Title
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Publication Date
2023-08-01

DOI
10.1016/j.jvs.2023.08.118

Peer reviewed

Long-term outcomes of carotid endarterectomy vs transfemoral carotid stenting in a Medicare-matched database

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ABSTRACT

Background: Carotid endarterectomy (CEA) is associated with lower risk of perioperative stroke compared with transfemoral carotid artery stenting (TFCAS) in the treatment of carotid artery stenosis. However, there is discrepancy in data regarding long-term outcomes. We aimed to compare long-term outcomes of CEA vs TFCAS using the Medicare-matched Vascular Quality Initiative Vascular Implant Surveillance and Interventional Outcomes Network database.

Methods: We assessed patients undergoing first-time CEA or TFCAS in Vascular Quality Initiative Vascular-Vascular Implant Surveillance and Interventional Outcomes Network from January 2003 to December 2018. Patients with prior history of carotid revascularization, nontransfemoral stenting, stenting performed without distal embolic protection, multiple or nonatherosclerotic lesions, or concomitant procedures were excluded. The primary outcome of interest was all-cause mortality, any stroke, and a combined end point of death or stroke. We additionally performed propensity score matching and stratification based on symptomatic status.

Results: A total of 80,146 carotid revascularizations were performed, of which 72,615 were CEA and 7531 were TFCAS. CEA was associated with significantly lower risk of death (57.8% vs 70.4%, adjusted hazard ratio [aHR], 0.46; 95% confidence interval [CI], 0.41-0.52; $P < .001$), stroke (21.3% vs 26.6%; aHR, 0.63; 95% CI, 0.57-0.69; $P < .001$) and combined end point of death and stroke (65.3% vs 76.5%; HR, 0.49; 95% CI, 0.44-0.55; $P < .001$) at 10 years. These findings were reflected in the propensity-matched cohort (combined end point: 34.6% vs 46.8%; HR, 0.53; 95% CI, 0.46-0.62) at 4 years, as well as stratified analyses of combined end point by symptomatic status (asymptomatic: 63.2% vs 74.9%; HR, 0.49; 95% CI, 0.43-0.58; $P < .001$; symptomatic: 69.9% vs 78.3%; HR, 0.51; 95% CI, 0.45-0.59; $P < .001$) at 10 years.

Conclusions: In this analysis of North American real-world data, CEA was associated with greater long-term survival and fewer strokes compared with TFCAS. These findings support the continued use of CEA as the first-line revascularization procedure. (J Vasc Surg 2023;■:1-9.)

Keywords: ■■■

Extracranial carotid artery stenosis is a major cause of stroke, accounting for approximately 9% to 36% of all ischemic strokes.[1,2] The mainstay objective of carotid artery stenosis treatment is primary and secondary prevention of stroke, which may be accomplished via medical management, surgery, or stenting.[3] Carotid endarterectomy (CEA) has been established as an effective procedure for lowering stroke rates in patients with symptomatic carotid artery stenosis of 50% to 99% or asymptomatic stenosis of 70% to 99%.[4-6] Transfemoral carotid artery stenting (TFCAS) was introduced in the last three decades as a minimally invasive treatment option for carotid artery stenosis in patients at high surgical risk.[7,8]

Multiple previous randomized trials have compared outcomes of CEA vs TFCAS. The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) revealed that there was no difference in the primary composite end point of periprocedural stroke/death/myocardial infarction (MI) and subsequent 4-year ipsilateral stroke/death between CEA and TFCAS.[9] However, concerns arose owing to the higher incidence of periprocedural stroke associated with TFCAS, which was associated with a more significant effect on health-related quality of life at 1 year than nonfatal MI.[10] Other randomized trials and observational studies further confirmed the higher risk of periprocedural stroke after TFCAS.[11-14]

Owing to these findings, CEA remains the gold standard revascularization option, whereas TFCAS is reserved for patients who are deemed high risk for CEA owing to specific anatomical or medical risk factors.[15,16]

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Additional material for this article may be found online at www.jvascsurg.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2023.08.118

Additionally, transcarotid artery revascularization with dynamic flow reversal has emerged as a minimally invasive revascularization option with comparable results to CEA and lower perioperative stroke risk than TFCAS.[17-20] These factors, along with changes in reimbursement policies, have caused the number of TFCAS procedures to decrease significantly over the last decade.[21,22]

Although many studies have focused on the perioperative outcomes of CEA vs TFCAS, less evidence is available regarding long-term outcomes. The 10-year results from the CREST trial demonstrated no difference in the primary end point (periprocedural stroke/death/MI or postprocedural ipsilateral stroke) or postprocedural ipsilateral stroke alone.[23] However, a 2019 study of Vascular Quality initiative (VQI) data linked to Medicare by Columbo et al[24] found higher 5-year mortality after TFCAS compared with CEA. These discrepancies warrant further investigation given the uncertain role of TFCAS in the modern landscape of carotid artery stenosis management. We aimed to compare the long-term outcomes of CEA and TFCAS among a large real-world cohort of patients using the Society for Vascular Surgery (SVS) VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) database, consisting of VQI data linked to Medicare records to provide robust long-term outcomes data with granular demographic variables.

METHODS

This study is a retrospective analysis of the prospectively collected SVS VQI-VISION database. The SVS VQI is a well-validated, risk-adjusted dataset with robust documentation of demographic, procedural and postoperative variables from >800 hospitals in the United States and Canada.[25] Variables are extracted from medical records by trained reviewers and quality and accuracy is assessed with robust auditing mechanisms overseen by regional quality groups.

VISION is a partnership between the SVS VQI and MDEpiNet that aims to enhance long-term outcome variables through linkage of SVS VQI Data to Medicare claims.[26] The database accomplishes this through the use of a validated matching algorithm incorporating Current Procedural Terminology and *International Classification of Diseases*, 9th and 10th edition codes.[27] Only deidentified information from participating institutions in VQI-VISION was used for this analysis; therefore, the need for institutional review board approval and informed consent is waived for this study.

All patients undergoing first-time CEA or TFCAS between January 1, 2003, to December 31, 2018, were included in this analysis. Patients were divided into two groups based on the modality of revascularization: CEA and TFCAS. Patients with a prior history of carotid revascularization, nontransfemoral stenting, stenting performed without distal embolic protection, multiple or nonatherosclerotic lesions, or concomitant procedures were excluded.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective review of prospectively collected data
- **Key Findings:** Carotid endarterectomy was associated with a 54% reduction in risk of mortality, a 37% reduction in risk of stroke, and a 51% reduction in risk of combined death and stroke at 10 years. These findings persisted after propensity matching at 4 years and stratification by symptomatic status at 10 years.
- **Take Home Message:** These findings support the continued use of carotid endarterectomy as the first-line revascularization option in most patients owing to perioperative advantages that persist in the long term.

