Carotid Repair Is Best for Asymptomatic Carotid Stenosis
Because Medical Management Alone Does Not Work

Peter A. Schneider, MD
Honolulu, Hawaii
Disclosure

Peter A. Schneider, MD

Potential conflicts of interest to report:

Consulting: Silk Road, Surmodics, Profusa, CSI, Cardinal, Terumo
Chief Medical Officer: Intact Vascular, Cagent, Vesper
Scientific Advisory Board: Abbott, Medtronic, Boston Scientific
What Is the Stroke Risk with Medical Therapy?

Recent cohort studies have found that ipsilateral stroke rates associated with asymptomatic carotid stenosis are currently less than 1% a year, compared with greater than 2% 10 years.

These must be the best possible available sources to convince us that the problem is solved with medication alone!!
Medical Therapy for Asymptomatic Carotid Stenosis
Is the current annual risk really less than 1%?

<table>
<thead>
<tr>
<th>Study</th>
<th>Purpose</th>
<th>Reference</th>
<th>Patients</th>
<th>PSV</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMART</td>
<td>Study vascular events at Univ of Utrecht</td>
<td>Goessens Stroke 2007</td>
<td>221 with &gt;50% stenosis Excluded 996 patients with history of cerebrovascular disease</td>
<td>150 cm/sec</td>
<td>Only 96 pts had PSV &gt;210, 7% had carotid repair</td>
</tr>
<tr>
<td>Oxford Vascular Study</td>
<td>Study vascular events in Oxford</td>
<td>Marquardt Stroke 2010</td>
<td>101 with &gt;50% stenosis (Only 32 with &gt;70%)</td>
<td>150 cm/sec</td>
<td>Vascular death in 7.7% (undefined)</td>
</tr>
<tr>
<td>ASED</td>
<td>Use TCD to find high risk group</td>
<td>Abbott Stroke 2005</td>
<td>202 with &gt;50% stenosis</td>
<td>150 cm/sec</td>
<td>10 underwent CEA</td>
</tr>
</tbody>
</table>

If we follow patients with minimal disease, don’t be surprised if nothing much happens to them.

Evidence for claims of low risk from real carotid lesions is poor.
Right ICA occlusion  Left ICA stenosis
What we know about asymptomatic carotid stenosis:

• The patients we see with a stroke caused by carotid stenosis (and the ones we don’t see because they had a fatal stroke) are patients that used to have asymptomatic carotid stenosis.
• Stroke prevention is better with repair plus best medical therapy for asymptomatic carotid stenosis.
• We should be focused on the patients with real lesions that used to be asymptomatic, not on the vast majority of patients with asymptomatic mild or moderate disease that do not need a repair.
What we know:
Three Positive Randomized Trials

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA</td>
<td>17/211</td>
<td>24/233</td>
<td></td>
<td>15.5 %</td>
<td>0.78 [ 0.43, 1.41 ]</td>
</tr>
<tr>
<td>ACAS</td>
<td>33/825</td>
<td>52/834</td>
<td></td>
<td>35.1 %</td>
<td>0.64 [ 0.42, 0.98 ]</td>
</tr>
<tr>
<td>ACST</td>
<td>53/1560</td>
<td>73/1560</td>
<td></td>
<td>49.5 %</td>
<td>0.73 [ 0.51, 1.03 ]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>2596</strong></td>
<td><strong>2627</strong></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.71 [ 0.55, 0.90 ]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 103 (Treatment), 149 (Control)
Heterogeneity: Chi² = 0.33, df = 2 (P = 0.85); I² = 0.0%
Test for overall effect: Z = 2.80 (P = 0.0051)

Repair plus medical management is better than medical management alone.
What we know:
ACST-Repair Decreased Risk by 50% at 5 Years

Despite the relatively high (3%) risk of stroke and death with CEA.
ACST-1: Any type of stroke or perioperative death at 10 years, by lipid-lowering status

Not on lipid-lowering therapy at entry

On lipid-lowering therapy at entry

Residual risk despite statins

Lancet 2010;376:1075-84
ACST was biased against CEA, and it still showed that CEA was better.

Enrolled patients with moderate disease.

Permitted crossover to repair.

Avoidance of enrollment in BMT as only treatment in patients with “worrisome” lesions.

A lot of repair versus some repair
Risk of stroke: An inflection point at a PSV >250

If you want to know whether asymptomatic carotid stenosis causes stroke…

Progression of Asymptomatic Carotid Stenosis Despite Optimal Medical Therapy

**Fig. 1.** Probability of progression from moderate ASCAS to severe stenosis. The rate of disease progression followed a linear trend, including 7.6% progression at 1 year, 17.6% at 2 years, and 35.9% at 4 years. Overall, disease progression from moderate ASCAS to severe stenosis occurred in 25.1% of patients.


Hicks et al Ann Vasc Surg 2015;29:1
Failure of Optimal Medical Therapy in Patients With “Real Lesions”

Freedom from Ipsilateral Neurological Events

MGH Experience
126 cases treated with OMT and no repair
One-year risk of neuro symptoms=16%

Statins did not seem to make a difference in “real lesions”

BMT vs CEA+BMT for 70-79% stenosis

70-79% stenosis

CEA+BMT

BMT alone

HR 5.1, 95% CI 1.53–16.79; P = .008

Stroke Risk Posed by Asymptomatic Carotid Stenosis?

<table>
<thead>
<tr>
<th>High risk factor</th>
<th>Annual stroke risk</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstable plaque by duplex JBA $&gt;$ 10mm</td>
<td>5%</td>
<td>Kakkos et al. J Vasc Surg 2013;57:609</td>
</tr>
<tr>
<td>Intraplaque hemorrhage by MRI</td>
<td>8.4%</td>
<td>Hellings et al. Circulation 2010;121:1941</td>
</tr>
</tbody>
</table>

We can select the most threatening lesions.

- The risk of repair is improving.
- We can identify the patients that will live long enough to benefit from repair.
- Mounting evidence about the association of carotid occlusive disease with cognitive impairment.
Conclusion

• Every patient should be on best medical therapy, but medical management alone is not adequate in many.
• Repair has consistently added a benefit in excess of medical therapy alone.
• Safety of repair has improved.
• Identify high risk groups to increase the benefit of repair.
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