Transcervical Carotid Stenting: Advantages and Pitfalls

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s): Co-investigator on Roadster I and Roadster II

☐ I do not have any potential conflict of interest
Randomized Trials: CAS vs CEA

- Composite endpoint (1yr):
  - CAS 3.8%
  - CEA 3.4% (ns)
- Stroke (periprocedural)
  - CAS 2.9%
  - CEA 1.7% (p=0.33)
- Composite endpoint (4yr):
  - CAS 7.2%
  - CEA 6.8% (ns)
- Stroke (periprocedural)
  - CAS 4.1%
  - CEA 2.3% (p=0.01)

- CAS clearly established as safe / effective
- Debate shifting away from CAS vs CEA
- Focus now on optimizing CAS outcomes
<table>
<thead>
<tr>
<th>30–Day Outcomes</th>
<th>CAS vs. CEA</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, Stroke or MI</td>
<td>5.3 vs 4.5%</td>
<td>1.18</td>
<td>0.82–1.68</td>
<td>0.38</td>
</tr>
<tr>
<td>All Death</td>
<td>0.7 vs 0.3%</td>
<td>2.25</td>
<td>0.69–7.30</td>
<td>0.18</td>
</tr>
<tr>
<td>All Stroke</td>
<td>4.1 vs 2.3%</td>
<td>1.79</td>
<td>1.14–2.82</td>
<td>0.01</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.9 vs 0.7%</td>
<td>1.35</td>
<td>0.54–3.36</td>
<td>0.52</td>
</tr>
<tr>
<td>MI</td>
<td>1.1 vs 2.3%</td>
<td>0.50</td>
<td>0.26–0.94</td>
<td>0.03</td>
</tr>
<tr>
<td>Cranial Nerve Palsy</td>
<td>0.3 vs 4.8%</td>
<td>0.07</td>
<td>0.02–0.18</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

- **Primary endpoint equivalent in CREST**
- **All stroke at 30d significantly higher in CAS**
- **All stroke and major ipsilateral stroke significantly higher out to 4 yrs**

Progression of EPD Technology in CAS

- Distal Protection
- Proximal Protection
- Transcervical Access with Flow Reversal
Transcervical Carotid Artery Revascularization

- 1-2cm Incision
- Local anesthesia
- Flow reversal circuit: carotid artery to femoral vein
Advantages of TCAR Procedure:

1) Establish embolic protection before lesion crossing (proximal protection)
2) Flow reversal ("surgical" back-bleeding)
3) Avoiding the aortic arch
Advantages of TCAR Procedure:

1) Establish embolic protection before lesion crossing (proximal protection)

Advantages of TCAR Procedure:

2) Flow reversal ("surgical" back-bleeding)

- Plaque components range from calcium to soft thrombotic core
- Filter porosity is variable
- Vasospasm at filter site
- Thrombus above filter
3) Avoiding the aortic arch

**Advantages of TCAR Procedure:**

**DW-MRI Lesions with CAS/CEA**
- Common after carotid intervention
- Evidence of correlation to neurocognitive decline
- Incidence / location varies approach
- Bilateral w/ transfemoral CAS

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### Advantages of TCAR Procedure:

3) Avoiding the aortic arch

<table>
<thead>
<tr>
<th>Study</th>
<th>Access</th>
<th>EPD</th>
<th>Embolic Protection</th>
<th>Patients</th>
<th>% w/ New DWI Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICSS²</td>
<td>CEA</td>
<td>Clamp, backbleed</td>
<td>Clamp, backbleed</td>
<td>107</td>
<td>17%</td>
</tr>
<tr>
<td>ICSS²</td>
<td>Femoral</td>
<td>Distal</td>
<td>Distal filter (various)</td>
<td>51</td>
<td>73%</td>
</tr>
<tr>
<td>PROFI¹</td>
<td>Femoral</td>
<td>Distal</td>
<td>Distal filter (Emboshield)</td>
<td>31</td>
<td>87%</td>
</tr>
<tr>
<td>PROFI¹</td>
<td>Femoral</td>
<td>Transfemoral CAS</td>
<td>Proximal occlusion (MoMA)</td>
<td>31</td>
<td>45%</td>
</tr>
<tr>
<td>PROOF³</td>
<td>Transcervical</td>
<td>Flow Reversal</td>
<td>Transcarotid Access, w/ Flow Reversal</td>
<td>56</td>
<td>19%</td>
</tr>
</tbody>
</table>
Transcervical Carotid Artery Revascularization

Advantages of TCAR Procedure:
3) Avoiding the aortic arch
Transcervical Carotid Artery Revascularization

**ROADSTER Trial**

- Prospective, single arm multicenter trial
- ENROUTE Transcarotid NPS during CAS procedures
- Pivotal trial enrolled 141 patients at 18 sites*
- Symptomatic (>50%) and Asymptomatic (>70%)
- High surgical risk patients only
- 30 day stroke, death, stroke/death, MI

* 220 included in continued access, equivalent all stroke rate at 30 days.
## ROADSTER Trial 12-month Outcomes

<table>
<thead>
<tr>
<th>High Surgical Risk</th>
<th>Pivotal Group, ITT (n=141)</th>
<th>Pivotal Group, PP (n=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/D/MI*</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>MI</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Stroke &amp; Death</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Cranial Nerve Injury (CNI)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>CNI Unresolved at 6 Mos</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Transcervical Carotid Artery Revascularization

