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Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis

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IMPORTANCE Several trials have observed higher rates of perioperative stroke following transfemoral carotid artery stenting compared with carotid endarterectomy. Transcarotid artery revascularization with flow reversal was recently introduced for carotid stenting. This technique was developed to decrease stroke risk seen with the transfemoral approach; however, its outcomes, compared with transfemoral carotid artery stenting, are not well characterized.

OBJECTIVE To compare outcomes associated with transcarotid artery revascularization and transfemoral carotid artery stenting.

DESIGN, SETTING, AND PARTICIPANTS Exploratory propensity score–matched analysis of prospectively collected data from the Vascular Quality Initiative Transcarotid Artery Surveillance Project and Carotid Stent Registry of asymptomatic and symptomatic patients in the United States and Canada undergoing transcarotid artery revascularization and transfemoral carotid artery stenting for carotid artery stenosis, from September 2016 to April 2019. The final date for follow-up was May 29, 2019.

EXPOSURES Transcarotid artery revascularization vs transfemoral carotid artery stenting.

MAIN OUTCOMES AND MEASURES Outcomes included a composite end point of in-hospital stroke or death, stroke, death, myocardial infarction, as well as ipsilateral stroke or death at 1 year. In-hospital stroke was defined as ipsilateral or contralateral, cortical or vertebrobasilar, and ischemic or hemorrhagic stroke. Death was all-cause mortality.

RESULTS During the study period, 5251 patients underwent transcarotid artery revascularization and 6640 patients underwent transfemoral carotid artery stenting. After matching, 3286 pairs of patients who underwent transcarotid artery revascularization or transfemoral carotid artery stenting were identified (transcarotid approach: mean [SD] age, 71.7 [9.8] years; 35.7% women; transfemoral approach: mean [SD] age, 71.6 [9.3] years; 35.1% women). Transcarotid artery revascularization was associated with a lower risk of in-hospital stroke or death (1.6% vs 3.1%; absolute difference, −1.52% [95% CI, −2.29% to −0.75%]; relative risk [RR], 0.51 [95% CI, 0.37 to 0.72]; *P* < .001), stroke (1.3% vs 2.4%; absolute difference, −1.10% [95% CI, −1.79% to −0.41%]; RR, 0.54 [95% CI, 0.38 to 0.79]; *P* = .001), and death (0.4% vs 1.0%; absolute difference, −0.55% [95% CI, −0.98% to −0.11%]; RR, 0.44 [95% CI, 0.23 to 0.82]; *P* = .008). There was no statistically significant difference in the risk of perioperative myocardial infarction between the 2 cohorts (0.2% for transcarotid vs 0.3% for the transfemoral approach; absolute difference, −0.09% [95% CI, −0.37% to 0.19%]; RR, 0.70 [95% CI, 0.27 to 1.84]; *P* = .47). At 1 year using Kaplan-Meier life-table estimation, the transcarotid approach was associated with a lower risk of ipsilateral stroke or death (5.1% vs 9.6%; hazard ratio, 0.52 [95% CI, 0.41 to 0.66]; *P* < .001). Transcarotid artery revascularization was associated with higher risk of access site complication resulting in interventional treatment (1.3% vs 0.8%; absolute difference, 0.52% [95% CI, −0.01% to 1.04%]; RR, 1.63 [95% CI, 1.02 to 2.61]; *P* = .04), whereas transfemoral carotid artery stenting was associated with more radiation (median fluoroscopy time, 5 minutes [interquartile range {IQR}, 3 to 7] vs 16 minutes [IQR, 11 to 23]; *P* < .001) and more contrast (median contrast used, 30 mL [IQR, 20 to 45] vs 80 mL [IQR, 55 to 122]; *P* < .001).

CONCLUSIONS AND RELEVANCE Among patients undergoing treatment for carotid stenosis, transcarotid artery revascularization, compared with transfemoral carotid artery stenting, was significantly associated with a lower risk of stroke or death.

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Among patients with carotid artery stenosis, carotid endarterectomy is the established treatment standard for carotid revascularization, although transfemoral carotid artery stenting has been used as an alternative technique for patients at high surgical risk for endarterectomy. Several studies have shown that transfemoral carotid artery stenting has a higher periprocedural stroke risk compared with carotid endarterectomy, particularly in patients who are symptomatic and elderly.[1-4] In 2015, transcarotid artery revascularization, with a specially designed transcarotid flow reversal neuroprotection system, was developed as a new technique for carotid stenting. In contrast with the transfemoral approach, transcarotid artery revascularization avoids catheter manipulation in the aortic arch by direct carotid access and initiates cerebral protection through an extracorporeal arteriovenous shunt from the carotid artery to femoral vein prior to manipulating the target lesion.

With approval from the Centers for Medicare & Medicaid Services (CMS) and the United States Food and Drug Administration (FDA), the Transcarotid Artery Revascularization Surveillance Project[5] was created to evaluate outcomes after transcarotid artery revascularization with flow reversal for patients with high surgical risk in clinical practice, without the limitations to highly selected patients and physicians typical of randomized trials. Preliminary analysis from this registry showed no significant difference in in-hospital stroke or death outcomes between transcarotid artery revascularization and endarterectomy, but significantly lower rates of cranial nerve injuries and decreased operative time with transcarotid artery revascularization.[6] Using data collected until December 2017, transcarotid artery revascularization was found to be associated with lower neurological complications, based on embolic events manifested as transient ischemic attacks compared with transfemoral carotid artery stenting, but at the time, the study was limited to a small sample size.[7] Therefore, the aim of this study was to provide an updated exploratory analysis of patients undergoing transcarotid artery revascularization and transfemoral carotid artery stenting from the launch of the Transcarotid Surveillance Project in September 2016 to April 2019.

Key Points

Question Is transcarotid artery revascularization or transfemoral carotid artery stenting associated with a lower risk of stroke or death among patients undergoing treatment for carotid artery stenosis?

Findings In this propensity score–matched analysis of data from 3286 matched pairs of patients who underwent transcarotid artery revascularization or transfemoral carotid artery stenting, the risk of in-hospital stroke or death was 1.6% with the transcarotid approach vs 3.1% with the transfemoral approach, a difference that was statistically significant.

