2023 MID-ATLANTIC CONFERENCE

11th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2023

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How to Discuss Surgical Risk to Patients Who Need Carotid Revascularization:

Risk Stratification and Surgical Options

Kimberly Seal, DO

April 21, 2023

- No disclosures

- Why we operate
- Medical options
- Surgical options
- Risk of intraoperative complications
- Follow up

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MEDICAL DECISION MAKING

BMT
Risk Factors
Stroke Risk

INTERVENTION

Selection
Indications

TECHNIQUE

Exposures
Difficult Lesions
Complications

FOLLOW UP

Medications
Imagin

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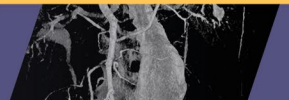
MEDICAL DECISION MAKING

BMT

Risk Factors

Stroke Risk



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Medical Decision Making

- Patients with extracranial carotid stenosis have increased overall risk of **cardiovascular events**.
  - Only ~20% of ischemic strokes are due to carotid disease.
  - About 15% of strokes are preceded by a TIA.

Medical Therapy

- Best Medical Therapy (BMT)
  - Risk factor modification
    - HTN - JNC8 guidelines.
    - Diabetic control - A1c < 7%.
    - Antiplatelet therapy - typically aspirin therapy.
    - High intensity statin therapy:
      - Lipitor (40 or 80mg) or Crestor (20 or 40mg)
    - Smoking cessation

Treatment	Goal	Comments
Antiplatelet therapy	Either single or dual drug acceptable	Reduces both stroke rate and overall MACEs
Antihypertensive therapy	Decrease BP by 10 mm Hg systolic 5 mm Hg diastolic or to 140/90 mm Hg with 130/90 mm Hg for recent lacunarin hypertensive patients	Reduces stroke recurrence Treat all patients regardless of baseline BP, after first 24 h
Diabetes mellitus	Aim for $HgbA_{1c}$ <7	Reduce overall stroke rate, no benefit in tight control
Smoking cessation	Total abstinence	Reduces stroke and MACEs
Statin therapy	Reduce LDL by 50% or <70 mg/dL	Treat hyperlipidemia and normolipemic patients with H/O stroke, may be beneficial before CEA/CAS
Alcohol	Avoid excessive consumption	

Medical Therapy

Risk factor modification:

- HTN
  - Exception: aggressive reduction in first 24 hrs after acute stroke should be avoided to optimize cerebral perfusion pressure.
- Diabetic control
  - Optimal control is <7% A1c.
  - Several studies have shown “tighter” control with <6.5% or <6% has no benefit and may be associated with adverse effects.

Medical Therapy

Risk factor modification:

- Statin therapy
  - Many meta-analyses have shown reduction of stroke risk with LDL < 70.
  - SPARCL trial:
    - Lipitor 80 mg decreased stroke risk and overall cardiovascular event rates.
    - Increased risk of hemorrhagic stroke.
- Smoking/alcohol cessation
  - Any smoking and excessive alcohol consumption elevates risk.

Medical Therapy

Risk factor modification:

- Antiplatelet therapy
  - **CAPRIE** trial: showed statistically significant benefit of Plavix over aspirin, but may not be clinically beneficial (cost).
  - **MATCH** trial: no benefit of DAPT but did increase bleeding risk.
  - **CHARISMA** trial: no difference between monotherapy and DAPT.
- Metabolic Syndrome
  - Increased waist circumference, triglycerides >150, HDL <50 (<40), fasting BGL >100, and BP above 135/85.
  - Results in increased insulin resistance and risk for adverse cardiovascular events.

INTERVENTION

Selection

Indications




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Surgical Options

- Carotid endarterectomy (CEA)
- Transfemoral carotid artery stent (CAS)
- Transcarotid artery revascularization (TCAR)

Why operate?

- Prevention of stroke or further embolic events
  - Symptomatic:
    - Disruption of plaque with embolic phenomenon
    - Includes both strokes and TIAs
  - Asymptomatic:
    - Quiescent plaques that may progress to ”unstable” plaques

Trial Results

Study	Population	Stroke Rate BMT	Stroke Rate BMT + CEA	Notes
NASCET	Sx ≥70%	2 yr: 26% 5 yr: 28%	2 yr: 9% 5 yr: 13%	CEA is beneficial for Sx ≥70%
NASCET	Sx ≥50-69%	2 yr: 15% 5 yr: 22.2%	2 yr: 9% 5 yr: 15.7%	CEA is beneficial for Sx ≥50%
ECST	Sx 80-99% (60-99% by NASCET)	3 yr: 20.6%	3 yr: 6.8%	CEA is beneficial for Sx ≥60%
ACAS	ASx ≥60%	5 yr: 11%	5 yr: 5.1%	CEA is beneficial for ASx ≥60%
ACST	ASx ≥60%	5 yr: 11.8%	5 yr: 6.4%	CEA is beneficial for ASx ≥60, benefit lasts >10 years

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When to operate?

- Asymptomatic – electively
- Symptomatic
  - Depends on neurological deficits (based on NIH scale), cerebral hemorrhage, and <30% hemisphere involvement of stroke.
  - Larger strokes (clinically, MRI) are more likely to suffer hemorrhagic transformation and less likely to be improved by early intervention.
  - **Early intervention** warranted for patients with **crescendo TIA or stroke in evolution** (waxing and waning neurologic events) due to highly unstable plaque vs compromised intracranial collateral circulation

Who Benefits?

- Increasing age
  - ARR in ipsilateral stroke at 5 years conferred by CEA in patients with 50-99% stenosis
    - Age <65: 5.6%
    - Age 65-75: 8.6%
    - Age >75: 19.2%
  - NASCET
    - ARR in ipsilateral stroke at 2 years in age >75 with 70-99% stenosis was 28.9%

Who Benefits?

- Patient sex
  - Males see greater benefit than females (ARR of 11% vs 2.8%)
- Presenting symptoms
  - ARR at 5 years with CEA
    - Stroke – 18%
    - TIA – 15%
    - Retinal ischemic sx – 5%
- Comorbidities
  - Number of risk factors had no influence on CEA outcomes

Operative Considerations

- Life expectancy:
  - NASCET, ECST, ACAS all enrolled patients w/ 5 yrs life expectancy.
    - Sx studies showed events occurred within 1-3 months of initial onset.
    - ASx studies showed decreased rates at 5 years.

- Functional status:
  - Baseline level of function sufficient that a further event would result in serious deterioration in functional/cognitive ability.
  - Informed consent becomes very important for patients with dense hemispheric deficits who may not benefit from further intervention, or patients with mild/moderate dementia or functional limitations.

Operative Considerations

- Cardiac status:
  - Up to 50% of patients who undergo CEA have CAD
  - 2014 AHA Guidelines
    - Consider CEA in selected asymptomatic patients who have a 70-99% stenosis if risk of perioperative stroke/MI or death is <3%
  - In Sx patients, clinical risk assessment alone is sufficient:
    - Stress testing reserved for active angina, new EKG changes, new CHF.
  - In ASx patients, a full cardiac risk stratification including evaluation for subclinical CAD should be strongly considered.

- Renal Insufficiency:
  - Moderate/severe CKD reduces life expectancy and is associated with increased complication rates after CEA and CAS.
  - Worsens plaque stability and is an independent risk factor for stroke.

