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Seven Years of The Transcarotid Artery Revascularization Surveillance Project, Comparison To Transfemoral Stenting And Endarterectomy

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TITLE: Seven Years of The Transcarotid Artery Revascularization Surveillance Project, Comparison To Transfemoral Stenting And Endarterectomy

SHORT TITLE: Comparing transcarotid artery revascularization, transfemoral carotid artery stenting, and carotid endarterectomy

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Conflicts of Interest

None

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ARTICLE HIGHLIGHTS

Type of Research: Retrospective analysis of prospectively collected data from the Vascular Quality Initiative

Key Findings: From a database encompassing over 50,000 transcarotid artery revascularization, 25,000 transfemoral carotid artery stenting, and 120,000 carotid endarterectomy patients, our analysis revealed transfemoral carotid artery stenting was associated with higher rates of in-hospital stroke/death compared with both transcarotid artery revascularization and carotid endarterectomy. Given the relatively smaller differences in stroke/death outcomes between transcarotid artery revascularization and endarterectomy, determining clinical significance becomes paramount in assessing the overall risk-benefit profile of these two interventions.

Take home Message: While transfemoral carotid artery stenting may be beneficial for select patients, the decision between carotid endarterectomy and transfemoral carotid artery revascularization should be multifactorial.

Table of Contents Summary (50 Words): In this retrospective review of over 50,000 transcarotid artery revascularization, 25,000 transfemoral carotid artery stenting, and 120,000 carotid endarterectomy patients, transfemoral carotid artery stenting had the highest rates of stroke/death. Given the relatively smaller differences in stroke/death rates between transcarotid artery revascularization and endarterectomy, evaluation of additional outcomes is important.

ABSTRACT

Objective: This study utilizes the latest data from the Vascular Quality Initiative (VQI), which now encompasses over 50,000 transcarotid artery revascularization (TCAR) procedures, to offer a sizeable dataset for comparing the effectiveness and safety of TCAR, transfemoral carotid artery stenting (tfCAS), and carotid endarterectomy (CEA). Given this substantial dataset, we are now able to compare outcomes overall and stratified by symptom status across revascularization techniques.

Methods: Utilizing VQI data from September 2016 to August 2023, we conducted a risk-adjusted analysis by applying inverse probability of treatment weighting to compare in-hospital outcomes between TCAR vs tfCAS, CEA vs tfCAS, and TCAR vs CEA. Our primary outcome measure was in-hospital stroke/death. Secondary outcomes included myocardial infarction and cranial nerve injury.

Results: A total of 50,068 patients underwent TCAR, 25,361 patients underwent tfCAS, and 122,737 patients underwent CEA. TCAR patients were older, more likely to have coronary artery disease, chronic kidney disease, and undergo coronary artery bypass grafting/percutaneous coronary intervention as well as prior contralateral CEA/CAS compared to both CEA and tfCAS. TfCAS had higher odds of stroke/death when compared with TCAR (2.9% vs 1.6%, aOR=1.84, 95% CI:1.65-2.06; P<.001) and CEA (2.9% vs 1.3%, aOR=2.21, 95% CI:2.01-2.43; P<.001). CEA had slightly lower odds of stroke/death compared with TCAR (1.3% vs 1.6%, aOR=0.83, 95% CI:0.76-0.91; P<.001). TfCAS had lower odds of cranial nerve injury compared with TCAR (0.0% vs 0.3%, aOR=0.00, 95% CI:0.00-0.00; P<.001) and CEA (0.0% vs 2.3%, aOR=0.00, 95% CI:0.0-0.0; P<.001) as well as lower odds of myocardial infarction compared with CEA (0.4% vs 0.6%, aOR=0.67, 95% CI:0.54-0.84; P<.001). CEA compared with TCAR had higher odds of myocardial infarction (0.6% vs 0.5%, aOR=1.31, 95% CI:1.13-1.54; P<.001) and cranial nerve injury (2.3% vs 0.3%, aOR=9.42, 95% CI:7.78-11.4; P<.001).

Conclusions: While tfCAS may be beneficial for select patients, the lower stroke/death rates associated with CEA and TCAR are preferred. When deciding between CEA and TCAR, it's important to weigh additional procedural factors and outcomes such as myocardial infarction and cranial nerve injury, particularly when stroke/death rates are similar. Additionally, evaluating subgroups that may benefit from one procedure over another is essential for informed decision-making and enhanced patient care in the treatment of carotid stenosis.

