What Is the Advantage of TCAR over Carotid Endarterectomy?

Why and When to Choose It?

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Professor and Chief

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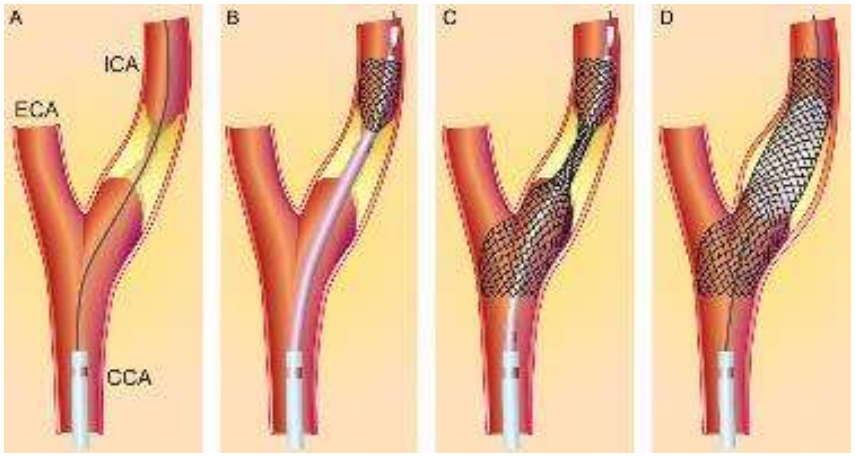
DISCLOSURES

None

– ***Symptomatic***

- **SPACE, EVA-3S, ICSS**
  - CAS→ **higher risk** stroke/death

- **SAPPHIRE, CaRESS, CREST**
  - Overall no difference in outcomes CEA vs CAS
  - **CREST**→Periprocedural risks differed:
    - » Higher risk **stroke(4.4 v 2.3%)**→CAS
    - » Higher risk MI(2.3 v 1.1%)→CEA



Most CAS proponents suggest a 4-6 week delay of the procedure

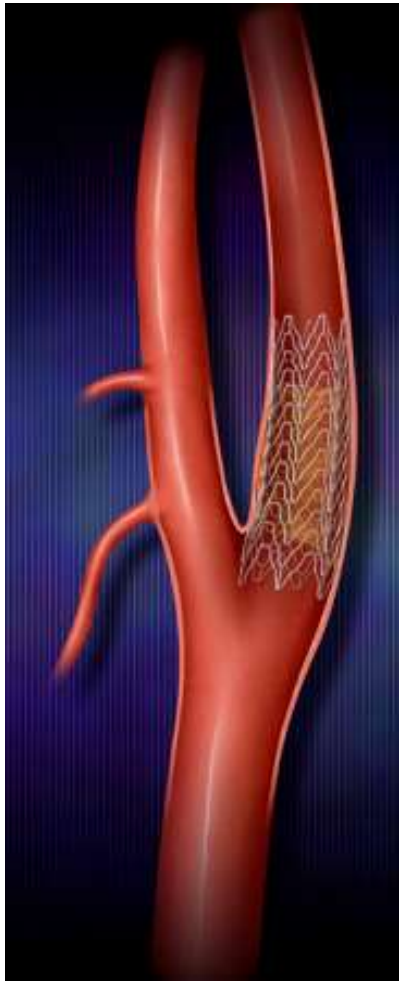
1. Ricotta JJ et al. Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease. *J Vasc Surg* **2011**; 54:e1-e31
2. Cronenwett and Johnston. Rutherford's Vascular Surgery, 8e. 2014

REAL WORLD DATA…

- **Nationwide Inpatient Sample**
  - 2003-2004
  - 259,080 CEA vs. CAS in the US

  - **Symptomatic**
    - Stroke rate **1.1%** vs. 4.2% (p<.0001)
    - Mortality rate **1.0%** vs. 7.5% (p<.0001)

  - **Asymptomatic**
    - Stroke rate **0.9%** vs. 1.8% (p<.0001)
    - Mortality rate 0.36 vs 0.44%(p=.36)



McPhee JT, Hill JS, Ciocca RG, et al: Carotid endarterectomy was performed with lower stroke and death rates than carotid artery stenting in the United States in 2003 and 2004. *J Vasc Surg* 2007; 46:1112-1118

