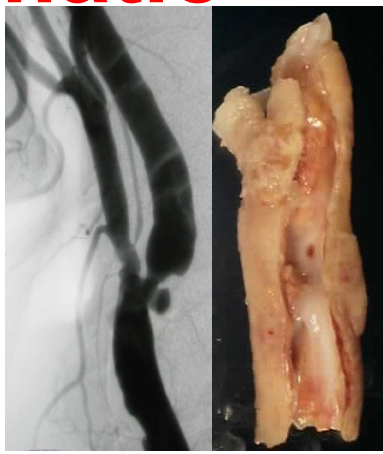
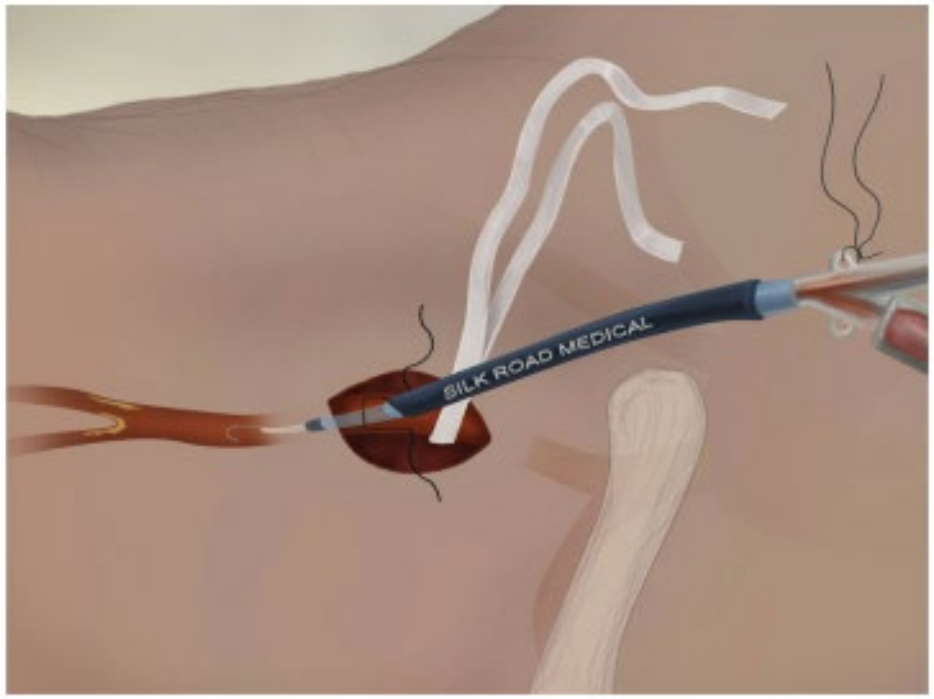
Role of TCAR in Patients with Symptomatic and Asymptomatic Carotid Stenosis



Rabih A. Chaer MD, MSc
Professor and Chief
UPMC Division of Vascular Surgery
Co director, UPMC Heart and Vascular Institute

Disclosure

I have no actual or potential conflicts of interest in relation to this presentation



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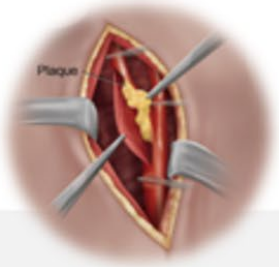
Evolution of Carotid Revascularization



1ST Successful CEA performed in **1953** Dr. Michael DeBakey

1990s

Trans Femoral Carotid Stenting

From 1994

- CREST
- SAPPHIRE

VQI TSP

From 2012

- PROOF
- ROADSTER
- ROADSTER2

TCAR for High-Risk Patients

VQI Presentation of TCAR in **Standard Surgical Risk Patients**
Liang et al, VAM 2021

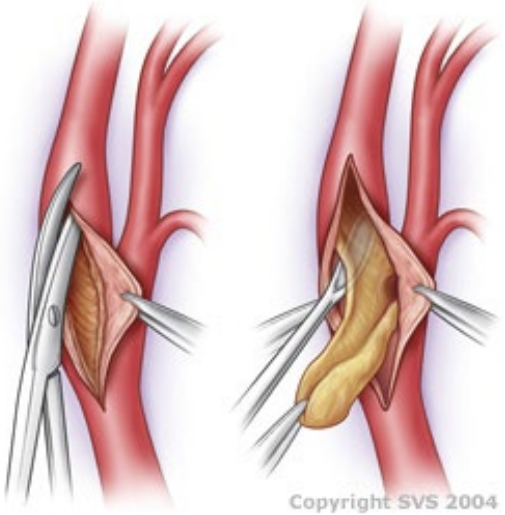
2021 *2022*

FDA Label Expansion of TCAR for **SSR Patients**

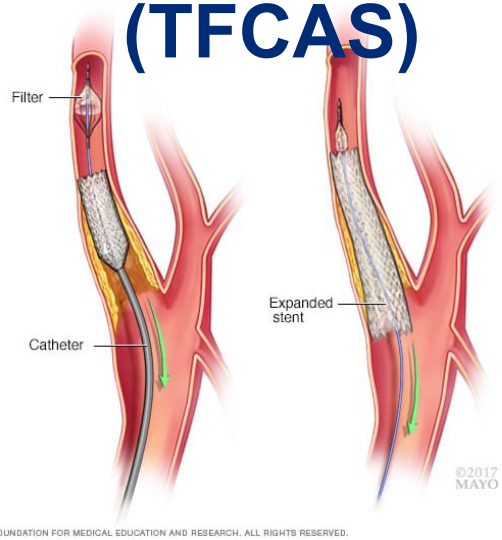
DeBakey ME. Successful carotid endarterectomy for cerebrovascular insufficiency. Nine-year follow-up. JAMA