TECHNIQUE

- CEA
- CAS
- TCAR

Exposure

Difficult Lesions

Complications

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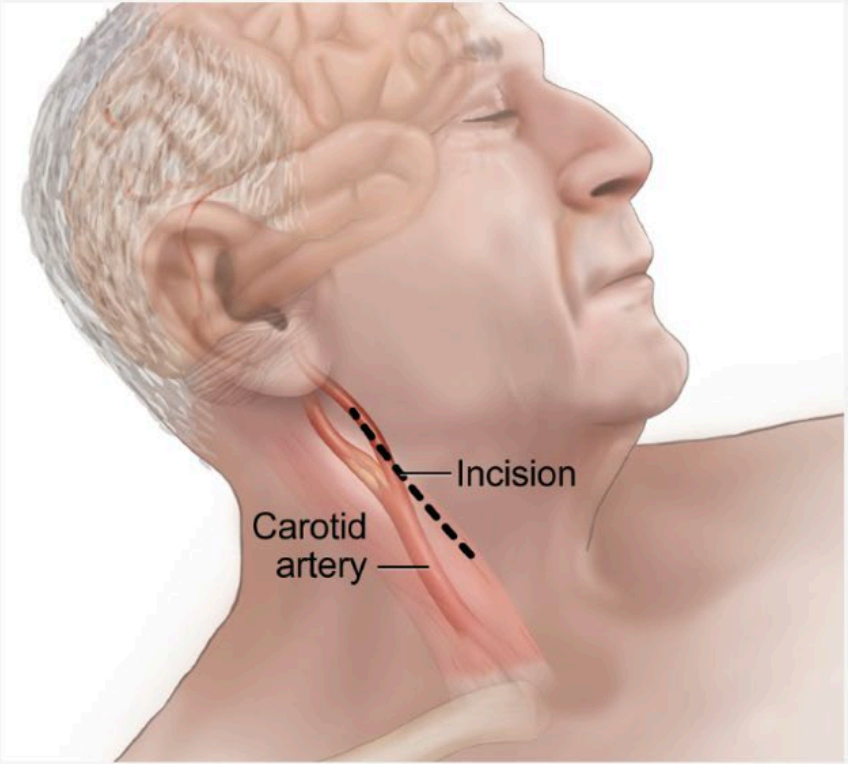
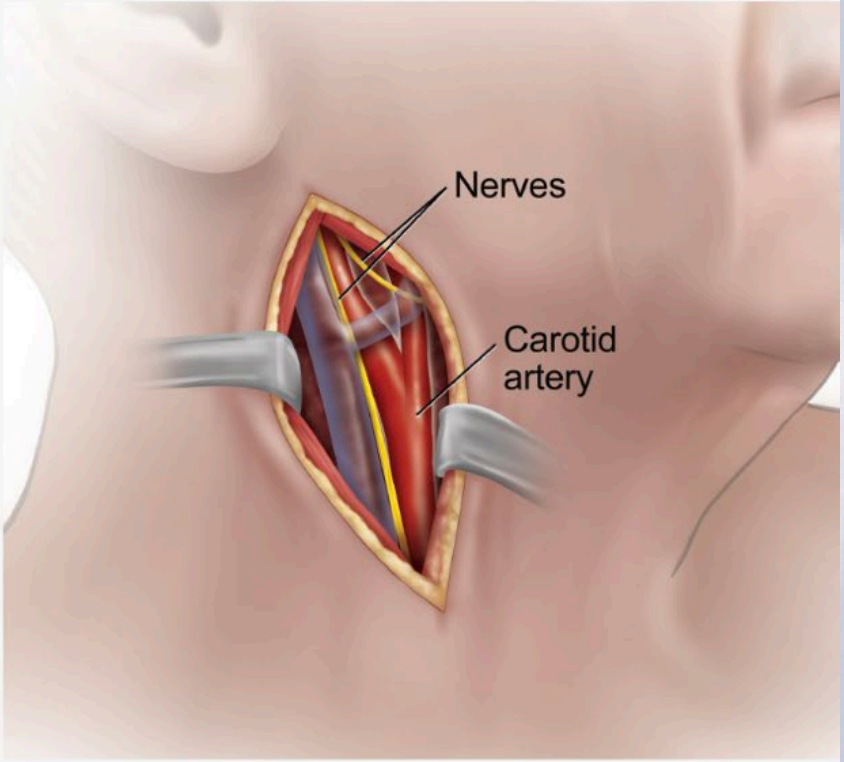
Carotid Endarterectomy



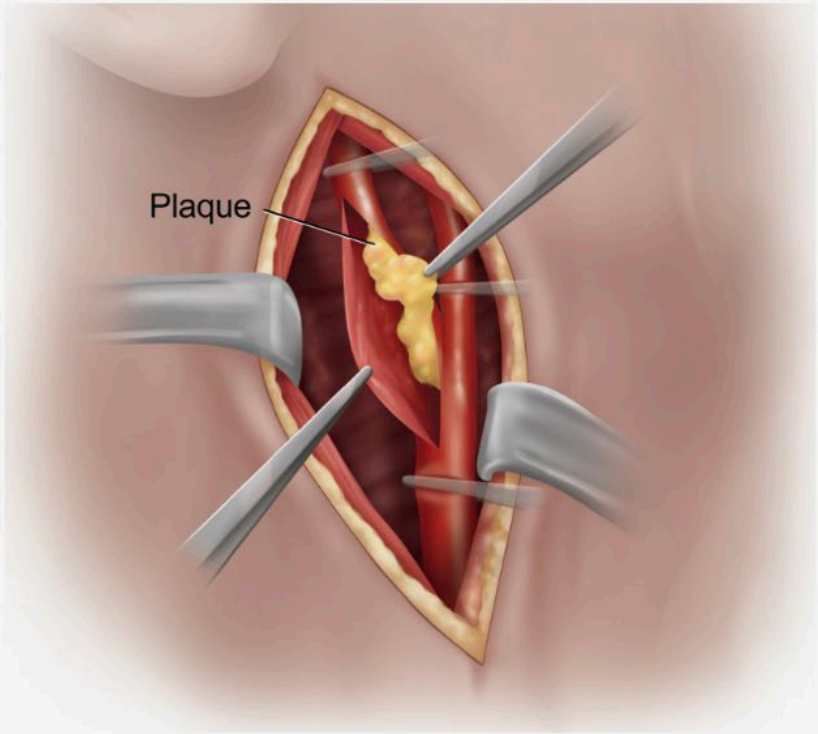
CEA – Step 1

The surgeon exposes your carotid artery through a 4-7 inch long cut in the side of your neck.



