2022 MID-ATLANTIC CONFERENCE

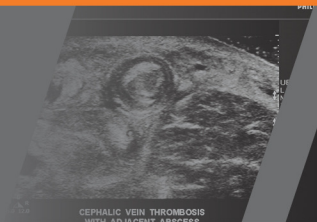
10th ANNUAL CURRENT CONCEPTS IN

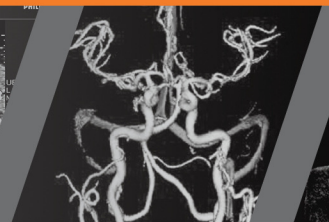
VASCULAR THERAPIES

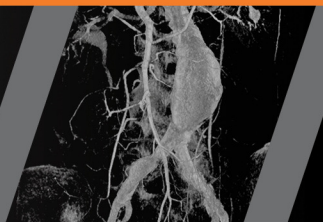
2022

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 28-30







Sentara Vascular Specialists

2022 MID-ATLANTIC CONFERENCE

10th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2022

TCAR 2022

THE END OF CEA?

Rasesh M. Shah, MD, FACS

Sentara Vascular Specialists

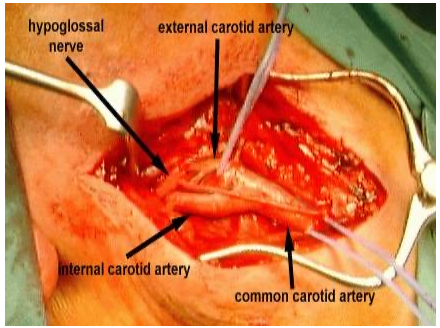
Carotid Disease & Stroke

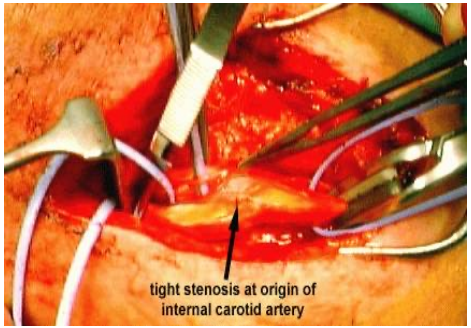
- 85% ischemic
- Most common source: extracranial carotid artery – especially carotid bulb
  - Embolic - plaque morphology; intraplaque hemorrhage and rupture
  - Thrombotic – cardiac embolus, in-situ thrombosis of critical stenosis
- Prevalence in US pop (>18) 2.7% and will increase to 3.9% by 2030

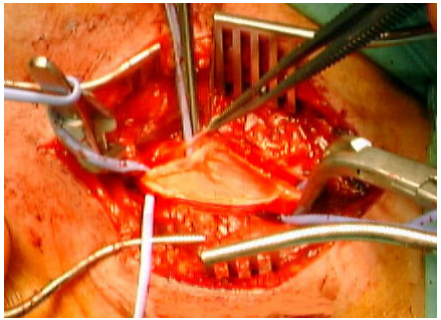
Best Medical Therapy

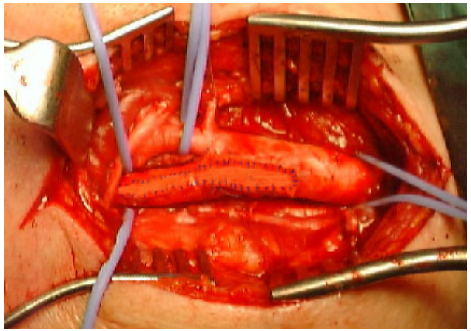
- STOP SMOKING
- Anti platelet
- Statin
- Hypertensive control
- Diabetes control
- Healthy diet / weight loss / exercise

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









Challenges of Surgical Intervention

- Scarring
- Lengthy hospital stay
- Open surgical procedure leads to quality of life issues for patients
- Risks of general anesthesia
- Inappropriate for patients at high-risk for surgery due to medical co-morbidities and/or anatomical considerations

TransFemoral Carotid Artery Stenting

Trials

- SAPPHIRE
- ARCHeR
- BEACH
- CABERNET
- CREST
- MAVErIC
- SECURITY
- CARESS
- CAPTURE
- PASCAL
- TACIT
- CAVATAS
- VIVA

- MOMA
- SPACE CANOPY
- EVA-3S SCAFFOLD
- CREATE
- CASES
- EXACT CONFIDENCE
- ACT-1
- EMPIRE
- EPIC EU
- SAPPHIRE WW
- SONOMA
- CHOICES
- PROTECT

Tf-CAS

Selective Lt Carotid Angio

Long Lt ICA ulcerated lesion
(>80% stenosis)

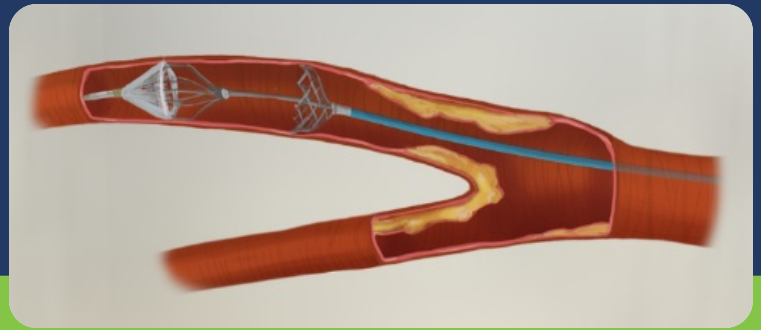
Tf-CAS

Completion Angiogram

Free flow into the ICA

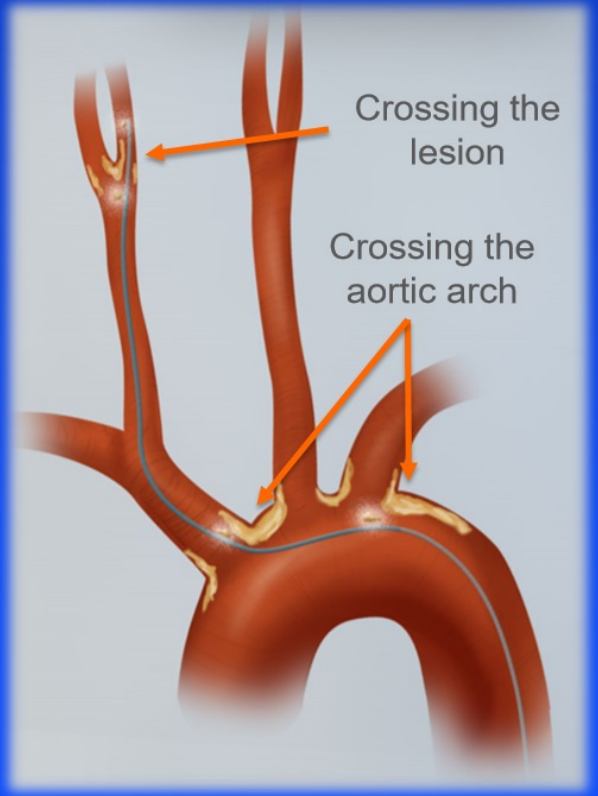
Current Treatments for Carotid Disease

- Less Invasive Alternative: **Carotid Artery Stenting, transfemoral approach**
- Patient friendly, durable[1], but…
- Excess procedural stroke risk[1]
- Procedure itself can create thrombo-embolism