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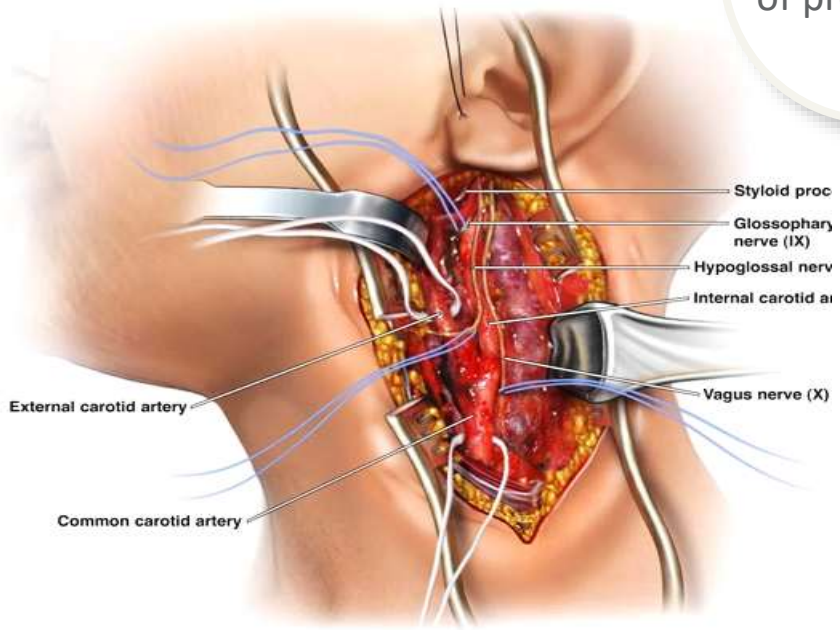
TF-CAS
15 years on Market

18%
of procedures

(CEA)
65 years: Gold standard

82%
of procedures



HIGH (2X) peri-procedural stroke risk

CREST 30-day All Stroke[1]: 2.3% CEA vs 4.1% TF CAS

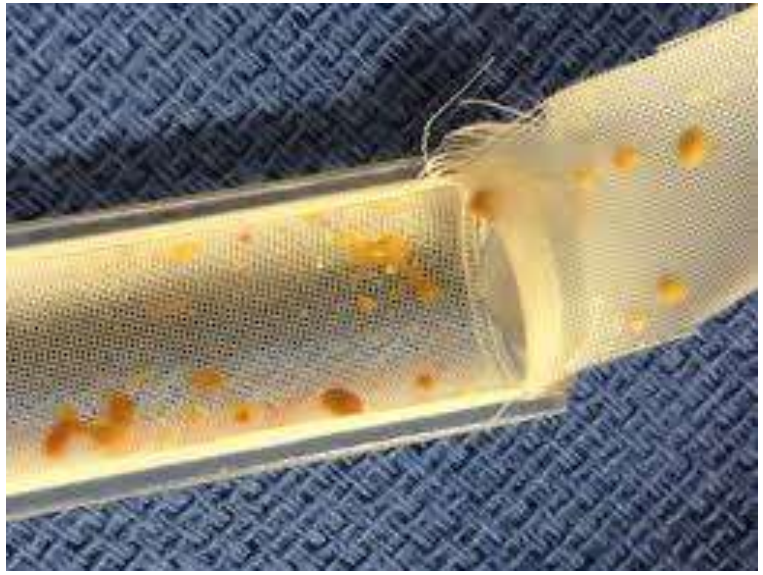
Low stroke rates & **Higher surgical morbidity**

CREST CNI[2]: 2.1% CNI unresolved at 6 months (80% motor)
CREST MI[1]: 2.3% CEA vs 1.1% TF CAS

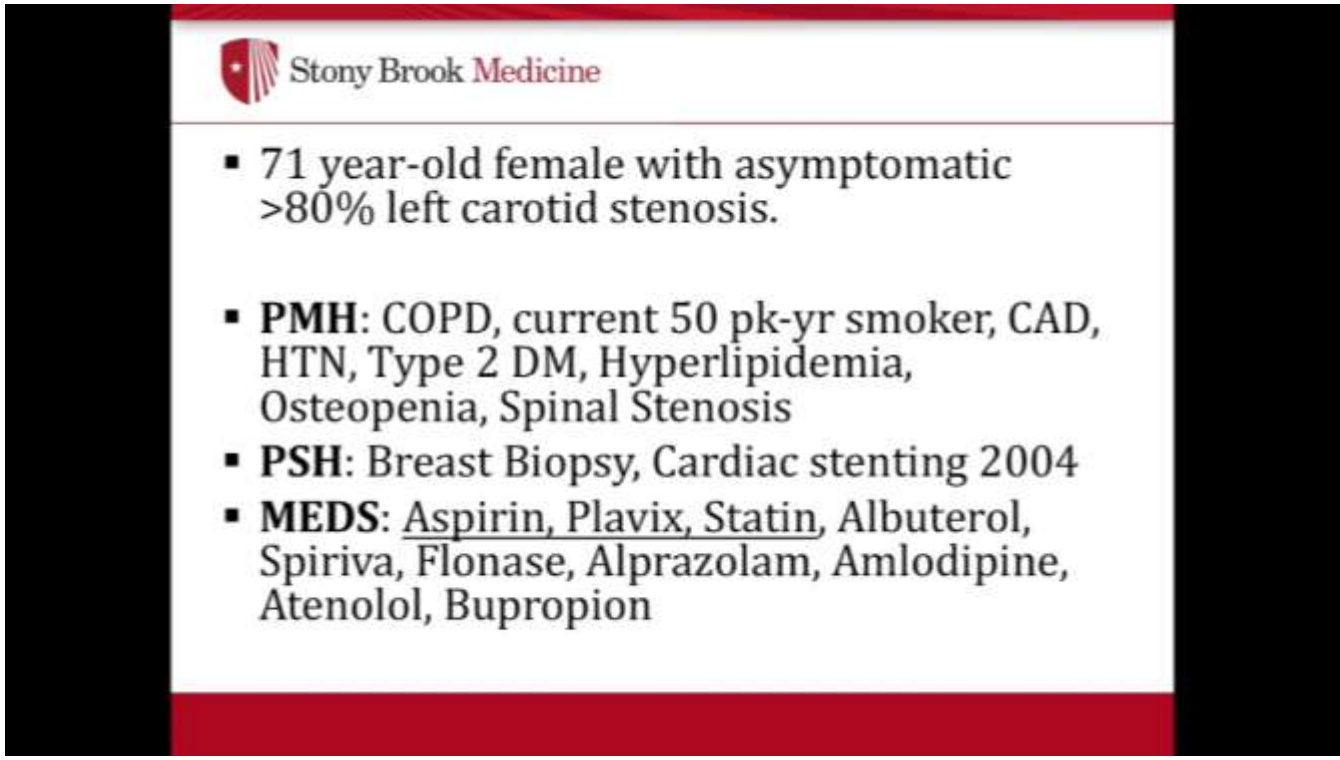
[1] CREST Trial: N Engl J Med 2010;363:11-23 [2] Circulation. 2012;125:2256-2264