Carotid Revascularization

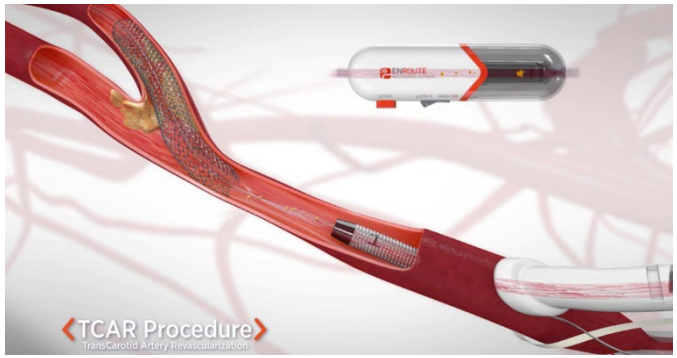
Carotid Endarterectomy (CEA)



Transfemoral Carotid Stenting (TFCAS)



TransCarotid Artery Revascularization (TCAR)



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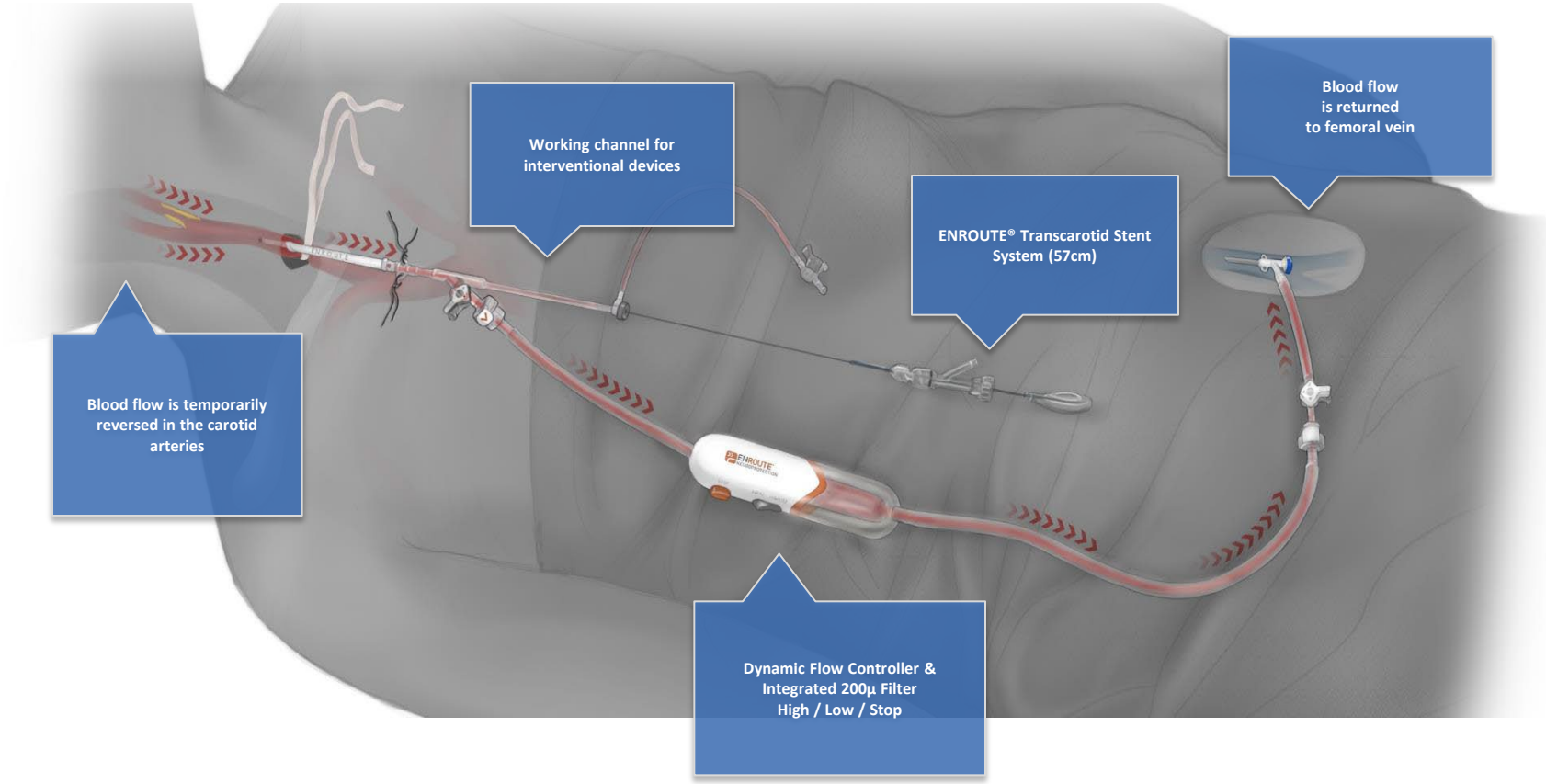
Proximal Protection with Flow Reversal



- Avoids the arch
- Proximal protection
- Protects prior to crossing
- Improved particle capture