Baseline characteristics compared between the two groups included: age, sex, race, ethnicity, smoking, American Society of Anesthesiologists class, diabetes, hypertension, coronary artery disease (CAD), congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), chronic kidney disease, dialysis, prior coronary artery bypass grafting/percutaneous coronary intervention, prior major amputation, ipsilateral stenosis >80%, elective procedure, symptomatic presentation, and preoperative medication usage. Smoking was divided into three categories: never, prior (>1 month before procedure), and current (<1 month before procedure). Hypertension was defined as a documented blood pressure of ≥130/80 mm Hg on three or more occasions. CAD was defined as any history of angina or MI. Chronic kidney disease was defined as an estimated glomerular filtration rate of <60. Elective procedure was defined as planned or scheduled procedure not performed within 24 hours of admission. Symptomatic presentation was defined as stroke, transient ischemic attack, or amaurosis fugax within 6 months of the index operation.

Outcomes. Outcomes were compared between CEA and TFCAS patients. The primary outcome of interest was 10-year all-cause mortality, any stroke, and stroke/death. Secondary outcomes included perioperative (30-day) mortality, stroke, and stroke/death. Mortality and stroke were obtained directly from SVS-VQI Medicare-derived outcomes. Censored time from procedure was defined as the time in days from the index procedure to the corresponding outcome as documented in Medicare claims data. Additional information regarding these outcomes, including matching algorithms and methodology, may be found at https://www.vqi.org/data-analysis/svs-vqi-vision/.

Table I. Demographics

Characteristics	Unmatched (n = 80,146)			Matched (n = 5312)		
	TFCAS (n = 7531 [9.4%])	CEA (n = 72,615 [90.6%])	Standard difference	TFCAS (n = 2656 [50%])	CEA (n = 2656 [50%])	Standard difference
Year of repair						
2003	0 (0)	442 (0.6)	0.111	0 (0)	0 (0)	N/A
2004	0 (0)	502 (0.7)	0.118	0 (0)	0 (0)	N/A
2005	20 (0.3)	523 (0.7)	0.065	0 (0)	0 (0)	N/A
2006	40 (0.5)	476 (0.7)	0.016	0 (0)	0 (0)	N/A
2007	25 (0.3)	548 (0.8)	0.058	0 (0)	0 (0)	N/A
2008	25 (0.3)	697 (1.0)	0.078	0 (0)	0 (0)	N/A
2009	26 (0.3)	693 (1.0)	0.076	0 (0)	0 (0)	N/A
2010	64 (0.8)	1192 (1.6)	0.071	0 (0)	N/A[a]	0.039
2011	186 (2.5)	2247 (3.1)	0.038	0 (0)	12 (0.5)	0.095
2012	524 (7.0)	4647 (6.4)	0.022	N/A[a]	N/A[a]	0.031
2013	619 (8.2)	6798 (9.4)	0.040	13 (0.5)	N/A[a]	0.044
2014	713 (9.5)	9093 (12.5)	0.098	12 (0.5)	N/A[a]	0.084
2015	984 (13.1)	9959 (13.7)	0.019	39 (1.5)	21 (0.8)	0.064
2016	1201 (15.9)	10,453 (14.4)	0.043	155 (5.8)	121 (4.6)	0.058
2017	1502 (19.9)	12,026 (16.6)	0.088	1037 (39.0)	1085 (40.9)	0.037
2018	1602 (21.3)	12,319 (17.0)	0.110	1395 (52.5)	1406 (52.9)	0.008
Age	73 (68-79)	73 (69-79)	−0.075	73 (68-79)	73 (68-79)	0.001
Female sex	2556 (33.9)	29,110 (40.1)	0.128	931 (35.1)	961 (36.2)	0.024
Race						
White	6764 (89.8)	66,967 (92.3)	0.086	2343 (88.2)	2316 (87.2)	0.031
Black	457 (6.1)	3085 (4.3)	0.082	174 (6.6)	182 (6.9)	0.012
Other	310 (4.1)	2519 (3.5)	0.034	139 (5.2)	158 (5.9)	0.031
Hispanic ethnicity	231 (3.1)	2311 (3.2)	0.006	99 (3.7)	119 (4.5)	0.038
Smoking						
Never smoker	2194 (29.2)	19,627 (27.1)	0.047	821 (30.9)	832 (31.3)	0.009
Prior smoker	3575 (47.6)	37,552 (51.7)	0.084	1218 (45.9)	1205 (45.4)	0.010
Current smoker	1745 (23.2)	15,346 (21.2)	0.050	617 (23.2)	619 (23.3)	0.002
ASA class						
1	137 (2.0)	433 (0.6)	0.120	45 (1.7)	49 (1.8)	0.011
2	1303 (18.8)	3338 (4.8)	0.444	376 (14.2)	241 (12.8)	0.039
3	4248 (61.3)	51,815 (74.7)	0.290	1712 (64.5)	1697 (63.9)	0.012
4	1215 (17.5)	13,734 (19.8)	0.058	517 (19.5)	566 (21.3)	0.046
5	24 (0.3)	18 (<0.1)	0.074	N/A[a]	N/A[a]	0.027
Diabetes	2924 (39.0)	26,225 (36.1)	0.060	1015 (38.2)	2021 (38.4)	0.005
HTN	6556 (89.0)	65,263 (89.9)	0.030	2340 (88.1)	2381 (89.6)	0.049
CAD	2921 (39.5)	31,042 (42.7)	0.067	1151 (43.3)	1124 (42.3)	0.021
CHF	1366 (18.2)	8272 (11.4)	0.191	489 (18.4)	498 (18.8)	0.009
COPD	2097 (27.9)	16,774 (23.1)	0.109	725 (27.4)	747 (28.1)	0.019
CKD	2944 (39.1)	28,494 (39.3)	0.003	1024 (38.6)	1015 (38.2)	0.007
Dialysis	127 (1.7)	872 (1.2)	0.041	46 (1.7)	34 (1.3)	0.037
Prior CABG/PCI	2655 (38.4)	25,910 (35.7)	0.055	943 (35.5)	919 (34.6)	0.019
Prior major amputation	90 (3.0)	644 (0.9)	0.155	69 (2.6)	88 (3.3)	0.042
Ipsilateral stenosis >80%	4590 (61.9)	43,750 (61.4)	0.010	1420 (55.1)	1568 (59.8)	0.093
Elective	5544 (73.7)	64,012 (88.2)	0.379	1881 (70.8)	1839 (69.2)	0.035
Symptomatic presentation	3564 (47.4)	21,148 (29.2)	0.382	1254 (47.2)	1339 (50.4)	0.064

(Continued on next page)

Table I. Continued.

