Published in final edited form as:

J Vasc Surg. 2020 January ; 71(1): 87–95. doi:10.1016/j.jvs.2018.11.029.

In-Hospital Outcomes of TransCarotid Artery Revascularization and Carotid Endarterectomy in the Society of Vascular Surgery Vascular Quality Initiative

Marc L. Schermerhorn, MD[a], **Patrie Liang, MD**[a], **Hanaa Dakour-Aridi, MD**[b], **Vikram S. Kashyap, MD**[c], **Grace J. Wang, MD, MSCE**[d], **Brian W. Nolan, MD**[e], **Jack L. Cronenwett, MD**[f], **Jens Eldrup-Jorgensen, MD**[e], **Mahmoud B. Malas, MD, MHS**[g]

[a.]Department of Surgery, Division of Vascular and Endovascular Surgery, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA

[b.]Johns Hopkins Bayview Vascular and Endovascular Research Center, Baltimore, MD

[c.]Department of Surgery, Division of Vascular Surgery and Endovascular Therapy, University Hospitals Cleveland Medical Center, Cleveland, OH

[d.]Department of Surgery, Division of Vascular Surgery and Endovascular Therapy, Hospital of the University of Pennsylvania, Philadelphia, PA

[e.]Department of Surgery, Division of Vascular and Endovascular Therapy, Maine Medical Center, Portland, ME

[f.]Department of Surgery, Section of Vascular Surgery and The Dartmouth Institute, Dartmouth-Hitchcock Medical Center, Lebanon, NH

[g.]Department of Surgery, Division of Vascular and Endovascular Surgery, University of California San Diego Health System, San Diego, CA

Abstract

Objective—TransCarotid Artery Revascularization (TCAR) with flow reversal offers a less invasive option for carotid revascularization in high risk patients and has the lowest reported overall stroke rate for any prospective trial of carotid artery stenting (CAS). However, outcome comparisons between TCAR and carotid endarterectomy (CEA) are needed to confirm the safety of TCAR outside of highly selected patients and providers.

Methods—We compared in-hospital outcomes between patients undergoing TCAR and CEA from January 2016 to March 2018, using the Society of Vascular Surgery (SVS) Vascular Quality Initiative (VQI) TCAR Surveillance Project (TSP) registry and the SVS-VQI carotid

Corresponding Author/Reprints: Marc L. Schermerhorn, MD, FACS, Beth Israel Deaconess Medical Center, 110 Francis Street, Suite 5B, Boston, MA 02215, *Telephone:* 617-632-9971, mscherm@bidmc.harvard.edu.

This study was presented at the Vascular & Endovascular Surgery Society at the Vascular Annual Meeting, Boston, MA, June 20–23, 2018.

endarterectomy database, respectively. The primary outcome was a composite of in-hospital stroke and death.

Results—A total of 1,182 patients underwent TCAR compared to 10,797 patients who underwent CEA. Patients undergoing TCAR were older (median age 74 vs 71 years, $P < .001$), more likely to be symptomatic (32 vs 27%, $P < .001$), and had more medical comorbidities including coronary artery disease (55 vs 28%, P < .001), chronic heart failure (20 vs 11%, $P < .001$), chronic obstructive pulmonary disease (29 vs 23%, $P < .001$), and chronic kidney disease (39 vs 34%, $P = .001$). On unadjusted analysis, TCAR had similar rates of in-hospital stroke/death (1.6 vs 1.4%, P = .33) and stroke/death/MI (2.5 vs 1.9%, P =.16) compared to CEA. There was no difference in rates of stroke (1.4 vs 1.2%, $P = .68$), in-hospital death (0.3 vs 0.3, $P = .88$), 30-day death (0.9 vs 0.4, $P = .06$), or MI (1.1 vs 0.6, $P = .11$). However, on average, TCAR was 33 minutes shorter than CEA (78 ± 33 vs 111 ± 43 minutes, $P < .001$). Patients undergoing TCAR were also less likely to incur cranial nerve injuries (0.6 vs 1.8%, $P < .001$) and less likely to have a post-operative length of stay greater than one day (27 vs 30%, $P = .046$). On adjusted analysis, there was no difference in terms of stroke/death (OR 1.3, 95% CI 0.8–2.2, $P = .28$), stroke/death/MI (OR 1.4, 95% CI 0.9–2.1, $P = .18$), or the individual outcomes.

Conclusion—Despite a substantially higher medical risk in patients undergoing TCAR, in-hospital stroke/death rates were similar between TCAR and CEA. Further comparative studies with larger samples sizes and longer follow-up will be needed to establish the role of TCAR in extracranial carotid disease management.

Table of Contents Summary

This retrospective analysis of the VQI-TSP Registry data comparing 1182 transcarotid artery revascularizations (TCARs) and 10,797 carotid endarterectomies showed similar outcomes of in-hospital post-operative stroke, stroke/death, and stroke/death/MI between the two techniques. These findings suggest that TCAR is a safe and effective alternative for carotid revascularization.

