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Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk

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Editorial

Supplemental content

IMPORTANCE Carotid artery stenting has been limited to use in patients with high surgical risk; outcomes in patients with standard surgical risk are not well known.

OBJECTIVE To compare stroke, death, and myocardial infarction outcomes following transcarotid artery revascularization vs carotid endarterectomy in patients with standard surgical risk.

DESIGN, SETTING, AND PARTICIPANTS This retrospective propensity-matched cohort study was conducted from August 2016 to August 2019 with follow-up until August 31, 2020, using data from the multicenter Vascular Quality Initiative Carotid Artery Stent and Carotid Endarterectomy registries. Patients with standard surgical risk, defined as those lacking Medicare-defined high medical or surgical risk characteristics and undergoing transcarotid artery revascularization (n = 2962) or carotid endarterectomy (n = 35 063) for atherosclerotic carotid disease. In total, 760 patients were excluded for treatment of multiple lesions or in conjunction with other procedures.

EXPOSURES Transcarotid artery revascularization vs carotid endarterectomy.

MAIN OUTCOMES AND MEASURES The primary outcome was a composite end point of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke.

RESULTS After 1:3 matching, 2962 patients undergoing transcarotid artery revascularization (mean [SD] age, 70.4 [6.9] years; 1910 [64.5%] male) and 8886 undergoing endarterectomy (mean [SD] age, 70.0 [6.5] years; 5777 [65.0%] male) were identified. There was no statistically significant difference in the risk of the primary composite end point between the 2 cohorts (transcarotid 3.0% vs endarterectomy 2.6%; absolute difference, 0.40% [95% CI, −0.43% to 1.24%]; relative risk [RR], 1.14 [95% CI, 0.87 to 1.50]; *P* = .34). Transcarotid artery revascularization was associated with a higher risk of 1-year ipsilateral stroke (1.6% vs 1.1%; absolute difference, 0.52% [95% CI, 0.03 to 1.08]; RR, 1.49 [95% CI, 1.05 to 2.11%]; *P* = .02) but no difference in 1-year all-cause mortality (2.6% vs 2.5%; absolute difference, −0.13% [95% CI, −0.18% to 0.33%]; RR, 1.04 [95% CI, 0.78 to 1.39]; *P* = .67).

CONCLUSIONS AND RELEVANCE In this study, the risk of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke was similar in patients undergoing transcarotid artery revascularization compared with those undergoing endarterectomy for carotid stenosis.

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Transcarotid artery revascularization has changed the treatment paradigm for carotid artery stenosis. The original method for carotid artery stenting was designed as a minimally invasive alternative to carotid endarterectomy and was commonly performed through a transfemoral approach, with gradual adoption of distal embolic filters. However, several trials have found a significantly higher risk of stroke or death with transfemoral carotid artery stenting compared with carotid endarterectomy in symptomatic and elderly patients.[1-4] Transcarotid artery revascularization is a newer technique for carotid stenting that avoids manipulation of the aortic arch by direct common carotid access and uses a novel flow-reversal neuroprotection system.[5,6]

The Centers for Medicare and Medicaid Services (CMS) has approved the use of carotid artery stenting for treatment of patients with high surgical risk and has created a list of medical and anatomic characteristics to qualify patients for procedural reimbursement.[7] Transcarotid artery revascularization has been found to be associated with a significantly lower risk of perioperative and 1-year stroke or death compared with transfemoral carotid artery stenting and equivalent outcomes compared with endarterectomy for treatment of patients with high surgical risk.[8,9] However, the role of transcarotid artery revascularization in patients with standard risk is currently unknown. This study was performed to evaluate the outcomes of transcarotid artery revascularization compared with carotid endarterectomy in patients with standard risk to see whether the use of this technology might be expanded to a broader patient population.

Key Points

Question Should transcarotid artery revascularization be expanded to patients with standard surgical risk?

Findings In this cohort study of 2962 patients with standard surgical risk who underwent transcarotid artery revascularization and 8886 who underwent carotid endarterectomy, the composite risk of 30-day stroke, death, and myocardial infarction or 1-year ipsilateral stroke was not significantly different after transcarotid artery revascularization or carotid endarterectomy.