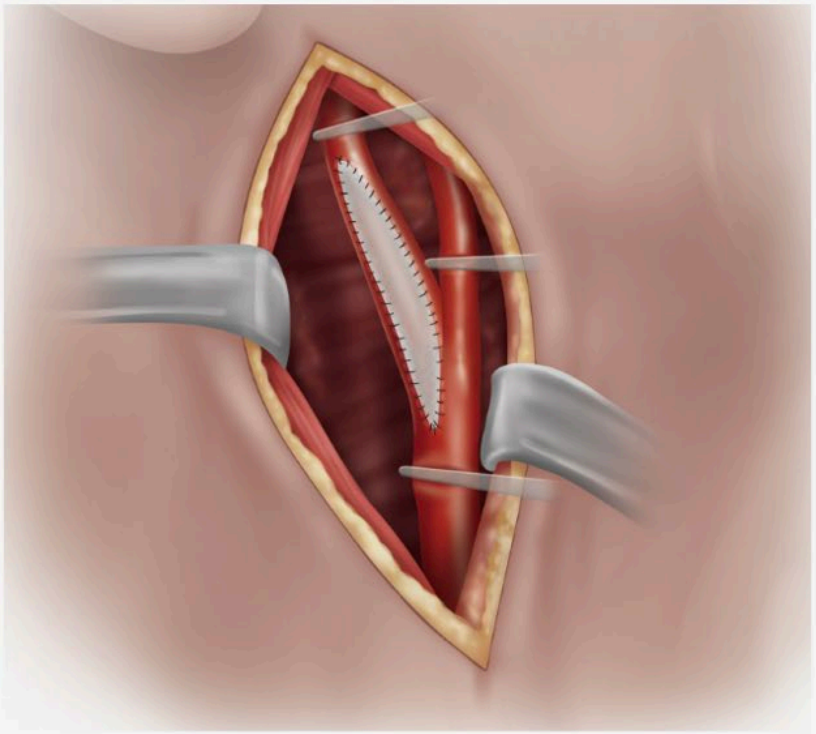
CEA – Step 2

Your surgeon will cut and pull back the skin and muscles in your neck to access your carotid artery.



CEA – Step 3

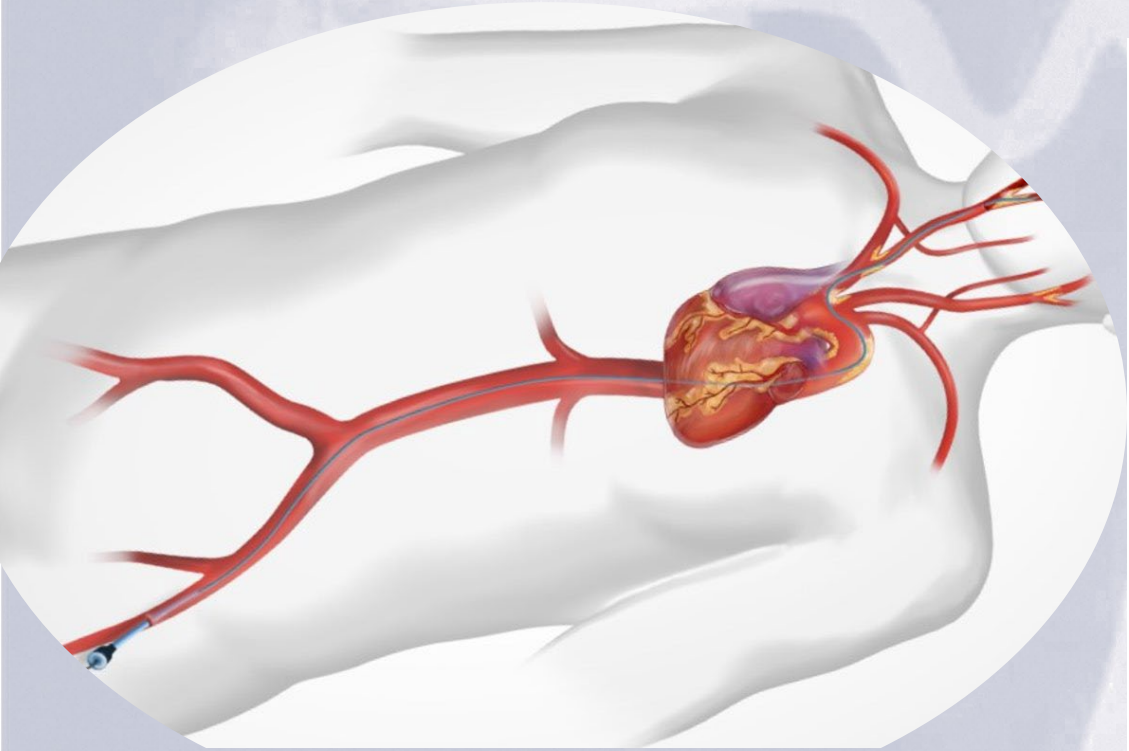
The artery is clamped on both sides of the blockage and opened. The disease-causing buildup is then removed.

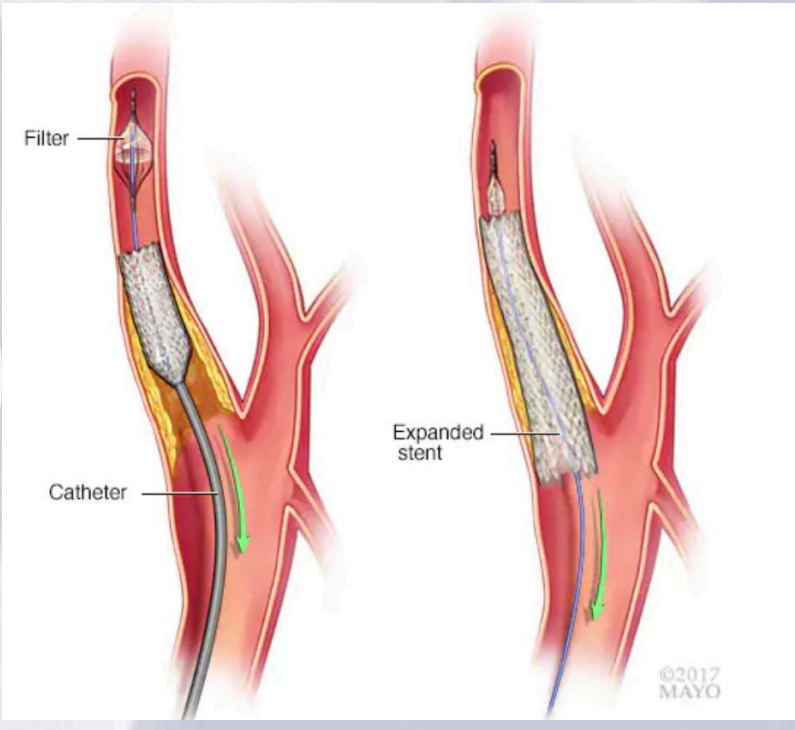


CEA – Step 4

The artery is sewn back together. Sometimes, it is necessary to use a patch or graft when sewing the artery walls together to make the artery wider.