Introduction

Carotid endarterectomy (CEA) remains the dominant treatment method for carotid revascularization despite various technological advancements in transfemoral carotid artery stenting (CAS).[1,2] The trepidation for utilizing transfemoral CAS stems from multiple reports of higher overall stroke rates compared to the gold standard technique of CEA.[3–7] Periprocedural strokes for transfemoral CAS can occur both ipsilateral and contralateral to the target lesion and in the presence of an embolic protection device, thereby validating the concerns for excessive intraprocedural aortic arch manipulation and inadequate cerebral protection.[3,8]

TransCarotid Artery Revascularization (TCAR) with the ENROUTE transcarotid flow reversal neuroprotection system (Silk Road Medical, Sunnyvale, CA) has been developed as a novel technique for carotid revascularization. TCAR attempts to minimize the risks of cerebral embolization by gaining access of the common carotid artery directly to avoid the aortic arch and using temporary dynamic flow reversal prior to crossing the carotid lesion. The favorable 30-day perioperative stroke rate of 1.4% in the multicenter ROADSTER trial has helped promote TCAR as a reasonable alternative to transfemoral carotid stenting.[9]

However, studies comparing the outcomes of TCAR with other standard forms of carotid revascularization are needed to confirm the safety of this minimally invasive procedure outside of highly selected patients and providers. Through a collaborative effort between the Society for Vascular Surgery (SVS), the US Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS), the TCAR surveillance project (TSP) was designed to evaluate the outcomes after TCAR within the centers participating in the Vascular Quality Initiative (VQI). Using this large quality improvement database, we assessed contemporary real-world outcomes of TCAR compared to CEA.

Methods

Dataset

All consecutive patients undergoing TCAR with the ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Sunnyvale, CA) and CEA were identified in the SVS-VQI database from January 2016 to March 2018. All patients undergoing TCAR in the VQI are enrolled in the SVS-VQI TSP, a trial registered on clinicaltrials.gov. The VQI collects over 200 patient/procedure specific variables and in-hospital outcome data from over 450 centers and 3,200 physicians in the United States and Canada. Additionally, 30-day mortality is determined though linkage to the Social Security Death Index (SSDI). The VQI-TSP was launched by the SVS Patient Safety Organization (PSO) in 2016 and is designed to evaluate the safety and effectiveness of TCAR in high surgical risk, asymptomatic and symptomatic patients using FDA-approved or FDA-cleared devices labeled for the transcarotid approach. Additional information on the VQI and TSP is available at www.vascularqualityinitiative.org. The VQI Research Advisory Committee approved this study. Permission to use VQI data, without the need for informed consent due to the retrospective, de-identified nature of the data, was obtained from the Institutional Review Board at Beth Israel Deaconess Medical Center.

Patients and Cohorts

We identified 1,202 TCAR cases and 11,211 CEA cases performed between 2016–2018. Both symptomatic and asymptomatic patients were included as well as elective, urgent, or emergent procedures. TCAR patients were identified by CAS procedure with carotid approach and use of the ENROUTE Transcarotid Neuroprotection System for flow reversal. For TCAR, 21 patients were excluded for tandem (N=10, 0.8%), traumatic (N=1, 0.08%), dissection, (N=2, 0.2%) or non-atherosclerotic/dysplastic lesions (N=8, 0.7%). For CEA, patients undergoing concomitant procedures (N=414, 3.7%) were excluded, resulting in a total of 1,182 TCAR cases and 10,797 CEA patients for analysis.

Variable Definitions

Coronary artery disease (CAD) was defined as any history of myocardial infarction, stable angina, or unstable angina. Congestive heart failure (CHF) was defined as history of CHF resulting in any limitation in physical activity. Chronic obstructive pulmonary disease (COPD) included any history of COPD, whether not treated, on medical treatment or home oxygen therapy. Chronic kidney disease (CKD) was defined as GFR less than 60, calculated by the CKD-EPI formula using preoperative creatinine values. Platelet inhibitor therapy,

other than aspirin, included clopidogrel, prasugrel, ticlopidine, or ticagrelor use. Aspirin and platelet inhibitors are recorded if taken within 36 hours of procedure. Pre-operative symptom status was defined as presence of ipsilateral cortical or ocular symptoms, either transient ischemic attack (TIA) or stroke, prior to intervention.

Outcomes

The primary outcome was perioperative stroke/death, a composite endpoint of in-hospital stroke and in-hospital death. Stroke was defined as either ipsilateral or contralateral vertebrobasilar or cortical strokes. In the VQI dataset, focal neurologic deficits lasting greater than 24 hours are considered strokes, whereas symptoms lasting less than 24 hours are TIAs. TIA events were not included in the composite endpoint of stroke/death. Secondary outcomes included composite stroke/death/myocardial infarction (MI), stroke, TIA, in-hospital mortality, 30-day mortality, MI, hemodynamic instability, reperfusion syndrome, dysrhythmia, acute CHF exacerbation, cranial nerve injury, access site bleeding, operative time, length of stay, and discharge disposition. Cranial nerve injuries include cranial nerve deficits that occurred following the procedure and persisted until time of discharge. Access site bleeding was defined as bleeding resulting in return to the operating room or needing any surgical/interventional treatment. Length of stay was categorized as post-procedural length of stay greater than one day and length of stay greater than two days. Patients with failed discharge home or length of stay greater than 2 days, a quality metric reported by the CMS, were identified. Patients are considered to be discharged “home” as long as they went back to where they came from prior to the operation, even if their home was a nursing home or rehab. Hemodynamic instability was defined as postoperative hypertension or hypotension requiring more than one dose or continuous infusion of intravenous blood pressure medication for 15 minutes or longer. Procedure time was measured from the start of skin incision to the time of closure.

