2024 MID-ATLANTIC CONFERENCE

12th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2024

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2024

TCAR – CEA – TF-CAS and CMS Updates on Carotid Management

Priyam K. Vyas
Assistant Professor of Surgery – Eastern Virginia Medical School
Sentara Vascular Specialists


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JURASSIC PARK

Agenda

- History of Medicare Coverage
- THE REQUEST
- Public comments
- Medicare Expansion & Final Decisions
- CEA vs. TF-CAS vs. TCAR
- Final thoughts


JURASSIC PARK

History

- Medicare Expanded Coverage for PTA and Stenting
  - March 17, 2005
  - High Risk for CEA
  - Symptomatic Carotid Artery Stenosis >=70%
  - Only performed in CMS approved facility for CAS with FDA- approved stenting system and EPD

History

- High Risk for CEA
  - Anatomic Risk factors – previous MRND, high lesion etc
  - Significant Medical Comorbidities
    - CHF, EF <30%, Unstable Angina, Contralateral Occlusion, Recent MI, previous CEA, radiation
  - High risk from other studies

History

- CMS Facilities
  - Minimum standard modeled by professional societies
  - The facility or a contractor must collect data on all carotid stenting procedures done
  - Re-credentialing about every 6 months

Agenda

- History of Medicare Coverage
- **THE REQUEST**
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THE REQUEST

- Expansion of CMS coverage to CEA standards
  - New Evidence to support reconsideration
    - 4 large multicenter RCT since last decision
- Revising Pt selection criteria
- Remove Facility and Operator requirements and leave them to local facilities
- Privileging and Credentialing Preformed by Facilities

THE REQUEST

- Facility Equipment Requirements be removed
- Handle Data Collection at local level
- Change benefit category determination (B benefit)

Table 1. Randomized Trials of CAS vs CEA in Asymptomatic Patients Since Last Reconsideration

Study/Year	Patients (n)	EPD Use	30-Day S/D/MI	Comment
CREST, 2010	CAS = 594 CEA = 587	YES	CAS = 3.5% CEA = 3.6%	ASR, >60% stenosis, Primary endpoint[#] CAS = 5.6%, CEA 4.9% (p = NS). S/D at 4 yrs CAS = 4.5%, CEA = 2.7% (p = 0.07). No difference between groups at 10 yrs.
ACT-1, 2016	CAS = 1,089 CEA = 364	YES	CAS = 3.3% CEA = 2.6%	ASR, Stenosis >70%, Primary endpoint was CAS = 3.8%, CEA = 3.4%* (p = NS).
SPACE-2, 2019	CAS = 197 CEA = 203 MED = 113	Optional (36%)	CAS = 2.5% CEA = 2.5% MED = 0%	ASR, Stenosis >70%, Primary endpoint CEA = 2.5%, CAS = 3.0%, MED = 0.9%; (p = NS).* In all CAS patients with major secondary outcome events, no EPD was used.
ACST-2, 2021	CAS = 1,811 CEA = 1,814	YES (85%)	CAS = 3.9% CEA = 3.2%	ASR, Stenosis >60%, Non-procedural stroke during follow-up CAS = 5.2%, CEA = 4.5%.

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Prepared for Centers for Medicare & Medicaid Services in Consideration of Coverage for Standard Risk Carotid Endarterectomy Patients

Prepared and endorsed by:

Gary Roubin, MD PhD, Interventional Cardiology, IMC Chair
Thomas Brott, MD, Neurology
Daniel G. Clair, Vascular Surgery
Guilherme Dabus, MD, Interventional Neuroradiology
William Gray, MD, Interventional Cardiology
Donald Heck, MD, Interventional Neuroradiology
Brian Jankowitz, MD, Neurosurgery
Tudor Jovin, MD, Interventional Neurology
Barry Katzen, MD, Interventional Radiology
Sean Lyden, MD, Vascular Surgery
James Meschia, MD, Neurology
Chris Metzger, MD, Interventional Cardiology
Kenneth Rosenfield, MD, Interventional Cardiology
Ravish Sachar, MD, Interventional Cardiology
Adnan Siddiqui, MD, Neurosurgery
Christopher White, MD, Interventional Cardiology

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Et tu, Brute?

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Public Comments

- Different organizations voice support
  - AANS
  - SNIS
  - SCAI
  - SIR
  - VIVA

Society of Vascular Surgery

Public Comments

- Negative Impact on patient safety
  - The risk of perioperative stroke is significantly higher for CAS compared to CEA (3.4% vs. 2.7%)
  - All Medicare fee-for-service beneficiaries undergoing carotid artery revascularization ’16-’22
- After median follow-up time of 3.3 years
  - CAS is associated with a 15% higher risk of stroke compared to CEA

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Public Comments

- Premature Decision prior to Crest 2
  - OMT and management of asymptomatic disease
- Impact on the Elderly
  - Inferior outcomes in elderly patients (CREST and CAPTURE-2)
- Learning Curve
  - Systemic review of TF-CAS defined 72 procedures needed for operators to achieve stroke/death <3%

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Public Comments

- Lack of Registry Participation Requirement

  “In the proposed decision summary, there is no recommendation or requirement for procedural or center certification and no requirement for monitoring outcomes”

SVS Recommendations

- Mandate Utilization of a standard “Shared” Decision Making tool that wound be designed in collaboration with applicable medical societies and stakeholders
- Emphasize collection of real time data + credentialing process and requirements for reporting standards

SVS Recommendations

- Revise what a qualitied physician is
  - Demonstrated core competency standards

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CMS Expansion

- Expansion of CMS coverage to CEA standards
  - Patients with symptomatic carotid stenosis >= 50%
  - Patients with asymptomatic disease >= 70%

- NIHSS before and after CAS procedure
- Duplex and CTA/MRA if not contraindicated
- DSA when discordance or if CTA/MRA contraindicated

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CMS Expansion

- Formal Shared Decision Making Interaction
  - Discussion of all treatment options- CEA/TCAR/CAS/OMT
  - Explain risk and benefit of each option
  - Integrate clinical guidelines
  - Discuss and incorporate patient's pref/priorities

CMS Expansion

- Facilities Stent Program Standards
  - Clearly delineate privileges by facility
  - Oversight committee to identify minimum volume and threshold of complication
  - Appropriately trained staff, personal, equipment
  - Ensure continuous quality improvement
- CMS or Third party facility approval removed