Transfemoral Carotid Artery Stenting (CAS)

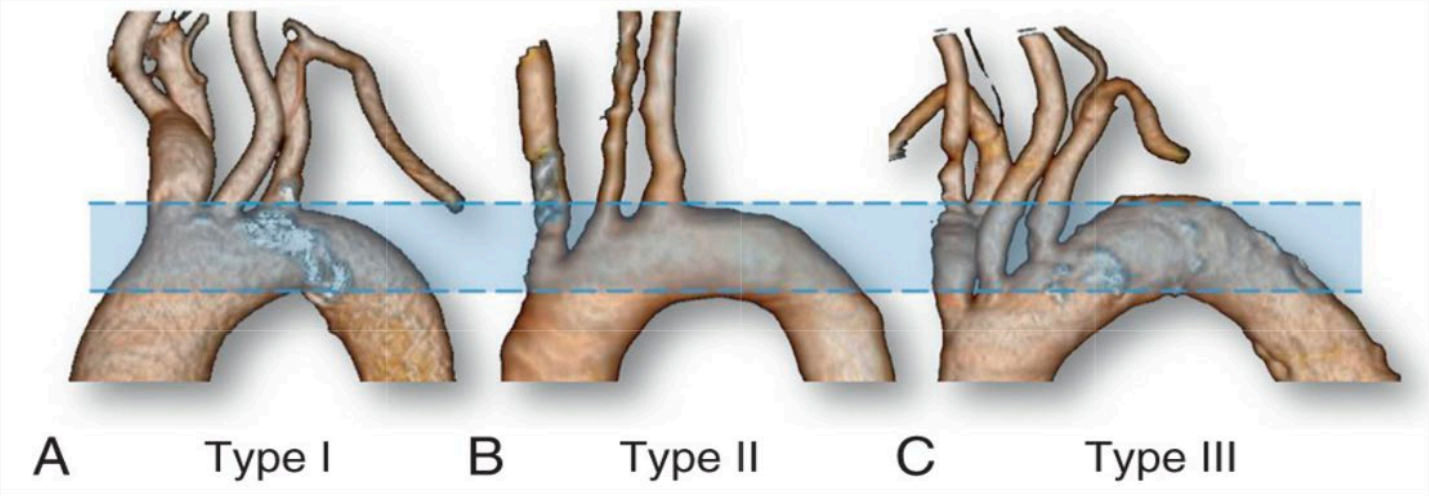




Indications for CAS

Carotid Endarterectomy	Carotid Artery Stent
Poorly compensated cardiac ischemia/heart failure	Symptomatic lesion
Lesion above C2 or below clavicle	Age >70
Scarring from prior surgery or XRT	Vessel/arch tortuosity
Recurrent carotid stenosis	Adverse lesion characteristics: Length >15 mm Echolucent, irregular Tandem lesions Preocclusive lesion Circumferential calcification
Stoma in neck	

CAS - Considerations



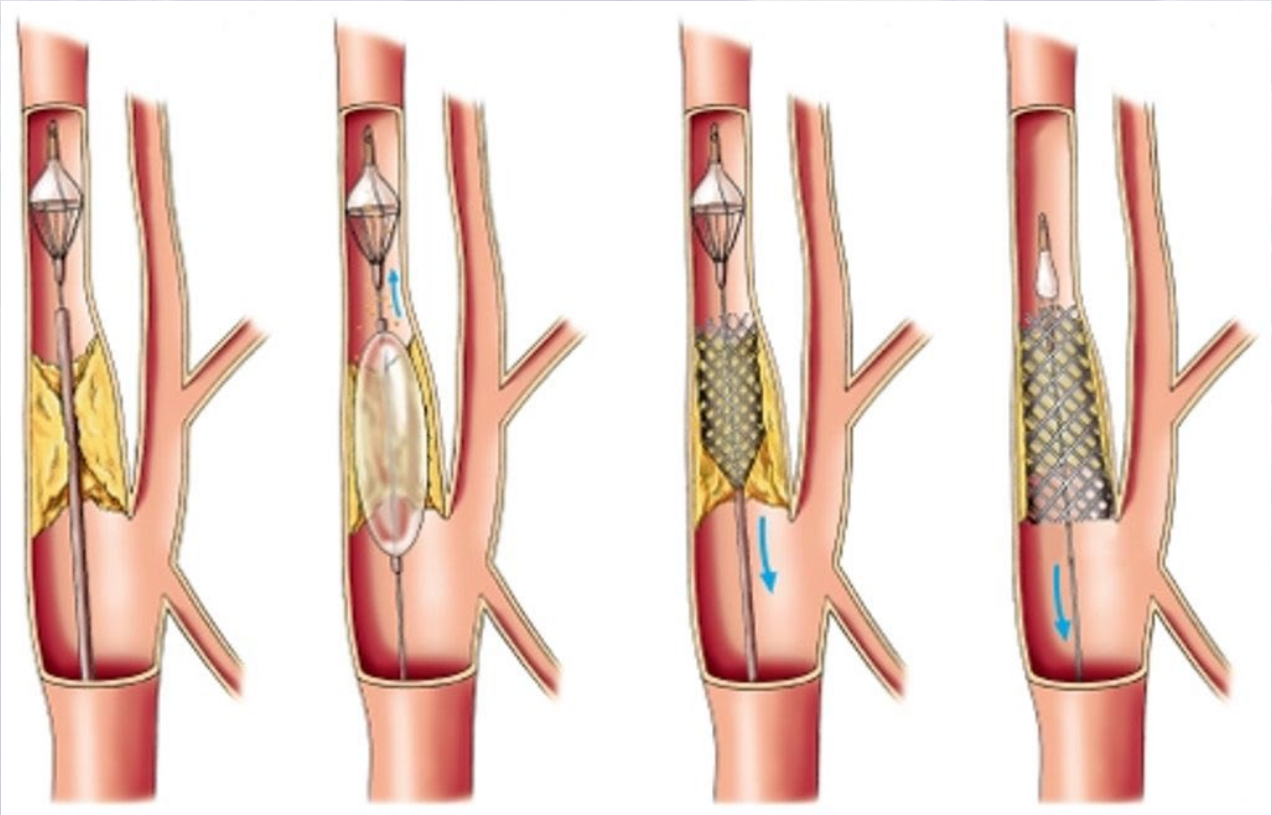
Aortic Arch Morphology

Type I: great vessels arise **at or above** the same horizontal plane as **outer curvature** of arch.

Type II: origin of innominate artery lies **between inner and outer curve**.

Type III: innominate artery lies **below inner** curvature of arch.

CAS – Concept Visualization



CAS

Landmark RCT comparing CAS to CEA:

1. SAPPHIRE: ≥50% Sx, ≥80% ASx; CAS was non-inferior to CEA @ 1 and 3 years (stroke, death, MI)
2. EVA-3S: >60% Sx; worse perioperative stroke/death with CAS (many issues with study though).
3. SPACE: ≥70% Sx; higher risk of perioperative adverse events with CAS.
4. ICSS: >50% Sx; long-term risk of disabling stroke was similar.
5. CREST: ≥70% Sx or ASx, or Sx ≥50%; CAS was non-inferior to CEA.
6. ACT-1: >80% ASx; CAS was non-inferior to CEA.