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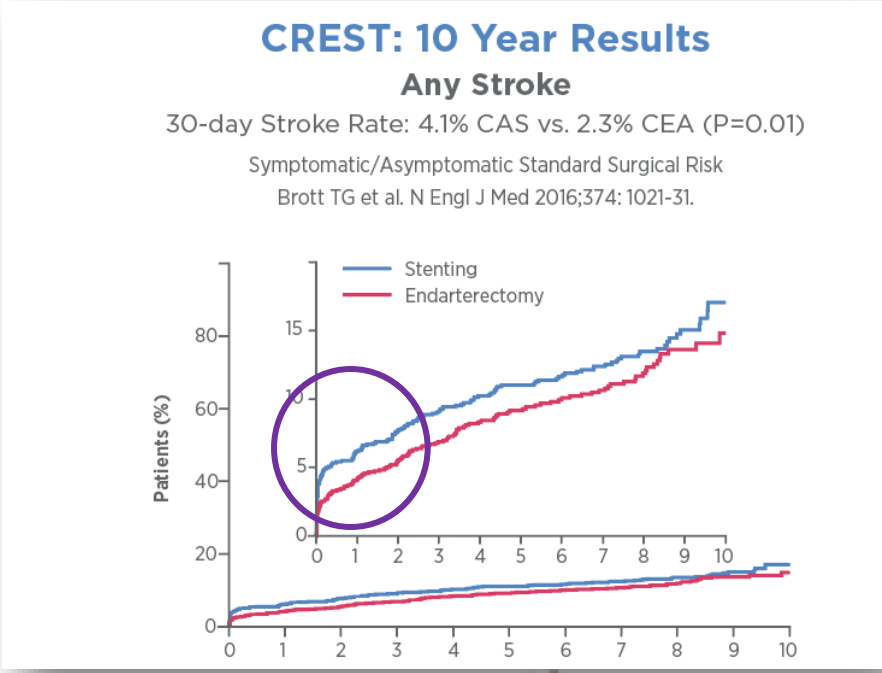
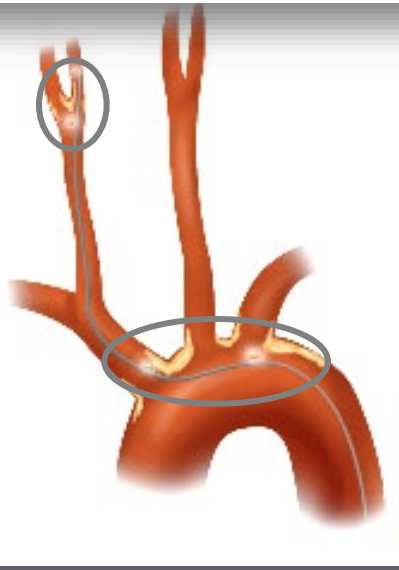
Why TCAR? Limitations of TF-CAS

- **Previous efforts to move to a less invasive procedure have not been successful**
- **TCAR is different**
  - **Avoids pitfalls experienced during TF-CAS**



Pitfalls of a TF approach

- Crossing the lesion
- Crossing the aortic arch



TCAR Outcomes

ROADSTER (N=208)

- Prospective, single arm, multi-center trial of TCAR Procedure
- High surgical risk patients
  - Symptomatic stenosis ≥50% stenosis
  - Asymptomatic stenosis ≥70% stenosis

30-day stroke (ITT) = 1.4%

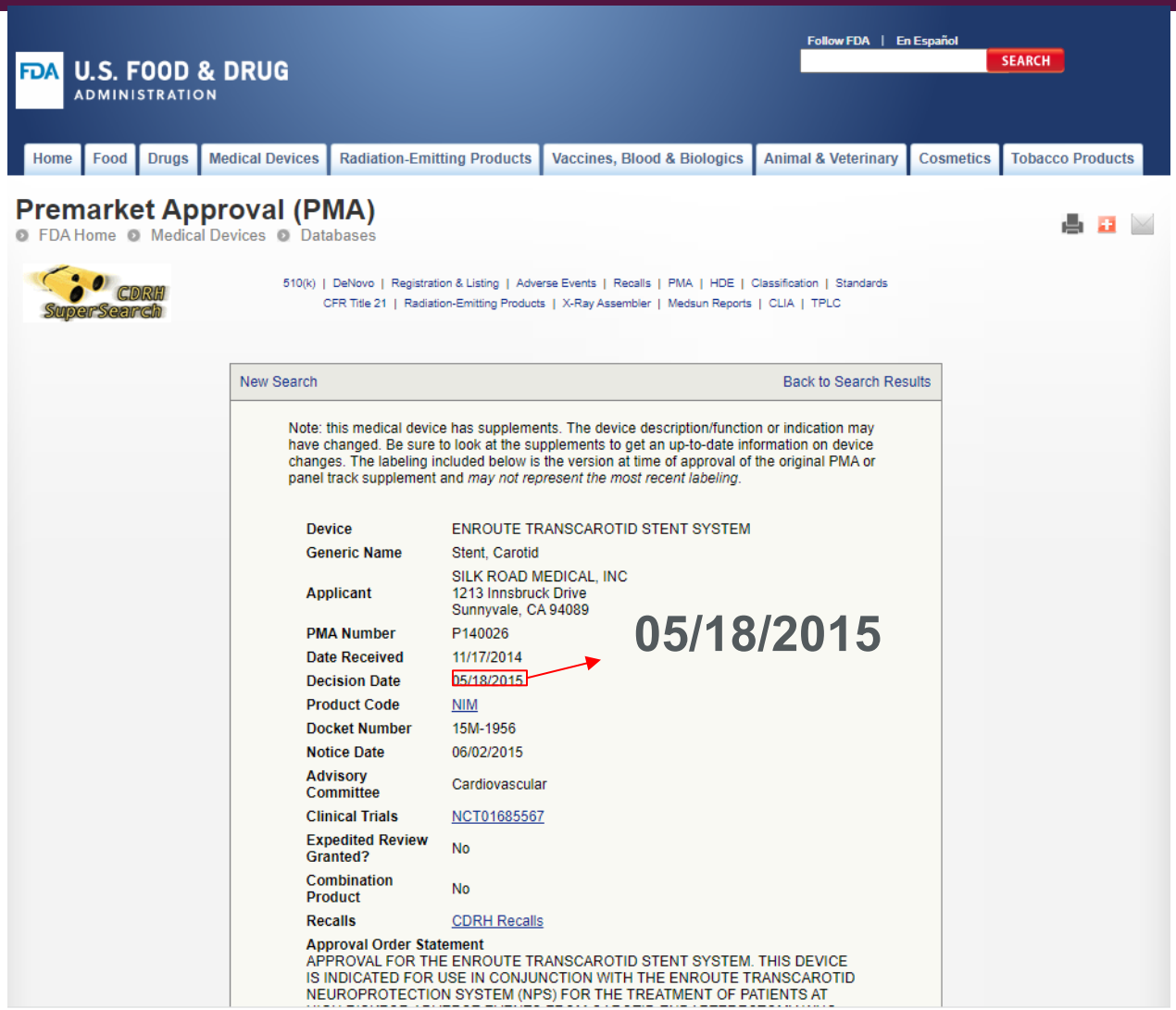
ROADSTER 2 (N=692)

- Prospective, open label, single arm, multicenter, post approval registry for patients undergoing TCAR
- High surgical risk patients
  - Symptomatic stenosis ≥50%
  - Asymptomatic stenosis ≥80%

30-day stroke (ITT) = 1.9%

Kwolek CJ et al. Vasc Surg. 2015 Nov;62(5):1227-34
Kashyap et al. Stroke. 2020 Sep;51(9):2620-2629.

