Endurant Broadens Standard EVAR Applicability in Challenging Necks *

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

* Medtronic does not have FEVAR/Branch EVAR devices approved for commercial use
Disclosure

Speaker name: Hence JM Verhagen, MD, PhD

I have the following potential conflicts of interest to report:

- Consulting
  - Medtronic
  - WL Gore
  - Philips
Achilles’ Heel of EVAR

- Endoleak, AAA enlargement, Migration
- Reinterventions, Surveillance, Ongoing risk of rupture
Potential Factors of Poor EVAR Performance

Unfavorable Proximal Aortic Neck Anatomy
Neck Length Impacts Standard EVAR Eligibility

Fig 2. Percentage of patients who would meet Instructions for Use (IFU) criterion as mandatory neck length is shortened, holding other neck IFU criterion constant.

Eligibility by length

Men
- 5mm: 48%
- 10mm: 60%
- 15mm: 77%

Women
- 5mm: 52%
- 10mm: 37%
- 15mm: 25%

Short Necks: Which Approach Should We Take?

- Standard EVAR?
- FEVAR/BEVAR?
...infrarenal neck length <15 mm is associated with significantly increased risk of short and midterm endoleaks...
Outcomes by Neck Length

Neck length <15mm is associated with significantly increased risk of short- and midterm endoleaks after EVAR

FEVAR Technical Limitations

• Technically demanding
• Require specific skills and expensive equipment
• Performed in special tertiary vascular centers
• Many patients are excluded for FEVAR due to anatomical constrains
• Limited graft availability: no urgent cases

• Antoniou et al. JVS 2013  • J.P. Becquemin, Critical Issues 2014
Cost-Effective?

- We can barely get EVAR to be cost-effective
- FEVAR will never ever be cost-effective

- Cost-prohibitive
  - FEVAR: €33,191 vs. OS: €14,661 (p<0.0001) *
- Potential waste of resource

* Presented by J.P. Becquemin, Critical Issues 2014
Question that Remain

Do new devices drive better EVAR performance in patients with short proximal necks?
Endurant Stent Graft: Design for Short Necks

Accurate, controlled deployment

Suprarenal stent interacts with “m” sealing stent to improve sealing characteristics in proximal neck
ENGAGE Global Registry
Study Sponsor - Medtronic

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
To compare the midterm results (4 yr) in patients having different neck lengths treated with Endurant SG.

**Hypothesis:**
- Endurant performs as well in short necks (8-15 mm) as it does in standard length necks (≥15 mm)
Analysis beyond 2 yrs excludes pts enrolled in Turkey because of Regulatory Issues.
## ENGAGE Global Registry
### Initial Implant

<table>
<thead>
<tr>
<th>Technical Observation</th>
<th>8-15 mm (N=137)</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Delivery and Deployment</td>
<td>100%</td>
<td>99.4%</td>
<td>0.35</td>
</tr>
<tr>
<td>Type I Endoleak (uncorrected)</td>
<td>0%</td>
<td>1.3%</td>
<td>0.18</td>
</tr>
</tbody>
</table>

*No Significant Difference*
## ENGAGE Global Registry
### Outcomes At Follow-Up

<table>
<thead>
<tr>
<th>Endoleak Type I (both Type IA and IB)</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1 yr</td>
<td>0.0% (0/113)</td>
<td>0.4% (4/942)</td>
<td>0.49</td>
</tr>
<tr>
<td>At 2 yr</td>
<td>0.0% (0/97)</td>
<td>0.9% (7/784)</td>
<td>0.35</td>
</tr>
<tr>
<td>At 3 yr</td>
<td>3.8% (1/26)</td>
<td>1.2% (8/652)</td>
<td>0.22</td>
</tr>
<tr>
<td>At 4 yr</td>
<td>2.4% (6/246)</td>
<td>2.4% (6/246)</td>
<td>0.67</td>
</tr>
</tbody>
</table>

*No Significant Difference*
ENGAGE Global Registry
Outcomes At Follow-Up

<table>
<thead>
<tr>
<th>Endoleak Type IA</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1 yr</td>
<td>0%</td>
<td>0.2%</td>
<td>0.62</td>
</tr>
<tr>
<td>(0/113)</td>
<td>(2/942)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 2 yr</td>
<td>0%</td>
<td>0.4%</td>
<td>0.54</td>
</tr>
<tr>
<td>(0/97)</td>
<td>(3/784)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 3 yr</td>
<td>1.6%</td>
<td>0.6%</td>
<td>0.39</td>
</tr>
<tr>
<td>(1/64)</td>
<td>(4/652)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 4 yr</td>
<td>0%</td>
<td>0.4%</td>
<td>0.75</td>
</tr>
<tr>
<td>(0/26)</td>
<td>(1/246)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No Significant Difference
## ENGAGE Global Registry
### Outcomes Through Follow-Up