Transcarotid Artery Revascularization (TCAR)

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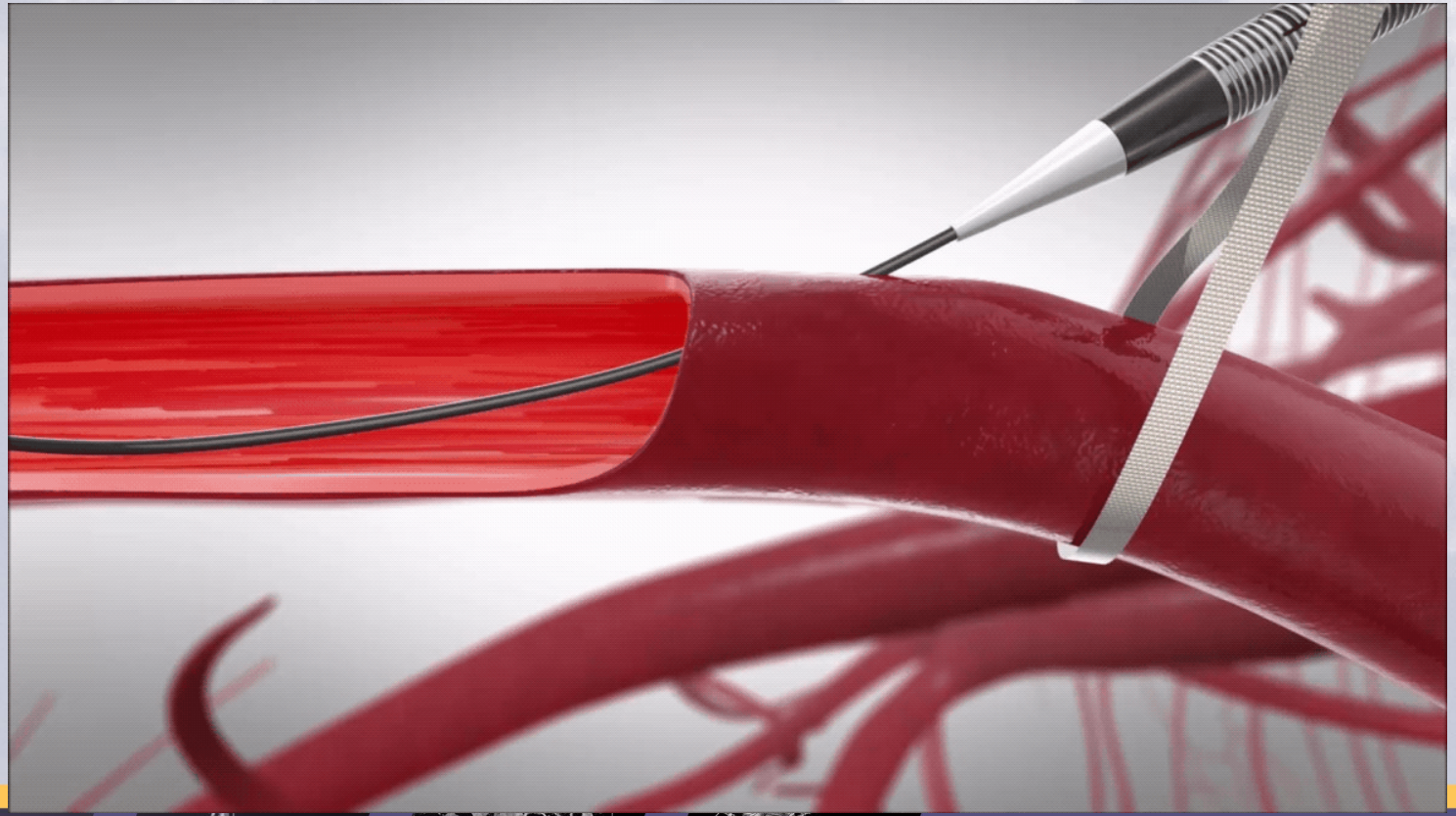
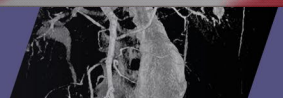
TCAR – Concept Visualization





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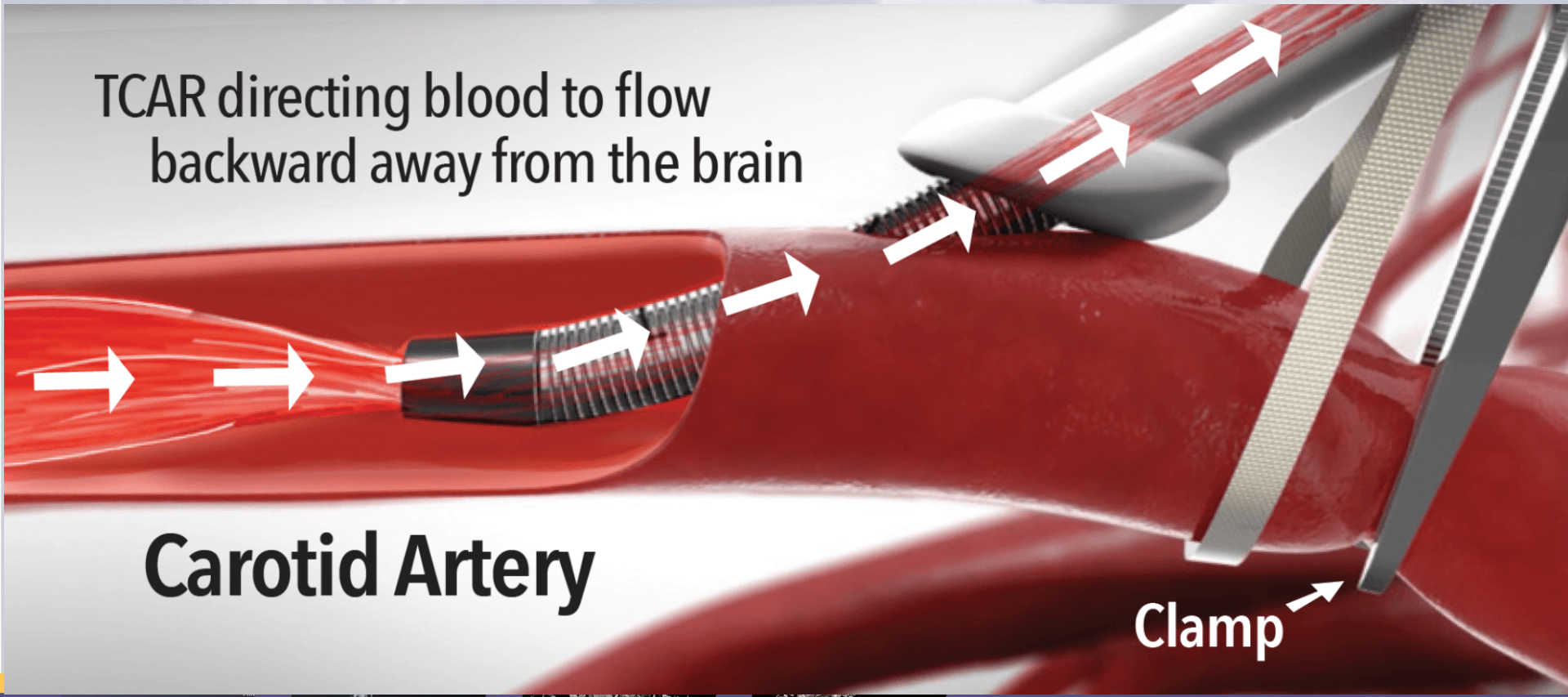
TCAR – Concept Visualization