TCAR: FDA Approval



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Note: this medical device has supplements. The device description/function or indication may have changed. Be sure to look at the supplements to get an up-to-date information on device changes. The labeling included below is the version at time of approval of the original PMA or panel track supplement and *may not represent the most recent labeling.*

Device	ENROUTE TRANSCAROTID STENT SYSTEM
Generic Name	Stent, Carotid
Applicant	SILK ROAD MEDICAL, INC 1213 Innsbruck Drive Sunnyvale, CA 94089
PMA Number	P140026
Date Received	11/17/2014
Decision Date	05/18/2015
Product Code	NIM
Docket Number	15M-1956
Notice Date	06/02/2015
Advisory Committee	Cardiovascular
Clinical Trials	NCT01685567
Expedited Review Granted?	No
Combination Product	No
Recalls	CDRH Recalls

Approval Order Statement

APPROVAL FOR THE ENROUTE TRANSCAROTID STENT SYSTEM. THIS DEVICE IS INDICATED FOR USE IN CONJUNCTION WITH THE ENROUTE TRANSCAROTID NEUROPROTECTION SYSTEM (NPS) FOR THE TREATMENT OF PATIENTS AT

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TCAR Surveillance Project

Ann Surg. 2022 Aug 1;276(2):398-403. doi: 10.1097/SLA.0000000000004496. Epub 2020 Sep 15.

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

Mahmoud B Malas [1], Hanaa Dakour-Aridi [1], Vikram S Kashyap [2], Jens Eldrup-Jorgensen [3], Grace J Wang [4], Raghu L Motaganahalli [5], Jack L Cronenwett [6], Marc L Schermerhorn [7]

- TCAR vs. CEA
- 2016-2019
- 53,869 patients
- Propensity matched

In-Hospital Outcome	CEA (N=6384)	TCAR (N=6384	RR (95% CI)
Stroke/death	1.6%	1.6%	1.01 (0.77–1.33)
Death	0.3%	0.4%	1.14 (0.64–2.02)
Ipsilateral stroke	1.0%	1.2%	1.21 (0.87–1.68)
Myocardial infarction	0.9%	0.5%	0.53 (0.35–0.83)
Stroke/death/MI	2.4%	2.0%	0.85 (0.67–1.07)
Cranial nerve injury	2.7%	0.4%	0.14 (0.08–0.23)

TCAR Surveillance Project

Ann Surg. 2022 Aug 1;276(2):398-403. doi: 10.1097/SLA.0000000000004496. Epub 2020 Sep 15.

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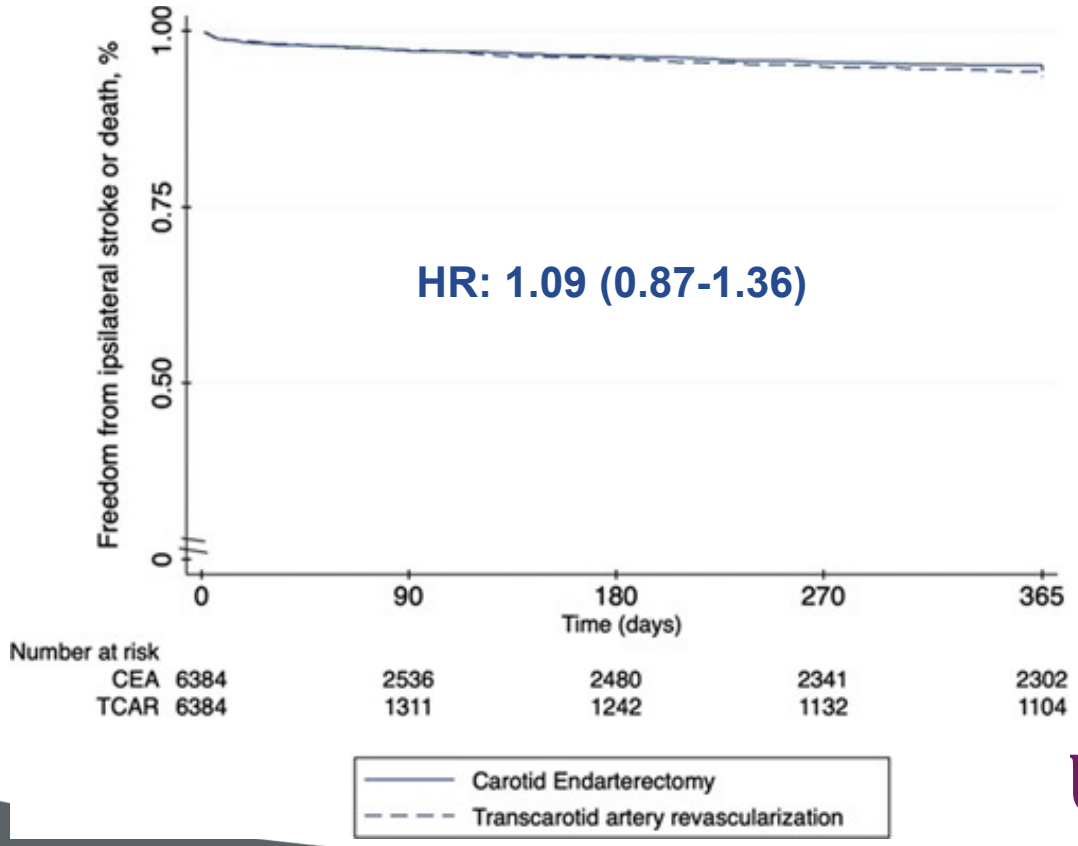

