2024 MID-ATLANTIC CONFERENCE

12th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2024

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 18-20

2024 MID-ATLANTIC CONFERENCE

12th ANNUAL CURRENT CONCEPTS IN VASCULAR THERAPIES

2024

CEA remains **SUPERIOR** to TF CAS and TCAR.

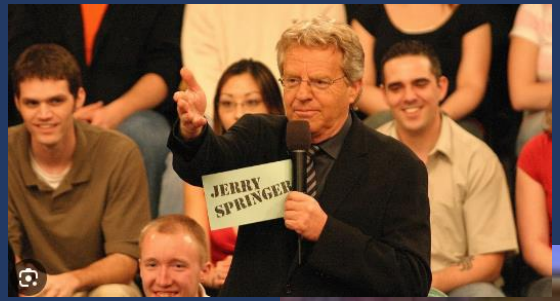
Do we Need to Limit Who and Where??

Justin Milligan MD FACS
Sentara Vascular Specialists

April 20, 2024

Disclosures

- Vascular Surgeon
- Loves doing CEA
- Loves doing TCAR
- Does TF CAS when no other option



VASCULAR SURGERY

IT'S NACHO CAROTID DISEASE!!

CARDIOLOGY

NEW MEDICARE GUIDELINES

CAROTID ARTERY STENTING 10/2023

Indications	**B4. Carotid Stent Placement** (Updated 10/11/2023)	**B4. Carotid Stent Placement** (Original thru 10/10/2023)
Clinical Criteria		
Surgical Risk Factor	• Standard Risk & High Risk	• High Risk
Symptom Status & Degree of Stenosis	• Symptomatic & ≥50% stenosis** • Asymptomatic & ≥70% stenosis**	• Symptomatic & ≥70% stenosis
Additional Criteria		
Facility Requirements	• Facility and physician standards for carotid stent program	• CMS facility approval and certification
Registry or Data Collection	• Not required for coverage	• Data collection
Neurological Assessments	• Pre & post-op neurological assessments by a neurologist or NIHSS certified HCP	• Not specified
Imaging Guidelines	• Duplex US and CTA/MRA or • Duplex US and DSA when non-invasive imaging is inconclusive or CTA/MRA are contraindicated	• Not specified
Shared Decision Making	• Shared decision-making with patients about CEA, CAS (including TCAR), and OMT before treatment	• Not specified

NEW MEDICARE GUIDELINES

Indications	B4. Carotid Stent Placement (Updated 10/11/2023)	B4. Carotid Stent Placement (Original thru 10/10/2023)
Clinical Criteria:		
Surgical Risk Factor	• Standard Risk & High Risk	• High Risk
Symptom Status & Degree of Stenosis	• Symptomatic & >50% stenosis** • Asymptomatic & >70% stenosis**	• Symptomatic & ≥70% stenosis

- Expands coverage for carotid stents to ALL (standard risk and high risk)
  - Periprocedural benefits for carotid stenting compared to CEA
  - Known long-term durability of carotid stents compared to CEA

The Multispecialty Carotid Alliance (MSCA)

- Thomas Brott, MD, Neurology, Mayo Clinic, Jacksonville, FL
- Daniel G. Clair, MD, Vascular Surgery, Vanderbilt University Medical Center, Nashville, TN
- William Gray, MD, Interventional Cardiology, Lankenau Heart, Main Line Health, Wynnewood, PA
- Donald Heck, MD, Interventional Neuroradiology, Triad Radiology Associations, Novant Health Forsyth Medical Center, Winston-Salem, NC
- Tudor Jovin, MD, Interventional Neurology, Cooper University Healthcare, Camden, NJ
- Sean Lyden, MD, Vascular Surgery, Cleveland Clinic, Cleveland, OH
- Chris Metzger, MD, Interventional Cardiology, Ballad Health CVA Heart & Vascular, Kingsport, TN
- Kenneth Rosenfield, MD, Interventional Cardiology and Vascular Medicine, Massachusetts General Hospital, Boston, MA
- Gary Roubin, MD, Interventional Cardiology, Chair of CREST2 Interventional Management Committee
- Ravish Sachar, MD, Interventional Cardiology, UNC-Rex Healthcare, Raleigh, NC
- Adnan Siddiqui, MD, Neurosurgery, Jacobs Institute, SUNY at Buffalo & Kaleida Health, Buffalo, NY
- Christopher White, MD, Interventional Cardiology, Ochsner Clinical School, University of Queensland, Australia and Ochsner Medical Center, New Orleans, LA

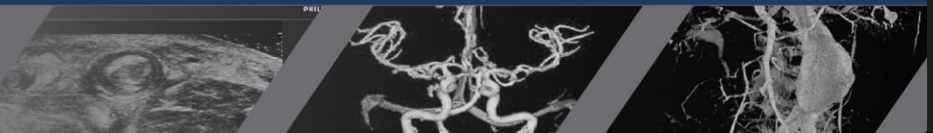
ITS ALL ABOUT PATIENT OUTCOMES AND ACCESS TO CARE!

List of General Payments in 2022

Showing 1-10 of 110

Download

Company making payment	Nature of payment	Date	Total amount
InspireMD Ltd	Consulting Fee	04/20/2022	$134,755.00
Centerline Biomedical Inc.	Consulting Fee	06/27/2022	$16,419.00



INSPIREMD

About Products Resources News & Events

Solutions that Save Lives
Innovation that Inspires

CGuard™ Carotid Stent System

Sustained stroke prevention in CAS[1].
Bringing patient safety through permanent embolic protection with MicroNet™[2]

“The SVS is disappointed with the CMS decision to finalize its proposal for expanded coverage for PTA with CAS (NCD 20.7)”

- We believe the coverage expansion outlined in the updated NCD 20.7 holds significant potential to increase risk in achieving quality of care and patient safety, particularly for our most vulnerable elderly patients.

SVS POSITION CONT'D

- "SVS remains concerned about the potential impact of this decision and will continue to stress the fundamental importance of vigilant reporting and monitoring of outcomes, requiring requisite training and experience in patient selection and performance of the procedure, and the need for a verified multispecialty 'Shared Decision-Making' tool, which is referenced in the decision but does not yet exist. The SVS will continue to actively promote quality and safety for the care of vascular patients through its published guidelines, appropriate care documents, and Patient Safety Organization-Vascular Quality Initiative (PSO-VQI) Registry and quality initiatives such as the ACS-SVS Vascular Verification Program. The SVS will continue to make its tools and resources widely available."