Meaning Among patients undergoing treatment for carotid stenosis, transcarotid artery revascularization, compared with transfemoral carotid artery stenting, was associated with a lower risk of stroke or death.

Methods

Data Set

The institutional review board at Beth Israel Deaconess Medical Center approved this study and gave permission to use the data from the Society for Vascular Surgery Vascular Quality Initiative Transcarotid Artery Revascularization Surveillance Project and the Transfemoral Carotid Artery Stent Registry without the need for informed consent due to the deidentified nature of the data. The Transfemoral Carotid Artery Stent Registry is a CMS-approved prospective study, and it is utilized by clinicians to obtain reimbursement for transcarotid artery revascularization procedures. Both the transcarotid artery revascularization and transfemoral carotid artery stent registries contain more than 250 patient- and procedure-specific variables and in-hospital outcome data from more than 280 centers and 1000 physicians in the United States and Canada. Additionally, 30-day and 1-year mortality rates are determined through linkage to the Social Security Death Index. The Society for Vascular Surgery Patient Safety Organization initiated this project to evaluate the outcomes of transcarotid artery revascularization in patients with high surgical risk using FDA-approved devices labeled for the transcarotid approach. Carotid revascularization procedures in this registry were performed by vascular surgeons, cardiologists, neurosurgeons, general surgeons, neurologists, and radiologists. Patients with asymptomatic or symptomatic carotid disease were eligible for carotid stenting.

Patients

All patients undergoing transcarotid artery revascularization with an FDA-approved transcarotid neuroprotection system and transfemoral carotid artery stenting with documented femoral artery access were identified from September 2016 to April 2019. The final date for data collection was May 29, 2019. For all participating centers, billing data from each institution were reviewed to ensure capture of all procedures and outcomes, including failed attempted procedures and failed placement of embolic protection devices. To evaluate treatment of only atherosclerotic or intimal hyperplastic disease, patients with traumatic, dissection, and uncharacterized carotid lesions were excluded. Patients in whom carotid stents were placed in conjunction with planned intracranial procedures and those with unknown presenting symptom status or unknown symptom severity (ie, transient ischemic attack vs stroke) were also excluded.

Variable Definitions

Race and ethnicity were documented and analyzed in this study because prior studies have suggested that these features modify response to carotid revascularization procedures.[8,9] Race was self-reported, obtained by review of the electronic medical record, and categorized as black, white, Asian, or other. Ethnicity was also self-reported and categorized as Hispanic or non-Hispanic. Coronary artery disease was defined as history of myocardial infarction, stable angina, or unstable angina.

$P2Y_{12}$ inhibitors included clopidogrel, prasugrel, ticlopidine, and ticagrelor. Preoperative medication use was documented if taken within 36 hours of the procedure, except for anticoagulants, which were recorded if taken up to 30 days before the procedure. CMS provides a list of several high-risk medical and anatomic factors used to identify patients at higher risk for carotid endarterectomy in whom carotid stenting would be reimbursed.[10] Patients were recorded as high-medical risk or high-surgical risk if they met at least 1 high-risk CMS criterion. Using deidentified unique physician and center identification numbers, physician and center procedural volume was determined by the number of carotid stent procedures performed within the previous 12 months of the index procedure. Based on this volume, physicians and centers were divided into quintiles. Low volume consisted of the lowest quintile, high volume of the highest quintile, and medium volume as the middle 3 quintiles.

Outcomes

Exploratory outcomes included in-hospital stroke or death (a composite end point), stroke, death, myocardial infarction, and transient ischemic attack, as well as ipsilateral stroke or death at 30 days and at 1 year. Additional outcomes included heart failure exacerbation, access site bleeding complication, hypotensive or hypertensive hemodynamic instability, reperfusion syndrome, technical failure, embolic device placement failure, procedure time, fluoroscopy time, contrast usage, length of stay, and discharge disposition. In-hospital stroke was defined as either ipsilateral or contralateral, cortical or vertebrobasilar, ischemic or hemorrhagic stroke. Stroke was determined clinically by perioperative neurological symptoms with or without imaging confirmation. Patients were seen for follow-up at 30 days and 1 year by the treatment team, and stroke symptoms were queried and determined by reported interval history, physical examination, and review of the electronic medical record. Transient ischemic attacks were defined as focal neurological symptoms lasing less than 24 hours and were not included in the primary end point of stroke or death. Myocardial infarction was defined as clinical symptoms (chest pain or radiation to the left arm or jaw) or electrocardiogram changes occurring in conjunction with abnormal troponin elevation. Troponin rise alone was not considered a myocardial infarction. Technical failure was defined as inability to access the common carotid artery, to cross the carotid lesion, or to deploy the carotid stent. Embolic protection failure was documented if the embolic protection device could not be inserted. Bleeding complication was defined as any access site bleeding resulting in hematoma or pseudoaneurysm formation. Bleeding complications were further characterized as those associated with interventional treatment, such as surgical re-exploration or thrombin injection, or those associated with blood transfusions. Hemodynamic instability was defined as postoperative hypertension or hypotension treated with more than 1 dose or continuous infusion of intravenous blood pressure medications for 15 minutes or longer. Reperfusion syndrome was defined as postoperative headaches associated with seizures or hemorrhage seen on brain imaging. As a quality metric reported by CMS, patients with failed discharge home or prolonged length of stay were identified. Prolonged length of stay was defined as length of stay extending beyond 2 days. Discharge to home was defined as the event when patients were discharged to where they resided prior to the operation, even if their home was a nursing home. Procedure time was recorded from time of skin access puncture or incision to sheath removal or skin closure.

Statistical Analyses

Preliminary analysis of this registry[7] found that a sample size of 5041 patients in each cohort would achieve a power of 80%, based on a stroke or death rate of 2.5% following transcarotid artery revascularization vs 1.7% following transfemoral carotid artery stenting. After comparing baseline characteristics between patients undergoing transcarotid artery revascularization vs transfemoral carotid artery stenting, propensity scores were generated for each covariate (**Table 1**) using log-odds. Treatment cohorts were matched on these propensity scores using a calibration of 0.1 absolute units, and intergroup differences were tested with the McNemar test for categorical variables and paired *t* test or Wilcoxon matched-pairs signed-rank test for continuous variables as appropriate. All variables had less than 5% missing data. Interaction terms were used to test for effect modification using regression analysis. Because there was a significant interaction found between presenting symptom status and procedure type for the outcome of stroke or death, propensity-matched analyses were performed for patients with asymptomatic and symptomatic carotid disease.