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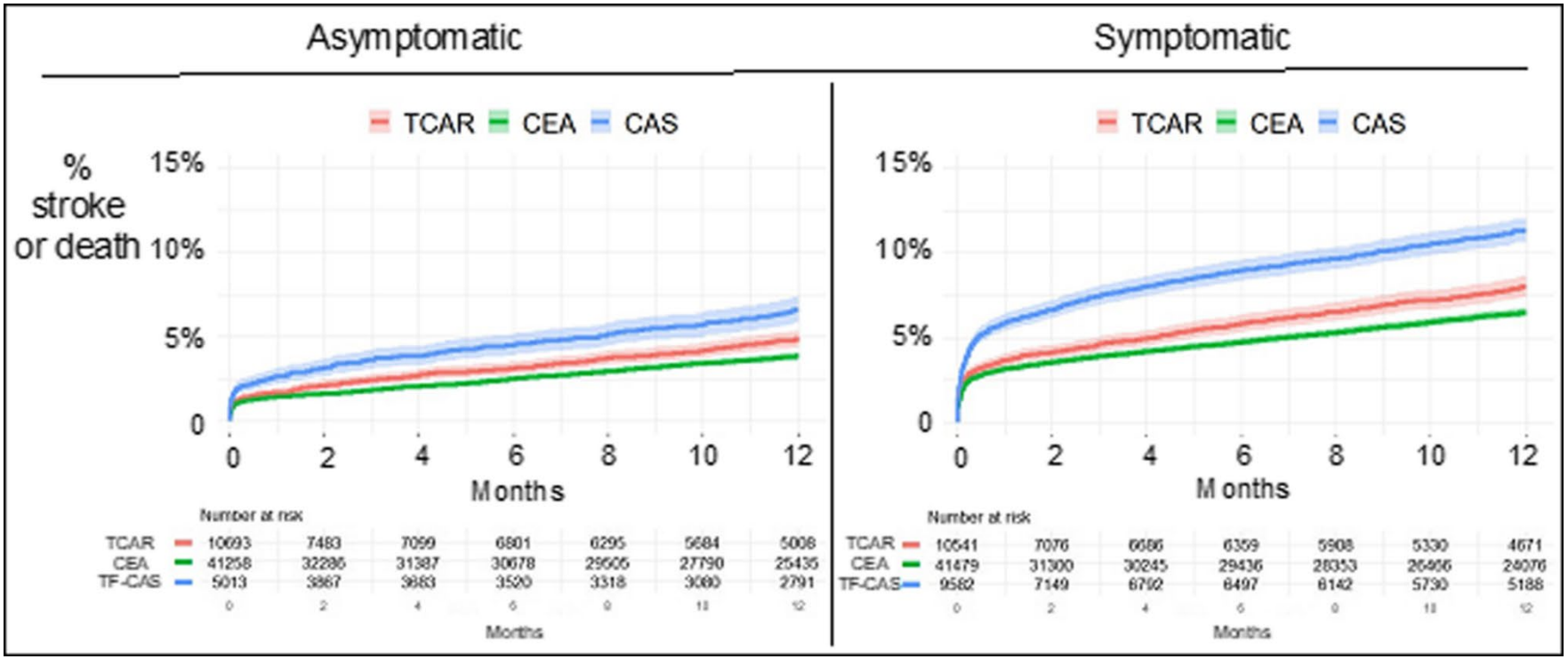
TCAR by Symptom Status



CEA vs. TCAR: HR 1.04 (0.77, 2.80)

CEA vs. TCAR: HR 1.30 (1.04, 1.64)

Columbo et al. J Am Heart Assoc. 2022 Oct;11(19):e024964.

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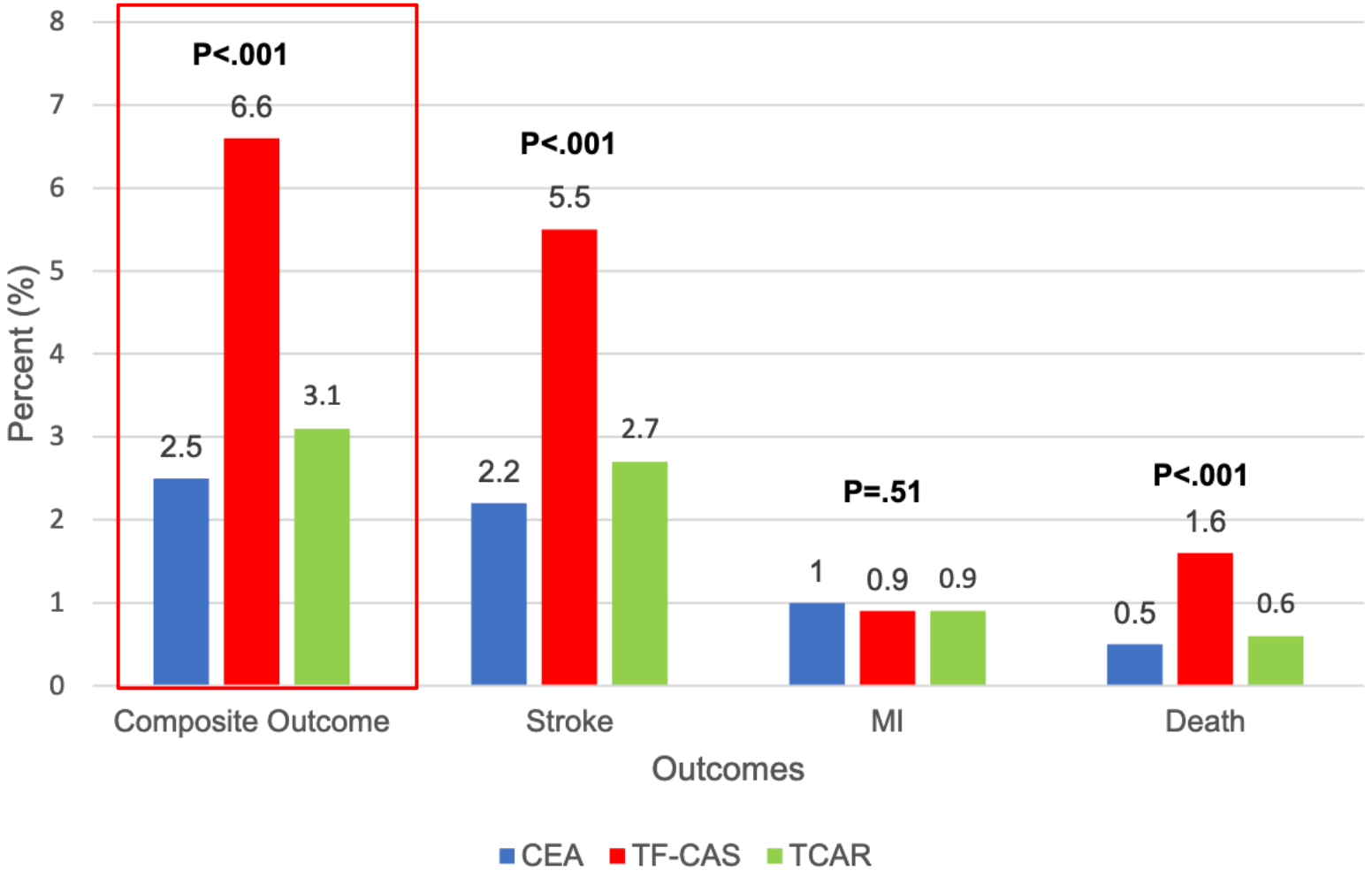
TCAR for Octogenarians