Meaning Transcarotid artery revascularization was associated with a similar risk of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke in patients with standard surgical risk undergoing carotid endarterectomy compared with those undergoing transcarotid artery revascularization.

Methods

Data Set

This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline for observational studies. The institutional review board at Beth Israel Deaconess Medical Center approved this study, with permission to use data from the Society for Vascular Surgery Vascular Quality Initiative (VQI) Carotid Artery Stent and Carotid Endarterectomy registries without the need for informed consent due to the deidentified nature of these data. The carotid stent registry includes data from the Transcarotid Artery Revascularization Surveillance Project, which is a US Food and Drug Administration (FDA)- and CMS-approved registry that captures more than 95% of all transcarotid artery revascularization procedures performed in the US.[8] These registries represent a wide range of medical and surgical subspecialities, including vascular surgery, interventional cardiology, neurosurgery, general surgery, neurology, and interventional radiology, and contain more than 250 patient- and procedure-specific variables as well as in-hospital and postdischarge outcomes data. Claims data are compared with registry data in VQI to ensure capture of all procedures from participating institutions. Mortality data are obtained through linkage with the Social Security Death Index and are checked for all cases and audited by the VQI routinely.

Patients

Patients undergoing transcarotid artery revascularization and carotid endarterectomy for treatment of atherosclerotic carotid disease at the carotid bifurcation or internal carotid artery were identified from August 2016 to August 2019. The final date for data collection was August 31, 2020, to allow for at least 1-year follow-up in all patients included. Patients undergoing stenting for more than 1 distinct carotid lesion (n = 16) and stents placed in conjunction with concomitant intracranial procedures (n = 71) were excluded, as were those undergoing carotid endarterectomy in conjunction with coronary artery bypass graft (n = 405) or hybrid surgical procedures with proximal or distal arterial stenting (n = 268).

Patients with the following CMS high-medical risk factors were excluded from both cohorts: 80 years and older, unstable angina, myocardial infarction within the past 6 months, moderate or serve congestive heart failure, chronic obstructive pulmonary disease and using home oxygen, dialysis dependence, and creatinine greater than 2.5 mg/dL (to convert to μmol/L, multiply by 88.4).[7] CMS approves carotid stenting for patients 75 years and older because this was the age cutoff used in the Carotid Artery Revascularization Using the Boston Scientific FilterWire EX/EZ and the EndoTex NexStent (CABERNET) trial.[10] However, patients aged between 75 and 80 years were included because this age group is not widely considered to be at high risk. Patients undergoing transcarotid artery revascularization due to multivessel coronary artery disease or need for cardiac or major surgery were not excluded because these variables are not similarly captured in the carotid endarterectomy database and therefore could not be equally excluded from both cohorts.

Patients with the following CMS high anatomic risk factors were excluded from both cohorts: prior ipsilateral carotid endarterectomy or stent, prior radical neck surgery, prior neck radiation or stoma, laryngeal nerve palsy, common carotid artery lesion below the clavicle, and contralateral internal carotid artery occlusion.[7] Patients undergoing transcarotid artery revascularization based on presence of a high cervical lesion or cervical immobility were not excluded because these specific anatomic risk factors are not defined in the endarterectomy data set. These exclusion criteria yielded patients with standard risk defined identically in the transcarotid artery revascularization and endarterectomy cohorts.

Variable Definitions

Race and ethnicity were documented and analyzed because prior studies have suggested that these features are associated with response to carotid revascularization procedures.[11,12] Race was self-reported according to the guidelines of each institution and collected in accordance with VQI data abstraction and categorization methods. Races reported were Asian, Black, White, and other, which included American Indian, Alaska Native, Native Hawaiian, Pacific Islander, or more than 1 race, consolidated owing to small numbers. Ethnicity was defined as Hispanic or non-Hispanic. Given the exclusion of patients at high risk, those remaining with coronary artery disease were characterized as having mild coronary artery disease, that is, asymptomatic coronary disease or stable angina. Similarly, congestive heart failure was defined as asymptomatic or having mild symptoms. Preoperative anticoagulation use was defined as any use of vitamin K antagonists, factor Xa inhibitors, or direct thrombin inhibitor within 30 days of the index operation. Degree of carotid stenosis was reported based on carotid duplex, computed tomography angiography, magnetic resonance angiography, or catheter-based carotid arteriography.

