Endurant Clinical Results: How Does This Impact Boundaries for Standard EVAR vs FEVAR

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Disclosures

Speaker/consultant:  Medtronic
Endovascular Aortic Aneurysm Repair

- Since its introduction 25 years ago, EVAR has essentially replaced traditional open surgery as the preferred treatment modality for abdominal aortic aneurysm.
- However, unfavorable, challenging aortic neck characteristics continue to limit its applicability.

Purpose:
- Review the available clinical data on Endurant stent graft
- Discuss boundaries of standard vs fenestrated EVAR
Eudurant Abdominal Stent Graft

- Designed to treat short and angulated proximal necks
- Instructions for use (IFU):
  - Proximal neck length of $\geq 10$ mm
  - Infrarenal neck angulation of $\leq 60$ degrees
  - Outside of US: also $\leq 75$ degree if $\geq 15$ mm
The Eudurant Experience

- Clinical study data is available on over 1900 patients worldwide.

- United States
  - US IDE (150)
  - AUI arm (44)
  - ENGAGE PAS (178)

- International
  - ENGAGE registry (1263)
  - Endurant France (180)
  - FIM & Cont Access (80)
The Eudurant Experience

- Focus on two clinical studies:
  - US IDE trial (150)
    - Characterize device performance
    - Evaluate long-term outcomes
    - Data supported FDA approval
  - International ENGAGE registry (1263)
    - Study “real world effectiveness”
    - Detailed collection of experience
    - Wide range of patients, aortic anatomies
    - 4 year follow-up
US IDE Trial

- 150 patients, prospective, nonrandomized study enrolling at 26 US sites in 2008-09
- Primary safety endpoint: 30 days MAE
- Primary effectiveness endpoint: 12 month successful aneurysm treatment

Inclusion:
- \( \geq 10 \text{ mm proximal neck length} \)
- \( \leq 60 \text{ degree infrarenal angulation} \)
- \( \leq 45 \text{ degree suprarenal angulation} \)
US IDE Trial – 5 year results

- Freedom from ARM: 99.2% through 5 years
- Freedom from secondary procedure: 89% through 5 years

<table>
<thead>
<tr>
<th>Treatment Outcomes</th>
<th>1 Year</th>
<th>2 Year</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-implant Rupture</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0.8%*</td>
<td>0%</td>
</tr>
<tr>
<td>Conversion to OSR</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

- Change in aneurysm diameter: 95.2% decreasing/stable at 5 years

1 Year

- Increase 4.8%
- Stable 29.8%
- Decrease 55.5%

2 Year

- Increase 2.3%
- Stable 35.9%
- Decrease 61.7%

5 Year

- Increase 4.8%
- Stable 29.8%
- Decrease 55.5%
US IDE Trial – Data Summary

- Clinical endpoints at 5 years
  - 0% migration or conversion
  - Low rate of aneurysm sac enlargement (significant shrinkage)
  - Only 1 instance of ARM through five years

- Clinically efficacious with good long-term durability
ENGAGE Registry

- ENdurate Stent Graft NAutural Selection Global Postmarket 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
ENGAGE Registry

• Prospective, consecutively enrolled, limited inclusion/exclusion criteria
• Follow-up: 30d, with subsequent annual visits
• Extensive ongoing monitoring
  • 100% data management review
  • Independent data monitoring (100% endpoints)
  • Independent Clinical Event Committee
ENGAGE Registry

- Current analysis: 1263 patients at 4 years
- Challenging “real world” patient population

Patient Demographics

- SVS 3: 35.5%
- Outside IFU: 17.8%
- Symptomatic AAA: 16.2%
- AAA >7cm: 15.2%
- Neck 10mm-<15mm: 10.0%
- ASA IV: 10.6%
- Female: 10.5%
ENGAGE Registry

- Low rates of mortality (aneurysm, device or procedure-related)