Key words: Carotid revascularization; transcarotid artery revascularization; transfemoral carotid artery stenting; carotid endarterectomy

MANUSCRIPT

Introduction

Among the various approaches for carotid revascularization, carotid endarterectomy (CEA) and transfemoral carotid artery stenting (tfCAS) are the most established options.[1] While CEA is the standard treatment, tfCAS was introduced as an alternative in high-risk patients with high-grade asymptomatic (>70%) or symptomatic stenosis.[2, 3]

After FDA approval in 2015,[4] transcarotid artery revascularization (TCAR) emerged as a potential alternative, providing cerebral protection through its flow reversal mechanism and eliminating the need for aortic arch crossing.[5, 6] Several retrospective studies have found TCAR consistently outperforms tfCAS, with lower rates of stroke/death during in-hospital stay and at 1-year follow-up.[3, 8] When comparing stroke/death outcomes between TCAR and CEA, studies have found no significance differences; however, when stratifying by symptomatic status, studies present conflicting results regarding outcomes.[7, 8, 9, 10] Nevertheless, TCAR's low reported stroke/death rates have led to its expanded indications and adoption by a considerable portion of physicians.[11, 12, 13, 14, 15]

When comparing CEA with tfCAS, higher in-hospital, 30-day, and long-term stroke/death rates have been observed for tfCAS in symptomatic patients, with no statistical difference in asymptomatic patients in retrospective studies and metanalyses.[16, 17, 18, 19] The findings from Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST) align with these observations, attributing the lack of significance in the asymptomatic subanalysis to lower statistical power.[20] The insufficient statistical power and lack of consensus emphasize the necessity for a thorough evaluation of in-hospital outcomes across all three procedures. Now with over 50,000 TCAR patients in the VQI dataset, there is a substantial sample size to provide updated insights into the comparative safety of TCAR, tfCAS, and CEA and stratify by symptom status.

Methods

Data Source

This is a retrospective cohort study using the Society for Vascular Surgery Vascular Quality Initiative (SVS-VQI) registry database (www.vqi.org). The VQI database includes information from over 1,000 international participating medical centers and provides de-identified data on major vascular procedures. Importantly, the TCAR Surveillance Project mandates that institutions conducting TCAR procedures adhere to the requirement of entering all TCAR and CAS data into the VQI registry to be eligible for Medicare reimbursement. The STROBE guidelines (https://www.strobe-statement.org/) were used to ensure proper reporting of methods, results, and discussion. Ethical approval for this study was provided by the VQI Research Advisory Committee and the Institutional Review Board at the Beth Israel Deaconess Medical Center. The need for informed consent was waived due to the retrospective and de-identified nature of the data.

Patient Cohort

From September 2016 to August 2023, all patients undergoing CAS (n=92,217), including both TCAR and tfCAS, and CEA (n=126,582) in the VQI were identified, aligning with the commencement of the TCAR Surveillance Project. Patients under 18 years-old were excluded. In the CAS cohort, patients with non-atherosclerotic lesions (i.e., trauma, dissection, and fibromuscular dysplasia) (n=3,438), more than one treated lesion (n=1,019), tandem internal carotid artery lesion >70% stenosis (n=3,132) and planned intracerebral intervention (n=1,498) were excluded. In the CEA cohort, patients undergoing other concomitant endovascular procedures, CABG, or other arterial interventions were excluded (n=3,607). Records with missing information regarding procedure type (TCAR, tfCAS, CEA) or symptom status were excluded.

Variable definitions and outcomes

The estimated glomerular filtration rate (eGFR) was calculated using the new Chronic Kidney Disease Epidemiology (CKD-EPI) Creatinine Equation (2021).[21] Patients were grouped based on eGFR as follows: eGFR>45 mL/min/1.73m^2, eGFR 30-45 mL/min/1.73m^2, eGFR<30 mL/min/1.73m^2, or preoperative dialysis (regardless of eGFR). Preoperative anemia was defined as hemoglobin <10 g/dL.[22] Symptom status was defined as the presence of ipsilateral ocular, ipsilateral cortical TIA, or ipsilateral stroke symptoms documented in medical records within six months prior to the index procedure in accordance with SVS reporting standards.[23]

The primary outcome was the composite variable in-hospital stroke/death. Secondary outcomes included in-hospital stroke, death, myocardial infarction (MI), composite variable stroke/death/MI, cranial nerve injury (CNI), prolonged length of stay ($\geq$ 2 days),[24] and bleeding. Stroke, MI, CNI, and bleeding were all defined according to the VQI criteria. Stroke was defined as the presence of symptoms lasting 24 hours or longer, involving neurological or visual deficits. MI was indicated by troponin level, EKG, or diagnosed clinically according to American College of Cardiology criteria.[25] CNI was defined as any occurrence of cranial nerve injuries (CN7, CN9, CN10, CN12) that began after the procedure. Bleeding was defined as procedure-related bleeding resulting in surgical repair or intervention, such as percutaneous thrombin injection or covered stent placement.

Statistical Analysis

We compared demographics, comorbidities, and procedural characteristics across the three procedures (TCAR, tfCAS, CEA). Categorical variables were presented as counts and percentages and were compared using Pearson's Chi-square or Fisher's exact tests as appropriate. Continuous variables were presented as mean ± standard deviation and compared using Student's t-test or median IQR. For non-normal distribution, the Wilcoxon rank sum test was utilized.

