UPDATE ON TCAR, TFCAS, AND CEA

This Population Based Study Shows That CEA Is Better Than TCAR Which Is Better Than TFCAS

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Disclosures

- PI: SVS TCAR Surveillance Project
- PI: Roadster 3
  - No personal income from either

ROADSTER TRIALS

ROADSTER 1

- **Design:** Prospective, single arm, multi-center trial of the TCAR Procedure using the ENROUTE® Transcarotid NeuroprotectionSystem
- **Cohort:** 141 high surgical risk patients with carotid artery stenosis.
- **30-day results:**

Stroke	1.4%
Death	1.4%
Stroke/Death	2.8%
Stroke/Death/MI	3.5%

ROADSTER 2

- **Design:** Usage of the ENROUTE® Transcarotid Stent System in conjunction with the ENROUTE® Transcarotid Neuroprotection System in high surgical risk patients with carotid artery stenosis
- **Cohort:** 692 patients across 43 sites, with 81% of the physician enrollers being new TCAR operators
- **30-day results:**

Stroke	1.9%
Death	0.4%
Stroke/Death	2.3%
Stroke/Death/MI	3.2%

ROADSTER 3

- **Design:** Single arm, multi-center post-approval study for the treatment of patients at standard risk for adverse events from carotid endarterectomy who require carotid revascularization and who are eligible for treatment using the ENROUTE Transcarotid Stent System and the ENROUTE Transcarotid Neuroprotection System
- **Cohort:** Will enroll a maximum of 400 per-protocol standard-risk patients at up to 60 sites
- **30-day results:** TBD

Vascular Quality Initiative (VQI) TCAR Surveillance Project (TSP)

- Launched by SVS Patient Safety Organization in 2016
- First registry-based trial
- Approved by FDA & CMS
- ClinicalTrials.gov NCT-2850588

VQI -TCAR vs tfCAS

Research

JAMA | Original Investigation

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

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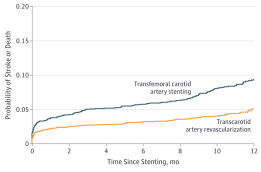
30d S/D/MI + Ipsilateral CVA to 1 year

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



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).

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VQI - TCAR vs CEA

ORIGINAL ARTICLE

TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project

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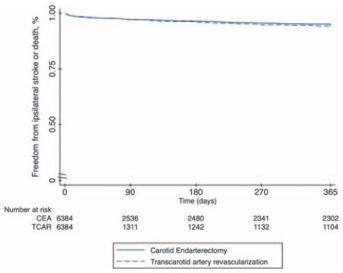
(*Ann Surg* 2022;276:398–403)

S/D to 1 year CEA vs TCAR



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JVS Journal of Vascular Surgery | SVS Society for Vascular Surgery

From the Society for Vascular Surgery

Seven years of the transcarotid artery revascularization surveillance project, comparison to transfemoral stenting and endarterectomy

Sabrina Straus, BS,[a,b] Sai Divya Yadavalli, MD,[a] Sara Allievi, MD,[a,c] Andrew Sanders, MD,[a] Roger B. Davis, ScD,[a] Mahmoud B. Malas, MD,[b] Grace J. Wang, MD,[d] Vikram S. Kashyap, MD,[e] Jack Cronenwett, MD,[f] Raghu L. Motaganahalli, MD,[g] Brian Nolan, MD,[h] Jens Eldrup-Jorgensen, MD,[h] and Marc Schermerhorn, MD,[a] *Boston, MA; San Diego, CA; Milan, Italy; Philadelphia, PA; Grand Rapids, MI; Lebanon, NH; Indianapolis, IN; and Portland, ME*

(JVS, 2024 Nov;80(5):1455-1463)

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TCAR vs tfCAS vs CEA (VQI)

From the Society for Vascular Surgery

Seven years of the transcarotid artery revascularization surveillance project, comparison to transfemoral stenting and endarterectomy

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(J Vasc Surg 2024;80:1455-63.)