Statistical Analysis

Continuous variables were presented as mean ± standard deviation or median with interquartile range (IQR). Categorical variables were presented as counts and percentages. Comparisons were made between patients undergoing TCAR and patients undergoing CEA. Univariate differences between cohorts were assessed using $\chi 2$ and Fisher’s exact tests for categorical variables and Student’s t-test or rank-sum test for continuous variables where appropriate. All tests were two-sided and $P < .05$ was considered statistically significant. Multivariable logistic regression was utilized to evaluate perioperative outcomes while adjusting for baseline patient characteristics. The risk factors used in these models were selected based on clinical judgment and the results of bivariate analysis. Variables included in the multivariable analysis included age, gender, ethnicity, symptom status, hypertension, COPD, CKD, prior smoker, current smoker, prior limb amputation, prior ipsilateral CAS or CEA, aspirin, platelet inhibitor, statin, and ACEi use. Observations were clustered with respect to centers to reduce the bias from hospital-level factors and to account for intergroup correlation. The C-statistic and Hosmer-Lemeshow goodness-of-fit tests were used to assess the discrimination and calibration of the multivariable models, respectively. Stata/SE 14.1 (StatCorp, College Station, TX) was used for all analysis.

Results

Demographics and Comorbidities

Of the 11,979 patients identified, 10,797 (90%) were treated with CEA and 1,182 (10%) with TCAR. Compared to patients undergoing CEA, TCAR patients were older (median age, 74 vs 71 years, $P < .001$) and more often white (91 vs 89%, $P = .02$) (Table I). They had more baseline comorbidities including CAD (55 vs 28%, $P < .001$), CHF (20 vs 11%, $P < .001$), COPD (29 vs 23%, $P = < .001$), CKD (39 vs 34%, $P = .001$), dialysis dependence (2.0 vs 0.9%, $P = .001$), and had higher rates of prior limb amputation (2.9 vs 0.8%, $P < .001$). They were more likely to be on aspirin (90 vs 82%, $P < .001$), platelet inhibitors (86 vs 35%, $P < .001$), statin (88 vs 81%, $P < .001$), beta-blocker (57 vs 53%, $P < .01$), and anticoagulation medication (14 vs. 9.9%, $P = <.001$) preoperatively.

Symptom Status and Anatomic/Operative Characteristics

In both cohorts, more patients were treated for asymptomatic disease compared to symptomatic disease (Table II). However, patients undergoing TCAR were more likely to be treated for symptomatic carotid stenosis compared to patients undergoing CEA (32 vs 27%, $P < .001$). TCAR patients were more likely to undergo redo carotid intervention given higher rates of prior ipsilateral CEA (16 vs 1.9%, $P <.001$). They were also more likely to have a prior contralateral CEA or CAS (20 vs 14%, $P < .001$) or contralateral carotid occlusion (10 vs 4.2%, P < .001). Most patients in both cohorts underwent general anesthesia for carotid revascularization, but compared to patients undergoing CEA, patients undergoing TCAR were more often treated under local or regional anesthesia (20 vs 6.5%, $P < .001$).

Outcomes following TCAR and CEA

No significant differences were found in terms of composite stroke or death following TCAR and CEA on unadjusted analysis (1.6 vs 1.4%, $P = .33$) (Table III). Neither any stroke alone (1.4 vs 1.2%, $P = .68$) nor ipsilateral cortical stroke (1.2 vs 0.9%, $P < .33$) was significantly higher after TCAR. Even in patients with contralateral carotid occlusions, there no differences in post-operative stroke (0.0 vs 1.4, P = .20). Additionally, there were no overall differences found for MI (1.1 vs 0.6%, $P =.11$) or the combined endpoint of stroke/death/MI (2.5 vs 1.9%, $P =.16$). However, TCAR was associated with lower rates of cranial nerve injuries (0.6 vs. 1.8%, $P <.001$) and shorter operative times (78 vs 111 minutes, $P <.001$).

