Trans Carotid Artery Revascularization (TCAR) in a Community Hospital

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15TH ANNUAL CARDIAC, VASCULAR, AND STROKE CARE CONFERENCE

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PIEDMONT ATHENS REGIONAL

Disclosure

None relevant to this presentation…

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Trans Carotid Artery Revascularization (TCAR) in a Community Hospital

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Carotid Disease

- Why do we care about carotid disease?


A
ATHENS REGIONAL MED CTR
CT Head Without Contrast
BaseSeq 3.0 H31s SOFT TISSU
05/25/2007 12:14:19
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LOC: 1143.4
THK: 3
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RD: 217
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C: 30
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Page: 25 of 51
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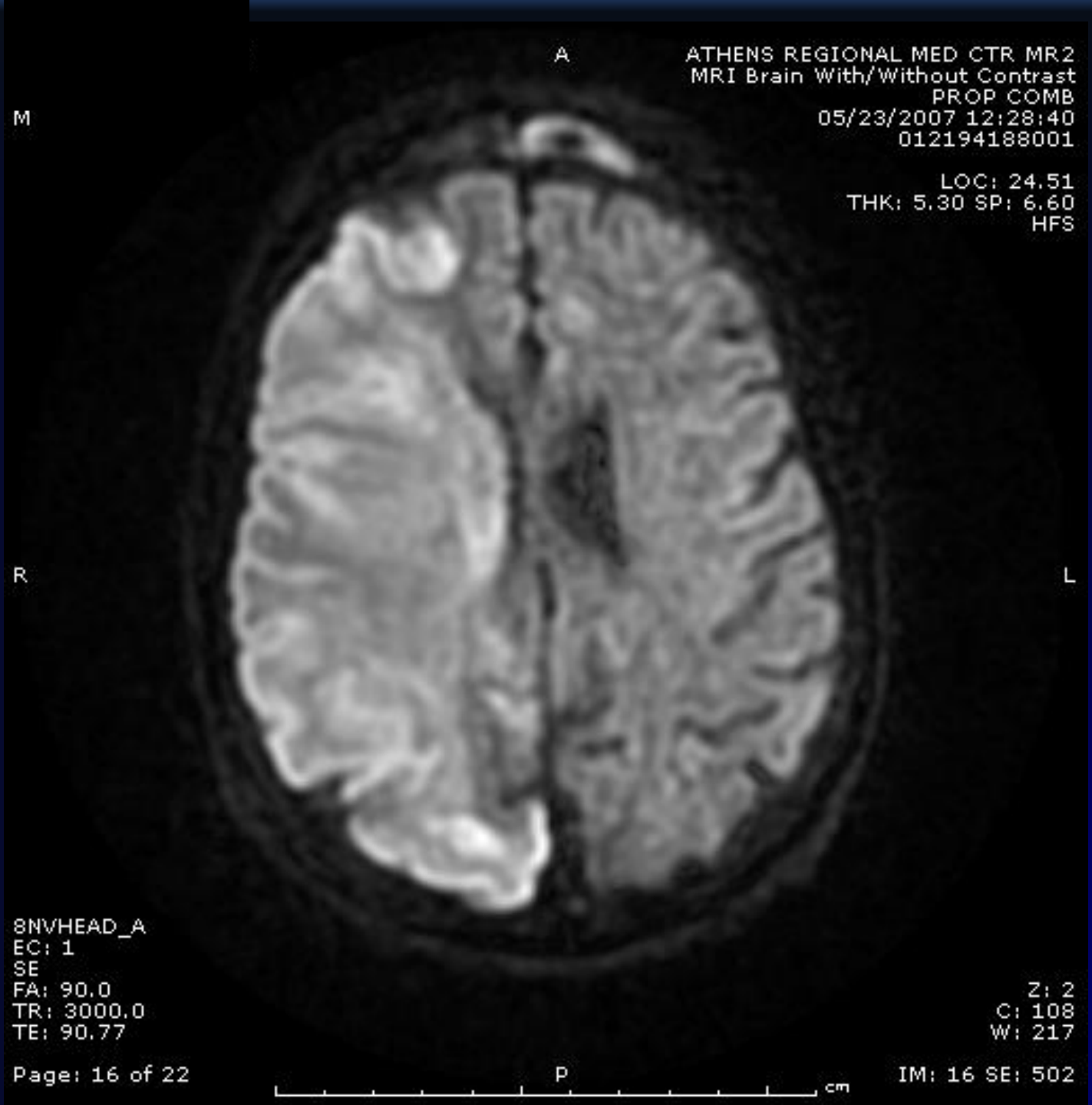
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MRI Brain With/Without Contrast
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TE: 90.77
Z: 2
C: 108
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cm
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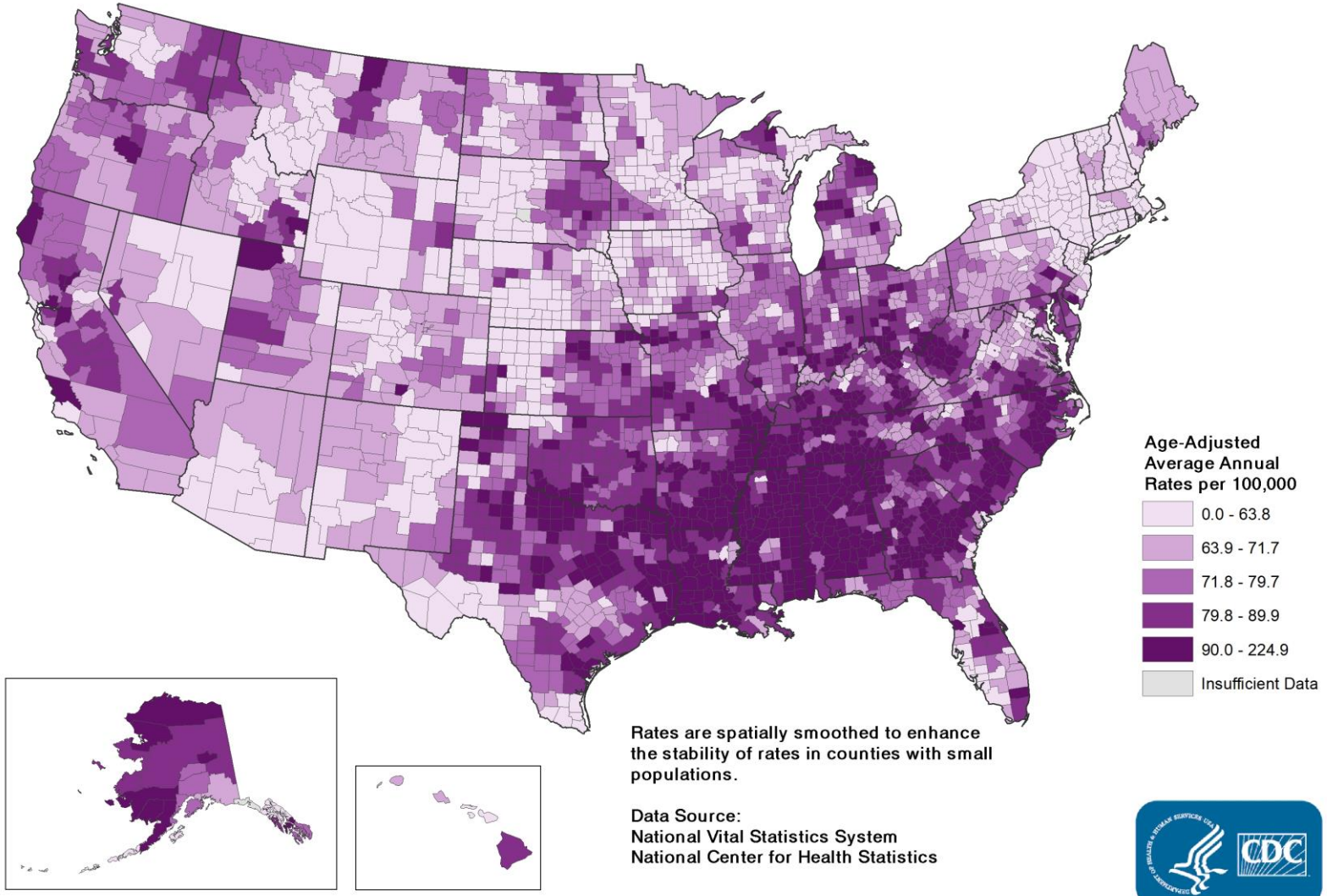
Stroke