Characteristics	Unmatched (n = 80,146) TFCAS (n = 7531 [9.4%])	Unmatched CEA (n = 72,615 [90.6%])	Unmatched Standard difference	Matched (n = 5312) TFCAS (n = 2656 [50%])	Matched CEA (n = 2656 [50%])	Matched Standard difference
Preoperative medications						
ACE inhibitors	3392 (49.1)	33,326 (52.2)	0.072	1286 (48.4)	1370 (51.6)	0.064
Anticoagulant	574 (8.3)	6864 (10.9)	0.087	124 (4.7)	121 (4.6)	0.005
P2Y12 Inhibitors	5538 (73.6)	22,047 (30.4)	0.959	1858 (70.0)	1917 (72.2)	0.049
Aspirin	6376 (84.8)	60,168 (82.9)	0.049	2193 (82.6)	2234 (84.1)	0.041
Beta-blocker	4163 (55.3)	42,674 (58.8)	0.071	1394 (52.5)	1376 (51.8)	0.014
Statin	5925 (78.8)	58,812 (81.0)	0.057	2105 (79.4)	2075 (78.1)	0.028

ACE, Angiotensin-converting enzyme; *ASA*, American Society of Anesthesiologists; *CABG/PCI*, coronary artery bypass grafting/percutaneous coronary intervention; *CAD*, coronary artery disease; *CEA*, carotid endarterectomy; *CHF*, congestive heart failure; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *HTN*, hypertension; *N/A*, not applicable; *TFCAS*, transfemoral carotid artery stenting.
Values are number (%) or median (interquartile range).
[a]Censored in accordance with Centers for Medicare and Medicaid Services cell suppression policy, which prohibits reporting of nonzero values of n < 11.

Statistical analysis. Categorical baseline characteristics were compared using Pearson χ^2 test or Fisher's exact test; continuous variables were compared using two-sample *t* tests. Multivariable logistic regression analysis was used to compare adjusted perioperative outcomes, clustered by centers. Initial models included all baseline characteristics. Variables included in the final models were chosen based on clinical relevance or backward stepwise selection with a threshold of a *P* value of <.10 (Supplementary Table I, online only). Hosmer-Lemeshow tests and the area under the curve were used to assess discrimination and calibration of each model.

Kaplan-Meier analysis, log-rank tests, and Cox proportional hazards regression clustered by centers were used to compare long-term outcomes. Initial models included all baseline characteristics. Variables included in the final models were chosen based on clinical relevance or backward stepwise selection with a threshold of a *P* value of <.10 (Supplementary Table I, online only). Subanalyses were additionally performed stratifying by symptomatic presentation (asymptomatic vs symptomatic) and time period of repair (2003-2010 vs 2011-2018).

To further minimize confounding by measured baseline characteristics, we additionally performed propensity score matching. Logistic regression was used to create a propensity score relating baseline characteristics to the treatment type (CEA or TFCAS). We then performed one-to-one matching with a caliper of 0.005. Perioperative and long-term outcomes were compared within the propensity-matched cohort without further adjustment as a balanced match was achieved with all standardized differences of <0.10[28] (Table I). Owing to substantial loss of sample size in the propensity matched cohort, we were only able to provide 4-year outcomes rather than 10-year outcomes. As such, we elected to additionally provide 4-year outcomes in the unmatched cohort to provide a point of comparison.

All analyses were completed using StataSE version 16.1 (SataCorp, College Station, TX). A *P* value of <.05 was considered statistically significant. Complete case analysis was used to handle missing data. All values of <11 were censored in accordance with the Centers for Medicare and Medicaid Services cell suppression policy.

RESULTS

A total of 80,146 patients were included in this analysis, of which 72,615 (90.6%) underwent CEA and 7531 (9.4%) underwent TFCAS. The mean patient age was 73 years and 39.5% were females. In the unmatched cohort, patients undergoing CEA were more likely to be female or undergo elective intervention. Patients undergoing TFCAS were more likely to have CHF, COPD, have prior major amputation, present symptomatically, or take preoperative P2Y12 inhibitor. Propensity matching generated 2656 well-matched pairs with all standardized differences of baseline characteristics of <0.10 (Table I).

Perioperative outcomes. Patients undergoing CEA had significantly lower rates of perioperative death (0.9% vs 3.0%; *P* < .001), stroke (3.4% vs 8.4%; *P* < .001), and combined death or stroke (4.0% vs 10.3%; *P* < .001) (Table II) compared with those undergoing TFCAS. After adjusting for potential confounders, patients undergoing CEA had lower adjusted odds of death (aOR, 0.33; 95% CI, 0.25-0.43; *P* < .001), stroke (aOR, 0.44; 95% CI, 0.38-0.50; *P* < .001), and combined death or stroke (aOR, 0.39; 95% CI, 0.33-0.46; *P* < .001).

These findings persisted in the propensity-matched cohort (death: 1.2% vs 3.7%; OR, 0.31; 95% CI, 0.21-0.47;

Table II. Perioperative, 4-year, and 10-year outcomes after carotid endarterectomy (*CEA*) or transfemoral carotid artery stenting (*TFCAS*)

Outcome	TFCAS (n = 7531 [9.4%])	CEA (n = 72,615 [90.6%])	*P* value	aOR (95% CI) (REF = TFCAS)	*P* value
Perioperative					
Death	223 (3.0)	639 (0.9)	<.001	0.33 (0.25-0.43)	<.001
Stroke	631 (8.4)	2435 (3.4)	<.001	0.44 (0.38-0.50)	<.001
Stroke/death	776 (10.3)	2893 (4.0)	<001	0.39 (0.33-0.46)	<.001
Outcome	**TFCAS (n = 7531 [9.4%])**	**CEA (n = 72,615 [90.6%])**	**Log-rank *P* value**	**aHR (95% CI) (REF = TFCAS)**	***P* value**
4-Year					
Death	1736 (35.0)	10,985 (22.6)	<.001	0.46 (0.41-0.52)	<.001
Stroke	1219 (19.6)	7194 (12.6)	<.001	0.62 (0.57-0.68)	<.001
Stroke/death	2492 (45.4)	15,965 (30.6)	<.001	0.49 (0.44-0.55)	<.001
Outcome	**TFCAS (n = 7531 [9.4%])**	**CEA (n = 72,615 [90.6%])**	**Log-rank *P* value**	**aHR (95% CI) (REF = TFCAS)**	***P* value**
10-Year					
Death	2045 (70.4)	14,838 (57.8)	<.001	0.46 (0.41-0.52)	<.001
Stroke	1282 (26.6)	8144 (21.3)	<.001	0.63 (0.57-0.69)	<.001
Stroke/death	2762 (76.5)	19,785 (65.3)	<.001	0.49 (0.44-0.55)	<.001

aHR, Adjusted hazard ratio; *CI,* confidence interval.
Values are number (%) unless otherwise indicated.