HISTORY

- DeBakey, 8/7/53, first successful CEA
- Eastcott, Pickering, & Rob, 5/19/54, resection of the bifurcation and end to end anastomosis of the CCA and ICA
- Cooley, et al, first report successful CEA 3/4/56

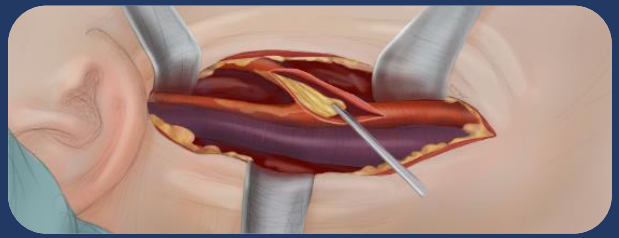
Landmark trials lead to CEA BOOM

- North American Symptomatic Carotid Endarterectomy Trial, NASCET, 1991
- Asymptomatic Carotid Atherosclerosis Study, ACAS, 1995
- European Carotid Surgery Trial, ECST, 1996

TREATMENT OPTIONS FOR CAROTID ARTERY DISEASE

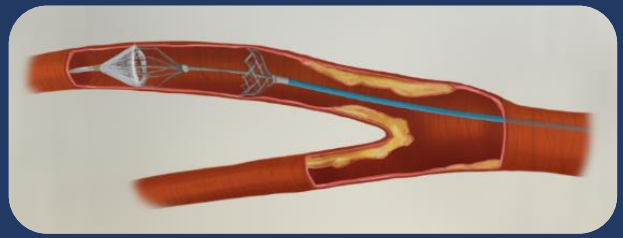
Gold Standard:
Carotid Endarterectomy

- Low stroke risk[1], but…
- Invasive; risk of surgical complications
  - **Risk of cranial nerve injury***
  - **Return to OR for wound complications**

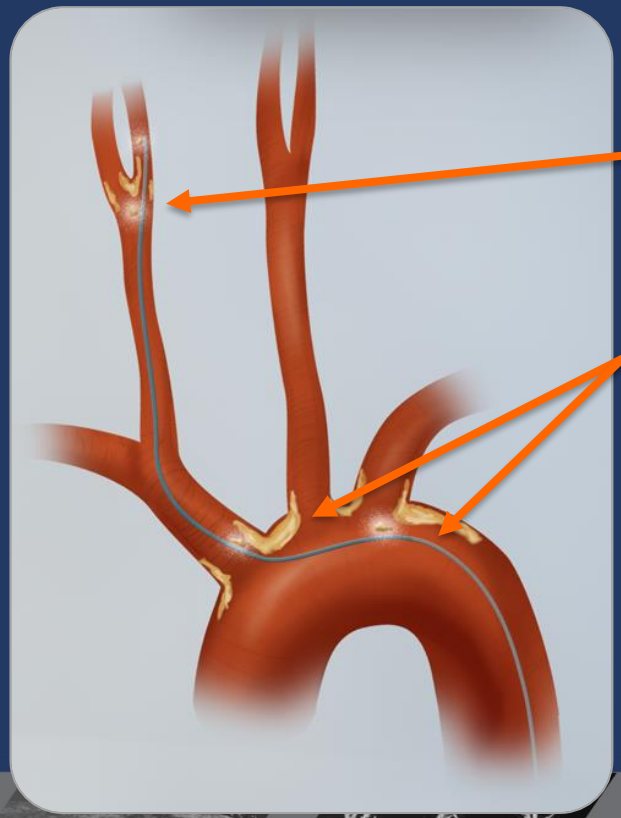


Less Invasive Alternative:
Transfemoral, Filter Protected CAS

- Patient friendly, long-term durability[1], **but…**
- Excess procedural stroke risk[1]
  - **Procedure itself can create thrombo-embolic event**



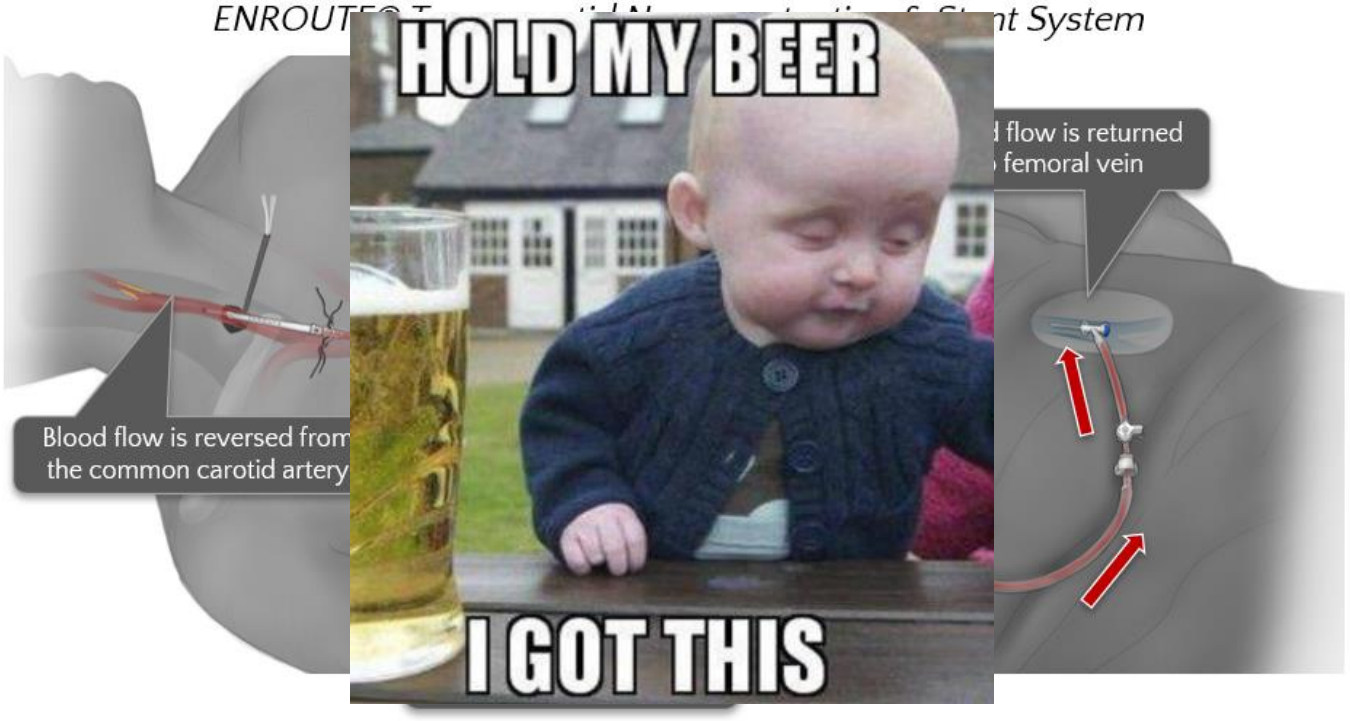
*[1] CREST: 2% unresolved at 6 month (80% motor)