ADVANTAGES

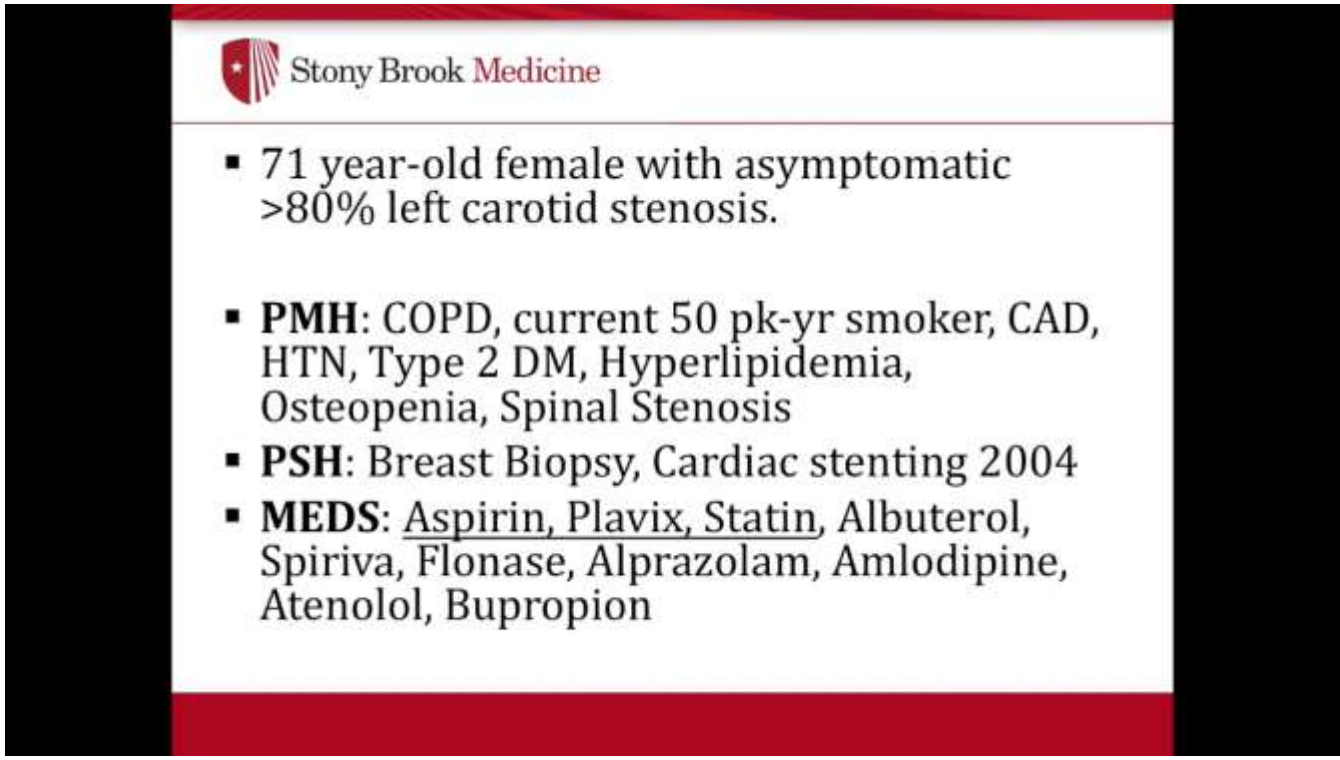
- Avoids embolic events from wire and sheath navigation through the aortic arch and the proximal CCA
- Prevents embolization during crossing of the carotid stenosis by initiating flow reversal prior to lesion crossing



