Transcarotid Artery Revascularization
A Transformative New Technique for Carotid Disease

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Epidemiology and Natural History

Stroke

- Symptoms of stroke due to carotid disease:
  - Sudden contralateral sensorimotor loss
  - Speech deficit
  - Ipsilateral monocular blindness
- Transient Ischemic Attack (TIA): ischemic parenchyma recovers and returns to baseline
- Full impact of a stroke can often not be apparent for up to two weeks

Epidemiology of Stroke

- In 2013, total cost in the US of stroke was $33.9 billion
- Prevalence in 2013 was 25.7 million
- Stroke causes 5.5 million deaths and > 44 million disabilities every year
- ~800,000 Americans have a stroke every year
- One stroke occurs every 40 seconds

Risk Factors for Stroke

- Sex
- Age
- Race
- HTN
- Family History
- Atrial Fibrillation
- Tobacco use
- Hyperlipidemia
- Physical activity
- Diabetes
- Diet
- Obesity
- Alcohol
- Renal failure

Outcome of Stroke

- Risk of recurrent stroke:
  - 7 days: 2%
  - 30 days: 4%
  - 1 year: 12%
  - 5 years: 29%
- Risk of death after stroke:
  - 7 days: 7%
  - 30 days: 14%
  - 1 year: 27%
  - 5 years: 53%

Transient Ischemic Attack

- Warning sign for future stroke:
  - 5% within 2 days
  - 11% within 90 days
  - 30% within 5 years
- 15% of all strokes are heralded by a TIA

Extracranial Carotid Atherosclerosis

- Carotid plaque causes stroke by two mechanisms:
  - Hypoperfusion (rare)
  - Embolization
- Degree of carotid stenosis is a critical risk factor for stroke
- Most asymptomatic patients are at low risk for stroke
- BUT, only 15% of ischemic strokes are heralded by a TIA
- There is a critical need to improve selection of asymptomatic patients to improve effectiveness of treatment.

When do we treat carotid stenosis?

- All patients with carotid stenosis get medical therapy and lifestyle modifications
  - Aspirin 81 mg
  - Statin
  - Smoking cessation, weight loss, etc
- Symptomatic carotid stenosis > 50%
- Asymptomatic carotid stenosis > 70-80%
  - Assuming 3-5 year life expectancy

Diagnostic Evaluation

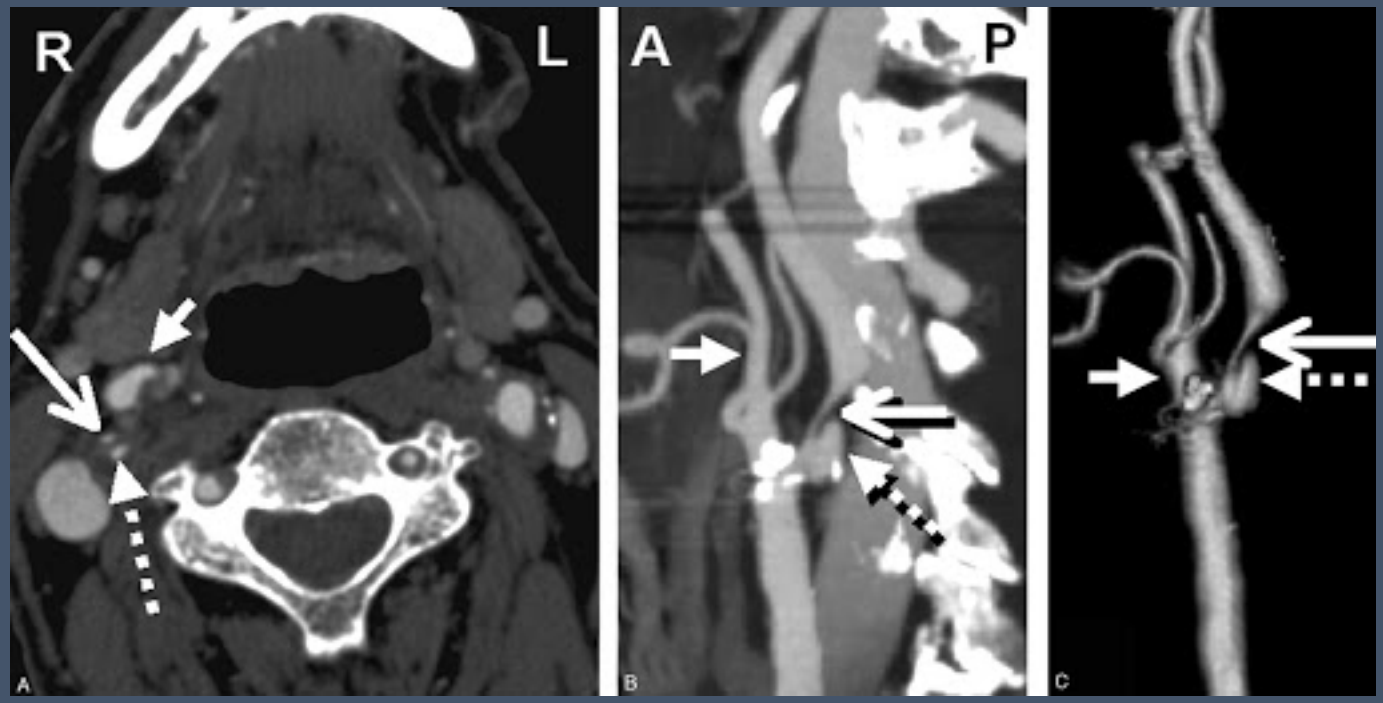
Duplex Ultrasound

Degree of Stenosis (%)	PRIMARY PARAMETERS		ADDITIONAL PARAMETERS	
	ICA PSV (cm/s)	Plaque Estimate (%)[a]	ICA/CCA PSV (ratio)	ICA EDV (cm/s)
Normal	<125	None	<2.0	<40
<50	<125	<50	<2.0	<40
50-69	125-230	≥50	2.0-4.0	40-100
>70 but less than near occlusion	>230	≥50	>4.0	>100
Near occlusion	High, low or undetectable	Visible	Variable	Variable
Total occlusion	Undetectable	Visible, no detectable lumen	Not applicable	Not applicable

Duplex U

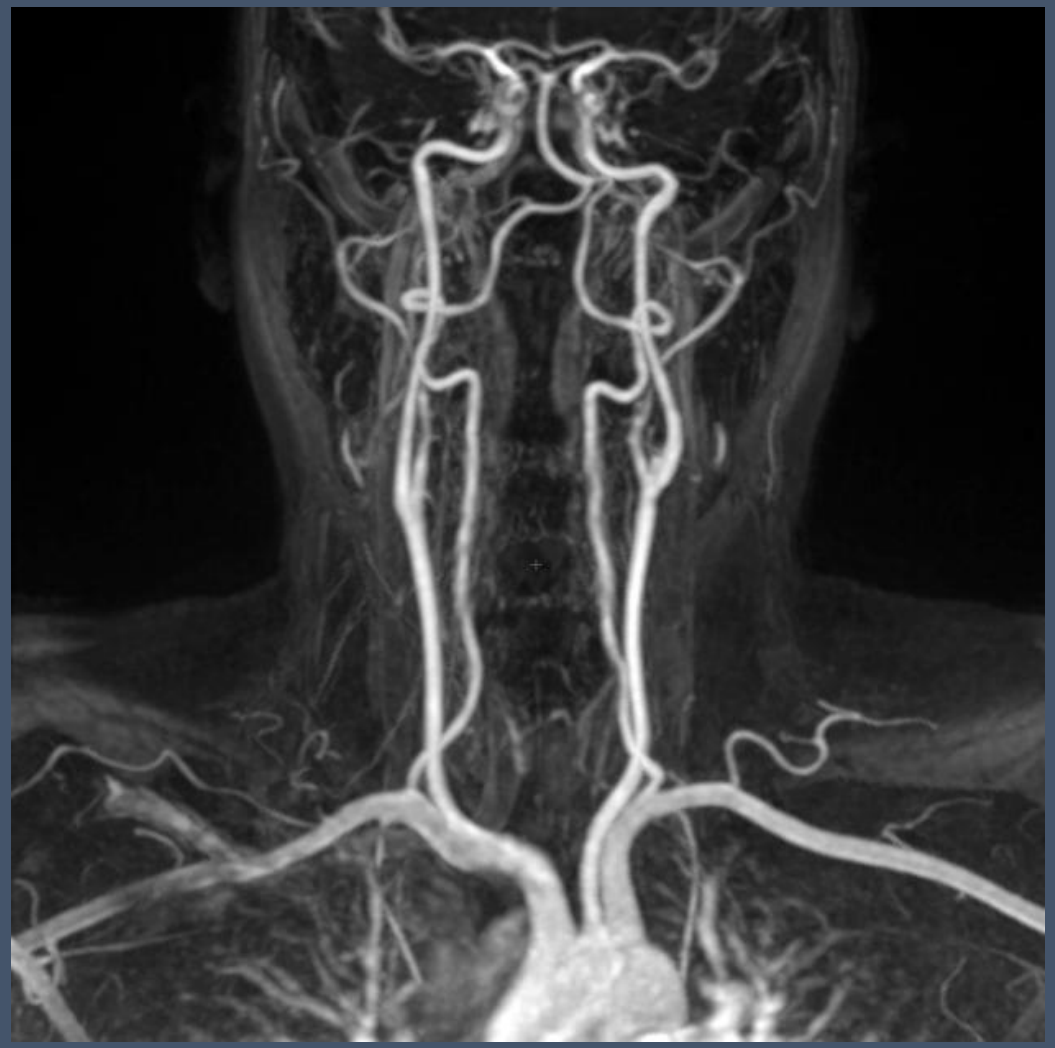
Computed Tomography Angiography (CTA)

- The new “gold standard”
- Fast
- Cheap(er)
- Can see calcium
- Can visualize surrounding structures
- Radiation
- Contrast



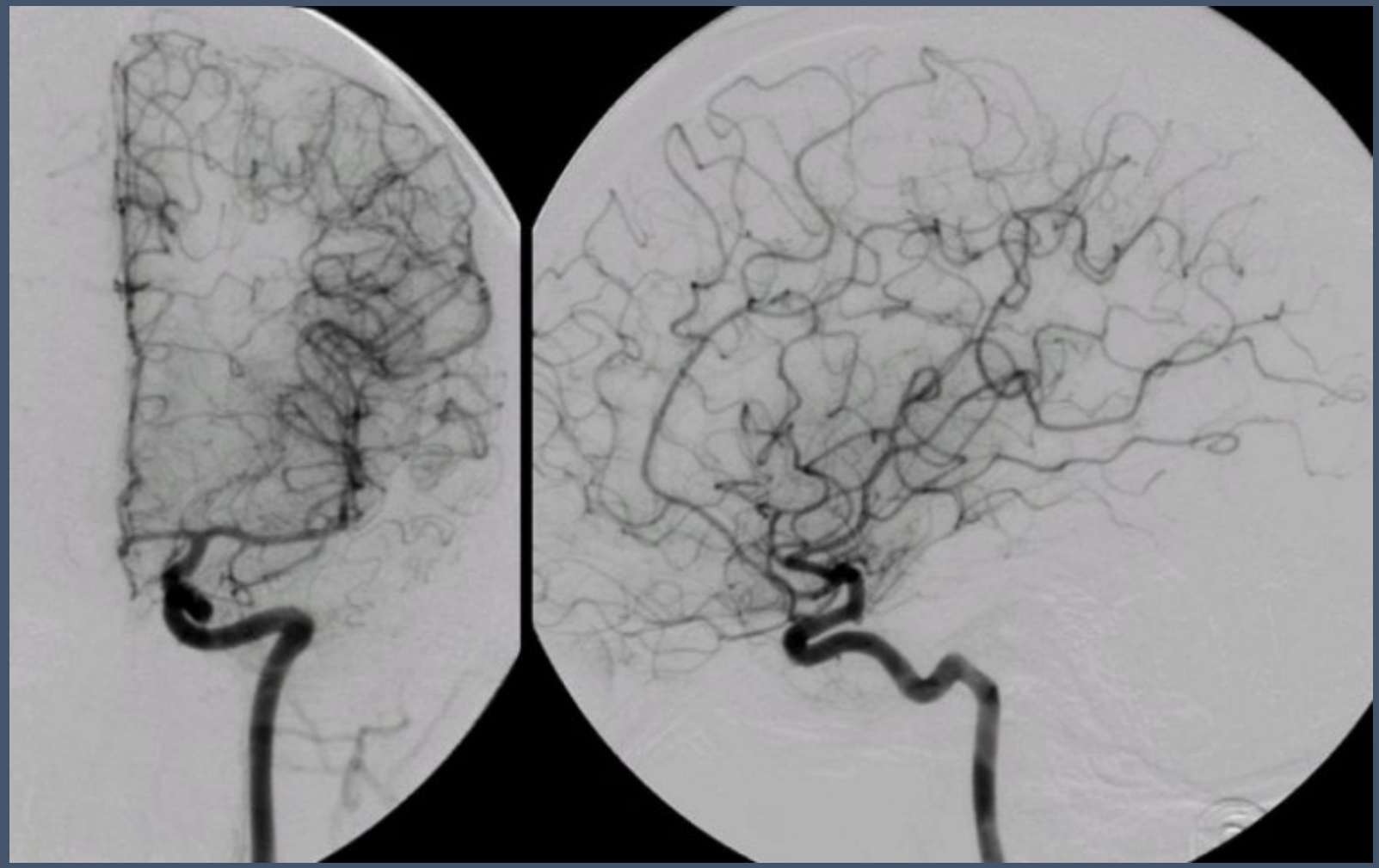
Magnetic Resonance Angiography (MRA)

- Expensive
- Time consuming
- Doesn’t visualize calcium well—overstimates stenosis
- Plaque morphology
- No radiation