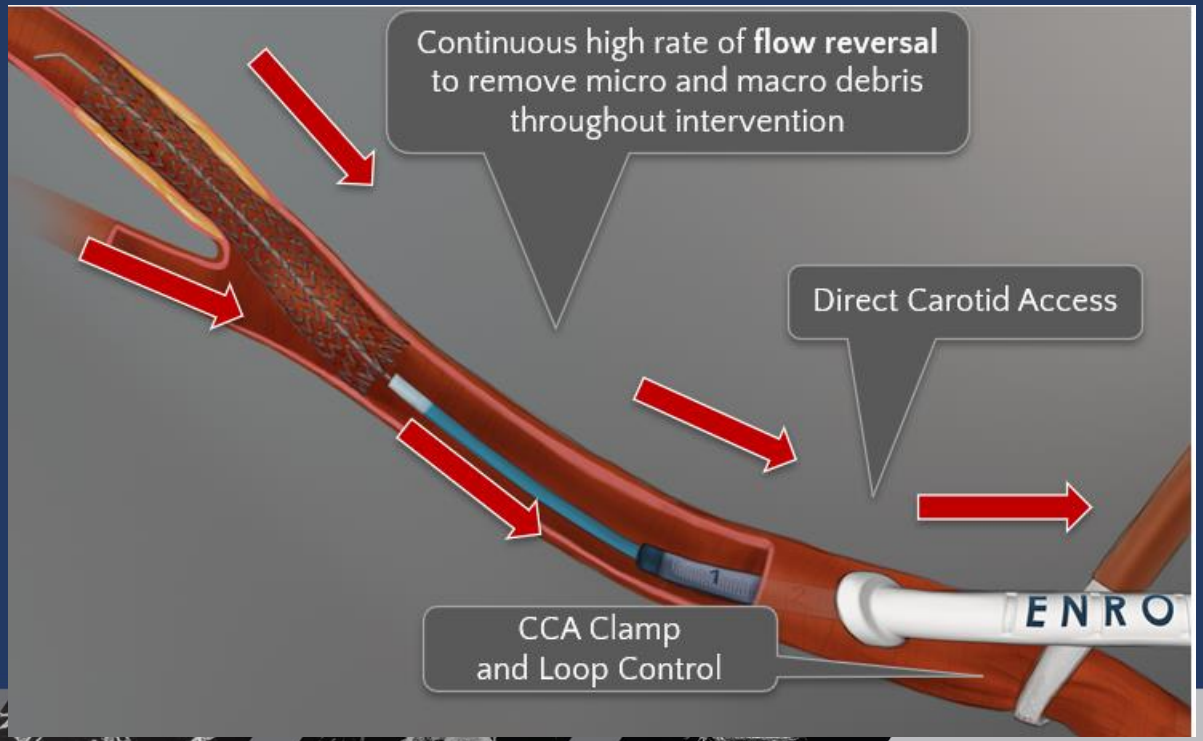
- Traditional transfemoral filter-protected CAS* requires 3 steps that create embolic risk
  1. Advancing a catheter through the aortic arch
  2. Navigating the lesion before neuroprotection established
  3. Inadequate neuroprotection from misaligned filters and manual extraction

TCAR PROCEDURE

ENROUTE® Transcarotid Neurovascular Protection System

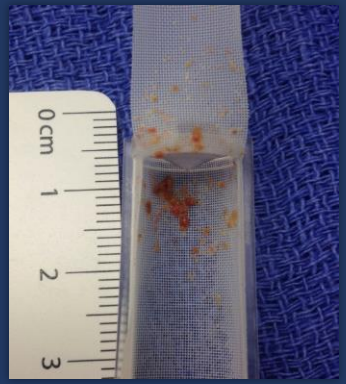


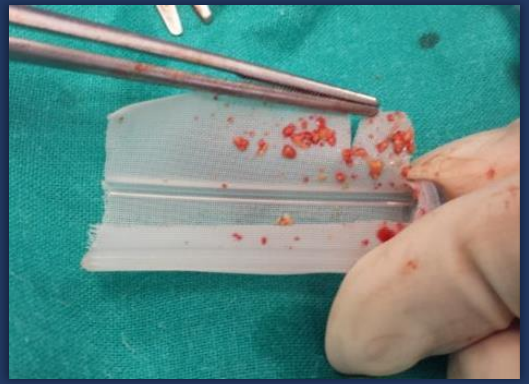
SURGICALLY INSPIRED CEA-LIKE NEUROPROTECTION??

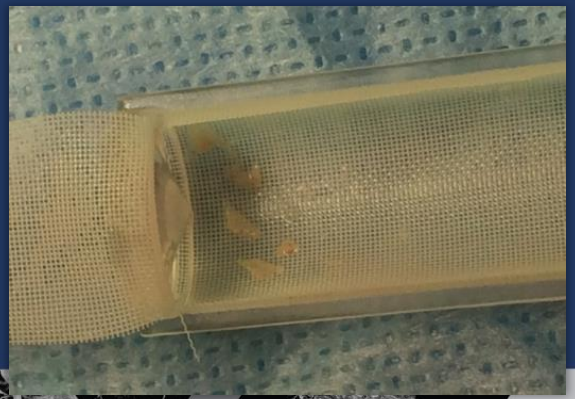


THE PROOF IS IN THE FILTER

MACRO & MICRO EMBOLI IN ENROUTE™ NPS FILTERS

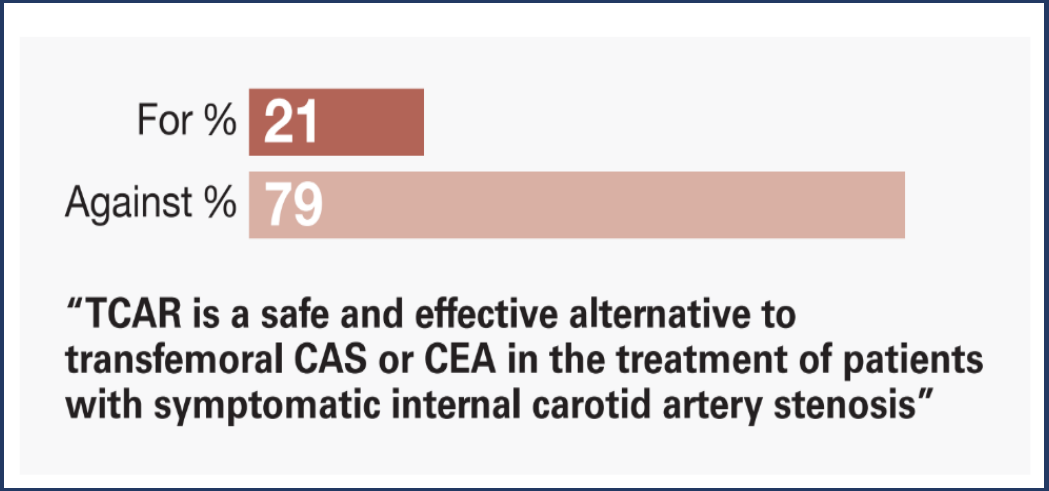






Charing Cross audience as-yet unconvinced by data supporting transcarotid artery revascularisation

24 May 2022 2739



TCAR Outcome Data: The Hype

TCAR vs CEA: Research shows fewer myocardial infarctions after TCAR with use of general anesthesia

By Bryan Kay - 14th May 2021 3006

A Vascular Quality Initiative (VQI) analysis uncovered a reduction in the risk of myocardial infarction after transcarotid artery revascularization (TCAR) compared to carotid endarterectomy (CEA) when general anesthesia is mainly found in patients with

SILKROAD MEDICAL

Silk Road Medical Announces FDA Approval of Expanded Indications for the ENROUTE® Transcarotid Stent System