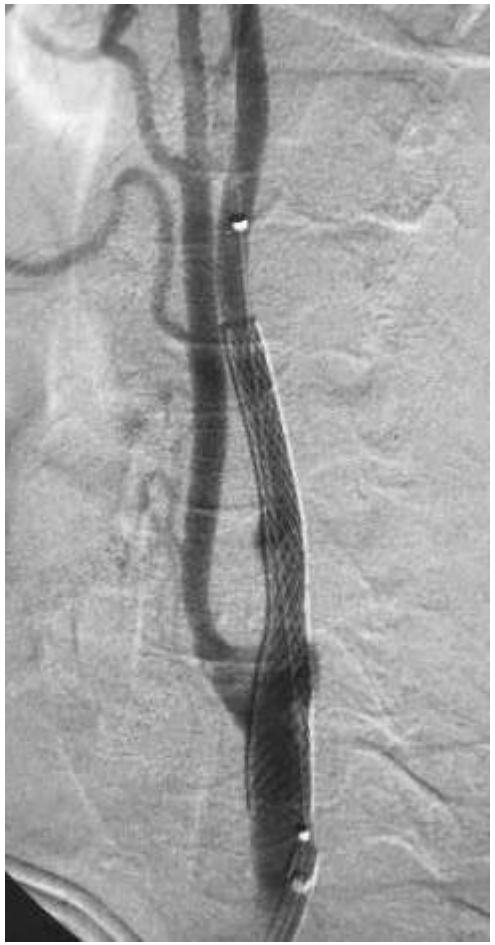
- Local or general anesthesia (Local preferred)
- CCA exposure at the base of the neck
- Common femoral vein US-guided access (8Fr)
- CCA direct access (8Fr)
- Carotid angiography
- Initiation of flow reversal
- Crossing of lesion under flow reversal



- Pre-dilatation of ICA stenosis after flow reversal is initiated
- Carotid stenting
- Completion carotid angiography
- Post-stent dilatation (selective)
- Cessation of flow reversal
- Removal of carotid sheath and closure



Case: 62yo M symptomatic with amaurosis fugax and >90% stenosis



ROADSTER Trial

- 208 patients who are **high risk** for CEA
  - 26% were symptomatic
  - 47% >75 years of age

(J Vasc Surg 2015;62:1227-35.)

ROADSTER TRIAL ENROLLMENT HIGH-RISK CRITERIA

Table I. Physiologic and anatomic high-risk inclusion criteria

Physiologic	*Anatomic*
>2 vessel CAD with history of angina, CCS III/IV or unstable angina, CHF NYHA III/IV, LVEF <30%	Contralateral carotid occlusion
Recent MI >72 hours and <6 weeks	Tandem stenoses >70%
Severe COPD (FEV_1 <50% and Po_2 ≤60 mm Hg)	High cervical carotid stenosis above C-2 vertebral body
Chronic renal insufficiency (serum creatinine >2.5 mg/dL)	Restenosis post-CEA
Permanent contralateral CNI	Hostile neck (irradiation, radical neck dissection, cervical spine immobility)
Age ≥75 years	Bilateral carotid artery stenosis requiring treatment ≤30 days

ROADSTER Trial

- 208 patients who are **high risk** for CEA
  - 26% were symptomatic
  - 47% >75 years of age
- The 30-d
- Stroke/de
- All stroke
- Conclusi
  patients v
  comparable with periprocedural rates in standard surgical risk patients for CEA”

FDA approved September 2016:

Centers participating in the **VQI TCAR Surveillance Project** approved for reimbursement by the Centers for Medicare and Medicaid Services (CMS) under the current ”National Coverage Determination”

(J Vasc Surg 2015;62:1227-35.)

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ROADSTER Study

Demographics and Technical Results

ROADSTER Pivotal ITT[1] (n=141) + Continued Access (n=78) = 219	ROADSTER (n=219)	CREST[2] CEA (n=1,240)
	High Surgical Risk	**Standard Risk**
Age (mean)	72.3 ±8.6	69.2 ±8.7
Age ≥75	**41.6%**	28.5%[3]
Female	37.9%	33.6%
Symptomatic	22.4%	52.7%
Local Anesthesia	**47.1%**	10.0%
Reverse Flow Time (median)	10 minutes	n/a

Clinical Results

	ROADSTER (n=219)		CREST[2] CEA (n=1,240)
	High Surgical Risk		**Standard Risk**
S/D/MI*	8	3.7%	4.5%
Major Stroke	**0**	**0%**	0.6%
Minor Stroke	**3**	**1.4%**	1.7%
Death	2	0.9%	0.3%
MI	3	1.4%	2.3%
All Stroke	**3**	**1.4%**	2.3%
Cranial Nerve Injury	1	0.5%	5.3%
CNI Unresolved 6 mths	**0**	**0.0%**	**2.1%**[4]

*Hierarchical

Primary Endpoint
All stroke, MI & death at 30-days

[1] J Vasc Surg 2015;62:227-35
[2] N Engl J Med 2010;363:11-23 Stroke 2011;42(12):3484-90. Circulation 2012;125:2256-2264