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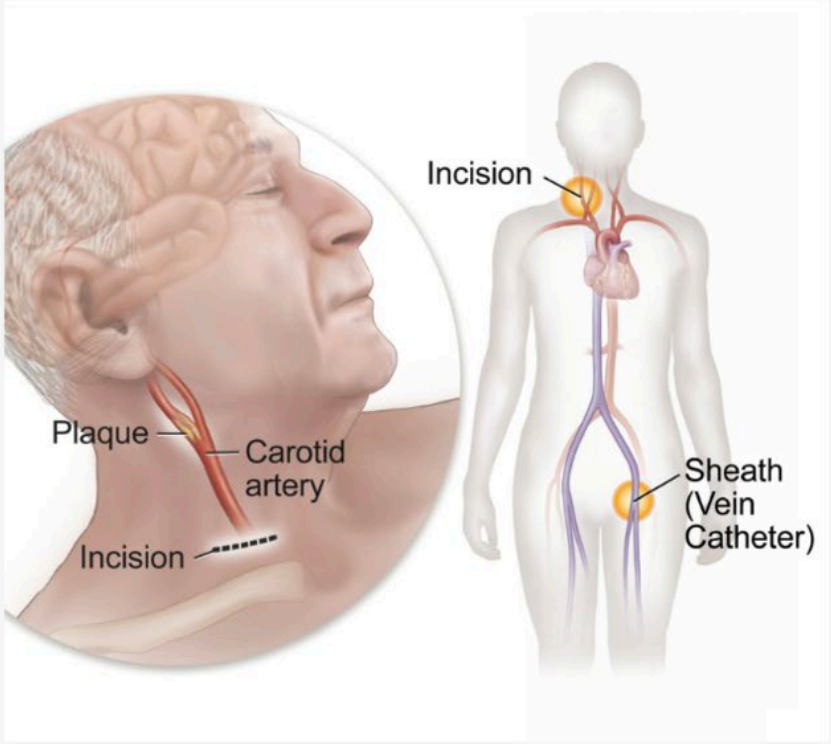
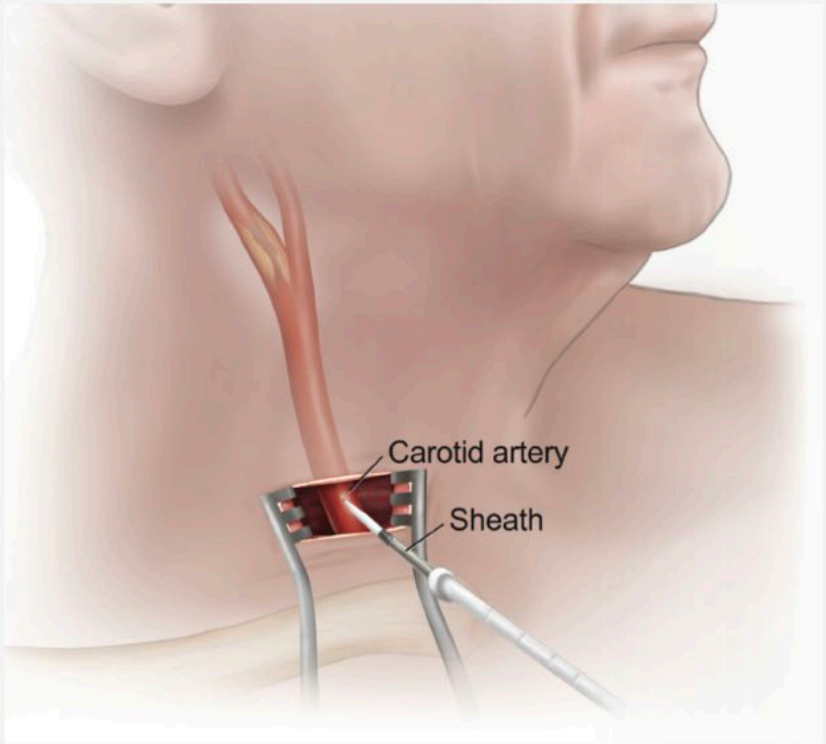


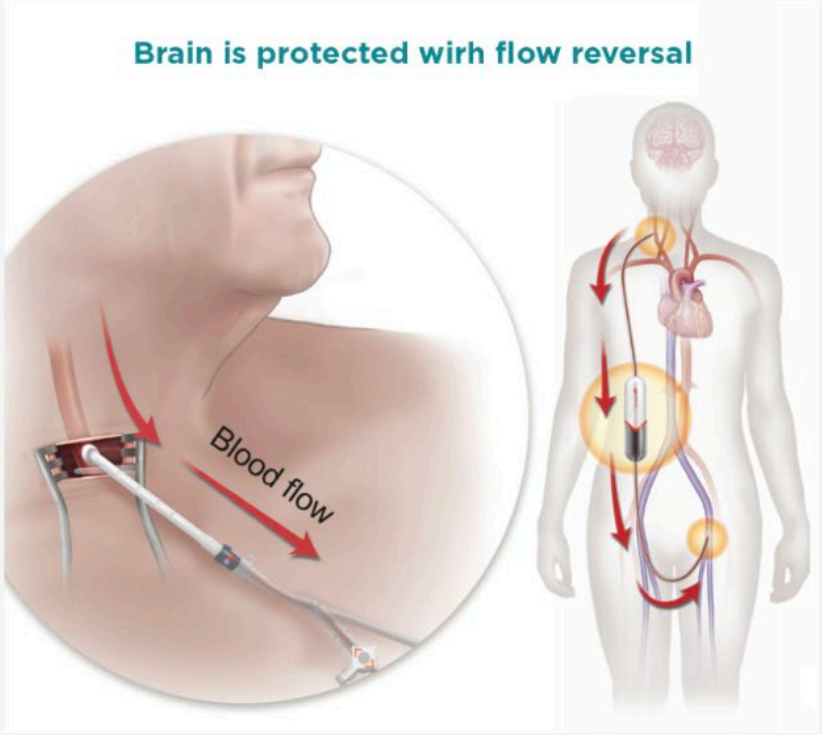
TCAR – Step 1

The surgeon exposes your carotid artery through a small incision in the side of your neck.



TCAR – Step 2

Your surgeon will cut and pull back the skin and muscles in your neck to access your carotid artery.



TCAR – Step 3

Blood flow is reversed away from the brain, and the blood is filtered and returned through the femoral vein in the thigh.

TCAR – Step 4

While blood flow is reversed, a stent is placed to stabilize plaque and minimize the risk of a future stroke.

- INSERT PICTURE FROM RUTHERFORD FOR TCAR

Indications for TCAR

CLINICAL	ANATOMIC
Uncontrolled diabetes	Contralateral occlusion
Severe pulmonary disease	Bilateral stenosis requiring treatment

CMS approves expanded coverage of TCAR for standard surgical risk patients

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TCAR Considerations

- Anatomy
  - Distance ≥ 5 cm “access to lesion” length.
  - Diameter ≥ 6 mm CCA.
  - Ensure CCA is “free of significant disease.”
- Lesion
  - No acute or floating thrombus.
  - < ⅔ circumference calcium, no large “rocks.”
  - No long-segment distal ICA disease.