- [1]CREST Trial: N Engl J Med 2010;363:11-23

The devastating Complication of a procedure intended to *prevent* stroke is… *Stroke*



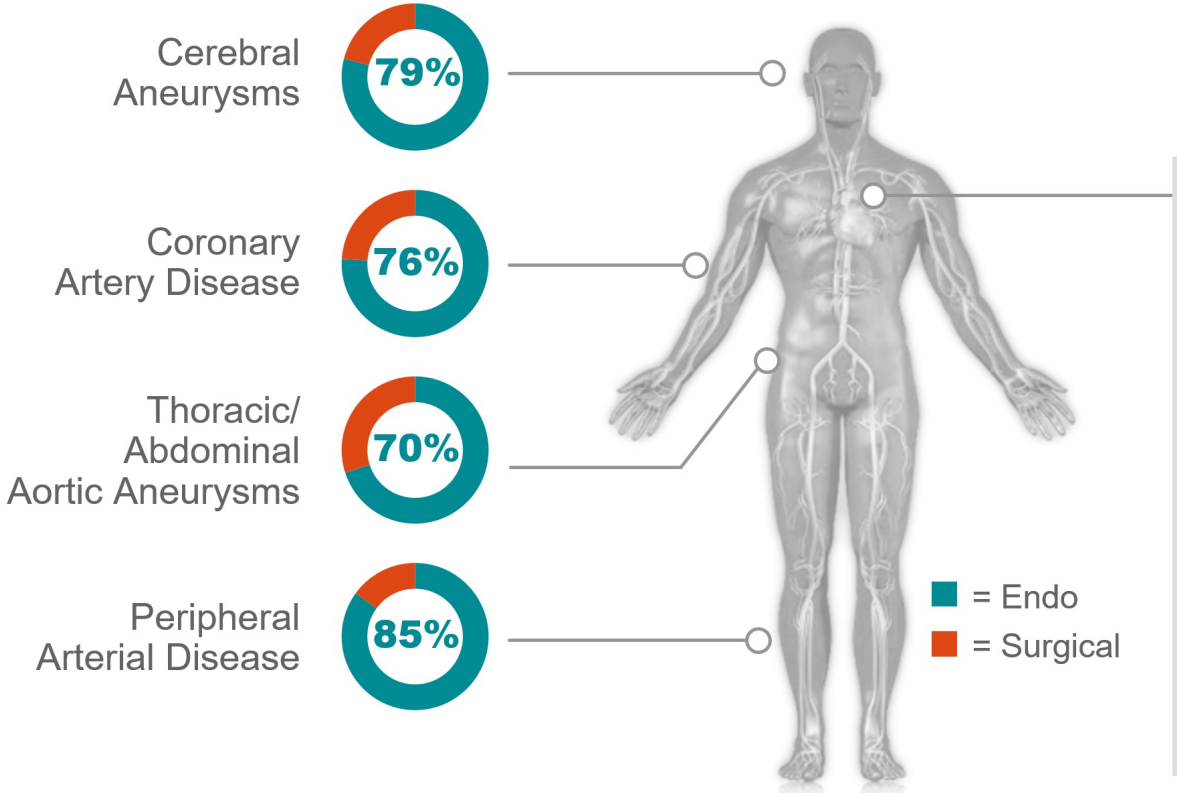
- Transfemoral CAS requires 3 steps that create embolic risk
  1. Advancing catheters through the aortic arch
     - 18% Non-Ipsilateral stroke rate in CAPTURE Study[1]

Diseased Aortic Arch

  2. Navigating the lesion before neuroprotection established
  3. Inadequate neuroprotection from misaligned filters and inadequate manual aspiration of emboli

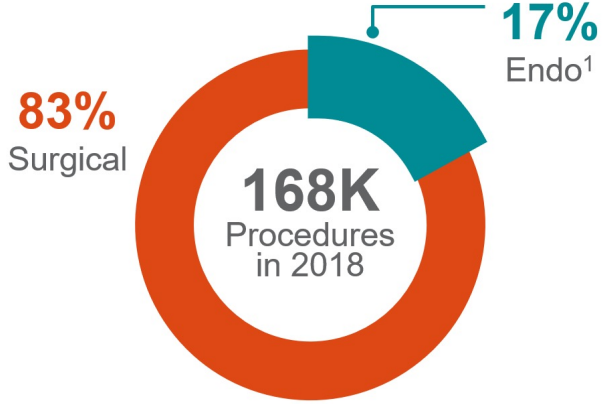
[1] Ann Surg 2007;245: 551–558.

Endovascular Treatment: “New Normal”



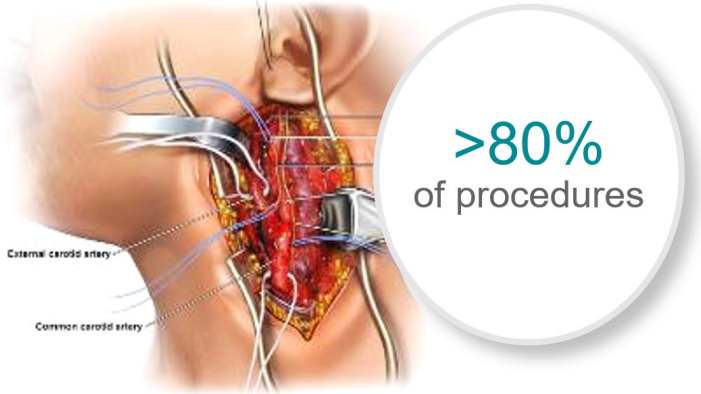
THE LAST FRONTIER:
Open to Endo Conversion

Carotid Artery Disease: U.S.



CEA: The “Gold Standard”

SURGICAL:
Carotid Endarterectomy (CEA)
65+ years



>80%
of procedures

LOW 30-day stroke risk

SIGNIFICANT adverse events

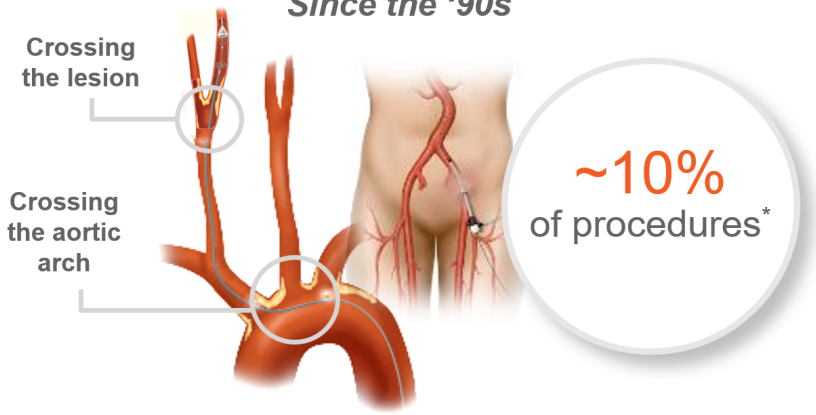
MI[1]: 2.3% CEA vs 1.1% TF-CAS

CNI[2]: 2.1% unresolved at 6 months

Is there a better alternative?