- 5th leading cause of death in US
- Kills ~ 140,000 in US each year – 1 out of every 20 deaths
- 1 stroke every 40 seconds – 1 stroke death every 4 minutes
- Every year ~ 800,000 people in the US have a stroke
- About 185,000 strokes are recurrent strokes ~ 1 / 4
- About 87% of strokes are ischemic, loss of blood flow to the brain
- Stroke costs in US ~ $34 billion each year
  - health care services, medications, loss of work days, etc
- Stroke is a leading cause of serious long-term disability
- Stroke reduces mobility in over half of survivors age 65 and over

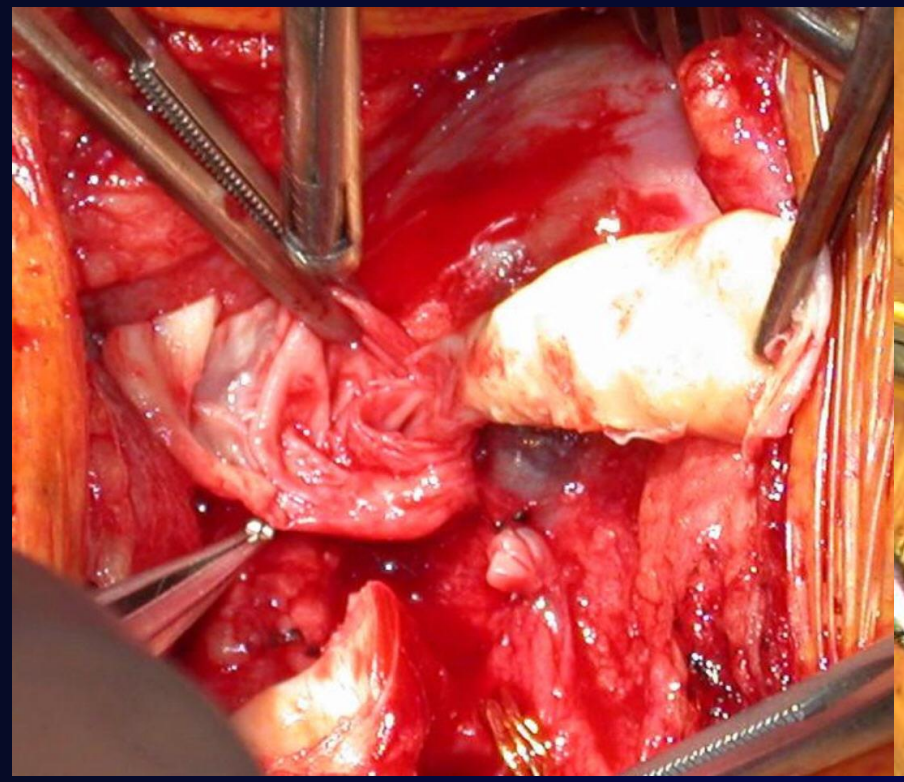
Stroke Death Rates, 2015 - 2017
Adults, Ages 35+, by County

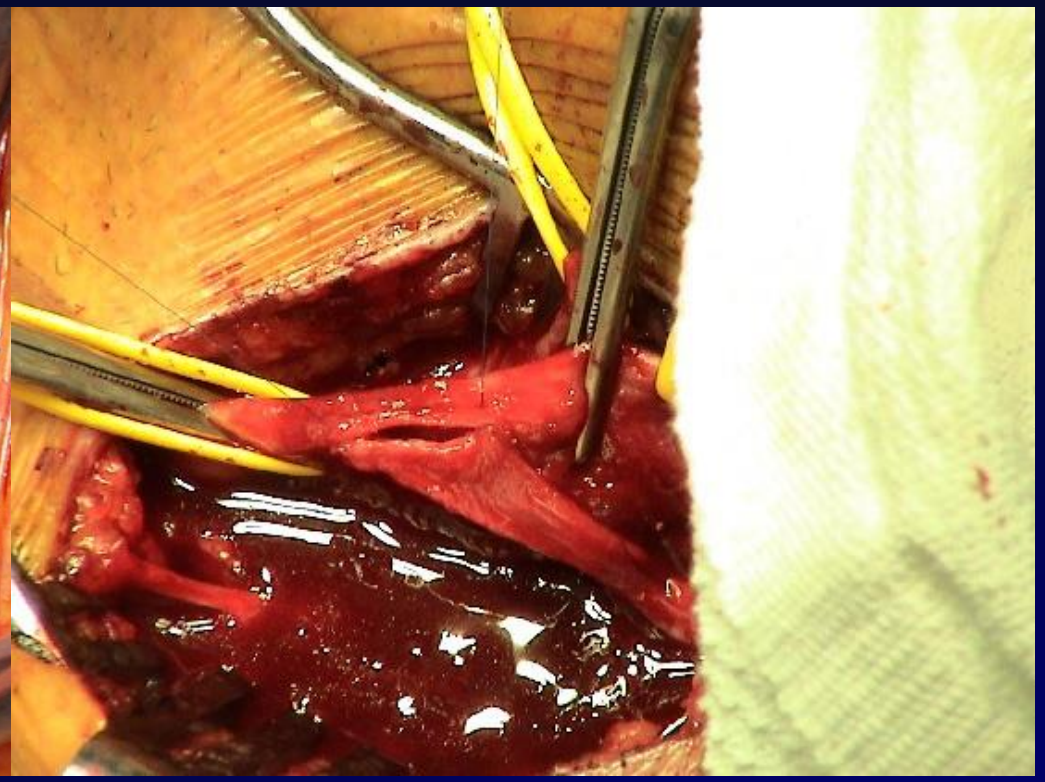


Rates are spatially smoothed to enhance the stability of rates in counties with small populations.

