Does Ovation offer a Long-Term Durable Solution for Female AAA Patients? Results from the ENCORE Gender Sub-Analysis

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Disclosure

Speaker name:  Sean Lyden MD

I have the following potential conflicts of interest to report:

- Consulting Phillips, Endologix, Shockwave, Abbott, BSC, Spectranetics, Medtronic, PQ Bypass
- Employment in industry: None
- Stockholder of a healthcare company: None
- Owner of a healthcare company: None
- Other(s) VIVA Physicians Inc 501c3 Board Member
Women Are Underserved By Conventional EVAR

**LANCET, June 2017**
Meta-Analysis and Systematic Review

<table>
<thead>
<tr>
<th>Conclusions</th>
<th>Women vs. Men</th>
<th>Studies</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less women are eligible for EVAR</td>
<td>34% 54%</td>
<td>5</td>
<td>400 women 1,507 men</td>
</tr>
<tr>
<td>More women were declined intervention</td>
<td>34% 19%</td>
<td>4</td>
<td>245 women 1,365 men</td>
</tr>
<tr>
<td>30 day mortality higher in women</td>
<td>2.3% 1.4%</td>
<td>9</td>
<td>11,076 women 52,018 men</td>
</tr>
</tbody>
</table>
Polymer EVAR

• Low Profile (14F OD)
• Broad IFU Applicability
• Device Deliverability
• Polymer Proximal Sealing
M2S Analysis of ~44,000 patients. Applicability based on IFU and access vessel parameters. Ovation iX neck length applicability measured at 13mm. Data on file (MM1660)

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Ovation® Stent Graft Suited for Women with AAA

64 y.o. female, 51mm AAA
Short neck; Tortuous, narrow calcific iliacs

1-Year
Successful aneurysm exclusion

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Does Ovation Offer a Solution for Female AAA Patients Underserved by Conventional EVAR?

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Studies actively following patients per respective protocol: †5 year FU completes in 2020 / ‡5y FU completes in 2019 / *1y FU completes in 2018
ENCORE Study Design and Methodologies

- Pooled, retrospective analysis of 6 prospectively enrolled studies*
- 1,296 patients treated from 2009-2017
- Global cohort (US, Europe, South America)
- 160 Centers and 339 Investigators
- Standardized variable definitions across each study
- Standardized follow-up intervals across studies for K-M calculations
- Median follow-up across all studies = 1034 days (Range 30d – 5y)
  - Gender Sub-Analysis: 19% (251) Female patients

*Retrospective analysis on available variable data includes data cuts available as of April 12, 2018. Data cuts: Ovation Pivotal Trial Aug 2, 2016 / EU PMR April 12, 2018 / LIFE Registry April 12, 2018 / LUCY Study April 12, 2018

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Female</th>
<th>Male</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>75 ± 8</td>
<td>73 ± 8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ASA Class 1/2</td>
<td>37%</td>
<td>35%</td>
<td>0.03</td>
</tr>
<tr>
<td>Class 3</td>
<td>54%</td>
<td>61%</td>
<td></td>
</tr>
<tr>
<td>Class 4</td>
<td>9%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>28 ± 7</td>
<td>28 ± 5</td>
<td>0.78</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>7%</td>
<td>6%</td>
<td>0.38</td>
</tr>
<tr>
<td>COPD</td>
<td>36%</td>
<td>32%</td>
<td>0.27</td>
</tr>
<tr>
<td>MI</td>
<td>15%</td>
<td>23%</td>
<td>0.01</td>
</tr>
<tr>
<td>Diabetes</td>
<td>23%</td>
<td>22%</td>
<td>0.69</td>
</tr>
<tr>
<td>CVA (Stroke)</td>
<td>10%</td>
<td>9%</td>
<td>0.67</td>
</tr>
<tr>
<td>Thoracic Aneurysm</td>
<td>1%</td>
<td>2%</td>
<td>0.75</td>
</tr>
<tr>
<td>Family History AAA</td>
<td>12%</td>
<td>12%</td>
<td>0.94</td>
</tr>
<tr>
<td>Tobacco Use</td>
<td>70%</td>
<td>72%</td>
<td>0.68</td>
</tr>
</tbody>
</table>