Outcomes

The primary outcome was a composite end point of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke. Myocardial infarction events were restricted to those occurring in-hospital because postdischarge events were not captured. Secondary outcomes included in-hospital outcomes of stroke, death, myocardial infarction, cranial nerve injury, and procedural time, as well as 30-day stroke and death, 1-year ipsilateral stroke, and 1-year all-cause mortality. In-hospital and 30-day stroke events were defined as ischemic or hemorrhagic, occurring either on the ipsilateral or contralateral side of intervention. Stroke was determined by neurological examination findings, and imaging confirmation was not required for determination of a perioperative stroke. Stroke events following discharge were determined based on patient report, physical examination, and review of electronic health records by the clinical team. Myocardial infarction was determined by postoperative electrocardiogram changes from preprocedural baseline or clinical symptoms of chest pain radiating to the left arm or jaw following the procedure with associated troponin elevation. Perioperative troponin elevation without any clinical symptoms or electrocardiogram changes was not considered as constituting myocardial infarction. Procedure time was measured from the start of skin incision to the time of closure.

Statistical Analysis

At the request of the FDA, all statistical analysis was performed by an independent analyst. Continuous variables were presented as means and standard deviations and categorical variables as counts and percentages. Baseline characteristics were compared between the 2 cohorts and multiple imputation was used for characteristics with more than 5% missing data. Univariate differences between cohorts were assessed using χ^2 for categorical variables and *t* test for continuous variables. All tests were 2-sided, and $P < .05$ was considered statistically significant.

A propensity score–matched analysis was performed to account for the remaining baseline differences between the 2 standard-risk cohorts. Propensity scores were generated for each covariate using a logistic regression model with the following variables in the model: presenting symptom status, age, sex, race, body mass index, ethnicity, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, dialysis dependence, American Society of Anesthesiologists physical status class, smoking history, hypertension, diabetes, prior coronary artery bypass graft, prior percutaneous coronary intervention, glomerular filtration rate, and surgical side. A matched population was then created using a 1:3 transcarotid artery revascularization to carotid endarterectomy propensity score match with no caliper bound. Balance was determined by the standardized difference, with 10% indicating balance. In-hospital outcomes between matched groups were tested using χ^2 test for categorical variables and paired *t* test for continuous variables. Postdischarge event rates were estimated using Kaplan-Meier life table methods, censoring patients lost to follow-up. Relative risk (RR) was determined using Cox proportional hazard regression models and estimated as the ratio of the probability of the outcome event in patients treated with transcarotid artery revascularization compared with those treated with endarterectomy. The proportionality assumption was confirmed using correlation testing based on Schoenfeld residuals. Interaction between the procedure (transcarotid artery revascularization vs carotid endarterectomy) was tested with individual covariates, including age, sex, race, ethnicity, and presenting symptom status (ie, asymptomatic, stroke, cortical transient ischemic attack, retinal transient ischemic attack, and unknown stroke severity).

As part of the data submission to the FDA for approval of transcarotid artery revascularization use in patients with standard risk, a noninferiority analysis was performed. Based on prior clinical trial data, a pooled clinical perspective from the authors, and discussion with the FDA, an acceptable observed difference for the primary composite outcome of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke between the 2 cohorts was determined to be 1.5% or less. Noninferiority would be claimed if the upper bound of the 95% CI of the outcome difference between transcarotid artery revascularization and endarterectomy was less than 5%. A noninferiority margin of 5% would render a power of more than 99% to establish noninferiority, calculated based on a carotid endarterectomy primary composite historical event rate of 3.0%, transcarotid artery revascularization of 4.5%, and sample size of 11 848 patients.