TF-CAS: The Suboptimal Alternative

ENDOVASCULAR:
Transfemoral Carotid Artery Stenting (TF-CAS)
Since the '90s



LOWER adverse events

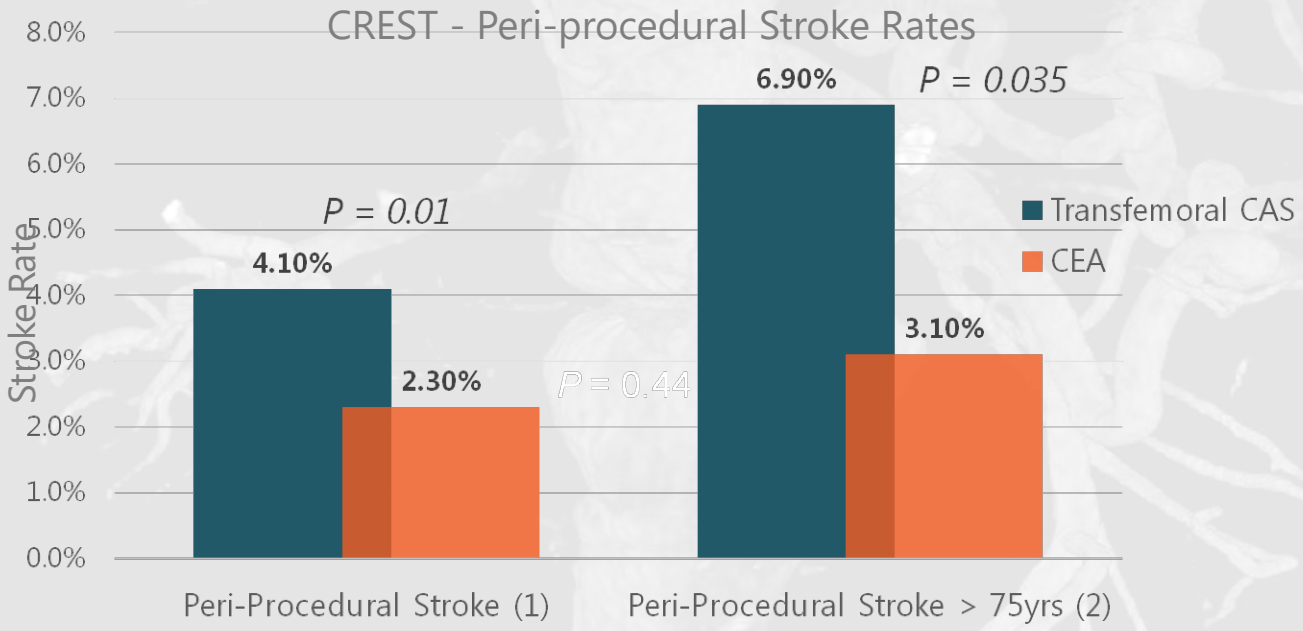
HIGHER (~2x) 30-day stroke risk

Stroke[1]: 4.1% TF-CAS vs 2.3% CEA

DW-MRI[2]: 87% new lesions w/distal embolic protection

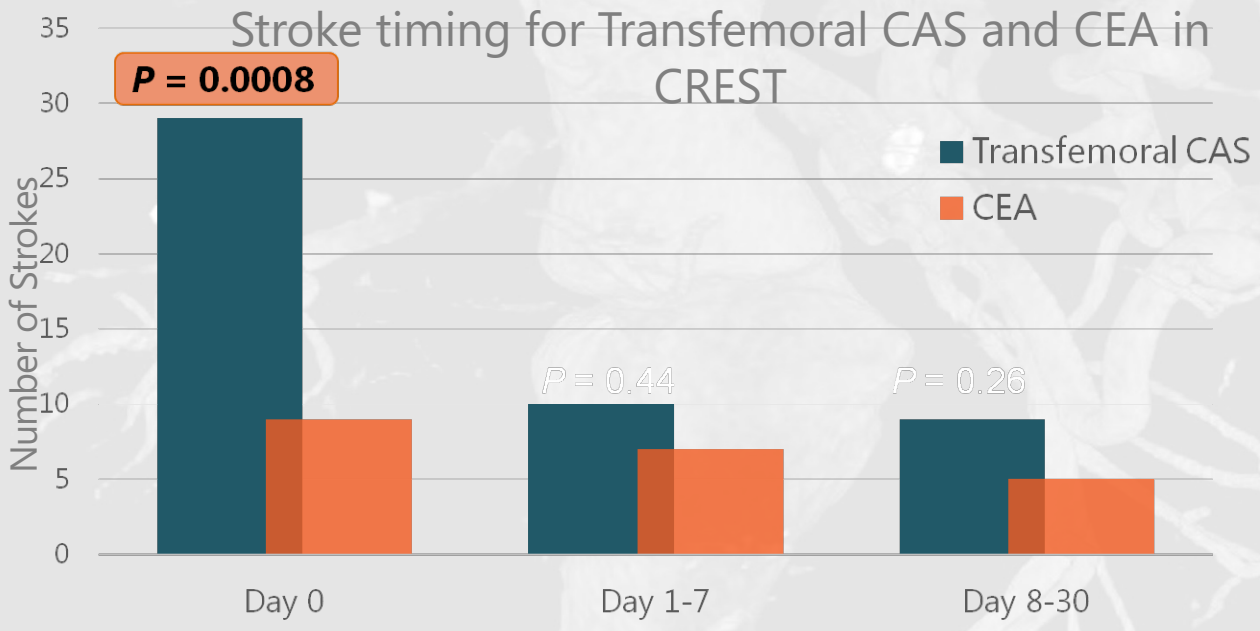
Is this a "niche procedure"?

2x Peri-Procedural Stroke rate for Transfemoral CAS



1. N Engl J Med. 2010;363:11-23
2. Stroke. 2011;42:00-00.

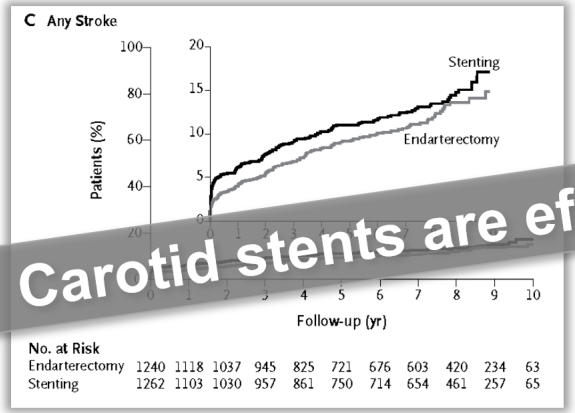
Day 0 Stroke is the Culprit



[1]Circulation. Nov 29, 2012. P-value calculated post hoc by independent statistician

Challenge: “Delivery”, Not “Performance/Durability”

Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis



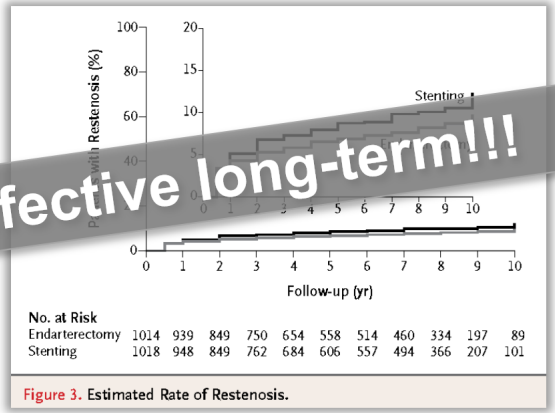
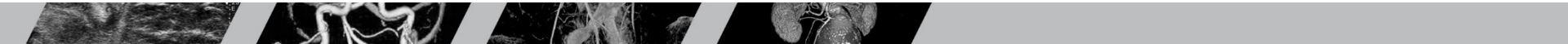


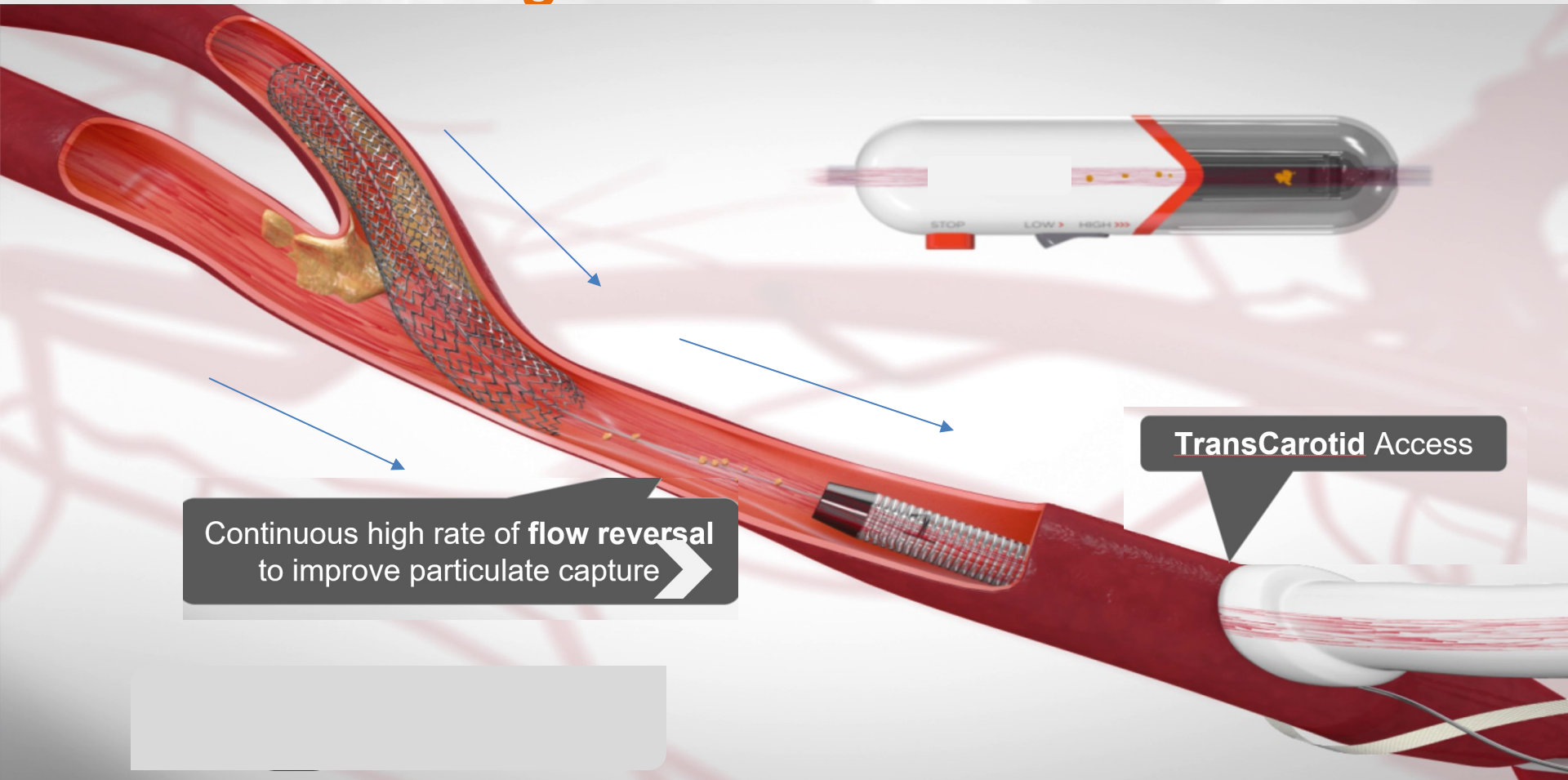
Figure 3. Estimated Rate of Restenosis.

Carotid stents are effective long-term!!!

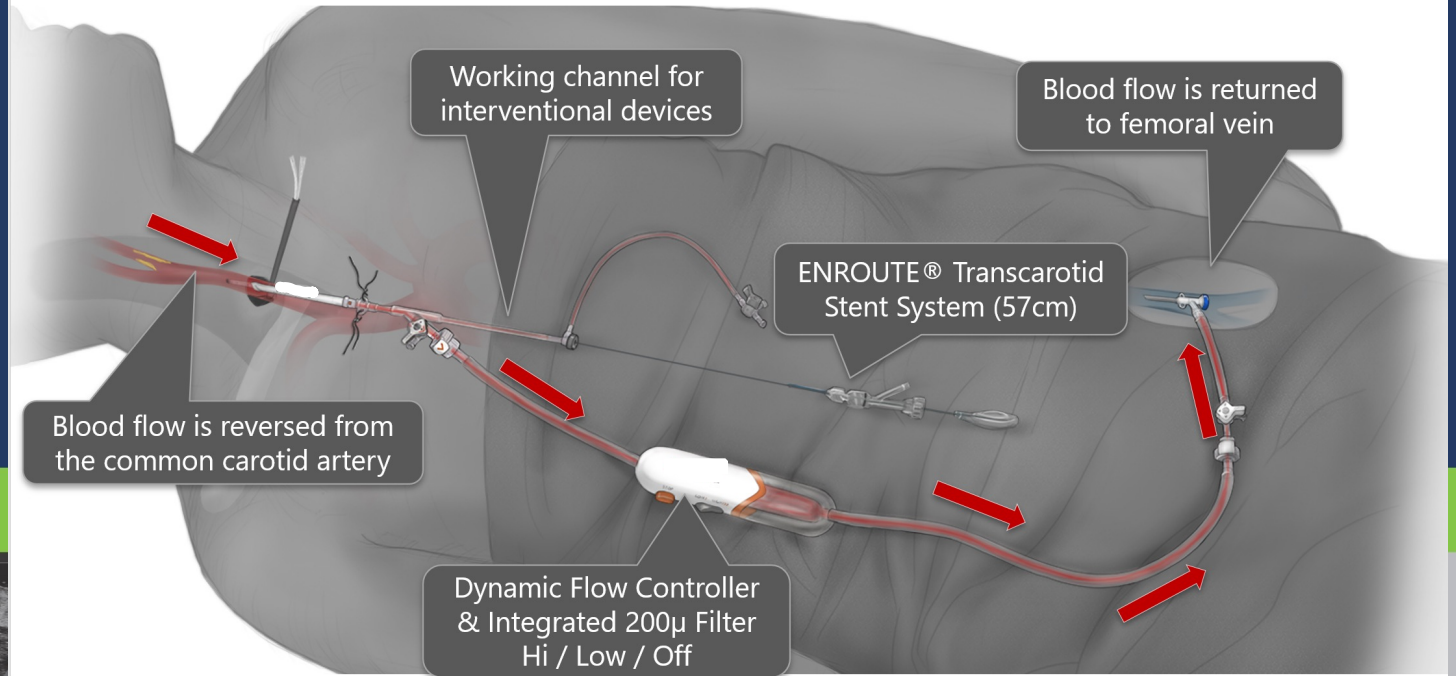
CREST (10 years data): **NO** difference in postprocedural **ipsilateral stroke** or **restenosis**