P < .001; stroke: 4.3% vs 9.7%; OR, 0.41; 95% CI, 0.32-0.53; *P* < .001; and combined death/stroke: 5.2% vs 12.0%; OR, 0.40; 95% CI, 0.32-0.50; *P* < .001) (Table III).

Upon stratification by time period, patients who underwent repair between 2011 and 2018 demonstrated similar differences in perioperative outcomes (death: 0.9% vs 3.0%; aOR, 0.33; 95% CI, 0.25-0.43; *P* < .001; stroke: 3.3% vs 8.4%; aOR, 0.46; 95% CI, 0.41-0.52; *P* < .001; and combined death/stroke: 4.0% vs 10.4%; aOR, 0.39; 95% CI, 0.33-0.46; *P* < .001) (Supplementary Table I, online only). Differences in perioperative outcomes among those who underwent repair between 2003 and 2010 demonstrated a similar trend, but did not reach statistical significance (stroke: 3.8% vs 6.0%; aOR, 0.72; 95% CI, 0.41-1.27; *P* = .26; and combined death/stroke: 4.3% vs 6.0%; aOR, 0.83; 95% CI, 0.48-1.43; *P* = .49).

Long-term outcomes. Over the study period, patients undergoing CEA had significantly lower rates of all-cause mortality (4-year: 22.6% vs 35.0%; *P* < .001; 10-year: 57.8% vs 70.4%; *P* < .001), any stroke (4-year: 12.6% vs 19.6%; *P* < .001; 10-year: 21.3% vs 26.6%; *P* < .001), and combined death/stroke (4-year: 30.6% vs 45.4%; *P* < .001; 10-year: 65.3% vs 76.5%; *P* < .001) (Table II, Fig 1). After adjusting for potential confounders, patients undergoing CEA had significantly lower adjusted hazards of death (4-year: aHR, 0.46; 95% CI, 0.41-0.52; *P* < .001; 10-year: aHR, 0.46; 95% CI, 0.41-0.52; *P* < .001), stroke (4-year: aHR, 0.62; 95% CI, 0.57-0.68; *P* < .001; 10-year: aHR, 0.66; 95% CI, 0.60-0.73; *P* < .001), and combined death/stroke (4-year: aHR, 0.49; 95% CI, 0.44-0.55; *P* < .001; 10-year: aHR, 0.49; 95% CI, 0.44-0.55; *P* < .001).

At 4 years, these findings persisted in unadjusted outcomes of the propensity-matched cohort at 4 years (death: 29.9% vs 41.7%; HR, 0.51; 95% CI, 0.43-0.61; *P* < .001; stroke: 12.8% vs 18.1%; HR, 0.52; 95% CI, 0.42-0.64; *P* < .001; and combined death/stroke: 34.6% vs 46.8%; HR, 0.53; 95% CI, 0.46-0.62; *P* < .001) (Table III, Fig 2), as well as after stratifying by time period of repair (2003-2010 death: 19.9% vs 36.0%; aHR, 0.54; 95% CI, 0.41-0.71; *P* < .001; 2011-2018 death: 23.0% vs 35.0%; aHR, 0.58; 95% CI, 0.54-0.63; *P* < .001; 2003-2010 stroke: 13.1% vs 21.0%; aHR, 0.49; 95% CI, 0.37-0.64; *P* < .001; 2011-2018 stroke: 12.5% vs 19.5%; aHR, 0.63; 95% CI, 0.57-0.69; *P* < .001; 2003-2010 combined death/stroke: 28.7% vs 43.0%; aHR, 0.57; 95% CI, 0.47-0.69; *P* < .001; 2011-2018 combined death/stroke: 30.9% vs 45.6%; aHR, 0.50; 95% CI, 0.44-0.55; *P* < .001) (Supplementary Table II, Supplementary Fig 1, online only).

At 10 years, these findings additionally persisted after stratifying by symptomatic status (asymptomatic death: 56.4% vs 68.4%; aHR, 0.47; 95% CI, 0.40-0.55; *P* < .001; symptomatic death: 60.8% vs 74.9%; aHR, 0.47; 95% CI, 0.38-0.57; *P* < .001; asymptomatic stroke: 19.2% vs 24.5%; aHR, 0.53; 95% CI, 0.44-0.65; *P* < .001; symptomatic stroke: 26.2% vs 28.0%; aHR, 0.63; 95% CI, 0.57-0.70; *P* < .001; asymptomatic combined death/stroke: 63.2% vs 74.9%; aHR, 0.49; 95% CI, 0.43-0.58; *P* < .001; symptomatic combined death/stroke: 69.9% vs 78.3%; aHR, 0.51; 95% CI, 0.45-0.59; *P* < .001) (Table IV, Supplementary

Table III. Perioperative and 4-year outcomes after carotid endarterectomy (*CEA*) or transfemoral carotid artery stenting (*TFCAS*) in the propensity-matched cohort

Outcome	TFCAS (n = 2656 [50%])	CEA (n = 2656 [50%])	*P* value	OR (95% CI) (REF = TFCAS)	*P* value
Perioperative					
Death	99 (3.7)	32 (1.2)	<.001	0.31 (0.21-0.47)	<.001
Stroke	257 (9.7)	113 (4.3)	<.001	0.41 (0.32-0.53)	<.001
Stroke/death	318 (12.0)	138 (5.2)	<.001	0.40 (0.32-0.50)	<.001
Outcome	**TFCAS (n = 2656 [50%])**	**CEA (n = 2656 [50%]**	**Log-rank *P* value**	**HR (95% CI) (REF = TFCAS)**	***P* value**
4-Year					
Death	368 (41.7)	197 (29.9)	<.001	0.51 (0.43-0.61)	<.001
Stroke	356 (18.1)	193 (12.8)	<.001	0.52 (0.42-0.64)	<.001
Stroke/death	620 (46.8)	354 (34.6)	<.001	0.53 (0.46-0.62)	<.001

CI, Confidence interval; *HR*, hazard ratio; *OR*, odds ratio.
Values are number (%) unless otherwise indicated.