Kibrik et al., J Vasc Surg. 2022 Sep;76(3):769-777.e2.

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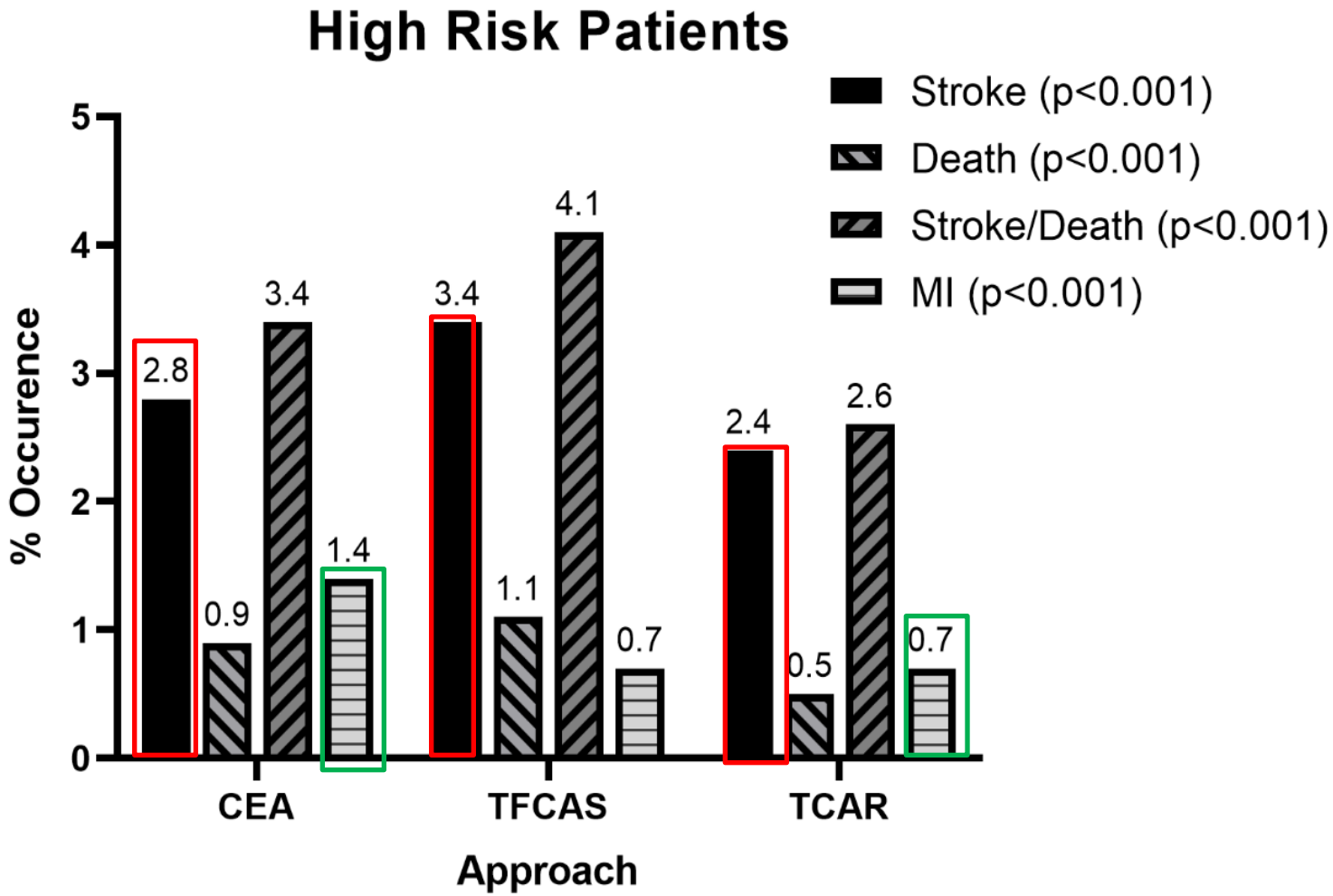
TCAR for High-Risk Patients



Zhang et al., J Vasc Surg. 2022 Aug;76(2):474-481.e3.