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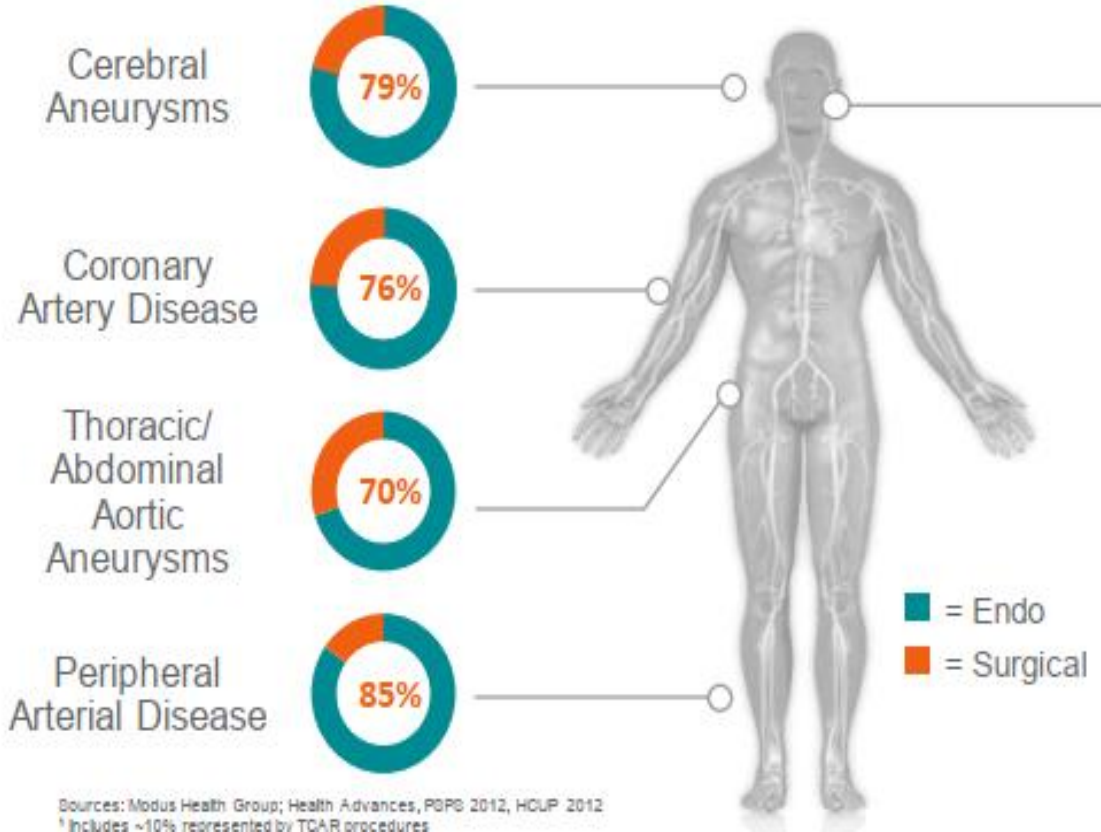
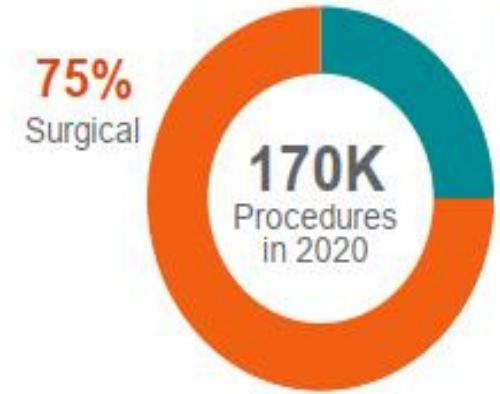
The New Normal: Endovascular Procedures

Realizing the Benefits of a Less Invasive Treatment Option



THE LAST FRONTIER:

Carotid Artery Disease: U.S.



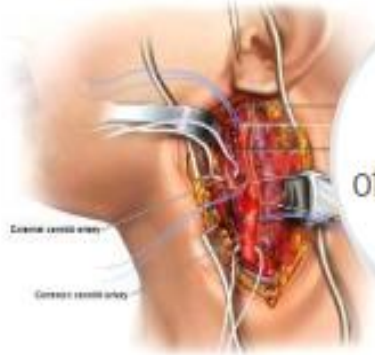
Sources: Modus Health Group; Health Advances, PDPS 2012, HCUP 2012

[1] Includes ~10% represented by TCAR procedures

SURGICAL:

Carotid Endarterectomy (CEA)

65+ years



~75% of procedures

SIGNIFICANT adverse events

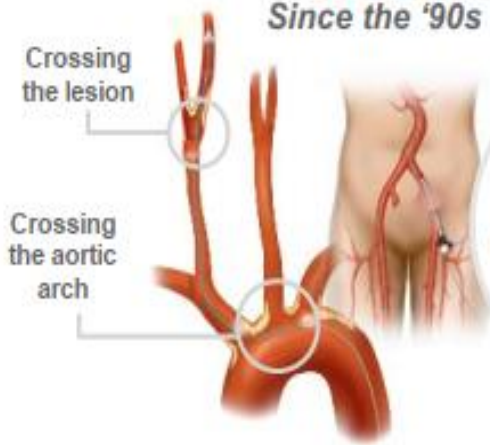
LOW 30-day stroke risk

A Dated Standard of Care

ENDOVASCULAR:

Transfemoral Carotid Artery Stenting (CAS)

Since the '90s



~15% of procedures*

LOWER adverse events

HIGHER (~2x) 30-day stroke risk

A Niche Procedure

TF-CAS vs. CEA

- TF-CAS continues show a signal of higher periop stroke comparatively to CEA

CREST Overview

- **DESIGN:** Randomized, multi-center trial from the year 2000 to 2011
- **OBJECTIVE:** Investigate the differences found in outcomes from CEA vs. TF-CAS
- **PRIMARY ENDPOINT:**
  - Stroke, Myocardial Infarction, or Death from any cause during the periprocedural period (30 days from procedure)
  - Any Ipsilateral Stroke within 4 years after procedure
- **CONCLUSION:** TF-CAS and CEA were associated with similar rates of the primary endpoint of *composite* S/D/MI and ipsilateral stroke at 4 years.
  - However, *individual* outcomes showed higher stroke rates and lower MI rates for TF-CAS vs. CEA

30-day Outcomes	CEA (N=1240)	TF-CAS (N=1262)	P-value
Stroke	2.3%	4.1%	0.01
Death	0.3%	0.7%	0.18
MI	2.3%	1.1%	0.03
Cranial Nerve Injury	4.7%*	0.3%	NR**

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Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis

- C
  -

ACT -1

- **Asymptomatic, Standard Risk Population**
- **2:1 randomization (CAS:CEA)**

	CAS	CEA	*p* value
1 yr S/D/MI	3.8%	3.4%	0.01
30d S/D/MI	3.3%	2.6%	0.6
30d All Stroke	2.8%	1.4%	0.23