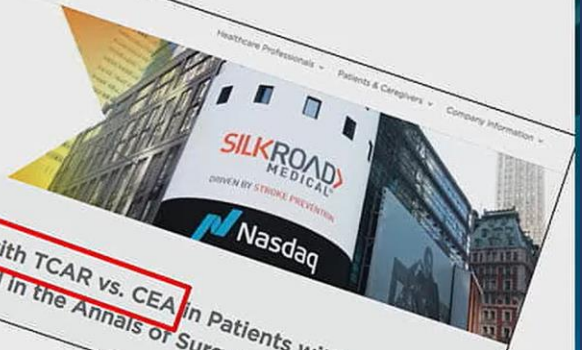
SUNNYVALE, Calif. – Ma... ical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of

SILKROAD MEDICAL

Press Release

For Investors

Healthcare Professionals Patients & Caregivers Company Information



Compelling Outcomes with TCAR vs. CEA in Patients with Carotid Artery Stenosis Published in the Annals of Surgery

Endovascular TODAY

NEWS ISSUE

CAROTID CODING DIALYSIS EMBOLIZATION EVAR HTN LIMB SALVAGE

June 12, 2019

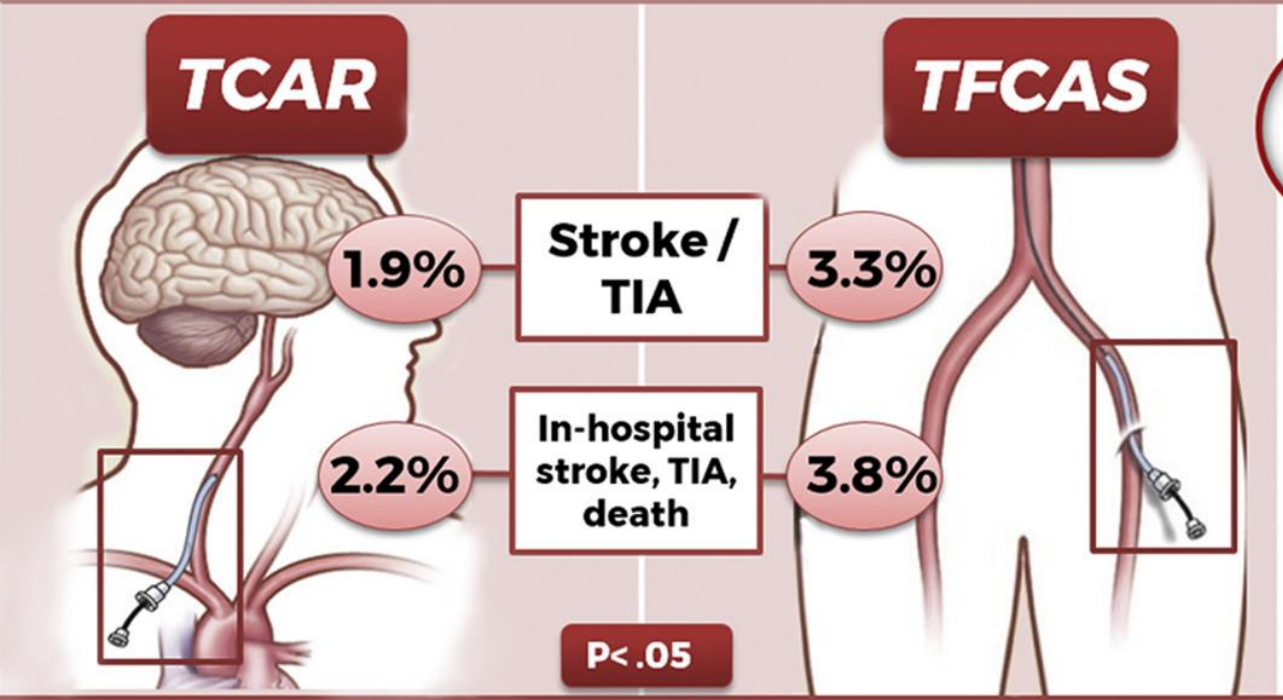
Favorable Outcomes for TCAR Versus CEA Presented at Vascular Annual Meeting

June 13, 2019—Silk Road Medical, Inc. announced real-world data from the ongoing TransCarotid Artery

Trans-Carotid (TCAR) vs. Trans-Femoral (TFCAS) Carotid Artery Stenting

SVS VQI TCAR Surveillance Project

638 TCARs vs. 10,136 TFCASs



2x Higher risk after **TFCAS** than after **TCAR** for:

- **All stroke & TIA** *(OR 2.21)*
- **Composite Stroke/TIA/Death** *(OR 2.10)*

P< .05

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

Malas et. al. *J Vasc Surg January 2019*

@JVascSurg
@TheJVascSurg

?STROKE

- CREST demonstrated that the Peri-Procedural stroke rate for transfemoral CAS was approximately 2x higher than CEA and even higher for patients over 75 years of age

Study	Procedure	Embolic Protection	Patients	% w/ New Ipsilateral DWI Lesions
ICSS[2]	CEA	Clamp, backbleed	107	17%
PROOF[3]	**Silk Road**	**TCAR**	**56**	**18%**
PROFI[1]	Transfemoral CAS	Proximal occlusion (MoMA)	31	45%
ICSS[2]	Transfemoral CAS	Distal filter (various)	51	73%
PROFI[1]	Transfemoral CAS	Distal filter (Emboshield)	31	87%

THE ARCH IS A HOSTILE TERRITORY:

The incidence of microemboli to the brain is less with endarterectomy than with percutaneous revascularization with distal filters or flow reversal

N = 42

Procedure	N	Incidence MES	Procedural Stage
CEA	15	15.3 (+/- 22)	Post procedure
Filter protected CAS	20	319.3 (+/- 110.3)	During protection
Flow reversal CAS	7	184.2 (+/- 110.5)	Pre protection

CEA vs filter p = 0.001
CEA vs flow reversal p = 0.007
Flow reversal vs filter p = 0.053

Gupta N et al. JVS. 2011;53:316-322

ICSS PRIMARY ANALYSIS CEA VS. CAS IN 1713 SYMPTOMATIC PATIENTS

ICSS Substudy: N = 231

New white lesions on DWI

62 of 124 (50%) transfemoral distal filter CAS

18 of 107 **(17%) CEA**

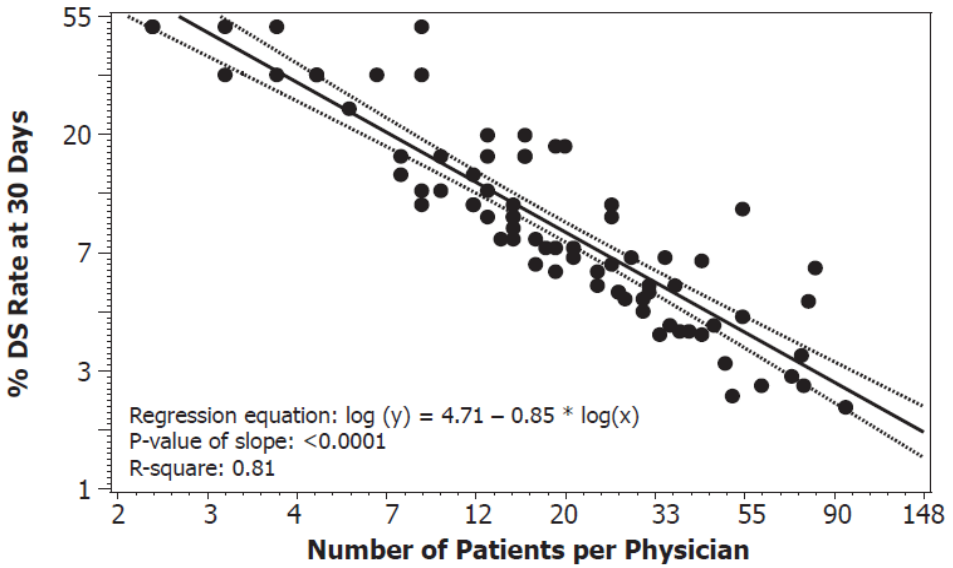
(OR 5.21, 2.78–9.79; *p < 0.0001*)

