We Will Have Agreed Upon Indications for Repair of Asymptomatic Carotid Stenosis: Yes or No?

D. Chris Metzger, MD  
Wellmont CVA Heart & Vascular Institute  
Kingsport, TN, USA
Disclosures

• **Symposia Honoraria & Proctor Fees:**
  • Abbott, Endologix/ TriVascular

• **Symposia Honoraria:**
  • Boston Scientific, Bard, Gore, CSI, Medtronic

• **VIVA Board Member**

• **National PI/Co-PI:** Confidence, SAPPHIRE WW, CANOPY

• **Research Grants, Stocks, Equity**
  • None
So, WE will have AGREED upon ASx CAS??
We Should be Able to Agree on This, Right?

- CEA > 50 years, CAS > 20 years
- RCT’s : CEA > (≥) Medical treatment
- North American rigorous RCT’s: CAS ≈ CEA (Both good!)
- > 100,000 CEA,CAS adjudicated trial patients w/ long term follow up
- Both procedures have been improved/ refined
- BOTH can be performed safely with excellent long-term patency and prevention of ipsilateral strokes
Barriers to the Global “We” Agreeing on Asymptomatic Carotid Artery Disease Treatment

• Poor understanding of the risk of the disease and of the success/results of treatment (CEA, CAS)
• TURF ISSUES, politics
• ≈ low event rates for asymptomatic carotid artery disease
• ↓ insight, ≈ nihilist viewpoint PCP’s, neurologists
• STRONG differences of opinions within our specialties
• Health care system can’t afford uncontrolled, widespread CAS
• CMS/payors receive dissenting opinions, conflicting data
Background: Carotid Disease, Revascularization

• MOST stroke patients (75%) were asymptomatic until their stroke
• We do poorly at predicting stroke in asymptomatic patients
  • (≥ 80%, rapid progression, ulcerated → ↑ risk [?])
• There is NO randomized data showing Medical therapy is superior to revascularization
• BOTH CEA and CAS when performed by experienced operators in selected patients:
  • Can be done safely (<1% major stroke, < 3% minor stroke)
  • Have excellent durability (>95% @ 4-10 years)
  • Do an excellent job at preventing ipsilateral stroke (>97% @ 4-10 years)
1:1 Randomization of “Standard Risk CEA Patients” to CEA or CAS in experienced centers, with well-defined protocol
Primary Endpoint ≤ 4 years
(any stroke, MI, or death within peri-procedural period plus ipsilateral stroke thereafter)

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2 vs. 6.8%</td>
<td>HR = 1.11; 95% CI: 0.81-1.51</td>
<td>0.51</td>
</tr>
</tbody>
</table>
Primary Endpoint

ITT analysis

% Event Free

Follow-up Time (years)

P = NS

Assignment  | CAS  | CEA
Ipsilateral Stroke after Peri-procedural Period ≤ 4 years

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0 vs. 2.4%</td>
<td>HR = 0.94; 95% CI: 0.50-1.76</td>
<td>0.85</td>
</tr>
<tr>
<td>30-day endpoint components</td>
<td>CAS (%)</td>
<td>CEA (%)</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>Peri-procedural CVA</td>
<td>4.1%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Peri-procedural MI</td>
<td>1.1%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Peri-procedural Major CVA</td>
<td>0.9%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Peri-procedural CN palsies</td>
<td>0.3%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Ipsilateral CVA after peri-procedural period ≤4 years</td>
<td>2.0%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Combined peri-procedural CN palsies and CVA</td>
<td>4.4%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>
ACT-1 Background

*RCT CEA vs CAS; Asx “Standard Risk” Patients*

- Comparison of carotid artery stenting with embolic protection and carotid endarterectomy in:
  - Patients <80 years of age
  - Severe carotid artery stenosis (≥70%)
  - Asymptomatic (i.e., No stroke, TIA, AF last 180 days)
  - Were not considered to be at high risk for surgical complications (i.e. ‘low-risk’)

A composite of death, stroke (ipsilateral or contralateral, major or minor) or myocardial infarction during the 30 days after the procedure or ipsilateral stroke during the 365 days after the procedure.

N = 1435

Primary Endpoint
ACT 1: Five Year Outcomes

30 day to 5 year Ipsilateral Stroke (nonprocedural stroke):

- 2.2% CAS V 2.7% CEA (p=0.51)

5 year Freedom from any stroke:

- 93.1% CAS V 94.7% CEA (p=0.44)

5 year clinically driven re-intervention:

- 1.6% CAS V 3.3% CEA (p=0.05)

5 year Survival:

- 87.1% CAS V 89.4% CEA (p=0.21)
Freedom from Ipsilateral Stroke between 31 Days to 5 Years

Event Free Survival

97.8%
97.3%

Days

CAS
CEA
Long-term Results of Stenting vs Endarterectomy for Carotid-Artery Stenosis

*Durability*: 10-Year CREST TCT Data

Thomas G. Brott, MD
On behalf of the CREST Investigators
Primary Composite End Point

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Endarterectomy</th>
<th>Stenting</th>
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CAS Results Continue to Improve

Total Stroke in Carotid Stent IDE Trials 2002-2010

Death or Major Stroke Rates Decrease for CAS over the Period of CREST Enrollment

Proximal protection, TCAR, Micro-mesh, ...
So Why is Most CAS Not Reimbursed?
CM Opinion on CMS Non-Reimbursement

- Honestly, good CMS people don’t know the answer, AND

- *IF CAS is approved, there will be a huge, unchecked or suboptimally-regulated increase in CAS procedures done by untrained operators and in poorly selected patients, leading to:*
  - Huge unsustainable cost burdens
  - ↑↑ number of strokes
  - ↑↑ disagreement amongst subspecialties
  - “Wild wild west” mentality
  - Disapproval by many of CMS and their decision making
We Know that Experience Matters for CEA & CAS
My Proposal for “Agreement”..

- **Couple reimbursement to experience/performance**
  - ONLY trained operators meeting a (HIGH) minimal standard
  - All patients entered into adjudicated registries (DC if ↑ events)
  - Accredited Centers of excellence; audited results

- Treat asymptomatic patients ONLY if:
  - ≥ 80%, AND well selected patient and experienced operator

- Treat all patients with maximized medical therapy, and individualize a careful risk/benefit assessment of the need for and the proper revascularization procedure

Oh, and CREST 2 is NOT “The answer”
If YOU or I Had a 90% Asx Carotid…

• And John Laird, Manny Mehta, Dierk Scheinert, Peter Schneider, or Yours Truly could do a procedure with <2% stroke rate AND 96%+ rate of long term patency and prevention of stroke, would you prefer Medical Therapy??
Conclusions

• Asymptomatic carotid disease is prevalent, and we do not do well at predicting which patients will have a stroke.

• Both CEA and CAS, when performed by experienced operators with good technique and case selection, can be performed at low stroke risk and with high vessel patency rates and prevention of ipsilateral strokes.

• I believe that a multi-disciplinary consensus is needed, coupling established standards for operators and centers, and linking payment only to credentialed operators/centers with excellent adjudicated results.
Thank You Very Much for Your Attention!
Attend the conference live from your computer!

November 5-8, 2018
at Wynn Las Vegas, Nevada, USA
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