	AHA Stroke/Death Threshold Rate
Asymptomatic	3%

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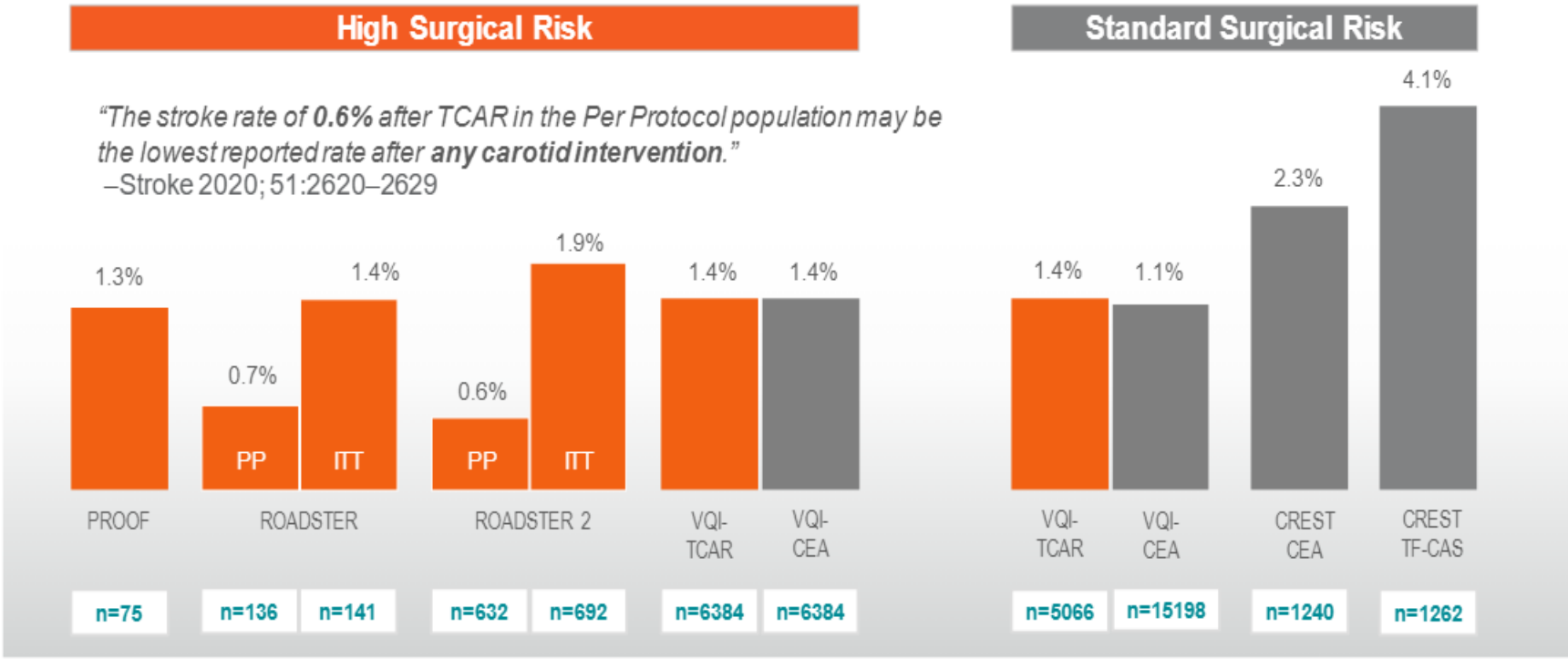
Periprocedural Stroke Rates

Publications of TCAR, CEA, & TF-CAS



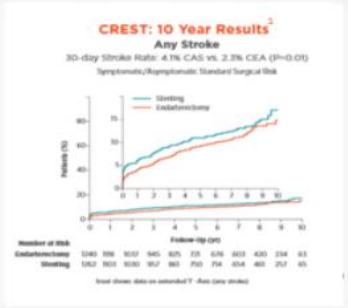
Stent Safety and Durability

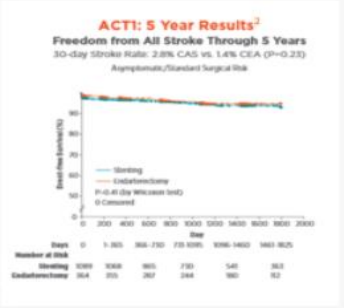
Pitfalls of a transfemoral approach

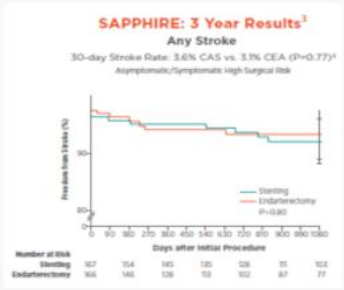
Risky delivery of the stent to the carotid bifurcation

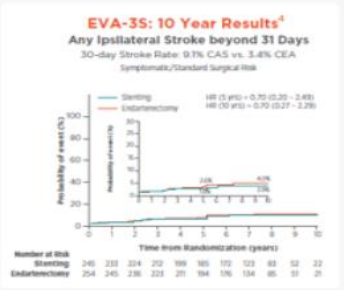
After safe delivery, stents afford equal protection from ipsilateral stroke in the intermediate & longer terms from many consistent randomized trials of CAS Vs. CEA

If the stent is DELIVERED safely, long term outcomes are equivalent to CEA









Safe transcarotid delivery of the stent mitigates periprocedural hazard

1. Brott TG, Howard G, Roubin GS, et al. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis. *N Engl J Med.* 2016;374(11):1021-1031. doi:10.1056/NEJMoa1505215
2. Rosenfield K, Matsumura JS, Chaturvedi S, et al. Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis. N Engl J Med. 2016;374(11):1011-1020. doi:10.1056/NEJMoa1515706
3. Gurm HS, Yadav JS, Fayad P, et al. Long-term results of carotid stenting versus endarterectomy in high-risk patients. N Engl J Med. 2008;358(15):1572-1579. doi:10.1056/NEJMoa0708028
4. Mas JL, Arquizan C, Calvet D, et al. Long-term follow-up study of endarterectomy versus angioplasty in patients with symptomatic severe carotid stenosis trial. Stroke. 2014;45(9):2750-2756. doi:10.1161/STROKEAHA.114.005871

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The Arch Is A Hostile Endovascular Territory

A transradial approach still involves complex reverse-curve catheter manipulation in the ascending aorta, close to the innominate
& the outflow vessels; the right subclavian
& right vertebral arteries

Stroke Location	Filter (n = 9,656)	Proximal Balloon (n = 590)	p Value
All strokes	209 (2.2)	9 (1.5)	0.296
Ipsilateral strokes	139 (1.4)	4 (0.7)	0.126
Contralateral strokes	26 (0.3)	2 (0.3)	0.675
Vertebral/unknown strokes	44 (0.5)	3 (0.5)	0.751

Reverse-curve catheter to be reformed in the ascending aorta for great vessel catheterization from a transradial approach

Giri J, Giri J, Parikh SA, Kennedy KF, et al. Proximal versus distal embolic protection for carotid artery stenting: a national cardiovascular data registry analysis. JACC Cardiovasc Interv. 2015;8(4):609-615. doi:10.1016/j.jcin.2015.02.001 SA, Kennedy KF, et al. Proximal versus distal embolic protection for carotid artery stenting: a national cardiovascular data registry analysis. JACC Cardiovasc Interv. 2015;8(4):609-615


THAT IS ONE BIG PILE O
yarn.co

TCAR Paradigm Shift: Transcarotid

TCAR combines advantages from both worlds: **surgical principles** of neuroprotection and game changing **endovascular technology**