New Paradigm: TransCarotid and Flow Reversal



TCAR: TRANSCAROTID ARTERY REVASCULARIZATION

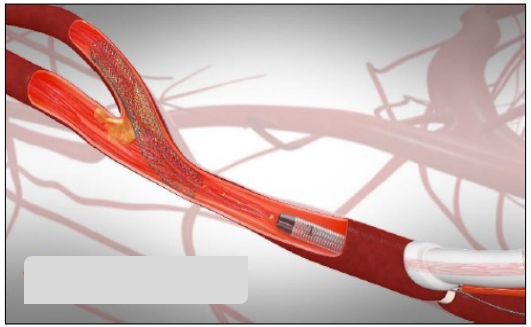


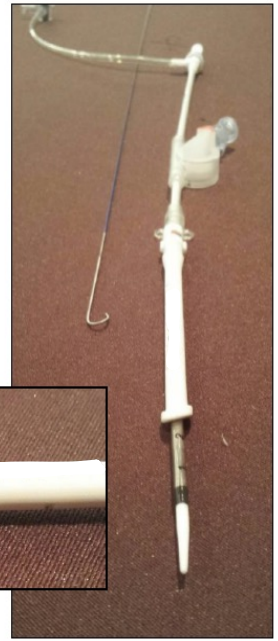
Transcervical Carotid Artery Revascularization

TCAR

Advantages of TCAR Procedure:

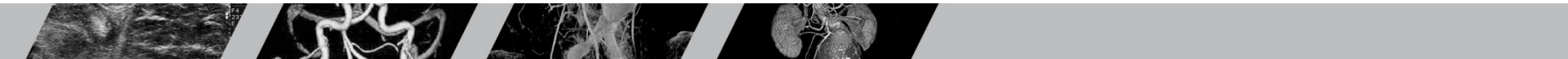
- Establish embolic protection before lesion crossing (proximal protection)
- Flow reversal ("surgical" back-bleeding)
- Avoiding the aortic arch





DW-MRI “Hits” Similar to CEA

Study	Procedure	Embolic Protection	Patients	New Ipsilateral DWI Lesions
ICSS[2]	CEA	Clamp, backbleed	107	17%
PROOF[3]	TCAR	Proximal clamp, reversed flow	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%



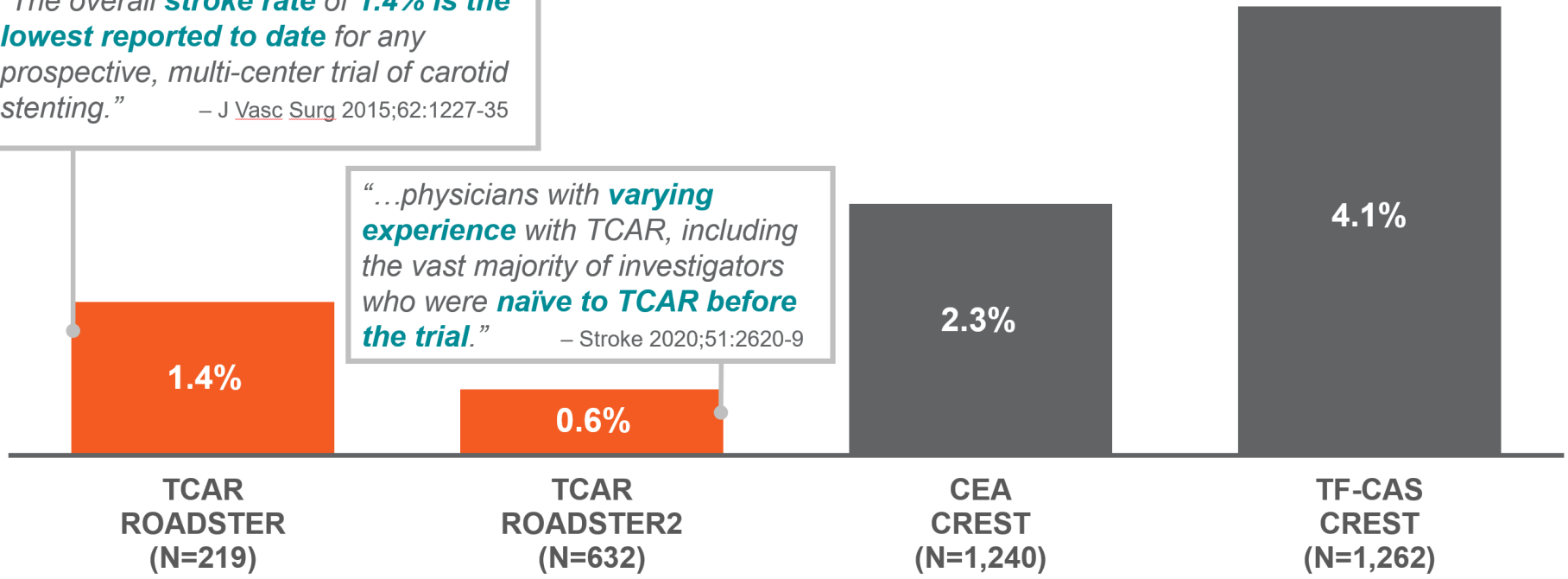
Should All Patients Be Treated with TCAR?