To account for differences among the three groups of patients, we used inverse probability of treatment weighting (IPTW) based on propensity scores.[26, 27] In contrast to pairwise propensity score matching, IPTW offers the advantage of leveraging the entire sample without constraints on the covariates included in the model. By accounting for covariates related to treatment selection, such as background demographics, comorbidities, symptom status, procedure history, and surgery year, IPTW ensures thorough adjustment and efficient utilization of all available data.[28] The covariates used were age, sex, race, BMI, hypertension, diabetes, coronary artery disease (CAD), prior congestive heart failure (CHF), preoperative smoking, chronic obstructive pulmonary disease (COPD), renal dysfunction, anemia, symptomatic amaurosis, symptomatic hemispheric TIA, symptomatic stroke, prior Coronary Artery Bypass Grafting (CABG)/Percutaneous Coronary Intervention (PCI), prior contralateral CEA/CAS, % stenosis of ipsilateral and contralateral carotid, and surgery year. Sensitivity analysis tested for differences after trimming extreme variables, but no differences were noted. We compared the weighted treatment groups in terms of baseline characteristics to assess the success of the propensity score weighting in achieving balance across the groups. Standardized mean differences (SMDs) were calculated for each covariate, and an SMD <.10 was considered indicative of a balanced distribution. Tests that compared all 3 groups simultaneously by using chi-squared tests involving higher degrees-of-freedom and F-tests for continuous predictors were conducted as appropriate. The in-hospital outcomes were reported in terms of adjusted rates and odds ratios for each of the treatment comparisons. A post-hoc analysis was also conducted to confirm that this study was sufficiently powered. As a subanalysis, we evaluated in-hospital outcomes, stratifying by symptom status.

Stata MP version 17.0 was used to combine datasets, define variables, and stratify data by carotid revascularization methodology. All subsequent statistical analyses were performed using R version 4.3.1 (http://www.r-project.org). All tests were two-sided and p-values <.05 were considered significant.

Results

All Patients

After exclusions, a total of 50,068 (25%) patients underwent TCAR, 25,361(13%) patients underwent tfCAS, and 122,737 (62%) patients underwent CEA during the study period (Table I). Before IPTW, TCAR patients compared with tfCAS and CEA were older, had more CAD and CKD, and were more likely to undergo CABG/PCI as well as prior contralateral CEA/CAS (Table I). Patients who received tfCAS were more likely to undergo local anesthesia (81% vs 13% vs 6%; P<.001), had minimal protamine usage (12% vs 88% vs 75%; P<.001), and experienced the shortest procedure duration (67±40 vs 70±55 vs 117±45; P<.001) compared to TCAR and CEA respectively.

Adjusted rates for baseline characteristics after IPTW were included (Table I). In-hospital outcomes were reported for the overall patient population (Table II), as well as for symptomatic (Table III) and asymptomatic patients (Table IV), comparing TCAR vs tfCAS, CEA vs tfCAS, and TCAR vs CEA. Adjusted stroke/death rates per year by procedure type were also plotted (Figure 1).

Prior to adjustment, the in-hospital stroke/death rates were highest for tfCAS compared to TCAR and CEA (2.8% vs 1.5% vs 1.3%). After adjustment (Table II), tfCAS compared with TCAR had higher odds of stroke/death (2.9% vs 1.6%; aOR=1.84, 95% CI:1.65-2.06; P<.001). For secondary outcomes, tfCAS also had higher odds of stroke (2.1% vs 1.3%; aOR=1.58, 95% CI:1.39-1.79; P<.001), death (1.1% vs 0.4%, aOR=2.80, 95% CI:2.29-3.42; P<.001), stroke/death/MI (3.2% vs 2.0%, aOR=1.62, 95% CI:1.46-1.80; P<.001), and prolonged length of stay (35.5% vs 29.6%; aOR=1.31, 95% CI:1.27-1.36; P<.001) compared to TCAR. However, tfCAS had lower odds of CNI (0.0% vs 0.3%; aOR=0.00, 95% CI:0.00-0.00; P<.001) and bleeding (0.4% vs 0.8%; aOR=0.52, 95% CI:0.41-0.67; P<.001).

Similarly, tfCAS compared with CEA had higher odds of stroke/death (2.9% vs 1.3%; aOR=2.21, 95% CI:2.01-2.43; P<.001) as well as secondary outcomes: stroke, death, stroke/death/MI, and prolonged length of stay (Table II). However, tfCAS had lower odds of in-hospital MI (0.4% vs 0.6%; aOR=0.67, 95% CI:0.54-0.84; P<.001), CNI (0.0% vs 2.3%; aOR=0.00, 95% CI:0.00-0.00; P<.001), and bleeding (0.4% vs 1.0%; aOR=0.38, 95% CI:0.30-0.47; P<.001).