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TCAR for Standard Risk

- TCAR vs. CEA
- 2016-2019
- 38,025 patients
- Propensity matched

Table 3. Thirty-Day and 1-Year Outcomes After Transcarotid Artery Stenting or Carotid Endarterectomy Stenting in a Propensity Score–Matched Study Population Using Kaplan-Meier Estimates

	%				
	Transcarotid artery stenting	Carotid endarterectomy	Absolute difference, % (95% CI)	Relative risk (95% CI)	*P* value
30-d Stroke/death/MI and 1-y ipsilateral stroke[a]	3.0	2.6	0.40 (−0.43 to 1.24)	1.14 (0.87 to 1.50)	.34
30-d					
Stroke/death	1.8	1.5	0.34 (−0.18 to 0.90)	1.24 (0.90 to 1.71)	.21
Stroke	1.6	1.1	0.42 (−0.06 to 0.93)	1.38 (0.97 to 1.96)	.07
Death	0.3	0.4	−0.07 (−0.33 to 0.18)	0.84 (0.42 to 1.69)	.62
Stroke/death/MI[a]	2.2	2.1	0.15 (−0.48 to 0.74)	1.07 (0.81 to 1.42)	.63
1-y					
Ipsilateral stroke	1.6	1.1	0.52 (0.03 to 1.08)	1.49 (1.05 to 2.11)	.02
Death	2.6	2.5	0.13 (−0.18 to 0.33)	1.04 (0.78 to 1.39)	.67

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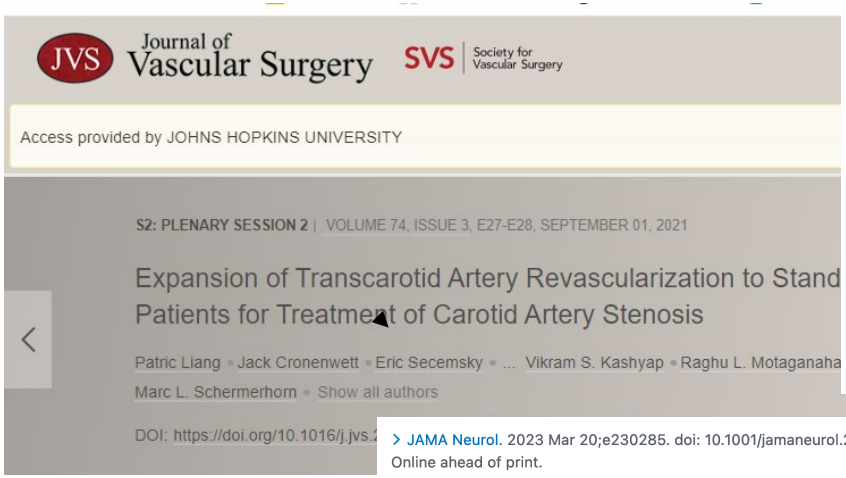
Liang et al., JAMA Neurol. 2023 Mar 20;e230285.

What About Standard Risk?



J Vasc Surg. 2022 Aug;76(2):474-481.e3. doi: 10.1016/j.jvs.2022.03.860. Epub 2022 Mar 31.

Transcarotid artery revascularization is associated with similar outcomes to carotid endarterectomy regardless of patient risk status

George Q Zhang [1], Sanuja Bose [2], David P Stonko [3], Christopher J Abularrage [4], Devin S Zarkowsky [5], Caitlin W Hicks [6]

Affiliations + expand

PMID: 35367564 PMCID: PMC9329175 (available on 2023-08-01) DOI: 10.1016/j.jvs.2022.03.860

JAMA Neurol. 2023 Mar 20;e230285. doi: 10.1001/jamaneurol.2023.0285. Online ahead of print.

Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk

Patric Liang [1], Jack L Cronenwett [2], Eric A Secemsky [3], Jens Eldrup-Jorgensen [4], Mahmoud B Malas [5], Grace J Wang [6], Brian W Nolan [4], Vikram S Kashyap [7], Raghu L Motaganahalli [8], Marc L Schermerhorn [1]

Affiliations + expand

PMID: 36939697 PMCID: PMC10028539 (available on 2024-03-20)
DOI: 10.1001/jamaneurol.2023.0285

SILKROAD MEDICAL

May, 2022

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

SUNNYVALE, Calif. – May 2, 2022 – Silk Road Medical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced that that the U.S. Food and Drug Administration (FDA) approved expanded indications for the ENROUTE stent to include patients at standard risk for adverse events from carotid endarterectomy (CEA). Previously, the stent was approved for use only in patients with anatomic or physiological criteria that put them at high risk of complications from more invasive surgical procedures.