Minimally Invasive

Avoids Aortic Arch

Avoids Cranial Nerve Plexus

High Rate Flow Reversal Neuroprotection

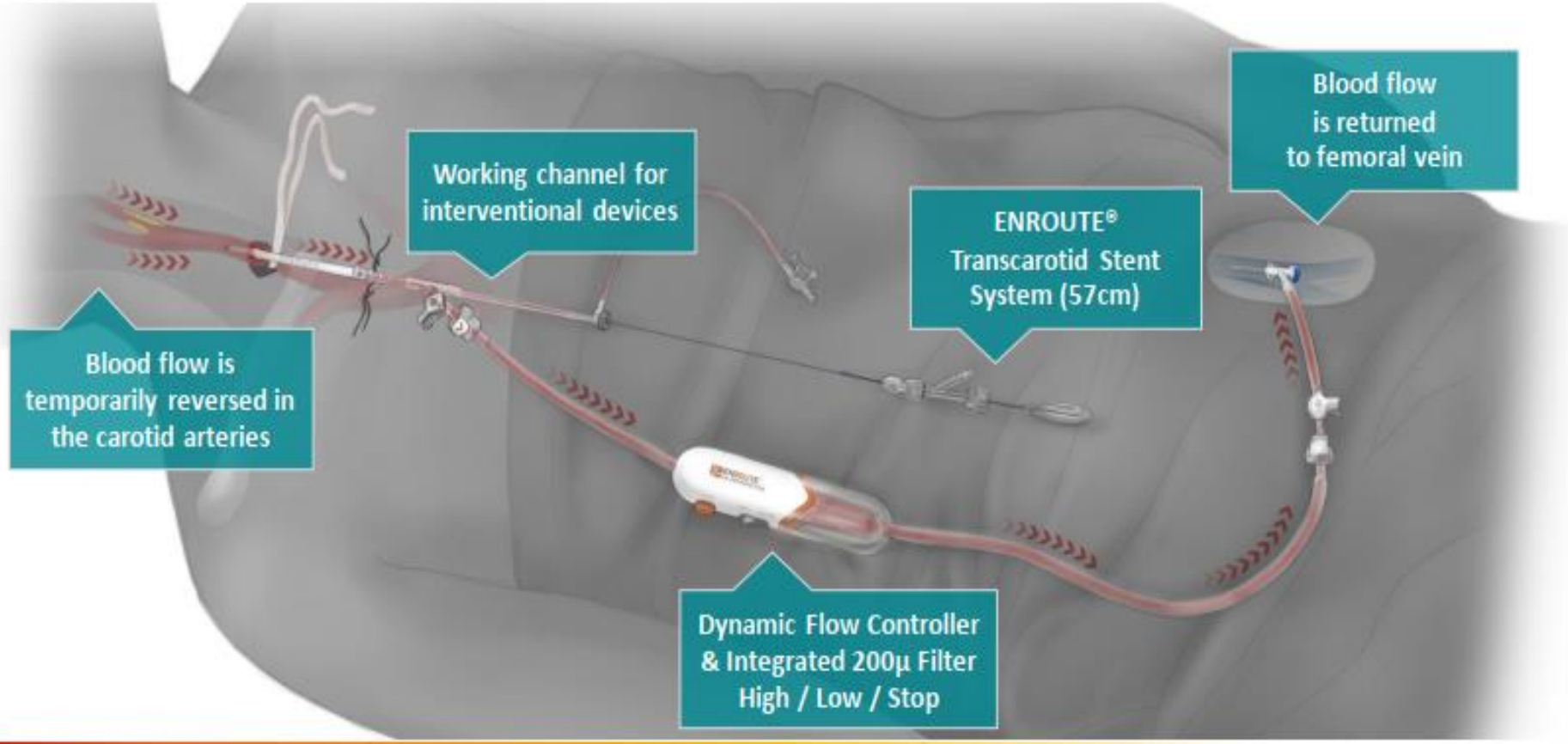
Accurate stenting

Silk Road's Response to the CMS Expansion

CEA vs. TCAR

- Neuroprotection
- Lower rates of CNI and MI
- Depending on the data lower or equal rates of stroke

ENROUTE® Transcarotid Neuroprotection & Stent System



VQI Data- High Surgical Risk: Propensity Matched (12,768 cases)

- **DESIGN:** Retrospective analysis using VQI-TCAR Surveillance Project data from September 2016 to October 2019
- **OBJECTIVE:** Compare perioperative outcomes after TCAR versus CEA
- **CONCLUSION:** This propensity-score matched analysis demonstrated significant reduction in the risk of postoperative myocardial infarction and cranial nerve injury after TCAR compared to CEA, with no differences in the rates of stroke/death

30-Day Outcomes	TCAR (N= 6,384)	CEA (N= 6,384)	P-Value
Stroke/Death/MI	2.0%	2.4%	0.172
Stroke/Death	1.6%	1.6%	0.945
Stroke	1.4%	1.4%	0.881
Death	0.4%	0.3%	0.662
Bleeding Requiring Intervention*	1.3%	1.6%	0.127
MI	**0.5%**	**0.9%**	**0.005**
CNI	**0.4%**	**2.7%**	**<0.001**
LOS more than 1 day	**29.8%**	**34.1%**	**<0.001**
OR Time	**72.5 min**	**121.4 min**	**<0.001**

Matched on symptomatic status, age, CAD, CHF, COPD, CKD, prior ipsilateral CEA, prior ipsilateral CAS, contralateral occlusion, ASA Class and statin use

Malas MB; Malas MB, Dakour-Aridi H, Kashyap VS, et al. TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. *Ann Surg*. 2022;276(2):398-403. doi:10.1097/SLA.0000000000004496 Surg 2020

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SVS Guidelines For Management of Extracranial Cerebrovascular Disease

- TCAR is the preferred approach in high surgical risk patients.

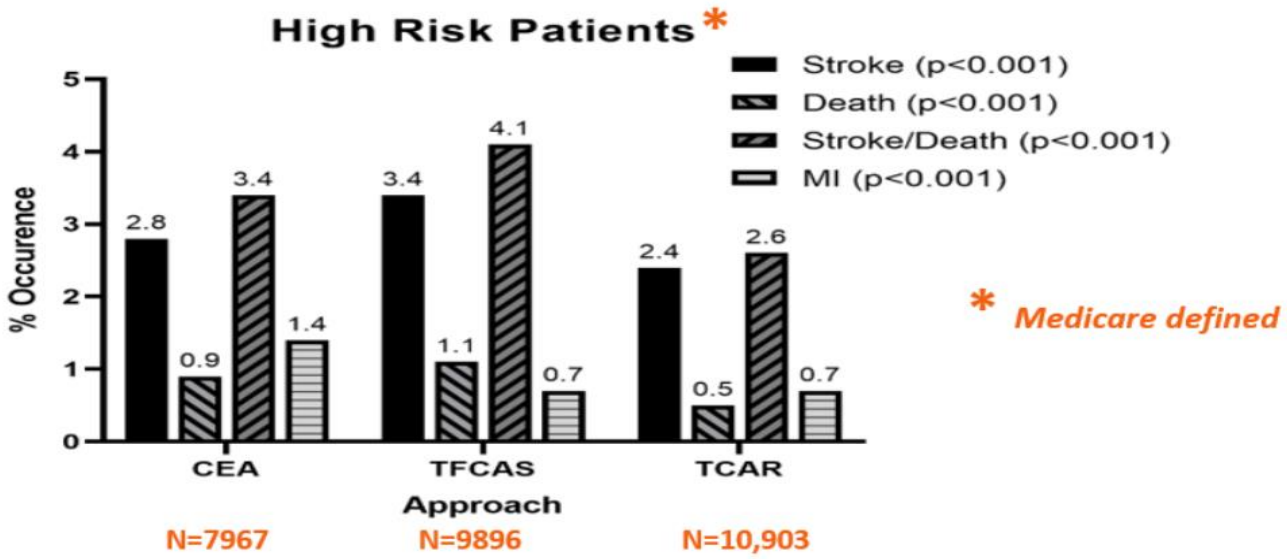
Physiologic risks	Anatomic risks
Age ≥75	Prior head/neck surgery or irradiation
Congestive heart failure	Spinal immobility
Left ventricular ejection fraction ≤35%	Restenosis after CEA
Two diseased coronaries with ≥70% stenosis	Surgically inaccessible lesion
Unstable angina	Laryngeal palsy: laryngectomy: permanent contralateral CNI
MI within 6 weeks	Contralateral occlusion
Abnormal stress test	Severe tandem lesions
Need for open heart surgery	
Need for major surgery (including vascular)	
Uncontrolled diabetes	
Severe pulmonary disease	

CNI, Cranial nerve injury; *MI*, myocardial infarction.