Post-operative hypertensive hemodynamic instability was less common after TCAR (10 vs 21%, $P <.001$), but hypotensive instability was more common (13 vs 9.8%, $P < .01$). Despite higher rates of hypertensive hemodynamic instability in patients undergoing CEA, there were no differences in rates of reperfusion syndrome (0.3 vs 0.1%, $P = .28$). Patients undergoing TCAR had similar length of stay (median 1 vs 1 day, $P = .59$), however, patients undergoing TCAR were less likely to have length of stay for more than 1 day (27 vs 30%, $P = .046$). There were no differences in terms of failed discharge home (5.9 vs 6.1%, $P = .88$), length of stay greater than 2 days (14 vs 14%, $P = .73$), or the composite endpoint of failed discharge home or length of stay greater than 2 days (16 vs 16%, $P = .50$)

Following multivariable adjustment for baseline differences, there were no differences in the composite endpoints of stroke/death for TCAR compared to CEA (OR 1.3, 95% CI 0.8–2.2, $P = .28$, OR>1 favors CEA) and stroke/death/MI (OR 1.4, 95% CI 0.9–2.1, $P = .18$) (Table IV). On both adjusted and unadjusted analysis, there was a trend towards more major adverse events following TCAR compared to CEA, except for in-hospital death. Because the difference in stroke/death rates between CEA and TCAR was only 0.2%, a substantially larger sample size of 46,000 per group would be needed to detect such a difference. Therefore, the small difference found between CEA and TCAR in terms of stroke/death is clinically insignificant.

Outcomes following TCAR and CEA fo r Redo Carotid Intervention

Although TCAR was more commonly used for redo carotid intervention, there was no difference seen in major adverse events including perioperative stroke (1.9 vs 1.6%, $P = .80$) and stroke/death (2.9 vs 1.6, $P = 0.35$) (Table V). Both TCAR and CEA had similar rates of failed discharge home or length of stay greater than 2 days (12 vs 12%, $P = .99$). There was a trend towards lower rates of cranial nerve injuries for TCAR compared to CEA in this cohort, however the difference was not statistically significant (0.0 vs 2.0%, $P = .07$). TCAR for redo carotid intervention had significantly shorter operative times by almost 40 minutes compared to CEA (83 vs 120 mins, $P < .001$).

Outcomes following TCAR and CEA by Symptom Status

On unadjusted analysis, asymptomatic patients undergoing TCAR were more likely to have a post-operative MI (1.3 vs 0.5%, $P < .01$), dysrhythmia (2.3 vs 1.2%, $P < .01$), and hypotensive hemodynamic instability (12 vs 9.4%, $P < .01$), but were less likely to have hypertensive hemodynamic instability (10 vs 20%, $P < .01$) (Table VI). Whereas all outcomes were similar for symptomatic patients undergoing TCAR compared to CEA, except for hypertensive hemodynamic instability, which was less common after TCAR (11 vs 23%, $P < .001$).

In the symptomatic cohort, there was a trend towards higher rates of stroke (2.4 vs 1.5%, $P = 0.19$) and stroke/death (2.7 vs 1.6%, $P = .16$) after TCAR on univariate analysis, however these differences were not statistically significant. After adjustment for baseline differences, no differences were found between TCAR and CEA for any major adverse event in either symptomatic or asymptomatic patients (Table VII). We further evaluated if the trend in higher stroke rates following TCAR in the symptomatic cohort was due to differences in preoperative neurological injury severity. For patients undergoing TCAR or CEA for TIA symptoms, there were no differences in major adverse events on univariate analysis (stroke/death: 1.8 vs 1.3%, $P = .63$, respectively) or after adjustment for baseline differences (OR 1.7, 95%CI 0.3–8.7, $P = .50$). Similarly, for symptomatic patients presenting with preoperative stroke, no differences were found on univariate (2.9 vs 2.3%, $P = .67$) or multivariable analysis (OR 1.4, 95%CI 0.54.0, $P = .50$).

Discussion

This study provides evidence that TCAR has similar rates of perioperative stroke, death, and MI compared to the gold standard for carotid revascularization, CEA. These outcome similarities were found for treatment of either asymptomatic or symptomatic disease and for redo carotid interventions. Additionally, due to the less invasive nature of the operation, TCAR had the added benefit of shorter operative times and decreased rates of cranial nerve injuries. These findings suggest that TCAR is a safe alternative for carotid revascularization.

Treatment of carotid stenosis has evolved with the rapid expansion of endovascular technology for atherosclerotic disease. CAS, in particular, has been subject to close scrutiny, as highlighted by the multiple randomized controlled trials comparing outcomes of transfemoral CAS versus CEA.[3,8,10–12] Most of these studies have shown significant discrepancies in major adverse events, including higher stroke rates following transfemoral CAS compared to CEA, particularly in symptomatic patients.

Although long-term stroke prevention is the primary goal for carotid revascularization, perioperative iatrogenic strokes caused by the intervention itself remain an important concern. Several studies have reported a significantly higher frequency of new ischemic lesions after CAS compared to CEA on diffusion-weighted imaging (DWI).[13] A strong focus has therefore been placed on developing techniques to decrease stroke rates during carotid stenting, specifically during timepoints when these microembolic events can occur. The maneuvers at highest risk of causing stroke are likely manipulation of the aortic arch to cannulate the common carotid artery, crossing the carotid lesion, and stent deployment.[14,15]

TCAR circumvents these high-risk maneuvers by not only avoiding the aortic arch with direct access to the common carotid artery, but also with use of flow reversal. Current embolic protection devices rely on placement of a filter distal to the carotid lesion; however, the lesion must still be crossed first with a wire and constrained filter to deploy the device distally, during which there is no embolic protection. Furthermore, microembolic events can occur even with the embolic filter device deployed, either due to incomplete apposition of the filter to the vessel wall, filter porosity, or thrombus formation on the distal filter surface.[15,16] The ENROUTE flow reversal system used during TCAR allows for flow reversal in the carotid artery prior to crossing the carotid lesion, thus providing added protection during the entirety of the case.[17] The neuroprotective effects found with flow reversal have been promising, with evidence that cerebral embolic rates on DWI imaging are similar to those found during CEA.[18] Given these potential benefits, TCAR has emerged as a promising option for carotid artery stenting.

