± 10.1	0.146
Gender			**0.009**
Male	15,028 (64.9)	568 (69.4)	
Female	8,118 (35.1)	251 (30.7)	
Race			0.970
White	20,590 (88.9)	727 (88.8)	
Black	1,432 (6.2)	51 (6.2)	
Other	1,116 (4.8)	41 (5.0)	
BMI	28.7 ± 6.3	29.4 ± 7.1	**0.002**
Hypertension	20,251 (88.63)	703 (86.9)	0.128
Diabetes	8,904 (38.6)	310 (38.1)	0.766
COPD	6,035 (26.1)	184 (22.6)	**0.024**
CHF	3,829 (16.6)	128 (15.7)	0.507
CAD	9,580 (41.9)	315 (38.9)	0.099
CKD	7,706 (34.3)	231 (31.6)	0.126
Dialysis	213 (0.93)	5 (0.61)	0.358
Current Smoker	6,504 (28.2)	227 (27.8)	0.815
ASA Class 4/5	4,062 (18.9)	126 (17.6)	0.385
Symptomatic Status	6,616 (28.6)	409 (49.9)	**<0.001**
Degree of Ipsilateral Stenosis ≥ 80%	13,391 (59.23)	456 (56.4)	0.112
Urgent/Emergent Case	6,017 (26.0)	322 (39.3)	**<0.001**
Anesthesia			0.796
Regional/Local	18,748 (81.7)	670 (82.0)	
General	4,213 (18.4)	147 (17.9)	
Prior Ipsilateral CEA/CAS	3,523 (15.2)	115 (14.0)	0.350
Preoperative medication			
P2Y12 inhibitor	17,260 (74.7)	656 (80.3)	**<0.001**
Statin	18,621 (80.6)	685 (83.8)	**0.020**
Aspirin	19,531 (84.5)	722 (88.3)	**0.003**
Beta-blocker	12,173 (52.7)	422 (51.7)	0.564
Ace Inhibitor	11,187 (49.2)	382 (46.9)	0.201
Anticoagulant	2,701 (11.9)	113 (13.9)	0.085
Intraoperative			
Contrast Volume, ml	98.5 ± 58.5	98.4 ± 53.3	0.954
Radiation Time mins, (median ± IQR)	15.9 ± 13.1	22.9 ± 18.2	<0.001
Procedure Time mins	72.7 (44.6)	69.8 (39.6)	0.089

Bold indicates Alpha <0.05.

Postoperative Outcomes

Patients who underwent CAS via TR/TB approach experienced similar rates of stroke (2.0% vs. 2.2%, $P = 0.599$), but significantly higher rates of postoperative death (2.3% vs. 1.4%, $P = 0.038$). Furthermore, the TR/TB approach was associated with a higher rate of non−home discharge (15.4% vs. 12.6%, $P = 0.019$) and technical failure (2.2% vs. 1.1%, $P = 0.002$). However, there was a lower rate of access site complications (1.8% vs. 3.3%, $P = 0.019$), and post procedure stay greater than 1 day (59.3% vs. 63.5%, $P = 0.015$). (Table II).

After adjusting for potential confounders, there was no significant difference in the risk of stroke/death (aOR 1.10, 95% confidence interval (CI) (0.69−1.76), $P = 0.675$) between the 2 approaches. However, patients with TR/TB approach had a 2-fold increased risk of MI (aOR 2.39, 95% CI (1.32−4.30), $P = 0.004$) and technical failure (aOR 2.21, 95% CI (1.31−3.73), $P = 0.003$). Additionally, there was an almost 50% reduction in the risk of access site complications among the TR/TB group (aOR 0.53, 95% CI (0.32−0.85), $P = 0.009$), (Table II). A regression analysis on postoperative MI found that when assessing different demographic risk factors, ASA class, and clinical history, the most significant factor for prediction was surgical approach (Fig. 1).

