Ovation endograft: 4 – year real world results form the Ovation European post market registry

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Conflict of interest

Speaker honorariums and travel grants from:

- Endologix Inc.
- Medtronic Inc.
Traditional EVAR treatment presents limitations to women with AAA

<table>
<thead>
<tr>
<th>Women are less eligible than men for EVAR</th>
<th>Women have greater complications rates and mortality</th>
<th>Women may derive benefits from low profile polymer based devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only 34% women with AAA are eligible for EVAR treatment as compared to 54% in men due to anatomical restrictions.(^1)</td>
<td>Women are more likely to have perioperative morbidity and mortality including access related complications.(^3) At 30 days, women experience higher mortality (2.9% vs. 1.1%; (p &lt; .001)) and major complications (9.6% vs. 5.8%; (p &lt; 0.001))(^4)</td>
<td>While there is no endograft specifically designed for women, the literature suggests that newer, lower-profile devices that can better accommodate the challenging anatomy found in women may improve outcomes(^1).</td>
</tr>
</tbody>
</table>

In-Hospital Mortality after EVAR higher in Women

http://www.hcup-us.ahrq.gov/
Procedure Code 39.71 End
http://www.hcup-us.ahrq.gov/
Procedure Code 39.71 Endo Impl Grft Abd Aorta
o Impl Grft Abd Aorta
Low Profile Endografts are well suited for EVAR in Females

14F ultra low profile enables access to more patients
Conformable, kink resistant PTFE iliac limbs designed to reduce risk of occlusion

Staged deployment of suprarenal stent allows precise placement
Polymer-filled sealing ring creates a custom seal and protects the aortic neck
Low permeability PTFE enables effective aneurysm exclusion and device patency
Pre-Op
64 y.o. female, 51mm AAA
Short neck; tortuous, narrow calcific iliacs

1-Year
Successful aneurysm exclusion
Real World Results: Gender-Specific Outcomes

- Multicenter, prospective
- 501 patients, 30 EU sites
- Patients enrolled May 2011 – Dec 2013 (first patient in Karlsruhe)
- Follow Up 1 month, 6 months, and annually through 5 years
- Primary endpoints: technical success and freedom from Type I/III endoleak, rupture, sac expansion, conversion, occlusion, and migration.
- CEC adjudication of device-related adverse events
- **GENDER SUB-ANALYSIS: 14% Female**

Women were older (77 vs. 73 years, p<0.01) although men reported a higher frequency of ASA class III/IV (54% vs. 34%).

Women had more severe proximal and distal morphology, including minimum external iliac diameter <7mm (65% vs. 38%, p<0.001) and neck length <10mm (12% vs. 4%, p=0.02).
Women had similar procedural outcomes compared to men including 100% technical success in women.

**PMR Gender Analysis**

**Procedural outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Men N=432</th>
<th>Women N=69</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success*</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>Bilateral Percutaneous Access</td>
<td>39%</td>
<td>39%</td>
</tr>
<tr>
<td>Local Anesthesia</td>
<td>37%</td>
<td>40%</td>
</tr>
<tr>
<td>Minimal Blood Loss (100mL)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Median Length of Stay</td>
<td>4.0 days</td>
<td>4.0 days</td>
</tr>
</tbody>
</table>

Procedural Outcomes: Ovation European Post Market Registry
Women and Men Derived similar outcomes through four years

<table>
<thead>
<tr>
<th>Four Year Outcomes</th>
<th>Men</th>
<th>Women</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from AAA mortality</td>
<td>99%</td>
<td>100%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from All-Cause Mortality</td>
<td>80%</td>
<td>82%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from Type IA Endoleak</td>
<td>98%</td>
<td>96%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from Type III Endoleak</td>
<td>99%</td>
<td>100%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from Occlusion</td>
<td>99%</td>
<td>94%</td>
<td>0.003</td>
</tr>
<tr>
<td>Freedom from Conversion</td>
<td>99%</td>
<td>99%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from Rupture</td>
<td>99%</td>
<td>100%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from Aneurysm Enlargement ≥5mm</td>
<td>90%</td>
<td>88%</td>
<td>NS*</td>
</tr>
<tr>
<td>Freedom from Reintervention</td>
<td>88%</td>
<td>81%</td>
<td>NS*</td>
</tr>
</tbody>
</table>

Procedural Outcomes: Ovation European Post Market Registry
*Non-Significant Differences
### PMR Gender Analysis
#### Reinterventions

**AAA-Related Reintervention**

<table>
<thead>
<tr>
<th>Reason for Reintervention</th>
<th>Men N=432</th>
<th>Women N=69</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Ia</td>
<td>2.1% (9)</td>
<td>4.3% (3)</td>
<td>NS*</td>
</tr>
<tr>
<td>Type Ib</td>
<td>1.16% (5)</td>
<td>1.4% (1)</td>
<td>NS*</td>
</tr>
<tr>
<td>Type II</td>
<td>5.1% (22)</td>
<td>11.6% (8)</td>
<td>0.01</td>
</tr>
<tr>
<td>Type III</td>
<td>0.2% (1)</td>
<td>--</td>
<td>na</td>
</tr>
<tr>
<td>Occlusion</td>
<td>2.3% (10)</td>
<td>4.3% (3)</td>
<td>NS*</td>
</tr>
<tr>
<td>Stenosis</td>
<td>0.9% (4)</td>
<td>1.4% (1)</td>
<td>NS*</td>
</tr>
<tr>
<td>Limb Migration</td>
<td>0.7% (3)</td>
<td>1.4% (1)</td>
<td>NS*</td>
</tr>
</tbody>
</table>

Procedural Outcomes: Ovation European Post Market Registry
*Non-Significant Differences
PMR Gender Analysis

Freedom From Mortality Through 4 Years

Freedom from ARM
99% Men
100% Women

P=0.5717

Freedom from ACM
80% Men
82% Women

P=0.8373
PMR Gender Analysis

Freedom from Endoleak and Occlusion Through 4 years

**Freedom from Type IA Endoleak**
- 97% Men
- 93% Women
- P=0.1324

**Freedom from Type III Endoleak**
- 99% Men
- 100% Women
- P=0.4883

**Freedom from Occlusion**
- 98% Men
- 94% Women
- P=0.0072

Procedural Outcomes: Ovation European Post Market Registry
PMR Gender Analysis

Freedom from Rupture and Conversion Through 4 Years

**Freedom from Rupture**
- 99.7% Men
- 100% Women
- \( P = 0.6891 \)

**Freedom from Conversion**
- 99.5% Men
- 98.5% Women
- \( P = 0.3235 \)

Procedural Outcomes: Ovation European Post Market Registry
PMR Gender Analysis

Freedom from Sac Growth Through 4 Years

*Freedom from AAA Growth >5mm*

- 90% Men
- 88% Women

P=0.6894
Conclusions

• Women have limited eligibility for and worse outcomes after EVAR in the past

• Ovation expands EVAR eligibility for women

• The prospective, European Post Market Registry demonstrates than women and men derive similar benefits with the Ovation Stent Graft through 4 years
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