The difference in the probability of outcome events in the matched cohorts was evaluated by the McNemar test and paired *t* tests when appropriate. Relative risk (RR) was estimated as the ratio of the probability of the outcome event in patients treated using the transcarotid approach compared with patients treated using the transfemoral approach. The 95% CIs were constructed using methods that accounted for the matched nature of the cohorts.[11] Stroke or death rates in the matched cohorts were estimated at 1 year using Kaplan-Meier life-table methods, censoring patients lost to follow-up, and comparisons were made using bivariable Cox proportional hazard models. The proportionality assumption was confirmed by correlation testing based on Schoenfeld residuals. *P* values less than .05 were considered statistically significant and all tests were 2-sided. As all analyses were considered exploratory, no correction for multiplicity was performed. Stata/SE, version 14.1 (StataCorp) was used for all analyses.

Results

Patients

The number of transcarotid artery revascularization procedures rapidly increased since the registry began in 2016, with a concurrent decrease in the number of transfemoral carotid artery stenting procedures (**Figure 1**). In 2018, 46% of all carotid stenting procedures were performed via the transcarotid approach. Patients with traumatic (n = 42), dissection (n = 268), and uncharacterized (n = 553) carotid lesions or carotid stents

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

	All Patients[a]			Propensity Score–Matched Patients[a]		
	Transcarotid Artery Revascularization (n = 5251)	Transfemoral Carotid Artery Stenting (n = 6640)	Mean Standardized Difference	Transcarotid Artery Revascularization (n = 3286)	Transfemoral Carotid Artery Stenting (n = 3286)	Mean Standardized Difference
Age, mean (SD), y	73.1 (9.4)	69.7 (9.7)	.364	71.7 (9.8)	71.6 (9.3)	.010
Women	1905 (36.3)	2332 (35.1)	.023	1172 (35.7)	1154 (35.1)	−.011
Men	3346 (63.7)	4308 (64.9)	−.023	2114 (64.3)	2132 (64.9)	.011
Race						
White	4735 (90.2)	5920 (89.2)	.025	2958 (90.0)	2959 (90.0)	−.001
Black	249 (4.7)	386 (5.8)	−.052	166 (5.1)	173 (5.3)	−.010
Asian	41 (0.8)	77 (1.2)	−.041	31 (0.9)	29 (0.9)	.006
Other[b]	222 (4.2)	256 (3.9)	.040	131 (4.0)	125 (3.8)	.009
Hispanic ethnicity	209 (4.0)	194 (2.9)	.065	121 (3.7)	120 (3.7)	.002
Insurance status						
Medicare	3453 (65.9)	3672 (55.4)	.215	2026 (61.7)	2037 (62.0)	−.007
Private insurance	1502 (28.7)	2390 (36.0)	−.156	1052 (32.0)	1040 (31.6)	.008
Medicaid	240 (4.6)	478 (7.2)	−.116	177 (5.4)	178 (5.4)	−.001
Self-pay	47 (0.9)	93 (1.4)	−.044	31 (0.9)	31 (0.9)	
Symptomatic	2596 (49.4)	4301 (64.8)		1822 (55.4)	1817 (55.3)	
Stroke	1596 (30.4)	2871 (43.3)	−.257	1071 (32.6)	1050 (32.0)	.014
Transient ischemic attack	1000 (20.0)	1430 (23.1)	−.080	751 (22.9)	767 (23.3)	−.012
Risk factors						
Hypertension	4761 (90.8)	5851 (88.7)	.055	2963 (90.2)	2976 (90.6)	−.013
Prior smoker	3908 (74.5)	4957 (74.8)	.002	2458 (74.8)	2465 (75.0)	−.005
Current smoker	1193 (22.7)	1838 (27.7)	−.105	815 (24.8)	823 (25.0)	−.006
Coronary artery disease	2668 (50.8)	2885 (43.7)	.149	1610 (49.0)	1604 (48.8)	.004
CKD, GFR<60 mL/min/1.73 m^2	2089 (39.8)	2331 (35.1)	.091	1252 (38.1)	1269 (38.6)	−.011
Hemodialysis	89 (1.7)	95 (1.4)	.017	56 (1.7)	55 (1.7)	.002
Diabetes	2014 (38.4)	2599 (39.2)	−.032	1272 (38.7)	1284 (39.1)	−.007
Insulin dependent	753 (14.3)	1079 (16.3)	−.063	487 (14.8)	508 (15.5)	−.018
Percutaneous coronary intervention	1764 (26.6)	1469 (28.0)	.036	928 (28.2)	948 (28.8)	.013
COPD	1448 (27.6)	1852 (27.9)	−.011	932 (28.4)	927 (28.2)	.003
Coronary artery bypass	1173 (22.4)	1361 (20.5)	.051	712 (21.7)	733 (22.3)	−.015
Congestive heart failure	976 (18.6)	1087 (16.4)	.058	590 (18.0)	619 (18.8)	−.023
Moderate-to-severe heart failure	192 (3.7)	246 (3.7)	−.014	137 (4.2)	125 (3.8)	.019
Prior CEA or stenting	869 (16.5)	1409 (21.2)	−.121	626 (19.1)	635 (19.3)	−.007
Body mass index, mean (SD)[c]	28.4 (6.5)	29 (6.3)	−.069	28.6 (7.0)	28.6 (6.1)	−.002
Preoperative medications						
Aspirin	4704 (89.6)	5744 (86.5)	.102	2927 (89.1)	2938 (89.4)	−.011
$P2Y_{12}$	4547 (86.6)	5138 (77.4)	.243	2757 (83.9)	2759 (84.0)	−.002
Statin	4659 (88.7)	5471 (82.5)	.171	2864 (87.2)	2846 (86.6)	.016
β-Blocker	2909 (55.4)	3473 (52.4)	.054	1807 (55.0)	1794 (54.6)	.008
Anticoagulation	748 (14.3)	813 (12.3)	.046	452 (13.8)	424 (12.9)	.025
CMS high-risk CEA criteria						
Medical high risk[d]	2967 (56.7)	2424 (36.8)	.410	1590 (48.4)	1586 (48.3)	.002
Anatomic high risk[e]	2610 (49.9)	2902 (44.0)	.135	1590 (48.4)	1606 (48.9)	−.010
Carotid lesion stenosis, mean (SD), %	84.1 (10.0)	83.7 (11.3)	.044	83.8 (10.2)	83.8 (11.1)	.002
Annual physician carotid stent procedures						
Low (0-3)	1369 (26.1)	1614 (24.3)	.040	853 (26.0)	838 (25.5)	.010
Medium (4-24)	2923 (55.7)	3689 (55.6)	.000	1817 (55.3)	1852 (56.4)	−.021
High (25-87)	959 (18.3)	1337 (20.1)	−.043	616 (18.7)	596 (18.1)	.016

