The 2011 SVS Guidelines For Extracranial Carotid Disease: Do They Still Impact On Clinical Practice?

Enrico Ascher, MD

NYU-Lutheran Medical Center and
The Vascular Institute of New York ©
Brooklyn, New York

Global opinion about management of 70% - 80% ICA stenosis (67 year old man, HTN, ↑cholest)

Stroke: Scope of the Problem

795,000 new / recurrent stroke/year
#1 cause of disability
3rd leading cause of death
$73.7 billion in 2010

American Heart Association

US Presidents

Treatment Modalities

- Pharmacologic
- Carotid Stenting
- Carotid Endarterectomy

No disclosures
**Best Medical Therapy**

- Statins for lipid control (LDL, HDL)
- Antiplatelet therapy
- Low sodium intake
- Smoke cessation
- Regular exercise
- Weight loss
- DM control
- HTN control

**Current Control of CVD Risk Factors**

“Ideal” cardiovascular health < 1%

*Drug Des Devel Ther May 2011*

**SPARCL**

*(Stroke Prevention by Aggressive Reduction in Cholesterol Levels)*

Double-blind placebo controlled international industry supported trial

- Post TIA/Stroke patients had a 16% relative risk reduction in repeat stroke/TIA (13.1% without statin and 11.2% with statin) - Less than anticipated!
- Higher rate of hemorrhagic stroke

*N EJM 2006*

**Opponents of CEA / stenting**

Benefit of CEA is small and highly dependent on both the operative risks and the efficacy of the medical therapy employed…

- Stroke prevention of 1% / year.
- Risk of stroke falling…
- Statins and more statins!

**Abbott AL et al. Stroke 2013**

- Improvement in medical treatment is clear from robust analyses of all published comparable, quality stroke rate calculations of patients with 50% to 99% asymptomatic carotid stenosis. Using the same standardized rate calculations, we are now seeing an average annual rate of ipsilateral stroke of ≈0.5% with medical treatment alone.

Marquardt L et al. Stroke. 2010
Guessenis BM et al. SMART study. Stroke. 2007
Markus HS et al. ACES study. Lancet Neurol. 2010

**Asymptomatic Carotid Artery: Natural History**

Annual rates of ipsilateral stroke in patients with asymptomatic carotid stenosis stratified for stenosis severity

A.R. Naylor et. al Eur J Vasc Endovasc Surg 2009;37:625-32
Contralateral Asymptomatic ICA (ECST Trial)

- < 70% stenosis: <2% annual stroke
- 70-79% stenosis: 9.8% annual stroke
- 80-99% stenosis: 14.4% annual stroke


The REACH Study
Reduction of Atherothrombosis for Continued Health Registry

- 3164 patients ≥ 70% ICA stenosis
  - 3.1% annual stroke
  - 70% on statins

*Published in* Lancet 1995;345:209-12.

The natural history of asymptomatic severe carotid artery stenosis

*Mark F. Connolly, MD, MSc, Michael J. Mackay, BS, Anessa Ogden, BS, Vivendra I. Patel, MD, MPH, Glenn M. Libby, MD, and Richard P. Candeias, MD, Seattle, Wash.

Background: Although level 1 evidence suggests carotid endarterectomy (CEA) for stroke prevention in patients with asymptomatic severe carotid artery stenosis (ASPECTS >70%), medical therapy alone has been predominant by virtue of equipoise. The goal of the single arm, multicenter, randomized control trial of medically treated patients with ASPECTS >70% (REACH) was to provide evidence to inform the clinical decision for individual patient treatment. The REACH study demonstrated an absolute risk reduction of 3.7% at 2 years for patients treated medically.*

*Published in* Lancet 1995;345:209-12.

Causes of Stroke
20% to 30%
Carotid Artery Plaque

Management ???
Industry & Non-Industry Sponsored Trials

70% left ICA stenosis
Cognitive decline: Odds Ratio 6.7

*Johnston et al, Ann Int Med 2004*
SVS Clinical Practice Guidelines Committee
2011

The Knowledge and Encounter Unit
Mayo Clinic, Rochester, Minnesota
...systematic reviews to answer specific questions

CEA vs Stenting

Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease
John J. Ricotta, MD, Ali Abdollahi, MD, FACS, Enrico Archer, MD, Mark Eckert, MD

- RCTs 13
- Total Patients 7484 (80% sympt)