Results

Patients

A total of 38 025 patients with standard risk underwent carotid revascularization for treatment of asymptomatic or symptomatic carotid atherosclerotic disease during the study period, of whom 2962 (7.8%) received transcarotid artery revascularization and 35 063 (92%) received carotid endarterectomy. Transcarotid artery revascularization procedures were performed by 1039 physicians across 414 centers, and carotid endarterectomy procedures were performed by 2075 physicians across 412 centers. **Table 1** lists the baseline characteristics and coexisting conditions before and after 1:3 propensity score matching.

After matching, 2962 patients with transcarotid artery revascularization (100%; mean [SD] age, 70.4 [6.9] years; 1910 [64.5%] male; 22 Asian, 175 Black, 142 Hispanic, 2655 White, and 121 of another race or ethnicity, including American Indian, Alaska Native, Native Hawaiian, Pacific Islander, or more than 1 race, consolidated owing to small numbers) and 8886 with endarterectomy (25.3%; mean [SD] age, 70.0 [6.5] years; 5777 [65.0%] male; 71 Asian, 508 Black, 385 Hispanic, 7986 White, and 321 of another race or ethnicity, including American Indian, Alaska Native, Native Hawaiian, Pacific Islander, or more than 1 race, consolidated owing to small numbers) remained in the study. These 2 cohorts were well matched, with balance in most characteristics (Table 1). Thirty-day follow-up data were available for 1520 patients undergoing transcarotid artery revascularization (51.3%) and 22 879 undergoing carotid endarterectomy (65.3%). One-year follow-up data were available for 983 patients undergoing transcarotid artery revascularization (33.2%) and 17 438 undergoing carotid endarterectomy (49.7%). Baseline characteristics of patients with and without 30-day and 1-year follow-up are listed in eTables 1-4 in Supplement 1.

Perioperative In-Hospital Outcomes

The in-hospital composite risk of stroke, death, or myocardial infarction was 2.0% for transcarotid artery revascularization and 1.7% for carotid endarterectomy, a difference that was not statistically significant (absolute difference, 0.26% [95% CI, −0.31% to 0.82%]; *P* = .35) (**Table 2**). There were also no significant differences in the individual end points of death (0.2% vs 0.2%; absolute difference, 0.04% [95% CI, −0.14% to 0.23%]; *P* = .61) or myocardial infarction (0.5% vs 0.7%; absolute difference, −0.24% [95% CI, −0.54 to 0.06%]; *P* = .17). Transcarotid artery revascularization was associated with a higher risk of stroke (1.5% vs 1.0%; absolute difference, 0.46% [95% CI, 0.01% to 0.94%]; *P* = .04). However, transcarotid artery revascularization was associated with a significantly lower rate of cranial nerve injury (0.3% vs 2.7%; absolute difference, −2.4% [95% CI, −2.8 to −2.0]; *P* < .001) and shorter mean (SD) operative times (72.2 [29.4] minutes vs 117 [43.7] minutes; *P* < .001). There were no statistically significant differences in the rates of failed discharge to home or prolonged hospital stay more than 2 days.

Thirty-Day and 1-Year Outcomes

The primary composite end point of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke was 3.0% for transcarotid artery revascularization and 2.6% for carotid endarterectomy, a difference that was not statistically significant (absolute difference, 0.40% [95% CI, −0.43% to 1.24%]; RR, 1.14 [95% CI, 0.87 to 1.50]; *P* = .34) (**Table 3**, **Figure**). The upper limit of the 2-sided 95% CI was 1.24% and less than the prespecified noninferiority margin of 5.0%, thus supporting noninferiority of transcarotid artery revascularization to endarterectomy. There were also no statistically significant differences in 30-day death (0.3% vs 0.4%; absolute difference, −0.07% [95% CI, −0.33% to 0.18%]; RR, 0.84 [95% CI, 0.42 to 1.69]; *P* = .62) or 1-year all-cause mortality (2.6% vs 2.5%; absolute difference, 0.13% [95% CI, −0.18% to 0.33%]; RR, 1.04 [95% CI, 0.78 to 1.39]; *P* = .67). However, transcarotid artery revascularization was associated with a trend toward a higher risk of 30-day stroke (1.6% vs 1.1%; absolute difference, 0.42% [95% CI, −0.06% to 0.93%]; RR, 1.38 [95% CI, 0.97 to 1.96]; *P* = .07) and a significantly higher risk of 1-year ipsilateral stroke (1.6% vs 1.1%; absolute difference, 0.52% [95% CI, 0.03 to 1.08]; RR, 1.49 [95% CI, 1.05 to 2.11%]; *P* = .03). For the primary composite end point, no significant interactions were found between the intervention and age (≥65 years vs <65 years), presenting symptom status, sex, race (White vs non-White), or ethnicity (Hispanic vs non-Hispanic).