(continued)

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

	All Patients[a]			Propensity Score–Matched Patients[a]		
	Transcarotid Artery Revascularization (n = 5251)	Transfemoral Carotid Artery Stenting (n = 6640)	Mean Standardized Difference	Transcarotid Artery Revascularization (n = 3286)	Transfemoral Carotid Artery Stenting (n = 3286)	Mean Standardized Difference
Annual center carotid stent procedures						
Low (0-14)	1324 (25.2)	1223 (18.4)	.167	741 (22.6)	732 (22.3)	.007
Medium (15-66)	3109 (59.2)	3915 (59.0)	.025	1928 (58.7)	1945 (59.2)	−.011
High (67-210)	818 (15.6)	1502 (22.6)	−.207	617 (18.8)	609 (18.5)	.006
Procedure year						
2016	100 (1.9)	471 (7.1)	−.254	92 (2.8)	87 (2.6)	.009
2017	1222 (23.3)	2554 (38.5)	−.316	975 (29.7)	975 (29.7)	.000
2018	2932 (55.8)	2939 (44.3)	.223	1721 (52.4)	1754 (53.4)	−.020
2019	997 (19.0)	676 (10.2)	.247	498 (15.2)	470 (14.3)	.024

Abbreviations: CEA, carotid endarterectomy; CMS, Centers for Medicare & Medicaid Services; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate.

[a] Values are reported as No. (%) unless otherwise indicated.

[b] Includes American Indian, native Alaskan, native Hawaiian, Asian Pacific Islander, or more than 1 race.

[c] Calculated as weight in kilograms divided by height in meters squared.

[d] Included factors: age older than 75 years, congestive heart failure with New York Heart Association Criteria Class III or IV, left ventricular ejection fraction less than 30%, unstable angina, myocardial infarction within 6 weeks, or severe pulmonary disease.

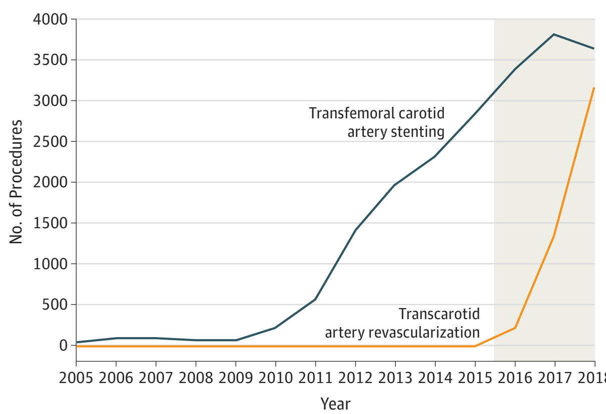
[e] Included factors: prior carotid endarterectomy, contralateral internal carotid artery occlusion, laryngeal nerve palsy, high carotid lesion above cervical spine level 2, lesion below clavicle, prior neck radiation, prior radical neck surgery, prior neck stoma, cervical immobility, or tandem internal carotid artery stenoses.

placed in conjunction with planned intracranial procedures (n = 408) were excluded. Patients with unknown presenting symptom status (n = 890) or unknown symptom severity (n = 998) were also excluded, resulting in 11 891 patients who underwent carotid artery stenting. Of these patients, 5251 (44%) underwent transcarotid artery revascularization and 6640 (56%) underwent transfemoral carotid artery stenting. These procedures were performed by 1035 physicians from 319 centers. The majority of transcarotid procedures were performed by vascular surgeons (85%), followed by general surgeons (9%), neurosurgeons (2%), and cardiologists (1%); whereas transfemoral carotid artery stenting was performed by vascular surgeons (28%), radiologists (21%), cardiologists (20%), neurosurgeons (13%), neurologists (11%), and general surgeons (3%). Baseline characteristics and coexisting conditions before and after propensity-score matching can be found in Table 1 and unadjusted outcomes can be found in eTable 1 in the Supplement. Overall, patients undergoing transcarotid artery revascularization were older and had more medical coexisting conditions. After matching, 3286 pairs of patients remained in the study population and the 2 cohorts were well matched. Among these matched pairs, data on in-hospital stroke or death were available for all patients, and data on ipsilateral stroke or death at 1 year were available for 46% of patients undergoing transcarotid artery revascularization and 54% of patients undergoing transfemoral carotid artery stenting.

Overall Outcomes

In-hospital risk of stroke or death was 1.6% in the transcarotid cohort vs 3.1% in the transfemoral cohort (absolute difference, −1.52% [95% CI, −2.29% to −0.75%]; RR, 0.51 [95% CI, 0.37 to 0.72]; *P* < .001) (**Table 2**). Transcarotid artery revascularization was associated with significantly lower risks of both stroke (1.3% vs 2.4%; absolute difference, −1.10% [95% CI, −1.79% to −0.41%]; RR, 0.54 [95% CI, 0.38 to 0.79]; *P* = .001)

Figure 1. Trend in Transcarotid Artery Revascularization and Transfemoral Carotid Artery Stenting in the Vascular Quality Initiative



Yellow shading indicates the trend during the study period.

and death (0.4% vs 1.0%; absolute difference, −0.55% [95% CI, −0.98% to −0.11%]; RR, 0.44 [95% CI, 0.23 to 0.82]; *P* = .008). Risks between the transcarotid and transfemoral cohorts were not statistically different for myocardial infarction (0.2% vs 0.3%; absolute difference, −0.09% [95% CI, −0.37% to 0.19%]; RR, 0.70 [95% CI, 0.27 to 1.84]; *P* = .47) and transient ischemic attack (0.7% vs 1.0%; absolute difference, −0.30% [95% CI, −0.77% to 0.16%]; RR, 0.69 [95% CI, 0.40 to 1.18]; *P* = .17).