•Lancet Neurol. 2010 Apr;9(4):353–62

Influence of Site and Operator Characteristics on Carotid Artery Stent Outcomes

Analysis of the CAPTURE 2 (Carotid ACCULINK/ACCUNET Post Approval Trial to Uncover Rare Events) Clinical Study

"Threshold of 72 cases necessary for consistently achieving a S/D rate of <3%"



Gray WA et al JAmCollCardiol 2011;4:235-246

TCAR Real World Data: The Facts

Journal of the American Heart Association

ORIGINAL RESEARCH

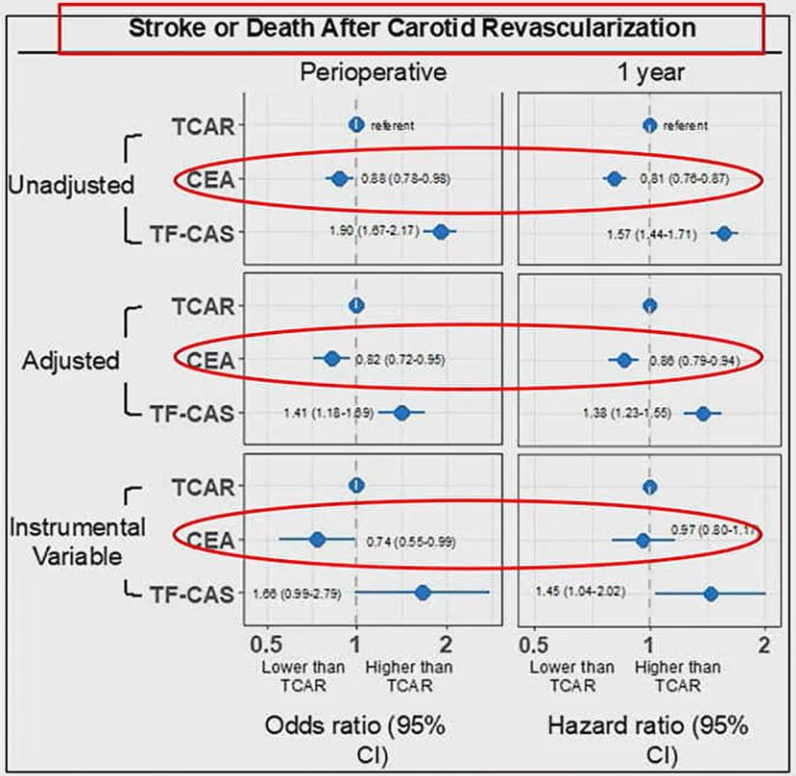
Procedural Safety Comparison Between Transcarotid Artery Revascularization, Carotid Endarterectomy, and Carotid Stenting: Perioperative and 1-Year Rates of Stroke or Death

Jesse A. Columbo, MD, MS; Pablo Martinez-Camblor, PhD; David H. Stone, MD; Philip P. Goodney, MD, MS; A. James O'Malley, PhD

VQI registry

2016-2021 *662 Centers*

- *TCAR* *21,234 patients*
- *CEA* *82,737 patients*
- *TFCAS* *14,595 patients*



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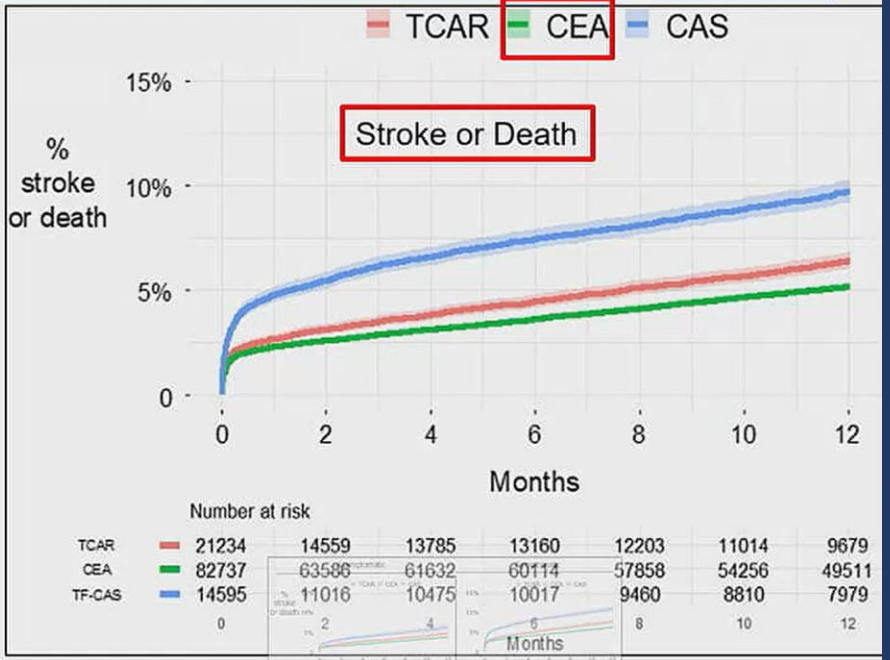


TF CAS

TCAR Cost Effectiveness or Lack Thereof: More Facts

Carotid endarterectomy remains cost-effective for the surgical management of carotid stenosis

Natalie D. Sridharan, MD, MS,[a] Rabih A. Chaer, MD, MS,[a] Kenneth Smith, MD, MS,[b] *and* Mohammad H. Eslami, MD,[a] *Pittsburgh, Pa*

Results: In the base-case scenario, TCAR cost $160,642/QALY gained compared with CEA, greater than the frequently cited $100,000/QALY gained threshold. TFCAS was more expensive and less effective than other strategies, largely due to a greater periprocedural stroke risk. In one-way sensitivity analysis, if TCAR stroke risk was <0.9% (base-case risk, 1.4%), than it was economically favorable compared with CEA at its current procedural cost. Alternatively, if TCAR procedural costs were reduced by approximately $2000 (base-case cost, $15,182), it would also become economically favorable. In a probabilistic sensitivity analysis, varying all parameters simultaneously over distributions, CEA was favored in 80% of model iterations at $100,000/QALY, with TCAR favored in 19%.