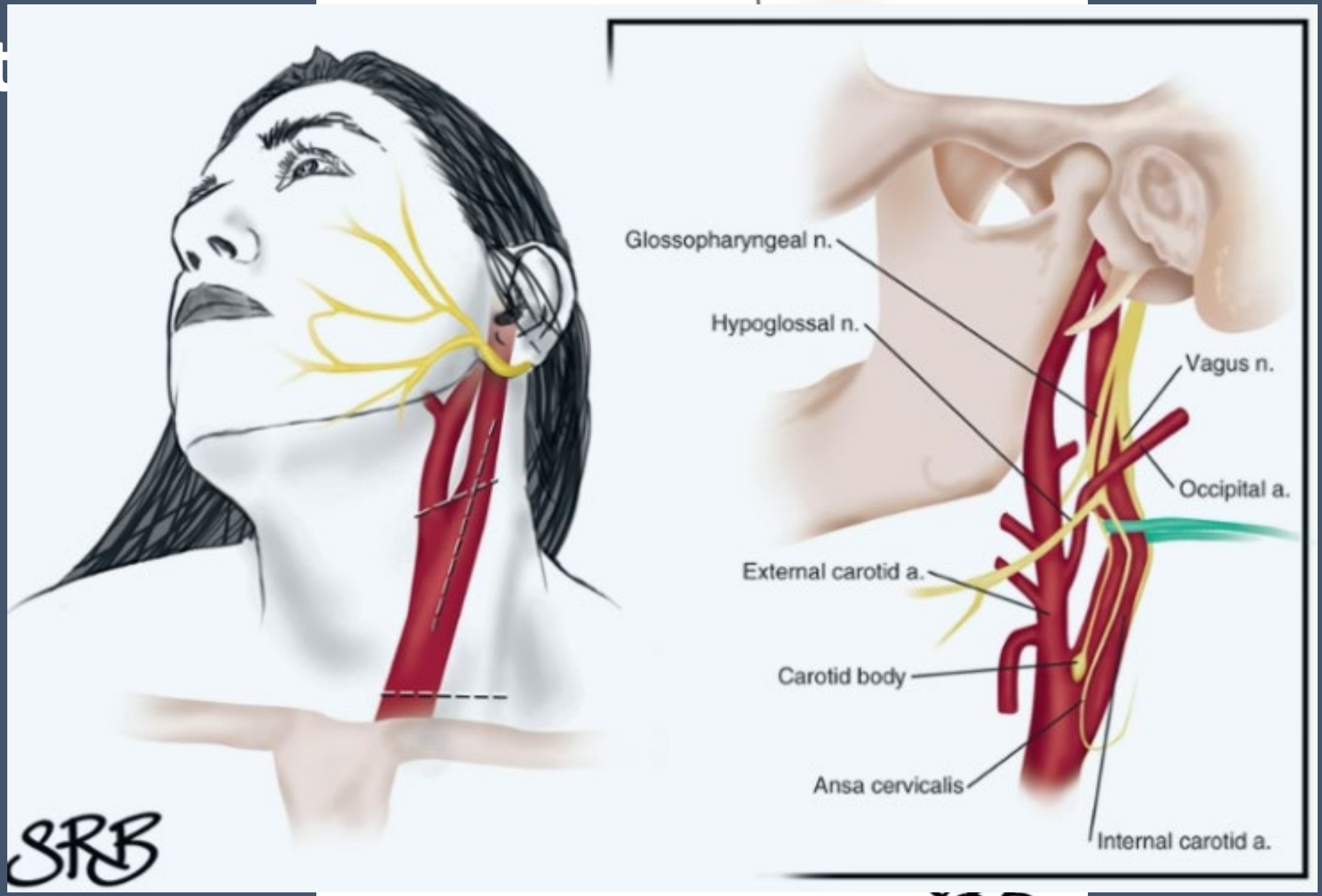
Digital Subraction Angiography (DSA)

- The old “gold standard”
- Minor stroke risk: 0.6%
- Major stroke risk: 0.2%
- TIA risk: 3.2%
- No role for routine use
- Very narrow indications

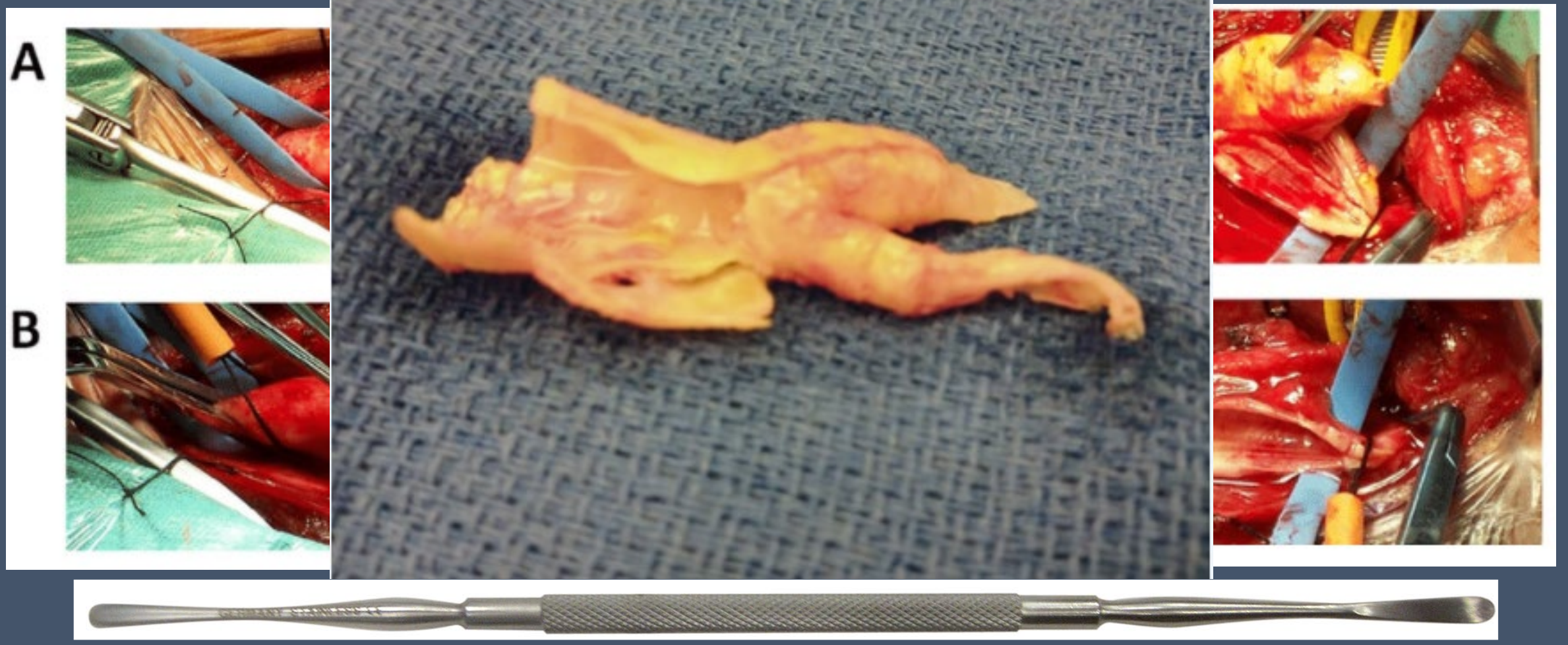


Carotid Endarterectomy (CEA)

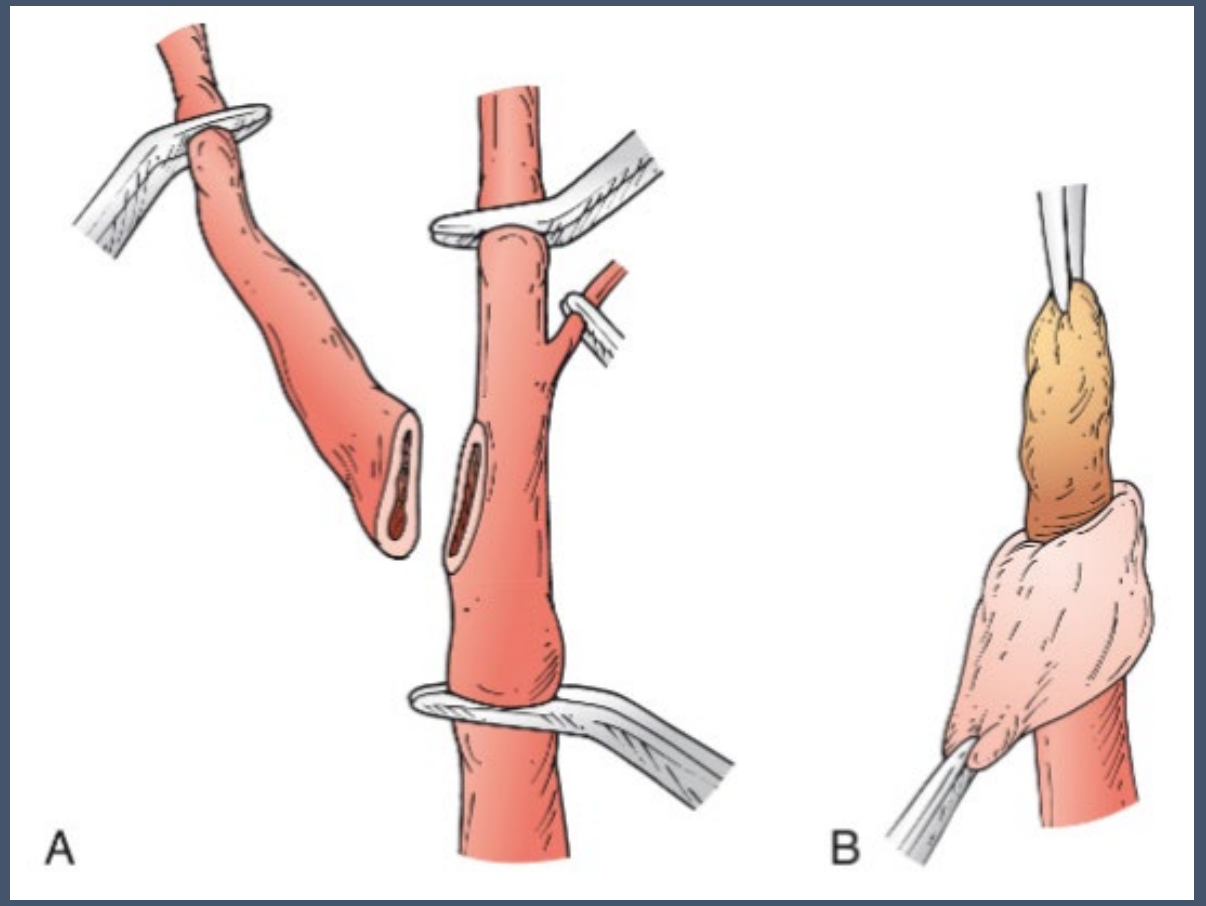
Carot

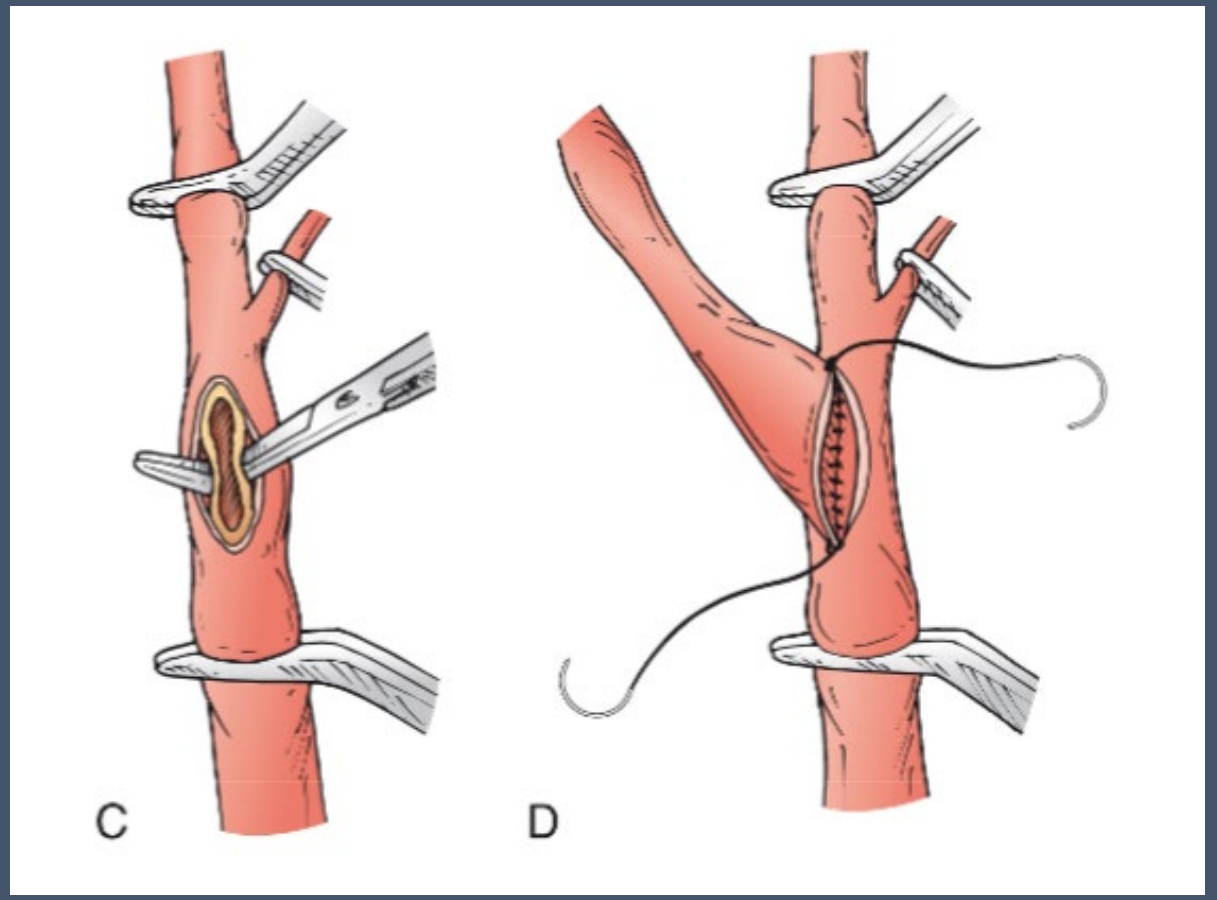

Divided common facial vein
Glossopharyngeal n.
Hypoglossal n.
Vagus n.
Occipital a.
External carotid a.
Carotid body
Ansa cervicalis
Internal carotid a.
SRB