On the other hand, CEA compared with TCAR had lower odds of stroke/death (1.3% vs 1.6%; aOR=0.83, 95% CI:0.76-0.91; P<.001), stroke (1.1% vs 1.3%; aOR=0.84, 95% CI:0.76-0.93; P<.001), and death (0.3% vs 0.4%, aOR=0.76, 95% CI:0.64-0.92; P=.004), similar odds of stroke/death/MI (1.9% vs 2.0%, aOR=0.94, 95% CI:0.87-1.02; P=.14), and higher odds of MI (0.6% vs 0.5%, aOR=1.31, 95% CI:1.13-1.54; P<.001), prolonged length of stay (30.1% vs 29.6%; aOR=1.02, 95% CI:1.00-1.05; P=.047), CNI (2.3% vs 0.3%; aOR=9.42, 95% CI:7.78-11.4; P<.001), and bleeding (1.0% vs 0.8%; aOR=1.38, 95% CI:1.22-1.57; P<.001).

Symptomatic Patients

TfCAS compared with TCAR still had higher odds of stroke/death (4.4% vs 2.4%; aOR=1.87, 95% CI:1.59-2.21; P<.001) and notably death (1.9% vs 0.6%; aOR=3.35, 95% CI:2.50-4.48; P<.001) and prolonged length of stay (52.2% vs 41.1%; aOR=1.56, 95% CI:1.47-1.66; P<.001) (Table III). Similarly, tfCAS compared with CEA still had higher odds of stroke/death (4.4% vs 2.1%; aOR=2.18, 95% CI:1.91-2.48; P<.001) and prolonged length of stay (52.2% vs 42.9%; aOR=1.45, 95% CI:1.38-1.53; P<.001). Nevertheless, tfCAS still had the lowest rates of CNI compared with both TCAR and CEA.

CEA compared with TCAR still had lower odds of stroke/death (2.1% vs 2.4%; aOR=0.86, 95% CI:0.75-0.99; P=.039) and stroke (1.8% vs 2.1%; aOR=0.84, 95% CI:0.72-0.98; P=.029), although death was no longer significant (0.5% vs 0.6%; aOR=0.83, 95% CI:0.62-1.10; P=.2). Furthermore, CEA still had higher odds of in-hospital MI (0.6% vs 0.4%; aOR=1.44, 95% CI:1.05-1.96; P=.022), prolonged length of stay (42.9% vs 41.1%; aOR=1.08, 95% CI:1.03-1.12; P<.001), CNI (2.8% vs 0.3%; aOR=8.60, 95% CI:6.20-11.9; P<.001).

Asymptomatic Patients

TfCAS still had higher odds of stroke/death compared with TCAR (2.1% vs 1.3%; aOR=1.68, 95% CI:1.44-1.96; P<.001) and CEA (2.1% vs 1.0%; aOR=2.15, 95% CI:1.87-2.47; P<.001). When comparing tfCAS with TCAR, tfCAS patients had similar although now statistically significant lower odds of MI (0.3% vs 0.5%; aOR=0.67, 95% CI:0.48-0.94; P=.020). CEA compared with TCAR still had lower odds of stroke/death (1.0% vs 1.3%; aOR=0.78, 95% CI:0.70-0.88; P<.001). The remaining outcomes remained similar to the overall unstratified population (Table IV).

Discussion

By utilizing a modern database with almost 200,000 carotid revascularization procedures, our study reveals important, updated findings regarding the comparative safety of carotid revascularization techniques. In the overall population, rates of stroke and stroke/death were statistically lowest for CEA compared to TCAR and tfCAS. When comparing the difference in stroke/death rates between the three groups, the difference in stroke/death rates between TCAR and CEA (0.3%) is relatively smaller compared to that of tfCAS to TCAR (1.3%) or tfCAS to CEA (1.6%). As a result, when comparing CEA and TCAR, additional outcomes such as MI and CNI should factor into clinical decision-making. Particularly, when evaluating CNI and length of stay, TCAR consistently exhibited superior outcomes compared with CEA. As a result, the choice between TCAR versus CEA should be based on patient risk factors and anatomy, using shared decision making. On the other hand, the relatively larger discrepancies in stroke/death outcomes associated with tfCAS may suggest that tfCAS should be reserved for select circumstances, such as prohibitive neck anatomy.[29]

When comparing TCAR with CEA, previous literature has found that TCAR performs similar to CEA in terms of post-operative outcomes for all patients and when stratifying by symptomatic status, consistent with our current findings.[9, 10] In previous studies comparing in-hospital outcomes between TCAR and CEA using VQI data, both analyses found no statistically significant differences of stroke/death when analyzing the general patient population.[9, 14] The second study also found no statistical difference in stroke/death/MI (OR, 1.4; 95% CI, 0.9-2.1; P=.18). Similarly, in three separate meta-analyses, no statistical differences were found between TCAR and CEA stroke or stroke/death outcomes in the overall population as well as the symptomatic and asymptomatic cohorts.[13, 30, 31] In terms of statistical significance, our findings likely reached significance due to the substantially larger pool of TCAR patients, which exceeded the largest meta-analysis study cohort (n=18,300) by nearly 32,000 patients. In a more recent and expansive VQI study involving 21,234 TCAR patients, CEA was associated with slightly lower odds of in-hospital stroke/death when compared with TCAR (1.7% vs 2.0%; aOR=0.82, 95% CI:0.72-0.95; P<.001), in line with our findings.[7] However, a significant limitation of these studies was the failure to delineate the preoperative symptom (amaurosis, hemispheric TIA, stroke) when adjusting for symptomatic status. Previous studies have demonstrated varying outcomes for patients presenting with amaurosis, hemispheric TIA, and stroke, with TCAR patients showing a higher incidence of preoperative strokes, while CEA patients tend to exhibit more preoperative ocular TIAs.[32, 33, 34] Consequently, amalgamating these diverse symptom statuses into a single 'symptomatic' variable could introduce bias into the analysis. Therefore, by preserving the distinction between these different symptom statuses during IPTW, we ensured a more nuanced and granular analysis.