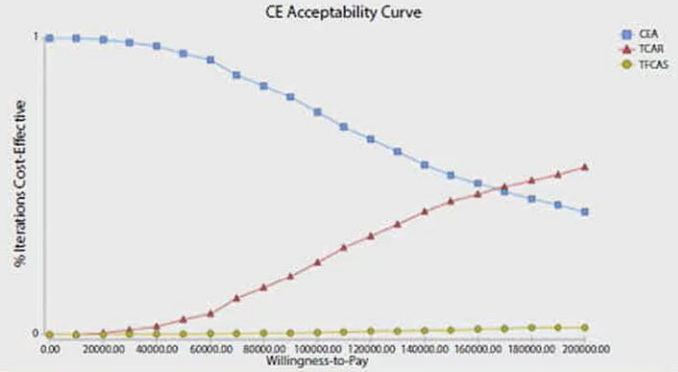


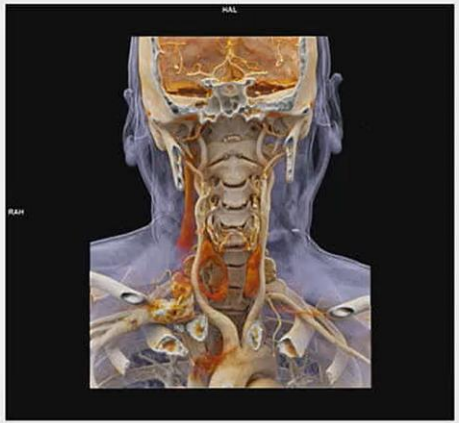
Fig 2. Monte Carlo sensitivity analysis shows the results of 1000 iterations of the model over predefined distributions across the range of willingness-to-pay (WTP) thresholds. At

TCAR Cost Effectiveness: The Hype and the Facts

News | Stents Carotid | January 05, 2022

Transcarotid Artery Revascularization (TCAR) Versus Carotid Endarterectomy (CEA) Cost-Effectiveness Shows Benefit for Stenting

TCAR was considered cost-effective 49% of the time



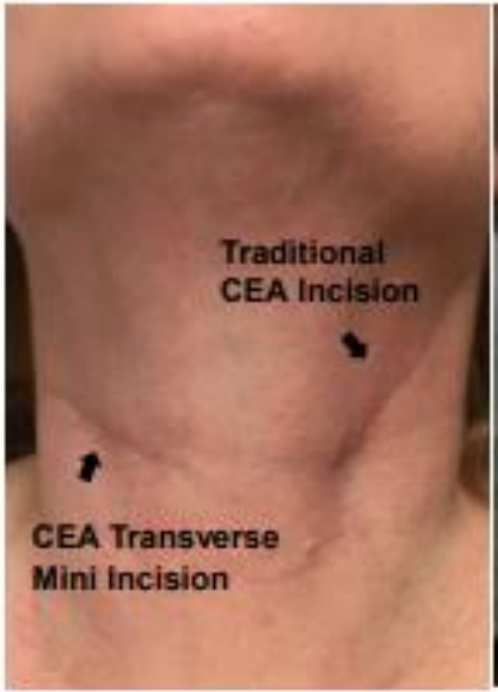
Cost-effectiveness of transcarotid artery revascularization versus carotid endarterectomy

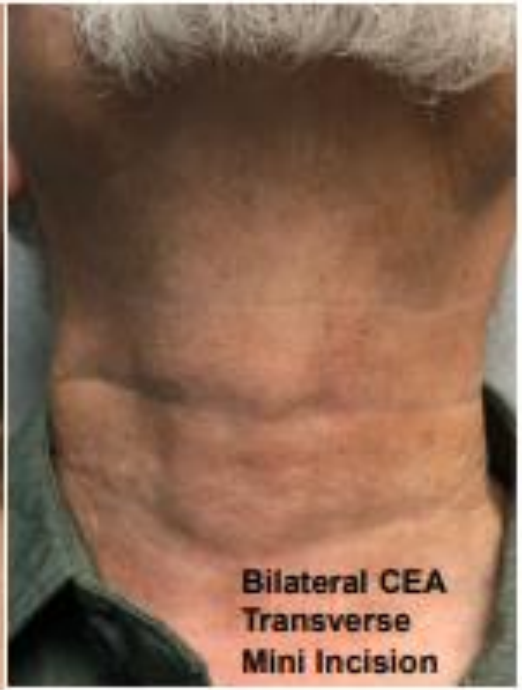
Christina Cui, BA,[a] Ganesh Ramakrishnan, BS,[b] James Murphy, MD, MS,[c] *and* Mahmoud B. Malas, MD, MHS, RPVI, FACS,[b] *La Jolla, Calif*

TCAR	CEA
5-year cost: $19,154 for 2.92 Quality Adjusted Life Years (QALY)	5-year cost: $7,821 for 2.85 Quality Adjusted Life Years (QALY)

- 5-year costs for TCAR were greater, but it afforded greater QALY.
- ICER (Incremental Cost Effectiveness Ratio) was $152,229/QALY for TCAR compared to CEA
- TCAR was cost effective in 49% and became cost-effective at 6 years

But TCAR is faster, less invasive, has better cosmetic result..!