Table II. Univariate and multivariate logistic regression analysis of postoperative outcomes in CAS—stratified by approach

	Univariable			Multivariable	
Outcome	Femoral (TF) *N* (%)	Radial and brachial (TR/TB) *N* (%)	*P* Value	Adjusted OR[b] (95% CI)	*P* Value
Stroke	516 (2.23)	16 (1.95)	0.599	0.90 (0.55—1.48)	0.681
Death	332 (1.43)	19 (2.32)	**0.038**	1.26 (0.67—2.20)	0.514
TIA	239 (1.03)	11 (1.34)	0.390	1.32 (0.64—2.72)	0.446
MI	133 (0.58)	9 (1.10)	0.055	2.39 (1.32—4.30)	**0.004**
Stroke/Death	771 (3.33)	33 (4.03)	0.275	1.10 (0.69—1.76)	0.675
Stroke/TIA	751 (3.24)	27 (3.30)	0.934	1.05 (0.70—1.59)	0.813
Stroke/Death/MI	870 (3.76)	38 (4.64)	0.194	1.17 (0.80—1.71)	0.408
Non—home Discharge	2,918 (12.61)	126 (15.38)	**0.019**	1.13 (0.80—1.60)	0.480
Access Site Complications[a]	766 (3.31)	15 (1.83)	**0.019**	0.53 (0.32—0.85)	**0.009**
Technical Failure	246 (1.06)	18 (2.20)	**0.002**	2.21 (1.31—3.73)	**0.003**
Extended Length of Stay (>1 day)	14,703 (63.52)	486 (59.34)	**0.015**	0.94 (0.73—1.22)	0.667

Bold indicates Alpha <0.05.
[a]Hematoma, stenosis, infection, pseudoaneurysm and AV fistula.
[b]Adjusted for age, gender, race, degree of stenosis, symptomatic status, anesthesia, comorbidities, and preoperative medications.

DISCUSSION

The femoral artery has been the most common access site for CAS but entry of this vessel may be limited due to severe atherosclerotic disease, groin infection, pseudoaneurysm, unfavorable abdominal, thoracic or aortic arch anatomy, and iliac tortuosity.[15] In these situations, alternative access via the radial and brachial artery may be desirable. In this study comparing TF CAS to TR/TB CAS, a similar risk of stroke and death risk was observed in both groups with 50% reduction in risk of access site complication in the TR/TB group. However, compared to TF access, patients with TR/TB CAS experienced a 2-fold increased risk of inhospital MI and technical failure.

In the management of carotid stenosis, several studies have illustrated that TFCAS, when compared to CEA and TCAR, is associated with the highest risk of stroke.[16–19] Explicitly with TCAR, TFCAS's higher stroke rate (1.3% vs. 2.4%; $P = 0.001$) has been postulated to be due to manipulation in the aortic arch which contributes to embolization before a distal protective device is in place.[19] With a TR/TB approach, traversal of the aortic arch may occur depending on the anatomy of the target vessel. For instance, with a right TR or TB for left common carotid artery stenosis with a bovine arch, the aortic arch is avoided which may contribute to a lower risk of stroke.[4,20] Whereas, in a right TR approach in a nonbovine arch, the guide wire crosses the arch to access the left common carotid artery.[21] Movement within the arch with this approach may be the contributor to the similar stroke risk observed in our study. Laterality of upper extremity approach was unavailable. As such, the stroke risk between right TR/TB versus left TR/TB was unable to be assessed.

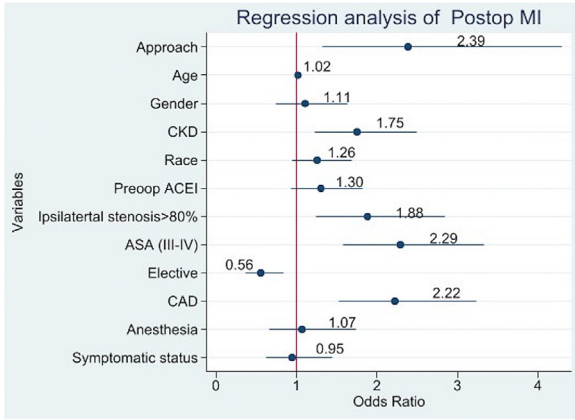

Fig. 1. Regression analysis of postoperative MI.

Access site complications with a TF approach during coronary interventions is well documented in the literature.[22–24] Specifically, in the management of carotid artery stenosis, access site complications with TFCAS has been compared with TR CAS in the RADCAR study and a significant difference in site complication between both groups was not found. Since this randomized control trial included only 260 patients, it is possible that the sample size was not large enough to detect a difference in outcomes. However, our study includes real-world data from a larger patient cohort which is more representative of the general patient population.