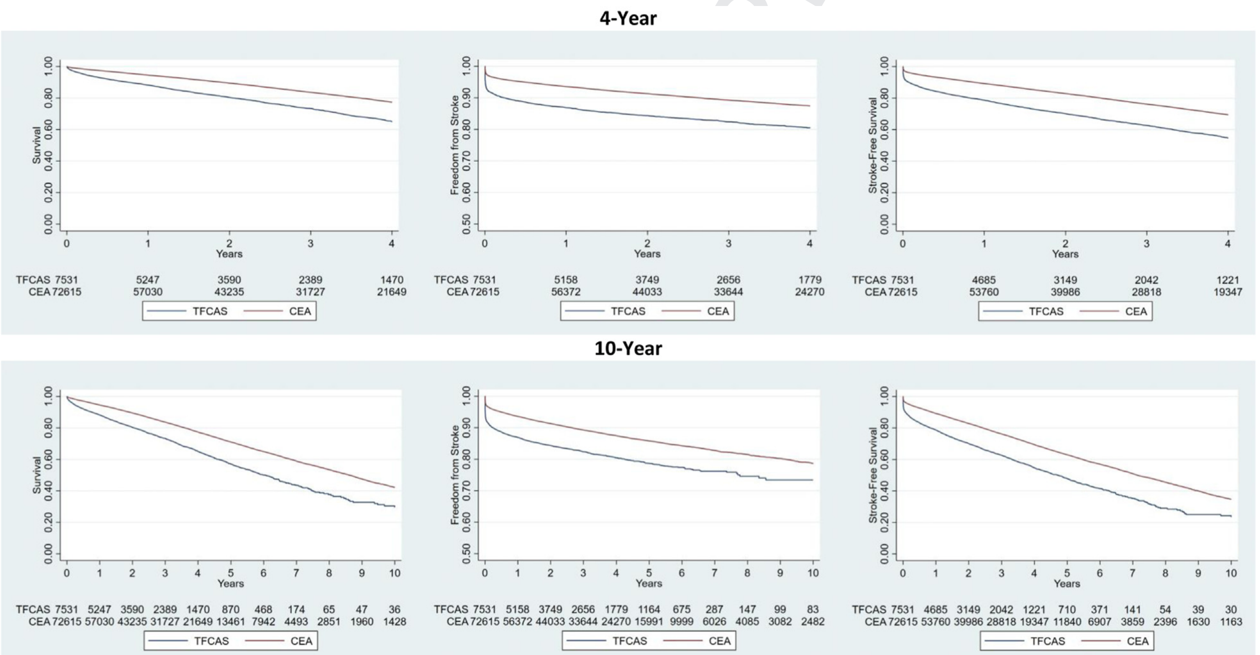

Fig 1. Four- and 10-year survival, freedom from stroke, and stroke-free survival after carotid revascularization. *CEA*, Carotid endarterectomy; *TFCAS*, transfemoral carotid artery stenting.

Fig 2, online only). Of note, the absolute difference in stroke rate among symptomatic patients (26.2% vs 28.0%) is statistically significant, but may not be clinically significant.

DISCUSSION

This study shows improved long-term durability of CEA compared with TFCAS for treatment of carotid artery stenosis in an international, real-world database. Using the Medicare-matched VQI VISION database, we found CEA to be superior to TFCAS at the 10-year follow-up with a 54% decrease in all-cause mortality, a 37% decrease in the risk of any stroke, and a 51% decrease in composite death/stroke. These findings were reflected in our one-to-one propensity score-matched analysis at 4 years, as well as stratification based on symptomatic status at 10 years.

The perioperative stroke rate observed in our study was 3.4% after CEA and 8.4% after TFCAS. These values lie within the range observed in randomized controlled trials such as the Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial (CEA 3.5%, TFCAS 9.2%),[11] the Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE) trial (CEA 6.16%, TFCAS 7.51%),[12] the International Carotid Stenting Study (ICSS)

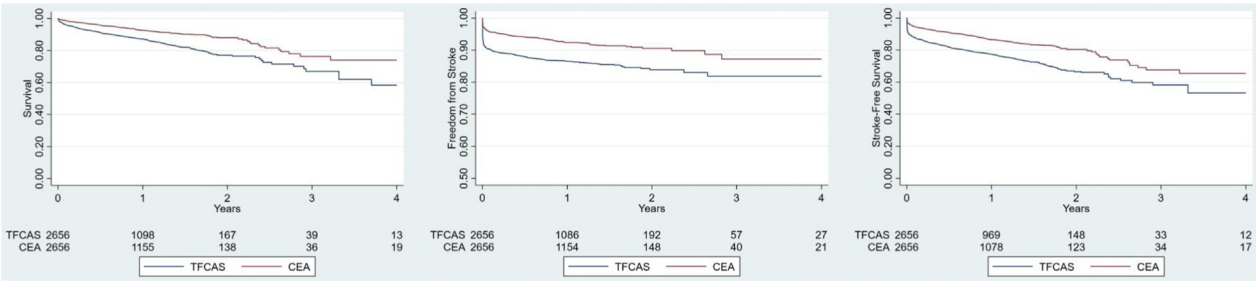

Fig 2. Four-year survival, freedom from stroke, and stroke-free survival in the propensity-matched cohort. *CEA*, Carotid endarterectomy; *TFCAS*, transfemoral carotid artery stenting.

Table IV. Ten-year outcomes after carotid endarterectomy (*CEA*) or transfemoral carotid artery stenting (*TFCAS*) stratified by symptomatic status

Outcome	TFCAS (n = 3957 [7.2%])	CEA (n = 51,369 [92.9%])	Log-rank *P* value	aHR (95% CI) (REF = TFCAS)	*P* value
Asymptomatic					
Death	1074 (68.4)	9822 (56.4)	<.001	0.47 (0.40-0.55)	<.001
Stroke	558 (24.5)	4869 (19.2)	<.001	0.53 (0.44-0.65)	<.001
Stroke/death	1377 (74.9)	12,790 (63.2)	<.001	0.49 (0.43-0.58)	<.001
Outcome	**TFCAS (n = 3564 [14.4%])**	**CEA (n = 21,148 [85.6%])**	**Log-rank *P* value**	**aHR (95% CI) (REF = TFCAS)**	***P* value**
Symptomatic					
Death	966 (74.9)	4979 (60.8)	<.001	0.47 (0.38-0.57)	<.001
Stroke	721 (28.0)	3266 (26.2)	<.001	0.63 (0.57-0.70)	<.001
Stroke/death	1379 (78.3)	6954 (69.9)	<.001	0.51 (0.45-0.59)	<.001

aHR, Adjusted hazard ratio; *CI*, Confidence interval; *OR*, odds ratio.
Values are number (%) unless otherwise indicated.

trial (CEA 4.1%, TFCAS 7.7%)[13] and CREST-1 (CEA 2.3%, TFCAS 4.1%).[9] The stroke rate in CREST-1 was notably lower than other randomized trials, likely owing to the inclusion of asymptomatic patients as well as strict inclusion and exclusion criteria and operator credentialing requirements.[29] We additionally performed a stratified analysis by time period (2003-2010 vs 2011-2018) to investigate whether outcomes may have varied over time. Our results indicate that differences in perioperative stroke rates have likely persisted over time despite advancements in endovascular technology (2003-2010: CEA 3.8%, TFCAS 6.0%; $P = .103$; 2011-2018: CEA 3.3%, TFCAS 8.4%; $P < .001$) (Supplementary Table II, online only).