The VQI TSP registry was designed to prospectively collect data on TCAR procedures as a quality improvement project. Whereas the current published data on the safety and efficacy of TCAR reflect only that of highly selective providers and centers within clinical trials, this surveillance project instead allows for real-world evaluation of patients treated with TCAR. Additionally, because there are no randomized controlled trials comparing TCAR to other established methods of carotid revascularization, this retrospective analysis is an important step in the initial evaluation of outcomes between TCAR and CEA.

We found that patients selected for TCAR were older and had more comorbidities. This is expected given that TCAR is currently only reimbursed if performed in high-risk patients based on CMS criteria. Although it is unclear whether transfemoral CAS is any safer than CEA in high-risk patients, a well-accepted indication to perform CAS instead of CEA is for redo carotid intervention given presence of scar tissue and for patients with significant co-morbidities.[19,20]. Despite these resulting baseline differences between our TCAR and CEA cohorts, we found no differences in terms of stroke or stroke/death in the unadjusted or adjusted analyses. The postoperative stroke rate of 1.4% found in this study is similar to that found in the ROADSTER trial, which showed a 1.4% 30-day stroke rate and a 2.8% 30-day stroke/death rate.[9] The stroke/death rate in our study was lower at 1.6%, which likely reflect differences in in-hospital versus 30-day outcome reporting. With most patients discharged just one day following TCAR, some adverse events are likely to occur after discharge and will therefore not be captured in this study. We have previously shown the importance of evaluating 30-day outcomes over in-hospital outcomes given the significant number of major adverse events that occur post-discharge following carotid revascularization.[21]

Compared to results from the CREST trial, which showed a 30-day 2.3% perioperative stroke rate following CEA and a 4.1% stroke rate following transfemoral CAS with embolic filter protection (used in 96.1% of patients), we found lower in-hospital stroke rates following both CEA (1.2%) and TCAR (1.4%).[3] Although these differences are partially due to a reporting bias of only in-hospital events, the extrapolated 30-day stroke rate after CEA in this study is still lower at 1.8% compared to CREST, which is estimated based on prior findings that 33% of strokes after CEA occur post-discharge.[21] This difference is likely because the VQI does not require institutions to perform formal neurological evaluations following carotid revascularization, which can lead to an under-reporting of true neurologic events. However, this reporting bias is unlikely to affect our comparisons between TCAR vs CEA within the VQI database. Lastly, the low stroke rate following TCAR may reflect the benefit of an improved embolic protection system with flow-reversal and avoidance of the aortic arch.

Additional factors used to evaluate the advantage a new carotid revascularization technique include operative efficiency, recovery time, and safety. TCAR operative times were found to be more than 30 minutes shorter than traditional CEA. This benefit was also seen in patients undergoing redo carotid interventions. TCAR may lead to cost-saving benefits with earlier discharges because hospitals can incur a financial loss for patients who stay more than one postoperative day after carotid revascularization.[22] Lastly, TCAR is more often performed under local/regional anesthesia compared to CEA, thereby minimizing the theoretical cardiovascular and cognitive risks associated with general anesthesia. As TCAR techniques continue to improve, it is possible that more cases will be performed under local or regional anesthesia rather than general anesthesia.

This study must be interpreted in the context of its design and the database used. Based on the retrospective nature of this study, the treating physician determined the selection for carotid revascularization and therefore no randomization occurred between treatment options. VQI outcomes are limited to only in-hospital events and a 30-day mortality variable through linkage with the SSDI, so outcomes such as post-operative stroke and MI are only

captured during the index hospitalization. Clinical registries such as the VQI are subject to coding error and selection bias given voluntary participation in the VQI. However, given the size of the VQI dataset, this is unlikely to have a large effect and is unlikely to selectively affect one treatment versus another. Additionally, the VQI reviews all data to ensure capture of procedures and outcomes including deaths, as well as audits select institutions with outlying outcome data.

Although we found no statistical difference in major adverse events following TCAR versus CEA, there is a possibility of type II error given the relatively small number of TCAR patients studied. For the primary outcome of stroke/death, the difference of 0.2% would not be clinically meaningful even if it were statistically significant. However, larger subgroup analyses may yield clinically significant differences particularly in symptomatic patients. Future follow-up studies using the VQI-TSP database once more patients undergoing TCAR are captured will help clarify these findings.

