Carotid Artery Disease
How the 2014-2015 Data Will Influence Management
The Symptomatic vs. the Asymptomatic Patient

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DISCLOSURE

Relevant to Carotid Artery Stenting

- Relationships with industry:
  - Research: None
  - Stock Ownership: None
  - Speakers Bureau: None
  - Consultant: None

“So, I’m the only one who sees a conflict of interest here?”
Stroke Prevention

- Carotid plaque most often causes symptoms due to EMBOLIZATION, rather than thrombosis.
- Extracranial carotid OCCLUSION is the source of ischemic stroke in fewer than 20%.
- Symptomatic patients have a much higher stroke rate than asymptomatic patients.
- Asymptomatic patients outnumber symptomatic patients by 4:1.
FACT(s)

We do NOT need more trials to establish equipoise for CAS vs. CEA

- CAS is one of the most studied procedures of all time.
  - 7 systems approved as “safe and effective” by the FDA, all with “pivotal” and post-approval trials, that account for more than 10,000 published cases.
  - 3 poorly executed European trials (SPACE, EVA-3s, & ICSS) tell us “trainees” cannot do CAS as well as experienced surgeons can do CEA.
  - SAPPHIRE, a small RCT in high surgical risk patients, showed that CAS is the procedure of choice in those pts.
  - CREST was a very large, well conducted trial in average risk patients with no difference between CEA and CAS.
Stroke Prevention
BARRIERS to CAS

- Low volumes.
- No reimbursement.

Nallamothu, BK et al JAMA. 2011;306(12):1338-1343
Do I Have to Explain Why Experience Matters?

CREST Lead-In Specialty Outcomes


Unadjusted Patient Outcomes by Annual Operator Volume

30-Day mortality

<table>
<thead>
<tr>
<th>Operator Volume, Procedures/y</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low (&lt;6)</td>
<td>2.5±0.3</td>
</tr>
<tr>
<td>Low (6-11)</td>
<td>1.9±0.3</td>
</tr>
<tr>
<td>Medium (12-23)</td>
<td>1.6±0.3</td>
</tr>
<tr>
<td>High (≥24)</td>
<td>1.4±0.3</td>
</tr>
</tbody>
</table>

Failure to use EPD

<table>
<thead>
<tr>
<th>Operator Volume, Procedures/y</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low (&lt;6)</td>
<td>4.0±0.3</td>
</tr>
<tr>
<td>Low (6-11)</td>
<td>3.0±0.3</td>
</tr>
<tr>
<td>Medium (12-23)</td>
<td>2.0±0.3</td>
</tr>
<tr>
<td>High (≥24)</td>
<td>1.5±0.3</td>
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</table>

P < 0.001
2500 PATIENTS RANDOMIZED
Level I Evidence for Equipoise
CAS = CEA for Average Surgical Risk
### 4-Yr Study Period (Including Periprocedural Period)

<table>
<thead>
<tr>
<th></th>
<th>Absolute Treatment Effect of CAS vs. CEA (95% CI)</th>
<th>Hazard Ratio for CAS vs. CEA (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of patients (% ±SE)</td>
<td>percentage points</td>
<td></td>
</tr>
<tr>
<td><strong>Any periprocedural stroke or postprocedural ipsilateral stroke</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic patients</td>
<td>24 (4.5±0.9)</td>
<td>13 (2.7±0.8)</td>
<td>1.9 (−0.5 to 4.3)</td>
</tr>
<tr>
<td>Symptomatic patients</td>
<td>48 (7.6±1.1)</td>
<td>37 (6.4±1.1)</td>
<td>1.2 (−1.8 to 4.1)</td>
</tr>
</tbody>
</table>

No statistical difference for stroke out to 4 years between CAS and CEA.
WE DON’T NEED MORE TRIALS....WE NEED TO USE THE DATA WE HAVE TO ALLOW PHYSICIANS AND PATIENTS TO MAKE REASONABLE CHOICES, BASED UPON THE EVIDENCE.

- Patients with CAD.
- Younger age.
- Experienced operator.
- Experienced team.

- High CAS risk.
- Older age.
- Experienced operator.
- Experienced team.
There IS overall equipoise for CEA and CAS but....