AbuRahma AF, Avgerinos ED, Chang RW, et al. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *J Vasc Surg*. 2022;75(1S):4S-22S. doi:10.1016/j.jvs.2021.04.073

Transcarotid artery revascularization is associated with similar outcomes to carotid endarterectomy regardless of patient risk status N=124,531

George Q. Zhang, MD, MPH,[a] Sanuja Bose, MD,[b] David P. Stonko, MD, MS,[c] Christopher J. Abularrage, MD,[c,d] Devin S. Zarkowsky, MD,[e] *and* Caitlin W. Hicks, MD, MS,[c,d] *Boston, MA; Baltimore, MD; and Denver, CO*



Zhang GQ, Bose S, Stonko DP, Abularrage CJ, Zarkowsky DS, Hicks CW. Transcarotid artery revascularization is associated with similar outcomes to carotid endarterectomy regardless of patient risk status. *J Vasc Surg*. 2022;76(2):474-481.e3. doi:10.1016/j.jvs.2022.03.860

Perioperative Outcomes in Transcarotid Artery Revascularization Versus Carotid Endarterectomy or Stenting Nationwide

TABLE 2. Transcarotid Artery Revascularization Outcomes Compared With Carotid Endarterectomy and Carotid Artery Stenting, 2015 to 2019

	TCAR vs CEA					
	Unadjusted model		Multivariate		Propensity-matched model	
Outcome	OR (95% CI)	*P* value	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Death	1.52 (0.91, 2.53)	.11	0.96 (0.55, 1.67)			
Stroke	0.56 (0.30, 1.05)	.070				
Myocardial infarction	0.93 (0.67, 1.31)					
Death/stroke	0.95 (0.64					.58
MAE[b]					0.99)	.043[a]

			Multivariate		Propensity-matched model	
			OR (95% CI)	Outcome	OR (95% CI)	*P* value
		<.0001[a]	0.41 (0.24, 0.71)	0.0013[a]	0.47 (0.27, 0.81)	.0068[a]
	0.82)	.01[a]	0.48 (0.26, 0.91)	0.024[a]	0.46 (0.24, 0.90)	.022[a]
	0.70 (0.50, 0.98)	.039[a]	0.75 (0.53, 1.07)	0.11	0.77 (0.53, 1.13)	.18
stroke	0.37 (0.25, 0.55)	<.0001[a]	0.46 (0.30, 0.69)	0.00020[a]	0.46 (0.30, 0.71)	.00037[a]
MAE[b]	0.54 (0.42, 0.70)	<.0001[a]	0.64 (0.49, 0.86)	0.0014[a]	0.66 (0.50, 0.87)	.0038[a]

CAS, carotid artery stenting; CEA, carotid endarterectomy; MAE, major adverse events; TCAR, transcarotid artery revascularization.
[a]*P* < .05, statistically significant.
[b]MAE is a composite outcome of death, stroke, and myocardial infarction.

CONCLUSION: TCAR is underutilized relative to other revascularization techniques yet has favorable outcomes compared with CEA and CAS. TCAR may be preferred to CAS in patients not surgical candidates for CEA and has a less invasive possibility for those eligible for CEA.

KEY WORDS: Stroke, Carotid artery, Carotid artery stenosis, Endarterectomy, Carotid

Operative Neurosurgery 00:1–8, 2023 https://doi.org/10.1227/ons.0000000000000865

National Inpatient Sample N= 369,045

Ramsay IA, Burks JD, Lu VM, et al. Perioperative Outcomes in Transcarotid Artery Revascularization Versus Carotid Endarterectomy or Stenting Nationwide. *Oper Neurosurg (Hagerstown)*. 2023;25(5):453-460. doi:10.1227/ons.0000000000000865

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Number Needed to Adequately Power a Randomized Trial With Current Stroke/Death Rates for TCAR Vs. CEA

"57,942 patients needed ***per group*** to detect a 0.2% difference in stroke/death at 30-days"

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Standard Surgical Risk Patients from the VQI: 3:1 propensity matching

Standard Risk Patients

30-day Outcomes	CEA N = 15,198	TCAR N = 5,066	Relative Risk (95% CI)	P-value
Stroke or Death	1.4%	1.6%	1.15 (0.89 to 1.48)	0.29
Stroke	1.1%	1.4%	1.25 (0.95 to 1.65)	0.11
Death	0.4%	0.3%	0.90 (0.52 to 1.54)	0.69
Stroke, Death, or Myocardial Infarction	2.0%	2.0%	1.02 (0.81 to 1.27)	0.88
Cranial Nerve Injury	2.7%	0.3%	0.11 (0.07 to 0.18)	<.001

1-year Outcomes	CEA N = 15,198	TCAR N = 5,066	Relative Risk (95% CI)	P-value
Ipsilateral Stroke	1.1%	1.4%	1.31 (0.99 to 1.74)	0.06
Death	2.0%	1.9%	0.95 (0.74 to 1.22)	0.67

Liang P, Cronenwett JL, Secemsky EA, et al. Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk. *JAMA Neurol*. 2023;80(5):437-444. doi:10.1001/jamaneurol.2023.0285

TCAR vs. TF-CAS

- Lower Stroke rate
- Lower overall complication rate
- Rigorously monitored by VQI
- Much easier to learn
- Better outcomes in Elderly

TCAR vs TF-CAS in the VQI Database

The authors reviewed patient data **(n = 3286** matched) collected from the VQI-TSP to compare outcomes of TCAR vs TF-CAS; published in the **Journal of the American Medical Association (JAMA)**.[1]

TCAR Safety

The investigators found a significant decrease in stroke, death and stroke/death for patients who underwent TCAR

Durability and Efficiency

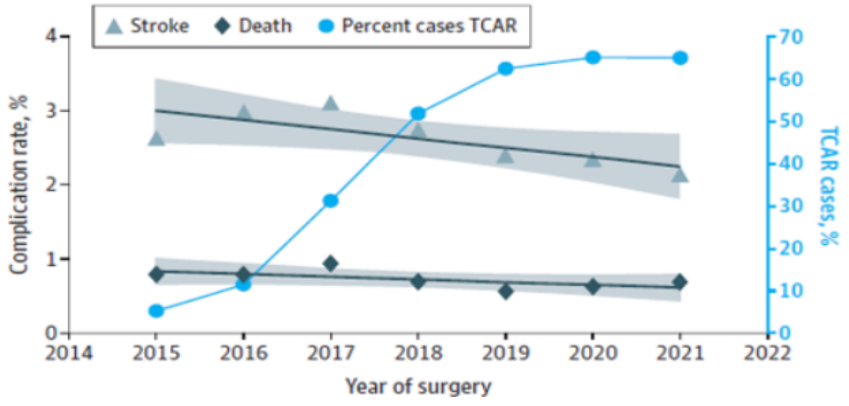
The investigators found a significant decrease in stroke or death at one year as well as procedural efficiencies with TCAR

Conclusion: TCAR had a *significantly lower* risk of stroke or death compared to TF-CAS with improved procedural efficiencies (radiation/contrast).