<table>
<thead>
<tr>
<th></th>
<th>0-365 days N=1263</th>
<th>0-731 days N=1263</th>
<th>0-1096 days N=1263</th>
<th>0-1461 days N=1231</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cause mortality</td>
<td>7.5% (95)</td>
<td>13.9% (175)</td>
<td>19.8% (250)</td>
<td>24.0% (296)</td>
</tr>
<tr>
<td>Device-related</td>
<td>0.2% (2)</td>
<td>0.3% (4)</td>
<td>0.3% (4)</td>
<td>0.5% (6)</td>
</tr>
<tr>
<td>Procedure-related</td>
<td>0.7% (9)</td>
<td>0.8% (10)</td>
<td>0.8% (10)</td>
<td>0.9% (11)</td>
</tr>
<tr>
<td>Both device- and procedure-related</td>
<td>0.1% (1)</td>
<td>0.2% (2)</td>
<td>0.2% (2)</td>
<td>0.2% (3)</td>
</tr>
<tr>
<td>Aneurysm-related mortality</td>
<td>1.4% (18)</td>
<td>1.5% (19)</td>
<td>1.5% (19)</td>
<td>1.6% (20)</td>
</tr>
</tbody>
</table>
ENGAGE Registry

- Freedom from all cause mortality: 74.1% at 4 years
- Freedom from ARM: 98.3% at 4 years
ENGAGE Registry

- Low rate of rupture or conversion

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<th>0-1461 days N=1231</th>
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<tr>
<td>Rupture</td>
<td>0.2% (2)</td>
<td>0.3% (4)</td>
<td>0.5% (6)</td>
<td>0.9% (11)</td>
</tr>
<tr>
<td>Conversion to OSR</td>
<td>0.6% (7)</td>
<td>0.8% (10)</td>
<td>0.9% (11)</td>
<td>1.1% (13)</td>
</tr>
</tbody>
</table>

- Change in aneurysm diameter
  - 89.2% decreasing/stable at 4 years
ENGAGE Registry – Data Summary

• Clinical endpoints at 4 years
  • Low rate of migration (1 case) or conversion (1%)
  • Low rate of aneurysm sac enlargement (significant shrinkage)
  • Very low rate of ARM on follow-up

• Encouraging midterm results...study extended to f/u of 10 years
EVAR for Short Aortic Necks

- Options include “standard” EVAR, chEVAR, FEVAR

- Fenestrated EVAR
  - Commercially available for treatment of short necks (juxtarenal AAAs) of at least 4 mm non-aneurysmal neck
  - Clinical trial data and early post-approval outcomes were encouraging
  - However, there are some limitations:
    - Time for manufacturing of the graft
    - Large sheath size for device delivery
    - Rates of peri-procedural morbidity and mortality
    - Diffusion of this technology and “real-world” outcomes
EVAR for Short Aortic Necks

- “Real-world” effectiveness
  - Excellent outcomes from high volume centers of excellence
  - FEVAR more complex procedure
    - Careful patient selection
    - Pre-procedural planning (sizing of device)
    - Dedicated surgeon, team, facility (imaging)
    - Technical skills (navigate challenges, “bail-out”)

- What is the performance of the “standard EVAR” using the Endurant stent graft in unfavorable, challenging aortic necks?
ENGAGE Registry – Challenging Neck