Conclusions

Despite a substantially higher medical risk in patients undergoing TCAR, we found similar rates of in-hospital post-operative stroke, stroke/death, and stroke/death/MI between TCAR and CEA. These outcome similarities remained even after adjustment for baseline differences. TCAR was found to have added benefits of shorter operative times and decreased rates of cranial nerve injuries. These data suggest that TCAR is a safe and effective alternative for carotid revascularization, however, studies with longer term follow-up and larger samples sizes are needed to confirm the equivalence of TCAR compared to CEA.

Acknowledgments

PL is supported by the Harvard-Longwood Research Training in Vascular Surgery NIH T32 Grant 5T32HL007734–22

Reference

1. Eslami MH, Rybin DV, Doros G, Farber A. The Association of Publication of Center for Medicaid and Medicare Services Guidelines for Carotid Artery Angioplasty and Stenting (CAS) and CREST Results on the Utilization of CAS in Carotid Revascularization In: Annals of Vascular Surgery. 2015.
2. Salzler GG, Farber A, Rybin DV, Doros G, Siracuse JJ, Eslami MH. The association of Carotid Revascularization Endarterectomy versus Stent Trial (CREST) and Centers for Medicare and Medicaid Services Carotid Guideline Publication on utilization and outcomes of carotid stenting among “high-risk” patients. In: Journal of Vascular Surgery. 2017.
3. Brott TG, Hobson RW, Howard G, Roubin GS, Clark WM, Brooks W, et al. Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis. N Engl J Med. 2010;
4. Moresoli P, Habib B, Reynier P, Secrest MH, Eisenberg MJ, Filion KB. Carotid Stenting Versus Endarterectomy for Asymptomatic Carotid Artery Stenosis: A Systematic Review and Meta-Analysis. Stroke. 2017.
5. Sardar P, Chatterjee S, Aronow HD, Kundu A, Ramchand P, Mukherjee D, et al. Carotid Artery Stenting Versus Endarterectomy for Stroke Prevention: A Meta-Analysis of Clinical Trials. J Am Coll Cardiol. 2017 5 9;69(18):2266–75. [PubMed: 28473130]

6. Cui L, Han Y, Zhang S, Liu X, Zhang J. Safety of Stenting and Endarterectomy for Asymptomatic Carotid Artery Stenosis: A Meta-Analysis of Randomised Controlled Trials. European Journal of Vascular and Endovascular Surgery. 2018.
7. Gurm HS, Yadav JS, Fayad P, Katzen BT, Mishkel GJ, Bajwa TK, et al. Long-term results of carotid stenting versus endarterectomy in high-risk patients. N Engl J Med. 2008;
8. Yadav JS, Wholey MH, Kuntz RE, Fayad P, Katzen BT, Mishkel GJ, et al. Protected Carotid-Artery Stenting versus Endarterectomy in High-Risk Patients. N Engl J Med. 2004;
9. Kwolek CJ, Jaff MR, Leal JI, Hopkins LN, Shah RM, Hanover TM, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal.J Vasc Surg. 2015;
10. Rosenfield K, Matsumura JS, Chaturvedi S, Riles T, Ansel GM, Metzger DC, et al. Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis. N Engl J Med. 2016;
11. Ederle J, Dobson J, Featherstone RL, Bonati LH, van der Worp HB, de Borst GJ, et al. Carotid artery stenting compared with endarterectomy in patients with symptomatic carotid stenosis (International Carotid Stenting Study): an interim analysis of a randomised controlled trial. Lancet. 2010;
12. Mas J-L, Chatellier G, Beyssen B, Branchereau A, Moulin T, Becquemin P, et al. Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. N Engl J Med. 2006;
13. Schnaudigel S, Gröschel K, Pilgram SM, Kastrup A. New brain lesions after carotid stenting versus carotid endarterectomy: a systematic review of the literature. Stroke. 2008;
14. Ackerstaff RGA, Suttorp MJ, Van Den Berg JC, Overtoom TTC, Vos JA, Bal ET, et al. Prediction of early cerebral outcome by transcranial Doppler monitoring in carotid bifurcation angioplasty and stenting. J Vasc Surg. 2005;
15. Vos JA, van den Berg JC, Ernst SMPG, Suttorp MJ, Overtoom TTC, Mauser HW, et al. Carotid Angioplasty and Stent Placement: Comparison of Transcranial Doppler US Data and Clinical Outcome with and without Filtering Cerebral Protection Devices in 509 Patients. Radiology. 2005;
16. Müller-Hülsbeck S, Jahnke T, Liess C, Glass C, Paulsen F, Grimm J, et al. In vitro comparison of four cerebral protection filters for preventing human plaque embolization during carotid interventions. J Endovasc Ther. 2002;
17. Alpaslan A, Wintermark M, Pintér L, Macdonald S, Ruedy R, Kolvenbach R. Transcarotid artery revascularization with flow reversal: The PROOF study. J Endovasc Ther. 2017;
18. Pinter L, Ribo M, Loh C, Lane B, Roberts T, Chou TM, et al. Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF Study. J Vasc Surg. 2011;
19. Hicks CW, Nejim B, Locham S, Aridi HD, Schermerhorn ML, Malas MB. Association between Medicare high-risk criteria and outcomes after carotid revascularization procedures. J Vasc Surg. 2018;
20. Schermerhorn ML, Fokkema M, Goodney P, Dillavou ED, Jim J, Kenwood CT, et al. The impact of Centers for Medicare and Medicaid Services high-risk criteria on outcome after carotid endarterectomy and carotid artery stenting in the SVS Vascular Registry. J Vasc Surg. 2013;
21. Fokkema M, Bensley RP, Lo RC, Hamden AD, Wyers MC, Moll FL, et al. In-hospital versus postdischarge adverse events following carotid endarterectomy. In: Journal of Vascular Surgery. 2013.
22. Glaser J, Kuwayama D, Stone D, Schanzer A, Eldrup-Jorgensen J, Powell R, et al. Factors that determine the length of stay after carotid endarterectomy represent opportunities to avoid financial losses. J Vasc Surg. 2014;