At 30 days, the transcarotid approach was associated with significantly lower risk of stroke or death (1.9% vs 3.7%; absolute difference, −1.73% [95% CI, −2.57% to −0.90%]; RR, 0.53 [95% CI, 0.39 to 0.72]; *P* < .001) as well as the individual end points of stroke (1.3% vs 2.5%; absolute difference, −1.19% [95% CI, −1.89% to −0.49%]; RR, 0.53 [95% CI, 0.37 to 0.76]; *P* < .001) and death (0.8% vs 1.5%; absolute difference, −0.70% [95% CI,

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

Outcome	Transcarotid Artery Revascularization[a] (n = 3286)	Transfemoral Carotid Artery Stenting[a] (n = 3286)	Absolute Difference (95% CI), %	Relative Risk (95% CI)	P Value
Stroke or death	52 (1.6)	102 (3.1)	−1.52 (−2.29 to −0.75)	0.51 (0.37 to 0.72)	<.001
Stroke or death, 30 d	64 (1.9)	121 (3.7)	−1.73 (−2.57 to −0.90)	0.53 (0.39 to 0.72)	<.001
Stroke	43 (1.3)	79 (2.4)	−1.10 (−1.79 to −0.41)	0.54 (0.38 to 0.79)	.001
Stroke, 30 d	44 (1.3)	83 (2.5)	−1.19 (−1.89 to −0.49)	0.53 (0.37 to 0.76)	<.001
Transient ischemic attack	22 (0.7)	32 (1.0)	−0.30 (−0.77 to 0.16)	0.69 (0.40 to 1.18)	.17
Death	14 (0.4)	32 (1.0)	−0.55 (−0.98 to −0.11)	0.44 (0.23 to 0.82)	.008
Death, 30 d	25 (0.8)	48 (1.5)	−0.70 (−1.24 to −0.16)	0.52 (0.32 to 0.84)	.007
Myocardial infarction	7 (0.2)	10 (0.3)	−0.09 (−0.37 to 0.19)	0.70 (0.27 to 1.84)	.47
Heart failure exacerbation	14 (0.4)	21 (0.6)	−0.21 (−0.60 to 0.17)	0.67 (0.34 to 1.31)	.24
Access site bleeding complication	116 (3.5)	125 (3.8)	−0.27 (−0.01 to 0.66)	0.93 (0.72 to 1.19)	.55
Interventional treatment	44 (1.3)	27 (0.8)	0.52 (−0.01 to 1.04)	1.63 (1.02 to 2.61)	.04
Blood transfusion	60 (1.8)	71 (2.2)	−0.34 (−1.04 to 0.37)	0.85 (0.60 to 1.19)	.33
Hemodynamic instability					
Hypotension	424 (15.0)	541 (18.8)	−3.65 (−5.74 to −1.55)	0.80 (0.71 to 0.91)	<.001
Hypertension	469 (16.3)	432 (15.6)	0.66 (−1.41 to 2.72)	1.04 (0.92 to 1.18)	.53
Reperfusion syndrome[b]	9 (0.3)	17 (0.5)	−0.24 (−0.58 to 0.09)	0.53 (0.24 to 1.19)	.12
Technical failure	15 (0.5)	41 (1.2)	−0.79 (−1.27 to −0.32)	0.37 (0.20 to 0.66)	<.001
Unable to access CCA	2 (0.1)	14 (0.4)	−0.37 (−0.63 to −0.10)	0.14 (0.03 to 0.63)	.003
Unable to cross carotid lesion	5 (0.2)	21 (0.6)	−0.49 (−0.82 to −0.15)	0.24 (0.09 to 0.63)	.002
Unable to deploy stent	8 (0.2)	6 (0.2)	0.01 (−0.19 to 0.31)	1.33 (0.46 to 3.84)	.59
Embolic device placement failure[c]	9 (0.3)	191 (5.8)	−5.54 (−6.40 to −4.69)	0.05 (0.02 to 0.09)	<.001
Unable to insert	3 (0.1)	34 (1.0)	−0.94 (−1.34 to −0.55)	0.09 (0.03 to 0.29)	<.001
Procedure time, median (IQR), m	68 (53 to 87)	62 (47 to 85)			<.001
Fluoroscopy time, median (IQR), m	5 (3 to 7)	16 (11 to 23)			<.001
Contrast volume, median (IQR), mL	30 (20 to 45)	80 (55 to 122)			<.001
Length of stay, median (IQR), d	1 (1 to 2)	1 (1 to 2)			.15
Failed CMS discharge criteria	540 (16.4)	747 (22.7)	−6.30 (−8.21 to −4.39)	0.72 (0.66 to 0.80)	<.001
Prolonged length of stay[d]	457 (13.9)	625 (19.0)	−5.11 (−6.91 to −3.31)	0.73 (0.66 to 0.82)	<.001
Failed discharge home[e]	239 (7.3)	417 (12.7)	−5.42 (−6.90 to −3.94)	0.57 (0.49 to 0.67)	<.001

Abbreviations: CCA, common carotid artery; CMS, Centers for Medicare & Medicaid Services; IQR, interquartile range.

[a] Values are reported as No. (%) unless otherwise indicated.

[b] Defined as postoperative headaches associated with seizures or hemorrhage shown on brain imaging.

[c] Embolic protection device was defined as flow reversal system for the transcarotid approach and distal embolic filter protection device placement for the transfemoral approach.