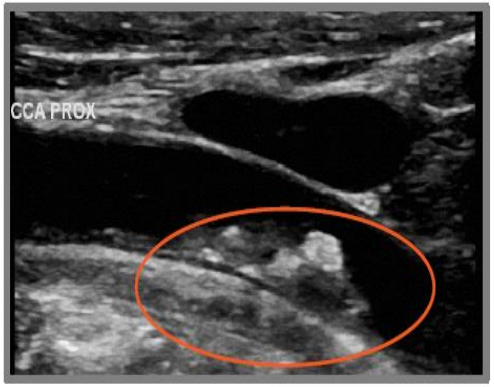


Redo CEA | TCAR for Restenosis

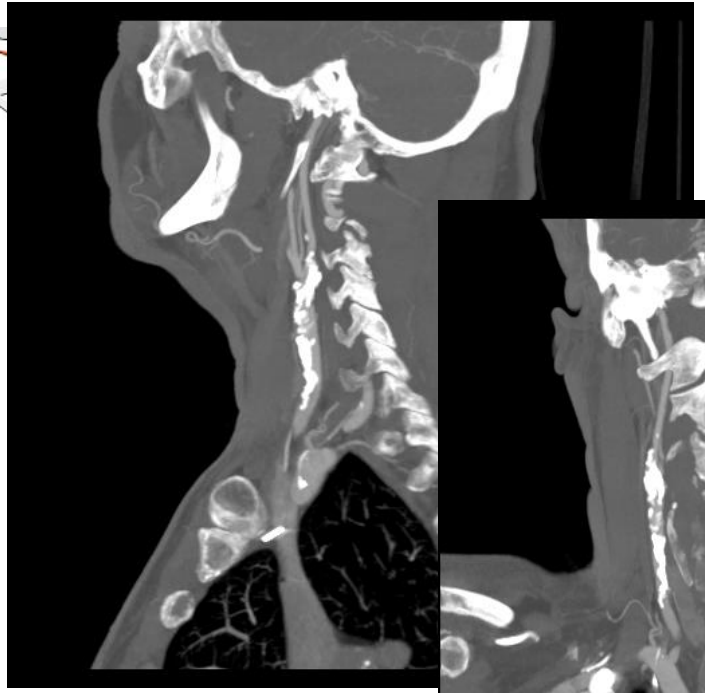

30 Days
6 months
>1 Year

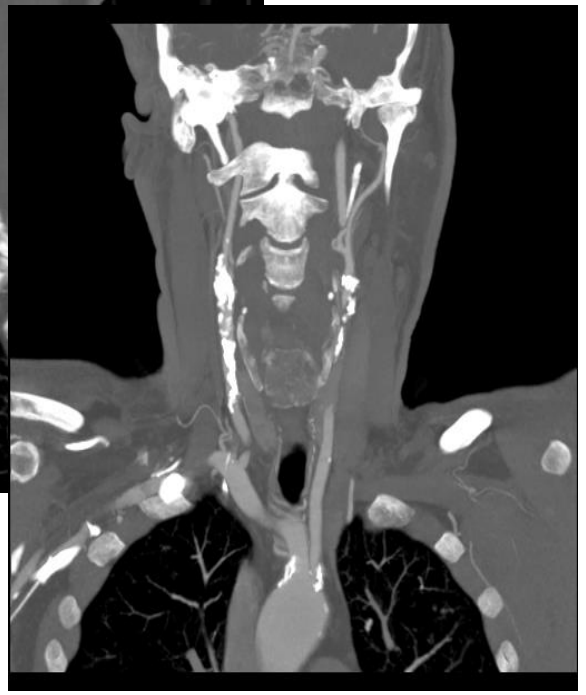
Anatomical Considerations

SEVERE CCA DISEASE
NOT ACCEPTABLE FOR TCAR



SEVERE DISEASE





Gastrointestinal Injury Caused by Aspirin or Clopidogrel Monotherapy Versus Dual Antiplatelet Therapy*

FREE ACCESS

Editorial Comment

John A. Bittl and Loren Laine

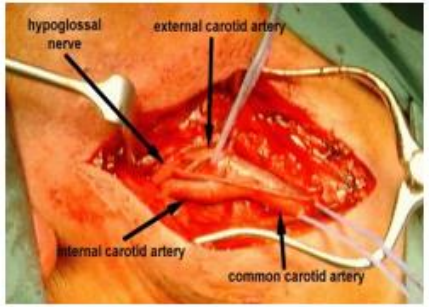
J Am Coll Cardiol. 2022 Jan, 79 (2) 129–131

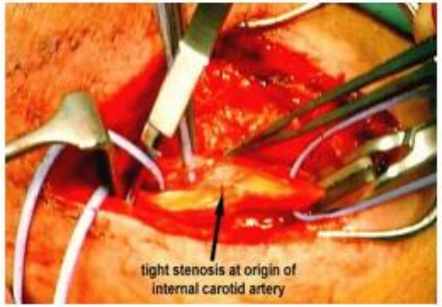
The investigators (**4**) found that the secondary endpoint of any type of GI bleeding between 6 and 12 months was less with SAPT compared with DAPT (0.6% vs 5.4%; *P* = 0.001), without an increase in ischemic events (0% vs 0%). Moreover, overt GI bleeding was 90% lower with SAPT than with DAPT (incidence of 0.3% with SAPT [aspirin 0% vs clopidogrel 0.6%] vs 3.0% with DAPT; relative risk [RR]: 0.10; 95% confidence interval [CI]: 0.01-0.85). The other secondary outcome of clinically overt bleeding at any site, which was primarily Bleeding Academic Research Consortium 1, was also lower with SAPT than with DAPT (5.9% vs 11.9%; RR: 0.50; 95% CI: 0.28-0.90), which was similar to the treatment effect reported in most contemporary trials evaluating SAPT after a short course of DAPT (**3**).

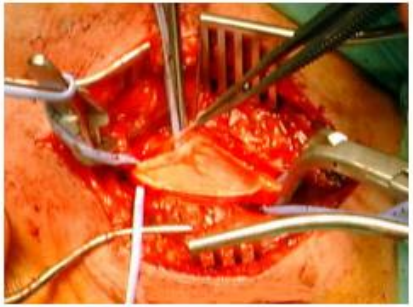
the FACTS are

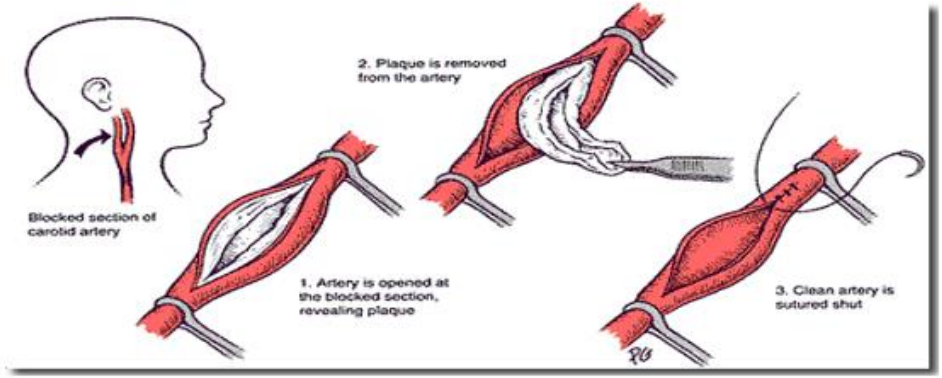
- Lack of RCT of TCAR vs CEA vs Tf-CAS
- Most of the data from company-sponsored, single-arm studies
- three quarters of all the included patients originate from the VQI registry—limiting generalisability—and there is an underreporting of anatomic suitability and exclusion criteria

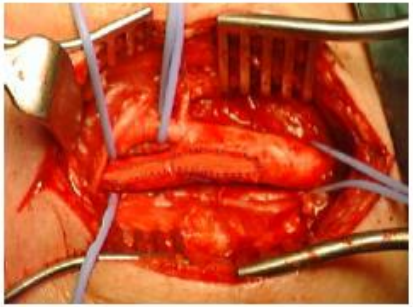
carotid endarterectomy (CEA) is still the standard of care for carotid revascularization











CLINICAL RESEARCH STUDY CAROTID ARTERY DISEASE | VOLUME 73, ISSUE 5, P1675-1682.E4, MAY 2021

Carotid endarterectomy remains safe in high-risk patients

Nathan M. Droz, MD • Sean P. Lyden, MD • Christopher J. Smolock, MD • Jarrad W. Rowse, MD • Levester Kirksey, MD • Francis J. Caputo, MD

Results

During a 10-year period, 1347 patients had undergone CEA at the Cleveland Clinic main campus. Of the 1347 patients, 1152 met the criteria for analysis. Propensity score matching found adequate matches for 424 high-risk patients, with 173 patients having at least one physiologic high-risk factor and 293 at least one anatomic high-risk factor. No significant differences were found in the primary composite outcome or any of its components. Overall, the stroke rate for the standard-risk and high-risk patients was 1.9% and 1.4%, respectively. The high-risk patients were significantly more likely to have experienced a cranial nerve injury, although most were temporary. When patients with one or multiple risk factors were analyzed, no significant difference was found in the primary composite outcome or any of its components. Patients with two or more risk factors were significantly more likely to have experienced a cranial nerve injury, with most being temporary.

Conclusions

In our large series, CEA remained a viable and safe surgical solution for patients with high-risk anatomic and physiologic risk factors, with acceptable stroke, myocardial infarction, and 30-day mortality rates.