Carotid Endarterectomy



Eversion Endarterectomy

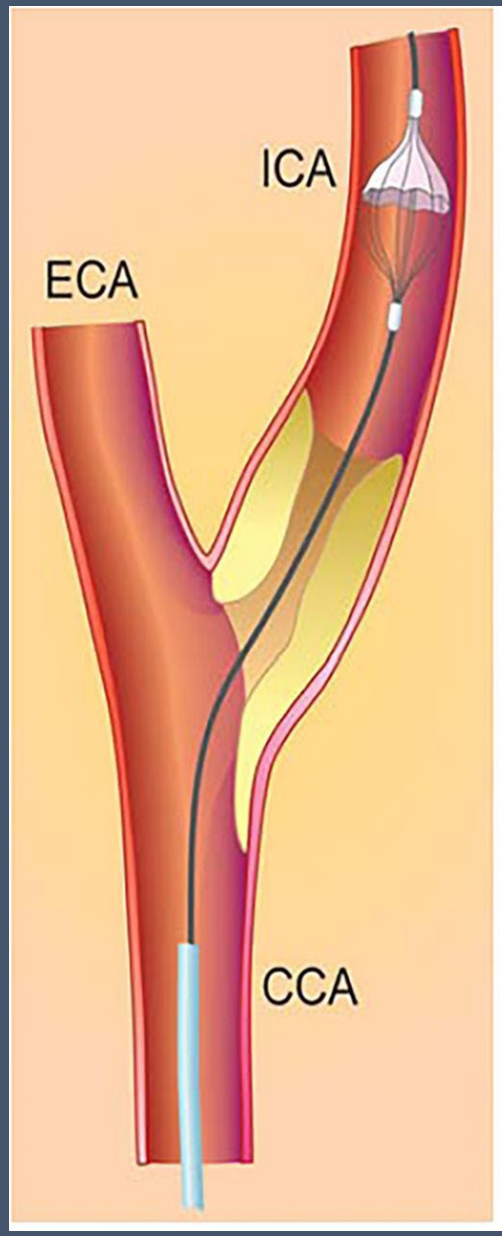


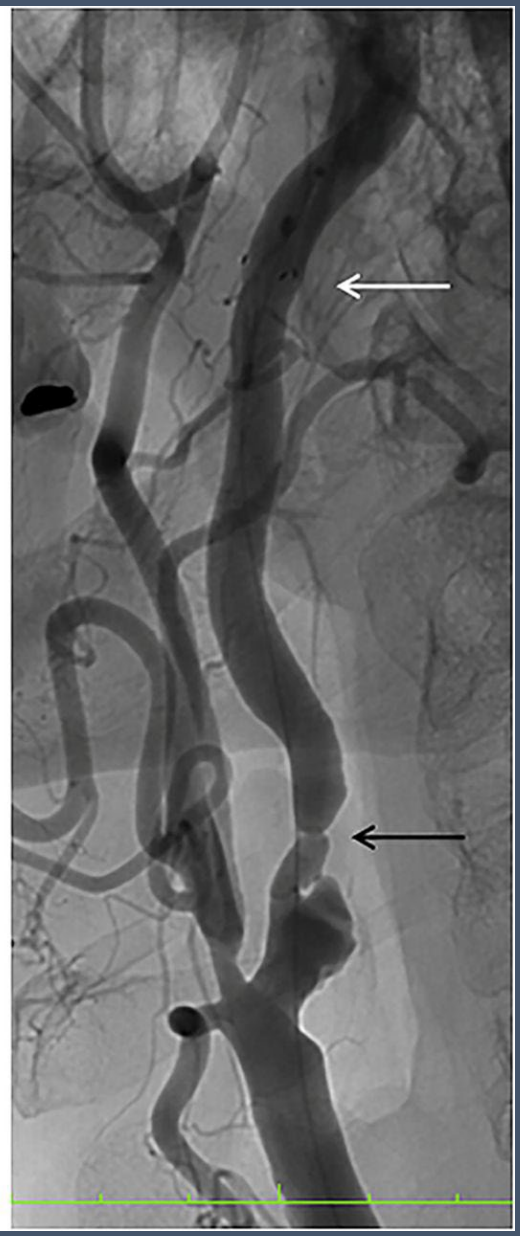


Transfemoral Carotid Artery Stenting (TF-CAS)

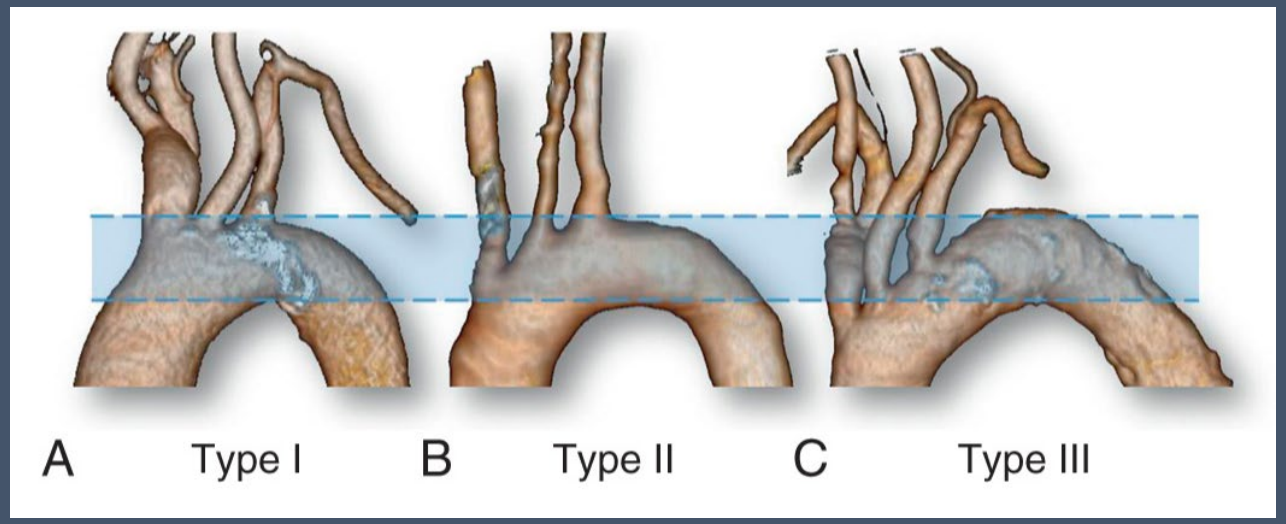
TF-CAS Technique

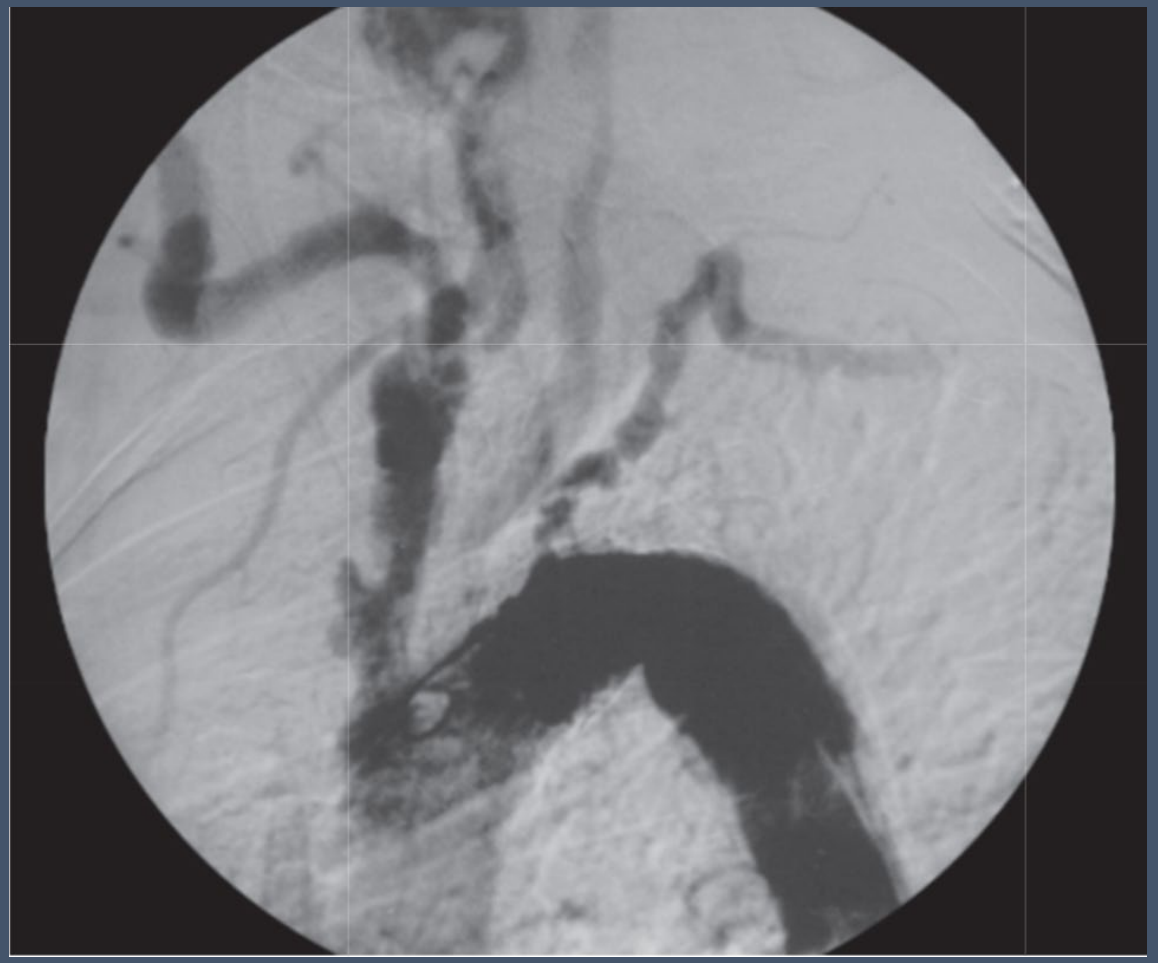
- Embolic protection
- Predilation
- Stent placement
- Angiogram
- EPD retrieval
- Completion angio