With regards to in-hospital MI and CNI, we found that TCAR consistently had lower odds compared with CEA. In line with our findings, a systematic review and metanalysis comparing TCAR with CEA found that TCAR was associated with a lower incidence of MI and CNI.[30] While TCAR exhibited lower odds compared to CEA, it is noteworthy that the disparity in MI rates was relatively small. Additionally, although TCAR demonstrated a 2.0% lower CNI rate compared with CEA, the presence of a 0.3% CNI rate remains significant, given the potential impact on patient quality of life.[35] As a result, our findings are consistent with previous studies, indicating that stroke/death outcomes, as well as MI and CNI are significant factors to consider when choosing between TCAR and CEA. However, further research is required to ascertain whether these statistically significant differences translate into clinically meaningful outcomes for patients, and more data on patient preferences are warranted.[37, 38, 39, 40] Additionally, physicians should account for anatomic considerations, procedure duration, anesthesia type, and procedural costs.[24, 36] With regards to anatomical considerations, CEA has been indicated for heavily calcified stenosis, angulated ICA, or low bifurcation where TCAR is not indicated. On the other hand, TCAR is often utilized for patients with a high bifurcation, prior endarterectomy, or other neck surgery/radiation that does not involve the base of the neck.[41]

When comparing TCAR with tfCAS and CEA with tfCAS, our study revealed worse outcomes for tfCAS, regardless of symptom status. Both arch manipulation and incomplete embolic protection are commonly cited factors thought to account for this increased risk of stroke/death associated with tfCAS.[42] While prior randomized control trials have found tfCAS stroke/death rates to be higher compared with TCAR and CEA, the low event rate and small patient numbers resulted in the inability to detect a statistically significant difference.[19] Nevertheless, this stroke/death difference may still be considered clinically important to patients and physicians. In a randomized control trial comparing tfCAS with CEA for patients with asymptomatic stenosis, the trial reported stenting was noninferior to endarterectomy, despite the higher stroke/death rates with tfCAS (2.9% vs 1.7%; P=.33).[44] The Second Asymptomatic Carotid Surgery Trial (ACST-2) also found no statistical difference despite tfCAS having a stroke/death rate of 3.7% compared to 2.7% of CEA.[45]

Beyond considering the comparative stroke/death rates, it is also important to contextualize these outcomes over time and within the framework of acceptable standards. When investigating stroke/death rates over time, TCAR and CEA remain similar (with the exception of 2016 potentially attributable to the initiation of the TCAR Surveillance Project). In contrast, tfCAS stroke/death rates have remained high throughout the years with the exception of 2016 as well as a slight decrease in 2019. In terms of acceptable standards, the American Heart Association (AHA), Society for Vascular Surgery (SVS), and European guidelines recommend 30-day stroke/death rates to be <6% for symptomatic patients and <3% for asymptomatic patients based on the North American Symptomatic Carotid Endarterectomy Trial, European Carotid Surgery Trial, Asymptomatic Carotid Atherosclerosis Trial, and Asymptomatic Carotid Surgery Trial.[46, 47, 48, 49, 45] However, prior studies have shown that at least 1/3 of 30-day stroke/death events occur post-discharge, and therefore, these in-hospital rates are underestimating adverse outcomes.[50, 51] Consequently, there is a growing consensus that acceptable in-hospital stroke/death rates should be reevaluated, with suggestions proposing ~4% for symptomatic cases and ~2% for asymptomatic cases.[52, 53, 54, 55, 56] In this context, our results indicate that while both CEA and TCAR fall within the threshold of acceptability, tfCAS would not meet these benchmarks for either symptomatic or asymptomatic patients. These findings substantiate existing safety concerns surrounding tfCAS and emphasize the importance of careful patient selection.