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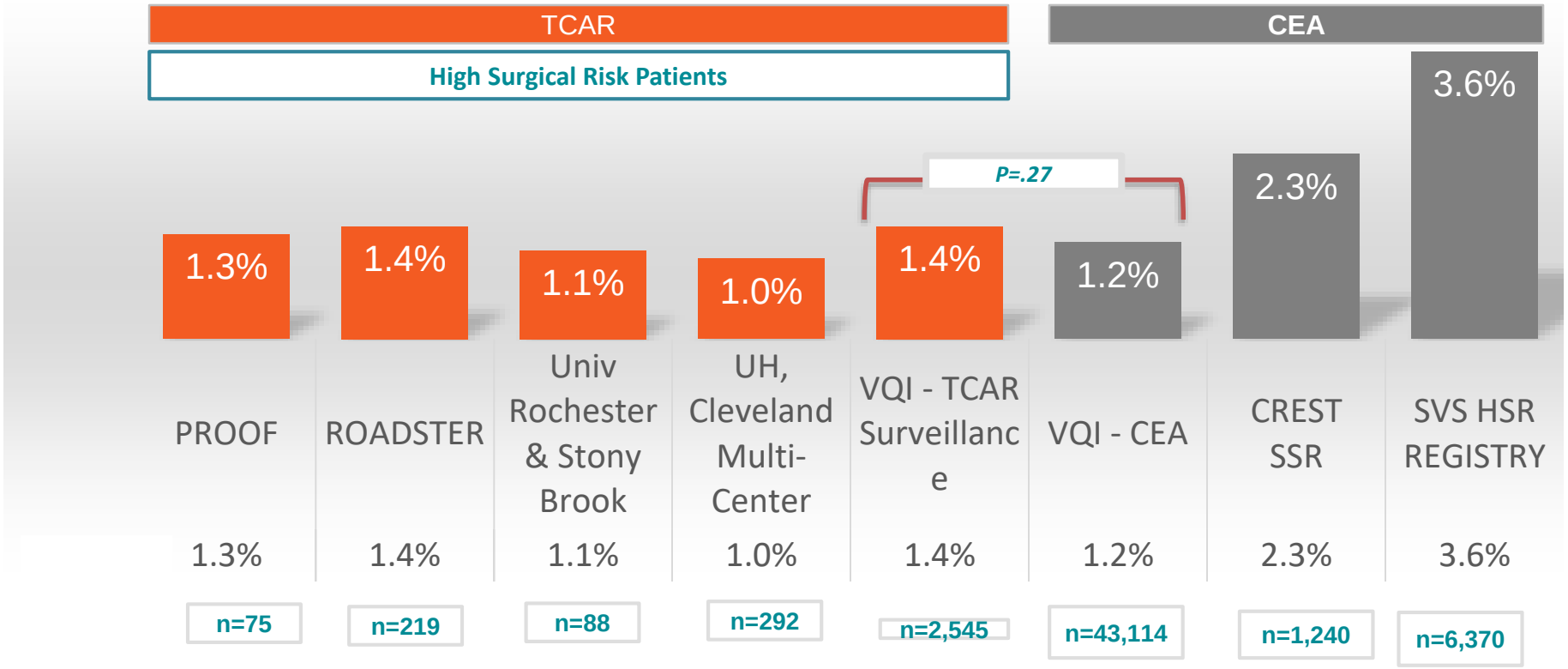
Periprocedural Stroke Rates

Presentations & Publications of TCAR & CEA



PROOF: J Endovasc Ther. 2017 Apr;24(2):265-270
ROADSTER: J Vasc Surg. 2015 Nov;62(5):1227-34. The Silk Road System for Transcervical Access with Reversal of Flow to Perform TCAR: Results of the ROADSTER Trial - VEITH, 2016
Univ Rochester & Stony Brook: Transcarotid Arterial Revascularization: First Post-Approval Safety & Efficacy Study – VAM, 2018 Poster Presentation
UH Cleveland: A Multi Institutional Analysis of TCAR Compared to CEA – VAM, 2018 Poster Presentation
VQI TCAR + CEA: In-Hospital Outcomes of TCAR & CEA in the SVS-VQI TCAR Surveillance Project – VEITH Symposium 2018 Presentation Unadjusted Outcomes – M. Schermerhorn, MD
CREST Standard Surgical Risk: N Engl J Med. 2016 Mar 17;374(11):1011-20.
SVS Registry: J Vasc Surg. 2013 May;57(5):1318-24.