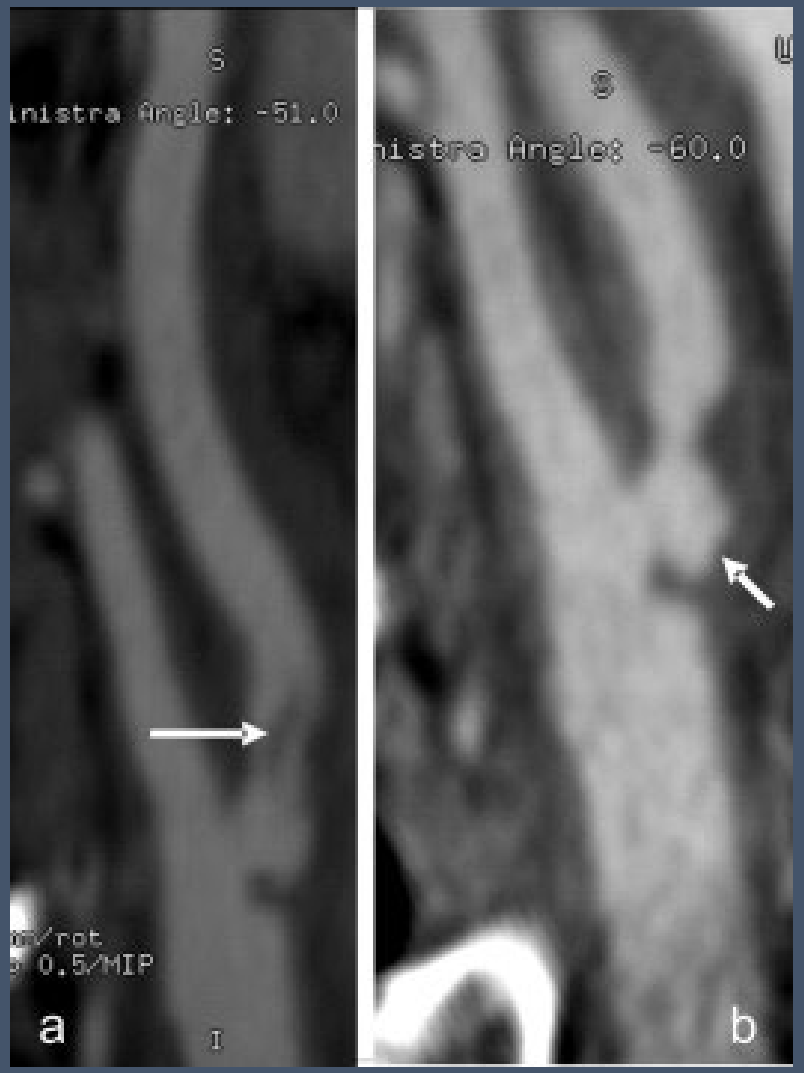
Anatomic Considerations – Aortic Arch

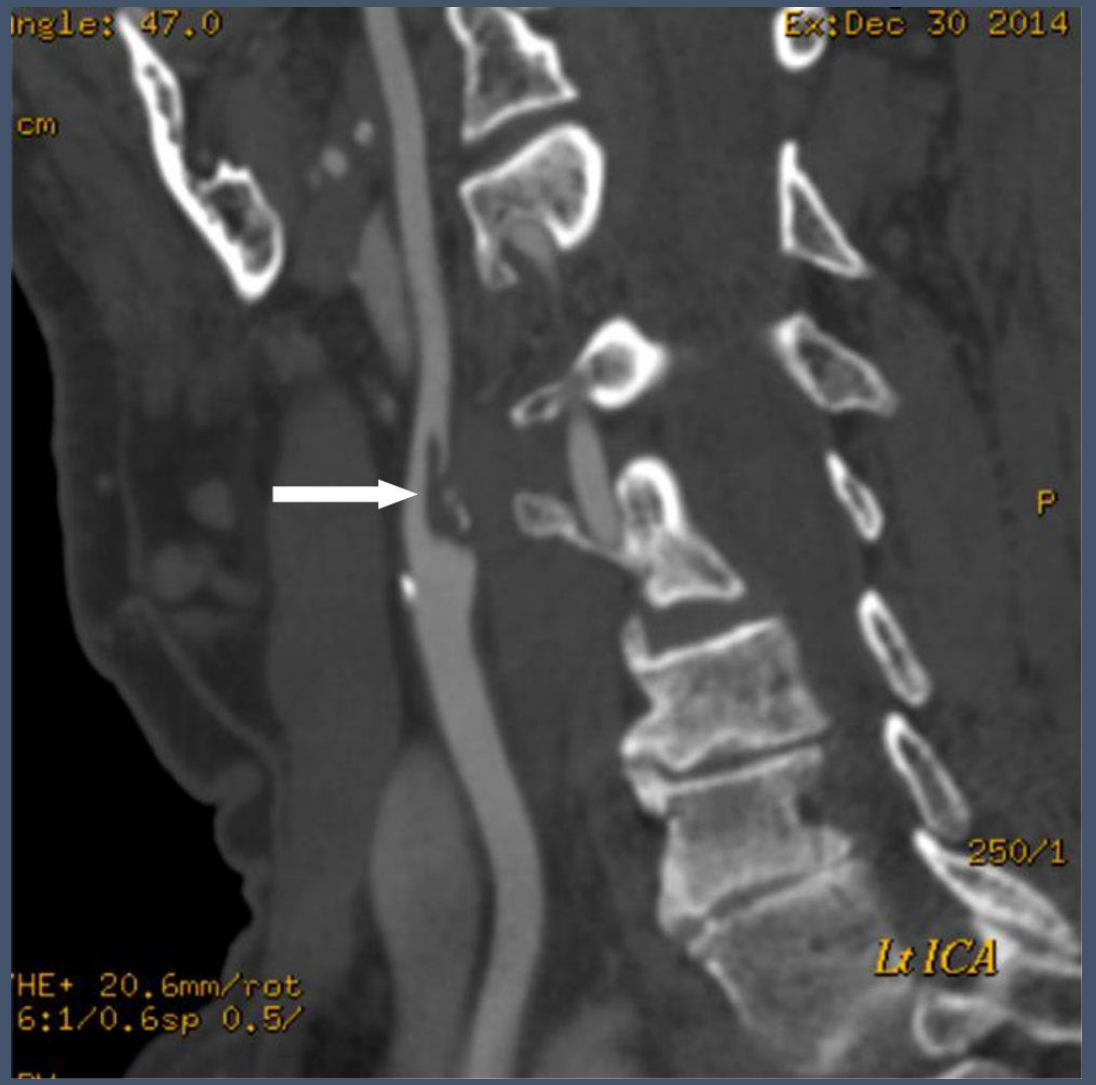




Anatomic Considerations – Carotid Morphology

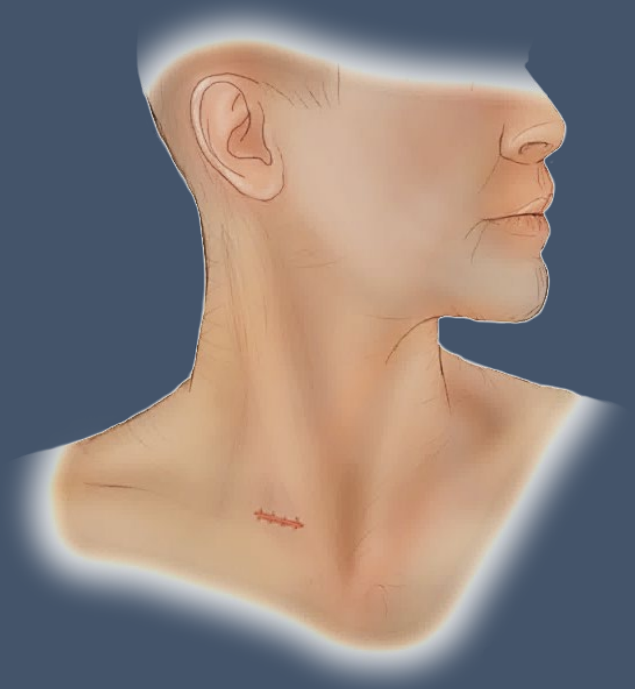
Anatomic Considerations – Plaque Morphology

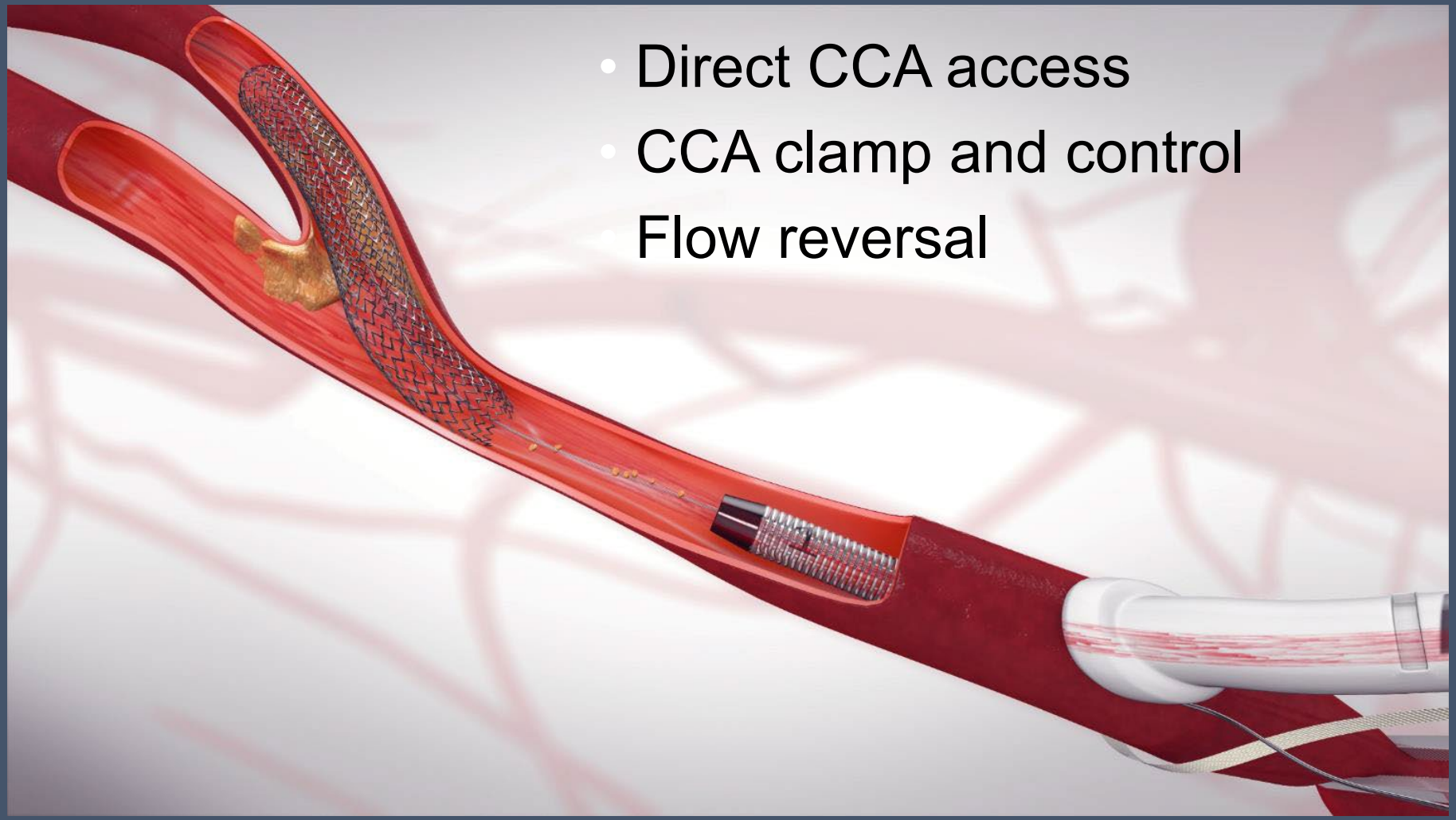




Transcarotid Artery Revascularization (TCAR)

A True Hybrid Procedure





- Direct CCA access
- CCA clamp and control
- Flow reversal

Dedicated TCAR Toolset

Access	Neuroprotection	Guidewires	Carotid Stent	Balloons
✓	✓	✓	✓	

ENROUTE® Transcarotid Stent System*

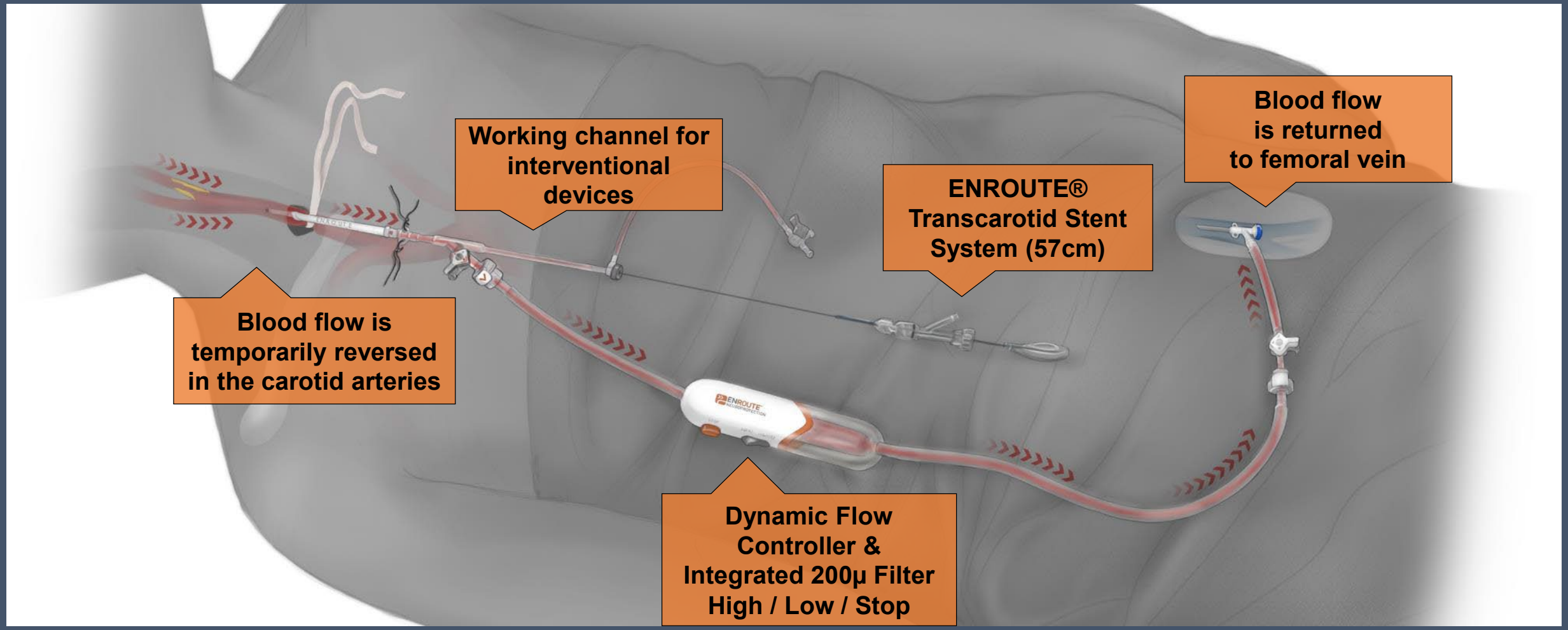
ENROUTE® 0.014" Guidewire

ENROUTE® Transcarotid Neuroprotection System*

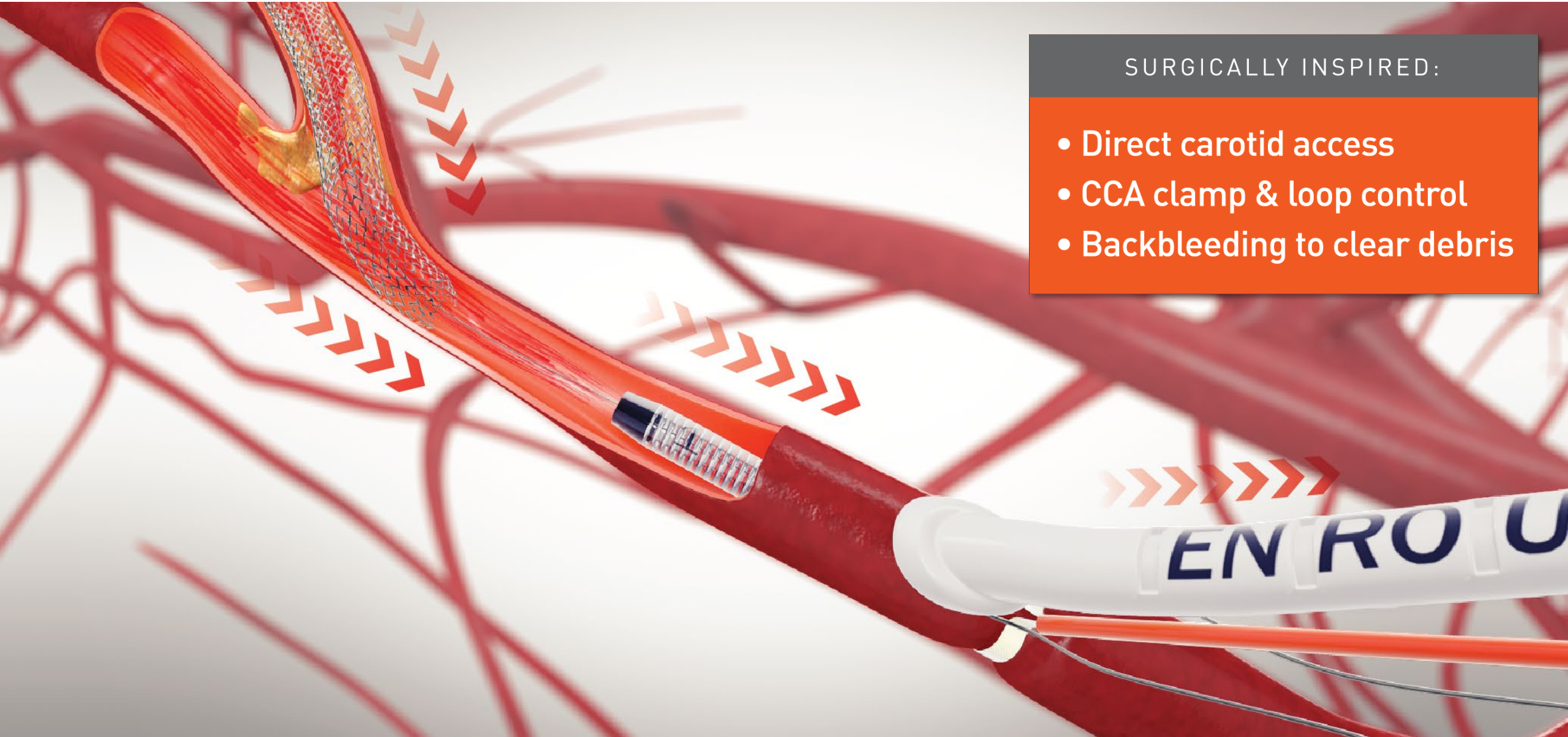
ENHANCE™ Transcarotid Peripheral Access Kit*

*FDA-approved Transcarotid Labeling for ENROUTE® Neuroprotection System, ENROUTE® Stent System and ENHANCE™ Access Kit

