EVAR in female anatomy – the gender registry

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Disclosure

Speaker name: Prof. M. Storck

I have the following potential conflicts of interest to report:

- **Endologix** (Speaker honorarium, Travel Expenses)
- Andramed
- Cardinal Health
- Medtronic
Women with AAA: An Underserved Population

- More women than men are ineligible for EVAR
  - Inadequate neck length
  - Narrow access vessels
- Outcomes in women are worse
- Women are underrepresented
  - Enrollment of women in Cardiovascular clinical trials is disproportionately low

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In-Hospital Mortality Greater in Women after EVAR

% In-Hospital Deaths after EVAR

Early Outcomes in Women are Worse

UK analysis of Hospital Episode Statistics (HES) of 20,780 EVAR cases performed between 2006-2015:

- Women (11.2%) have longer length of stay, higher readmission rates within one year, and greater 1-year mortality

Small Access Vessel Diameter and Short Neck Length Preclude IFU eligibility

From the New England Society for Vascular Surgery

The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair

Matthew P. Sweet, MD, Mark F. Fillinger, MD, Tina M. Morrison, PhD, and Dorothy Abel, BSME, Lebanon, NH; and Rockville, Md

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%)</td>
<td>812 (76)</td>
<td>251 (24)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>74 ± 9</td>
<td>77 ± 8</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Maximum sac diameter (mm)</td>
<td>59 ± 12</td>
<td>58 ± 10</td>
<td>.15</td>
</tr>
<tr>
<td>Neck diameter (mm)</td>
<td>25 ± 4</td>
<td>24 ± 4</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Neck length (mm)</td>
<td>19 ± 12</td>
<td>15 ± 12</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Infrarenal neck angle (degrees)</td>
<td>40 ± 16</td>
<td>48 ± 18</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Suprarenal aortic angle (degrees)</td>
<td>20 ± 13</td>
<td>28 ± 19</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>External iliac artery diameter (mm)</td>
<td>7.0 ± 1.6</td>
<td>5.6 ± 1.3</td>
<td>&lt; .0001</td>
</tr>
</tbody>
</table>

Small Access Vessel Diameter and Short Neck Length Preclude IFU eligibility

The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair

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% Patients with Bilateral Iliac Diameters Above Given Diameter

% of Patients with Neck Lengths Above Given Length, By Gender

"Women nonetheless continue to suffer higher complication rates, a problem that may be expected to improve with the development of newer, lower-profile devices that can better navigate challenging aortoiliac anatomy"
Women and AAA: An Underserved Population

~10% of patients enrolled in EVAR IDE studies are female

<table>
<thead>
<tr>
<th>Female Subjects %</th>
<th>Nellix IDE</th>
<th>Zenith IDE</th>
<th>Endurant IDE</th>
<th>Powerlink IDE</th>
<th>Ovation IDE</th>
<th>Excluder IDE</th>
<th>Aorfix IDE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5.3%</td>
<td>6%</td>
<td>8.7%</td>
<td>11.5%</td>
<td>12.4%</td>
<td>13%</td>
<td>14.5%</td>
</tr>
</tbody>
</table>

IDE Enrollment for EVAR devices shown per the respective US FDA Summary of Safety and Effectiveness Data (SSED) and Annual Clinical Reports.
Endograft Well Suited for EVAR in Females

14F ultra low profile enables access to more patients

Staged deployment of suprarenal stent allows precise placement

Polymer-filled sealing ring creates a custom seal and protects the aortic neck

Conformable, kink resistant PTFE iliac limbs designed to reduce risk of occlusion

Low permeability PTFE enables effective aneurysm exclusion and device patency

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.
Ovation Well Suited for Female Anatomy

Lowest Profile of any FDA approved device

- Lombard Aorfix™: 22F OD
  Addresses 27% of AAA population*

- Cook Zenith Flex®: 21F OD
  Addresses 36% of AAA population*

- Gore Excluder®: 20F OD
  Addresses 40% of AAA population*

- Endologix AFX™: 19F OD
  Addresses 49% of AAA population*

- Medtronic Endurant®: 18F OD
  Addresses 59% of AAA population*

- Endologix Ovation iX™: 14F OD
  Addresses 83% of AAA population*

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

1-Year
Successful aneurysm exclusion

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First LUCY Case 10.1. 2017

Female, 66 ys. AAA 48 mm. Diameter left external iliac 5.4 mm!