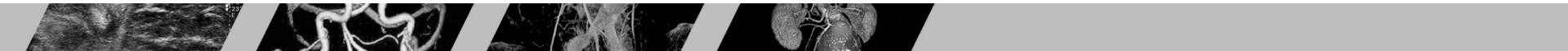
Excellent Clinical Trial Data

ROADSTER(2) - High Surgical Risk Patients | **CREST -** Standard Surgical Risk Patients

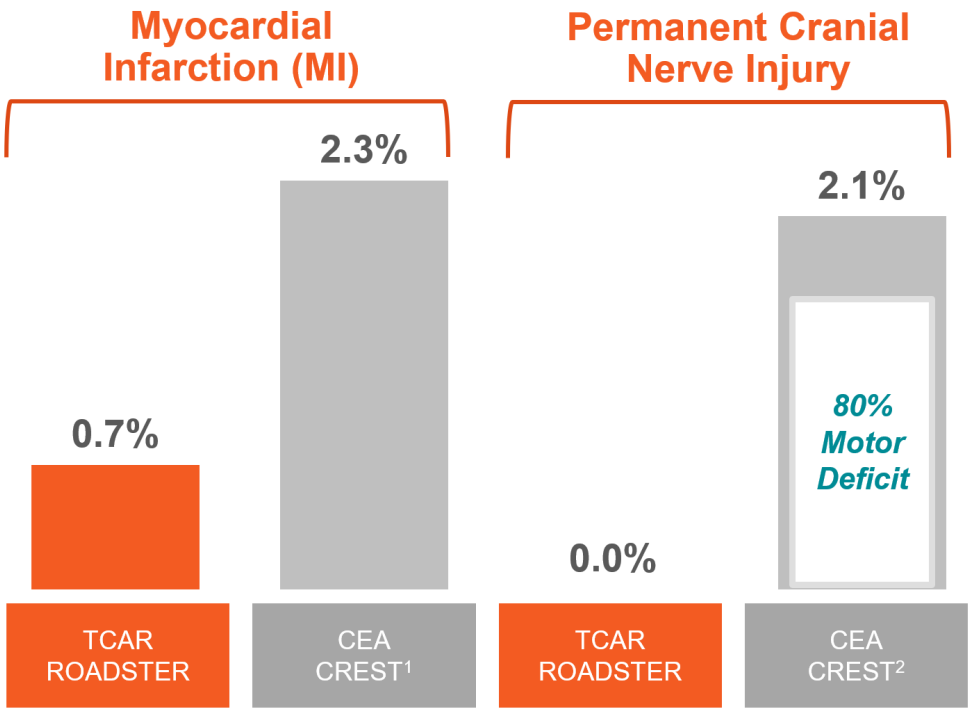
*"The overall **stroke rate** of **1.4% is the lowest reported to date** for any prospective, multi-center trial of carotid stenting."* – J Vasc Surg 2015;62:1227-35

*"…physicians with **varying experience** with TCAR, including the vast majority of investigators who were **naïve to TCAR before the trial**."* – Stroke 2020;51:2620-9



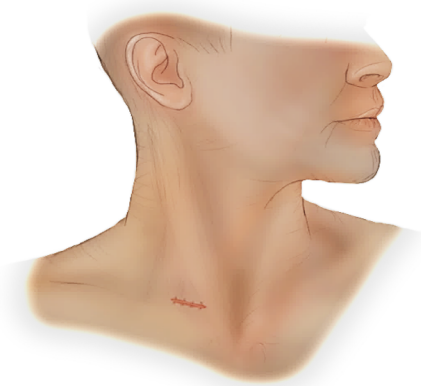


TCAR: Powerful Reduction In Surgical Morbidity



ROADSTER[1] - High surgical risk

CREST[2] - Standard surgical risk



- Patient satisfaction w/less invasive
- Shorter procedure duration
- Favorable for local anesthesia
- More likely for next day discharge

TCAR: Easy to Learn

Learning Curve for Surgeons Adopting Transcarotid Artery Revascularization Based on the Vascular Quality Initiative-Transcarotid Artery Revascularization Surveillance Project

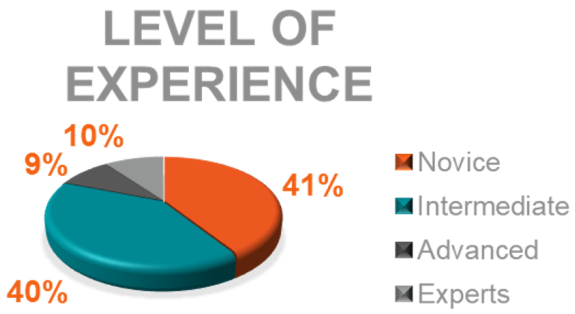
Check for updates

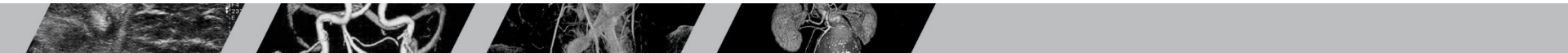
(J Am Coll Surg 2020;230:113–120.

Reproducibility Regardless of Experience Level

Experience Level (cases)
Novice (1-5)
Intermediate (6-20)
Advanced (20-30)
Experts (30+)

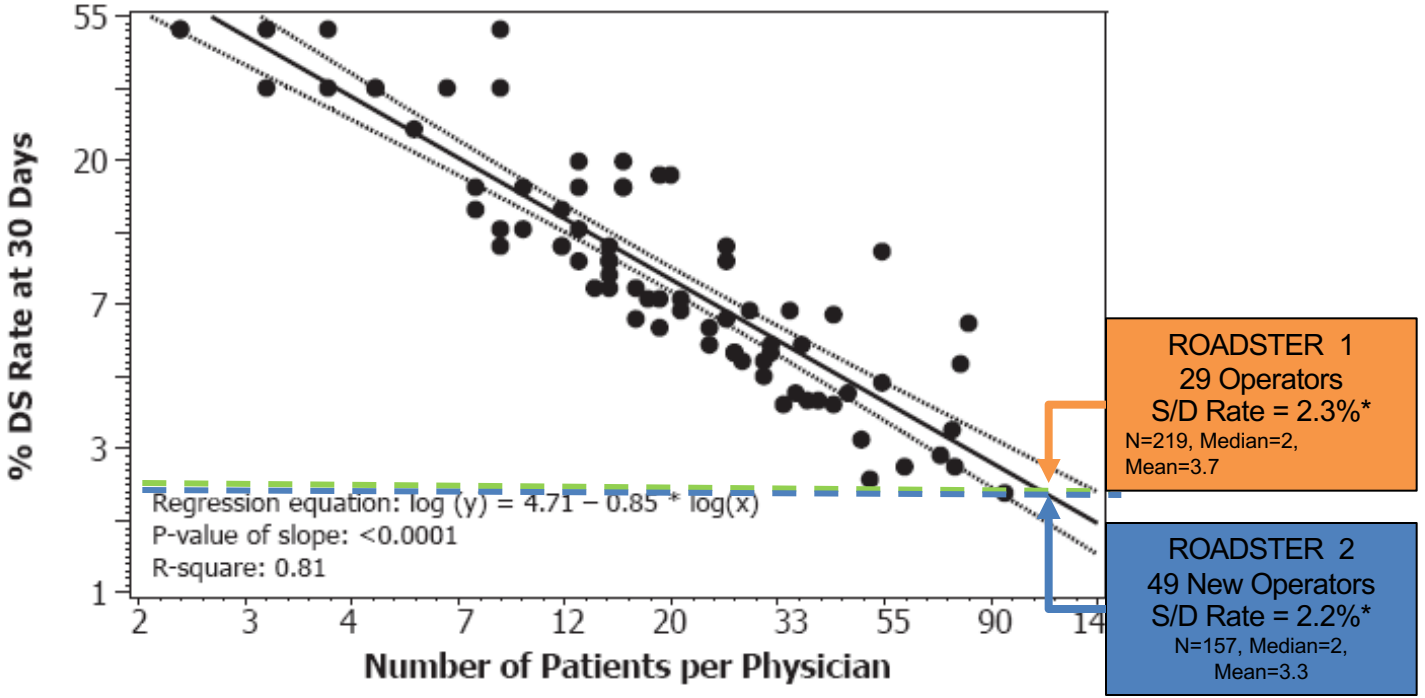
	Statistically Equivalent
Stroke	✓
S/D	✓
S/D/MI	✓
MI	✓
CNI	✓