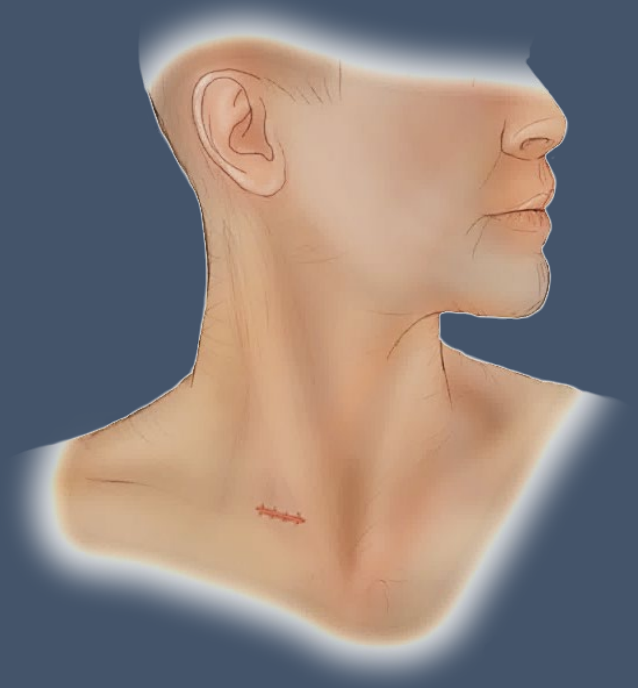
Enroute® Neuroprotection System



SURGICALLY INSPIRED CEA-LIKE NEUROPROTECTION

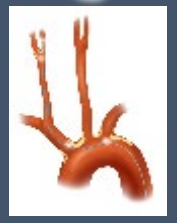


Advantages of TCAR

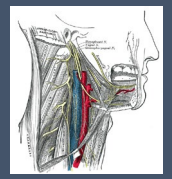


TCAR provides a hybrid approach:
transcarotid direct access to avoid arch
Robust reversal of flow for neuroprotection

Minimally Invasive



Avoids Aortic Arch



Avoids Cranial Nerve Plexus

High Rate Flow Reversal Neuroprotection

Accurate stenting

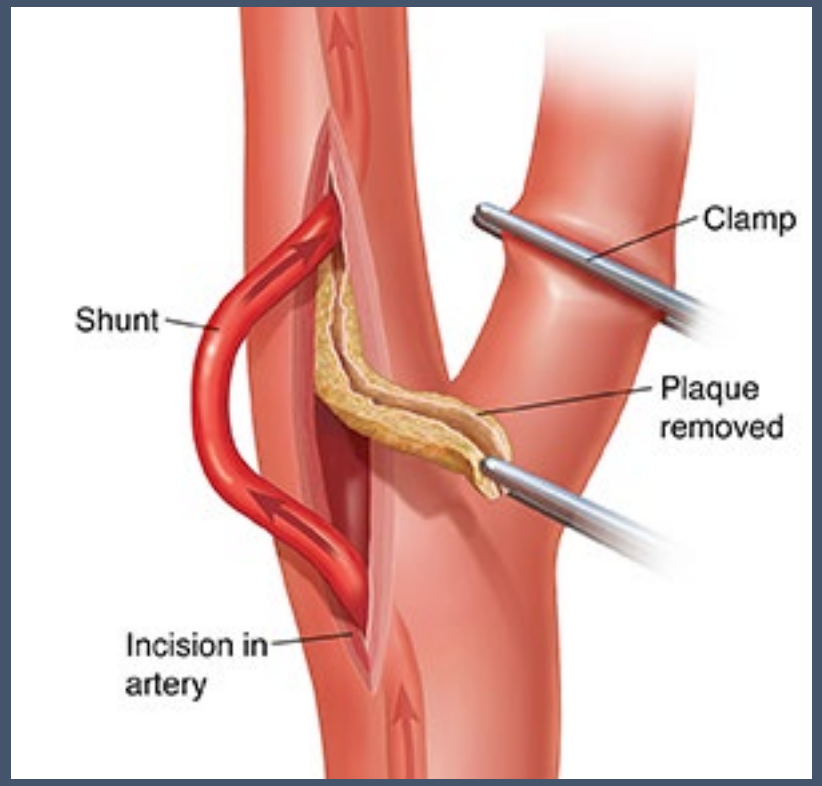
Criteria Required for TCAR Eligibility

- Adequate femoral venous access
- Common carotid artery diameter 6 mm
- Clavicle to bifurcation distance of 5 cm
- *Dual anti-platelet therapy* + *statin for 5 days before and 30 days after*
  - *Plavix resistance: prasugrel (Effient); ticagrelor (Brilinta)*

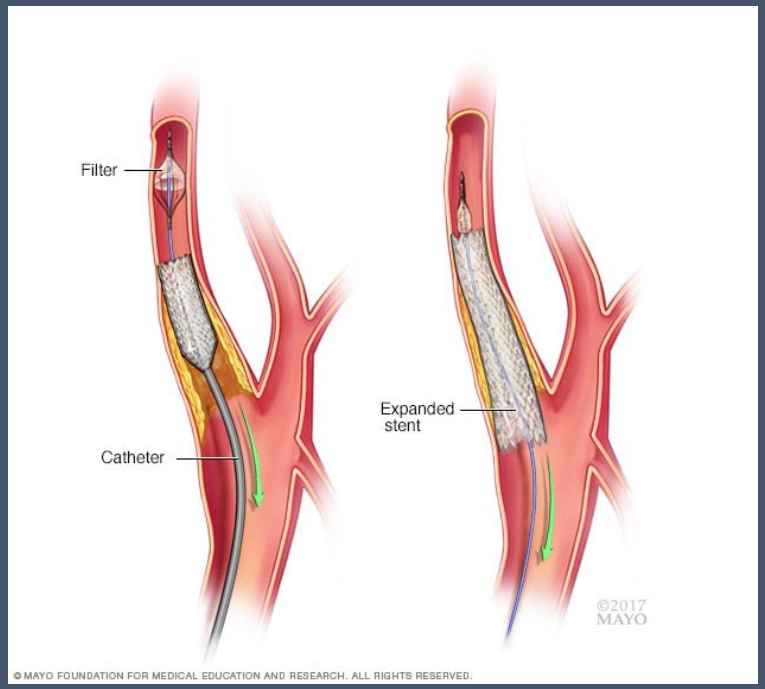
- Do not stent circumferential plaque

Decision Making

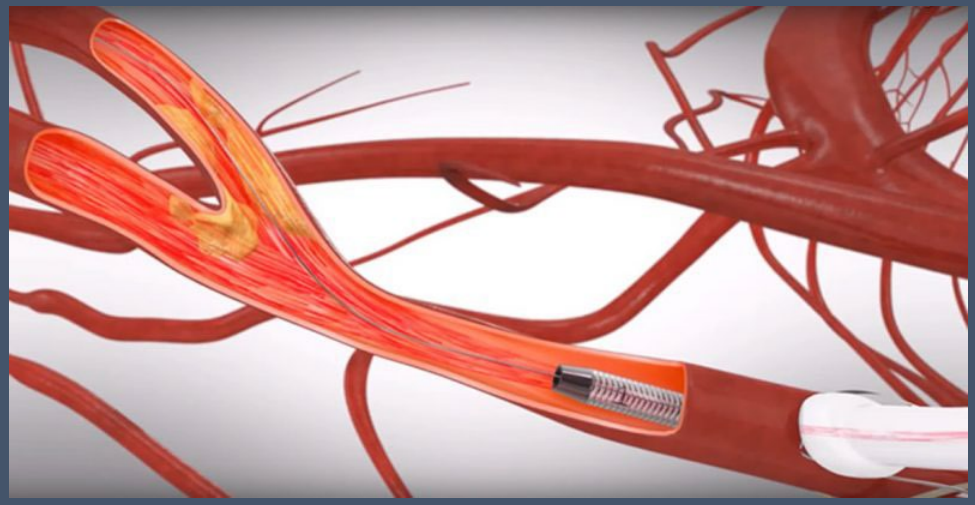
What Are the Options?



CEA



TF-CAS



TCAR

Factors That Influence Choice of Treatment

- Neurologic symptoms
- Hostile neck: radiation; prior surgery; tracheostomy
- High/low lesions: below the clavicle or above C2; tandem lesions.
- Vessel tortuosity: aortic arch or CCA tortuosity, arch athero
- Lesion character: high risk plaque more likely to embolize with TFCAS

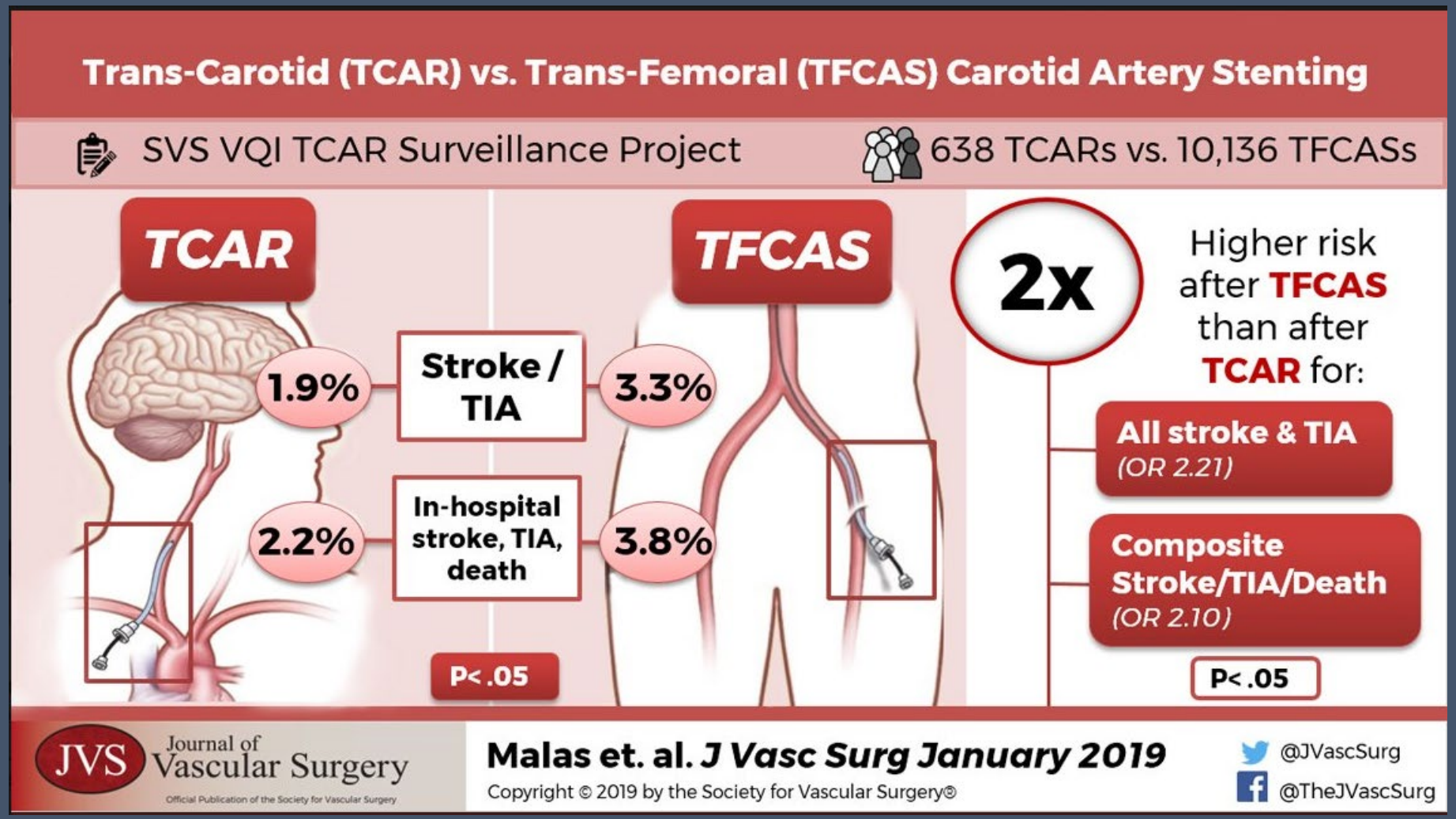
Endarterectomy vs Stenting: CREST + others

- Transfemoral carotid artery stenting:
  - 1.5 – 2 x increased post op stroke (especially in symptomatic and patients >70).
  - 55% reduction in rate of post op MI compared with CEA
    - Stroke results in lower quality of life than MI (per CREST)
  - No cranial nerve injury
  - No difference in mortality
  - No difference in rate of restenosis
- CEA is treatment of choice in “normal risk” pts who are fit for surgery.

