Should All CEA Closures Be Patched: Could The RCTs Indicating That All CEA Patients Should Have Patch Closures Be Misleading

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Background
• CEA closure has been controversial over past few decades
• However, most authorities tilted towards CEA with patch closure over past 2 decades: 1990’s and 2000-2010

Proponents of Patching
• ↓ Perioperative carotid thrombosis
• ↓ Perioperative stroke
• ↓ Late stroke & restenosis

Background (cont.)
• Most authorities agree on patching of:
  – Small carotid arteries (≤4 mm) – may avoid restenosis
  – Lateral tears at the apex of ICA – may avoid narrowing of arteriotomy
  – Excessive thickening of intima of distal ICA – can smooth transition zone
  – Kinked or elongated arteries – helps maintain lumen & prevents postop. occlusion
  – Redo CEA
  – Patching may decrease chance of technical errors

Opponents of Patching
• Prolonged op. time/shunt & clamp time & hemostasis time
• Potential patch infection
• Potential patch disruption <1%
CEA Closure: Primary vs. Patching

Several Randomized Trials

- Eikelboom et al, JVS, 1988
- Lord et al, JVS, 1989
- Ranaboldo et al, BJ, 1993
- Katz et al, JVS, 1994
- AbuRahma et al, JVS, 1996
- AbuRahma et al, JVS, 1998
- AbuRahma et al, Stroke, 1999
- AbuRahma et al, JVS, 2002
- AbuRahma et al, JVS, 2005
- AbuRahma et al, JVS, 2007
- AbuRahma et al, JVS, 2008
- CREST, Stroke, 2015

Periop. (30-Day) Outcome in 10 Randomized Controlled CEA Trials (2,157 Pts.)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Patch Closure Event/Cases</th>
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<td>Ipsilat. stroke</td>
<td>10/641 (1.6)</td>
<td>24/500 (4.8)</td>
<td>0.32</td>
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<td>All death</td>
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<td>73/679 (12.0)</td>
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<td>75/777 (13)</td>
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<td>41/921 (4.3)</td>
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(Rerkasem & Rothwell, Stroke, 2010)

Long-Term Outcome in 10 Randomized Controlled CEA Trials

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(Rerkasem & Rothwell, Stroke, 2010)

One Randomized Study Supported Primary Closure

- All done by single surgeon
- 1ry closure using operating microscope
- Used Dacron patch: 7 Type
- 153 patching vs. 175 1ry closure
- 30-d stroke rate was similar: 2.9% vs. 3.9%
- Study was stopped on basis of futility
- Follow-up was only 12 mos.
- Concluded: both are equivalent


Prospective Randomized Trial of Bilateral CEAs: 1ry Closure vs. Patching

- 74 pts.: bilat. sequential CEA
- Randomized to either patching/1ry or 1ry/patching
- Each pt. was their own control
- Ipsilat. stroke: 1ry – 4%, patching – 0%, ipsilat. TIA/stroke – 1% (p=0.02)
- Late mean follow-up of 29 mos.: ≥80% restenosis: 1ry – 22%, patching – 1% (p<0.003)
- Carotid occ: 0% vs. 8% (p=0.04)

(AbuRahma et al, Stroke, 1999)

Effect of Patching on Reducing Stroke in the CREST Trial

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<tr>
<th>Outcome</th>
<th>Patch (N=753)</th>
<th>No Patch (N=329)</th>
<th>P-value</th>
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<tr>
<td>Stroke</td>
<td>1.2</td>
<td>4.0</td>
<td>0.02</td>
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<td>1.2</td>
<td>4.0</td>
<td>0.02</td>
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<td>3.7</td>
<td>5.5</td>
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(Malas et al, Stroke, 2015)
Effect of Patching on Reducing Stroke in the CREST Trial (cont.)

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<td>Stroke</td>
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<td>0.047</td>
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(Malas et al, Stroke, 2015)

Effect of Patching on Reducing Restenosis in the CREST Trial (cont.)

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P<.0001

(Malas et al, Stroke, 2015)

Systematic Review of Patch Angioplasty vs Primary Closure for CEA

- Cochrane Central Register of Controlled Trials, MEDLINE & Embase databases searched (Jan. 1966-Sept. 2017)
- 29 articles met inclusion criteria, 20 non-randomized & 9 randomized studies (13,219 CEAs)
- PRC group ↑ 30-day stroke risk (OR 1.9)
- Restenosis rate ↑ after PRC (2.2)
- Concluded periop. stroke rate ↓ after PAC & restenosis rate ↑ after PRC, clinical sig. unclear for long-term stroke prevention
- Many 1ry closures selected in larger arteries

(Huizing et al, JVS, 2019)

Long-Term Impact of the Vascular Study Group of New England Carotid Patch Quality Initiative

- 12 yr. study of CEA pts. (2003-2014) (N=14,636)
- Patch use increased from 71%-91% (P<.001)
- 1 yr. restenosis/occ. (P<.001) & 1 yr. stroke/TIA (P<.003) statistically ↓ w/patch closure
- High-volume surgeons ↓ 1 yr. stroke/TIA from 4.9%-1.9% (P<.001) & restenosis rate from 9.0%-1.2% & ↑ patch use from 50%-90%

(Edenfield et al, JVS, 2018)

Could RCTs Advocating CEA/Patch Closure Be Misleading?

- 1ry closure method: microscopic vs routine
- Shunting use?
- ICA diameter differences (small vs large)
- Provider volume/experience
- Post CEA completion imaging
- Definition of restenosis

Conclusions

- Some vascular surgeons still don’t use carotid patching routinely
- However, there is Level I evidence to support a Grade A recommendation for routine carotid patching in most
- 1ry closure may be safely practiced in large ICA (>6mm) (Grade II, Evidence B/C)
Thank You!

Autumn in West Virginia