While tfCAS did have the lowest rates of CNI compared to both TCAR and CEA, the relatively larger stroke/death rates support the prioritization of TCAR and CEA, with the use of tfCAS for select indications such as patients with a tracheostomy, prior neck surgery, significant plaque at the TCAR sheath access site, or contralateral CNI.[57, 58] Nevertheless, CMS has expanded tfCAS indications to include asymptomatic patients and patients at standard risk for adverse events from CEA without a need for registry participation or center certification. The label expansion will also allow a larger number of patients and physicians access to tfCAS.[59, 60] The current analysis highlights the importance of continued investigation with registry data collection, randomized clinical trials such as CREST 2, and observational studies to ensure patient safety.[61]

While our study brings additional insight to the field through analysis of a larger TCAR population on the comparative safety of TCAR, tfCAS, and CEA, it is important to acknowledge the following limitations. First, our study was observational and subjected to the limitations inherent in a retrospective study, including the presence of unmeasured confounding. Furthermore, the lack of data concerning the nature of carotid lesions, stroke severity, Instructions for Use status, and the clinical significance of CNI, MI, and stroke on quality of life precludes further analysis on these topics. Additionally, our findings predominantly address in-hospital outcomes, limiting our ability to draw conclusions regarding long-term outcomes and recurrence rates. VQI captures >95% of TCAR patients, however, many CEA and tfCAS patients are not included in the VQI dataset, potentially limiting the comprehensiveness of the results in reflecting national practice patterns and variations across different specialties. Moreover, physician information is also blinded, which prevents an analysis of outcomes by specialty (e.g., vascular surgery vs interventional radiology vs cardiology). While specific breakdowns are not provided, the VQI does include a substantial number of cardiologists and interventional radiologists, particularly since the merger of the ACC NCDR dataset into the VQI in 2021. Furthermore, during the initial years of our analysis, TCAR and tfCAS were exclusively recommended for high-risk patients. Consequently, these early years may have led to a higher occurrence of adverse outcomes compared to CEA. To control for this, we incorporated the year of surgery into our model. Of note, this potential bias would not hamper a comparison of TCAR with tfCAS. Nevertheless, the recent increase in TCAR utilization and respective decrease in tfCAS use may impact outcomes, further underscoring the importance of continuously updating clinical data to reflect current practice patterns. Additionally, it is noteworthy that not all physicians may possess expertise in all three techniques, and some patients may be ineligible for a certain procedure. Consequently, continuous research is needed to address the current limitations of the VQI to facilitate the selection of the most appropriate revascularization technique tailored to individual clinical or regional contexts. A randomized trial comparing CEA, TCAR, and tfCAS, coupled with ongoing monitoring of outcomes using registry data, holds significance in optimizing patient care. Nonetheless, the present findings serve to guide shared decision-making discussions when exploring treatment options.

Conclusion

In the VQI registry, TCAR had clinically similar rates of stroke/death compared to CEA. On the other hand, tfCAS in-hospital outcomes proved inferior to the other two procedures, with higher rates of stroke/death. As a result, this 7-year analysis underscores the comparability of

TCAR and CEA, highlights the relatively poor outcomes of tfCAS, and serves as a valuable resource for shared decision-making in revascularization.

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Table I: Baseline characteristics of patients undergoing CEA, TCAR, or tfCAS for carotid stenosis

	Baseline comparison				Adjusted Rates			
	TCAR	**TFCAS**	**CEA**	***P value***	**TCAR**	**TFCAS**	**CEA**	***P value***
N	50068	25361	122737					
Age mean (SD[1])	73.5 (8.59)	70.5 (9.45)	71.0 (8.90)	*< .001*	72.2 (0.05)	72.8 (0.06)	71.1 (0.03)	*.774*
Female Sex	37.3%	36.2%	39.4%	*< .001*	37.3%	36.2%	39.4%	*<.001*
White Race	89.9%	88.7%	89.8%	*< .001*	89.5%	89.3%	89.9%	*<.001*
Hispanic Ethnicity	4.4%	4.0%	3.3%	*< .001*	4.5%	4.1%	3.3%	*<.001*
Symptomatic	24.7%	36.9%	29.6%	*< .001*	27.6%	32.1%	29.3%	*<.001*
Diabetes	39.0%	39.5%	37.1%	*< .001*	39.1%	39.7%	37.1%	*<.001*
CAD[2]	53.7%	50.8%	39.6%	*< .001*	52.9%	53.8%	39.7%	*<.001*
CHF[3]	16.7%	16.8%	12.1%	*< .001*	16.4%	18.1%	12.2%	*<.001*
CKD[4]	38.8%	34.9%	24.0%	*< .001*	37.8%	37.7%	24.7%	*<.001*
COPD[5]	24.7%	25.3%	22.9%	*< .001*	25.0%	24.9%	22.9%	*<.001*
CABG/PCI[6]	38.6%	36.9%	33.4%	*< .001*	37.3%	39.8%	33.6%	*<.001*
Prior Contralateral CEA/CAS	16.2%	15.1%	12.4%	*< .001*	15.4%	16.7%	12.5%	*<.001*
Prior Ipsilateral CEA/CAS	12.6%	17.2%	1.4%	*< .001*	12.4%	17.4%	1.5%	*<.001*
Betablocker	53.7%	50.8%	49.8%	*< .001*	53.3%	52.1%	49.9%	*<.001*
ACE-Inhibitor	54.2%	49.8%	53.6%	*< .001*	53.8%	50.3%	53.7%	*<.001*
Aspirin	89.8%	84.5%	83.9%	*< .001*	89.9%	84.0%	83.9%	*<.001*
Anticoagulant	4.0%	4.5%	12.8%	*< .001*	3.9%	4.3%	12.9%	*<.001*
Antiplatelets	89.1%	76.8%	38.5%	*< .001*	88.8%	76.8%	38.6%	*<.001*
Statin	90.2%	83.2%	85.9%	*< .001*	90.2%	83.6%	85.9%	*<.001*
Ipsilateral Stenosis >80%	47.0%	52.1%	44.6%	*< .001*	48.4%	52.2%	45.6%	*<.001*