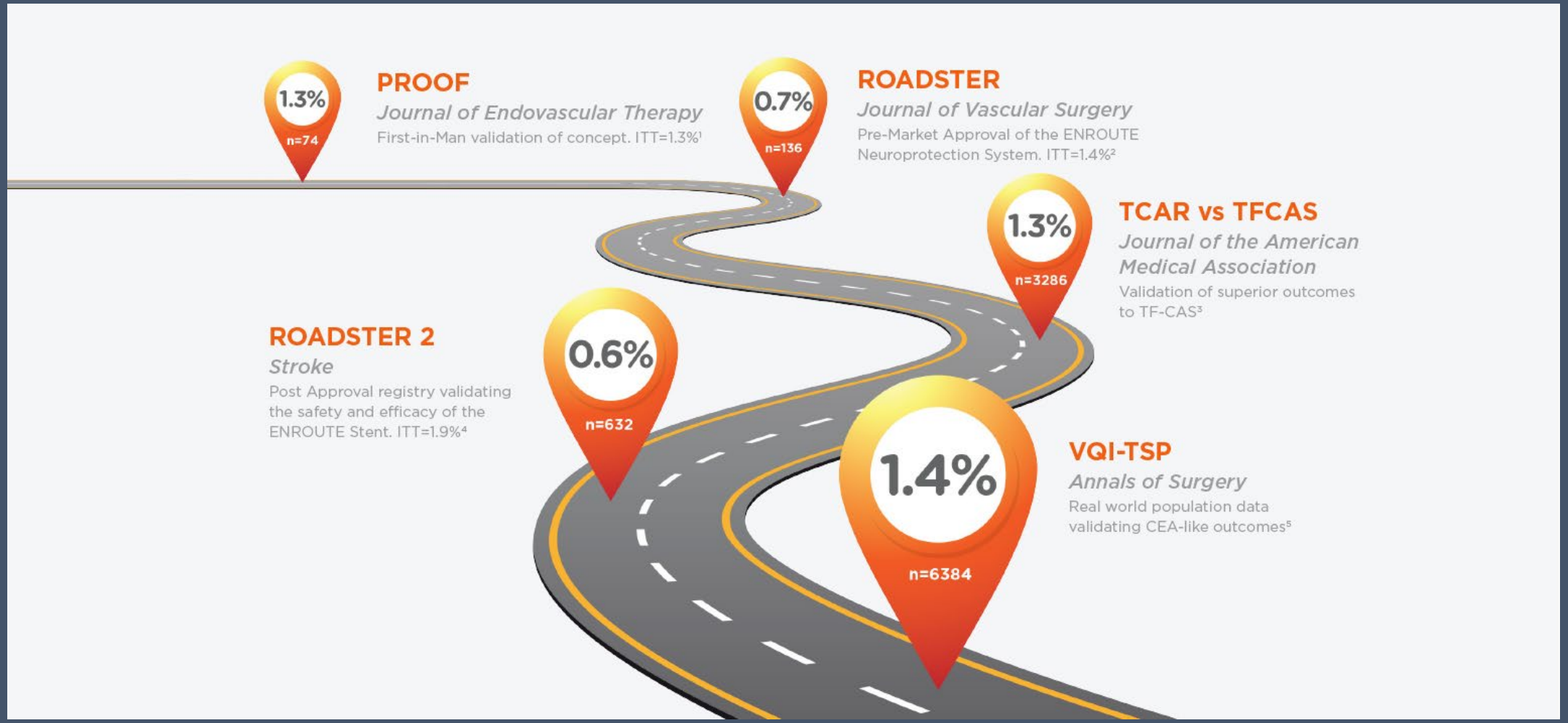
Endarterectomy vs Stenting: CREST + others

CAS with embolic protection is reasonable and necessary for the following:
1. Patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis ≥70%. Coverage is limited to procedures performed using US Food and Drug Administration (FDA)-approved carotid artery stenting systems and embolic protection devices.
2.Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation, as a routine cost under the clinical trials policy, or in accordance with the National Coverage Determination on CAS post approval studies.
3. Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80%, in accordance with the Category B IDE clinical trials regulation, as a routine cost under the clinical trials policy, or in accordance with the National Coverage Determination on CAS post approval studies.
Patients who are at high risk for CEA include those with any of the following: • CHF class III/IV • EF < 30% • Unstable angina • CCO* • Recent MI • Previous CEA • Radiation

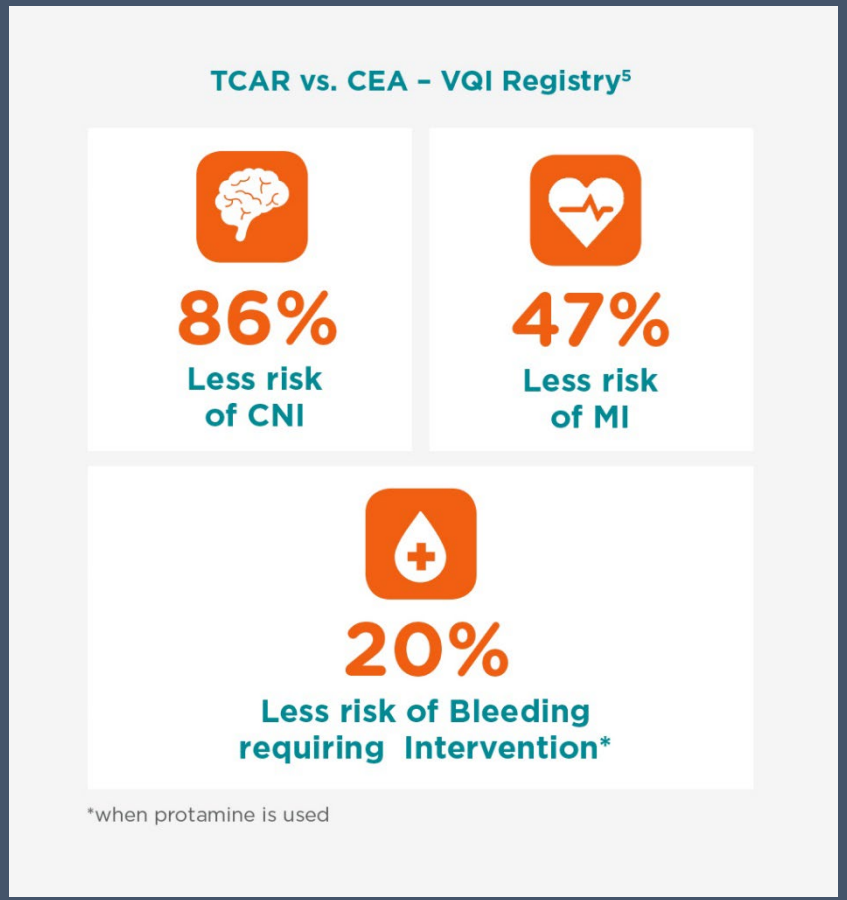
What about TCAR vs TF-CAS?



What about TCAR vs CEA?



What about TCAR vs CEA?



Modified High Risk Criteria

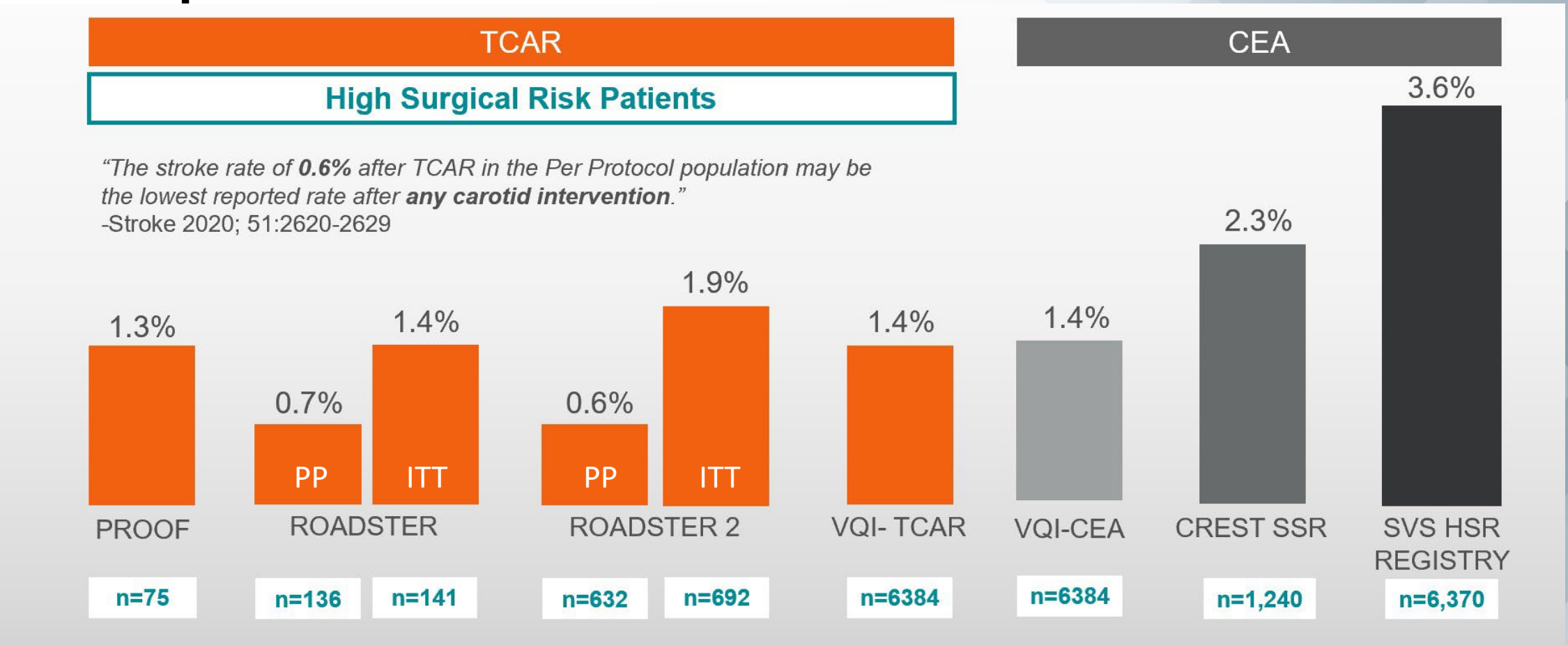
Comorbid conditions:

1. **Age ≥75**
2. Congestive Heart Failure
3. Left Ventricular Ejection Fraction ≤35%
4. Two or more diseased coronary arteries with ≥70% stenosis
5. Unstable angina
6. Myocardial infarction within 6 weeks
7. Abnormal stress test
8. Need for open heart surgery
9. Need for major surgery (including vascular)
10. Uncontrolled diabetes
11. Severe pulmonary disease
12. History of liver failure with elevated prothrombin time

Anatomic conditions

1. Prior head/neck surgery or irradiation
2. Spinal immobility
3. At risk for wound infection
4. Restenosis post CEA
5. Tracheostomy or tracheostoma
6. Surgically inaccessible lesion
7. Laryngeal palsy; Laryngectomy; Permanent contralateral cranial nerve injury
8. Contralateral occlusion
9. Severe tandem lesions
10. Bilateral stenosis requiring treatment
11. Dissection

Periprocedural Stroke Rates



PROOF: Alpaslan A, et al. Transcarotid Artery Revascularization With Flow Reversal. J Endovasc Ther. 2017 Apr;24(2):265-270.
ROADSTER: Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015 Nov;62(5):1227-34.
ROADSTER 2: . Kashyap VS, et al. ROADSTER 2 Investigators*. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020 Sep;51(9):2620-2629.
VQI: Malas MB, et al. TransCarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. 2020 Sep 15. doi: 10.1097/SLA.0000000000004496. Epub ahead of print.
CREST: Brott TG, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. N Engl J Med. 2010 Jul 1;363(1):11-23.
SVS Registry: Schermerhorn ML, 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.

ROADSTER Study

Prospective, Multi-Center, Single-Arm Trial of TCAR in High Surgical Risk Patients with Carotid Stenosis - *Pivotal Results*

- **DESIGN:** IDE study with OPC of 11% S/D/MI at 30 days
- **OBJECTIVE:** Evaluate safety and efficacy of TCAR Procedure with ENROUTE Transcarotid Neuroprotection System
  - Direct carotid access
  - High rate flow reversal
  - FDA-approved carotid stents
- **CONCLUSION:** The results of the ROADSTER trial demonstrate that the use of the ENROUTE Transcarotid NPS is safe and effective at preventing stroke during CAS.

Demographics and Technical Results

ROADSTER Pivotal ITT[1] (n=141)	ROADSTER (n=141)	CREST[2] CEA (n=1,240)
	High Surgical Risk	Standard Risk
Age (mean)	72.9 ±9	69.2 ±8.7
Age ≥75	**47%**	28.5%[3]
Female	35%	33.6%
Symptomatic	25.5%	52.7%
Local Anesthesia	**53%**	10.0%
Reverse Flow Time (median)	12.9 minutes	n/a

1. Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015 Nov;62(5):1227-34.
2. Brott TG, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. N Engl J Med. 2010 Jul 1;363(1):11-23.
3. Voeks JH, et al. Age and outcomes after carotid stenting and endarterectomy: the carotid revascularization endarterectomy versus stenting trial. Stroke. 2011 Dec;42(12):3484-90.
4. Gray WA, et al. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel meeting on the ACCULINK and ACCUNET Carotid Artery Stent System. Circulation. 2012 May 8;125(18):2256-64.

ROADSTER Study

Prospective, Multi-Center, Single-Arm Trial of TCAR in High Surgical Risk Patients with Carotid Stenosis - *Pivotal Results*

Clinical Results			
ROADSTER[1]	**PP (n=136)**	**ITT (n=141)**	**CREST[2] CEA**
	High Surgical Risk	**High Surgical Risk**	**Standard Risk**
S/D/MI*	2.9%	3.5%	4.5%
Stroke	**0.7%**	**1.4%**	2.3%
Death	1.5%	1.4%	0.3%
MI	0.7%	0.7%	2.3%
Stroke/Death	**2.2%**	**2.8%**	2.6%
Cranial Nerve Injury (CNI)	0.7%	0.7%	5.3%
CNI Unresolved 6 Months	0%	0%	**2.1%**[4]

*Hierarchical

Primary Endpoint

All stroke, MI & death at 30-days

1. Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015 Nov;62(5):1227-34.
2. Brott TG, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. N Engl J Med. 2010 Jul 1;363(1):11-23.

ROADSTER 2 Study

Post-Approval Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease

- **DESIGN:** Prospective, single arm, multicenter, post-approval study
- **OBJECTIVE:** Evaluate safety and efficacy of the TCAR Procedure with the ENROUTE Stent when used with the ENROUTE NPS and performed by a broad group of physicians with variable TCAR experience
- **CONCLUSION:** TCAR is a safe and effective procedure in a **broad user base** with varying TCAR experience levels. Excellent outcomes are achievable if you follow the protocol and society guidelines.

Demographics and Technical Results

ROADSTER 2	PP (n=632)	ITT (n=692)
Age ≥80	21.2%	21.1%
Age ≥75	41.8%	42.1%
Female	32.3%	32.2%
Symptomatic	26.3%	26%
Local Anesthesia	28.3%	28.3%
Reverse Flow Time (median)	10.9 minutes	11 minutes

Kashyap VS, et al. ROADSTER 2 Investigators*. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020 Sep;51(9):2620-2629.

ROADSTER 2 Study

Post-Approval Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease – V. Kashyap MD; Stroke 2020

Clinical Results		
ROADSTER 2	**PP (n=632)**	**ITT (n=692)**
Procedural Success	**97.9%**	**96.5%**
S/D/MI*	1.7%	3.2%
Stroke	**0.6%**	**1.9%**
Death**	0.2%	0.4%
MI	0.9%	0.9%
Stroke/Death	**0.8%**	**2.3%**
Cranial Nerve Injury***	1.3%	1.4%

*Hierarchical
**One patient expired ~2 weeks post-procedure due to ruptured AAA
***Out of the 10 patients with CNI, 6 consented to an extended follow-up at 90 days. The CNI resolved in all 6 of those patients.

0.6%

Stroke Rate in the FDA Analysis Population (PP)

81% of Physicians were New to TCAR

Excellent Outcomes Achievable with Adherence to Protocol

ROADSTER 2: . Kashyap VS, et al. ROADSTER 2 Investigators*. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020 Sep;51(9):2620-2629.