TCAR Considerations

- DAPT:
  - **Optimal: >72 hours** prior to procedure
    - Aspirin 75-325 mg daily
    - Plavix 75 mg daily
  - **Urgent: <72 hours** but at least 4 hours prior to procedure
    - Aspirin 650 mg
    - Plavix 300-600 mg
    - Daily dosing afterwards
  - Alternatives: Brilinta 90 mg (180 mg) and Effient 10 mg (60 mg)

CEA – PERIOPERATIVE MANAGEMENT

BLOOD PRESSURE

Intraoperative and **postoperative** control, **hyperperfusion** syndrome.

ANTI-PLATELET

Aspirin, **Plavix**, or **both** for use before and after CEA.

DEXTRAN

Can help **prevent platelet aggregation** on CEA site with 24 hr perioperative infusion.

BETA-BLOCKERS

Several studies have shown benefit of continued **perioperative** beta-blockade.

HEPARIN

For use in **crescendo TIA** and **intraoperative** administration.

PROTAMINE

Evidence suggests it **does not increase** perioperative stroke risk.

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Complications

- MI
  - Responsible for 25-50% of all perioperative deaths after CEA
  - Occurs in 1.6 – 17% (depending on how it is defined)
    - Anemia requiring transfusion is associated with increased mortality and 30 day risk of MI
      - Fourth level
        - » Fifth level

Complications – CEA

- Cranial Nerve Injury

Nerve	Reported Incidence (%)
Hypoglossal	4.4-17.5
Recurrent laryngeal	1.5-15
Superior laryngeal	1.8-4.5
Marginal mandibular	1.1-3.1
Glossopharyngeal	0.2-1.5
Spinal accessory	<1.0

Complications

- Hyperperfusion Syndrome
  - Typically occurs if patient had bilateral severe stenosis and contralateral side had already been revascularized
  - Symptoms and signs: severe headache, seizures, intracerebral hemorrhagic stroke.
  - Mortality can be as high as 75-100%.
  - Pathology: increased regional cerebral blood flow 2/2 disordered intracerebral autoregulation after revascularization.
  - Risk factors: systemic HTN, contralateral ICA occlusion/severe stenosis.

Complications

- Perioperative stroke
- Three broad categories:
  - Perioperative arterial thrombosis/embolization
  - Cerebral ischemia during clamping (watershed)
  - Intracerebral hemorrhage

TCAR vs CEA VQI

	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%

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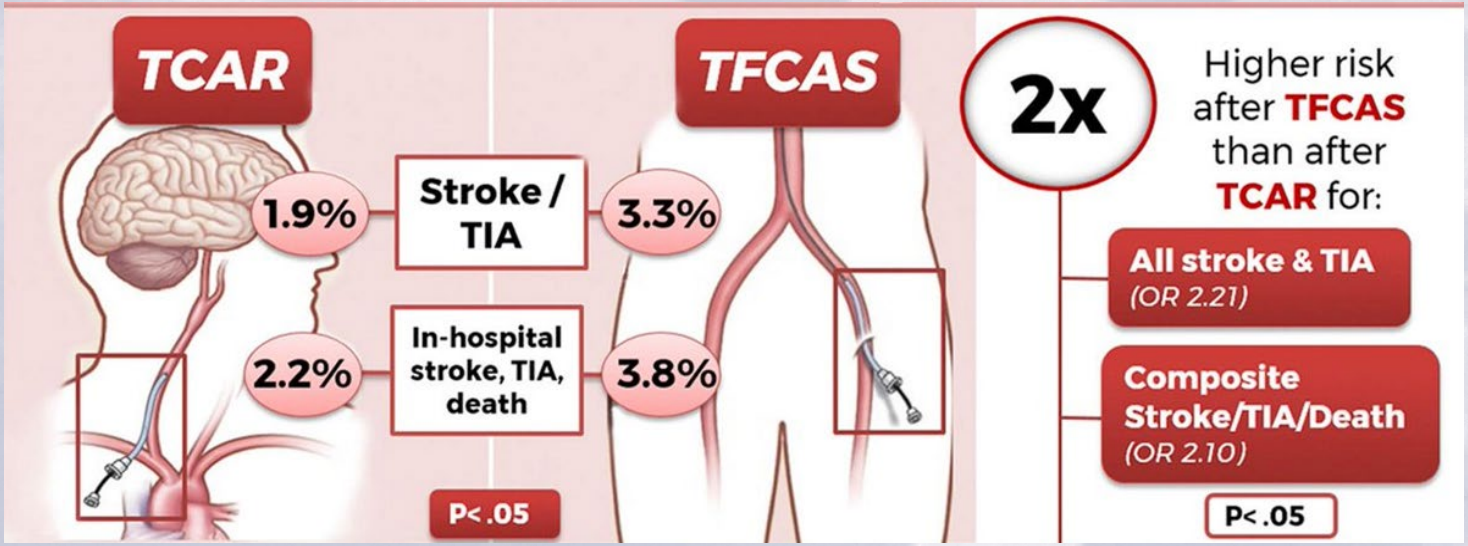
TCAR vs CAS VQI



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

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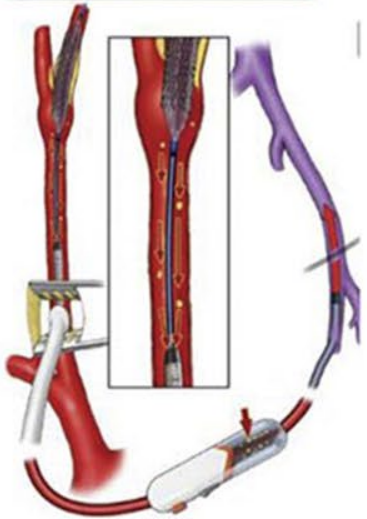
Impact of Age on In-Hospital Outcomes After Transcarotid Artery Revascularization (TCAR), Transfemoral Carotid Artery Stenting (TFCAS) and Carotid Endarterectomy (CEA)

Retrospective non-randomized study using the Vascular Quality Initiative database

TCAR
N=3152

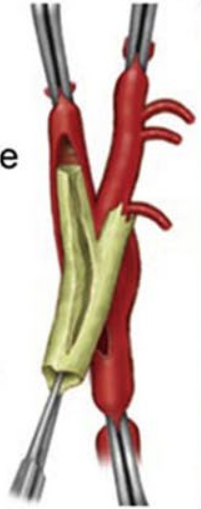


VS:

CEA
N=61,650

No significant difference in outcomes except:

- TCAR was associated with significant decrease in **cranial nerve injury**



TFCAS
N=10,381

In patients ≥ 80 years, TCAR was associated with:

72% Reduction in **stroke risk**

65% Reduction in **risk of stroke/death**

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Official Publication of the Society for Vascular Surgery

Dakour-Aridi et al. *J Vasc Surg* September 2020

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CLINICAL PRACTICE GUIDELINES

Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease

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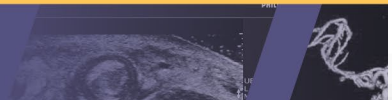
1. **Is CEA recommended over maximal medical therapy for asymptomatic carotid stenosis in low surgical risk patients?**

   1.1. For low surgical risk patients with asymptomatic carotid bifurcation atherosclerosis and stenosis of >70% **(documented by validated duplex ultrasound or CTA/angiography)**, we recommend CEA with best medical therapy instead of maximal medical therapy alone for the long-term prevention of stroke and death. **Level of recommendation: grade 1 (strong); quality of evidence: B (moderate)**.