CEA

- VQI data reports overall stroke rate for all patients undergoing CEA is 1.7 %

The Facts: SVS Practice Guidelines

Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease

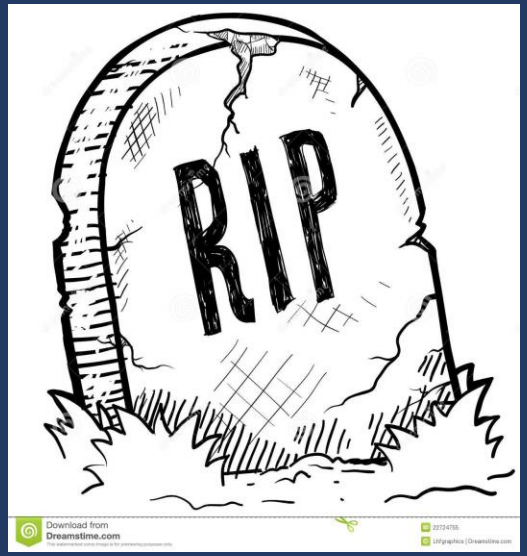
Ali F. AbuRahma, MD,[a] Efthymios D. Avgerinos, MD, PhD,[b] Robert W. Chang, MD,[c] R. Clement Darling III, MD,[d] Audra A. Duncan, MD,[e] Thomas L. Forbes, MD,[f] Mahmoud B. Malas, MD, MHS,[g] Mohammad Hassan Murad, MD, MPH,[h] Bruce Alan Perler, MD, MBA,[i] Richard J. Powell, MD,[j] Caron B. Rockman, MD,[k] *and* Wei Zhou, MD,[l] *Charleston, WVa; Pittsburgh, Pa; San Francisco and La Jolla, Calif; Albany and New York, NY; London and Toronto, Ontario, Canada; Rochester, Minn; Baltimore, Md; Lebanon, NH; and Tucson, Ariz*

ABSTRACT

Management of carotid bifurcation stenosis in stroke prevention has been the subject of extensive ……..

A separate implementation document will address other important clinical issues in extracranial cerebrovascular disease. Recommendations are made using the GRADE (grades of recommendation assessment, development, and evaluation) approach, as was used for other Society for Vascular Surgery guidelines. The committee recommends CEA as the first-line treatment for symptomatic low-risk surgical patients with stenosis of 50% to 99% and asymptomatic patients with stenosis of 70% to 99%. The perioperative risk of stroke and death in asymptomatic patients must be <3% to ensure benefit for the patient.

Why embolic protection?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Safety and Efficacy of Transcarotid Artery Revascularization in a Community Hospital

Aaron L. Zebolsky, MS, Jesse Chou, BA, Phillip Key, BS, Patrick Knight, MD, Gulrez Mahmood, MD, Krishna Jain, MD, *and* Mark Rummel, MD, *Kalamazoo, Mich*

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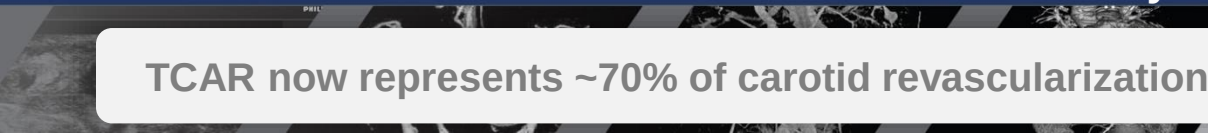
Methods

- 147 patients underwent TCAR for carotid artery stenosis in a “real-world” community setting from 2017-2020.
- Seven vascular surgeons from two surgical groups contributed to the included cases.
- The technical success rate was 98.7%.
- Perioperative and 30-day major adverse events (death, cerebrovascular accident [CVA], myocardial infarction) rates were 0.7% and 3.4%.

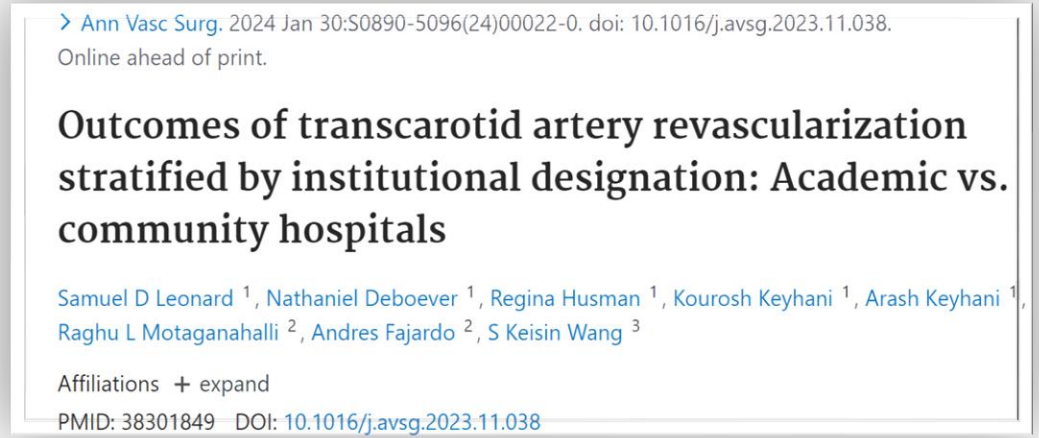
Take Home Message

After evaluating the outcomes and complications of TCAR outside of academic vascular surgery programs, Transcarotid artery revascularization is safe and effective in community hospitals.



TCAR now represents ~70% of carotid revascularizations in this community hospital

TCAR Outcomes by Institutional Designation: Academic vs. Community Hospitals



Ann Vasc Surg. 2024 Jan 30:S0890-5096(24)00022-0. doi: 10.1016/j.avsg.2023.11.038.
Online ahead of print.

Outcomes of transcarotid artery revascularization stratified by institutional designation: Academic vs. community hospitals

Samuel D Leonard [1], Nathaniel Deboever [1], Regina Husman [1], Kourosh Keyhani [1], Arash Keyhani [1], Raghu L Motaganahalli [2], Andres Fajardo [2], S Keisin Wang [3]

Affiliations + expand

PMID: 38301849 DOI: 10.1016/j.avsg.2023.11.038

"These findings emphasize the adaptability and effectiveness of TCAR in diverse healthcare environments..."

Ann Vasc Surg 2024;Jan 30:S0890-5096(24)00022-0

Retrospective review of prospectively maintained TCAR database from two institutions with patient stratification based on academic or community-based hospital

973 patients underwent TCAR. 570 (58.6%) were at an academic facility while 403 (41.4%) were at a community hospital.

Stroke rates were similar at 2.7% (academic) vs 2.0% community p=0.51.

"There were no differences in perioperative outcomes and adverse events between the cohorts, suggesting TCAR can be safely performed, regardless of practice setting."

- CEA should still remain the gold standard for patients with Carotid Stenosis
- TCAR however is clearly a very promising technique with excellent outcomes and deserves in my opinion to be widely adopted at all facilities performing carotid revascularization.
- TF-CAS has consistently performed inferiorly to both CEA and TCAR but in certain circumstances is a viable option. BUT unclear why this technique should be widely available outside of major stroke centers.

THANK YOU!