ROADSTER 1 vs ROADSTER 2

When the results from both population groups are compared between ROADSTER 1 and ROADSTER 2, we see that the data is **statistically equivalent**.

PER PROTOCOL

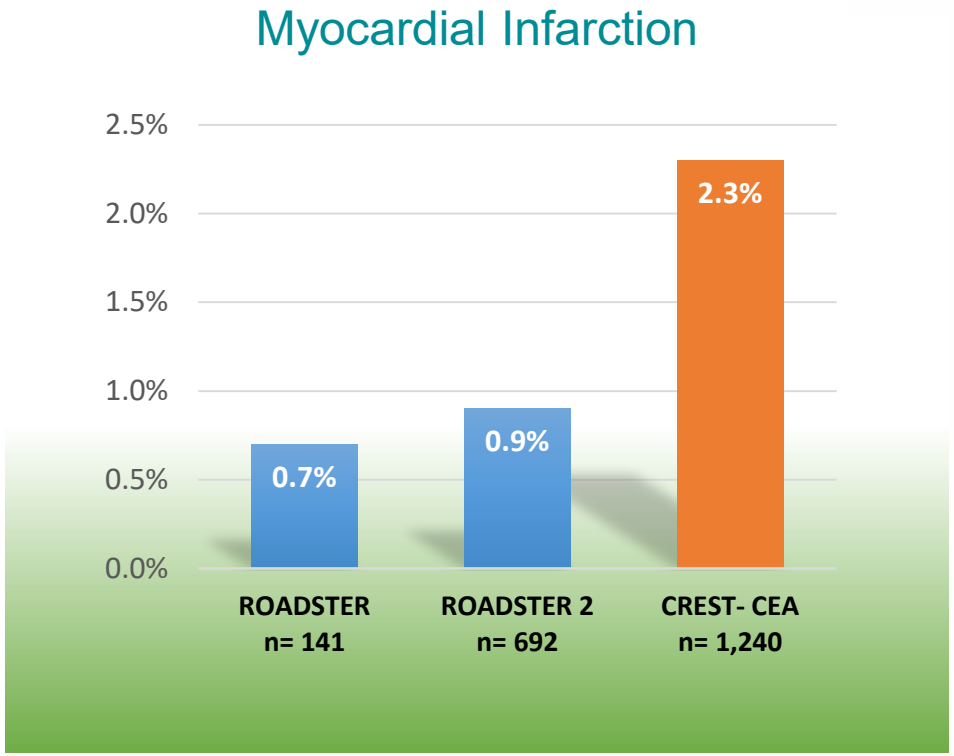
	R1 Pivotal Only n=136	R1 Pivotal + Continued Access n=203	R2 n=632	P Value
S/D/MI*	2.9%	2.5%	1.7%	0.27
Stroke	0.7%	0.5%	0.6%	1.00
Death**	1.5%	1.0%	0.2%	0.15
MI	0.7%	1.5%	0.9%	0.46
Stroke/Death	2.2%	1.5%	0.8%	0.41

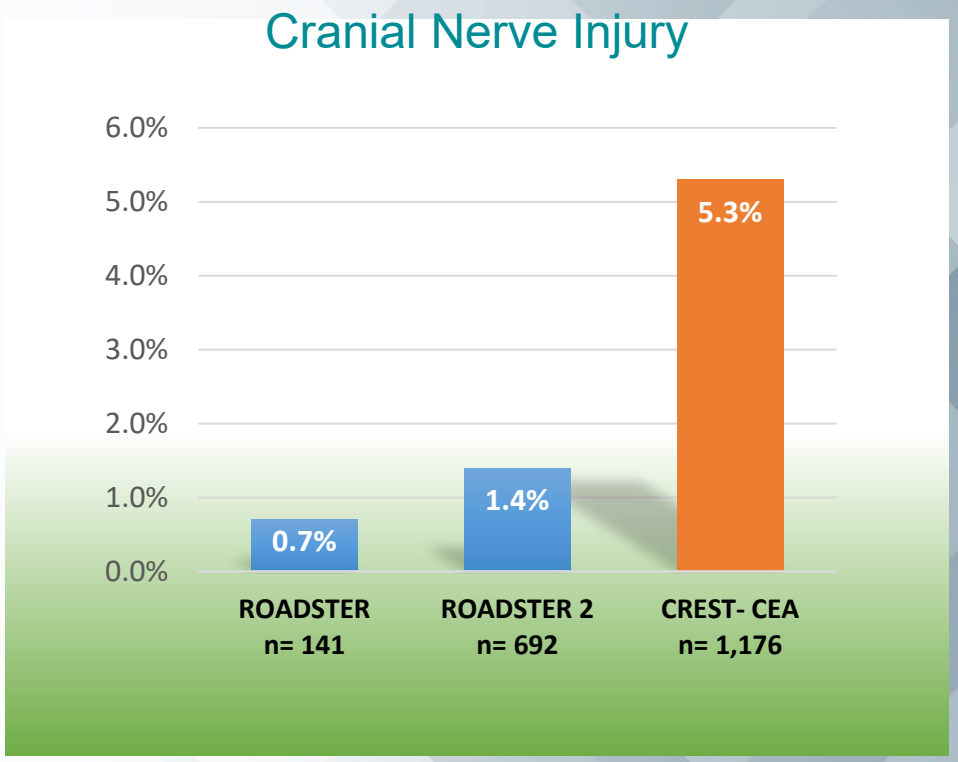
INTENT TO TREAT

	R1 Pivotal Only n=141	R1 Pivotal + Continued Access n=219	R2 n=692	P Value
S/D/MI*	3.5%	3.7%	3.2%	0.67
Stroke	1.4%	1.4%	1.9%	0.77
Death**	1.4%	0.9%	0.4%	0.60
MI	0.7%	1.4%	0.9%	0.46
Stroke/Death	2.8%	2.3%	2.3%	1.00

ROADSTER: Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015 Nov;62(5):1227-34.
ROADSTER 2: . Kashyap VS, et al. ROADSTER 2 Investigators*. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020 Sep;51(9):2620-2629.

MI & CNI Rates: TCAR vs. CEA





ROADSTER: Kwolek, C. et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg 2015;62:1227-35.
ROADSTER 2: Kashyap, V. et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020;51:2620–2629.
CREST: Gray, W. et al. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel Meeting on the ACCULINK and ACCUNET Carotid Artery Stent System. Circulation. 2012;125:2256–2264.

TCAR vs TF-CAS in the VQI Database

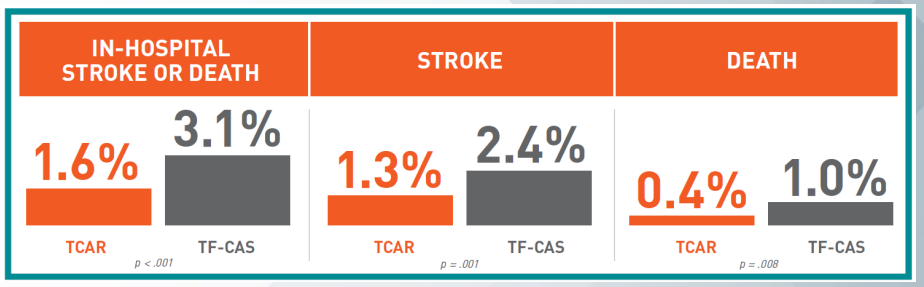
The authors reviewed patient data **(n = 3286** matched**)** collected from the VQI-TSP to compare outcomes of TCAR vs TF-CAS; published in the **Journal of the American Medical Association (JAMA)**.[1]

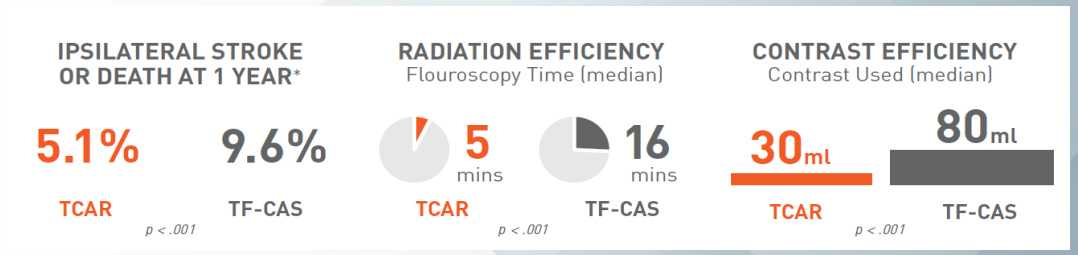
TCAR Safety

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).

1. . Schermerhorn ML, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis. JAMA. 2019 Dec 17;322(23):2313-2322.

THE EFFECTS OF TIMING ON CAROTID INTERVENTION IN SYMPTOMATIC PATIENTS

TCAR

Effects of Timing on In-hospital and One-year Outcomes after TransCarotid Artery Revascularization[1]

Journal of Vascular Surgery 2020

Objective: To study the impact of timing on outcomes after TransCarotid Artery Revascularization (TCAR).

Methods: Patient data from the VQI-TSP representing **2,608 TCARs** was stratified by time from symptom onset to procedure: urgent (TCAR within 48-hours), early (TCAR between 3-14 days after symptoms), and late (TCAR greater than 14 days after symptoms). The primary outcome was in-hospital rates of stroke/death and evaluated using logistic regression.

Results:	Urgent < 48 hours (n=144)	Early 3 - 14 days (n=928)	Late > 2 weeks (n=1536)	(P-Value)
Stroke	5.6%	2.5%	2.0%	P=0.03
Stroke/Death	6.5%	2.9%	2.3%	P=0.02
Ipsilateral Stroke at 1 year	0.7%	0.2%	0.1%	P=0.13
Ipsilateral Death at 1 year	0.7%	1.6%	1.8%	P=0.71

Conclusions: TCAR is safest in symptomatic patients when performed at least three-days after symptoms.

CEA and TF-CAS

Systematic Review and Meta-Analysis of Very Urgent Carotid Intervention for Symptomatic Carotid Disease[2]

European Journal of Vascular and Endovascular Surgery 2018

Objective: To investigate the impact of timing on outcomes of carotid endarterectomy (CEA) and transfemoral carotid artery stenting (TF-CAS).

Methods: A systematic literature review of 13 observational studies and randomized control trials (RCT) representing **5,385 CEA** and **366 TF-CAS** procedures stratified by time to procedure: very urgent (< 48 hours) and urgent (≥48 hours). Ipsilateral stroke and death were the primary outcome endpoints.

Results:	CEA Very Urgent < 48 hours (n=723)	CEA Urgent ≥ 48 hours (n=4662)	Significance (P-Value)	TF-CAS Very Urgent < 48 hours (n=39)	TF-CAS Urgent ≥ 48 hours (n=327)	(P-Value)
Stroke	6.9%	3.1%	P<0.001	0%	4.2%	P=0.47
Death	1.6%	1.2%	P=0.25	1.6%	1.2%	P=0.46

Conclusions: Very urgent carotid intervention (within 48 hours) is significantly associated with increased risk of stroke.

≥48 hrs = 

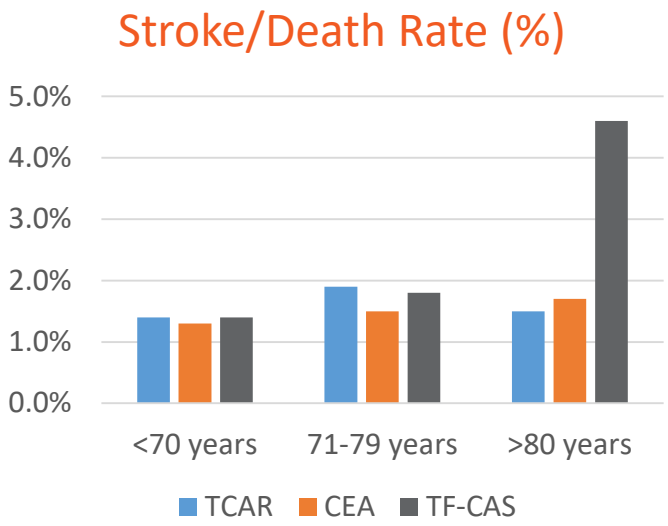
The TCAR stroke rate of **2.5%** in the **Early** group is one of the lowest published rates for treatment between 48 hours and 2 weeks

<48 hrs = 

Multiple studies conclude that symptomatic patients receiving **any** carotid intervention within 48 hours have higher risk of stroke

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 Sep;72(3):931-942.e2

PROOF Study

TCAR – First in Man Experience

PROOF Study Safety Results[1,2]	Result (n=75)
Subjects completing 30-day follow-up	71 (94.7%)
Primary Endpoint: Composite of any major stroke, myocardial infarction and death from the index procedure through the 30-day post-procedural period	0/71 (0%)
Minor stroke *Minor contralateral stroke adjudicated as not device or procedure-related*	1/71 (1.3%)
Cranial nerve injury (Hoarseness)	2/71 (2.7%)

Study	Procedure	Embolic Protection	Patients	% w/ New DW-MRI Lesions
ICSS[3]	CEA	Clamp, backbleed	107	17%
PROOF[2]	**TCAR**	**Proximal Flow Reversal**	**56**	23% **(18% Ipsilateral)**
PROFI[4]	Transfemoral CAS	Proximal occlusion (MoMA)	31	45%
ICSS[3]	Transfemoral CAS	Distal filter (various)	51	73%
PROFI[4]	Transfemoral CAS	Distal filter (Emboshield)	31	87%

[1] Pinter L, et al. Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF Study. J Vasc Surg. 2011 Nov;54(5):1317-23.
[2] Alpaslan A, et al. Transcarotid Artery Revascularization With Flow Reversal. J Endovasc Ther. 2017 Apr;24(2):265-270.
[3] Bonati LH, 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). Lancet Neurol. 2010 Apr;9(4):353-62.
[4] Bijuklic K, et al. The PROFI study (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting): a prospective randomized trial. J Am Coll Cardiol. 2012 Apr 10;59(15):1383-9.

TCAR vs CEA Embolization Rates

- 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

Plessers M, et al. Transcervical Carotid Stenting With Dynamic Flow Reversal Demonstrates Embolization Rates Comparable to Carotid Endarterectomy. J Endovasc Ther. 2016 Apr;23(2):249-54.

ASSOCIATION OF ADOPTION OF TRANSCAROTID ARTERY REVASCULARIZATION WITH CENTER-LEVEL PERIOPERATIVE OUTCOMES

Clinical Summary Sheet

JAMA Open Network 2021; Feb 1;4(2):e2037885. doi: 10.1001/jamanetworkopen.2020.37885; Columbo JA, Martinez-Camblor P, O'Malley AJ, Stone DH, Kashyap VS, Powell RJ, Schermerhorn ML, Malas M, Nolan BW, Goodney PP.