ARTICLE HIGHLIGHTS

Type of research:

Retrospective analysis of prospectively collected data from the Vascular Quality Initiative TCAR Surveillance Project registry.

Key Finding:

Rates of in-hospital post-operative stroke, stroke/death, and stroke/death/MI were similar between 1,182 patients who underwent transcarotid artery revascularization (TCAR) and 10,797, who had carotid endarterectomy. TCAR has added benefits of shorter operative times and decreased rates of cranial nerve injuries.

Take Home Message:

In this study TCAR was a safe and effective alternative for carotid revascularization.

Table I.

Preoperative Characteristics of Patients with Carotid Stenosis undergoing TCAR and CEA

	TCAR N = 1,182 (%)	CEA N = 10,797 (%)	*P*-value
Age, median (IQR)	74 (66–79)	71 (64–77)	**<.001**
Male	63	60	.10
White	91	89	**0.02**
BMI, median (IQR)	28 (24–32)	28 (25–32)	.73
Coronary Artery Disease	55	28	**<.001**
CHF	20	11	**<.001**
Hypertension	91	89	.09
COPD	29	23	**<.001**
Diabetes	37	36	.50
Chronic Kidney Disease	39	34	**.001**
Dialysis Dependence	2.0	0.9	**.001**
Prior Limb Amputation	2.9	0.8	**<.001**
Smoking History			**<.01**
Never	23	27	
Prior	52	48	
Current	26	26	
Preoperative Medications			
Aspirin	90	82	**<.001**
Platelet inhibitor	86	35	**<.001**
Statins	88	81	**<.001**
Beta Blockers	57	53	**<.01**
Anticoagulants	14	9.9	**<.001**
ACE inhibitors	54	53	0.7
Ambulatory Status			**<.001**
Ambulatory	96	90	
Ambulation with assistance	3.8	9.1	
Wheelchair	0.0	1.3	
Bedridden	0.2	0.1	
Insurance			**<.001**
Medicare	67	57	
Medicaid	3.5	4.2	
Private	30	39	
Transfer Status			**<.01**
None	94	96	
Hospital	6.2	4.1	
Rehabilitation	0.3	0.4	

ACE, angiotensin converting enzyme; BMI, body mass index; CEA, carotid endarterectomy; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; IQR, interquartile range; TCAR, transcarotid artery revascularization. Bolded values indicate statistical significance at $P < .05$.

Table II.

Preoperative Symptom Status and Anatomic/Operative Characteristics

	TCAR N = 1,182 (%)	CEA N = 10,797 (%)	*P*-value
Symptomatic	32	27	**<.001**
Degree of ipsilateral stenosis			**<.001**
0–49%	2.2	3.2	
50–69%	11	12	
70–79%	28	33	
80–99%	59	50	
Occluded	0.6	1.8	
Contralateral carotid occlusion	10	4.2	**<.001**
Prior carotid intervention			
Ipsilateral CEA	16	1.9	**<.001**
Ipsilateral CAS	0.6	0.3	**0.12**
Ipsilateral CEA and CAS	0.7	0.1	**<.001**
Contralateral CEA or CAS	20	14	**<.001**
Urgency of operation			**<.001**
Elective	91	87	
Urgent	9.1	12	
Emergent	0.1	0.6	
Anesthesia type			**<.001**
Local/Regional	20	6.5	
General	80	94	
Anticoagulation during case	99	99	.83
Protamine	75	74	.35

CAS, carotid artery stenting; CEA, carotid endarterectomy; TCAR, transcarotid artery revascularization. Bolded values indicate statistical significance at $P < .05$.

Table III.