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First LUCY Case / Simulation vs Results

Implantation CT Day 30 on Feb. 10

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Ovation Well Suited for Female Anatomy

~40% of patients in Pivotal IDE had access vessels <6mm, neck length <10mm, or both


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Women and men derive comparable benefits with an ultra low-profile endograft: 1-year results of the European OVATION registry

Martin STORCK, Thomas NOLTE, Matthias TENHOLT, Lieven MAENE, Geert MALEUX Dierk SCHEINERT

J Cardiovasc Surg 2016 Jun 21 [Epub ahead of print]
Ovation European Post Market Registry: Gender Analysis

- Multicenter (30), Prospective
- 501 patients, 16% (69) Female
- Enrollment May 2011 – Dec 2013

**Primary Endpoints**
- Technical success
- Freedom from Type I/III endoleak, rupture, sac expansion, conversion, occlusion, and migration

Three Year Results

The Ovation® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.
Ovation European Post Market Registry: Gender Analysis

Women had More Complex Anatomy Compared to Men

Severe morphology based on SVS/AAVS anatomic scoring.

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## Ovation European Post Market Registry: Gender Analysis

Women and Men Derive Similar **In-Hospital** 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>

*Two male technical failures involved inability to implant left iliac limb; both uni-iliac procedures completed successfully, one using fem-fem crossover and one using covered nitinol stent graft.


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Freedom from Mortality through 3 Years

**Freedom from ARM**
- 99% Men
- 100% Women
- $P=0.5717$

**Freedom from ACM**
- 87% Men
- 90% Women
- $P=0.7682$


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Freedom from Endoleak and Occlusion through 3 Years

**Freedom from Type I/III Endoleak**
- 97% Men
- 94% Women

**Freedom from Occlusion**
- 98% Men
- 99% Women

P=0.0225

P=0.0027


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Freedom from Rupture and Conversion through 3 Years

Freedom from Rupture

99% Men
100% Women

P=0.6894

Freedom from Conversion

99% Men
99% Women

P=0.3244


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## 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>1.6% (7)</td>
<td>2.9% (2)</td>
<td>0.08</td>
</tr>
<tr>
<td>Type Ib</td>
<td>0.9% (4)</td>
<td>1.4% (1)</td>
<td>0.10</td>
</tr>
<tr>
<td>Type II</td>
<td>3.0% (13)</td>
<td>10% (7)</td>
<td>0.08</td>
</tr>
<tr>
<td>Type III</td>
<td>0.5% (2)</td>
<td>--</td>
<td>0.08</td>
</tr>
<tr>
<td>Occlusion</td>
<td>2.5% (11)</td>
<td>2.9% (2)</td>
<td>0.03</td>
</tr>
<tr>
<td>Stenosis</td>
<td>0.9% (4)</td>
<td>1.4% (1)</td>
<td>0.18</td>
</tr>
<tr>
<td>Limb Migration</td>
<td>0.7% (3)</td>
<td>1.4% (1)</td>
<td>0.32</td>
</tr>
<tr>
<td>Infection (AEF)</td>
<td>0.2% (1)</td>
<td>--</td>
<td></td>
</tr>
</tbody>
</table>

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Freedom from Sac Growth through 3 Years

Freedom from AAA Growth >5mm

93% Men
91% Women

P=0.5917

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Conclusions

• Women traditionally have limited eligibility for and worse outcomes after EVAR
• Prospective, European Post Market Registry demonstrates Women and Men derive similar benefits with the Ovation Stent Graft through 3 years
  • Broadened eligibility, on-IFU
  • Similar clinical outcomes
• LUCY Study to further evaluate Ovation performance in females
Evaluation of Female Les who are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair

**LUCY**
US Prospective Study
225 patients: 2:1 Male to Female
Up to 45 Centers
Enrollment Q3 2016 to Q1 2017

**LUCY EU**
EU Post Market Registry
60 patients, Female single-arm
Up to 12 EU Centers
Enrollment starting Q4 2016

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