VEITH SYMPOSIUM Connecting The Vascular Community

UC San Diego Health System

What Are The Real Risk Factors For CEA, TFCAS And TCAR: Why Has CMS Gotten Their Risk Factors Wrong And How Have They Messed Up Their Reimbursement Incentives

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Presenter Disclosure Information

Principal Investigator:
1. CREST
2. ACT I
3. CAPTURE II
4. CHOICE
5. FREEDOM
6. ROADSTER
7. SAPHIRE W
8. ROADSTER II
9. CREST II
10.CREST Companion Study
11. CREST H

- International Principal Investigator For "The ROADSTER Long Term Follow Up"
- SVS VQI TCAR Surveillance Project (TSP) Steering Committee
- Silk Road Medical, Educational Grant to support postdoctoral fellow

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CMS High Risk Criteria For CAS

Anatomical Criteria	Medical Comorbidities
• Lesion at C2 or higher • Lesion below clavicle • Prior radical neck surgery or radiation • Contralateral carotid occlusion • Prior ipsilateral CEA • Contralateral laryngeal nerve palsy • Tracheostoma	• Age ≥80 yrs • Class III/IV congestive heart failure • Class II/ IV angina pectoris • Left main/≥2 vessel coronary disease • Urgent (<30 days) heart surgery • LV ejection fraction =30% • Recent (<30 days) myocardial infarction • Severe chronic lung disease • Severe renal disease

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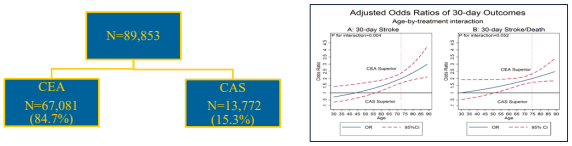
Journal of Vascular Surgery®

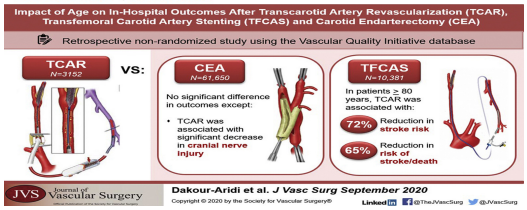
Age modifies the efficacy and safety of carotid artery revascularization procedures

Besma Nejim, MBChB, MPH,[a] Widian Alshwaily, MD,[a] Hanaa Dakour-Aridi, MD,[a] Satinderjit Locham, MD,[a] Philip Goodney, MD, MS,[b] *and* Mahmoud B. Malas, MD, MHS, FACS,[a,c] *Baltimore, Md. Lebanon, NH; and San Diego, Calif*



The impact of age on in−hospital outcomes after transcarotid artery revascularization, transfemoral carotid artery stenting, and carotid endarterectomy

Hanaa Dakour-Aridi [1], Vikram S Kashyap [2], Grace J Wang [3], Jens Eldrup-Jorgensen [4], Marc L Schermerhorn [5], Mahmoud B Malas [6]



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Restenosis

JVS Journal of Vascular Surgery
Official Publication of the Society for Vascular Surgery

Comparative Study > J Vasc Surg. 2017 Jan;65(1):1-11. doi: 10.1016/j.jvs.2016.07.115. Epub 2016 Oct 1.

Stenting versus endarterectomy after prior ipsilateral carotid endarterectomy

Isibor Arhuidese [1], Tammam Obeid [1], Besma Nejim [1], Satinderjit Locham [1], Caitlin W Hicks [1], Mahmoud B Malas [2]

> J Vasc Surg. 2017 May;65(5):1418-1428. doi: 10.1016/j.jvs.2016.11.041. Epub 2017 Feb 9.

Endarterectomy versus stenting in patients with prior ipsilateral carotid artery stenting

Isibor J Arhuidese [1], Besma Nejim [2], Susruth Chavali [2], Satinderjit Locham [2], Tammam Obeid [2], Caitlin W Hicks [2], Mahmoud B Malas [3]

Stroke

Clinical Trial > Stroke. 2017 Nov;48(11):3086-3092. doi: 10.1161/STROKEAHA.117.016963. Epub 2017 Oct 3.