A reason for an increased risk of access complication with TFCAS could be explained by the location and accessibility. The more superficial radial and brachial arteries are more easily accessible and visualized while the common femoral artery, deep within the groin, may be difficult to palpate due to anatomic variations, body habitus, and or the presence of scar tissue.[25] Size of the vessel or unfavorable anatomy, particularly in the older population may necessitate the use of a larger arterial sheath which has been noted to be associated with an increased risk of vascular complications.[26–29] The depth and location of the vessels might also effect the success of closure devices with TR approach having less failure than TF. Multiple trials have showed significantly lower or comparable access site complications with percutaneous coronary interventions using radial access, including the RIVAL trial which showed the incidence of major vascular access site complications in TR group as 1.4% vs. 3.7% in TF group.[30,31] Additionally, in percutaneous interventions, radiation exposure is a major concern. Compared to TF, TR CAS has been associated with increased fluoroscopy time in some studies while others have reported no difference.[11,12] In our study, we saw an increase in radiation time among the TR/TB group.

In the CREST trial, stenting compared to endarterectomy was associated with a lower perioperative risk of MI.[18] There is a paucity of studies comparing MI risk with a TF approach versus a TR/TB approach in the treatment of coronary artery stenosis. The Access study comparing a radial, brachial and femoral approach in patients undergoing percutaneous transluminal coronary angioplasty found no significant difference in myocardial infarction among the 3 groups.[23] Contrary to this, we found a significantly higher risk of MI among the TR/TB group. We assessed for collinearity between TF and TR/TB approaches in our regression model and no evidence of multicollinearity was found. While the patients in both groups were found to be well matched in baseline CAD and other comorbidities, unmeasured patient and operative factors could be the source of this difference in our study. In addition, it is likely that patients who are offered an upper extremity approach are already at higher risk of complications due to more advanced atherosclerotic disease. In this study, patients undergoing a TR/TB approach were more likely to be on statins and P2Y12 inhibitors which could be markers for more severe CAD and atherosclerotic burden.

Increased technical failure with a TR or TB approach may be due to the lack of operator experience as most CAS are performed via the femoral route. In addition, the anatomic constraints may present a challenge. Specifically, with a TR approach in a nonbovine left common carotid artery (LCCA), technical failure was found to be the result of a lack of structural support normally provided by the surrounding aorta and the steep angulation of the LCCA.[18,32] In contrast, a bovine arch presents an ideal path for sheath advancement due to the stability afforded by the subclavian artery and shared origin of the innominate and LCAA.[4]

With a similar stroke and death risk and a lower incidence of access site complications, TR and TB CAS can be potential options for patients who are not suitable for CEA and TCAR, have unfavorable transfemoral access and are at a high risk of access site complications. Due to the higher risk of MI and technical failure, we recommend a TF approach as first line and that TR/TB approaches be reserved for cases in which femoral access and is not feasible. Further investigation is needed for better delineation of the risks associated with upper extremity approaches.

Limitations

This study is nonrandomized and retrospective due to the inherent nature of the VQI database. This also subjects our analysis to the possibility of unmeasured confounders and coding errors. Another limitation is the lack of anatomic data on the indication of TR/TB versus TF approach in this study resulting in potential confounding by indication. Additionally, we were unable to assess if upper extremity access was utilized when femoral access was viable. Furthermore, because the follow-up period was limited to the postoperative period, long-term outcomes could not be determined. These are common limitations of registry studies but the large sample size in a representative national population is a particular strength of these data. Finally, we believe that patients undergoing upper extremity access have a higher risk of developing a postoperative MI due to both advanced and diffuse atherosclerotic disease and more active underlying CAD. Despite our adjustments, there might be residual confounders unaccounted for.

CONCLUSION

Our results suggest a similar stroke and death risk in the TF and TR/TB CAS groups, and a lower risk of access site complications with TR/TB access. However, this alternative approach is associated with a 2-fold increased risk of technical failure and procedure related myocardial infarction. These findings

highlight TR/TB CAS as a viable alternate in CAS management when TF access is unattainable.

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