Unadjusted Outcomes following CEA and TCAR

	TCAR N = 1,182 (%)	CEA N = 10,797 (%)	*P*-value
Stroke/Death	1.6	1.4	.33
Stroke/Death/MI	2.5	1.9	.16
Stroke	1.4	1.2	.68
Ipsilateral stroke	1.2	0.9	.33
Transient Ischemic Attack	0.9	0.5	.11
In-hospital Death	0.3	0.3	.88
30-day Death	0.9	0.4	.06
Myocardial Infarction	1.1	0.6	.11
Hemodynamic Instability			
Hypertension	10	21	**<.001**
Hypotension	13	9.8	**<.01**
Reperfusion Syndrome	0.3	0.1	.28
Dysrhythmia	1.8	1.3	.15
Acute CHF	0.3	0.4	.58
Cranial Nerve Injury	0.6	1.8	**<.001**
Access site bleeding	1.7	1.2	0.18
Operative time, minutes, mean ± SD	78 ± 33	111 ± 43	**<.001**
LOS, days, median, (IQR)	1 (1–2)	1 (1–2)	.59
LOS >1 day	27	30	**.046**
LOS >2 days	14	14	.73
Failed discharge home	5.9	6.1	.88
Failed discharge home or LOS >2 days	16	16	.50

CEA, carotid endarterectomy; CHF, congestive heart failure; ECG, electrocardiography; IQR, interquartile range; LOS, length of stay; MI, myocardial infarction; SD, standard deviation; TCAR, transcarotid artery revascularization. Bolded values indicate statistical significance at $P < .05$.

Table IV.

Adjusted Analysis Comparing TransCarotid Artery Stenting to Carotid Endarterectomy

	OR	95% CI	*P*-value
Stroke/Death	1.3	0.8–2.2	.28
Stroke/Death/MI	1.4	0.9–2.1	.18
Stroke	1.4	0.8–2.5	.26
In-hospital Death	0.7	0.3–2.1	.58
30-day Death	1.5	0.7–3.2	.34
Myocardial infarction	1.5	0.7–2.9	.29

CI, confidence interval; MI, myocardial infarction; OR, odds ratio. OR>1 favors CEA.

Table V.

Outcomes following CEA and TCAR for Redo Carotid Intervention

	TCAR N = 208 (%)	CEA N = 241 (%)	*P*-value
Stroke/Death	2.9	1.6	.35
Stroke/Death/MI	3.4	2.4	.54
Stroke	1.9	1.6	.80
In-hospital Death	1.0	0.4	.46
30-day Death	1.9	1.2	.53
Myocardial Infarction	1.4	1.2	.83
Cranial Nerve Injury	0.0	2.0	.07
Access Site Bleeding	2.4	1.2	.48
Operative Time, minutes, mean ± SD	83 ± 40	120 ± 48	**<.001**
LOS >1 day	21	24	.38
LOS >2 days	11	11	.95
Failed discharge home	4.8	3.6	.52
Failed discharge home or LOS >2 days	12	12	.99

CEA, carotid endarterectomy; LOS, length of stay; SD, standard deviation; TCAR, transcarotid artery revascularization. Bolded values indicate statistical significance at $P < .05$.

Table VI.

Unadjusted Outcomes by Symptom Status

	Asymptomatic **N=8,735**			***Symptomatic*** **N=3,239**		
	TCAR N=802 (%)	**CEA N=7933 (%)**	***P*-value**	**TCAR N=375 (%)**	**CEA N=2864 (%)**	***P*-value**
Stroke/Death	1.1	1.3	.65	2.7	1.6	.16
Stroke/Death/MI	2.2	1.7	.30	3.2	2.5	.41
Stroke	0.9	1.1	.53	2.4	1.5	.19
In-hospital Death	0.3	0.3	.57	0.3	0.2	.58
30-day Death	0.9	0.4	.07	0.8	0.5	.50
Myocardial Infarction	1.3	0.5	**<.01**	0.8	0.9	.89
Reperfusion Syndrome	0.4	0.1	.11	0.0	0.1	.53
Acute CHF	0.3	0.3	.27	0.3	0.6	.46
Dysrhythmia	2.3	1.2	**<.01**	0.8	1.6	.25
Hemodynamic Instability						
Hypertension	10	20	**<.001**	11	23	**<.001**
Hypotension	12	9.4	**<.01**	13	11	.24
Access site bleeding	1.5	1.2	.40	2.1	1.4	.30

CEA, carotid endarterectomy; CHF, congestive heart failure; Cl, confidence interval; MI, myocardial infarction; OR, odds ratio. Bolded values indicate statistical significance at $P < .05$.

Table VII.

Adjusted Analysis by Symptom Status Comparing TransCarotid Artery Stenting to Carotid Endarterectomy

	***Asymptomatic* N=8,735**			***Symptomatic* N=3,239**		
	OR	**95% CI**	***P*-value**	**OR**	**95% CI**	***P*-value**
Stroke/Death	1.1	0.5–2.3	.86	1.5	0.7–3.1	.33
Stroke/Death/MI	1.4	0.8–2.4	.20	1.1	0.6–2.2	.72
Stroke	1.1	0.5–2.5	.86	1.9	0.9–4.1	.10
In-hospital Death	0.6	0.2–2.2	.46	1.0	0.3–3.6	.95
30-day Death	1.7	0.7–4.0	.24	1.3	0.4–4.1	.64
Myocardial Infarction	1.5	0.7–3.2	.28	0.6	0.2–2.2	.44

CI, confidence interval; MI, myocardial infarction; OR, odds ratio. OR>1 favors CEA.