Outcomes of Primary and Secondary Carotid Artery Stenting

Isibor J Arhuidese [1], Muhammad Rizwan [1], Besma Nejim [1], Mahmoud Malas [2]

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Outcomes of Carotid Revascularization in the Treatment of Restenosis After Prior Carotid Endarterectomy

Nadin Elsayed, Ganesh Ramakrishnan, Isaac Naazie, Sharvil Sheth, Mahmoud B. Malas

Outcomes of Carotid Revascularization in the Treatment of Restenosis After Prior Carotid Endarterectomy (CEA)

Retrospective review of the Vascular Quality Initiative database — 4,425 patients with prior ipsilateral CEA undergoing carotid revascularization

Redo-CEA N=963 VS. Transcarotid artery revascularization (TCAR) N=1,676 VS. Transfemoral carotid stenting (TFCAS) N=1,786

TCAR was associated with:

Reduction in:

Stroke	54%
MI	68%
Stroke/TIA	58%
Stroke/Death	52%
Stroke/Death /MI	59%

Crossing the lesion

Crossing the aortic arch

63% Reduction in Stroke/TIA

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Carotid Artery Revascularization in Patients with Contralateral Carotid Artery Occlusion: Stent or Endarterectomy?

Beema Nejim, Jasvinder Dhaliwal, Sameen Meshkin, Muhammad Rizwan, Akshay Gupta, Satinderjit Locham, Hanaa Dakour Arid, Caitlin Hicks, Mahmoud B. Malas
Johns Hopkins School of Medicine, Baltimore, Md

Total patients 4,326 with CCO, CEA=3,274, CAS=1,052

Outcomes	Asymptomatic patients		Symptomatic patients	
	Adjusted Risk estimate* (95%CI)	P- value	Adjusted Risk estimate* (95% CI)	P- value
30-day stroke	1.27 (0.54-2.98)	.580	2.90 (1.06-7.94)	.038
30-day mortality	1.53 (0.62-3.78)	.356	6.10 (2.20-16.92)	.001
30-day MACE	1.23 (0.70-2.17)	.475	2.05 (1.05-3.99)	.035
2-year ipsilateral stroke[1]	1.47 (0.67-3.22)	.34	1.57 (0.60-4.11)	.356
2-year stroke/death[2]	1.42 (1.08-1.86)	.011	1.94 (1.18-3.19)	.009
2-year ipsilateral stroke post 30days[3]	3.49 (0.68-18.03)	.136	1.56 (0.31-7.79)	.586
2-year stroke/death post 30days[4]	1.36 (0.94-1.98)	.105	1.36 (0.75-2.47)	.318

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JACS

Outcomes of Carotid Revascularization in Patients with Contralateral Carotid Artery Occlusion

Hanaa Dakour-Arid, MD · Nadin Elsayed, MD · Mahmoud Malas, MD, MHS, FACS

Outcomes of Carotid Revascularization in Patients with Contralateral Carotid Artery Occlusion

Society for Vascular Surgery (SVS) Vascular Quality Initiative data (VQI) 2016-2020 — In-hospital outcomes — 4,853 patients undergoing carotid revascularization with contralateral occlusion

TransCarotid artery revascularization (TCAR) N=1,144 VS Carotid Endarterectomy (CEA) N=2,527 TransFemoral artery stenting (TFCAS) N=1,182

TCAR was associated with:

50% Reduction in risk of stroke, death, or myocardial infarction (MI)

TCAR was associated with:

70% Reduction in death

74% Reduction in stroke/death

65% Reduction in stroke/death/MI

Malas et al. J Am Coll Surg, May 2021

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International Stroke Conference 2017

Nursing Symposium & Pre-Con Symposia: Feb. 21, 2017
Sessions: Feb. 22–24, 2017
George R. Brown Convention Center | Houston, TX

N=51,942

- NR N=28,581 (55.0%)
  - CEA N=26,900 (94.1%) — NR: Unmatched; NR: Many:1; NR: 1:1
  - CAS N=1,681 (5.9%)
- HR N=23,361 (45.0%)
  - CAS N=5,349 (22.9%) — HR: Unmatched; HR: Many:1; HR: 1:1
  - CEA N=18,012 (77.1%)

Odds ratio of CAS vs. CEA

30-day Stroke | 30-day Stroke/Death | 30-day Stroke/Death/MI

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JVS Journal of Vascular Surgery

Modality-specific outcomes of patients undergoing carotid revascularization in the setting of recent myocardial infarction

Presented at the Vascular Annual Meeting of the Society for Vascular Surgery, National Harbor, Maryland, June 14-17, 2023; Presented at the Thirty-eighth Annual Meeting of the Western Vascular Society, Koloa, Hawaii, September 9-12, 2023.