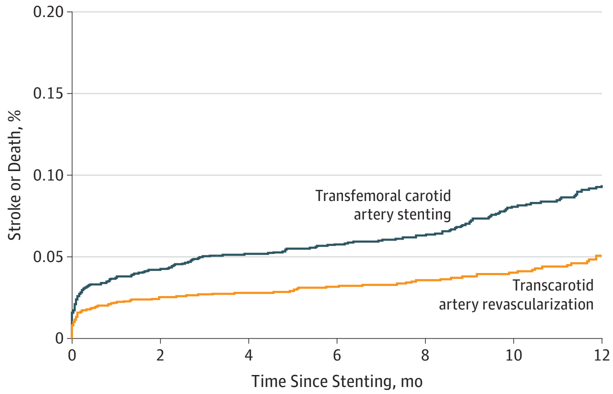
[d] Defined as greater than 2 days.

[e] Defined as discharge to a location other than the patient's preoperative place of residence.

−1.24% to −0.16%]; RR, 0.52 [95% CI, 0.32 to 0.84]; *P* = .007). At 1 year, the transcarotid approach was associated with a significantly lower risk of ipsilateral stroke or death compared with the transfemoral approach (5.1% vs 9.6%; hazard ratio, 0.52 [95% CI, 0.41 to 0.66]; *P* < .001) (**Figure 2**).

Transcarotid artery revascularization was associated with significantly lower rates of technical failure (0.5% vs 1.2%; absolute difference, −0.79% [95% CI, −1.27% to −0.32%]; RR, 0.37 [95% CI, 0.20 to 0.66]; *P* < .001). Embolic protection placement failure was significantly lower for the transcarotid approach compared with distal filter placement for the transfemoral approach (0.3% vs 5.8%; absolute difference, −5.54% [95% CI, −6.40% to −4.69%]; RR, 0.05 [95% CI, 0.02 to 0.09]; *P* < .001). The transcarotid approach was associated with significantly less radiation (median fluoroscopy time, 5 minutes [interquartile range {IQR}, 3 to 7] vs 16 minutes [IQR, 11 to 23]; *P* < .001) and less contrast (median contrast used, 30 mL [IQR, 20 to 45] vs 80 mL [IQR, 55 to 122]; *P* < .001). Although there were no statistically significant differences in overall access site bleeding complications (3.5% vs 3.8%; absolute difference, −0.27% [95% CI, −0.01% to 0.66%]; RR, 0.93 [95% CI, 0.72 to 1.19]; *P* = .55), transcarotid artery revascularization was associated with higher risks of access site bleeding resulting in interventional treatment (1.3% vs 0.8%; absolute difference, 0.52% [95% CI, −0.01% to 1.04%]; RR, 1.63 [95% CI, 1.02 to 2.61; *P* = .04). Patients who underwent transcarotid artery revascularization were significantly less likely than patients who underwent transfemoral carotid artery stenting to fail the CMS-recommended discharge criteria (16.4% vs 22.7%; absolute difference, −6.30% [95% CI, −8.21% to −4.39%]; RR, 0.72 [95% CI, 0.66 to 0.80]; *P* < .001), including length of stay greater than 2 days (13.9% vs 19.0%; absolute difference, −5.11%

Figure 2. Kaplan-Meier Estimated Stroke or Death in Patients Undergoing Transcarotid Artery Revascularization or Transfemoral Carotid Artery Stenting



No. at risk							
Transfemoral procedure	3285	2023	1825	1681	1493	1224	899
Transcarotid procedure	3285	1890	1707	1551	1350	1088	757

Median observation time for transcarotid artery revascularization was 286 days (interquartile range [IQR], 35 to 371), and for transfemoral carotid artery stenting was 294 days (IQR, 36 to 393; hazard ratio, 0.52 [95% CI, 0.41 to 0.66]; *P*<.001).

[95% CI, −6.91% to −3.31%]; RR, 0.73 [95% CI, 0.66 to 0.82]; *P* < .001), and failed discharge home (7.3% vs 12.7%; absolute difference, −5.42% [95% CI, −6.90% to −3.94%]; RR, 0.57 [95% CI, 0.49 to 0.67]; *P* < .001).

Symptomatic Carotid Stenosis

There was interaction between presenting symptom status and the outcomes of in-hospital stroke or death (*P* value for interaction = .007), stroke (*P* value for interaction = .09), and death (*P* value for interaction = .007). Propensity-score matching of patients with symptomatic carotid disease resulted in 1829 pairs (eTable 2 in the Supplement). Transcarotid artery revascularization was associated with significantly lower risk of in-hospital stroke or death (2.1% vs 4.2%; absolute difference, −2.02% [95% CI, −3.21% to −0.83%]; RR, 0.51 [95% CI, 0.35 to 0.75]; *P* < .001), stroke (2.0% vs 3.1%; absolute difference, −1.10% [95% CI, −2.17% to −0.02%]; RR, 0.64 [95% CI, 0.42 to 0.97]; *P* = .04), and death (0.5% vs 1.5%; absolute difference, −1.04% [95% CI, −1.74% to −0.33%]; RR, 0.32 [95% CI, 0.15 to 0.68]; *P* = .002) (**Table 3**). There were no statistically significant differences in overall bleeding complications (4.0% vs 4.1%; absolute difference, −0.05% [95% CI, −1.40% to 1.29%]; RR, 0.99 [95% CI, 0.72 to 1.36]; *P* = .93) or bleeding reinterventions (1.3% vs 0.7%; absolute difference, 0.49% [95% CI, −0.20% to 1.19%]; RR, 1.69 [95% CI, 0.85 to 3.36]; *P* = .13) between the 2 cohorts (Table 3).

Asymptomatic Carotid Stenosis

After propensity matching patients with asymptomatic disease, 1438 pairs of patients remained (eTable 3 in the Supplement). There was no statistically significant difference in in-hospital stroke or death (1.0% vs 1.5%; absolute difference, −0.42% [95% CI, −1.30% to 0.47%]; RR, 0.71 [95% CI, 0.37 to 1.39]; *P* = .32), stroke (0.7% vs 1.3%; absolute difference, −0.56% [95% CI, −1.35% to 0.23%]; RR, 0.56 [95% CI, 0.26 to 1.20]; *P* = .13), and death (0.4% vs 0.2%; absolute difference, 0.21% [95% CI, −0.27% to 0.69%]; RR, 2.00 [95% CI, 0.50 to 8.00]; *P* = .32). Although there were no statistically significant differences in overall bleeding complications (2.6% vs 2.8%; absolute difference, −0.21% [95% CI, −1.43% to 1.01%]; RR, 0.93 [95% CI, 0.60 to 1.42]; *P* = .72), transcarotid artery revascularization was associated with higher risks of bleeding reinterventions (1.3% vs 0.5%; absolute difference, 0.77% [95% CI, 0.04% to 1.49%]; RR, 2.57 [95% CI, 1.11 to 5.94]; *P* = .02) (Table 3).

