EVAS FORWARD Global Registry: One Year Outcomes

VEITH SYMPOSIUM
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Disclosures and Disclaimers

- Andrew Holden MBChB, FRANZCR, EBIR
  - Clinical Investigator for Endologix Inc.
  - Medical Advisory Board Member for Endologix Inc.

Cohorts

- Principal Investigators
  - Andrew Holden, MBChB, Auckland, NZ
  - Matt Thompson, MD, London, UK

- 300 patients, 30 centers with five year follow-up
- Real-world experience; no prospective screening of patients
- CT scan core lab analysis (Cleveland Clinic Core Lab)
- Independent adverse events adjudication
- Primary outcomes typical of EVAR therapy

Mean time in study: 425d; 14mo (0-21mo)
Median time in study: 434d (Min=0, Max=643, 25%ile 369 75%ile 490)

AAA Complexity across All-Comer Registries

<table>
<thead>
<tr>
<th>Classification</th>
<th>≤30 days (n=277)</th>
<th>31d – 1yr (n=272)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Cause Death</td>
<td>3 (1.1%)</td>
<td>11 (4.0%)</td>
</tr>
<tr>
<td>Perioperative mortality</td>
<td>3 (1.1%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>AAA-related mortality</td>
<td>0 (0.0%)</td>
<td>1 (0.4%)*</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0 (0.0%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>2 (0.7%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Bowel Ischemia</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>2 (0.7%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (0.4%)</td>
<td>3 (1.1%)</td>
</tr>
<tr>
<td>Blood loss &gt;1000 mL</td>
<td>2 (0.7%)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Patients with one or more MAE</td>
<td>8 (2.9%)</td>
<td>16 (5.9%)</td>
</tr>
</tbody>
</table>

Major Adverse Events

*One late AAA-related death due to aorto-duodenal fistula at day 148
Freedom from All Endoleak

Through 1 yr 94.5%

Type Ia Endoleak – Most Common Causes

Low stent deployment
Stent Misalignment

Persistent Endoleaks

<table>
<thead>
<tr>
<th>Endoleak (Total)</th>
<th>At 30 Days N=277</th>
<th>At 1 Year N=269</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type IA</td>
<td>1.3% (3)</td>
<td>0.4% (1)</td>
</tr>
<tr>
<td>Type IB</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Type II</td>
<td>0.4% (1)</td>
<td>0.4% (1)</td>
</tr>
<tr>
<td>Type III</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Endoleaks at 1 Year

- EVAS
- ENGAGE

Resolution of Type II Endoleak

Transcatheter Embolization Of Type IA Endoleak

Conclusions from Endoleak Data

- The incidence of ≤ 30 day and 1 year endoleak remains very low
- The root causes are attributed to procedural factors
- Type 1A and 1B endoleak can be effectively treated
- Higher incidence of ≤ 30 day Core Laboratory reported type 2 endoleak compared to 1 year window, but these are small and most resolve
Conclusions – 1 Year Follow Up

- Impressive results in the first-ever prospective, EVAS all-comers clinical study showing durability of repair
- Low endoleak and reintervention rates in complex patient population
- Excellent one year aneurysm related and overall survival outcomes
- Longer follow-up and additional EVAS studies essential