Discussion

In this cohort study of patients with standard surgical risk, transcarotid artery revascularization was noninferior to carotid endarterectomy and associated with a similar composite outcome risk of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke. Although transcarotid artery revascularization was found to have a higher rate of in-hospital and 1-year ipsilateral stroke, the overall stroke rate for both cohorts was low and within clinically acceptable ranges. Transcarotid artery revascularization was associated with a lower risk of cranial nerve injury and shorter operative times. Based on these findings, the FDA approved the use of transcarotid artery revascularization for patients with standard surgical risk on May 2, 2022.

The CMS high-risk carotid endarterectomy criteria have been adopted by several surgical and medical societies to guide the use of carotid artery stenting.[7,13] However, several of these criteria have not been found to be independently associated with 30-day stroke or death following carotid endarterectomy, including age greater than 80 years and treatment of carotid restenosis.[14,15] When transcarotid artery revascularization was introduced as an alternative carotid stenting approach in 2016, these same high-risk criteria were implemented for approval and reimbursement. Using retrospective data from the VQI Transcarotid Artery Surveillance Project, we found that transcarotid artery was associated with a significantly lower risk of 1-year stroke or death for treatment of patients with high risk compared with transfemoral carotid artery stenting (5.1% vs 9.6%; *P* < .001) and equivalent to endarterectomy (5.7% vs 6.6%; *P* = .44).[8,9] These findings raised interest in expanding the use of transcarotid artery stenting in patients with standard surgical risk.

We were able to identify a subset of patients with standard risk in this transcarotid artery revascularization registry based on inclusion of patients aged between 75 and 80 years

Table 1. Baseline Characteristics of Patients Before and After 1:3 Propensity Score Matching