Objective: To determine the center-level association of TCAR adoption with overall perioperative outcomes for TCAR and CEA combined at centers performing both procedures.

Methods: Retrospective data from the Vascular Quality Initiative (VQI) from over 400 centers in North America who underwent **TCAR (n= 7,664)** and **CEA (n=78,363)** for carotid artery stenosis (2015-2019) were included in the comparative analysis. The rate of major adverse cardiovascular events (MACE), a composite of in-hospital stroke, myocardial infarction, or death at 30 days, was measured.

Findings: The number of centers performing both TCAR and CEA increased from 15 centers in 2015 to 247 centers in 2019, a more than 16-fold increase. **The proportion of all carotid procedures that were TCARs increased from 90 of 12,276 (0.7%) in 2015 to 2718 of 15 956 (17.0%) in 2019, a 24-fold increase.** Overall, the crude rate of MACE was similar for TCAR and CEA (178 patients [2.3%] after TCAR vs 1842 patients [2.4%] after CEA; P = .91). However, the rate of MACE over time decreased for CEA (406 of 16,404 patients [2.5%] in 2015 vs 189 of 10,097 patients [1.9%] in 2019; P for trend < .001). The rate of MACE over time decreased for TCAR as well, but the change was not statistically significant (4 of 128 patients [3.1%] in 2016 vs 59 of 2718 patients [2.2%] in 2019; P for trend = .07). Difference-in-difference analysis demonstrated that **centers that adopted TCAR had a 10% decrease in the likelihood of MACE at 12 months after TCAR adoption vs if those centers had continued to perform CEA alone** (odds ratio, 0.90; 95%CI, 0.81-0.99; P = .04).

Conclusions: This study of patients who underwent TCAR or CEA found that **availability of TCAR at a hospital was associated with a decrease in the likelihood of perioperative MACE after carotid revascularization.**

Case Presentations

Case 1

- 86F hx of HTN and PVD
- Presented with crescendo TIAs
  - L facial droop
  - L foot weakness
  - L arm weakness
- CTA →
- Loaded with DAPT
- OR urgently for R TCAR

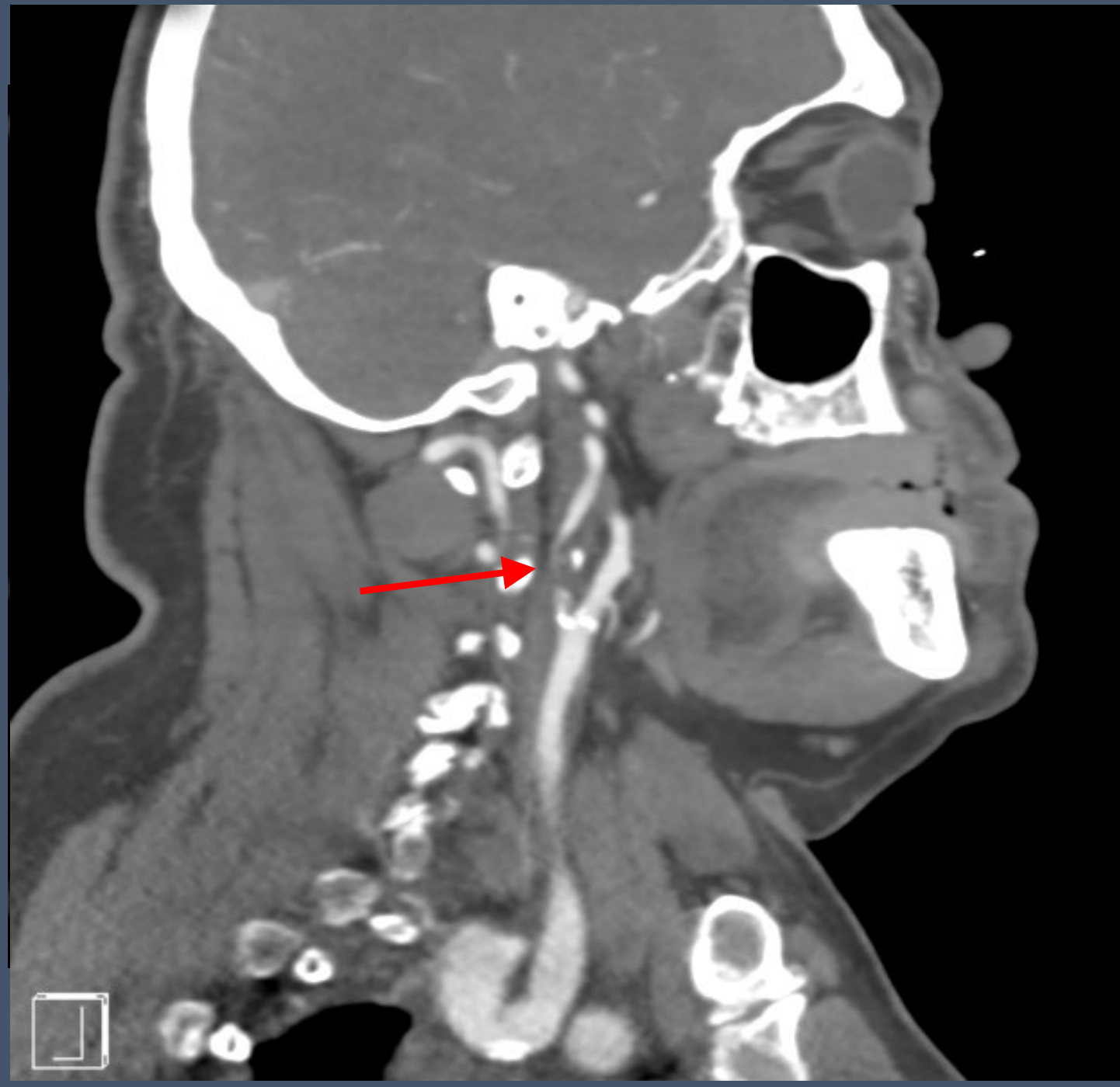

Contrast B
65.

Case 1

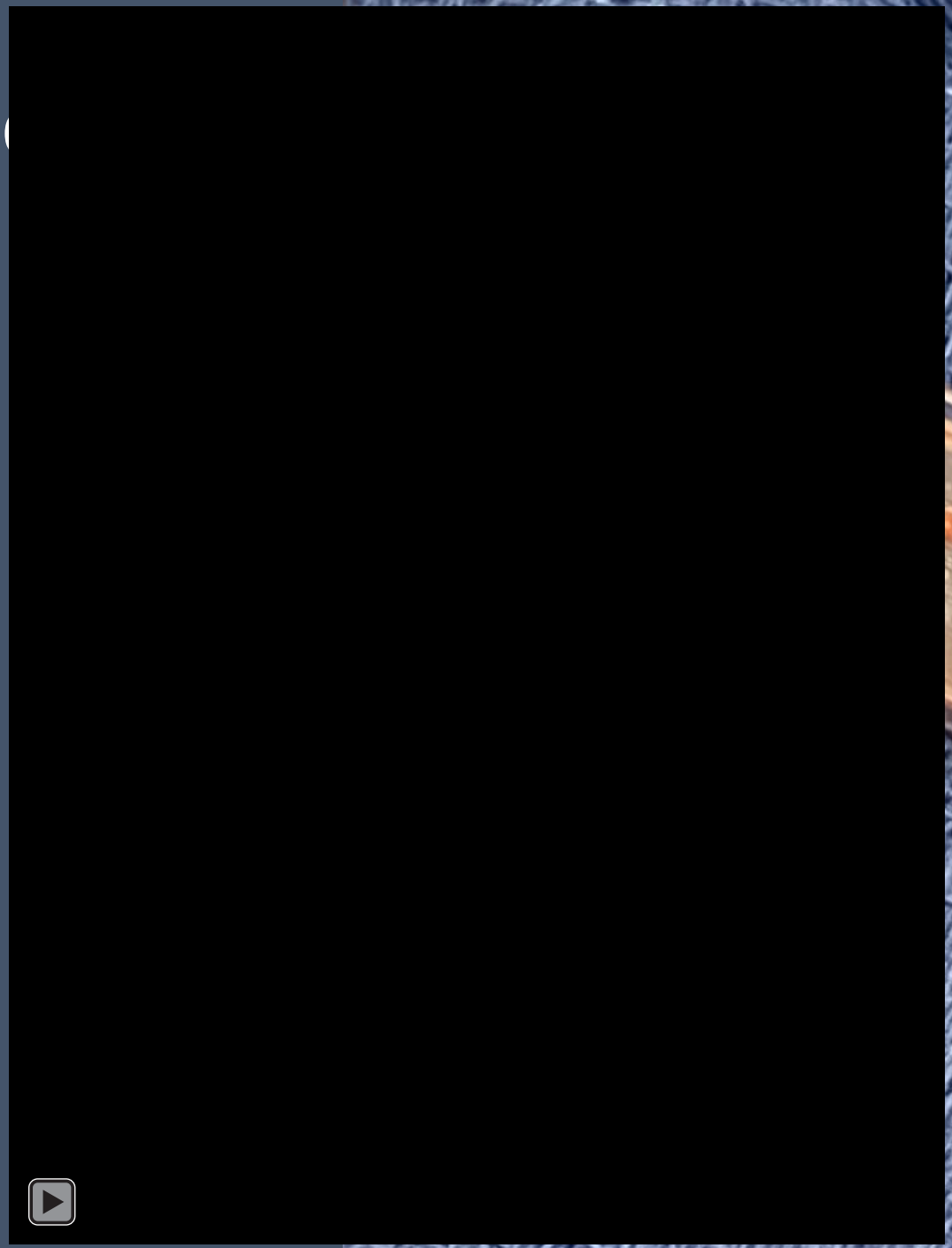
- Discharged home POD1
- One year follow up:
  - No stroke/TIA symptoms
  - Carotid stent widely patent

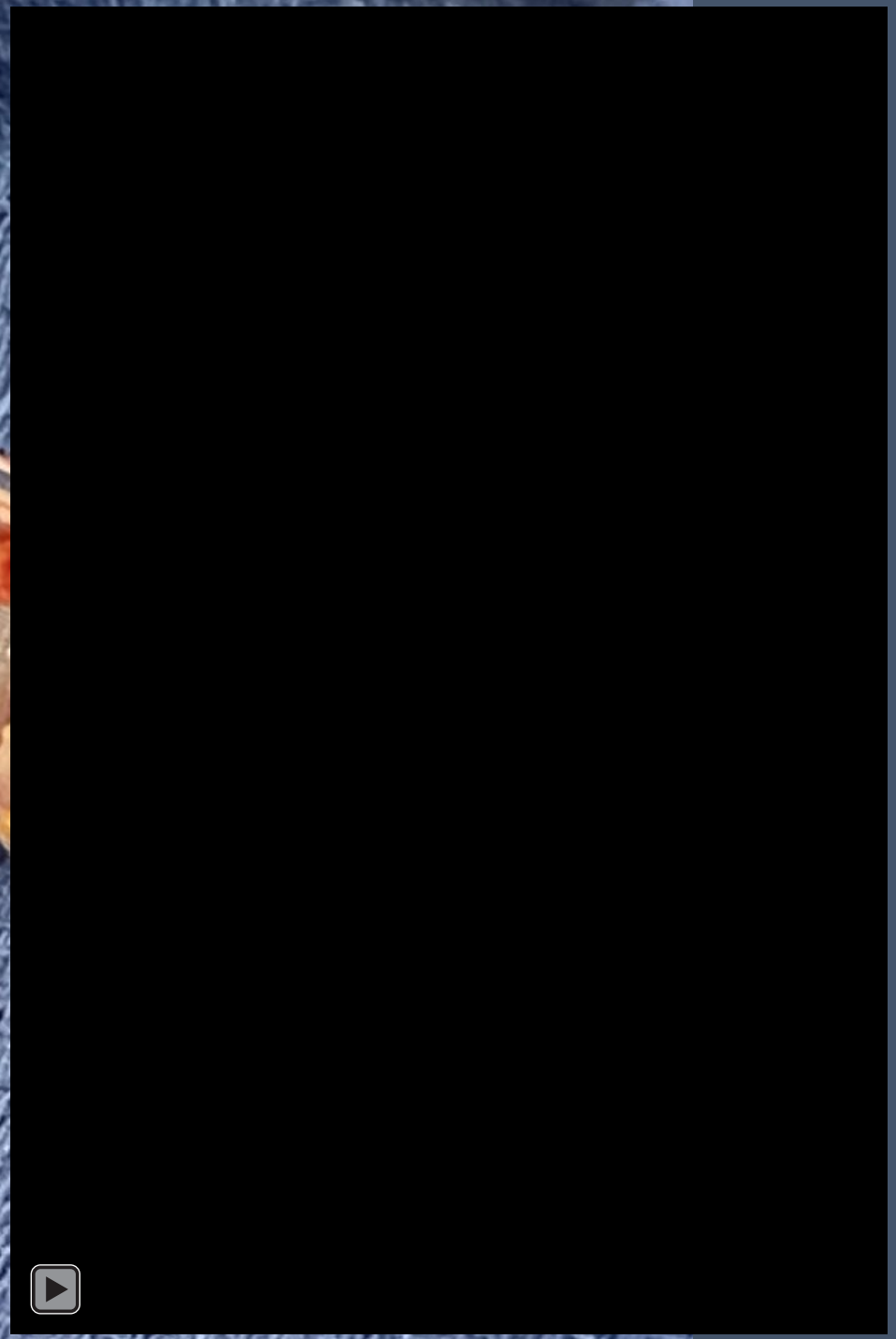
Case 2

- 66M HTN, HLD, DM, obesity
- Presented with left arm weakness
- MRI: acute right frontal CVA
- CTA →
- Loaded with DAPT
- OR urgently for TCAR



Cas





Case 2

- Discharged POD1
- Six month follow up:
  - No stroke/TIA symptoms
  - Widely patent carotid stent

Incontrovertible Conclusions (for now)

- TCAR is superior to TF-CAS
- CEA is preferred to CAS/TCAR for symptomatic > 50% unless high risk
- Symptomatic >50% and high risk for CEA should have TCAR
- In good-risk pts (3-5 years) with asymptomatic stenosis >60%, CEA can be offered as long as combined stroke/death rate is <3%

Questions/comments?

"The tragedies of life are largely arterial."
– Sir William Osler

CCFMG
Central California Faculty Medical Group

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In affiliation with UCSF Fresno

Thank You!

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