Discussion

In this prospective registry that evaluated patients undergoing treatment for carotid stenosis, transcarotid artery revascularization, compared with transfemoral carotid artery stenting, was associated with a lower risk of stroke or death. For several decades, carotid endarterectomy has been the criterion standard for carotid revascularization, with perioperative stroke or death rates typically less than 2 percent for asymptomatic patients.[12-14] Transfemoral carotid artery stenting was introduced in 1996 as an alternative, more minimally invasive technique.[15] However, several randomized trials have since identified an increased risk of stroke following transfemoral carotid artery stenting compared with endarterectomy.[1-4] For example, the CREST trial (Carotid Revascularization Endarterectomy Versus Stenting Trial) compared endarterectomy and carotid stenting before the introduction of the transcarotid approach and found higher rates of 30-day perioperative stroke after transfemoral carotid artery stenting compared with endarterectomy (4.1% vs 2.3%; *P* = .01), most notably in the treatment of symptomatic patients (5.5% vs 3.2%; *P* = .04).[1] Additional randomized trials and large retrospective database studies have now further confirmed the higher perioperative stroke risk associated with transfemoral carotid artery stenting.[16-19]

As a response to the high rates of perioperative stroke with transfemoral carotid artery stenting, transcarotid revascularization with flow reversal was developed as a new carotid stenting technique, specifically to avoid the high-risk maneuvers

Table 3. In-Hospital Perioperative Outcomes After Transcarotid Artery Revascularization or Transfemoral Carotid Artery Stenting for Symptomatic and Asymptomatic Patients in a Propensity Score–Matched Study Population

	Symptomatic Patients (n = 3658)					Asymptomatic Patients (n = 2876)				
Outcome[a]	Transcarotid Artery Revascularization[b] (n = 1829)	Transfemoral Carotid Artery Stenting[b] (n = 1829)	Absolute Difference (95% CI), %	Relative Risk (95% CI)	*P* Value	Transcarotid Artery Revascularization[b] (n = 1438)	Transfemoral Carotid Artery Stenting[b] (n = 1438)	Absolute Difference (95% CI), %	Relative Risk (95% CI)	*P* Value
Stroke or death	39 (2.1)	76 (4.2)	−2.02 (−3.21 to −0.83)	0.51 (0.35 to 0.75)	<.001	15 (1.0)	21 (1.5)	−0.42 (−1.30 to 0.47)	0.71 (0.37 to 1.39)	.32
Stroke or death, 30 d	47 (2.6)	88 (4.8)	−2.22 (−3.53 to −0.96)	0.53 (0.38 to 0.76)	<.001	18 (1.3)	26 (1.8)	−0.56 (−1.53 to 0.42)	0.69 (0.38 to 1.26)	.23
Stroke	36 (2.0)	56 (3.1)	−1.10 (−2.17 to −0.02)	0.64 (0.42 to 0.97)	.04	10 (0.7)	18 (1.3)	−0.56 (−1.35 to 0.23)	0.56 (0.26 to 1.20)	.13
Stroke, 30 d	36 (2.0)	58 (3.2)	−1.20 (−2.29 to −0.12)	0.62 (0.41 to 0.94)	.02	11 (0.8)	20 (1.4)	−0.63 (−1.45 to 0.20)	0.55 (0.26 to 1.15)	.11
Transient ischemic attack	14 (0.8)	25 (1.4)	−0.60 (−1.33 to 0.12)	0.56 (0.29 to 1.08)	.08	6 (0.4)	6 (0.4)	0.00 (−0.54 to 0.54)	1.00 (0.32 to 3.10)	>.99
Death	9 (0.5)	28 (1.5)	−1.04 (−1.74 to −0.33)	0.32 (0.15 to 0.68)	.002	6 (0.4)	3 (0.2)	0.21 (−0.27 to 0.69)	2.00 (0.50 to 8.00)	.32
Death, 30 d	17 (0.9)	39 (2.1)	−1.20 (−2.06 to −0.35)	0.44 (0.25 to 0.77)	.003	8 (0.6)	6 (0.4)	0.14 (−0.44 to 0.72)	1.33 (0.46 to 3.84)	.59
Myocardial infarction	1 (0.1)	6 (0.3)	−0.27 (−0.61 to 0.06)	0.17 (0.02 to 1.38)	.06	4 (0.3)	5 (0.3)	−0.07 (−0.55 to 0.41)	0.80 (0.21 to 2.98)	.74
Heart failure exacerbation	11 (0.6)	17 (0.9)	−0.33 (−0.95 to 0.29)	0.65 (0.30 to 1.38)	.26	3 (0.2)	2 (0.1)	0.07 (−0.30 to 0.44)	1.50 (0.25 to 8.98)	.65
Access site bleeding complication	74 (4.0)	74 (4.1)	−0.05 (−1.40 to 1.29)	0.99 (0.72 to 1.36)	.93	37 (2.6)	40 (2.8)	−0.21 (−1.43 to 1.01)	0.93 (0.60 to 1.42)	.72
Interventional treatment	23 (1.3)	13 (0.7)	0.49 (−0.20 to 1.19)	1.69 (0.85 to 3.36)	.13	18 (1.3)	7 (0.5)	0.77 (0.04 to 1.49)	2.57 (1.11 to 5.94)	.02
Blood transfusion	41 (2.2)	48 (2.6)	−0.38 (−1.45 to 0.68)	0.85 (0.56 to 1.30)	.46	15 (1.0)	23 (1.6)	−0.56 (−1.47 to 0.35)	0.65 (0.34 to 1.25)	.19
Hemodynamic instability										
Hypotension	239 (15.4)	313 (20.0)	−5.14 (−8.13 to −2.16)	0.75 (0.63 to 0.88)	<.001	184 (14.7)	243 (18.5)	−4.20 (−7.35 to −1.04)	0.78 (0.65 to 0.94)	.008
Hypertension	285 (17.9)	288 (18.7)	−0.67 (−3.70 to 2.37)	0.96 (0.82 to 1.13)	.66	201 (15.9)	126 (10.5)	6.07 (3.05 to 9.09)	1.59 (1.27 to 2.00)	<.001
Reperfusion syndrome[c]	7 (0.4)	16 (0.9)	−0.49 (−1.06 to 0.08)	0.44 (0.18 to 1.06)	.06	4 (0.3)	1 (0.1)	0.21 (−0.17 to 0.58)	4.00 (0.45 to 35.8)	.18
Procedure time, median (IQR), m	68 (54 to 88)	64 (48 to 90)			<.001	69 (53 to 87)	60 (46 to 81)			<.001
Fluoroscopy time, median (IQR), m	5 (3 to 7)	16 (11 to 24)			<.001	5 (4 to 7)	15 (10 to 20)			<.001
Contrast volume, median (IQR), mL	30 (20 to 45)	80 (55 to 125)			<.001	30 (20 to 45)	80 (50 to 120)			<.001
Failed CMS discharge criteria	397 (21.7)	588 (32.1)	−10.4 (−13.4 to −7.53)	0.68 (0.61 to 0.75)	<.001	146 (10.2)	142 (9.9)	0.28 (−1.96 to 2.52)	1.02 (0.83 to 1.28)	.80
Prolonged length of stay, d	322 (17.6)	475 (26.0)	−8.37 (−11.1 to −5.63)	0.68 (0.60 to 0.77)	<.001	130 (9.0)	133 (9.2)	−0.21 (−2.38 to 1.96)	0.98 (0.78 to 1.23)	.85
Failed discharge home	378 (20.7)	378 (20.7)	−9.24 (−11.6 to −6.84)	0.55 (0.47 to 0.65)	<.001	29 (2.0)	40 (2.8)	−0.76 (−1.95 to 0.42)	0.73 (0.45 to 1.16)	.18