Data Source:
National Vital Statistics System
National Center for Health Statistics

Carotid Endarterectomy – CEA





1978 Dr Costantino first CEA by fellowship trained vascular surgeon

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Asymptomatic Carotid Disease

- Presence of atherosclerotic narrowing of the extracranial internal carotid artery in individuals without a history of recent TIA or stroke
- Stenosis ≥ 50% annual stroke risk is approx 0.5 – 2.0%
- Asymptomatic carotid atherosclerosis is also a marker of increased risk for myocardial infarction and vascular death
- Receive intensive medical therapy using all available risk reduction strategies including:
  - Statin
  - Anti-platelet
  - BP control
  - Lifestyle modification – smoking cessation, limit alcohol, weight control, regular aerobic physical activity, Mediterranean diet

Asymptomatic Carotid Disease

- What to do?
- Alphabet soup of trials

	BMT	CEA
• ACAS	11%	5%
• ACST	12%	6%
• VA Trial	20%	8%

CEA cuts stroke risk in half !!!

Asymptomatic Carotid Disease

- Carotid stenosis ≥ 80%
- Medically stable patient
- Life expectancy of at least five years
- On intensive medical therapy
- CEA as long as…
  - Combined periop risk of stroke and death is < 3% for surgeon and center
- CEA should be considered a long-term investment
  - Benefit only emerges after a number of years

Symptomatic Carotid Disease

- Presence of atherosclerotic narrowing of the extracranial internal carotid artery in individuals with TIA or stroke in the carotid artery distribution within 6 months
- Symptomatic carotid atherosclerosis is also a marker of increased risk for myocardial infarction and vascular death
- Receive intensive medical therapy using all available risk reduction strategies including:
  - Statin
  - Anti-platelet
  - BP control
  - Lifestyle modification – smoking cessation, limit alcohol, weight control, regular aerobic physical activity, Mediterranean diet

Symptomatic Carotid Disease

- What to do?
- Alphabet soup of trials

	BMT	CEA	Stenosis
• NASCET	26%	9%	> 70%
	22%	16%	50-69%
• ECST	17%	3%	> 80%

- Pooled analysis confirms above

CEA dramatically reduces stroke risk !!!

Symptomatic Carotid Disease

- Carotid stenosis ≥ 50%
- Medically stable patient
- Life expectancy of at least five years
- On intensive medical therapy
- CEA as long as…
- Combined periop risk of stroke and death is < 6% for surgeon and center
- CEA between 2 days and 2 weeks (day 3-14)
- CEA should be considered a short and long-term investment

Bottom Line

- Only 2 things matter
  - Stenosis
  - Symptoms

- 70 - 99% → CEA

- 50 - 69%
  SYMPTOMATIC → CEA
  ASYMPTOMATIC → OBSERVE

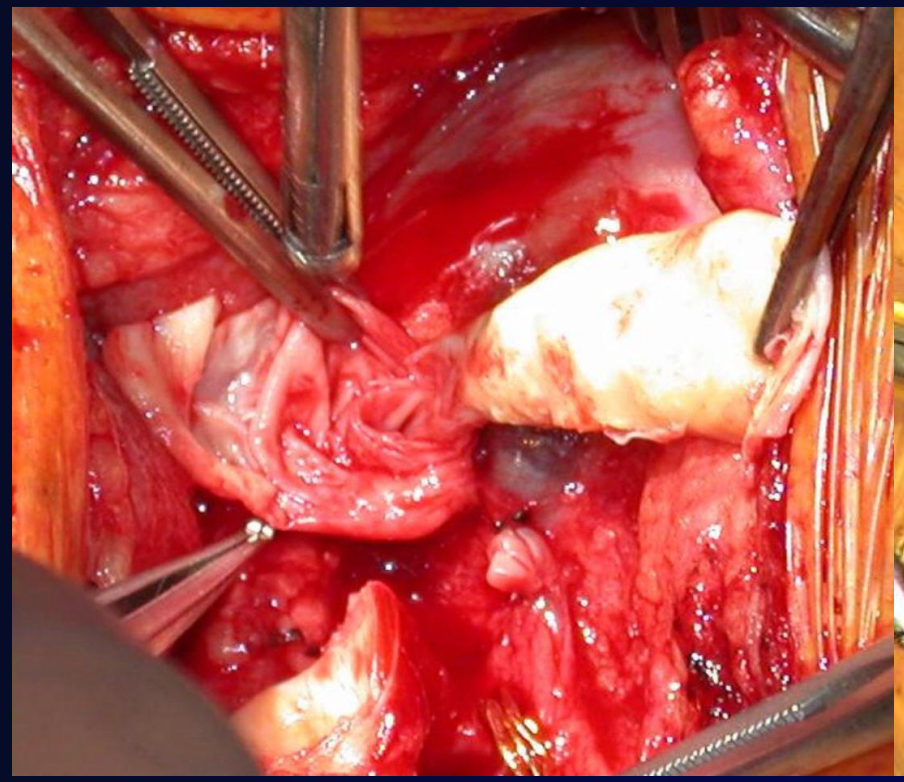
  (Symptomatic 50% / Asymptomatic 80%)