CEA-like outcomes with shorter learning curve than transfemoral-distal filter CAS

Gray WA et al. CAPTURE 2 Registry. JACC Cardiovasc Interv 2011;4:235-246



*Includes patients with Major Protocol Deviations

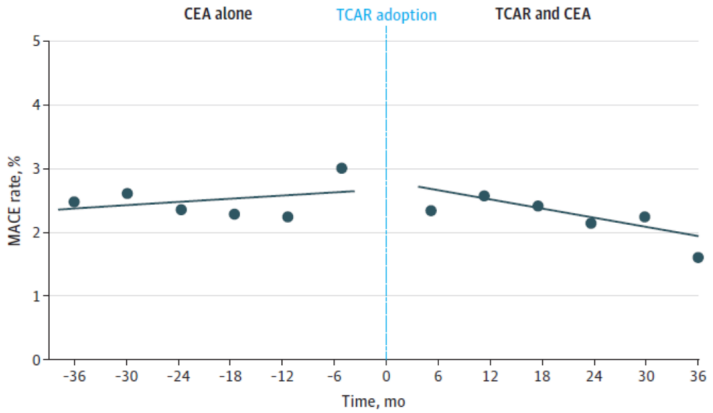
The Benefits of TCAR in Your Practice

Original Investigation | Surgery

JAMA Network Open. 2021;4(2):e2037885. doi:10.1001/jamanetworkopen.2020.37885

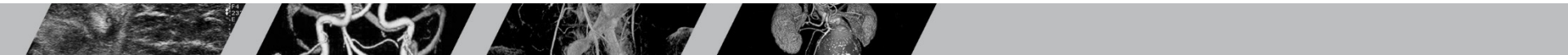
Association of Adoption of Transcarotid Artery Revascularization With Center-Level Perioperative Outcomes

Figure 2. Rate of Perioperative Major Adverse Cardiovascular Events (MACE)



Availability of TCAR associated with **10% decrease in MACE at 12 months** after all carotid revascularization

- Allowed proceduralist to align patients with procedure best suited to them
- Improvement across ALL patients undergoing carotid revascularization



WHO IS A CANDIDATE FOR TCAR?

- **Anatomical Requirements (per IFU)**
  - **≥5cm** = Working distance from clavicle to bifurcation (**"access to lesion"**)
  - **≥6mm** = CCA reference diameter
  - CCA free of significant disease for safe sheath insertion and vessel occlusion
  - AND: lesion amenable to stent placement

Anatomic eligibility for transcarotid artery revascularization and transfemoral carotid artery stenting (J Vasc Surg 2019;69:1452-60.)

Anatomic criteria in the selection of treatment modality for atherosclerotic carotid artery disease (J Vasc Surg 2020;72:1395-404.)

~70-85% are anatomically "optimal" for TCAR

WHO IS ELIGIBLE FOR REIMBURSEMENT?

- **National Coverage Decision (NCD) for Carotid Stenting**
  - Since 2005: Symptomatic, **high risk** for CEA, >70% stenosis
  - TCAR Surveillance Project (VQI)
    - Asymptomatic, **high risk**, >80% stenosis
    - Symptomatic, **high risk**, >50% stenosis
    - Inpatient (overnight); use of “transcarotid-labeled stent”
    - Modified Rankin Scale <3

2 out of 3 qualifies as “high risk” for CEA

"HIGH RISK" CRITERIA FOR REIMBURSEMENT

*Any **ONE** risk factor qualifies patient for CMS high surgical risk status*

PHYSIOLOGIC HIGH RISK

- **Age ≥75**
- **Congestive Heart Failure**
- **Left Ventricular Ejection Fraction ≤35%**
- **≥2 diseased coronaries with ≥70% stenosis**
- **Unstable angina**
- **Myocardial infarction within 6 weeks**
- **Abnormal stress test**
- **Need for open heart surgery**
- **Need for major surgery (including vascular)**
- **Uncontrolled diabetes**
- **Severe pulmonary disease**

ANATOMIC HIGH RISK

- **Prior head/neck surgery or irradiation**
- **Restenosis post CEA**
- **Surgically inaccessible lesion**
- **Spinal immobility**
- **Laryngeal palsy; Laryngectomy**
- **Permanent contralateral cranial nerve injury**
- **Contralateral occlusion**
- **Severe tandem lesions**
- **Bilateral stenosis requiring treatment**

Above list is a compendium of all risk factors across all carotid stent and EPD IDE trials.

"Among patients undergoing treatment for carotid stenosis, transcarotid artery revascularization, compared with transfemoral carotid artery stenting, was significantly associated with a lower risk of stroke or death."

JAMA. 2019 Dec 17;322(23):2313-2322

TCAR Vs. TF-CAS Results*

The investigators found a significant decrease in stroke and death for patients who underwent TCAR as well as procedural efficiencies such as less radiation and less contrast. The investigators also found a significant decrease in stroke or death at one year.

In-Hospital Stroke or Death

TCAR 1.6%

TF-CAS 3.1%

p < .001

Stroke

TCAR 1.3%

TF-CAS 2.4%

p = .001

Death

TCAR 0.4%

TF-CAS 1.0%

p = .008

Outcomes from the VQI-TSP Database published in 2020*

The updated VQI data continues to validate and strengthen TCAR's clinical story as a safe, less invasive option to CEA and will continue to drive adoption of TCAR towards the standard of care.

The VQI data also continues to point to the additional "non-stroke" related benefits of TCAR such as lower rates of MI, CNI and reduced procedure time.

	TCAR (n=6384)		CEA (n=6384)
Stroke	**1.4%**	P=0.881	1.4%
Death	0.4%	P=0.662	0.3%
MI	0.5%	P=0.005	0.9%
Stroke/Death	1.6%	P=0.945	1.6%
Stroke/Death/MI	2.0%	P=0.172	2.4%
Ipsilateral Stroke	1.2%	P=0.247	1.4%