Sabrina Straus BS, Marjan Maghaddam BS, Sina Zarrintan MD, MPH, MS, Daniel Willie-Permor MD, MPH, CPH, Yasan Jagadeesh BS, Mahmoud Malas MD, MHS, RPVI, FACS

CEA had lower odds of stroke/death compared with tfCAS but similar odds when compared with TCAR

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Objective

With recent CMS approval for Transcarotid Artery Revascularization (TCAR) and Transfemoral Carotid Artery Stenting (TFCAS) in high and standard risk patients, we aim to assess and update the CMS guidelines using national data to identify high-risk indicators for each procedure compared to Carotid Endarterectomy (CEA)

Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

CAG-00085R8 — Expand All | Collapse All

FROM: Coverage and Analysis Group (CAG)

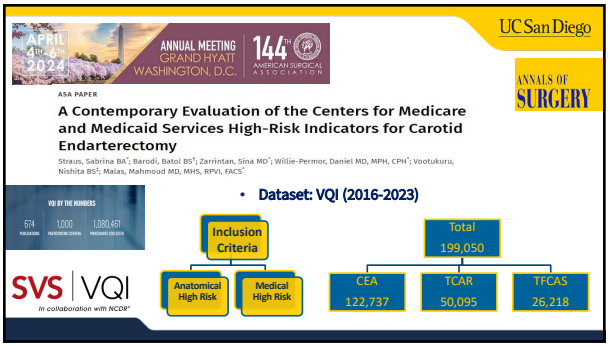
SUBJECT: Proposed National Coverage Determination for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concur

DATE: July 11, 2023

I. Proposed Decision

The Centers for Medicare & Medicaid Services (CMS) proposes that coverage of percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following conditions:

A. Patients with symptomatic carotid artery stenosis ≥50%; and
B. Patients with asymptomatic carotid artery stenosis ≥70%.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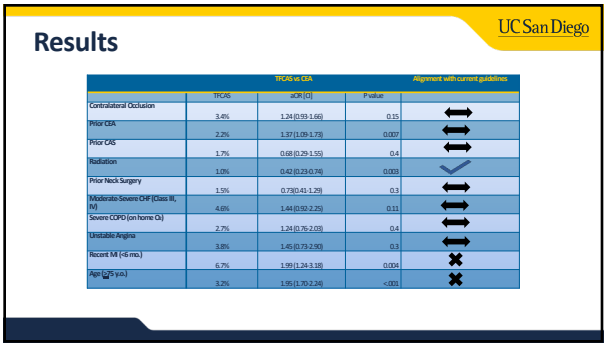
APRIL 4TH-6TH 2024
ANNUAL MEETING
GRAND HYATT
WASHINGTON, D.C.
144TH AMERICAN SURGICAL ASSOCIATION
ANNALS OF SURGERY
ASA PAPER
A Contemporary Evaluation of the Centers for Medicare and Medicaid Services High-Risk Indicators for Carotid Endarterectomy
Straus, Sabrina BA*; Barodi, Batol BS*; Zarrintan, Sina MD*; Willie-Permor, Daniel MD, MPH, CPH*; Vootukuru, Nishita BS*; Malas, Mahmoud MD, MHS, RPVI, FACS*
VQI BY THE NUMBERS
674
1,000
1,080,461
SVS | VQI
In collaboration with NCDR®
• Dataset: VQI (2016-2023)
Inclusion Criteria
Anatomical High Risk
Medical High Risk
Total 199,050
CEA 122,737
TCAR 50,095
TFCAS 26,218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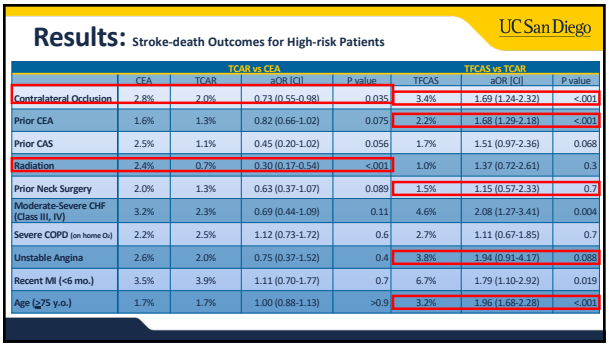
Results
TFCAS vs CEA
Alignment with current guidelines
TFCAS
aOR (CI)
P value
Contralateral Occlusion 3.4% 1.24 (0.93-1.66) 0.15
Prior CEA 2.2% 1.37 (1.09-1.73) 0.007
Prior CAS 1.7% 0.68 (0.29-1.55) 0.4
Radiation 1.0% 0.42 (0.23-0.74) 0.003
Prior Neck Surgery 1.5% 0.73 (0.41-1.29) 0.3
Moderate-Severe CHF (Class III, IV) 4.6% 1.44 (0.92-2.25) 0.11
Severe COPD (on home O2) 2.7% 1.24 (0.76-2.03) 0.4
Unstable Angina 3.8% 1.45 (0.73-2.90) 0.3
Recent MI (<6 mo.) 6.7% 1.99 (1.24-3.18) 0.004
Age (≥75 y.o.) 3.2% 1.95 (1.70-2.24) <.001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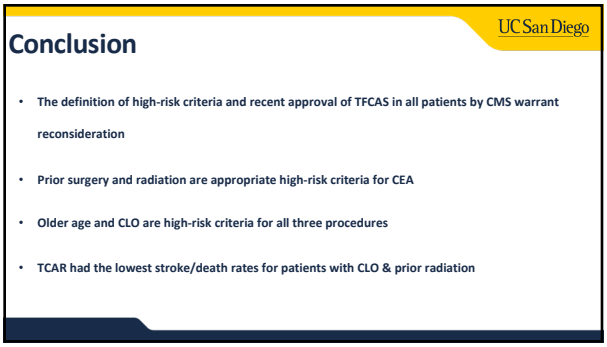
Results: Stroke-death Outcomes for High-risk Patients
TCAR vs CEA
TFCAS vs TCAR
CEA TCAR aOR (CI) P value TFCAS aOR (CI) P value
Contralateral Occlusion 2.8% 2.0% 0.73 (0.55-0.98) 0.035 3.4% 1.69 (1.24-2.32) <.001
Prior CEA 1.6% 1.3% 0.82 (0.66-1.02) 0.075 2.2% 1.68 (1.29-2.18) <.001
Prior CAS 2.5% 1.1% 0.45 (0.20-1.02) 0.056 1.7% 1.51 (0.97-2.36) 0.068
Radiation 2.4% 0.7% 0.30 (0.17-0.54) <.001 1.0% 1.37 (0.72-2.61) 0.3
Prior Neck Surgery 2.0% 1.3% 0.63 (0.37-1.07) 0.089 1.5% 1.15 (0.57-2.33) 0.7
Moderate-Severe CHF (Class III, IV) 3.2% 2.3% 0.69 (0.44-1.09) 0.11 4.6% 2.08 (1.27-3.41) 0.004
Severe COPD (on home O2) 2.2% 2.5% 1.12 (0.73-1.72) 0.6 2.7% 1.11 (0.67-1.85) 0.7
Unstable Angina 2.6% 2.0% 0.75 (0.37-1.52) 0.4 3.8% 1.94 (0.91-4.17) 0.088
Recent MI (<6 mo.) 3.5% 3.9% 1.11 (0.70-1.77) 0.7 6.7% 1.79 (1.10-2.92) 0.019
Age (≥75 y.o.) 1.7% 1.7% 1.00 (0.88-1.13) >0.9 3.2% 1.96 (1.68-2.28) <.001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Conclusion
• The definition of high-risk criteria and recent approval of TFCAS in all patients by CMS warrant reconsideration
• Prior surgery and radiation are appropriate high-risk criteria for CEA
• Older age and CLO are high-risk criteria for all three procedures
• TCAR had the lowest stroke/death rates for patients with CLO & prior radiation


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Thank you!