What Is New In Cerebral Embolic Protection Devices

Veith Mtg. 2015
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Very Little is New
Carotid Device Research Either Dead or Badly Damaged

• Very little is new in carotid device development following CMS refusal for reimbursement of asymptomatic cases outside of an IDE approved trial.
• Carotid reimbursement for symptomatic patients is based on strict guidelines, covered as inpatient only, and only if embolic protection devices are utilized.

Peri-procedural Stroke and MI

<table>
<thead>
<tr>
<th></th>
<th>CAS vs. CEA</th>
<th>Hazard Ratio 95% CI</th>
<th>P- Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>4.1 vs. 2.3%</td>
<td>HR = 1.79; 95% CI: 1.14-2.82</td>
<td>0.01</td>
</tr>
<tr>
<td>MI</td>
<td>1.1 vs. 2.3%</td>
<td>HR = 0.50; 95% CI: 0.26-0.94</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Filter Issues As A Cause For Stroke

Nav 6, is 50% more efficient than Accunet

CAS is a technology in evolution
CEA has been around for 63 years!
By the time carotid trials are completed, devices are frequently obsolete
Capture Efficiency 147um Size Particles

Filter Tip Transitions

Filter Wire - Animation
Filters have an a OD of 3 fr. and raise question of micro embolic source

Filter Evaluation Study

Asymptomatic 73 yr male with Critical stenosis of Lt. internal Carotid and Lt. vertebral. Refused surgery because relative had CEA with non healing cranial Nerve injury and swallowing Dysfunction. CMS refused Payment. Hospital charge would be around 25,000 $ After lengthy appeal was covered
We are not capturing particles less than 100u

Before After CAS
these silent ischemic embolic lesions can’t be good
And long term could become a major issue

Particle analysis in 20 filters
- Microscopic emboli composition
- Fibrin conglomerates
- Trapped erythrocytes
- Inflammatory cells
- Foam cells
- Cholesterol clefts
- Calcified deposits
- Fresh thrombus

Diffusion Weighted MRI
MO.MA Ultra

- CCA clamping: blockage of antegrade blood flow
- ECA clamping: blockage of retrograde blood flow
- Debris removal: syringe blood aspiration
- Micro emboli still occur

Schofer J., 2011
Incidence of new Cerebral Ischemic Lesions
Subgroups

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedure</th>
<th>Embolic Protection</th>
<th># subjects</th>
<th>% w/ New DWI Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICSS</td>
<td>Transfemoral CAS</td>
<td>Distal filter (various)</td>
<td>51</td>
<td>73</td>
</tr>
<tr>
<td>ICSS</td>
<td>CEA</td>
<td>Clamp, back-bleed</td>
<td>107</td>
<td>17</td>
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<tr>
<td>PROFIT</td>
<td>Transfemoral CAS</td>
<td>Distal filter (EmboShield)</td>
<td>31</td>
<td>87</td>
</tr>
<tr>
<td>Leal</td>
<td>Transfemoral</td>
<td>Distal filter (FilterWire)</td>
<td>33</td>
<td>33</td>
</tr>
<tr>
<td>PROFIT</td>
<td>Transfemoral CAS</td>
<td>Proximal occlusion (MoMA)</td>
<td>31</td>
<td>45</td>
</tr>
<tr>
<td>DESERVE</td>
<td>Transfemoral CAS</td>
<td>Proximal occlusion (MoMA)</td>
<td>127</td>
<td>30</td>
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<tr>
<td>PROOF</td>
<td>Transcarotid CAS</td>
<td>High flow rate flow reversal</td>
<td>48</td>
<td>16.7</td>
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<tr>
<td>Leal</td>
<td>Transcarotid CAS</td>
<td>Flow Reversal</td>
<td>31</td>
<td>12.9</td>
</tr>
</tbody>
</table>

Silent Cerebral Ischemia Detected by Diffusion-Weighted MRI After CEA

A Preoperative brain DWI of a 74-year-old woman with an asymptomatic high-grade carotid stenosis on the right side. B, Postoperative brain DWI demonstrating a single new hyperintensity in the ipsilateral subcortical temporal region (arrow), which was highly suggestive of a perioperative embolus.

Gore Carotid Stent

Here’s my take home message

- Micro emboli could become a major problem
- Should this be included in informed consent
- Continued DWI MRI follow up re cognitive defect, stroke, dementia, parkinson, etc.
- These newly described limitations could become an issue for Crest 2
- Is covered or fenestrated carotid stent option