Schermerhorn ML et al. JAMA Schermerhorn ML, Liang P, Eldrup-Jorgensen J, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis. JAMA. 2019;322(23):2313-2322. doi:10.1001/jama.2019.18441

Association of Year of Surgery and Carotid Stenting Outcomes in High-risk Patients, 2015- 2021 (TFCAS & TCAR)

Figure. Proportional Use and In-Hospital Outcomes of Patients at High-Risk for Carotid Endarterectomy Who Underwent Carotid Stenting From 2015-2021



Proportional use is shown by the blue line and in-hospital outcomes by the black line with 95% confidence bands.

After controlling for baseline characteristics, increasing year of surgery was associated with increasing TCAR use & decreasing odds of in-hospital S/D

TCAR Vs. TFCAS was additionally associated with decreased odds of S/D

TCAR use explained 30% of observed reduction in stroke

TCAR use explained 67% of observed reduction in death

TCAR represented 65% of all HSR stenting cases within the VQI by 2021

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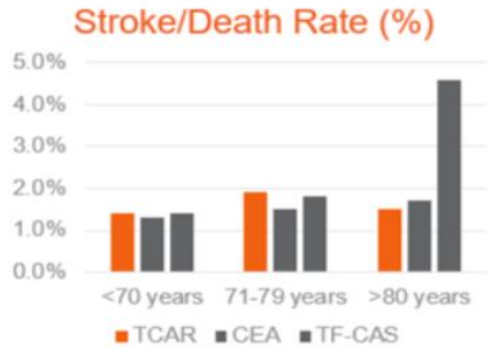
The Impact of Age on Outcomes

Multi-center, retrospective review of data collected from the VQI-TSP to compare the association between age and outcomes after TCAR, TF-CAS, and CEA.[1]



TCAR vs TF-CAS in the Elderly (>80 years)

- 72% less risk of stroke
- 65% less risk of stroke/death
- 76% less risk of stroke/ death/ myocardial infarction

TCAR vs CEA

- No significant difference in outcomes across different age groups
- Significant decrease in CNI across all patient groups for TCAR

Conclusion: TCAR is a safe procedure regardless of the patient's age. TCAR's advantages are more pronounced in elderly patients when compared to TF-CAS. TCAR showed statistically equivalent outcomes to CEA regardless of age with a significant decrease in CNI

Dakour-Aridi H, Kashyap VS, Wang GJ, Eldrup-Jorgensen J, Schermerhorn ML, Malas MB. The impact of age on in-hospital outcomes after transcarotid artery revascularization, transfemoral carotid artery stenting, and carotid endarterectomy. *J Vasc Surg*. 2020;72(3):931-942.e2. doi:10.1016/j.jvs.2019.11.037

Learning Curve:

- Met after 4 Procedures
- Procedural and Flow Reversal Times Significantly shortened after 4 TCAR Procedures
- Fluoroscopy Times and Contrast Usage

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Clinical Research

Transcarotid Arterial Revascularization Adoption Should not Be Hindered by a Concern for a Long Learning Curve

Abdullah A Alfawaz,[1] Matthew J Rossi,[2] Misaki M Kiguchi,[2] Raghuveer Vallabhaneni,[2] Javairiah Fatima,[2] Steven D Abramowitz,[2] and Edward Y Woo,[2] Kuwait; Washington DC

Background: Transcarotid arterial revascularization (TCAR) offers a novel technique for carotid artery stenting (CAS) that provides flow reversal in the carotid artery and avoids aortic arch manipulation, thus, potentially lowering ipsilateral and contralateral periprocedural stroke rates. As a new technology, adoption may be limited by concern for learning a new technique. This study seeks to examine the number of cases needed for a surgeon to reach technical proficiency.
Methods: Retrospective analysis was performed using a prospectively collected database of all TCAR procedures performed in a tertiary health care system between 2016 and 2020. Patient demographics and anatomic characteristics were collected. Intraoperative variables and perioperative outcomes were examined. These variables were collated into groups for the first 4 procedures, procedures 5–8, and after 8. Independent Samples *t* test, 1-way ANOVA, and logarithmic regression were used to statistically analyze the data.
Results: One-hundred and eighty-seven TCARs were performed by 14 surgeons. One hundred and twenty-two (65%) were male, 59 (32%) were older than 75 years, and 83 (44%) were symptomatic. The most common indications were high-lesions in 87 patients (47%) and recurrent stenosis after CEA in 37 patients (20%). Significant differences were found between the first and second groups of 4 cases when comparing mean operative time (71 vs. 58 min; $P = 0.001$) and flow reversal time (10.8 vs. 7.9 min; $P = 0.004$). similar significant differences were found between the first and third groups of 4 cases but not between the second and third groups. There was a reduction in contrast usage and fluoroscopy time after the first 4 cases, however, this did not reach statistical significance. There was no ipsilateral perioperative strokes. One patient had a contralateral stroke on postoperative day 2 due to intracranial atherosclerosis, and there was one perioperative mortality that occurred on postoperative day 3 after discharge.
Conclusions: Procedural and flow reversal times significantly shorten after 4 TCAR procedures are performed. Other metrics, such as fluoroscopy time and contrast usage, are also decreased. Complications, in general, are minimal. Proficiency in TCAR, as measured by these metrics, is met after performing only 4 procedures.

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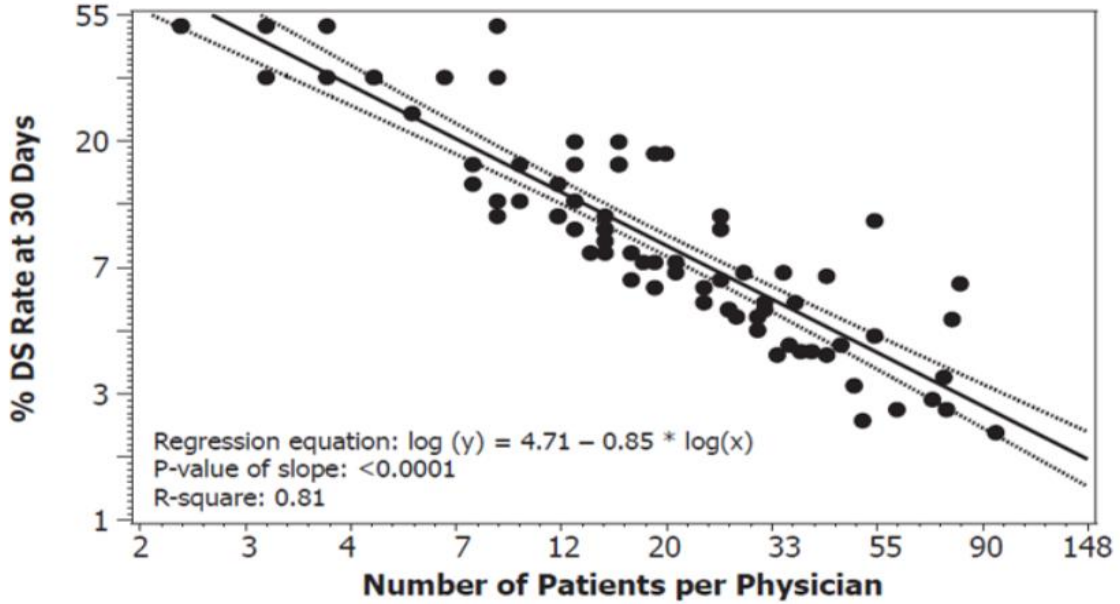
Influence of Site and Operator Characteristics on Carotid Artery Stent Outcomes