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ENCORE includes results from real-world post market studies. 4% of patients had vascular characteristics beyond FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

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### Vascular Characteristics

<table>
<thead>
<tr>
<th>Baseline Aortoiliac Characteristics</th>
<th>Female</th>
<th>Male</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Sac Diameter (mm)</td>
<td>51.6 ± 7.5</td>
<td>54.5 ± 9.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic Size Index (ASI)</td>
<td>2.9 ± 0.51</td>
<td>2.7 ± 0.53</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic Neck Angulation (°)</td>
<td>24.2 ± 20.3</td>
<td>17.6 ± 17.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Proximal neck length (mm)</td>
<td>21.7 ± 11.5</td>
<td>24.6 ± 12.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic Neck Diameter IR (mm)</td>
<td>20.8 ± 3.3</td>
<td>22.6 ± 2.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic Neck Diameter IR + 13 (mm)</td>
<td>22.2 ± 3.7</td>
<td>23.5 ± 3.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Distal Common Iliac Dia (mm)</td>
<td>11.8 ± 2.9</td>
<td>13.9 ± 3.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>External Iliac Artery Dia (mm)</td>
<td>6.9 ± 1.6</td>
<td>8.3 ± 2.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Vascular Characteristics

Women had more challenging baseline anatomic characteristics than men.

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### Procedural Characteristics

<table>
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<th>Characteristic</th>
<th>Female</th>
<th>Male</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>100%</td>
<td>99.7%</td>
<td>0.77</td>
</tr>
<tr>
<td>Procedure time, minutes</td>
<td>104.2 ± 45.8</td>
<td>99.9 ± 40.5</td>
<td>0.23</td>
</tr>
<tr>
<td>Device Time, minutes</td>
<td>37.6 ± 19.1</td>
<td>38.0 ± 17.3</td>
<td>0.83</td>
</tr>
<tr>
<td>Fluoroscopy Time, minutes</td>
<td>17.0 ± 19.9</td>
<td>16.1 ± 18.5</td>
<td>0.50</td>
</tr>
</tbody>
</table>

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Freedom From All-Cause Mortality

FF ACM
Women: 80.8%
Men: 76.3%

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Freedom from Endoleak

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<table>
<thead>
<tr>
<th>Category</th>
<th>Women (93.9%)</th>
<th>Men (94.4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IB</td>
<td>Women (97.2%)</td>
<td>Men (99.2%)</td>
</tr>
<tr>
<td>III</td>
<td>Women (100%)</td>
<td>Men (99.4%)</td>
</tr>
</tbody>
</table>
Freedom from Sac Enlargement

FF Device
Related
Women: 77.9%
Men: 82.8%

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Freedom from Device Related Interventions

FF Device Related
Women: 90.1%
Men: 92.2%
Freedom From Interventions for Type Ia

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FF Device Related
Women: 96.7%
Men: 97.7%
Freedom From Interventions for Occlusions

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Women: 97.7%
Men: 97.1%
Summary

- Women continue to be underserved by conventional EVAR
- Women comprised 19% of the patients treated in ENCORE
- Women were older and had higher ASA classification at baseline
- Women had more complex aortic morphology and were more likely to be treated off of the Ovation IFU

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Encore Gender Sub-Analysis

- **Women** treated with Ovation Stent Graft have equivalent outcomes to Men through 5 years including:
  
  - 99% FF AAA-Related Mortality
  
  - 99% FF Rupture
  
  - 98% FF Conversion
  
  - 97% FF Reintervention for Type Ia Endoleak
  
  - 91% FF Device-Related Reintervention

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