2. **Is CEA recommended over TF-CAS for low surgical risk patients with symptomatic carotid artery stenosis of >50%?**

   2.1. We recommend CEA over TF-CAS in low- and standard-risk patients with >50% symptomatic carotid artery stenosis. Level of recommendation: **grade 1 (strong); quality of evidence: A (high)**.



3. What is the optimal timing of carotid intervention for patients presenting with acute stroke? Management of acute neurologic syndrome:

3.1. In patients with recent stable stroke (modified Rankin scale score 0-2), we recommend carotid revascularization for symptomatic patients with >50% stenosis to be performed as soon as the patient is neurologically stable after 48 hours but definitely before 14 days after the onset of symptoms. **Level of recommendation: grade 1 (strong); quality of evidence: B (moderate)**.

3.2. In patients undergoing revascularization within the first 14 days after the onset of symptoms, we recommend CEA rather than carotid stenting. Level of recommendation: **grade 1 (strong); quality of evidence: B (moderate)**.

3.3. We recommend against revascularization, regardless of the extent of stenosis for patients who experienced a disabling stroke, have a modified Rankin scale score of ≥3, whose area of infarction is >30% of the ipsilateral middle cerebral artery territory, or who have altered consciousness to minimize the risk of postoperative parenchymal hemorrhage. **These patients can be reevaluated for revascularization later if their neurologic recovery is satisfactory. Level of recommendation: grade 1 (strong); quality of evidence: C (low)**.

4. Screening for carotid artery stenosis in asymptomatic patients

4A. Is screening for asymptomatic carotid stenosis recommended for the general population?

4.1. We recommend against routine screening for clinically asymptomatic carotid artery stenosis in individuals without cerebrovascular symptoms or significant risk factors for carotid artery disease. **Level of recommendation: grade 1 (strong); quality of evidence: B (moderate)**.

4B. Is screening for carotid stenosis recommended for high-risk asymptomatic patients?

4.2. In selected asymptomatic patients who are at an increased risk of carotid stenosis, we suggest screening for clinically asymptomatic carotid artery stenosis, especially if patients are willing to consider carotid intervention if significant stenosis is discovered. **Level of recommendation: grade 2 (weak); quality of evidence: B (moderate)**.

4C. What imaging test is best for screening for carotid stenosis in asymptomatic patients?

4.3. In asymptomatic patients who are undergoing screening for carotid artery stenosis, we recommend duplex ultrasound performed in an accredited vascular laboratory as the imaging modality of choice instead of CTA, MRA, or other imaging modalities. **Level of recommendation: grade 1 (strong); quality of evidence: B (moderate)**.

5. What is the optimal sequence for intervention in patients with combined carotid artery stenosis and CAD?

5.1. For patients with symptomatic carotid stenosis of 50% to 99%, who require both CEA and CABG, we suggest CEA before, or concomitant with, CABG to potentially reduce the risk of stroke and stroke/death. The sequencing of the intervention depends on the clinical presentation and institutional experience. **Level of recommendation: grade 2 (weak); quality of evidence: C (low)**.

5.2. In patients with severe (70%-99%) bilateral asymptomatic carotid stenosis or severe asymptomatic stenosis and contralateral occlusion, we suggest CEA before, or concomitant with, CABG. **Level of recommendation: grade 2 (weak); quality of evidence: C (low)**.

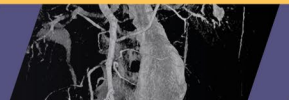
5.3. In patients requiring carotid intervention, staged or synchronous with coronary intervention, we suggest that the decision between CEA and CAS be determined by the timing of procedure, the need for anticoagulation or antiplatelet therapy, patient anatomy, and patient characteristics. **Level of recommendation: grade 2 (weak); quality of evidence: B (moderate)**.

FOLLOW UP

Medications

Imaging



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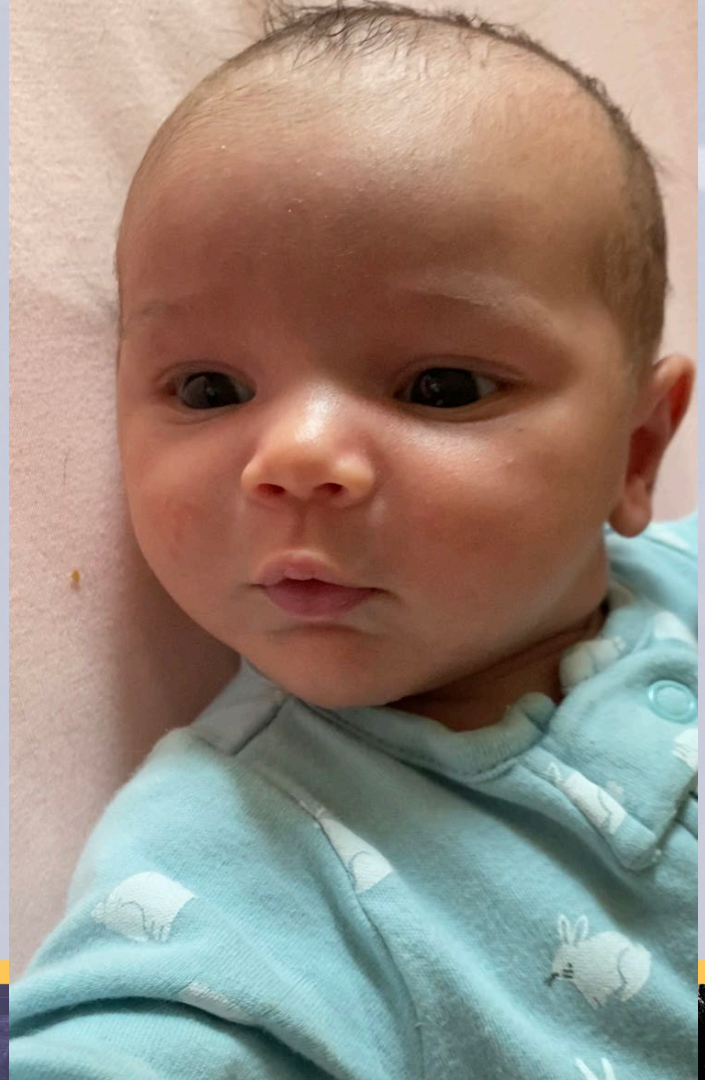
Follow up

- Post Op Duplex
  - 1 month, 6 months, yearly
  - Restenosis after CEA in 5-22%; symptomatic in only 3%
  - Within 2 years → intimal hyperplasia
  - > 2 years → atherosclerosis
- Lipid lowering therapy
  - Decreasing low-density lipoprotein (LDL) cholesterol by 1 mmol/L reduces the 5-year risk of stroke by approximately 25%
  - Meta-Analysis of 26 Randomized trials with > 90,000 patients
    - Each 10% reduction in LDL reduced the risk of all strokes by 15.6%
    - Each 10% reduction in LDL reduced the carotid intima-media thickness (IMT) by 0.73% per year



Thank you!

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Questions

- With the addition of statins, is there any controversy or question about whether carotid surgery is still relevant for asymptomatic patients?
- What ongoing trials are evaluating best medical therapy vs carotid intervention?