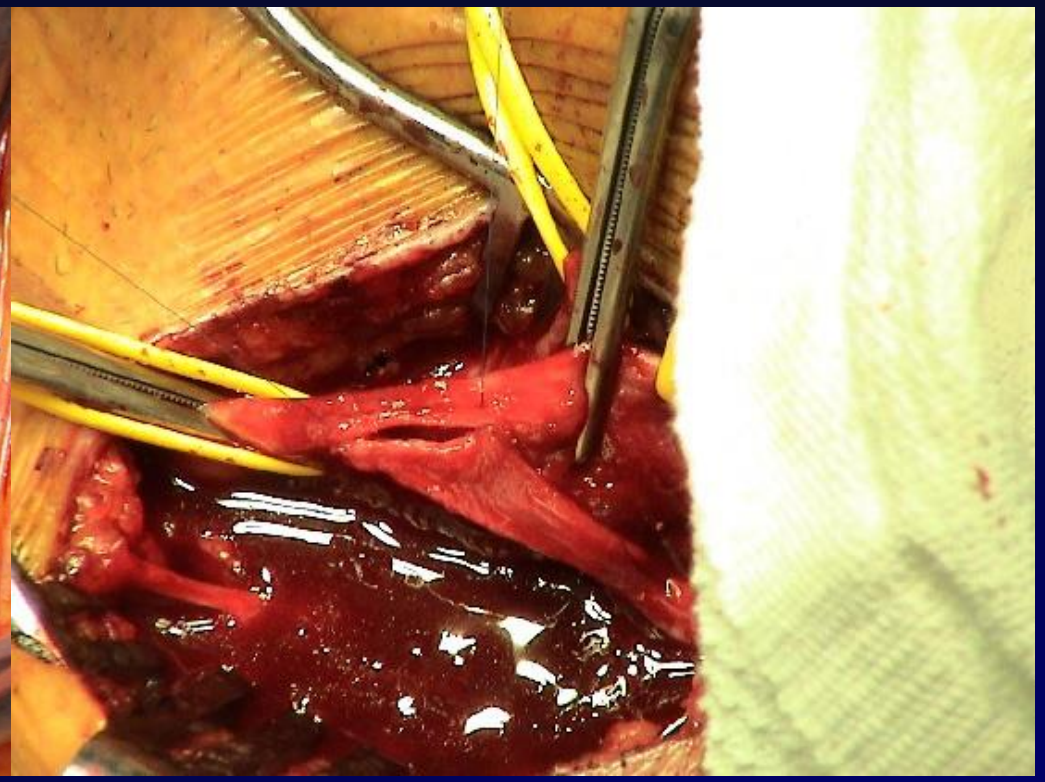
As long as good risk and good results…

ALL PATIENTS

- Should receive intensive medical therapy using all available risk reduction strategies including:
- Statin
- Anti-platelet
- BP control
- Lifestyle modification
  - smoking cessation, limit alcohol, weight control, regular aerobic physical activity, Mediterranean diet

Carotid Endarterectomy – CEA





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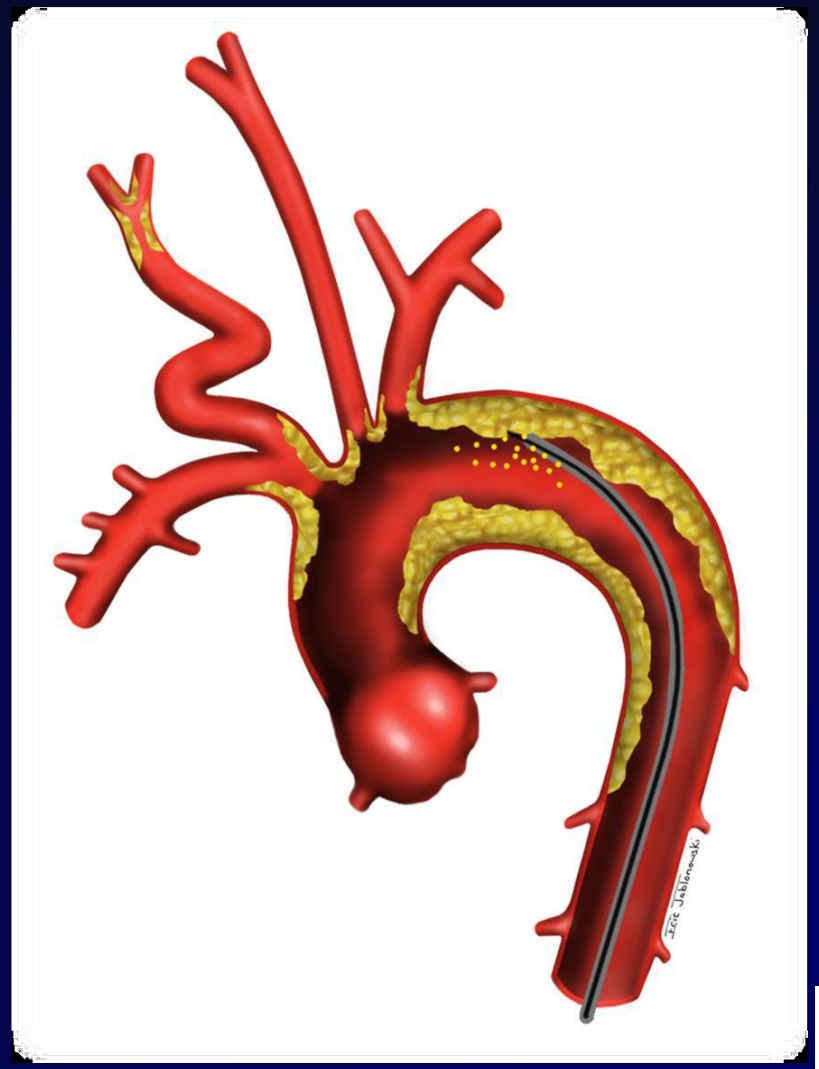
TFCAS – transfemoral carotid stenting
arch manipulation



