DEBATE:
Not So! Off-label Use Of EVAR Devices Is Sometimes Justified and Does Not Yield Higher Long-Term Failure Rates if Certain Requirements Are Fulfilled

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• Research fund by Medtronic
• Research fund by Biotronik

LEVEL OF EVIDENCE

EVAR should be performed cautiously in hostile circumstances
• Women and coronary disease

QUESTION THAT REMAINS

Do new devices drive better EVAR performance in hostile anatomy with more violation of the IFU?

ENGAGE GLOBAL REGISTRY

SUB-ANALYSIS

• To compare the midterm results in patients treated according to device-specific instructions for use (IFU) vs. those treated in an off-label (OL) situation from the ENGAGE Registry.

• HYPOTHESIS:
“The Endurant Stent Graft performs as well in patients treated in OL conditions as it does in standard IFU”
Patients consecutively enrolled (2009-2011)
Follow-up: 30-day, annual visits through 10 years
Extensive monitoring on-going
100% data review by an independent panel
Independent Data Monitoring (100% endpoints)
Independent Clinical Event Committee

High quality registry data

Patient Baseline Characteristics n=1263

ENGAGE GLOBAL REGISTRY

CHALLENGING REAL WORLD POPULATION

Patient Baseline Characteristics n=1263

ENGAGE REGISTRY

INITIAL IMPLANT

TECHNICAL OBSERVATIONS (1)

<table>
<thead>
<tr>
<th></th>
<th>OL (N=215)</th>
<th>IFU (N=1048)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Delivery and Deployment</td>
<td>99.5% (214)</td>
<td>99.4% (1042)</td>
<td>0.847</td>
</tr>
<tr>
<td>Type I Endoleak (uncorrected)</td>
<td>0.5% (1)</td>
<td>1.2% (13)</td>
<td>0.323</td>
</tr>
</tbody>
</table>

ENGAGE REGISTRY

OUTCOMES AT 4 YEAR FOLLOW-up

TECHNICAL OBSERVATIONS (2)

<table>
<thead>
<tr>
<th></th>
<th>OL (N=102)</th>
<th>IFU (N=548)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I Endoleak</td>
<td>1.9% (1)</td>
<td>2.2% (12)</td>
<td>0.423</td>
</tr>
<tr>
<td>Type IA Endoleak</td>
<td>0.0% (0)</td>
<td>0.9% (5)</td>
<td>0.333</td>
</tr>
<tr>
<td>Type IB Endoleak</td>
<td>1.0% (1)</td>
<td>1.5% (8)</td>
<td>0.704</td>
</tr>
<tr>
<td>Type III Endoleak</td>
<td>0.0% (0)</td>
<td>0.2% (1)</td>
<td>0.666</td>
</tr>
</tbody>
</table>

ENGAGE REGISTRY

OUTCOMES THROUGH 4 YEAR FOLLOW-up

TECHNICAL OBSERVATIONS (3)

<table>
<thead>
<tr>
<th></th>
<th>OL (N=208)</th>
<th>IFU (N=1006)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Body Migration</td>
<td>0.0% (0)</td>
<td>0.1% (1)</td>
<td>0.651</td>
</tr>
<tr>
<td>Limb Migration</td>
<td>1.5% (3)</td>
<td>0.4% (4)</td>
<td>0.068</td>
</tr>
<tr>
<td>SG Occlusion</td>
<td>2.9% (6)</td>
<td>4.4% (4)</td>
<td>0.337</td>
</tr>
</tbody>
</table>

ENGAGE REGISTRY

OUTCOMES WITHIN 4 YEAR FOLLOW-up

SECONDARY ENDOVASCULAR PROCEDURE

<table>
<thead>
<tr>
<th></th>
<th>OL (N=208)</th>
<th>IFU (N=1023)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Endovascular Procedures</td>
<td>13.9% (27)</td>
<td>10.7% (103)</td>
<td>0.330</td>
</tr>
<tr>
<td>Secondary Endovascular Procedures to Correct Type I/III Endoleak</td>
<td>6.7% (34)</td>
<td>3.1% (32)</td>
<td>0.013</td>
</tr>
</tbody>
</table>
ENGAGE REGISTRY
OUTCOMES WITHIN 4 YEAR FOLLOW-UP

<table>
<thead>
<tr>
<th>Treatment Failures</th>
<th>OL (N=208)</th>
<th>IFU (N=1023)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rupture</td>
<td>0.1% (2)</td>
<td>0.9% (9)</td>
<td>0.909</td>
</tr>
<tr>
<td>Conversion to OS</td>
<td>0.5% (1)</td>
<td>1.2% (12)</td>
<td>0.373</td>
</tr>
</tbody>
</table>

ENGAGE REGISTRY
OUTCOMES THROUGH AT 4 YEAR FOLLOW-UP

STABLE/DECREASING AAA SAC DIAMETER

Shanzer, Circ. 2011

ENGAGE

ENGAGE REGISTRY
SUMMARY

- No differences between IFU vs. OL pts in terms of:
  - Technical observations at index procedure
  - Type III endoleak rate
  - Overall secondary endovascular procedures
  - Migration
  - SG occlusion
  - Rare instances of rupture and conversion to OS

ENGAGE REGISTRY
CONCLUSION

- In the ENGAGE Registry, Endurant seems to close the gap between IFU and OL indications and has achieved good results in the mid-term up to 4 years in both OL and IFU patients.
- However, these pts require more often secondary re-intervention to fix type III EL.
- We need to better understand which specific anatomical features that are related to the need for these secondary interventions.
- Standard EVAR treatment in OL pt indications is feasible with the Endurant Stent Graft if strict follow up is considered.