- Subgroup analysis from ENGAGE registry
ENGAGE Registry – Challenging Neck

- Initial Device Implantation

<table>
<thead>
<tr>
<th></th>
<th>Neck Length (mm)</th>
<th>Neck Angulation (°)</th>
<th>Neck Ca²⁺/Thrombus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 to&lt;15</td>
<td>≥15</td>
<td>P</td>
</tr>
<tr>
<td>Successful Delivery and</td>
<td>100% (123/123)</td>
<td>99.4% (1093/1101)</td>
<td>0.38</td>
</tr>
<tr>
<td>Deployment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100% (74/74)</td>
<td>99.5% (1095/1101)</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>&gt;60</td>
<td>≤60</td>
<td>P</td>
</tr>
<tr>
<td>Type I Endoleak (uncorrected)</td>
<td>0% (0/123)</td>
<td>1.3 % (14/1094)</td>
<td>0.21</td>
</tr>
<tr>
<td></td>
<td>1.4 % (1/74)</td>
<td>1.0 % (11/1096)</td>
<td>0.77</td>
</tr>
<tr>
<td></td>
<td>2.1% (4/188)</td>
<td>1.0 % (10/1048)</td>
<td>0.16</td>
</tr>
</tbody>
</table>

- Early technical success affected by calcification/thrombus
ENGAGE Registry – Challenging Neck

• Through 4-year follow-up:

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<td>≥15</td>
<td>P</td>
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<tr>
<td>Type I endoleak</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.6%</td>
<td>1.6%</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>(2/55)</td>
<td>(9/576)</td>
<td></td>
</tr>
<tr>
<td>Type IA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.8%</td>
<td>0.5%</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>(1/55)</td>
<td>(3/576)</td>
<td></td>
</tr>
<tr>
<td>Secondary Procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>9.4%</td>
<td>11.0%</td>
<td>0.61</td>
</tr>
<tr>
<td></td>
<td>(11/117)</td>
<td>(118/1076)</td>
<td></td>
</tr>
<tr>
<td>Secondary for type I/III</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.3%</td>
<td>3.3%</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>(5/117)</td>
<td>(36/1076)</td>
<td></td>
</tr>
</tbody>
</table>

• The presence of type I/IA endoleak and need for secondary intervention not affected by challenging neck anatomy
ENGAGE Registry – Challenging Neck

- Through 4 year follow-up

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<tbody>
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<td>≥15</td>
<td>P</td>
<td>&gt;60</td>
<td>≤60</td>
</tr>
<tr>
<td>Migration</td>
<td>0% (0/116)</td>
<td>0.1% (1/1059)</td>
<td>0.74</td>
<td>0% (0/72)</td>
<td>0.1% (1/1056)</td>
</tr>
<tr>
<td>Conversion</td>
<td>1.7% (2/117)</td>
<td>1.0% (11/1076)</td>
<td>0.50</td>
<td>0% (0/72)</td>
<td>1.1% (12/1074)</td>
</tr>
<tr>
<td>Rupture</td>
<td>2.6% (3/117)</td>
<td>0.7% (8/1076)</td>
<td>0.050</td>
<td>1.4% (1/72)</td>
<td>0.9% (10/1074)</td>
</tr>
</tbody>
</table>

- 3 ruptures in short neck
  - Type III endoleak, treatment on 34 mm neck
  - Type I endoleak failed FEVAR cuff
ENGAGE Subgroup – Data Summary

- EVAR w/Endurant in challenging neck
  - No instances of migration
  - No differences in rate of
    - Type I or type IA endoleak
    - Need for conversion
    - Reintervention rate
  - Rare instances of aneurysm rupture

- Encouraging midterm results in challenging subgroup of patients

- Can “standard EVAR” continue to improve?
Endoanchors – Proximal Fixation

- Designed to resist neck dilatation
- Strength equal to surgical anastomosis
- Augment seal in complex neck anatomies
- Provide stability and enhance durability
Conclusions

• Challenging aortic neck anatomy continues to limit the applicability of EVAR.

• Clinical data demonstrated the Endurant stent graft to have excellent long-term durability and is effective in aneurysm treatment in the “real-world” setting.

• Furthermore, there were also excellent outcomes when used in patients with challenging aortic neck characteristics.

• “Standard EVAR” may be an acceptable alternative in treatment of AAA with short necks.
Thank You!
Endurant Clinical Results: How Does This Impact Boundaries for Standard EVAR vs FEVAR

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