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TCAR - TransCarotid Artery Revascularization

First Post-Approval Safety and Efficacy Study (2 Center Analysis)

Patient Characteristics	TCAR N=88
Age, Mean	72.3
Age 75+	**45%**
Age 80+	**27%**
Female	33%
Medical History	
Diabetes	36%
Hypertension	93%
CHF	32%
CAD	56%
Current Smoker	30%
Symptomatic	**38%**

Lesion Characteristics	TCAR N=88
Side	
Right	55%
Left	45%
Stenosis, Mean	87.6%
Length	**20.0mm**
Type	
Atherosclerosis	82%
Re-stenosis CEA	13%
Re-stenosis stent	6%
Calcification	
None	6%
≤25%	52%
26 - 50%	23%
51 – 99%	13%
100%	6%

Procedure Detail	TCAR N=88
Time (Mean)	
Procedure	91.7min
Flow Reversal	13.3min
Fluoro	6.5min
Tech Success	98%
Pre-Dilate	**48%**
Med Mgmt	
DAPT	**95%**
Statin	**95%**
Number of Stents	
One	91%
Two	8%
Local Anesthesia	**32%**

30 Day Outcomes	TCAR N=88
Stroke	**1.1% (1)**
MI	**0% (0)**
Death	**0% (0)**

CONCLUSIONS:

- All patients tolerated flow reversal. There were no MI or death within 30 day. One patient developed a post-op watershed event (1.1%).
- In comparison to the ROADSTER trial, there were more symptomatic patients (26% vs 38%) with a similar profile of major comorbidities.
- In spite of these high risk factors, the data demonstrate an excellent safety profile with only a single post-op neurologic event.

Mark D. Balceniuk, MD[1], Michael C. Stoner, MD[1], Brian C. Ayers, MBA[1], Angela Kokkosis, MD[2], Apostolos Tassiopoulos, MD[2]

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TCAR vs. CAS in the SVS Vascular Quality Initiative

Baseline Characteristics	TCAR N=638	TF-CAS N=10,136	P-value
Age, Median (IQR)	74 (66-80)	70 (63-77	<.001
Female	35.1%	35.5	0.83
Coronary Artery Disease	47.3%	34%	<.001
CHF	19.8%	15.3%	<.01
Prior CABG/PCI	41.5%	19.5%	<0.001
Hypertension	91.2%	90.0%	0.31
COPD	26.5%	25.7%	.64
Symptomatic	33.5%	41.9%	<.001
Prior Ipsilateral CEA or CAS	18.7%	26.9%	<.001
Prior Contralateral CEA or CAS	18.3%	13.2%	<.001
Anatomic High Risk	50.6%	46.2%	0.03
Medical High Risk	59.4%	41.4%	<.001
Local Anesthesia	21%	88.5%	<.001

In-Hospital Outcomes	TCAR N=638	TF-CAS N=10,136	P-value
Stroke	**1.4%**	2.0%	0.29
Stroke/TIA	**1.9%**	3.3%	0.04
Stroke/TIA/Death	**2.2%**	3.8%	0.04
Myocardial Infarction	1.1%	0.6%	0.15
TIA Alone	0.5%	1.3%	0.06
Any Neurological Event	1.9%	3.2%	0.06
Neurological Events/Death	2.2%	3.7%	0.05
Discharge Destination			
Home	**93.9%**	90.8%	0.01
Rehab Unit	3.0%	6.0%	
30-Day Mortality	0.9%	1.3%	0.42

– J Vasc Surg Vol69, Issue 1, Pages 92–103.e2
Malas MB, MD, MHS; Dakour Aridi H, MD, Wang GJ, MD; Kashyap VS, MD; Motaganahalli R, MD; Eldrup-Jorgensen J, MD; Cronenwett JL, MD; Schermerhorn ML, MD

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TCAR vs. CAS in VQI

TransCarotid Artery Revascularization (TCAR) vs. Transfemoral Carotid Artery Stenting (TF-CAS) in the SVS Vascular Quality Initiative

– J Vasc Surg Vol69, Issue 1, Pages 92–103.e2

Malas MB, MD, MHS; Dakour Aridi H, MD, Wang GJ, MD; Kashyap VS, MD; Motaganahalli R, MD; Eldrup-Jorgensen J, MD; Cronenwett JL, MD; Schermerhorn ML, MD

- The rates of in-hospital TIA/Stroke as well as TIA/Stroke/Death were significantly higher with TF-CAS compared to TCAR
  - TIA/Stroke - 3.3% TF-CAS vs 1.9% TCAR (P=0.04)
  - TIA/Stroke/Death – 3.8% TF-CAS vs 2.2% TCAR (P=0.04)

- On multi-variable analysis, TF-CAS was associated with TWICE the odds of in-hospital neurologic events and TIA/Stroke/Death compared to TCAR

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TCAR: TCD Embolization Rates Comparable to CEA

- No significant differences in number of emboli (p=0.486) and seconds of embolic showers (p=0.493) between TCAR and CEA
  - TF-CAS showed significantly higher emboli rates compared with CEA or TCAR (p<0.001)

Pre-Protection	Protection	Post-Protection
• No significant difference b/w TCAR & CEA (p=0.177) • TF-CAS generated more discrete emboli than TCAR & CEA (p<0.001)	• No significant difference b/w TCAR & CEA (p=0.424) • TF-CAS generated more embolic events than TCAR & CEA (p<0.001)	• All 3 techniques showed similar rates of embolic events