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TCAR vs TFCAS

- Despite higher medical comorbidities in TCAR group:

	TIA / Stroke / Death
• TCAR	2.2%
• TFCAS	3.8%

TCAR cuts risk in half vs TFCAS

Malas et al, JVS 2019

TCAR vs CEA

- Despite higher medical comorbidities in TCAR group:

Stroke rate	30 days	1 year
• TCAR	1.0%	2.8%
• CEA	1.1%	3.0%

TCAR and CEA have similar outcomes

Kashyap et al, JVS 2019

TCAR - Trans Carotid Artery Revascularization

- Novel and unique approach to treatment of carotid disease

- Combines optimal features of CEA and CAS
  - Direct / surgical carotid access
  - Neuroprotection with dynamic flow reversal vs distal embolic protection
  - Transcarotid vs transfemoral stent placement
  - Avoid aortic arch manipulation

- Initial results in high risk patients compare favorably to CEA and CAS
  - ROADSTER

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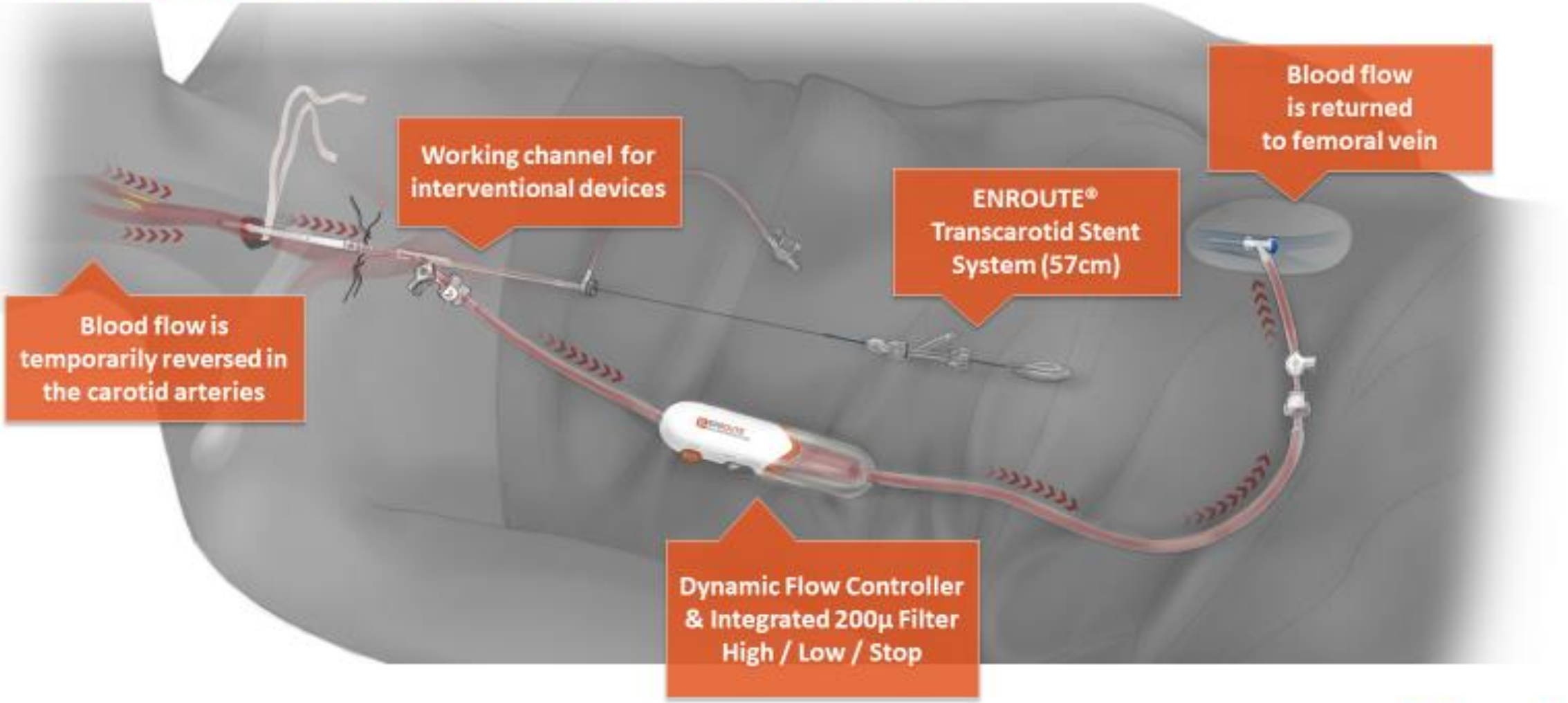
ENROUTE® TRANSCAROTID NEUROPROTECTION & STENT SYSTEM