Abbreviations: CMS, Centers for Medicare & Medicaid Services; IQR, interquartile range.

[a] Outcomes are in-hospital events unless otherwise indicated.

[b] Values are reported as No. (%) unless otherwise indicated.

[c] Defined as postoperative headaches associated with seizures or hemorrhage shown on brain imaging.

that have been associated with transfemoral carotid artery stenting, including manipulation of the aortic arch to cannulate the common carotid artery and crossing the carotid lesion unprotected to deploy the embolic protection filter distally.[20,21] Even when deployed, filter devices can allow passage of small embolic particles through their pores or around the filter if incompletely apposed to the vessel wall.[22,23] Transcarotid artery revascularization avoids the aortic arch with direct common carotid access and utilizes flow reversal prior to crossing the lesion. In patients with carotid disease, 68% of carotid arteries have been found to be anatomically eligible for the transcarotid approach, and 79% are eligible for the transfemoral approach, indicating a wide range of suitability for either procedure.[24]

The theoretical benefits with transcarotid artery revascularization were first confirmed clinically in the multicenter single-group ROADSTER trial (Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure), which showed a 30-day stroke rate of 1.4% and 95% stroke-free survival at 1 year.[25,26] This study found a similar but slightly lower perioperative stroke rate of 1.2% following transcarotid artery revascularization compared with the ROADSTER trial. Similarly, the 30-day perioperative stroke or death rate of 3.7% in this study was also lower than that found for transfemoral carotid artery stenting in randomized clinical trials such as CREST (4.4%). This difference is likely attributable to an underreporting of stroke events as patients were not assessed for potential stroke by neurologists, and the nonneurologic assessors did not use formal operationalized neurologic examinations and structured interviews to detect stroke symptoms and signs.

Whereas transcarotid artery revascularization was associated with a statistically significant decrease in stroke rates compared with transfemoral carotid artery stenting for treatment of symptomatic patients, there was no statistically significant difference in stroke rates for treatment of asymptomatic patients. However, the study may have been underpowered to detect an association given the overall low event rates in asymptomatic patients.

Several trials have shown a reduction in perioperative myocardial infarctions with transfemoral carotid artery stenting compared with endarterectomy, likely attributable to its more minimally invasive approach.[16,18] Transcarotid artery revascularization, which also uses a less invasive approach than endarterectomy, showed no significant difference in perioperative myocardial infarction profile as compared with transfemoral carotid artery stenting in both asymptomatic and symptomatic patients. These benefits were found despite the higher rates of bleeding complications associated with intervention following transcarotid artery revascularization.

Limitations

This study has several limitations. First, treatment options were not randomized but were selected by the treating physician, introducing the possibility of confounding by indication. Second, because of the study's observational design, causal inferences cannot be made. Third, because the end point of stroke was determined clinically by perioperative neurological symptoms and there was no requirement for formalized neurologic testing or imaging, this study is subject to ascertainment bias. Fourth, clinical registries are subject to selection bias since not all US hospitals participate. Although not all patients undergoing carotid stenting nationally are captured in this study, based on industry reporting,[27] 95.4% of all transcarotid procedures utilizing flow reversal performed in the United States are recorded in this registry. Fifth, while this registry contains multiple predefined anatomic and medical variables specific to carotid disease, unmeasured confounding may still be present. Sixth, this study's definition of transient ischemic attack was based on focal neurological symptoms lasting less than 24 hours and does not reflect the current definition of transient ischemic attack set forth by the American Heart Association and American Stroke Association. Seventh, there are no details captured to differentiate between ischemic vs hemorrhagic strokes nor guidance provided regarding classifying location of subcortical anterior circulation and occipital cortex strokes. Eighth, 1-year follow-up is not complete for all patients in the study. However, this is accounted for with Kaplan-Meier censoring, and multiple randomized trials have demonstrated no statistically significant difference in stroke or death occurring beyond the perioperative period between stenting and endarterectomy, so there is no reason to suspect that adverse events past this study period would be different for transcarotid vs transfemoral stents.[28,29]

Conclusions

Among patients undergoing treatment for carotid stenosis, transcarotid artery revascularization, compared with transfemoral carotid artery stenting, was significantly associated with a lower risk of stroke or death.

ARTICLE INFORMATION

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