Proximal Embolic Protection
Some Form of Proximal Brain Protection Should Be the Method of Choice With CAS & Why?

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DISCLOSURE:
CMO (Silk Road Medical)

Clinical Endpoints:

A meta-analysis of Proximal Occlusion Device Outcomes in Carotid Artery Stenting
N = 2,397
Mixed risk profile
MoMa & Gore NPS (includes ARMOUR & EMPiRE)
• 30-day all-stroke = 1.7%
• 30-day all-stroke < 3% in all subgroups (symptomatic/octogenarian)

Bersin RM, Stabile E, Ansari GM, Clair DG, Cremonesi A, Hopkins LN, Nikas D, Reimers B, Sievert H, Rubino P
Catheter Cardiovasc Interventino 2012 Dec 1;80(7):1072-8

Surrogate Markers:

Silent cerebral ischaemia: hidden fingerprints of invasive medical procedures

Bendszus M et al. The Lancet Neurology 2006;5:364-372
The clinical importance of white matter hyperintensities on brain magnetic resonance imaging: systematic review and meta-analysis

- 45 longitudinal studies; general population & hospital based

**Association WM lesions & incident stroke**

Debette S, Markus H. BMJ 2010;341:c3666

**Distal Embolic Protection**

(Filters)

**ICSS Substudy: N = 231**

- 2/7 centres performed unprotected CAS
- 5/7 centres performed filter-protected CAS

**Proximal Protection 1:**

Randomized Trial:

*Filter - Protected Vs. MoMa*

**PROFE: A Prospective, Randomized Trial of Proximal Balloon Occlusion vs. Filter Embolic Protection in Patients Undergoing Carotid Stenting**

**Incidence of new Cerebral Ischemic Lesions (Primary Endpoint)**

- N = 62

**Mean Volume of new Cerebral Ischemic Lesions**

(Secondary Endpoint)

Bijuklic K et al. JACC 2012;59:1383-1389
**Proximal Protection 2: Prospective Analysis**

*Filter - Protected Vs. Gore Flow Reversal*

**The Arch Is A Hostile Territory:**

The incidence of microemboli to the brain is less with endarterectomy than with percutaneous revascularization with distal filters or flow reversal.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>N</th>
<th>Incidence MES</th>
<th>Procedural Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEA</td>
<td>15</td>
<td>15.3 (±22)</td>
<td>Post procedure</td>
</tr>
<tr>
<td>Filter protected CAS</td>
<td>20</td>
<td>19.3 (±10.3)</td>
<td>During protection</td>
</tr>
<tr>
<td>Flow reversal CAS</td>
<td>7</td>
<td>18.4 (±10.5)</td>
<td>Pre protection</td>
</tr>
</tbody>
</table>

CEA vs filter p = 0.001
CEA vs flow reversal p = 0.007
Flow reversal vs filter p = 0.053  

N = 42

Gupta N et al. JVS. 2011;53:316-322

**PROXIMAL PROTECTION 3:**

Transcarotid Access with High Flow Rate Flow Reversal

(ENROUTE NPS; Silk Road Medical)

**The TCAR procedure with the ENROUTE™ Neuroprotection System**

**PROOF DWI Sub Study**

- Baseline scan within 72 hours
- Post-procedure scan within 12-48 hours
- Submitted to core laboratory for blinded evaluation by two independent neuroradiologists

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with new DW-MRI lesion(s)</td>
<td>8 (16.7%)</td>
</tr>
</tbody>
</table>
Study | Procedure | Embolic Protection | # Subjects | % w/ New DWI Lesions
--- | --- | --- | --- | ---
ICSS | Transfemoral CAS | Distal Filter (varied) | 51 | 73
ICSS | CEA | Clamp, backbleed | 107 | 17
PROFI | Transfemoral CAS | Distal Filter (Embossed) | 31 | 87
Leal | Transfemoral | Distal Filter (FilterWire) | 33 | 33
PROFI | Transfemoral CAS | Proximal occlusion (MoMA) | 31 | 45
PROOF | Transcervical CAS | High Flow rate Flow reversal | 48 | 16.7
Leal | Transcervical CAS | Flow Reversal | 31 | 12.9

**CONCLUSIONS:**
- Proximal embolic protection devices are superior to distal filters for control of the microembolic burden of CAS
- Proximal systems have better but variable device-dependent control of microemboli
- Establishment / retrieval are universally emboligenic: THE ARCH IS DANGEROUS
- Some of the lowest stroke & death rates are reported with proximal EPD

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**A diffusion-weighted magnetic resonance imaging-based study of transcervical carotid stenting with flow reversal vs transfemoral filter protection**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Relative Risk</th>
<th>95% CIs</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.022</td>
<td>1.021 - 1.041</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Recent symptoms</td>
<td>4.109</td>
<td>1.74 - 9.65</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stent design (OC Vs. CC)</td>
<td>0.082</td>
<td>0.019 - 0.359</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*Impacted on transfemoral filter CAS **BUT not** transcervical flow reversal CAS*

Leal I et al JVS 2012;56:1585-1590

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**CVC Frankfurt**
- Carotid stenting with proximal protection in all-comers
- 207 consecutive patients regardless of anatomy
  - No periprocedural stroke
  - One stroke after discharge due to stent thrombosis
- 30 day stroke rate = 0.5%

ICSS Substudy: N = 231

New white lesions on DWI

62 of 124 (50%) transfemoral distal filter CAS
18 of 107 (17%) CEA

(OR 5.21, 2.78-9.79; p < 0.0001)