Study design

- Retrospective cohort study of TCAR, CEA, or tfCAS in the VQI from 9/2016 to 8/2023
- Overall population: 50,068 TCAR, 122,737 CEA, 25,361 tfCAS (N=198,166)
  - Asymptomatic: 37,826 TCAR, 85,828 CEA, 15,607 tfCAS
  - Symptomatic: 12,242 TCAR, 36,909 CEA, 9,754 tfCAS

Outcomes

- Primary outcome: in-hospital stroke or death (composite endpoint)
- Acceptable In-Hosp S/D Threshold:
  ASX: 2% SX: 4% (~1/3 of 30-d S/D occur after discharge- Fokkema 2013, Liang, 2020)

Statistical Analysis

- Propensity Scores with Inverse Probability of Treatment Weighting

JVS Journal of Vascular Surgery | SVS Society for Vascular Surgery

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Table II. Postoperative outcomes for all carotid stenosis patients

	TCAR	tfCAS	CEA	tfCAS vs TCAR aOR (95% CI)	tfCAS vs TCAR *P* value	tfCAS vs CEA aOR (95% CI)	tfCAS vs CEA *P* value	CEA vs TCAR aOR (95% CI)	CEA vs TCAR *P* value
In-hospital stroke	1.3%	2.1%	1.1%	1.58 (1.39-1.79)	<.001	1.88 (1.68-2.10)	<.001	0.84 (0.76-0.93)	<.001
In-hospital death	0.4%	1.1%	0.3%	2.80 (2.29-3.42)	<.001	3.66 (3.10-4.32)	<.001	0.76 (0.64-0.92)	.004
Perioperative MI	0.5%	0.4%	0.6%	0.88 (0.69-1.13)	.3	0.67 (0.54-0.84)	<.001	1.31 (1.13-1.54)	<.001
Stroke or death	1.6%	2.9%	1.3%	1.84 (1.65-2.06)	<.001	2.21 (2.01-2.43)	<.001	0.83 (0.76-0.91)	<.001
Stroke, death, MI	2.0%	3.2%	1.9%	1.62 (1.46-1.80)	<.001	1.72 (1.58-1.88)	<.001	0.94 (0.87-1.02)	.14
Length of stay >2 days	29.6%	35.5%	30.1%	1.31 (1.27-1.36)	<.001	1.28 (1.24-1.32)	<.001	1.02 (1.00-1.05)	.047
CNI	0.3%	0.0%	2.3%	0.00 (0.00-0.00)	<.001	0.00 (0.00-0.00)	<.001	9.42 (7.78-11.4)	<.001
Bleeding	0.8%	0.4%	1.0%	0.52 (0.41-0.67)	<.001	0.38 (0.30-0.47)	<.001	1.38 (1.22-1.57)	<.001

aOR, Adjusted odds ratio; *CEA*, carotid endarterectomy; *CI*, confidence interval; *CNI*, cranial nerve injury; *MI*, myocardial infarction; *TCAR*, transcarotid artery revascularization; *tfCAS*, transfemoral carotid artery stenting.
Inverse probability of treatment weighting accounted for the following variables: age, sex, race, body mass index, hypertension, diabetes, coronary artery disease, congestive heart failure, preoperative smoking, chronic obstructive pulmonary disease, renal dysfunction, anemia, symptomatic amaurosis, symptomatic hemispheric transient ischemic attack, symptomatic stroke, coronary artery bypass grafting/percutaneous coronary intervention, prior contralateral CEA/carotid artery stenting, % ipsilateral and contralateral occlusion, and surgery year.

Beth Israel Deaconess Medical Center | Harvard Medical School Teaching Hospital — Postoperative outcomes for symptomatic carotid stenosis patients

Table III. Postoperative outcomes for symptomatic carotid stenosis patients

	TCAR	tfCAS	CEA	tfCAS vs TCAR aOR (95% CI)	tfCAS vs TCAR *P* value	tfCAS vs CEA aOR (95% CI)	tfCAS vs CEA *P* value	CEA vs TCAR aOR (95% CI)	CEA vs TCAR *P* value
In-hospital stroke	2.1%	3.0%	1.8%	1.46 (1.21-1.76)	<.001	1.73 (1.48-2.02)	<.001	0.84 (0.72-0.98)	.029
In-hospital death	0.6%	1.9%	0.5%	3.35 (2.50-4.48)	<.001	4.06 (3.26-5.05)	<.001	0.83 (0.62-1.10)	.2
Perioperative MI	0.4%	0.6%	0.6%	1.39 (0.93-2.07)	.10	0.97 (0.71-1.32)	.8	1.44 (1.05-1.96)	.022
Stroke or death	2.4%	4.4%	2.1%	1.87 (1.59-2.21)	<.001	2.18 (1.91-2.48)	<.001	0.86 (0.75-0.99)	.039
Stroke, death, MI	2.8%	4.8%	2.6%	1.78 (1.53-2.08)	<.001	1.89 (1.67-2.14)	<.001	0.94 (0.83-1.08)	.4
Length of stay >2 days	41.1%	52.2%	42.9%	1.56 (1.47-1.66)	<.001	1.45 (1.38-1.53)	<.001	1.08 (1.03-1.12)	.001
CNI	0.3%	0.0%	2.8%	0.00 (0.00-0.00)	<.001	0.00 (0.00-0.00)	<.001	8.60 (6.20-11.9)	<.001
Bleeding	0.8%	0.5%	1.3%	0.58 (0.39-0.87)	.009	0.36 (0.25-0.51)	<.001	1.61 (1.28-2.04)	<.001