[1] Standard Deviation (SD)
[2] Coronary Artery Disease (CAD)
[3] Congestive Heart Failure (CHF)
[4] Chronic Kidney Disease (CKD)
[5] Chronic Obstructive Pulmonary Disorder (COPD)
[6] Coronary Artery Bypass Grafting / Percutaneous Coronary Intervention (CABG/PCI)

Table II: Postoperative outcomes for all carotid stenosis patients

				TFCAS vs TCAR		TFCAS vs CEA		CEA vs TCAR	
	TCAR	**TFCAS**	**CEA**	**aOR [CI]**	***P value***	**aOR [CI]**	**P value**	**aOR [CI]**	***P value***
In-hospital Stroke	1.3%	2.1%	1.1%	1.58 (1.39-1.79)	*<.001*	1.88 (1.68-2.10)	*<.001*	0.84 (0.76-0.93)	*<.001*
In-hospital Death	0.4%	1.1%	0.3%	2.80 (2.29-3.42)	*<.001*	3.66 (3.10-4.32)	*<.001*	0.76 (0.64-0.92)	*.004*
Perioperative MI	0.5%	0.4%	0.6%	0.88 (0.69-1.13)	*.3*	0.67 (0.54-0.84)	*<.001*	1.31 (1.13-1.54)	*<.001*
Stroke or Death	1.6%	2.9%	1.3%	1.84 (1.65-2.06)	*<.001*	2.21 (2.01-2.43)	*<.001*	0.83 (0.76-0.91)	*<.001*
Stroke, Death, MI	2.0%	3.2%	1.9%	1.62 (1.46-1.80)	*<.001*	1.72 (1.58-1.88)	*<.001*	0.94 (0.87-1.02)	*.14*
Length of Stay > 2 days	29.6%	35.5%	30.1%	1.31 (1.27-1.36)	*<.001*	1.28 (1.24-1.32)	*<.001*	1.02 (1.00-1.05)	*.047*
Cranial Nerve Injury	0.3%	0.0%	2.3%	0.00 (0.00-0.00)	*<.001*	0.00 (0.00-0.00)	*<.001*	9.42 (7.78-11.4)	*<.001*
Bleeding	0.8%	0.4%	1.0%	0.52 (0.41-0.67)	*<.001*	0.38 (0.30-0.47)	*<.001*	1.38 (1.22-1.57)	*<.001*

*IPTW accounted for the following variables: age, sex, race, BMI, hypertension, diabetes, CAD, CHF, preoperative smoking, COPD, renal dysfunction, anemia, symptomatic amaurosis, symptomatic hemispheric TIA, symptomatic stroke, CABG / PCI, prior contralateral CEA/CAS, % ipsilateral and contralateral occlusion, and surgery year.

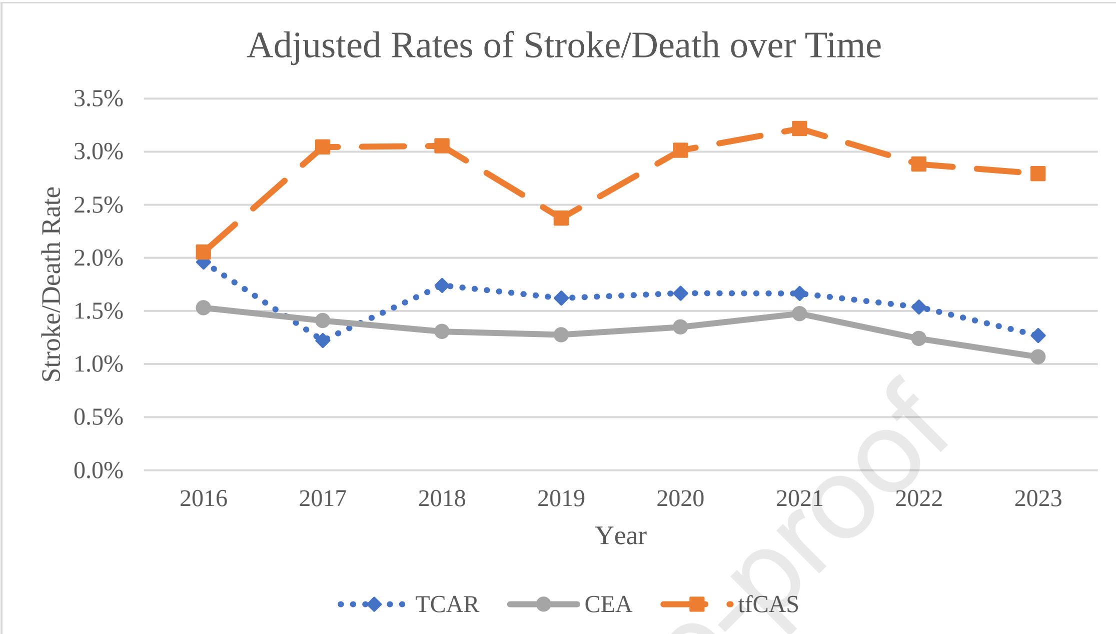
Table III: Postoperative outcomes for symptomatic carotid stenosis patients

