Long-Term Results Of EVAR Outside Device IFUs Is Not So Bad: When Is It Acceptable To Use EVAR Devices Outside Their IFUs

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Disclosures

• Received research funding assistance from Atrium Medical Corporation.
• Consultant for Getinge, Biotronik, and Medtronic

Background

• EVAR has become the preferred intervention for AAA repair. A durable proximal seal is necessary to ensure optimal long-term results.
• Proximal seal can be challenged by patient's anatomy, especially hostile proximal necks. Device IFUs (instructions for use) are structured around these known risks.
• It's estimated ~20% of AAA patients have neck morphology outside of IFU guidelines.
• Device use outside of IFU is not uncommon – some studies report up to 53% of patients being treated outside of IFU.

ENGAGE Global Post-Market Registry for Endurant

Largest Contemporary EVAR Registry with Single Manufacturer's Stent Graft Collecting Key Clinical Outcomes

1263 Patients
30 Countries
6 Continents

Real-world patients:
- Limited inclusion/exclusion criteria
- Real-world practice:
- Limited procedural specifications
- Standard follow-up

Background Objectives

• Prospectively collect global 'real-world' safety and clinical performance on the Endurant Stent Graft System from patients with infrarenal AAAs.

19 publications and >100 presentations at global conferences characterizing ENDURANT and patients implanted with Endurant.
Today's ENGAGE Registry Sub-Analysis

**OBJECTIVE:**
To compare the 5-year results for patients treated On- versus Off-IFU with the Endurant stent graft

**HYPOTHESIS:**
From the ENGAGE Registry, Endurant performs as well in patients treated Off-Label as it does for patients treated within the IFU

### Baseline Patient Characteristics

**Challenging Real-World Population**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Off-Label Patients</th>
<th>On-Label Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck length &lt;15mm</td>
<td>16.2%</td>
<td>16.2%</td>
</tr>
<tr>
<td>25.1% vs 9.3%, p&lt;0.001</td>
<td></td>
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<tr>
<td>Infrarenal neck angle &gt;60˚</td>
<td>34.6%</td>
<td>5.0%</td>
</tr>
<tr>
<td>34.6% vs 5.0%, p&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More often female</td>
<td>19.1%</td>
<td>8.7%</td>
</tr>
<tr>
<td>19.1% vs 8.7%, p&lt;0.001</td>
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<td></td>
</tr>
</tbody>
</table>

### Index Procedure with Endurant

**Successful delivery and deployment of Endurant:**
- Off-label: 99.6%
- On-label: 99.4%, p=0.002

**Duration of implant procedure:**
- Off-label: 109.6 min
- On-label: 97.2 min, p<0.002

**Total fluoro time:**
- Off-label: 22.4 min
- On-label: 20.3 min, p=0.005

**Volume of contrast:**
- Off-label: 145.3 cc
- On-label: 128.6 cc, p<0.002

Off-label procedures took longer and required more contrast load.

**Technical Success was similar and high at Implantation Index**

### Key Technical Outcomes through 5-Years

**Freedom from Type IA Endoleak**
- Off-label: 89.4%
- On-label: 96.7%, p<0.0001

**Freedom from Main Body Migration**
- Off-label: 100%
- On-label: 99.7%, p=0.2128

**Freedom from Limb Occlusion**
- Off-label: 97.1%
- On-label: 95.8%, p=0.2243

**Freedom from Type IB Endoleak**
- Off-label: 94.7%
- On-label: 96.2%, p=0.0762

**Freedom from Type III Endoleak**
- Off-label: 99.0%
- On-label: 97.3%, p=0.6079

**Migration and Limb Occlusions were infrequent and similar between groups. Incidence of Type IB and III endoleaks were also similar but Off-label patients experienced more Type IA endoleaks.**

### Mortality Outcomes Similar through 5-Years

**Freedom from Aneurysm-Related Mortality**
- Off-label: 97.2%
- On-label: 97.9%, p=0.3947

**Freedom from All-Cause Mortality**
- Off-label: 65.6%
- On-label: 67.7%, p=0.6093

### Overall 2nd Endovascular Procedures Similar through 5-Years

**Freedom from 2nd Endo Proc**
- Off-label: 84.1%
- On-label: 84.3%, p=0.8003
**2nd Endo Proc to Treat Type I Endoleaks through 5-Years**

- Off-label patients required more 2nd Endovascular Procedures to treat Type I Endoleaks.

**AAA Rupture and Conversion Similar through 5-Years**

- Freedom from Aneurysm Rupture:
  - Off-label: 98.8%
  - On-label: 98.5%, p=0.8727

- Freedom from Conversion:
  - Off-label: 99.6%
  - On-label: 97.6%, p=0.1610

**AAA Sac Dynamics at 5-Year Follow-Up**

<table>
<thead>
<tr>
<th>5-Years</th>
<th>Off-Label (%)</th>
<th>On-Label (%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA Diameter Increase</td>
<td>18.6%</td>
<td>9.2%</td>
<td>0.030</td>
</tr>
<tr>
<td>AAA Diameter Stable</td>
<td>31.4%</td>
<td>27.5%</td>
<td>0.340</td>
</tr>
<tr>
<td>AAA Diameter Decrease</td>
<td>50.0%</td>
<td>63.3%</td>
<td>0.040</td>
</tr>
</tbody>
</table>

**ENGAGE Registry On- vs Off-Label Sub-Analysis**

- No differences between On- and Off-label patients in terms of:
  - Technical success at Index procedure
  - Migration
  - Type IB and III endoleaks
  - All-cause mortality
  - Aneurysm-related mortality
  - 2nd endovascular procedures overall
  - Rare instances of Rupture or Conversion to Open Repair

**Summary**

- Off-label: 92.8%
- On-label: 96.3%, p=0.0066

**Conclusion**

- In the ENGAGE Registry, Endurant seems to close the gap and has achieved good results up to 5 years in both On- and Off-label patients.
- However, Off-label patients had a higher incidence of type IA endoleaks and 2nd endovascular procedures to treat these proximal leaks.
- Not surprising as majority of patients in ENGAGE were off-label due to proximal neck characteristics
- To improve long-term durability of EVAR, patients with hostile proximal neck anatomy may benefit from complimentary procedures:
  - C/HEVAR / TEVAR – to lengthen the proximal seal
  - EndoAnchors – to strengthen the proximal seal
- When possible, adherence to a device’s IFU is encouraged

**THANK YOU**

- Long-term results of EVAR outside device IFUs is not so bad: When is it acceptable to use EVAR devices outside their IFUs