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, Rosenfield KA, Jaff MR, et al. 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. *JACC Cardiovasc Interv*. 2011;4(2):235-246. doi:10.1016/j.jcin.2010.10.009

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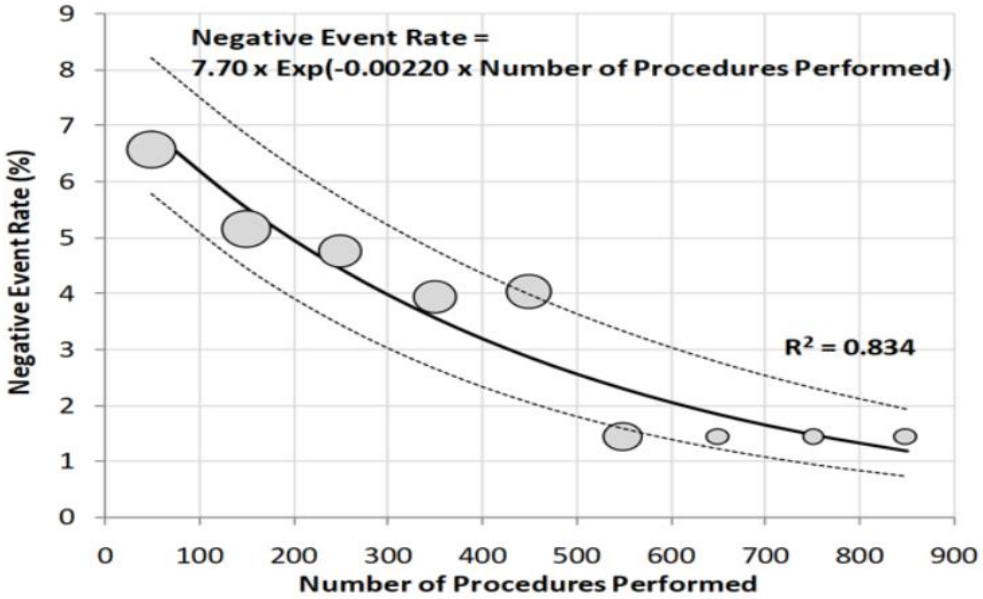
Carotid artery stenting: relationship between experience and complication rate

Learning Curve TF-CAS



Negative Event Rate	Number of Procedures Performed (95% CI)
6%	114 (37, 224)
5%	197 (107, 325)
4%	298 (193, 449)
3%	429 (304, 609)
2%	614 (460, 834)

Smout J, Macdonald S, Weir G, Stansby G. Carotid artery stenting: relationship between experience and complication rate. *Int J Stroke*. 2010;5(6):477-482. doi:10.1111/j.1747-4949.2010.00488.x

Adverse events are not increased with trainee participation in transcarotid revascularization

N= 486; 173 with trainee present, 313 without trainee present

Comparison of perioperative outcomes of patients undergoing TCAR with and without a trainee present.

	Trainee present	Trainee absent	p-Value
Length of stay	2.4 ± 4.5 days	1.7 + 1.4 days	.55
Reintervention	2 (1.1%)	4 (1.2%)	.91
Cranial nerve palsy	1 (0.5%)	0 (0%)	.18
Ipsilateral stroke	2 (1.1%)	9 (2.8%)	0.22
Contralateral stroke	0 (0%)	0 (0%)	N/A
Myocardial infarction	0 (0%)	0 (0%)	N/A
Hematoma	3 (1.7%)	2 (0.6%)	.25
Thrombosis	0 (0%)	2 (0.6%)	.29
Death	0 (0%)	5 (1.6%)	.10

"One of the challenges of surgical education is to teach trainees to operate through hands-on learning without jeopardizing patient safety & quality of care"

Husman R, Tanaka A, Saqib NU, et al. Adverse events are not increased with trainee participation in transcarotid revascularization. *Vascular*. Published online November 15, 2022. doi:10.1177/17085381221140158

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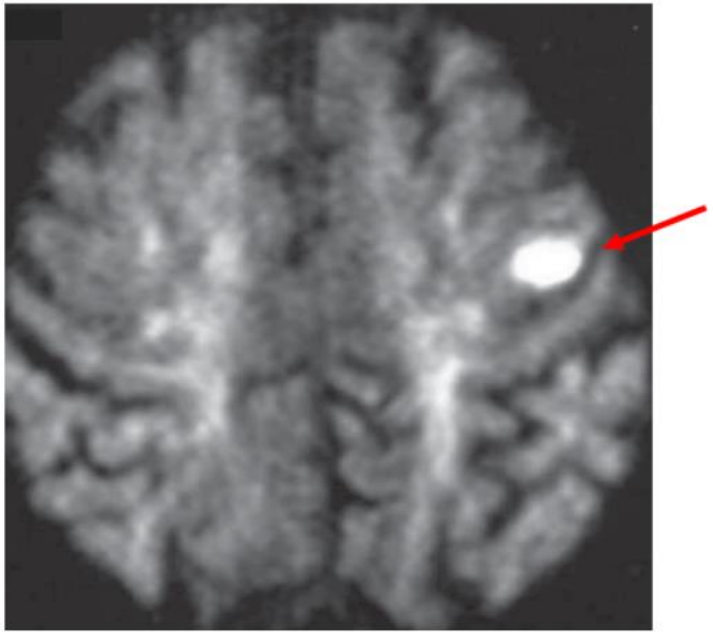
Silent cerebral ischaemia: hidden fingerprints of invasive medical procedures

Martin Bendszus, Guido Stoll



Bendszus M, Stoll G. Silent cerebral ischaemia: hidden fingerprints of invasive medical procedures. *Lancet Neurol.* 2006;5(4):364-372. doi:10.1016/S1474-4422(06)70412-4