	All patients (N = 38 025)			1:3 Propensity matched			
	No. (%)			No. (%)			
	Transcarotid artery stenting (n = 2962)	Carotid endarterectomy (n = 35 063)	*P* value	Transcarotid artery stenting (n = 2962)	Carotid endarterectomy (n = 8886)	*P* value	Mean standardized difference
Age, mean (SD), y	70.4 (6.9)	68.2 (7.5)	<.001	70.4 (6.9)	70.0 (6.5)	.64	.01
≥65	2394 (80.8)	24 893 (71.0)	<.001	2394 (80.8)	7240 (81.5)	.43	.02
Sex							
Female	1052 (35.5)	14 023 (40.0)	<.001	1052 (35.5)	3109 (35.0)	.60	.01
Male	1910 (64.5)	21 040 (60.0)	<.001	1910 (64.5)	5777 (65.0)	.60	.01
Race[a]			<.001				
Asian	22 (0.7)	397 (1.1)		22 (0.7)	71 (0.8)		
Black	175 (5.9)	1684 (4.8)		175 (5.9)	508 (5.7)		
White	2644 (89.3)	31 319 (89.3)		2644 (89.3)	7986 (89.9)	.84	.03
Other[b]	121 (4.1)	1663 (4.8)		121 (4.1)	321 (3.6)		
Hispanic ethnicity[a]	142 (4.8)	1279 (3.6)		142 (4.8)	385 (4.3)	.29	.02
Presenting symptom status							
Asymptomatic	1358 (45.8)	18 049 (51.5)		1358 (45.8)	4070 (45.8)		
Stroke	894 (30.2)	8393 (23.9)		894 (30.2)	2678 (30.1)		
Cortical transient ischemic attack	365 (12.3)	3846 (11.0)	<.001	365 (12.3)	1121 (12.6)	.99	.01
Retinal transient ischemic attack	116 (3.9)	2259 (6.4)		116 (3.9)	343 (3.9)		
Unknown stroke severity	229 (7.7)	2516 (7.2)		229 (7.7)	674 (7.6)		
Medical risk factors							
Hypertension	2679 (90.4)	31 045 (88.5)	.001	2679 (90.4)	8064 (90.7)	.62	.01
Coronary artery disease[c]	1373 (46.4)	8377 (23.9)	<.001	1373 (46.4)	4071 (45.8)	.61	.01
Diabetes							
None	1753 (59.2)	22 119 (63.1)		1753 (59.2)	5318 (59.8)		
Diet controlled	127 (4.3)	1474 (4.2)	<.001	127 (4.3)	363 (4.1)	.88	.02
Noninsulin	610 (20.6)	6879 (19.6)		610 (20.6)	1828 (20.6)		
Insulin/medication dependent	472 (15.9)	4591 (13.1)		472 (15.9)	1377 (15.5)		
Percutaneous coronary intervention	737 (24.9)	7179 (20.5)	<.001	737 (24.9)	2225 (25.0)	.86	.00
COPD[d]	655 (22.1)	7650 (21.8)	.71	655 (22.1)	1924 (21.7)	.60	.01
CABG	554 (18.7)	6235 (17.8)	.21	554 (18.7)	1579 (17.8)	.25	.02
GFR, mean (SD), mL/min/1.73m^2	74.8 (18.2)	77.8 (18.5)	<.001	74.8 (18.2)	75.0 (18.4)	.50	.01
GFR <60	686 (23.2)	6612 (18.9)	<.001	686 (23.2)	2017 (22.7)	.60	.01
Congestive heart failure[e]	362 (12.2)	2862 (8.2)	<.001	362 (12.2)	1065 (12.0)	.73	.01
Smoking history							
None	749 (25.3)	8597 (24.5)		749 (25.3)	2236 (25.2)		
Prior	1478 (49.9)	16 406 (46.8)	<.001	1478 (49.9)	4417 (49.7)	.94	.01
Active	735 (24.8)	10 060 (28.7)		735 (24.8)	2233 (25.1)		
Preoperative medications							
Aspirin	2666 (90.0)	29 783 (84.9)	<.001	2666 (90.0)	7993 (90.0)	.93	.00
Statin	2676 (90.3)	29 755 (84.9)	<.001	2676 (90.3)	8034 (90.4)	.91	.00
Anticoagulation	362 (12.2)	3286 (9.4)	<.001	362 (12.2)	1086 (12.2)	>.99	.00
Preadmission living status							
Home	2924 (98.7)	34 709 (99.0)		2924 (98.7)	8785 (98.9)		
Nursing home	35 (1.2)	315 (0.9)	.30	35 (1.2)	93 (1.0)	.81	.01
Homeless	3 (0.1)	39 (0.1)		3 (0.1)	8 (0.1)		

(continued)

Table 1. Baseline Characteristics of Patients Before and After 1:3 Propensity Score Matching (continued)

	All patients (N = 38 025)			1:3 Propensity matched			
	No. (%)			No. (%)			
	Transcarotid artery stenting (n = 2962)	Carotid endarterectomy (n = 35 063)	*P* value	Transcarotid artery stenting (n = 2962)	Carotid endarterectomy (n = 8886)	*P* value	Mean standardized difference
% Lesion stenosis							
<50%	0	389 (1.1)	<.001	0	0	.58	.03
50%-60%	203 (6.9)	906 (2.6)		203 (6.9)	553 (6.2)		
61%-70%	92 (3.1)	2014 (5.7)		92 (3.1)	298 (3.4)		
71%-80%	365 (12.3)	10 609 (30.3)		365 (12.3)	1078 (12.1)		
>80%	2302 (77.7)	20 461 (58.4)		2302 (77.7)	6957 (78.3)		
Occluded	0	684 (2.0)		0	0		
Lesion laterality							
Right	1537 (51.9)	17 680 (50.4)	.13	1537 (51.9)	4613 (51.9)	.74	.01
Left	1425 (48.1)	17 383 (49.6)		1425 (48.1)	4273 (48.1)		

Abbreviations: CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate.