SILKROAD MEDICAL®

ENROUTE Stent

Uber Flex Sheath

ENROUTE Neuroprotection System

CMS Coverage

- Symptomatic $\geq$ 50%
- Asymptomatic $\geq$ 80%
- Must meet at least one high risk criteria
- FDA approved carotid stent
- FDA approved neuroprotection system
- TCAR Surveillance Project (TSP)
  - FDA approved post-approval carotid stenting study
  - Obtain data about real-world outcomes of TCAR vs CEA in centers participating in the SVS Vascular Quality Initiative (VQI).

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High Risk Criteria

must meet at least one

Comorbid conditions

Age ≥75
Congestive Heart Failure
Left Ventricular Ejection Fraction ≤35%
Two or more diseased coronary arteries 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
History of liver failure with elevated prothrombin time

Anatomic conditions

Prior head/neck surgery or irradiation
Spinal immobility
At risk for wound infection
Restenosis post CEA
Tracheostomy or tracheostoma
Surgically inaccessible lesion
Laryngeal palsy / Laryngectomy / Permanent contralateral cranial nerve injury
Contralateral occlusion
Severe tandem lesions
Bilateral stenosis requiring treatment
Dissection

Methods

- Retrospective review of first 50 patients underwent TCAR
- December 2017 – March 2019
- Four vascular surgeons
  - All trained by SilkRoad / Individual case volume 8 – 17
- All patients underwent pre op CTA neck
- All cases reviewed / approved by SilkRoad Medical
- Company rep present for all cases
- Data entered in TSP (TCAR Surveillance Project) SVS / VQI
- Our case data compared with SilkRoad National TCAR Database
  - All cases done since January 2017

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Results

ALL PATIENTS

- Typical vascular risk factors – HTN, Hyperlipidemia, DM, Smoking
- Met at least one high risk criteria
- Dual anti-platelet therapy – aspirin plus clopidogrel
- Statin therapy
- General anesthesia

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Results

	PARMC	Natl TCAR Database
Mean Age	70 (45-89)	70
Male	62%	65%
Gen Anes	100%	79%
Symptomatic	52%	37%
Severe Stenosis	96%	54%
Engage Ext Carotid	58%	37%
Mean Proc Time	59 mins	64 mins
Mean Flow Rev Time	11 mins	11 mins
Contrast Volume	30 ml	30 ml

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Results

- Right 24 / Left 26
- Technical success 100%
- One post op hematoma requiring evacuation
- One transient recurrent laryngeal nerve palsy
- 30 day follow up all patients – NO strokes
- One year follow up 11 patients – NO strokes

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Results

- Follow up imaging available on 43 patients
  - Carotid U/S
  - One had CTA for post op headache
- 40 minimal disease
- 3 significant disease (> 50% stenosis)
- 93% minimal disease on follow up imaging

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Results

- Persistent / Residual Stenosis
- 3 patients had > 50% stenosis on follow up imaging
- 2 extensively calcified
  - Calcium wins
- 1 lesion just distal to stent – felt to be spasm vs residual stenosis
  - Residual stenosis – U/S lesion same exact location as intra op angio

Lessons learned

→ Calcium > balloon / stent

→ Two view completion angio

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Random Thoughts

- Few patients with prior contralateral CEA – prefer TCAR
- Early adopters of technique – MD, OR, Admin
- More TCAR than any other hospital in GA (> 70 cases)
  - 2019 CEA 45 / TCAR 39
- PARMC is a TCAR Center of Excellence in 2018 and 2019
  - Piedmont Athens Regional, Piedmont Atlanta, Northside Forsyth

