Trans Carotid Artery Revascularization (TCAR) in a Community Hospital

Jonathan D Woody, MD, FACS

Attending Surgeon – University Vascular
Adjunct Clinical Associate Professor – University of Georgia

15th Annual Cardiac, Vascular, and Stroke Care Conference
February 22, 2020
Piedmont Athens Regional
Disclosure

None relevant to this presentation...
Trans Carotid Artery Revascularization (TCAR) in a Community Hospital

Sabina M Sorondo
Medical College of Georgia / AU-UGA Medical Partnership

Jonathan D Woody, MD
University Vascular
Adjunct Clinical Associate Professor / Faculty of Medical Sciences / University of Georgia
Carotid Disease

• Why do we care about carotid disease?
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
Carotid Endarterectomy – CEA

1978 Dr Costantino first CEA by fellowship trained vascular surgeon
Asymptomatic Carotid Disease

- Presence of atherosclerotic narrowing of the extracranial internal carotid artery in individuals without a history of recent TIA or stroke
- Stenosis $\geq 50\%$ 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

<table>
<thead>
<tr>
<th></th>
<th>BMT</th>
<th>CEA</th>
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<tbody>
<tr>
<td>ACAS</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td>ACST</td>
<td>12%</td>
<td>6%</td>
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<tr>
<td>VA Trial</td>
<td>20%</td>
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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**

<table>
<thead>
<tr>
<th></th>
<th>BMT</th>
<th>CEA</th>
<th>Stenosis</th>
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<tbody>
<tr>
<td>NASCET</td>
<td>26%</td>
<td>9%</td>
<td>&gt; 70%</td>
</tr>
<tr>
<td></td>
<td>22%</td>
<td>16%</td>
<td>50-69%</td>
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<tr>
<td>ECST</td>
<td>17%</td>
<td>3%</td>
<td>&gt; 80%</td>
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</table>

- **Pooled analysis confirms above**

*CEA dramatically reduces stroke risk !!!*
Symptomatic Carotid Disease

- Carotid stenosis $\geq 50$
- 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
1978 Dr Costantino first CEA by fellowship trained vascular surgeon
TFCAS – transfemoral carotid stenting

arch manipulation
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:

<table>
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<th></th>
<th>30 days</th>
<th>1 year</th>
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<tbody>
<tr>
<td>TCAR</td>
<td>1.0%</td>
<td>2.8%</td>
</tr>
<tr>
<td>CEA</td>
<td>1.1%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

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
ENROUTE® TRANSCAROTID NEUROPROTECTION & STENT SYSTEM

Blood flow is temporarily reversed in the carotid arteries

Working channel for interventional devices

ENROUTE® Transcarotid Stent System (57cm)

Blood flow is returned to femoral vein

Dynamic Flow Controller & Integrated 200µ Filter High / Low / Stop
ENROUTE Stent  Uber Flex Sheath
ENROUTE Neuroprotection System
CMS Coverage

• Symptomatic ≥ 50%
• Asymptomatic ≥ 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).
## 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
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
## Results

<table>
<thead>
<tr>
<th></th>
<th>PARMC</th>
<th>Natl TCAR Database</th>
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</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>70 (45-89)</td>
<td>70</td>
</tr>
<tr>
<td>Male</td>
<td>62%</td>
<td>65%</td>
</tr>
<tr>
<td>Gen Anes</td>
<td>100%</td>
<td>79%</td>
</tr>
<tr>
<td><strong>Symptomatic</strong></td>
<td><strong>52%</strong></td>
<td><strong>37%</strong></td>
</tr>
<tr>
<td><strong>Severe Stenosis</strong></td>
<td><strong>96%</strong></td>
<td><strong>54%</strong></td>
</tr>
<tr>
<td>Engage Ext Carotid</td>
<td>58%</td>
<td>37%</td>
</tr>
<tr>
<td>Mean Proc Time</td>
<td>59 mins</td>
<td>64 mins</td>
</tr>
<tr>
<td>Mean Flow Rev Time</td>
<td>11 mins</td>
<td>11 mins</td>
</tr>
<tr>
<td>Contrast Volume</td>
<td>30 ml</td>
<td>30 ml</td>
</tr>
</tbody>
</table>
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
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
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
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
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
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…
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
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- 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