Is proximal protection the way forward? Options, techniques and results

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Embolic Protection Devices (EPD)

**Bottom Line**

- There is no level 1 support documenting superiority of one EPD over another.

- Both proximal and distal protection have a role and physicians can be educated when which may best serve the patient’s procedure.
Distal Protection

**Upright**
- Intuitive
- Maintain flow
  - Perfusion
  - Visibility
- Low Profiles

**Downside**
- Pass lesion unprotected
- Suitable landing zone
- Wall apposition?
- Tight lesions
- Tortuosity
- System stability
- Pores allow some embolization
Outcomes of DEP CAS Trials Over Time

- CAS results have improved over time due to:
  1) more experience;
  2) better patient selection;
  3) technology

Year: 2000
- ARCHer: 8.3%
- SAPPHIRE: 2.9%
- SECURITY: 6.9%
- CAPTURE: 7.5%
- EXACT: 3.3%
- CAPTURE: 6.1%
- CHOICE: 4.1%
- PROTECT: 1.5%

Year: 2008
- (Enrollment: 2000-2008) CREST – 5.7%
- (Enrollment: 2000-2008) CREST – 1.1%
Proximal Flow Protection

**Upside**
- Near total protection
- Wire freedom
- Not effected by ICA anatomy
  - No landing zone
  - No need to straighten tortuosity
  - Severe stenoses
- ? Choice for high risk lesion

**Downside**
- Larger profile (8-9 fr)
- Intolerance (3-8%)
- New mechanism to learn
- May be ECA dependent
Typical Distal EPD Anatomic Struggles

- Distal tortuosity
- Short landing zone
- Acute angle
EMPIRE (WL Gore): MAE by Subgroup (Stroke, Death, MI)

- Octogenarians (n=38): 2.6%
- Symptomatic (n=78): 3.8%
- Asymptomatic (n=167): 3.6%
- Co-Morbid Risk (n=76): 5.3%

% of Subjects in Subgroup with MAE
Results 1° Endpoint

30d Results (ITT & Full Population)

ARMOUR 30d  ITT (220)  ITT + Roll-in (257)

Major Stroke  0.9%  0.8%  2.7%  2.3%
Minor Stroke  1.4%  1.2%  0.9%  0.8%
Death         0.9%  0.8%  0.0%  0.0%
MI            0.0%  0.0%  0.9%  1.2%
TIA           0.9%  1.2%  2.7%  2.3%

1° Endpoint cumulative MACCE

30d Results by Symptoms and Age (ITT)

30d Strokes  2.3%  2.7%  2.7%  3.2%  2.3%  2.3%  2.1%  2.1%
30d MACCE    2.3%  0.0%  0.0%  0.0%  75y  2.1%  2.1%

ALL          0.9%  0.8%  2.7%  2.3%  0.0%  0.0%  3.2%  2.7%
Asymptomatics 2.7%  3.2%  0.0%  0.0%  0.0%  0.0%  0.0%  0.0%
Symptomatics  0.9%  1.2%  2.7%  2.3%  0.0%  0.0%  0.0%  0.0%
Age >75     0.0%  0.0%  0.0%  0.0%  0.0%  0.0%  0.0%  0.0%
Symptomatics & 2.3%  2.3%  75y  2.1%  2.1%
Age >75
Roadster Stroke (Silk Road)

* n = 141 Increased surg risk pivotal group

* cranial nerve injury 7% all resolved

* S/D/MI = 3.5%
* S/D = 2.8%
* Stroke rate = 1.4%

(0% in octogenarians and symptomatic)
So It’s a matter of choice and individualization

- **Anatomy**
  - Severe angulation
  - Tortuosity

- **Lesion characteristics**
  - Ulceration
  - Long smooth lesions
  - Hypoechoic lesions
  - Significant calcification
  - High grade stenosis

- Age > 80
- Symptomatic state
Effect different neuroprotection systems on microembolization

Distal EPD (filter wire) vs Proximal protection (MO.MA)

- N = 42
- Transcranial doppler
- Single center
- nonrandomized

Comparison of TCD counts

<table>
<thead>
<tr>
<th>MES counts (filter)</th>
<th>MES counts (MO.MA)</th>
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<tbody>
<tr>
<td>- 25 +/- 22</td>
<td>- 1.8 +/- 3.2</td>
</tr>
<tr>
<td>- 73 +/- 49</td>
<td>- 11 +/- 19</td>
</tr>
<tr>
<td>- 70 +/- 31</td>
<td>- 12 +/- 21</td>
</tr>
<tr>
<td>- 196 +/- 84</td>
<td>- 57 +/- 41</td>
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(p < 0.0001).
Why you can’t compare registries

• Besides from the well known reasons…
  – Not randomized
  – Different timings
    • Learning curve effect
    • More aggressive on pts selection with experience
  – Different patient population (symptoms, age, morphology)
  – Different inclusion and exclusion criteria
  – Different operators experience
  – Difference in end point definition
  – Difference in end point calculation and reporting
Summary

• Carotid Stenting is evolving
• Individualizing devices and being conservative appears optimal
• Proximal protection “may” represent the industry standard but trial is indicated
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