Pre-protection

Before clamping, filter deployed, or reverse flow established

Protection

Until clamp removed, filter retrieved, or antegrade flow reestablished

Post-protection

After clamp/filter removed, or normal flow established

1 Vermassen,et al J Endovasc Ther April 2016 23: 249-254

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In-Hospital Outcomes of TCAR and CEA in the SVS-VQI TCAR Surveillance Project

Baseline Characteristics	TCAR N=2,545	CEA N=43,114	*P*-value
Age, Mean (SD)	73.1 ± 9.4	70.6 ± 9.6	<.001
Female	36%	39%	<.01
Black	5%	5%	.61
Hypertension	90%	89%	.50
Diabetes Mellitus	37%	36%	.52
Coronary Artery Disease	51%	27%	<.001
CHF	19%	11%	<.001
COPD	29%	23%	<.001
Chronic Kidney Disease (GFR <60)	41%	34%	<.001
Prior CEA/CAS	31%	15%	<.001
Asymptomatic	53%	51%	.37
General Anesthesia	83%	92%	<.001

Unadjusted Outcomes	TCAR N = 2,545	CEA N = 43,114	*P*-value
Stroke/Death	1.8%	1.4%	.09
Stroke/Death/MI	2.1%	1.8%	.17
Stroke	1.4%	1.2%	.27
In-hospital Death	0.5%	0.3%	.04
30-day Death	0.9%	0.6%	.08
Myocardial Infarction	0.4%	0.4%	.71
Hemodynamic Instability			
Hypertension	12%	20%	<.001
Hypotension	13%	10%	<.001
Bleeding with Intervention	1.4%	1.0%	.05
Reperfusion Syndrome	0.2%	0.2%	.54
CNI	0.2%	2.7%	<.001
Operative Time, Mins, Mean	75 ± 31	116 ± 45	<.001
LOS, Days, Median (IQR)	1 (1-2)	1 (1-2)	.34
LOS >1 day	29%	32%	<.01

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A Multi-Institutional Analysis of TCAR Compared to CEA

Alexander H. King, MS[1], Vikram S. Kashyap, MD[1], Mazin I. Foteh, MD[2], Matthew Janko, MD[1], Jeffrey Jim, MD[3], Raghu Motaganahalli, MD[4], Jeffrey M. Apple, MD[2], Saideep Bose, MD[1], Norman H. Kumins, MD[1] - **VAM, June 2018**

METHODS:

- Multi-center, retrospective review of patients undergoing TCAR or CEA between 2013-2017
- TCAR patients had higher risk factors and most were enrolled in prospective trials

Baseline Characteristics	TCAR N=292	CEA N=371	*P*-value
Male, Gender	65.8%	59.6%	0.06
Age (yrs)	71.1	70.7	0.73
Symptomatic	35.3%	38.5%	0.42
Diabetes	**45.9%**	35.6%	**0.01**
Hyperlipidemia	**82.9%**	72.8%	**0.02**
Hypertension	91.1%	87.9%	0.21
Coronary Artery Disease	**53.4%**	36%	**<.01**
PVD	24.7%	27.9%	0.49
Smoking History	59.6%	**72.0%**	**<0.01**
Renal Insufficiency	21.2%	12.7%	**<0.01**

Overall Outcomes	TCAR N =292	CEA N = 371	*P*-value
Stroke/MI/Death – 30 Day	2.1%	2.4%	0.80
Stroke/Death – 30 Day	1.4%	1.9%	0.76
Stroke – 30 Day	**1.0%**	**1.1%**	**1.00**
Mortality – 30 Day	0.3%	0.8%	0.63
MI – 30 Day	0.7%	0.5%	1.00
Stroke/Death – 1 Year	4.6%	6.8%	0.32
Stroke – 1 Year	**2.8%**	**3.0%**	**1.00**
Mortality – 1 Year	1.8%	3.9%	**0.15**
CNI	0.3%	4.1%	**<.01**
Unresolved at 6 Months	0.0%	1.9%	**0.02**

SUMMARY:

- Stroke and death rates were the same at 30 days and 1 year
- TCAR demonstrated a significant decrease in CNI
- “Particularly in patients at high risk for surgery, TCAR should be considered in treatment of carotid artery disease.”

1. Harrington Heart and Vascular Institute, University Hospitals Cleveland Medical Center, Cleveland, OH
2. Cardiothoracic and Vascular Surgeons, Austin, TX
3. Division of Vascular Surgery, Washington University, St. Louis, MO
4. Division of Vascular Surgery, Indiana University School of Medicine, Indianapolis, IN

