Ensuring clinical effectiveness in challenging EVAR

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I have the following potential conflicts of interest to report:

- Consulting and speakers fee
- WL Gore & Associates
- Medtronic

Unrestricted research grants

- Medtronic
- W.L. Gore & Associates
- Philips Medical Systems
Challenging EVAR?

There’s no univocal definition.

In general:

- Neck length $\leq 15$ mm?
- Neck angulation $\geq 60^\circ$?
- Double angled necks?
- Irregular (thrombus, bulge, calcium)?
- Wide ($> 28$ mm)?

Or outside instructions for use??
Which are the risks related to treatment of a challenging neck?

- Endoleak
- Migration

Aneurysm rupture
Infrarenal neck: the most likely reason of failure

- Angulation of the infrarenal aortic neck
- Length of the infrarenal aortic neck
- Presence of reverse taper
Solutions:

Improve accuracy

- Proper C-Arm angles
- Early fixation
- Repositioning of device after initial deployment
- But, probably most important…..

Maximize sealing zone
Solutions:

- Improve accuracy
  - Early Fixation
  - Proper C-Arm Angles
  - Repositioning of device after initial deployment

- Maximize seal zone
  - Planning and anticipation of device deployment
  - Use of aortic cuffs
  - Use of balloon expandable stents
  - Achieve optimal apposition
Optimalisation of sealing zone is about the maximum area of apposition.
EXCeL Registry is a multi-center, post-market, non-interventional, non-randomized, single-arm, prospective observational study. 150 consented subjects from 10 high-volume sites across Europe will be included. Follow-up 3 years
<table>
<thead>
<tr>
<th>Neck Angulation</th>
<th>&gt; 15 mm neck length</th>
<th>10-15 mm neck length</th>
<th>5-10 mm neck length</th>
<th>&lt; 5 mm neck length</th>
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</thead>
<tbody>
<tr>
<td>&lt; 60° neck angulation</td>
<td>Inside IFU</td>
<td>Inside IFU</td>
<td>Challenging anatomy</td>
<td>Extreme anatomy</td>
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<tr>
<td>60-90° neck angulation</td>
<td>Inside IFU</td>
<td>Challenging anatomy</td>
<td>Extreme anatomy</td>
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<tr>
<td>&gt; 90° neck angulation</td>
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<td>Neck Length</td>
<td>&lt; 60° Neck Angulation</td>
<td>60-90° Neck Angulation</td>
<td>&gt; 90° Neck Angulation</td>
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<td>&gt; 15 mm</td>
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<td>&lt; 5 mm</td>
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</table>

*Data received by December 31 2020. Actual number of inclusion is higher*
EVAR continues to evolve as the treatment option for AAA

New generation devices will extend the applicability of EVAR

Data of EXCeL Registry will be presented on Thursday January 28