In 10-year results from the CREST-1 trial, the 1607 patients who were consented for long-term follow-up did not demonstrate any difference in the primary composite end point of any stroke, MI, or death during the periprocedural period or ipsilateral stroke thereafter.[23] Additionally, there was no difference in total stroke during the postprocedural period when excluding periprocedural period (aHR, 0.99; 95% CI, 0.64-1.52; $P = .96$). However, the composite of long-term stroke or periprocedural death was higher with stenting (aHR, 1.37; 95% CI, 1.01-1.86; $P = .04$), and total stroke when taking both the periprocedural and postprocedural periods into account was borderline significant (aHR, 1.33; 95% CI, 0.98-1.80; $P = .07$). Our study augments these previous findings by providing a real-world, long-term comparison of carotid interventions.

Our results support the findings of previous observational studies evaluating the outcomes of carotid interventions. Columbo et al[24] used VQI data linked to Medicare records and found a long-term survival advantage with CEA compared with carotid stenting (aHR, 0.75; 95% CI, 0.70-0.81). The current study builds upon that work using a larger patient sample with 5 additional years of follow-up in the VQI-VISION database. Our study also had 100% Medicare matching compared with 90% to 92% in their study and adds to their work with evaluation of stroke and stroke-free survival outcomes in addition to overall survival. In a multicenter Canadian retrospective cohort study, Hussain et al[30] found higher adjusted risk of stroke (aHR, 1.56; 95% CI, 1.40-1.73; $P < .001$) and death (aHR, 1.29; 95% CI, 1.22-1.36; $P < .001$) with stenting compared with endarterectomy.

The symptomatic status of a patient with carotid artery stenosis also greatly affects interventional decision making. The gold standard for symptomatic carotid stenosis is CEA, as reflected in the 2021 SVS extracranial cerebrovascular disease guidelines which recommend CEA over TFCAS in symptomatic patients with >50% stenosis.[15,16] TFCAS is only preferred in these patients if there is a tracheal stoma, local tissue scarring, or fibrosis from prior radiation or in patients with uncorrectable CAD, CHF, or COPD. However, there is no recommended intervention modality for asymptomatic patients with >70% stenosis, with consideration of CEA, TFCAS, or transcarotid artery revascularization based on the presence or absence of high-risk features.[16]

When we stratified patients by symptomatic status in the present study, we found that the hazard ratios of death and combined stroke/death were nearly equivalent, while stroke reduction was more pronounced in the asymptomatic group (asymptomatic aHR, 0.53; symptomatic ,aHR 0.63). Our findings suggest that CEA should be prioritized over TFCAS in asymptomatic patients as well as symptomatic patients. These results are particularly relevant in the context of the ongoing CREST-2, consisting of two parallel randomized trials comparing (1) CEA plus intensive medical management (IMM) vs IMM alone and (2) TFCAS plus IMM vs IMM alone.[31] Although results from this trial are not yet available, initial data from the companion CREST-2 registry reports promising results for TFCAS with a 30-day stroke/death rate of 1.4% for asymptomatic patients.[32] The results of our study indicate that such findings should be interpreted with caution in terms of generalizability to real-world outcomes and that long-term outcomes should be followed closely.

The importance of our findings highlight the current recommendations and guidelines by several societies such as the SVS and AHA.[15,16,33] It is critical that we only perform carotid revascularization in patients with carotid artery stenosis who are likely to benefit from these procedures by decreasing the long-term risk of stroke and improving stroke-free survival. Our findings do not support the performance of TFCAS in asymptomatic patients because of the significant postoperative and long-term risk of stroke or death.

There are several limitations to consider with the present study. First and foremost, there is high potential for selection bias; patients who undergo stenting are often those with anatomical or medical contraindications to CEA, which have the potential to influence outcomes. Although we performed rigorous adjustment based on the variables available to us via both logistic regression and propensity score matching, confounding from unmeasured variables is inevitable with this retrospective study design. Additionally, the variables available to us may not fully capture the severity of preoperative comorbidities such as CAD, CHF, and COPD. These factors can all have a deleterious effect on long-term survival after TFCAS compared with CEA. Furthermore, the number cases we have here is still likely only a fraction of the overall number of carotid procedures performed over 15 years, creating additional potential for selection bias. In particular, because our cohort is composed of Medicare beneficiaries, the population was older with a median age of 73 years, which is approximately 4 years older than the population of CREST-1. This finding is relevant because age has been demonstrated as a treatment effect modifier for outcomes of CEA vs TFCAS.[34,35] As with any retrospective study, we are limited in our analysis by the variables available to us. Among our baseline characteristics, we were unable to assemble a modified 5-item frailty index owing to lack of data on functional status. Owing to lack of mortality cause, long-term stroke laterality, and MI variables in the VISION database, analysis was restricted to all-cause mortality and all strokes. We were unable to analyze stroke-specific mortality, long-term ipsilateral stroke or MI.

CONCLUSIONS

In this North American real-world study of Medicare beneficiaries, we demonstrate significantly lower rates of 10-year stroke, death, and stroke/death after CEA compared with TFCAS. These findings support the continued use of CEA as the first-line revascularization option. However, patient-specific characteristics, including comorbidities, life expectancy, and anatomical features, should be considered carefully when choosing the optimal carotid intervention. Future studies comparing long-term outcomes of transcarotid stenting with dynamic flow reversal will be needed as more data on this procedure become available.

AUTHOR CONTRIBUTIONS

Conception and design: KY, CJ, NE, IN, AS, MM
Analysis and interpretation: KY, NE, IN, MM
Data collection: Not applicable
Writing the article: KY, CJ
Critical revision of the article: KY, NE, IN, AS, MM
Final approval of the article: KY, CJ, NE, IN, AS, MM
Statistical analysis: KY, NE, IN
Obtained funding: Not applicable
Overall responsibility: MM Q6

DISCLOSURES

None.

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Submitted Feb 11, 2023; accepted Aug 22, 2023.

Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table I (online only). Final adjusted models

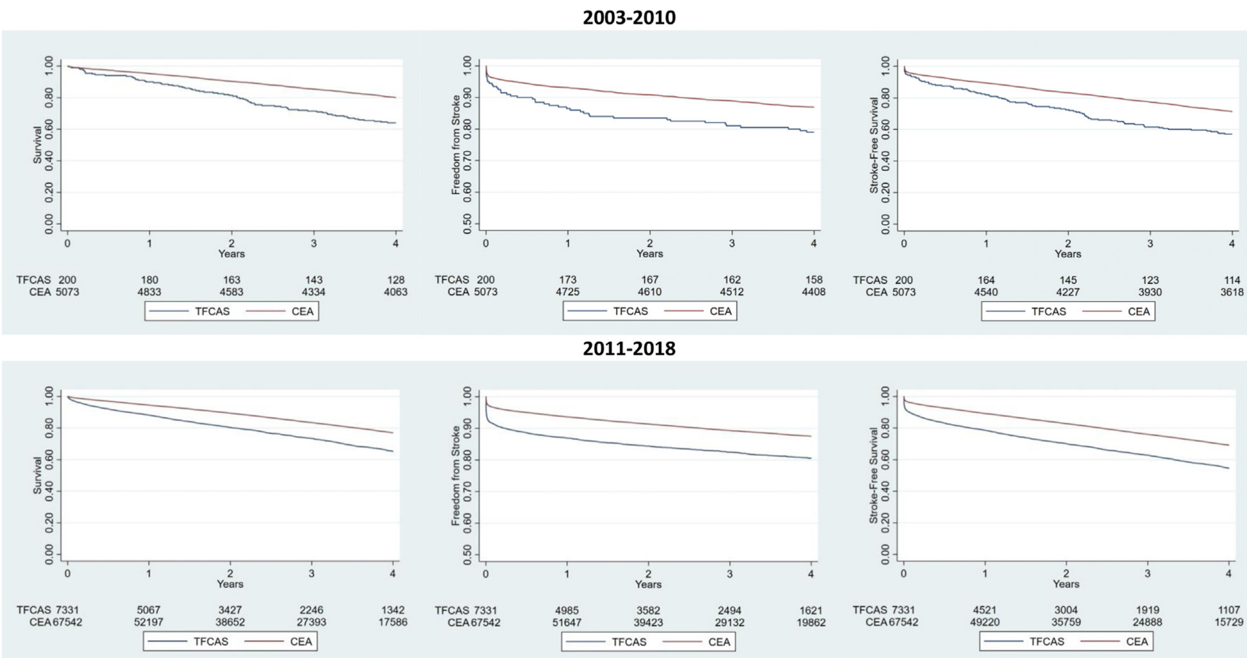
Outcome	Variables
Perioperative	
Death	Year, age, sex, smoking, DM, CAD, prior CABG/PCI, CHF, COPD, dialysis, CKD, prior major amputation, ipsilateral stenosis >80%, elective procedure, symptomatic, preoperative aspirin, statin, ASA class
Stroke	year, age, sex, race, smoking, HTN, DM, CAD, prior CABG/PCI, CHF, dialysis, CKD, elective procedure, preoperative aspirin, statin, ASA class
Stroke/death	Year, age, sex, smoking, COPD, prior major amputation, ipsilateral stenosis >80%, HTN, DM, CAD, prior CABG/PCI, CHF, dialysis, CKD, elective procedure, symptomatic, preoperative aspirin, statin, ASA class
2003-2010 - death	Year, age, sex, ethnicity, ipsilateral stenosis >80%, CHF, preoperative beta-blocker, ASA class
2003-2010 - stroke	Year, age, sex, race, smoking, ipsilateral stenosis >80%, symptomatic, elective procedure, ASA class
2003-2010 - stroke/ death	Year, age, sex, symptomatic, elective procedure, ASA class
2011-2018 - death	Year, age, sex, CKD, dialysis, DM, CAD, CHF, smoking, prior CABG/PCI, prior major amputation, ipsilateral stenosis >80%, elective procedure, symptomatic, preoperative aspirin, statin ASA class
2011-2018 - stroke	Year, age, sex, ethnicity, dialysis, CKD, CHF, HTN, DM, CAD, prior CABG/PCI, elective procedure, symptomatic, preoperative aspirin, statin, ASA class
2011-2018 - stroke/ death	Year, age, sex, ethnicity, CKD, CHF, smoking, dialysis, DM, CAD, prior CABG/PCI, ipsilateral stenosis >80%, prior major amputation, elective procedure, symptomatic, preoperative aspirin, statin, ASA class
Long term	
Death	Year, age, sex, race, smoking, diabetes, CAD, prior CABG/PCI, CHF, COPD, dialysis, CKD, prior major amputation, elective, symptomatic, preoperative beta-blocker, aspirin, statin, P2Y12 inhibitor, ASA class
Stroke	Year, age, sex, ethnicity, smoking, HTN, DM, CAD, CHF, COPD, dialysis, CKD, ipsilateral stenosis >80%, elective procedure, symptomatic, preoperative beta-blocker, aspirin, statin, P2Y12 inhibitor, ASA class
Stroke/death	year, age, sex, smoking, symptomatic, DM, CAD, prior CABG/PCI, CHF, COPD, dialysis, CKD, prior major amputation, preoperative beta-blocker, preoperative aspirin, statin, P2Y12 inhibitor, ASA class
Asymptomatic - death	Year, age, sex, race, smoking, diabetes, CAD, CHF, COPD, dialysis, CKD, prior major amputation, preoperative aspirin, beta-blocker, statin, P2Y12 inhibitor, ASA class
Asymptomatic - stroke	Year, age, sex, ethnicity, smoking, DM, CHF, COPD, dialysis, CKD, prior major amputation, ipsilateral stenosis >80%, elective procedure, preoperative aspirin, beta-blocker, statin, P2Y12 inhibitor, ASA class
Asymptomatic - stroke/death	Year, age, sex, race, smoking, DM, CAD, CHF, COPD, dialysis, CKD, prior major amputation, elective procedure, preoperative aspirin, beta-blocker, statin, P2Y12 inhibitor, ASA class
Symptomatic - death	Year, age, sex, ethnicity, smoking, DM CAD, CHF, COPD, dialysis, CKD, prior major amputation, ipsilateral stenosis >80%, elective procedure, preoperative aspirin, beta-blocker, statin, P2Y12 inhibitor, ASA class
Symptomatic - Stroke	Year, age, sex, race, CKD, smoking, HTN, DM, CAD, elective procedure, CHF, dialysis, preoperative aspirin, statin, ASA class
Symptomatic - stroke/ death	Year, age, sex, race, smoking, HTN, DM, CAD, CHF, COPD, dialysis, CKD, prior major amputation, elective procedure, preoperative aspirin, beta-blocker, statin, ASA class
2003-2010 - death	Year, age, sex, race, smoking, dialysis, COPD, CHF, CKD, CAD, DM, symptomatic, preoperative statin, ASA class
2003-2010 - Stroke	Year, age, sex, CKD, DM, symptomatic, ASA class
2003-2010 - stroke/ death	Year, age, sex, ethnicity, smoking, CKD, COPD, DM, CHF, symptomatic, preoperative beta-blocker, statin, ASA class
2011-2018 - death	Year, age, sex, smoking, dialysis, CKD, COPD, CHF, HTN, DM, CAD, prior CABG/PCI, symptomatic, ipsilateral stenosis >80%, preoperative aspirin, beta-blocker, statin, ASA class
2011-2018 - stroke	Year, age, sex, ethnicity, smoking, CKD, dialysis, DM, CAD, CHF, COPD, prior CABG/PCI, elective procedure, ipsilateral stenosis >80%, symptomatic, preoperative beta-blocker, P2Y12 inhibitor, statin, ASA class
2011-2018 - stroke/ death	Year, age, sex, , smoking, COPD, dialysis, CKD, CHF, DM, CAD, prior major amputation, prior CABG/PCI, symptomatic, elective procedure, preoperative aspirin, beta blocker, P2Y12 inhibitor, statin, ASA class

ASA, American Society of Anesthesiologists; *CABG/PCI*, coronary artery bypass graft/percutaneous coronary intervention; *CAD*, coronary artery disease; *CHF*, congestive heart failure; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *DM*, diabetes mellitus.