aOR, Adjusted odds ratio; *CEA*, carotid endarterectomy; *CI*, confidence interval; *CNI*, cranial nerve injury; *MI*, myocardial infarction; *TCAR*, transcarotid artery revascularization; *tfCAS*, transfemoral carotid artery stenting.

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Postoperative outcomes for symptomatic carotid stenosis patients

Table IV. Postoperative outcomes for asymptomatic carotid stenosis patients

	TCAR	tfCAS	CEA	tfCAS vs TCAR		tfCAS vs CEA		CEA vs TCAR	
				aOR (95% CI)	*P* value	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value
In-hospital stroke	1.1%	1.7%	0.9%	1.57 (1.32-1.86)	< .001	1.94 (1.66-2.27)	< .001	0.81 (0.71-0.91)	< .001
In-hospital death	0.3%	0.7%	0.2%	2.13 (1.59-2.85)	< .001	3.07 (2.37-3.98)	< .001	0.69 (0.54-0.88)	.003
Perioperative MI	0.5%	0.3%	0.6%	0.67 (0.48-0.94)	.020	0.53 (0.39-0.73)	< .001	1.26 (1.06-1.51)	.011
Stroke or death	1.3%	2.1%	1.0%	1.68 (1.44-1.96)	< .001	2.15 (1.87-2.47)	< .001	0.78 (0.70-0.88)	< .001
Stroke, death, MI	1.7%	2.4%	1.5%	1.42 (1.23-1.64)	< .001	1.56 (1.37-1.77)	< .001	0.91 (0.82-1.01)	.067
Length of stay >2 days	25.3%	27.6%	24.7%	1.12 (1.07-1.18)	< .001	1.16 (1.11-1.21)	< .001	0.97 (0.94-1.00)	.027
CNI	0.2%	0.0%	2.2%	0.00 (0.00-0.00)	< .001	0.00 (0.00-0.00)	< .001	9.67 (7.64-12.3)	< .001
Bleeding	0.7%	0.4%	0.9%	0.49 (0.36-0.68)	< .001	0.38 (0.29-0.51)	< .001	1.29 (1.12-1.50)	< .001

aOR, Adjusted odds ratio; *CEA*, carotid endarterectomy; *CI*, confidence interval; *CNI*, cranial nerve injury; *MI*, myocardial infarction; *TCAR*, transcarotid artery revascularization; *tfCAS*, transfemoral carotid artery stenting.

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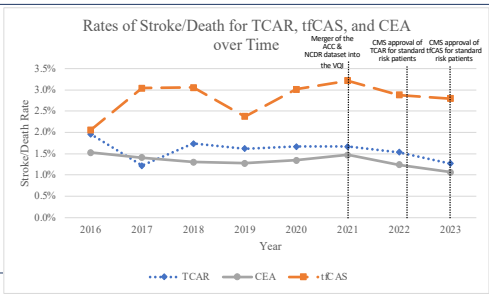

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- TCAR (and CEA) has a superior safety profile to tfCAS, in Asx and Sx patients
- TCAR has a similar has a similar safety profile to CEA,in Asx and Sx patients.
- Patient selection between CEA and TCAR (and tfCAS) should be based on anatomy and anticipated risks

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Choosing TCAR vs CEA vs tfCAS

Patient Characteristic	Procedure Choice
Normal Risk	TCAR or CEA depending on anatomy & patient preference High Bifurcation, prior CEA, XRT – TCAR Low Bifurcation, Ca++, Angulation, Thrombus – CEA (Vast Majority are Candidates for Both)
High Anatomic/Medical Risk	TCAR
HR but Not TCAR Candidate	CEA TCAR w/conduit (for low bifurcation) tfCAS in select patients Stoma, Radical neck, XRT at base of neck Medical Mgmt

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