Asymptomatic Carotid Stenosis—Risks of CEA/CAS Outweigh Potential Benefit: None Should Undergo CEA or CAS As ‘Routine’ Practice

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Disclosures

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Only ACS Subgroup to Benefit from CEA in RTs: ‘Average Surgical’ Risk Men Aged < 75 - 80 with >60% stenosis. ie, No disorder to seriously complicate CEA. Plus:

- Age > 40
- No aspirin contra-indication
- No prior ipsilateral CEA
- No non-carotid cerebral embolic source
- No reason to limit study participation or produce disability or death < 5 years

Selection criteria for ACAS & ACST

Trans-Femoral/Aortic CAS:
Is Out- Worse Than CEA

CAS Stroke Risk Not Compensated by MI

<table>
<thead>
<tr>
<th>Randomized Trial</th>
<th>n</th>
<th>30-day Strokes</th>
<th>30-day MIs</th>
<th>30-day Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CAS</td>
<td>CEA</td>
<td>CAS</td>
</tr>
<tr>
<td>ACT-1, 2016</td>
<td>1420</td>
<td>30</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>CREST-1, 2010</td>
<td>2502</td>
<td>52</td>
<td>29</td>
<td>14</td>
</tr>
<tr>
<td>ICSS, 2010</td>
<td>1649</td>
<td>56</td>
<td>27</td>
<td>3</td>
</tr>
<tr>
<td>CAVATAS, 2009</td>
<td>502</td>
<td>33</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>BACASS, 2008</td>
<td>20</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>EVA-3S, 2006</td>
<td>520</td>
<td>34</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>SAPPHIRE, 2004</td>
<td>334</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Kentucky, 2001</td>
<td>104</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td><strong>7051</strong></td>
<td><strong>382</strong></td>
<td><strong>99</strong></td>
<td><strong>23</strong></td>
</tr>
</tbody>
</table>

Overall, CAS had 1.6 x more strokes or MIs +/- death (ORs 1.44, 95%CI 1.15,1.80; P=0.002) Bonati et al 2012

SCS: CAS had 1.4 x more strokes or MIs +/- death (ORs 1.44, 95%CI 1.15,1.80; P=0.002) Bonati et al 2012
PLUS: CEA/CAS Outcomes often Worse Outside Trials

30-day CEA Stroke/Death Rates: 47 Selected High-Vol ACS Registries (204,000 CEAs, no angiographic risk):
- 3.9% in 1992
- 1.2% in 2013

ACAS (1988-1993)
- 2.3% actual
- 1.5% without angiographic risk

Muirhead et al, Neurology, 2015; 85:1-8
Exec Committee, JAMA, 1995

Trans-Carotid Arterial Revascularisation: TCAR?

- Assessed only in registries & compared with CEA or transaortic CAS
- Not going to establish a procedural benefit over current best medical intervention alone

No Evidence of Procedural Benefit Now
≥50-75% ACS & ‘Medical Revascularisation’ Alone...

Annual Ipsilateral Stroke Rate (Raw data, %)
- 1.7% fall in Absolute Rate
- 67% fall in Relative Rate to 0.8%

At Most Only About 4% of Persons with ACS Will Now Have Stroke Caused by the Lesion!

- Average annual ipsilateral stroke rate is 0.8%.
- Average age of diagnosing 50%-99% ACS: 70 yrs
- Average survival is 10 years (0.8 x 10 = 8%)
- About half the strokes occurring in the distribution of a 50%-99% ACS not are due to the stenosis.
- Assumes 30-day procedural stroke/death rate = 0


None Should have ‘Routine’ CEA Until we Know Who They Are-

Including the Elderly & Frail!

Unacceptably high 30-day stroke death rates: 6.2-12.5% for asymptomatic frail in NSQIP!

Sidawy et al 2014, Melin et al 2014

Risk Stratification of ACS is Currently Unable to identify those likely to benefit from CEA

Despite What Some Say…
ACS & Proposed High Stroke Risk


Endorsements for CEA (Class IIa) or CAS (Class IIb) for average surgical risk 50-99% ACS if >1 of these or other undefined features:^  
1. Silent Infarct on CT *  
2. Asymptomatic stenosis progression *  
3. Large Plaque area *  
4. Juxtaluminal black areas on U/S *  
5. Intra-plaque haemorrhage on MRI  
6. Impaired CVR  
7. Plaque echolucency on U/S *  
8. Transcranial embolic signals +/- echolucency  
9. Controllable TIA/stroke *  
10. [80-99% stenosis] *  

* And if peri-procedural stroke/death rate <3%, patient life expectancy >5 years. EJVES, 2017  
* From the ACSRS Study by Nicolaides et al +/- others  
* All studies performed with outdated medical intervention

In Isolation- All Lack Sufficient Specificity

<table>
<thead>
<tr>
<th>Marker Study</th>
<th>% Baseline Prevalence (% stenosis)</th>
<th>Annual Ipsilateral Stroke Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impaired CV reserve</td>
<td>Various 1996-2010</td>
<td>30-48 (&gt;70)</td>
</tr>
<tr>
<td>Echolucent plaque</td>
<td>Gupta et al, 2013</td>
<td>31 (&gt;50%)</td>
</tr>
<tr>
<td>TCD embolic signals</td>
<td>Various 2005-2010</td>
<td>10-42 (&gt;60)</td>
</tr>
<tr>
<td>Echolucent plaque and ES</td>
<td>Topakian et al 2011 (ACES)</td>
<td>0.6% (&gt;70% stenosis)</td>
</tr>
<tr>
<td>[Prior contra stroke/TIA]*</td>
<td>Nicolaides et al 2005</td>
<td>15 (12-99)</td>
</tr>
<tr>
<td>[80-99% stenosis]*</td>
<td>Nicolaides et al 2016</td>
<td>20 (11-99)</td>
</tr>
</tbody>
</table>

* From ACSRS Study; **From ACST; ***NASCET Stenosis, all studies performed with outdated medical intervention

PLUS

* Combined markers are better (ACSRS)  
* No stroke risk stratification studies on current best medical intervention  
* Efficacy + procedural standards not established in randomised trials

Contrary Healthcare Systems

McKeon Strategic Review of Health and Medical Research, 2013

Stopping Inappropriate ACS Procedures: A Multi-billion $/Year Industry of Waste Built on Misconceptions

7. Guidelines/leaders are always right  
6. CAS is best for ‘high-CEA-risk’  
5. CAS & CEA are equivalent  
4. All populations are equal + unchanging  
3. Medical intervention is unchanging  
2. ACST & ACAS results are the same  
1. ACAS results are always applicable, term. place. populations
Conclusion

Carotid procedures for ACS:

* Should only be done in appropriate trials
* No current proven benefit over medical intervention, just evidence of harm & waste

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