Redefining Adverse Neck Morphology With Newer EVAR Devices Which Perform Better In Short And Angulated Necks And Those With A Thrombus Burden: What Are The Limits: From The ENGAGE Registry

Hence JM Verhagen, MD, PhD
On behalf of ENGAGE Investigators
Professor and Chief of Vascular Surgery
Erasmus University Medical Center, Rotterdam, The Netherlands

Disclosure
Speaker name: Hence JM Verhagen, MD, PhD
I have the following potential conflicts of interest to report:
- Medtronic
- Gore
- Philips
- Endologix

Proximal Neck Anatomy: Achilles’ Heel of EVAR

- Endoleak, AAA enlargement, Migration
- Reinterventions, Surveillance, Ongoing risk of rupture

Question that Remains
Do new devices drive better EVAR performance in patients with challenging proximal neck anatomy?

Endurant Stent Graft Design
Specifically designed to treat more challenging anatomies

ENGAGE Global Registry
Largest Contemporary EVAR Registry with single manufacturer’s stent graft
1263 Patients 30 Countries 6 Continents
Real world patients Limited inclusion/exclusion criteria
Real world practice Limited procedural specifications Standard follow-up
**ENGAGE Global Registry**

**Study Design**

- Patients consecutively enrolled (2009-2011)
- Follow-up: 30-day, annual visits through 10 years
- Extensive monitoring on-going
- 100% data review
- Independent data monitoring (100% endpoints)
- Independent Clinical Event Committee
- High quality data management processes and procedures

**ENGAGE Registry**

**Study Sub-analysis**

**Objective:**
To compare the midterm results (4 yrs) in patients having challenging proximal neck anatomy treated with Endurant SG

- 3 subgroup analyses:
  - Short Necks
  - Angulated Necks
  - Calcified/Thrombus Necks

**Hypothesis:**
Endurant performs as well in pts w/ challenging proximal neck anatomy as it does in pts w/ standard neck anatomies

**Analysis beyond 2 yrs excludes pts enrolled in Turkey because of Regulatory Issues**

**ENGAGE Global Registry**

**Initial Implant**

- Early technical success impacted by Ca²⁺/thrombus, not impacted by neck length and angulation

**ENGAGE Global Registry**

**At 4 year FU**

- Type 1 EL and Type 1A EL at 4 year not impacted by challenging neck anatomy

**ENGAGE Global Registry**

**Through 4 year FU**

- Secondary endovascular procedures overall and to correct Type III EL are not impacted by challenging neck anatomy
ENGAGE Global Registry

Through 4 year FU

<table>
<thead>
<tr>
<th>Neck Length</th>
<th>Neck Angulation</th>
<th>Neck Calc/Trombus</th>
<th>&gt;60°</th>
<th>≤60°</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Body Migration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.2% (2/127)</td>
<td>0.7% (1/127)</td>
<td>0.73</td>
<td>0.73</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Rupture</td>
<td>2.3% (3/129)</td>
<td>0.7% (8/1076)</td>
<td>0.07</td>
<td>0.07</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Conversion to OS</td>
<td>1.4% (1/72)</td>
<td>0.9% (10/1074)</td>
<td>0.70</td>
<td>0.70</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Summary

Mid-term (4yr FU):
- No differences in
  - Type I and Type IA EL
  - Conversion to DB
  - Migration
  - Reintervention rate
- Rare instance of ruptures, although not significantly related to challenging neck features, need further investigation, focusing on the effect of single vs multiple challenging neck parameters

Conclusion

- Endurant stent-graft achieves promising 4 yr results in pts w/ challenging neck anatomy.
- Only large, high-quality registries such as ENGAGE have the potential to reveal infrequent events as well as guide us towards the cause and possible solutions.
- Further investigation is needed to get insight in the role of single vs multiple hostile neck features
- These findings can support decision-making in daily clinical practice.