Restenosis Rate after CAS is Probably Higher than after CEA in the RCTs: When Should Restenosis be Treated Invasively

Ali F. AbuRahma, M.D.
Professor of Surgery
Chief, Vascular & Endovascular Surgery
Director, Vascular Surgery Fellowship & Residency Programs
Medical Director, Vascular Laboratory
Co-Director, Vascular Center of Excellence
Department of Surgery
West Virginia University
Charleston Area Medical Center
Charleston, WV, USA

Speaker Disclosure:
– Nothing to Disclose

Background & Purpose
• Carotid in-stent stenosis varies between 1-30%
• Most studies have short follow-up, which may lead to under-estimation
• We conducted a study to analyze the incidence of ≥50% and ≥80% carotid in-stent stenosis & its clinical implications

Patient Population & Methods
• Retrospective analysis of prospectively collected data of 450/498 CAS procedures
• All pts. had postop CDUS, which was repeated @ 1 mo., 6 mos., and every 6-12 mos.
• KM analysis estimated freedom from:
  – ≥50% in-stent stenosis (ICA PSV of ≥224 cm/s)
  – ≥80% in-stent stenosis (ICA PSV of ≥325 cm/s)
  – Re-intervention
Results

- Mean age: 68 (40-88)
- 59% - males
- 89% - ↑ BP
- 44% - DM
- 72% - CAD
- 22% CHF
- Smoker: 63%
- Indications: Sx – 45%; Asx – 55%
- 1ry CAS – 65%; redo – 35%

Late Outcome

- Mean follow-up: 41 mos. (1-197 mos.)
- ≥50% in-stent stenosis: 101 (23%)
- ≥80% in-stent stenosis: 33 (7.4%)
- Late TIA: 19 (4.3%)
- Late stroke: 3 (0.7%)
- Re-intervention: 23 (5.2%)
Late Results

**Stroke Free >50% Resten. Free**

<table>
<thead>
<tr>
<th></th>
<th>1 yr</th>
<th>2 yrs</th>
<th>3 yrs</th>
<th>4 yrs</th>
<th>5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>99%</td>
<td>99%</td>
<td>98%</td>
<td>98%</td>
<td>98%</td>
<td>94%</td>
</tr>
</tbody>
</table>

(AbuRahma et al, JVS from randomized trials x 7)

Duplex Velocity Criteria for Diagnosing In-Stent Restenosis after CAS

<table>
<thead>
<tr>
<th>In-Stent Restenosis</th>
<th>PSV</th>
<th>EDV</th>
<th>ICA/CCA Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50%</td>
<td>&gt;200 cm/s*</td>
<td>≥2.5</td>
<td></td>
</tr>
<tr>
<td>&gt;70%</td>
<td>≥300 cm/s*</td>
<td>≥90 cm/s</td>
<td>≥3.8</td>
</tr>
<tr>
<td>≥50%</td>
<td>≥224 cm/s**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥80%</td>
<td>≥325 cm/s**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Based on data from Lal, et al, JVS, 2008; and Stanziale et al, J Endovasc Ther, 2005
**AbuRahma, et al, JVS, 2008

Meta-Analysis of Prevalence of Restenosis >70% or Occ. in Surveillance Data from RCTs Involving CEA & CAS

<table>
<thead>
<tr>
<th>No. of RCTs</th>
<th>No. of Patients</th>
<th>Mean Follow-up (mos.)</th>
<th>Restenosis &gt;70% or Occ. (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any CEA</td>
<td>11</td>
<td>4249</td>
<td>5.8% (4.1-8.2)</td>
</tr>
<tr>
<td>Patched CEA</td>
<td>5</td>
<td>1078</td>
<td>4.1% (2.0-8.4)</td>
</tr>
<tr>
<td>CAS or angioplasty</td>
<td>6</td>
<td>2916</td>
<td>10.3% (6.4-16.4)</td>
</tr>
<tr>
<td>CAS</td>
<td>5</td>
<td>2716</td>
<td>10.0% (6.0-16.3)</td>
</tr>
</tbody>
</table>

(Data from Naylor AR et al, Eur J Vasc Endovasc Surg, 2017)

PTA & Stenting for CAS

- Meta-analysis: CAS was associated with sig. higher >70% restenosis rates than after CEA (OR 2.41, p=0.007)
- CAVATAS: most pts. randomized to endovasc Rx were treated by PTA
- When meta-analysis was confined to the 5 RCTs using primary stenting, difference in severe restenosis between CEA & CAS was not statistically sig. (OR 1.97)


Rx of CAS Restenosis

**Sx ≥50% Restenosis**: as primary disease

- Redo PTA/CAS
- Best Medical Rx &
- Redo surgery (? interpositional graft)

PTA & Stenting for CAS

- Meta-analysis: CAS was associated with sig. higher >70% restenosis rates than after CEA (OR 2.41, p=0.007)
- CAVATAS: most pts. randomized to endovasc Rx were treated by PTA
- When meta-analysis was confined to the 5 RCTs using primary stenting, difference in severe restenosis between CEA & CAS was not statistically sig. (OR 1.97)


Meta-Analysis of Prevalence of Late Ipsilateral Stroke in CAS Pts. with & without an Ax. “Resten. >70% or occ” in the Constituent RCTs*

<table>
<thead>
<tr>
<th>No. of RCTs</th>
<th>Mean Follow-up (mos.)</th>
<th>Stroke Ipsilateral to &gt;70% Rest. **</th>
<th>Stroke Ipsilateral to Rest. &lt;70%</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS 7 RCTs (n=2810)</td>
<td>50</td>
<td>1/125 0.8%</td>
<td>37/1839 2.0%</td>
<td>0.87 (0.24-3.21), P=.8389</td>
</tr>
</tbody>
</table>

*Data derived from Kumar et al, Eur J Vasc Endovasc Surg, 2014
**All restenosis had been axed prior to stroke onset
Rx: Asx. In-Stent Restenosis

- Controversial
- No RCT comparing BMT vs re-PTA/CAS or redo CEA
- All should have BMT
- High risk → observe
- Good risk with ≥70% restenosis →
  - Re-PTA/stent: especially if MCA velocities <15 cm/s (TCD monitoring)
- Neuro sx. during balloon inflation (proximal flow reversal)

Conclusions

- Validated DUS velocity criteria should be used for Dx of in-stent stenosis
- Incidence of ≥80% in-stent stenosis is higher than post-CEA patch stenosis (>two fold) and ≥50% in-stent stenosis is even higher
- Treatment:
  - Sx in-stent stenosis - as primary disease
  - Asx in-stent stenosis – can be observed, except in certain select good-risk patients

Thank you!

Hawk’s Nest State Park

The Greenbrier
White Sulphur Springs, WV

Blackwater Falls, West Virginia