				TFCAS vs TCAR		TFCAS vs CEA		CEA vs TCAR	
	TCAR	**TFCAS**	**CEA**	**aOR [CI]**	***P value***	**aOR [CI]**	**P value**	**aOR [CI]**	***P value***
In-hospital Stroke	2.1%	3.0%	1.8%	1.46 (1.21-1.76)	*<.001*	1.73 (1.48-2.02)	*<.001*	0.84 (0.72-0.98)	*.029*
In-hospital Death	0.6%	1.9%	0.5%	3.35 (2.50-4.48)	*<.001*	4.06 (3.26-5.05)	*<.001*	0.83 (0.62-1.10)	*.2*
Perioperative MI	0.4%	0.6%	0.6%	1.39 (0.93-2.07)	*.10*	0.97 (0.71-1.32)	*.8*	1.44 (1.05-1.96)	*.022*
Stroke or Death	2.4%	4.4%	2.1%	1.87 (1.59-2.21)	*<.001*	2.18 (1.91-2.48)	*<.001*	0.86 (0.75-0.99)	*.039*
Stroke, Death, MI	2.8%	4.8%	2.6%	1.78 (1.53-2.08)	*<.001*	1.89 (1.67-2.14)	*<.001*	0.94 (0.83-1.08)	*.4*
Length of Stay > 2 days	41.1%	52.2%	42.9%	1.56 (1.47-1.66)	*<.001*	1.45 (1.38-1.53)	*<.001*	1.08 (1.03-1.12)	*.001*
Cranial Nerve Injury	0.3%	0.0%	2.8%	0.00 (0.00-0.00)	*<.001*	0.00 (0.00-0.00)	*<.001*	8.60 (6.20-11.9)	*<.001*
Bleeding	0.8%	0.5%	1.3%	0.58 (0.39-0.87)	*.009*	0.36 (0.25-0.51)	*<.001*	1.61 (1.28-2.04)	*<.001*

Table IV: Postoperative outcomes for asymptomatic carotid stenosis patients

				TFCAS vs TCAR		TFCAS vs CEA		CEA vs TCAR	
	TCAR	**TFCAS**	**CEA**	**aOR [CI]**	***P value***	**aOR [CI]**	**P value**	**aOR [CI]**	***P value***
In-hospital Stroke	1.1%	1.7%	0.9%	1.57 (1.32-1.86)	*<.001*	1.94 (1.66-2.27)	*<.001*	0.81 (0.71-0.91)	*<.001*
In-hospital Death	0.3%	0.7%	0.2%	2.13 (1.59-2.85)	*<.001*	3.07 (2.37-3.98)	*<.001*	0.69 (0.54-0.88)	*.003*
Perioperative MI	0.5%	0.3%	0.6%	0.67 (0.48-0.94)	*.020*	0.53 (0.39-0.73)	*<.001*	1.26 (1.06-1.51)	*.011*
Stroke or Death	1.3%	2.1%	1.0%	1.68 (1.44-1.96)	*<.001*	2.15 (1.87-2.47)	*<.001*	0.78 (0.70-0.88)	*<.001*
Stroke, Death, MI	1.7%	2.4%	1.5%	1.42 (1.23-1.64)	*<.001*	1.56 (1.37-1.77)	*<.001*	0.91 (0.82-1.01)	*.067*
Length of Stay > 2 days	25.3%	27.6%	24.7%	1.12 (1.07-1.18)	*<.001*	1.16 (1.11-1.21)	*<.001*	0.97 (0.94-1.00)	*.027*
Cranial Nerve Injury	0.2%	0.0%	2.2%	0.00 (0.00-0.00)	*<.001*	0.00 (0.00-0.00)	*<.001*	9.67 (7.64-12.3)	*<.001*
Bleeding	0.7%	0.4%	0.9%	0.49 (0.36-0.68)	*<.001*	0.38 (0.29-0.51)	*<.001*	1.29 (1.12-1.50)	*<.001*

Figure 1: Adjusted rates of stroke/death overtime for TCAR, tfCAS, and CEA



*Note: 2023 data includes up until mid-August