Table II. Absolute risk difference per 1000 patients

<table>
<thead>
<tr>
<th>Outcome</th>
<th>R (95% CI)</th>
<th>Quality of evidence</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>3.44 (1.29, 5.54)</td>
<td>Moderate</td>
<td>CAS is associated with 3.44 more deaths (from 1.29 to 5.54)</td>
</tr>
<tr>
<td>HI</td>
<td>-10.15 (-13.17, -7.13)</td>
<td>High</td>
<td>CAS is associated with 10.15 more HI (from -13.17 to -7.13)</td>
</tr>
<tr>
<td>Stroke</td>
<td>18.77 (12.64, 24.90)</td>
<td>High</td>
<td>CAS is associated with 18.77 more strokes (from 12.64 to 24.90)</td>
</tr>
</tbody>
</table>

CAS: Carotid artery stenting; CI: confidence interval; MD: moderate; MI: myocardial infarction; R: absolute risk difference per 1000 patients

Grade I Recommendation, High Quality Evidence
- ≥50% symptomatic: CEA
- ≥60% asymptomatic: CEA

CAS vs CEA
- Two large prospective controlled studies in 2010:
  - CREST
  - ICSS

Conclude: Stent vs. CEA – equivalent results.

ORIGINAL ARTICLE
Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis
Michael J. Simonton, MD, Stu Post, MD, Robert P. O'Byrne, MD, habilitation, in: 15th Congress European Society of Cerebrovascular Disease. Hins H.

Peri-Procedural

<table>
<thead>
<tr>
<th>SCA</th>
<th>CAS</th>
<th>CEA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Stroke</td>
<td>4.1%</td>
<td>2.3%</td>
<td>0.01</td>
</tr>
<tr>
<td>MI</td>
<td>1.1%</td>
<td>2.3%</td>
<td>0.03</td>
</tr>
<tr>
<td>Death</td>
<td>0.7%</td>
<td>0.3%</td>
<td>0.18</td>
</tr>
<tr>
<td>Stroke/death/MI</td>
<td>5.2%</td>
<td>4.5%</td>
<td>0.38</td>
</tr>
</tbody>
</table>

NEJM 2010
### Symptomatic Carotid Peri-Procedural Complications

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>CEA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>5.5 %</td>
<td>3.1 %</td>
<td>0.04</td>
</tr>
<tr>
<td>MI</td>
<td>1.0 %</td>
<td>2.3 %</td>
<td>0.08</td>
</tr>
<tr>
<td>Stroke / Death</td>
<td>6.0 %</td>
<td>3.2 %</td>
<td>0.02</td>
</tr>
</tbody>
</table>

### ICSS: International Carotid Stenting Study

**1710 Symptomatic patients**

**Lancet 2010: Multicenter, international, randomized trial**

30 days after randomization

<table>
<thead>
<tr>
<th></th>
<th>CAS (828)</th>
<th>CEA (821)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Stroke</td>
<td>7.0 %</td>
<td>3.3 %</td>
<td>0.001</td>
</tr>
<tr>
<td>Any Stroke / Death</td>
<td>7.4 %</td>
<td>3.4 %</td>
<td>0.0004</td>
</tr>
<tr>
<td>Stroke / Death / MI</td>
<td>7.4 %</td>
<td>4 %</td>
<td>0.003</td>
</tr>
<tr>
<td>Disabling Stroke / Death</td>
<td>4.0 %</td>
<td>3.2 %</td>
<td>NS</td>
</tr>
</tbody>
</table>

### CAS vs. CEA P-value

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>CEA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Stroke</td>
<td>2.5 vs. 1.4%</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>CEA by: Vascular Surgeons</td>
<td>2.6 vs. 1.1%</td>
<td>0.20</td>
<td></td>
</tr>
</tbody>
</table>

### Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack

**AHA/ASA Guideline**

- **Class I:** procedure should be performed.
- **Class IIa:** it is reasonable to perform the procedure.

CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by >70% by noninvasive imaging or >50% by catheter-based imaging or noninvasive imaging with carotid endarterectomy and the anticipated rate of peri-procedural stroke or death is <2% (Class Ia; Level of Evidence B).
Asymptomatic 60% - 79% ICA Stenosis

2011 SVS guidelines:
CEA & medical therapy good risk patient

2016 SVS guidelines:
Medical management and...

- Progression of disease (≥80%)
- Embolization detection by TCD
- Silent cerebral infarcts
- Low GSM plaque
- Large ulcerated plaque
- Intra-plaque hemorrhage

Mini-Incision CEA

Mini skin incision for carotid endarterectomy (CEA): A new and safe alternative to the standard approach.

30-Day Stroke / Death Rates
Asymptomatic and Symptomatic Carotid Stenoses (290 CEAs) *

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| Stroke           | 0      | (0%)
| Death            | 0      | (0%)
| MI               | 0      | (0%)
| Combined         | 0      | (0%)

* Personal experience

Thank you