[a] Self-reported race and ethnicity data were gathered according to the categories set forth by the Vascular Quality Initiative because prior studies have suggested that these features are associated with response to carotid revascularization procedures.[11,12]

[b] Other included American Indian, Alaska Native, Native Hawaiian, Pacific Islander, or more than 1 race. These groups were consolidated owing to small numbers.

[c] Coronary artery disease without unstable angina or history of myocardial infarction within 6 months.

[d] COPD not on home oxygen.

[e] Asymptomatic or mild congestive heart failure.

Table 2. In-Hospital Perioperative Outcomes After Transcarotid Artery Stenting or Carotid Endarterectomy Stenting in a Propensity Score–Matched Study Population

	No. (%)			
	Transcarotid artery stenting (n = 2962)	Carotid endarterectomy (n = 8886)	Absolute difference, % (95% CI)	*P* value
Stroke/death/myocardial infarction	58 (2.0)	151 (1.7)	0.26 (−0.31 to 0.82)	.35
Stroke	43 (1.5)	88 (1.0)	0.46 (0.01 to 0.94)	.04
Death	6 (0.2)	14 (0.2)	0.04 (−0.14 to 0.23)	.61
Myocardial infarction	14 (0.5)	63 (0.7)	−0.24 (−0.5 to 0.06)	.17
Cranial nerve injury	10 (0.3)	244 (2.7)	−2.4 (−2.8 to −2.0)	<.001
Total procedure time, mean (SD), min	72.2 (29.4)	117 (43.7)	−44.8 (−46.5 to −43.1)	<.001
Failed CMS discharge criteria	441 (14.9)	1439 (16.2)	−1.3 (−2.8 to 0.19)	.09
Failed discharge home	171 (5.8)	559 (6.3)	0.5 (−1.5 to 0.5)	.31
Length of stay >2 d	390 (13.2)	1263 (14.2)	−1.0 (−2.4 to 0.4)	.15

Abbreviation: CMS, Centers for Medicare and Medicaid Services.

and those treated for high cervical lesions. Advanced age alone has not been found to be associated with risk of perioperative stroke, death, or myocardial infarction following carotid revascularization.[16-18] Whereas most carotid stenting trials specified age older than 80 years to be a high-risk criterion, 1 study included a high-risk age cutoff of older than 75 years, so many patients have qualified for transcarotid artery revascularization based on this younger age cutoff and were included in this analysis.

Patients with high carotid lesions were included in the standard surgical risk cohort because of limitations in the carotid endarterectomy data set to identify and exclude similar patients. While high cervical lesions make carotid endarterectomy technically challenging and serve as an independent predictor of stroke or death,[14] the presence of high cervical lesions is unlikely to have a significant impact during carotid stenting due to the procedure's inherent lack of anatomic constraints related to a distal lesion. Furthermore, it is likely that most high, surgically inaccessible lesions are currently treated with carotid stenting.

Transcarotid artery revascularization was found to have a higher risk of in-hospital and 1-year ipsilateral stroke. This finding suggests that transcarotid artery revascularization may not offer the same degree of intraoperative neuroprotection as endarterectomy. However, the overall stroke risk in the standard-risk subset of patients undergoing either carotid revascularization procedure was low and within clinically acceptable periprocedural stroke rates. These findings warrant further investigative studies to clarify anatomic risk factors that may be associated with an increase in risk of stroke in carotid stent-

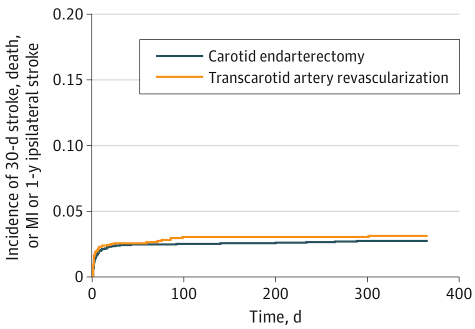
Table 3. Thirty-Day and 1-Year Outcomes After Transcarotid Artery Stenting or Carotid Endarterectomy Stenting in a Propensity Score–Matched Study Population Using Kaplan-Meier Estimates