TCAR is associated with a shorter LOS (≤1 day) vs. CEA

p < .001

Length of Stay

TCAR **0.4%** | CEA **2.7%**

p < .001

CNI

TCAR **0.5%** | CEA **0.9%**

p < .005

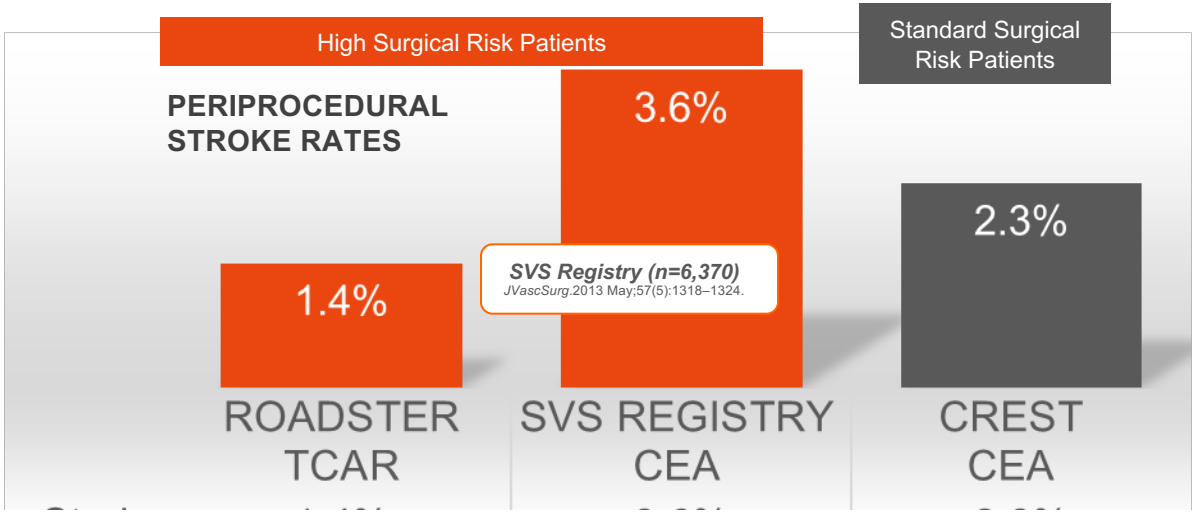
MI

TCAR **73** minutes | CEA **121** minutes

p < .001

Operative Time

CEA Periprocedural stroke rates
significantly worse in High Surgical Risk patients



ROADSTER: J Vasc Surg. 2015 Nov;62(5):1227-35.
SVS Registry: Schermerhorn, et al. The impact of Centers for Medicare and Medicaid Services high-risk criteria on outcome after carotid endarterectomy and carotid artery stenting in the SVS Vascular Registry. J Vasc Surg. 2013 May;57(5):1318-24.
CREST: N Engl J Med. 2016 Mar 17;374(11):1011-20.

Outcomes of TransCarotid Revascularization with dynamic flow reversal (TCAR) versus carotid endarterectomy (CEA) in the TCAR Surveillance Project

Malas MB, Dakour-Aridi H, Kashyap VS, Wang GJ, Motaganahalli RL, Cronenwett J, Eldrup-Jorgensen J, Schermerhorn ML – **VAM Presentation, June 2019**

Baseline Characteristics	TCAR N=5,716	CEA N=44,442	*P*-value
Age, Mean (SD)	74 (67-80)	71 (65-77)	<.001
Female	36.4%	39.4%	<.01
Non-White Race	9.8%	10.2%	.38
Hypertension	90.9%	89.5%	<.01
Diabetes Mellitus	38.0%	36.7%	.05
Coronary Artery Disease	51.8%	26.7%	<.001
CHF	18.8%	11.1%	<.001
COPD	27.7%	23.2%	<.001
Chronic Kidney Disease (GFR <60)	39.0%	33.4%	<.001
Ipsilateral Stenosis ≥ 80%	54.2%	47.0%	<.001
Prior Ipsilateral CEA	16.4%	1.7%	<.001
Prior CABG/PCI	40.7%	34.5%	<.001
Symptomatic	38.6%	29.6%	<.001
General Anesthesia	81.6%	92.6%	<.001

Outcomes of TransCarotid Revascularization with dynamic flow reversal (TCAR) versus carotid endarterectomy (CEA) in the TCAR Surveillance Project

Malas MB, Dakour-Aridi H, Kashyap VS, Wang GJ, Motaganahalli RL, Cronenwett J, Eldrup-Jorgensen J, Schermerhorn ML – **VAM Presentation, June 2019**

Unadjusted Outcomes (In-hospital)	TCAR N=5,716	CEA N=44,442	*P*-value
Stroke	1.4%	1.2%	.37
Stroke/Death	1.6%	1.4%	.23
Stroke/Death/MI	2.0%	2.0%	.98
In-hospital Death	0.5%	0.3%	.03
30-day Death	0.7%	0.7%	.95
Myocardial Infarction	0.5%	0.7%	.07
Hemodynamic Instability			
Hypertension	14.0%	19.9%	<.001
Hypotension	14.7%	10.1%	<.001
Bleeding with Intervention	1.3%	1.0%	.14
CNI	0.3%	2.6%	<.001
Non-Home Discharge	6.6%	6.4%	.70
LOS >1 day	29.6%	31.2%	0.03

Propensity Score Matching

	Propensity Score Matching (n=5,160 in each)	
In-Hospital Outcomes	*OR (95% CI)*	*P-value*
Death	0.86 (0.46-1.61)	0.63
Ipsilateral Stroke	0.92 (0.64-1.32)	0.64
Stroke	0.80 (0.58-1.11)	0.19
MI	0.41 (0.26-0.66)	<**0.001**
Stroke/Death	0.77 (0.57-1.04)	0.09
Stroke/Death/MI	0.65 (0.50-0.84)	**<0.01**
Cranial Nerve Injury	0.13 (0.07-0.22)	**<0.001**
Post-procedural Hypotension	1.66 (1.47-1.87)	**<0.001**
Post-procedural Hypertension	0.64 (0.57-0.71)	**<0.001**
Bleeding with intervention	1.17 (0.83-1.65)	0.38
Non-Home discharge	0.75 (0.64-0.87)	**<0.001**
Hospital Stay for more than 1 day	0.74 (0.68-0.80)	**<0.001**

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

Not great TCAR cases

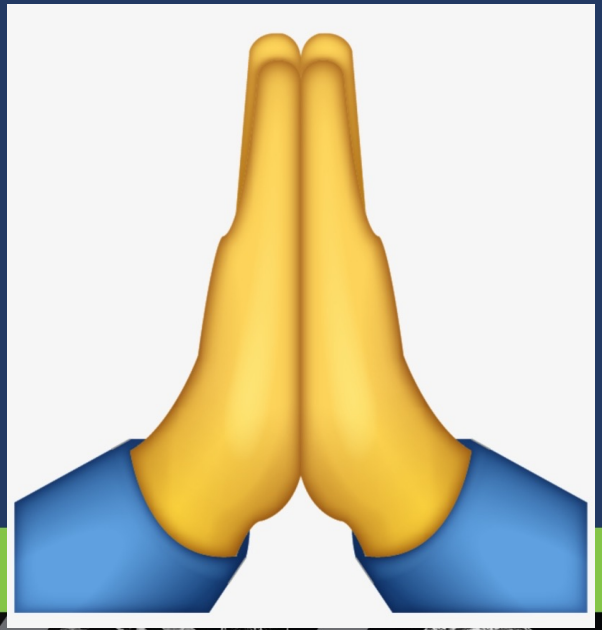
- Heavily Calcified lesions
- Short CCA (<5 cm from access site to lesion)
- Small CCA (<6 mm), heavily diseased CCA
- Open laryngeal stomas
- Severe radiation dermatitis

Carotid Endarterectomy

CEA


THINKING
CAP
Whoa.

Thank You



- Click to edit Master text styles
  - Second level
    - Third level
      - Fourth level
        - » Fifth levelAC