Surgical Treatment of Carotid Disease
The Old, the New, and the Future

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Disclosures

- None
Epidemiology

- Stroke is the 4th most common cause of death in the US in 2010
- Approximately 800,000 strokes occur every year
- 35% of which resulted in death and severe disability
- Extracranial cartoid disease represents the most preventable cause of ischemic stroke
Risk Factors

- HTN
- Smoking
- Hyperlipidemia
- Diabetes
- Age
- Males
- Family History
Pathophysiology of a Stroke

Image credit: Rutherford's Vascular Surgery
Treatment Options

- **Medical Management**
  - Aspirin, Plavix, Statin
  - Optimal blood pressure control

- **Surgical Intervention**
  - Carotid Endarterectomy (CEA)
  - Carotid Artery Stenting (CAS)
  - Trancarotid Revascularization (TCAR)
When to Operate?

**ACAS**
- 39 Medical Centers
- 1,662 Patients
- Risk of ipsilateral stroke over 5 years
  - Medical: 11%
  - Surgical: 5.1%
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- 659 Patients
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**Surgery for Asymptomatic Patients >60% stenosis**

**Surgery for Symptomatic Patients >50% Stenosis**
Carotid Endarterectomy

Image credit: Northern Sydney Vascular Website
Post-Operative Management

- Most patients go to a monitored bed postoperatively
- Neuro exams every few hours in the immediate post-operative period
  - Should include motor strength in bilateral extremities, smile, and sticking out their tongue
Complications

- Stroke
  - 1-2%

- Nerve Injury
  - Most common complication
  - 5-20% in most retrospective studies

- Myocardial infarction
  - 25-50% of all perioperative deaths

- Hyperperfusion syndrome
  - Infrequent but carries 75-100% mortality
Long-Term Results

- CEA has been proven to provide excellent long-term clinical and anatomic results
- 5-year stroke free survival reported to be 92-96%
- Durable intervention
Carotid Artery Stenting

- 1989 first balloon-expandable stent was deployed in the carotid artery
- Development of cerebral protection devices
- Carotid Artery Stenting deemed a feasible alternative to CEA
- Proponents: simple, quick, minimally invasive
Pitfalls of Carotid Artery Stenting

- Embolization during unprotected catheterization of the aortic arch and supra-aortic vessels
- Suboptimal embolic protection during CAS
So what are people doing?

- The 2013 National Inpatient Sample suggests that 85% of carotid patients undergo CEA and 15% of patients undergo carotid stenting.
- No consensus regarding widespread adoption of CAS.
- CAS has consistently demonstrated higher overall peri-procedural stroke rates.
CREST Trial

- Largest randomized trial comparing outcomes of CEA vs. CAS
- No significant difference in the 4-year rates of primary end point
- Stroke is more common after CAS
- MI is more common after CEA
- Long lesion length, sequential lesions, severe distal tortuosity, narrow mouth ulcers confer high procedural stroke risk of CAS
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Putting it all together...

1. High risk patient population that would not tolerate a CEA
2. Minimally invasive approach that may have a higher stroke rate
3. CEA remains the primary procedure even for patients with increased surgical risk
What it all means…

- High-risk patients requiring carotid revascularization constitute an unmet clinical need
What if?

- There was an approach that had a low stroke rate and was minimally invasive
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- This is where transcarotid revascularization comes into play.
Houston Firsts
ROADSTER Study Design

- A prospective, single arm, multicenter clinical trial of the ENROUTE Transcarotid Neuroprotection System

- **Primary** endpoint: Composite of all stroke, death, and myocardial infarction at 30 days
Results

- 208 patients enrolled at 18 sites
  - 67 lead in cases
  - 141 pivotal cases
    - 105 asymptomatic
    - 36 symptomatic
## Major Adverse Events

Table VIII. Hierarchical presentation of the major adverse event (MAE) rate for the intention to treat (ITT) population

<table>
<thead>
<tr>
<th>Parameters and statistics</th>
<th>ITT population (N = 141)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who experienced an MAE, No. (%)</td>
<td>5 (3.5)</td>
</tr>
<tr>
<td>Exact binomial, 95% CI</td>
<td>1.16-8.08</td>
</tr>
<tr>
<td>(P) value</td>
<td>.0047</td>
</tr>
<tr>
<td>Events ≤30 days of the index procedure</td>
<td></td>
</tr>
<tr>
<td>Patients who died, No. (%)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Patients who had a stroke, No (%)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Patients who had an MI, No. (%)</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

CI, Confidence interval; MI, myocardial infarction.

*Defined as stroke, death, myocardial infarction.*
Major Adverse Events

- All stroke rate in the pivotal group was 1.4% (2 of 141)
- Stroke and death rate was 2.8% (4 of 141)
- Stroke, death and MI was 3.5% (5 of 141)
Discussion

- CREST: CEA had an MI rate of 2.3% and CAS of 1.1%
  - TCAR: 0.7% MI rate
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TCAR matches MI rate of CAS and stroke/death rate of CEA
The Future

- Can minimally invasive be even more minimally invasive?
- Newer stents and devices
- Completely percutaneous procedures