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PRE

POST

CONCLUSION

- TCAR safe and effective treatment for carotid disease
  - Compares favorably to CEA
- Achieve excellent results
  - No strokes / 93% minimal disease – *can be 100%*
- Minimal learning curve
  - Vascular surgeons already have the skill set
- TCAR program easily developed in a community hospital
  - Physician and administrative commitment

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Take Home Message

- Stroke is a major public health concern
- Carotid disease causes stroke → treatable → *preventable*
- Risk factor modification for ASCVD
- Recommendation based on stenosis / symptoms
- CEA gold standard
- TCAR promising new technology
- TFCAS old news…

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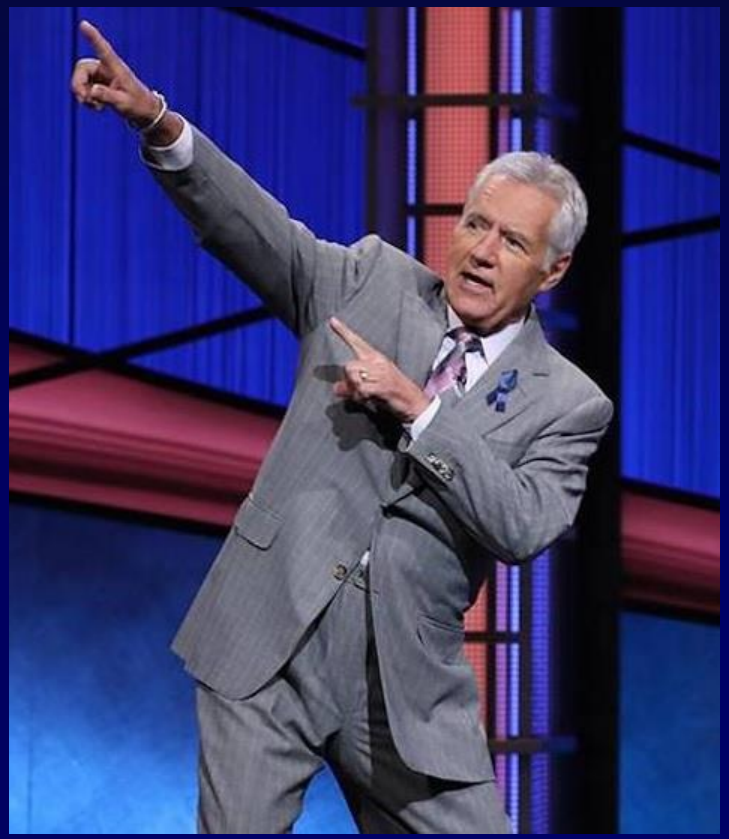
FINAL
JEOPARDY!


JEOPARDY!
THE
GREATEST OF ALL TIME


$0
What is Atlanta?
$13,900
$0
What is Austin
$13,800
$0
What is Springf
$6000



Patients with carotid disease should receive which of the following:

Statin therapy

Anti-platelet therapy

Blood pressure control

Lifestyle modification such as smoking cessation and regular aerobic physical activity

All of the above

None of the above

Patients with carotid disease should receive which of the following:

Statin therapy

Anti-platelet therapy

Blood pressure control

Lifestyle modification such as smoking cessation and regular aerobic physical activity

All of the above

None of the above

Which of the following is *FALSE*:

TCAR is a safe and effective treatment for carotid disease

TFCAS (transfemoral carotid stenting) has the lowest stroke rate of all carotid procedures

All patients with carotid disease should undergo aggressive risk factor modification

CEA is the gold standard for treatment of carotid disease

Which of the following is *FALSE*:

TCAR is a safe and effective treatment for carotid disease

TFCAS (transfemoral carotid stenting) has the lowest stroke rate of all carotid procedures

All patients with carotid disease should undergo aggressive risk factor modification

CEA is the gold standard for treatment of carotid disease

Which of the following is *TRUE*:

Carotid stenosis less than 50% should undergo surgical treatment

Severe ASYMPTOMATIC carotid stenosis should undergo surgical treatment when life expectancy is less than five years

Severe SYMPTOMATIC carotid stenosis should undergo surgical treatment if the patient is a good risk for surgery

Stroke is not a preventable condition

Which of the following is *TRUE*:

Carotid stenosis less than 50% should undergo surgical treatment

Severe ASYMPTOMATIC carotid stenosis should undergo surgical treatment when life expectancy is less than five years

Severe SYMPTOMATIC carotid stenosis should undergo surgical treatment if the patient is a good risk for surgery

Stroke is not a preventable condition

100th Year of the Greatest Rivalry in Sports