	%				
	Transcarotid artery stenting	Carotid endarterectomy	Absolute difference, % (95% CI)	Relative risk (95% CI)	*P* value
30-d Stroke/death/MI and 1-y ipsilateral stroke[a]	3.0	2.6	0.40 (−0.43 to 1.24)	1.14 (0.87 to 1.50)	.34
30-d					
Stroke/death	1.8	1.5	0.34 (−0.18 to 0.90)	1.24 (0.90 to 1.71)	.21
Stroke	1.6	1.1	0.42 (−0.06 to 0.93)	1.38 (0.97 to 1.96)	.07
Death	0.3	0.4	−0.07 (−0.33 to 0.18)	0.84 (0.42 to 1.69)	.62
Stroke/death/MI[a]	2.2	2.1	0.15 (−0.48 to 0.74)	1.07 (0.81 to 1.42)	.63
1-y					
Ipsilateral stroke	1.6	1.1	0.52 (0.03 to 1.08)	1.49 (1.05 to 2.11)	.02
Death	2.6	2.5	0.13 (−0.18 to 0.33)	1.04 (0.78 to 1.39)	.67

Abbreviation: MI, myocardial infarction.

[a] Myocardial infarction restricted to in-hospital events only.

Figure. Kaplan-Meier–Estimated 30-Day Stroke, Death, or Myocardial Infarction (MI) or 1-Year Ipsilateral Stroke in Patients Undergoing Transcarotid Artery Revascularization vs Carotid Endarterectomy



No. at risk				
Carotid endarterectomy	8886	4666	4567	3958
Transcarotid artery revascularization	2962	1045	1019	843

ing, such as treatment of bulky or circumferentially calcified carotid lesions.[19]

Limitations

This study has several limitations. First, due to the nonrandomized nature of the study design, the treating physician determined the procedure selection based on personal expertise and clinical judgement, thereby introducing confounding by indication. Second, the carotid artery stent registry collects predefined variables for anatomic high surgical risk factors for qualification of carotid stenting that are not present in the carotid endarterectomy registry, which can result in unadjusted confounders and bias favoring transcarotid artery revascularization. Third, the end point of stroke was determined by clinical evaluation. Ischemic and hemorrhagic strokes were not differentiated. Formalized neurologic tests, imaging confirmation, and certification in the National Institutes of Health Stroke Scale for study personnel were not universally required, which may have led to undercounting of events after discharge. Fourth, myocardial infarction events were limited to the periprocedural in-hospital period whereas stroke events were captured after discharge, which could have led to a bias in the primary composite end point favoring stroke outcomes. Fifth, the postdischarge follow-up was incomplete and was higher for endarterectomy, which could have led to bias. The 1-year follow up rates in this study were lower than previously recorded in VQI due to a slightly shorter 1-year data collection period, vs 2-year, to use the most updated data for analysis. Additionally, we defined 1-year follow-up as more than 320 days, as requested by the FDA, to better reflect 1-year follow-up, whereas the VQI defines 1-year follow-up as more than 273 days. Carotid revascularization for asymptomatic patients is reserved for those with at least a 3-year life expectancy. Longer-term follow-up with 3- and 5-year data are forthcoming to determine longer-term stroke-free survival and restenosis rates. Half of the study population was treated for asymptomatic disease and the results from the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis 2 (CREST-2) trial[20] may change the optimal management strategy (ie, medical vs surgical) for asymptomatic carotid stenosis.

Conclusions

Among patients in this study with standard surgical risk undergoing treatment for carotid stenosis, transcarotid artery revascularization was associated with an equivalent composite risk of 30-day stroke, death, or myocardial infarction or 1-year ipsilateral stroke compared with carotid endarterectomy. Although the rate of 1-year ipsilateral stroke was higher in the transcarotid artery revascularization cohort, the absolute difference was small, and the rate was clinically low.

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