Outcomes of Contemporary CAS & CEA Trials

Table 2: Periprocedural Stroke Rates in Contemporary Publications of TCAR, CEA and Transfemoral CAS

<table>
<thead>
<tr>
<th></th>
<th>ROADSTER</th>
<th>SVS CEA HSR</th>
<th>SVS CAS HSR</th>
<th>ACT 1 CEA</th>
<th>ACT 1 CAS</th>
<th>CREST CEA</th>
<th>CREST CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>1.4%</td>
<td>3.6%</td>
<td>4.9%</td>
<td>1.4%</td>
<td>2.8%</td>
<td>2.3%</td>
<td>4.1%</td>
</tr>
</tbody>
</table>

### High-Risk Groups for CAS: Symptomatic

#### ROADSTER Trial 12-month Outcomes

<table>
<thead>
<tr>
<th>High Surgical Risk</th>
<th>Pivotal Intention to Treat</th>
<th>Age ≥75</th>
<th>Symptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>n=66 (47%)</td>
<td>n=36 (26%)</td>
<td></td>
</tr>
<tr>
<td>S/D/MI</td>
<td>3 (4.5%)</td>
<td>1 (2.8%)</td>
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</tr>
<tr>
<td>Major Stroke</td>
<td>0%</td>
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### High-Risk Groups for CAS: Octogenarians

#### Increased adverse neurologic event rates and new DW-MRI lesions in older patients

<table>
<thead>
<tr>
<th>Study</th>
<th>Event(s) Description</th>
<th>Age Range 1 (Event Rate)</th>
<th>Age Range 2 (Event Rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonati LH (Eur J Vasc Endo Surg 2011)</td>
<td>Stroke/death</td>
<td>&lt; 70 yrs 5.8%</td>
<td>≥ 70 yrs 12.0%</td>
</tr>
<tr>
<td>Brott TG (NEJM 2010)</td>
<td>Stroke/death/MI</td>
<td>60-69 yrs 2.5%</td>
<td>70-79 yrs 6.4%</td>
</tr>
<tr>
<td>Rosenkranz M (Cerebrovasc Disease 2010)</td>
<td>New DWI lesion</td>
<td>&lt; 68 yrs 11.3%</td>
<td>≥ 69 yrs 30.0%</td>
</tr>
<tr>
<td>Stanziale S (J Vasc Surg 2010)</td>
<td>Stroke</td>
<td>&lt; 79 yrs 2.7%</td>
<td>≥ 80 yrs 8.0%</td>
</tr>
<tr>
<td></td>
<td>Stroke/death</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hobson RW (NEJM 2010)</td>
<td>Stroke/death/MI</td>
<td>&lt;70 yrs</td>
<td>≥ 80 yrs</td>
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</table>

*Consistently worse outcomes in older patients with transfemoral CAS*
## High-Risk Groups for CAS: *Octogenarians*

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<th>AGE</th>
<th>Type I</th>
<th>Type II</th>
<th>Type III</th>
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<tr>
<td>&lt; 60yrs</td>
<td>71.1%</td>
<td>21.0%</td>
<td>7.9%</td>
</tr>
<tr>
<td>≥ 60yr</td>
<td>48.1%</td>
<td>26.9%</td>
<td>25.0%</td>
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DeRubertis et al. SVS Annual Meeting 2013

*p=0.042*
## High-Risk Groups for CAS: **Octogenarians**

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Should All Patients Be Treated with TCAR?

Evolution of Carotid Stenting:
- 2003: 6.9%
- 2005: 4.8%
- 2007: 3.4%
- 2009: 1.7%

CAS maturity in the modern days:
- Higher operator’s experience
- Better Patient selection
- Technology improvement
- Proximal Protection
Transcervical Carotid Artery Revascularization

Disadvantages of TCAR Procedure:

1) Issues related to initial access
   - Short working distance from access to lesion
   - Access site dissections
2) Body habitus concerns and anatomic constraints
3) Ergonomics of current stent systems
4) Interpretation of reversed-flow angiograms
5) Optimal training requirements not clearly established
6) Limitations for non-surgeon interventionalists
Transcervical Carotid Artery Revascularization

**Disadvantages** of TCAR Procedure:

- Working distance with TCAR (<6cm)
- Working distance with transfemoral CAS (10-20cm)

Problems at initial access:
- Posterior CCA wall dissection (avoid stiffened micropuncture)
- Access wire traversing lesion during sheath placement (short-tipped micropuncture wire, access ECA, short tipped Amplatz)
Transcervical Carotid Artery Revascularization

Disadvantages of TCAR Procedure:

EnRoute Stent System: Only short shaft option, Open cell design
Disadvantages of TCAR Procedure:

TCAR: So easy that...

Just because anyone can do it doesn’t mean everyone should!

(or at least not without the proper training and background in trans-femoral carotid intervention)
Conclusions

Transcervical Carotid Artery Revascularization is:

- Probably worth considering in all CAS patients
- More likely to benefit some patients than others:
  - Unfavorable arch anatomy & target tortuosity
  - Octogenarians
  - Diseased (plaque, thrombus) arch vessel origins
  - Symptomatic patients
- Must be mindful of potential pitfalls and training requirements for any new technology or technique
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