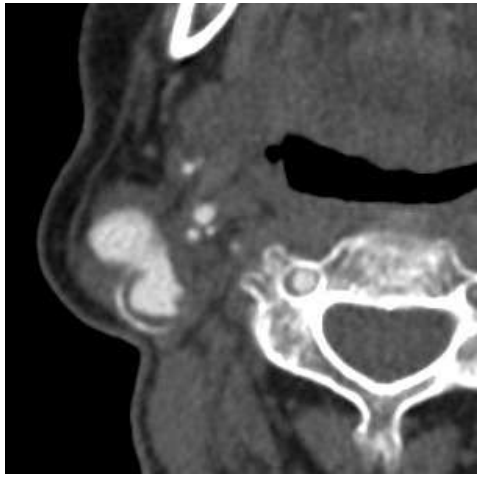
Favor CEA

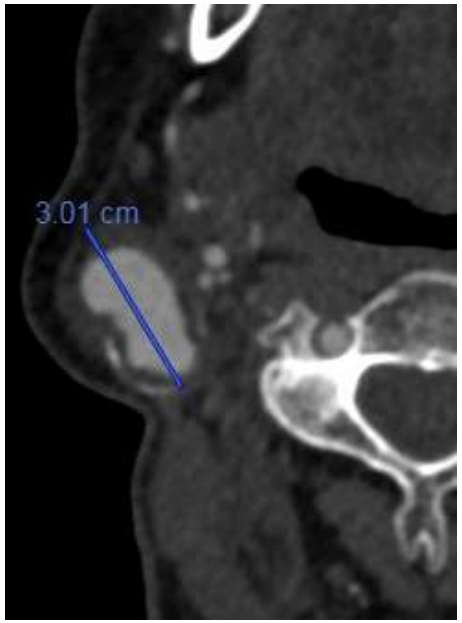
- Short CCA (<6cm clavicle to lesion)
- Atherosclerotic plaque involves long CCA segment
- Heavily calcified carotid plaque
- Good surgical risk

Favor TCAR

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

UNCOMMON USE OF FLOW REVERSAL PROTECTION



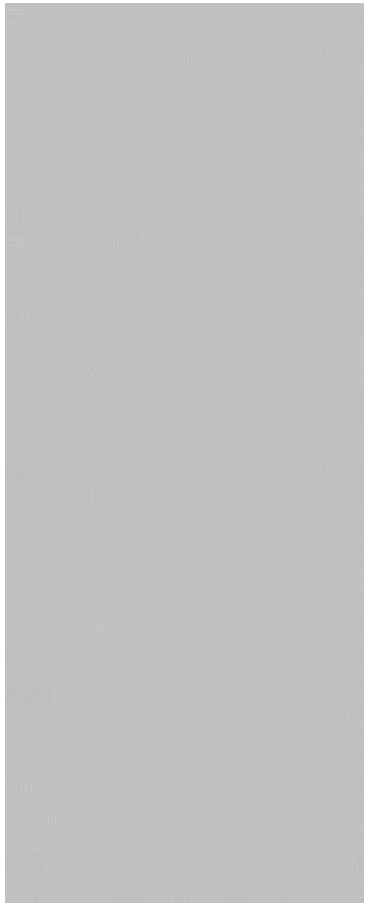


68 year old male with right CCA and ICA expanding pseudoaneurysm
Had previous CEA with vein patch, right radical neck dissection and radiation therapy for tonsillar Ca

UNCOMMON USE OF FLOW REVERSAL PROTECTION

Open resection and repair not favored due to extensive radiation (risk of CN injury, bleeding from pseudoaneurysm, stroke from intraluminal thrombus manipulation)

Repair of carotid pseudoaneurysm using Viabahn stent grafts under flow reversal

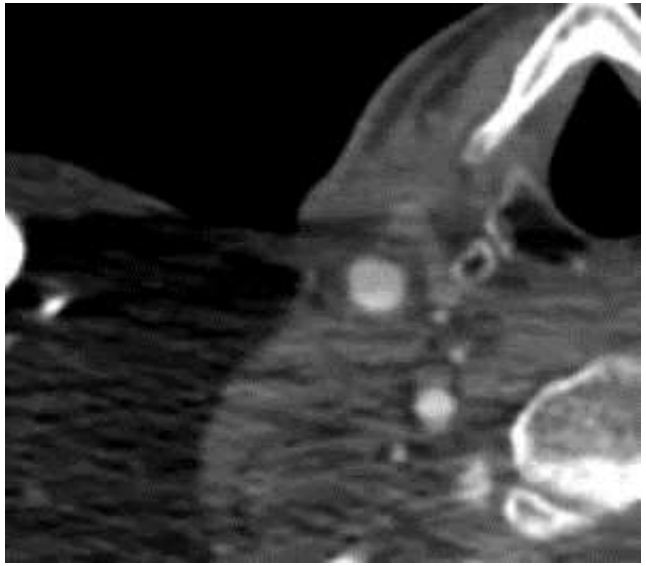


One month postoperative follow up

No new acute neurologic events

Complete exclusion of carotid pseudoaneurysm

Widely patent Viabahn stent grafts



CONCLUSIONS

- TCAR is associated with lower perioperative stroke rates compared top CAS
- TCAR is associated with perioperative stroke rates similar to CEA and significantly less risk of transient or persistent cranial nerve injury
- Limited long-term follow up data without evidence of worse results in 12 months postop

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THANK YOU