Carotid Stenting Indication And Case Review

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• NASCET Trial

• ACAS Trial
Symptomatic Carotid Stenosis

<50% stenosis
- trials showed that there was no significant benefit of surgery.
- in NASCET, there was no significant difference in the risk of ipsilateral stroke between those who were treated with endarterectomy and those who were treated medically.

North American Symptomatic Carotid Endarterectomy Trial (NASCET), the European Carotid Surgery Trial (ECST), and the trial by the Veterans Affairs Cooperative Studies Program.

Symptomatic Carotid Stenosis

- Moderate stenosis, 50 to 69%
  - In NASCET, the 5-year risk of fatal or nonfatal ipsilateral stroke among patients was 22.2% in the medical group and 15.7% in the surgical group.
  - Absolute risk reduction 6.5%
  - NNT 15
Symptomatic Carotid Stenosis

- 70% stenosis
  - The rate of ipsilateral stroke: 26% in the medical group and 9% in the surgical group*
  - Relative risk reduction 65%*
  - Absolute risk reduction 17%*
  - **NNT 7-8** (# patients who would need to undergo endarterectomy to prevent one stroke in a 5-year period)**

Asymptomatic Carotid Stenosis

- The risk of stroke is lower than that associated with symptomatic disease

- The risk in NASCET was 3.2% per year for asymptomatic stenosis of 60 to 99%
Asymptomatic Carotid Atherosclerosis Study (ACAS) - >60% stenosis

- The risk of ipsilateral stroke or any stroke or death was 5% during 5 years of follow-up in surgically treated patients and 11% in medically treated patients.
  - Absolute risk reduction (ARR) 6%
  - NNT 17

- Because of the lower ARR, a rate of perioperative complications (stroke or death) of more than 3% would eliminate the potential benefit of the operation.

- The benefit of surgery was greater for men than women (reduction in risk, 66% vs. 17%)

- The rate of perioperative complications was higher among women than men (3.6% vs. 1.7%).

So Why do we need to even think about Carotid Stenting?
NASCET Exclusions

- Age > 79
- Major Surgery Within One Month
- Atrial Fibrillation
- Valvular Heart Disease
- Uncontrolled Hypertension
- Uncontrolled Diabetes
- MI Within 6 Month
- Kidney Failure
- Severe Lung Disease
ACAS Exclusion Criteria

- Age > 79
- Atrial Fibrillation
- Valvular Heart Disease (Including Valve Replacement)
- Symptomatic CHF
- Active Ulcer Disease
- Uncontrolled Hypertension
- Uncontrolled Diabetes
- Kidney Failure
- Severe Lung Disease

ACT 1 Trial

- 1453 Patients
- Age < 79
- Non Inferiority design
- Asymptomatic Carotid Stenosis
- Randomized to CAS or CEA
- 30 Days Stroke or Death 2.9% to 1.7% respectively P 0.33
- 30 Days to 5 years freedom from Ipsilateral stroke 97.8% to 97.3 % respectively P 0.51
Crest trial 10 years outcome

- 2502 Patients
- Almost Half Asymptomatic
- Randomized to CAS or CEA
- Composite end points were 11.8% and 9.9% respectively
- 10 Years Rate Of Ipsilateral Stroke was 6.9% and 5.6%
- No statistically significant difference between the two groups
Features Suggested to Increase The Risk Of CAS

• Elderly > 80
• Symptoms Status
• Bleeding Risk
• Severe AS
• Renal Disease
• Type 3 Arch – tortuosity – Calcification – Thrombus – Heavy Arch Atheroma Burden
• Inexperienced Operator
Multidisciplinary Carotid Stent Guidelines

- Reasonable Option for Symptomatic Patients with high Risk Features for CEA  Class IIa
- Reasonable Option For Asymptomatic Patients With High Risk Features for CEA  Class IIb

Features Associated With High Risk CEA

- Elderly > 80
- CHF III / IV
- Unstable Angina CCS III / IV
- CAD with 2 or more vessels with 70% stenosis
- MI last 30 Days
- EF less than 30%
- Severe COPD
- Severe Renal Function
Features Associated With High Risk CEA

- Surgically Inaccessible lesion
- At or Above C2
- Below the Clavicle
- Ipsilateral Neck Radiation
- Spinal Immobility of the Neck
- Contra Lateral Carotid Occlusion
- Laryngeal Palsy
- Previous Ipsilateral CEA or Neck Surgery

So there is no clear difference between CEA and CAS

Do we need to revisit Medical management?
Landmark CEA studies
ACAS, ACST and NASCET: Comparative Results

What is Modern Medical Management

- 97% on Anti Platelet
- 10% On Anticoagulation
- 86% on Statin
- 51% Blood pressure below 160/90
- 39% blood pressure below 140/90

Marquardt L, et al, Stroke 2010: 41
Annual Risk of Events With Modern Optimal Risk Factors Modification

<table>
<thead>
<tr>
<th>Event</th>
<th>Average Annual Risk, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsilateral stroke</td>
<td>0.34 (0.01–1.87)</td>
</tr>
<tr>
<td>Ipsilateral TIA</td>
<td>1.78 (0.58–4.16)</td>
</tr>
<tr>
<td>Other territory stroke</td>
<td>8.32 (5.08–12.85)</td>
</tr>
<tr>
<td>Other territory TIA</td>
<td>5.15 (2.74–8.81)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4.70 (2.50–8.04)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>1.03 (0.21–3.01)</td>
</tr>
<tr>
<td>Vascular death</td>
<td>7.70 (5.79–12.98)</td>
</tr>
<tr>
<td>Nonvascular death</td>
<td>2.01 (0.82–4.76)</td>
</tr>
</tbody>
</table>
What have we learned?

- 84 Years old Female
- Chronic A.Fib On Anti-Coagulation
- No Previous history of CVA or TIA
- Right Carotid bruit found BY PCP
- Carotid Ultrasound showed 70-90% Right Carotid stenosis

- What would you do?
  - CEA ?
  - CAS ?
  - Medical management ?
Rate of Intervention in Asymptomatic Carotid Stenosis

- United State  90%
- Germany 60%
- Canada 15%
- Denmark 0%

CREST 2 Trial

- Two Parallel trials
- Asymptomatic Carotid stenosis
- Clinical decision for CEA or CAS
- Each arm randomized against modern medical management
Novel Approaches to Identify Patients at Risk

- Silent Embolic Infarcts on MRI
- Reduced Cerebral Flow Reserve
- Intra Plaque Hemorrhage on MRI

Summary

- Many of our patients were excluded from the trials
- Symptomatic Carotid stenosis would benefit from intervention
- No clear advantage between CEA and CAS
- Both have high risk features
- Benefit for asymptomatic patients less clear, if any
- Medical management deserves another look