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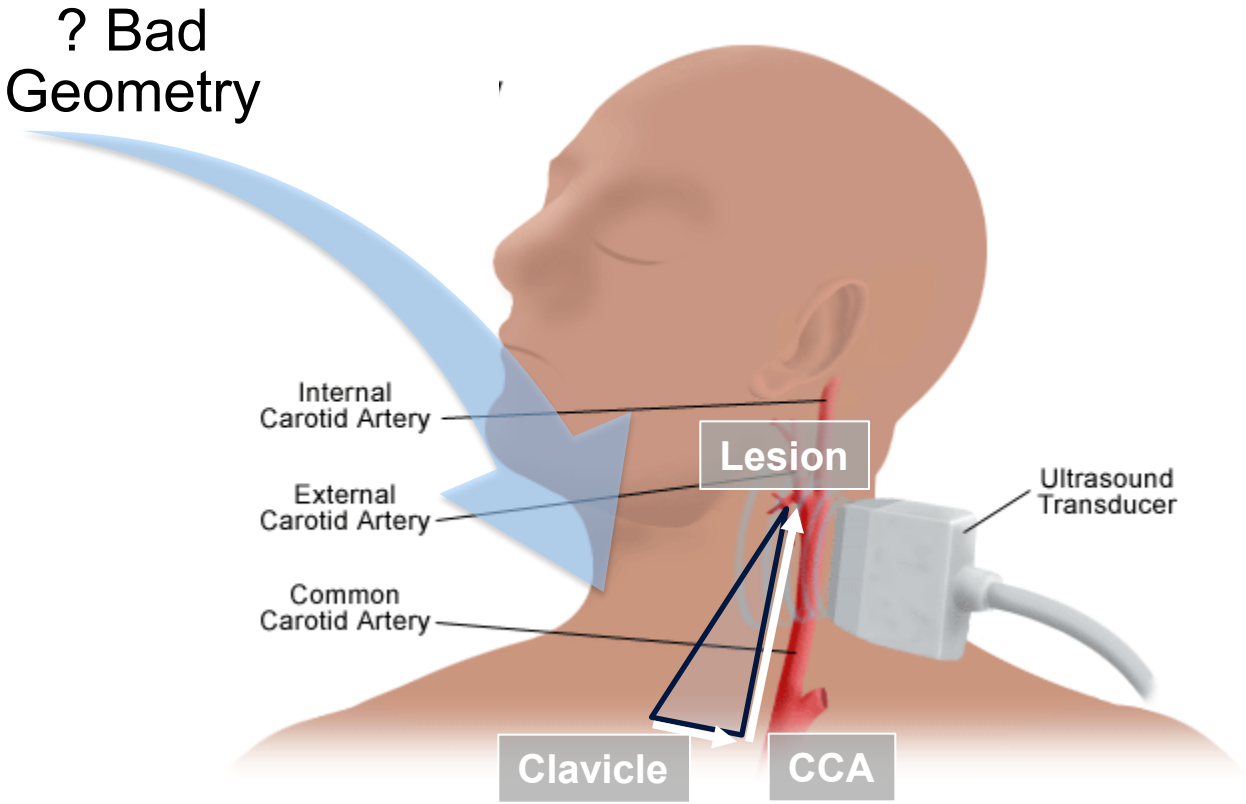
Limitations

- Anatomic requirements
  - >5cm = Working distance from clavicle to bifurcation (“access to lesion”)
  - Circumferential calcium or fresh thrombus contraindicated
- Close oversight of cases by industry → ? long term
- Limited data
  - Roadster 1, 2, 3 data & VQI-TSP
  - No RCT

Geometry



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Getting the CCA Out

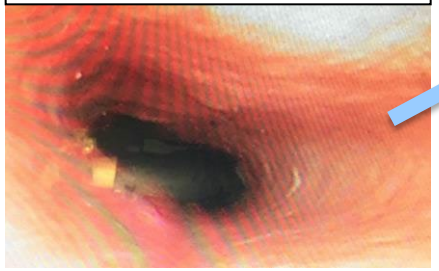
- Transverse or longitudinal incision between SCM heads immediately above clavicle
- Ultrasound to mark center
- Dissect caudal to get umbilical tape as low as possible
  - PTX risk

Carotid Dissection

Occurs in 1.4 – 5.7% of cases (Teter JVS 2021, Kwolek JVS 2015

Invagination – dull needle

Artery ovalized by vessel loop



Posterior wall nicked by micropuncture needle
½ of bevel in posterior wall

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Rescue Technique

- Maintain flow reversal if possible
- Wire and microcatheter into true-lumen
- Re-puncture
- Consider transfemoral and surgical bail-outs

Soft Plaque

- CT and duplex to evaluate plaque makeup
- Aggressive target-sized pre-dilation under flow reversal
- No post-dilation, deliberate reversal

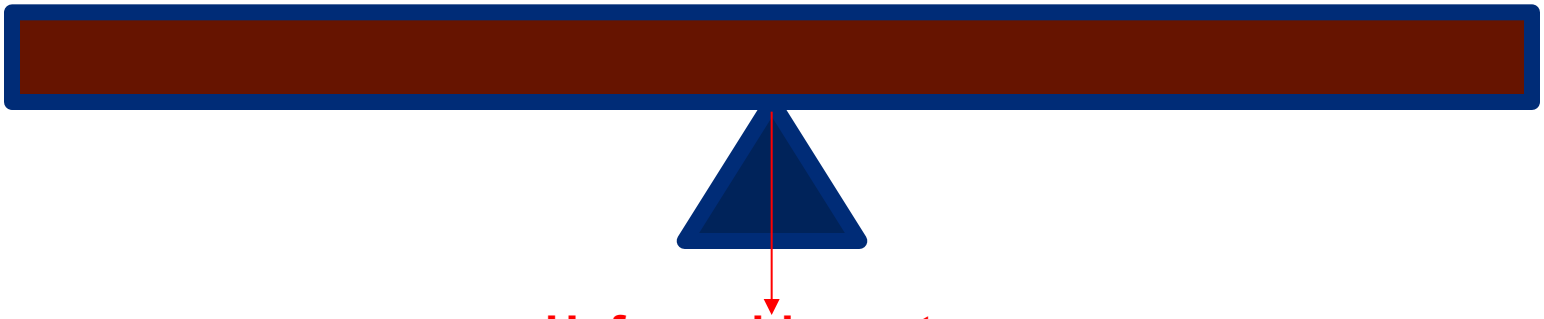
TCAR vs. CEA in Practice

Clear advantage CEA

- Low bifurcation (CCA <5cm)
- Significant CCA disease
- Lesions with prohibitive calcium
- ICA diameter >9mm or <4mm
- Liquid thrombus

Clear advantage TCAR

- High bifurcation
- Hostile neck (radiation, immobility)
- Reoperative site (CEA restenosis)
- Significant ICA tortuosity
- Circumferential calcification



Unfavorable anatomy

TF-CAS

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Conclusions

- TCAR > TFCAS
- TCAR = CEA for short term outcomes
  - TCAR ?> CEA for high-risk & symptomatic patients
  - VQI data suggests at least equivalency in both high and standard risk outcomes
- Longer term outcomes (and ideally an RCT) for CEA vs. TCAR needed

SAVE THE DATE

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THANK YOU

chaerra@upmc.edu