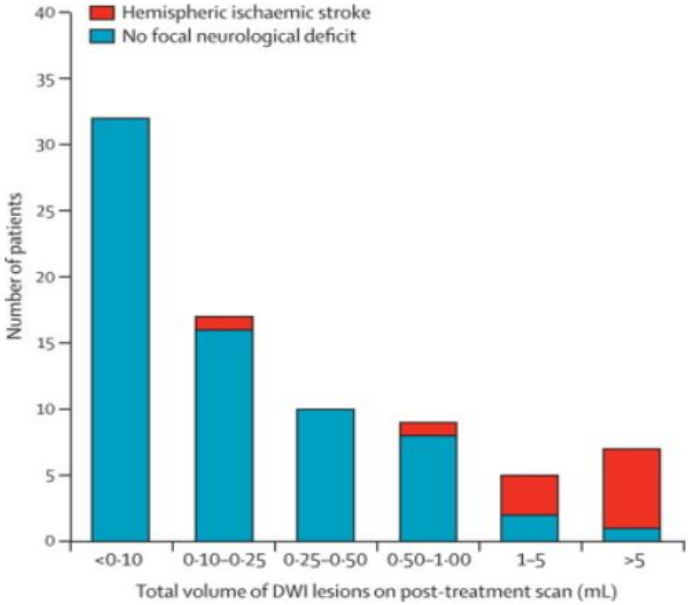
New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS)

*Leo H Bonati, Lisa M Jongen, Sven Haller, H Zwenneke Flach, Joanna Dobson, Paul J Nederkoorn, Sumaira Macdonald, Peter A Gaines, Annet Waaijer, Peter Stierli, H Rolf Jäger, Philippe A Lyrer, L Jaap Kappelle, Stephan G Wetzel, Aad van der Lugt, Willem P Mali, Martin M Brown, H Bart van der Worp, Stefan T Engelter, for the ICSS-MRI study group**

	Carotid stenting (n=124)	Carotid endarterectomy (n=107)	OR (95% CI)	p*
At least one new lesion	62 (50%)	18 (17%)	4·94 (2·67–9·16)† 5·21 (2·78–9·79)‡	<0·0001 <0·0001
Single lesion	18 (15%)	9 (8%)	–	–
Multiple lesions	44 (35%)	9 (8%)	–	–
Location of lesions				
Ipsilateral carotid circulation only	34 (27%)	14 (13%)	–	–
Ipsilateral carotid and non-ipsilateral (contralateral carotid or vertebrobasilar) circulations	22 (18%)	3 (3%)	–	–
Non-ipsilateral (contralateral carotid or vertebrobasilar) circulations only	6 (5%)	1 (1%)	–	–
Ischaemic events in patients with new DWI lesions§	9 (7%)	3 (3%)	–	–
Hemispheric stroke	8 (6%)	3 (3%)	–	–
Retinal infarct	1 (1%)	0	–	–
TIA	0	0	–	–
None	53 (43%)	15 (14%)	–	–

Data are number (%). DWI=diffusion-weighted imaging. TIA=transient ischaemic attack. *Logistic regression. †Unadjusted. ‡Adjusted for interval between treatment and post-treatment scan. §Events occurring between start of treatment and post-treatment scans only. No ischaemic event occurred between the start of treatment and the post-treatment scan in patients without new DWI lesions.

Table 4: **New DWI lesions on post-treatment scans**



Bonati LH, Jongen LM, Haller S, et al. New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS) [published correction appears in Lancet Neurol. 2010 Apr;9(4):345. Waaijer, Annet [corrected to Waaijer, Annet]]. *Lancet Neurol.* 2010;9(4):353-362. doi:10.1016/S1474-4422(10)70057-0

Transradial versus transfemoral arterial approach for cerebral angiography and the frequency of embolic events on diffusion weighted MRI

Univariate results for each predictor comparing MRI for acute findings following cerebral angiogram

	DWI positive*	DWI negative†	P value
Total (n=200)	23 (11)	177 (89)	
Approach (n (%))			
TRA (n=103)	18 (17.5)	85 (82.5)	
TFA (n=97)	5 (5.2)	92 (94.8)	0.007

Carraro do Nascimento V, de Villiers L, Hughes I, Ford A, Rapier C, Rice H. Transradial versus transfemoral arterial approach for cerebral angiography and the frequency of embolic events on diffusion weighted MRI. J Neurointerv Surg. 2023;15(7):723-727. doi:10.1136/inis-2022-019009

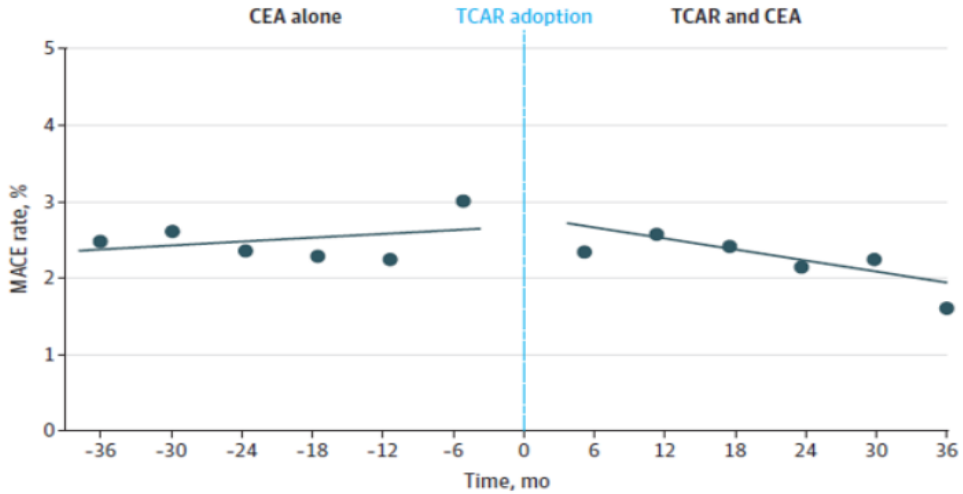
Institutional Policy Considerations

Original Investigation | Surgery

Association of Adoption of Transcarotid Artery Revascularization With Center-Level Perioperative Outcomes

Jesse A. Columbo, MD, MS; Pablo Martinez-Camblor, PhD; A. James O'Malley, PhD; David H. Stone, MD; Vikram S. Kashyap, MD; Richard J. Powell, MD; Marc L. Schermerhorn, MD; Mahmoud Malas, MD, MHS; Brian W. Nolan, MD, MS; Philip P. Goodney, MD, MS

Rate of Perioperative Major Adverse Cardiovascular Events (MACE)



Rate of MACE prior to the adoption of transcarotid artery revascularization (TCAR) represents the rate for carotid endarterectomy (CEA) alone at centers that never adopted TCAR or had not yet adopted TCAR. For centers adopting TCAR, the rate after TCAR adoption represents the rate of MACE for CEA and TCAR combined. Centers performing TCAR alone are not represented.

Columbo JA, Martinez-Camblor P, O'Malley AJ, et al. Association of Adoption of Transcarotid Artery Revascularization With Center-Level Perioperative Outcomes. *JAMA Netw Open*. 2021;4(2):e2037885. Published 2021 Feb 1.

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TCAR serves patients with carotid artery disease well:

- Short learning curve[1]
- Safe in the hands of fellows[2]
- Safe in low volume[3]
- Works equally well in community hospitals, teaching hospitals & academic institutions[4]
- Safe in octogenarians, females, recently symptomatic patients, ethnic minorities[5,6,7,8]
- Compared with TFCAS & CEA, 22 out of 31 exclusion criteria disappear[9]
- Patients prefer TCAR over CEA & would rather NOT suffer a periprocedural stroke (TFCAS)[10]

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Final Thoughts

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