- Patient selection for CEA/CAS should be individualized.
- Operator and Institutional volume matter for outcome quality in both CEA and CAS.
- Symptomatic patients have more to gain than Asx.
- Younger patients have more to gain, over the long-term, from revascularization, than do the very elderly.

“One size does not fit all”
### High Surgical Risk

- **Sapphire**: Level I evidence supporting equipoise for CAS and CEA.

#### Stent vs. CEA:

<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>CEA</th>
<th>%Difference [95% C.I.]</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.0%</td>
<td>19.2%</td>
<td>−7.2% [−14.9%, 0.6%]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>2002</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-inferiority limit</td>
<td></td>
<td></td>
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</tbody>
</table>

- **Stent Better**
- **CEA Better**

#### Carotid Stenting 30 Day Complications

- [Graph showing 30 day complications over years from 2002 to 2012]
Some patients present difficult challenges for CEA, and may be offered CAS as an alternative.

Some patients who are at increased risk for CEA will strongly prefer CAS.

Assumes operator and institutional experience and a track record for safety and quality.
Percent Choosing Treatment Options

- 67-year-old man with a carotid bruit and 70%-80% RICA.
  - nonsmoker
  - hypertension
  - hyperlipidemia
  - LICA 20% stenosis.

Asymptomatic Carotid Stenosis

• ACAS\textsuperscript{1} and ACST\textsuperscript{2} in the 1990’s:
  
  – CEA vs. MED
    
    • 5 yr relative risk reduction for ipsilateral stroke 50%.
    
    • 1 yr absolute risk reduction of 0.5% to 1.0%.
    
    • NNT 100-200 to prevent one stroke per year.
    
    • CEA did not reduce combined stroke and death.
    
    • CEA did not benefit women.
    
    • CEA did not benefit men ≥ 75 years.
  
  – CMS 2004-2006
    
    • Asx CEA = 88%, Asx CAS = 87%.

Asymptomatic Carotid Stenosis

- Risk of progression to occlusion is low.
  - ACST\textsuperscript{1}: 1,469 MED Group:
    - 94 progressed to occlusion.
    - 12 with symptoms.
    - 1 with stroke.
  - Yang et al\textsuperscript{2}: 3,681 MED for 20 yrs.
    - 254/316 (80\%) Occlusions before 2002.
    - Only 1 stroke with occlusion.

Asymptomatic Carotid Stenosis

Percent Stenosis

P = 0.80

Plaque Burden

P = 0.006

Consensus CAS vs. CEA

Asymptomatic

• Selection of asymptomatic patients for revascularization should be based on comorbid conditions and patient life expectancy (Class I, Level of Evidence: C).

• Highly selected patients may benefit from CEA if the perioperative stroke/death rate is <3% (Class IIa, Level of Evidence: A).

• CAS might be considered in highly selected patients if the perioperative stroke/death rate is <3% (Class IIb, Level of Evidence: B).

• The usefulness of CAS is not well established for patients at high risk for CEA (Class IIb, Level of Evidence: C).

Symptomatic

• Patients with a TIA or stroke ≤ 6 months and ipsilateral severe stenosis (70% to 99%), CEA is recommended if the perioperative stroke/death rate is estimated to be <6% (Class I, Level of Evidence: A).

• CAS is indicated as an alternative to CEA if the anticipated perioperative stroke/death rate is <6% (Class IIa, Level of Evidence: B).

• When revascularization is indicated, it is reasonable to perform it within 2 weeks rather than delay (Class IIa, Level of Evidence: B).

• It is reasonable to consider patient age in choosing between CEA and CAS (Class IIa, Level of Evidence: B).

FACT(s)

Patients hard to operate on safely.
- Class III/IV angina.
- Class III/IV heart failure.
- Intrathoracic or intracerebral lesions.
- Prior neck surgery or RT.

Patients hard to place stents safely.
- Type III Aortic Arch.
- Tortuous and calcified lesions.
- Unable to use EPD.
- Difficult vascular access.
Stroke Prevention Strategy

Revascularization includes aggressive risk factor modification.
Thank You