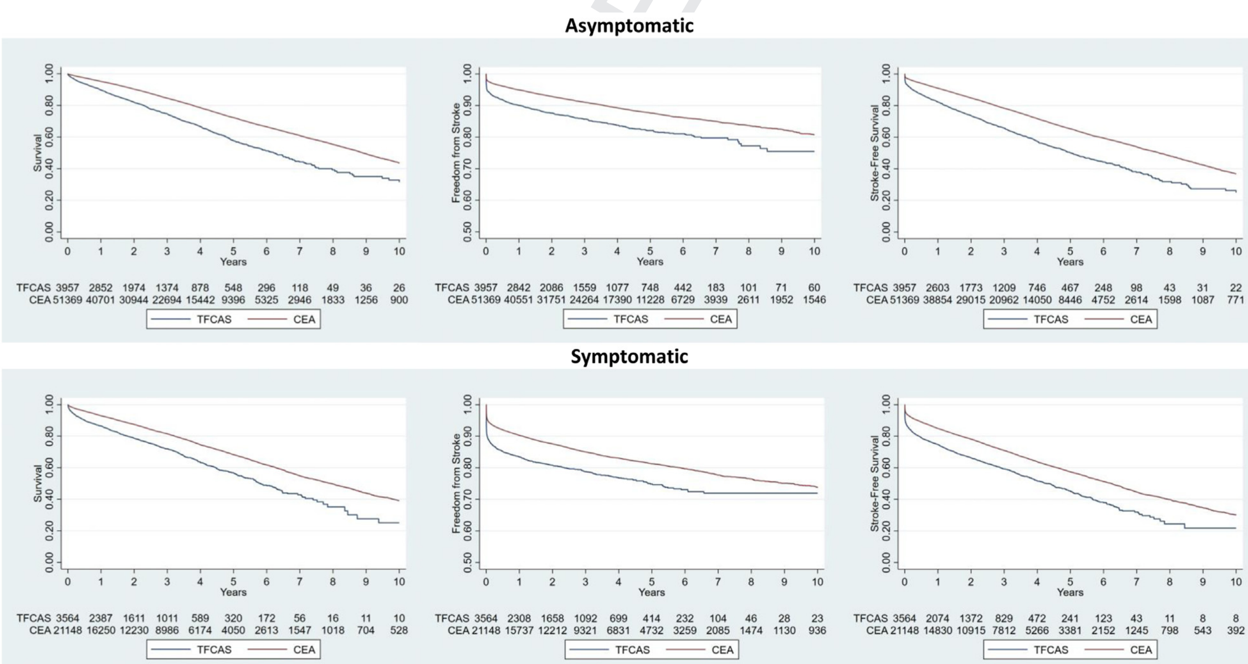
Supplementary Table II (online only). Perioperative and 4-year outcomes after carotid endarterectomy (*CEA*) or transfemoral carotid artery stenting (*TFCAS*) stratified by time period

Outcome	TFCAS (n = 200 [3.8%])	CEA (n = 5073 [96.2%])	*P* value	aOR (95% CI) (REF = TFCAS)	*P* value
2003-2010 perioperative					
Death	N/A[a]	46 (0.91)	N/A	N/A	N/A
Stroke	12 (6.0)	190 (3.8)	.103	0.72 (0.41-1.27)	.26
Stroke/death	12 (6.0)	218 (4.3)	.248	0.83 (0.48-1.43)	.49
Outcome	**TFCAS (n = 200 [3.8%])**	**CEA (n = 5073 [96.2%])**	**Log-rank *P* value**	**aHR (95% CI) (REF = TFCAS)**	***P* value**
2003-2010 4-year					
Death	72 (36.0)	1010 (19.9)	<.001	0.54 (0.41-0.71)	<.001
Stroke	42 (21.0)	665 (13.1)	<.001	0.49 (0.37-0.64)	<.001
Stroke/death	86 (43.0)	1455 (28.7)	<.001	0.57 (0.47-0.69)	<.001
Outcome	**TFCAS (n = 7331 [9.8%])**	**CEA (n = 67,542 [90.2%])**	***P* value**	**aOR (95% CI) (REF = TFCAS)**	***P* value**
2011-2018 perioperative					
Death	221 (3.0)	593 (0.9)	<.001	0.33 (0.25-0.43)	<.001
Stroke	619 (8.4)	2245 (3.3)	<.001	0.46 (0.41-0.52)	<.001
Stroke/death	764 (10.4)	2675 (4.0)	<.001	0.39 (0.33-0.46)	<.001
Outcome	**TFCAS (n = 7331 [9.8%])**	**CEA (n = 67,542 [90.2%])**	***P* value**	**aOR (95% CI) (REF = TFCAS)**	***P* value**
2011-2018 4-year					
Death	1664 (35.0)	9975 (23.0)	<.001	0.58 (0.54-0.63)	<.001
Stroke	1177 (19.5)	6529 (12.5)	<.001	0.63 (0.57-0.69)	<.001
Stroke/death	2406 (45.6)	14,510 (30.9)	<.001	0.50 (0.44-0.55)	<.001

aHR, Adjusted hazard ratio; *aOR*, adjusted odds ratio; *CI*, confidence interval; *N/A*, not applicable.
Values are number (%) unless otherwise indicated.
[a]Censored in accordance with Centers for Medicare and Medicaid Services cell suppression policy, which prohibits reporting of nonzero values of n < 11.



Supplementary Fig 1 (online only). Four-year survival, freedom from stroke, and stroke-free survival stratified by time period. *CEA*, Carotid endarterectomy; *TFCAS*, transfemoral carotid artery stenting.



Supplementary Fig 2 (online only). Ten-year survival, freedom from stroke, and stroke-free survival stratified by symptomatic status. *CEA*, Carotid endarterectomy; *TFCAS*, transfemoral carotid artery stenting.