<table>
<thead>
<tr>
<th>Secondary Endovascular Procedure</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through 1 yr</td>
<td>6.6% (9/137)</td>
<td>6.9% (65/1100)</td>
<td>0.76</td>
</tr>
<tr>
<td>Through 2 yr</td>
<td>8.0% (11/137)</td>
<td>7.6% (84/1100)</td>
<td>0.89</td>
</tr>
<tr>
<td>Through 3 yr</td>
<td>7.8% (4/51)</td>
<td>9.4% (103/1100)</td>
<td>0.61</td>
</tr>
<tr>
<td>Through 4 yr</td>
<td>7.8% (4/51)</td>
<td>11.1% (49/443)</td>
<td>0.48</td>
</tr>
</tbody>
</table>

**No Significant Difference**
### ENGAGE Global Registry
#### Outcomes Through Follow-Up

<table>
<thead>
<tr>
<th>Main Body Migration</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>No migration through 4 yrs for both short and normal necks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### ENGAGE Global Registry

#### Outcomes Through Follow-Up

<table>
<thead>
<tr>
<th>Rupture</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through 1 yr</td>
<td>0.7% (1/137)</td>
<td>0.1% (1/1100)</td>
<td>0.79</td>
</tr>
<tr>
<td>Through 2 yr</td>
<td>0.7% (3/1100)</td>
<td></td>
<td>0.374</td>
</tr>
<tr>
<td>Through 3 yr</td>
<td>1.5% (2/137)</td>
<td>0.4% (11/1100)</td>
<td>0.082</td>
</tr>
<tr>
<td>Through 4 yr</td>
<td>0% (0/51)</td>
<td>0.5% (2/443)</td>
<td>0.631</td>
</tr>
</tbody>
</table>

*No Significant Difference*
## ENGAGE Global Registry
### Outcomes Through Follow-Up

<table>
<thead>
<tr>
<th>Conversion</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through 1 yr</td>
<td>0.7%</td>
<td>0.5%</td>
<td>0.786</td>
</tr>
<tr>
<td></td>
<td>(1/137)</td>
<td>(9/1100)</td>
<td></td>
</tr>
<tr>
<td>Through 2 yr</td>
<td>0.7%</td>
<td>0.8%</td>
<td>0.913</td>
</tr>
<tr>
<td></td>
<td>(1/137)</td>
<td>(9/1100)</td>
<td></td>
</tr>
<tr>
<td>Through 3 yr</td>
<td>1.5%</td>
<td>0.8%</td>
<td>0.451</td>
</tr>
<tr>
<td></td>
<td>(2/137)</td>
<td>(9/1100)</td>
<td></td>
</tr>
<tr>
<td>Through 4 yr</td>
<td>0%</td>
<td>0.9%</td>
<td>0.496</td>
</tr>
<tr>
<td></td>
<td>(0/51)</td>
<td>(4/443)</td>
<td></td>
</tr>
</tbody>
</table>

*No Significant Difference*
Summary

Endurant stent-graft achieves good results in short necks in the midterm up to 4 years.

Endurant performs equally well in standard EVAR neck lengths as it does at short necks:

• No differences between short and standard neck length conditions in terms of:
  ✓ Procedural Technical Observations
  ✓ Type I Endoleak
  ✓ Migration
  ✓ Re-intervention
  ✓ Rare instances of rupture
  ✓ Conversion
Summary

• There is no doubt that the best results with EVAR will be achieved by following the IFU. However, in experienced hands, short neck length seems to be challenged by modern EVAR technology, like Endurant Stent Graft System.

• The current data supports
  ✓ the use of standard endografts such as the Endurant Stent Graft System in pts with challenging anatomy in terms of short (8-15mm) necks
  ✓ FEVAR/BEVAR should be limited to pts with shorter necks <8 mm/short necks accompanied with multifactorial challenging anatomy

• These results support the application of similar standard surveillance protocols for pts with short vs. standard necks
Conclusion

• AAAs with straight short necks (8-15 mm) should be treated with standard endografts

• Using fenestrated technology in these cases is a huge waste of resource
Endurant Broadens Standard EVAR Applicability in Challenging Necks *

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

* Medtronic does not have FEVAR/Branch EVAR devices approved for commercial use