NEW DEVICES FOR TREATMENT OF ASCENDING AORTIC
AND ARCH LESIONS AND AORTIC
DISSECTIONS; TEVAR AND CH/TEVAR

New Medtronic Valiant Navion Low Profile Endograft for
TEVAR:
Advantages and Results
Prof. Fabio Verzini, MD, PhD, FEBVS
Vascular Surgery
University of Turin, Italy

Disclosure Statement
Speaker name: Fabio Verzini
I have the following potential conflicts of interest to report:
Consulting for Cook, Gore, Medtronic

Opportunities to Improve Current TEVAR Devices
1. Smaller profile devices are needed to expand patient applicability
   - Reduction in profile can not compromise device performance and durability
2. Minimize unnecessary movement in arch while being accurate/precise
   - Expanded applicability will introduce more complex anatomy/pathology
   - Increasingly narrow, calcific, tortuous access vessels and aortas overall
3. Physicians need better TEVAR configuration options
   - Expanded size matrix (broader diameter range / extended lengths / enhanced tapering)
   - Proximal device with and without bare metal, both with tip-capture

Lower Profile to Increase Patient Applicability
- Up to a 4Fr reduction in outer diameter profile
- Lengths reduced ≥ 10 mm
- DS Lengthened by 10 cm
- New ergonomic materials
- Integrated flush port

Delivery System Enhancements
- Up to a 4Fr reduction in outer diameter profile
- Lengths reduced ≥ 10 mm
- DS Lengthened by 10 cm
- New ergonomic materials
- Integrated flush port

Accurate Deployment while Minimizing Movement
- Up to a 4Fr reduction in outer diameter profile
- Lengths reduced ≥ 10 mm
- DS Lengthened by 10 cm
- New ergonomic materials
- Integrated flush port
- Deliver to Target
- Deploy at Target
Optimized Graft Material & Expanded Size Matrix

- Multi-Filament Weave (Endurant yarn)
  - Enhanced conformability / flexibility
  - Lower permeability (endoleak resistance)

Treat Wider Range of Anatomies
- Increased Length (225 mm)
- Smaller Diameter (20 mm)
- Short Cuff (60 mm)
- Refined Tapering (5 & 6 mm)

Valiant Navion

Valiant Captivia

Multi-Filament Weave

- Enhanced conformability / flexibility
- Lower permeability (endoleak resistance)

Proximal Device Configuration Options

1. FreeFlo
   - Allows trans-vessel flow
   - Tip-capture mechanism
   - ≥ 2 cm landing zone

2. CoveredSeal
   - No proximal bare metal
   - Tip-capture mechanism
   - ≥ 2.5 cm landing zone

Global IDE Trial for Valiant Navion

- Prospective, multi-center, single-arm trials in North America & EU
- 100 subjects enrolled
- First consecutive 87 subjects submitted for 30-day primary endpoint analysis

Demographics & Primary Indication

<table>
<thead>
<tr>
<th>性别</th>
<th>数量 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>37.9% (33/87)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>年龄 (年)</th>
<th>数值 (mean ± standard deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>70.8 ± 8.7</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>ASA Class</th>
<th>数量 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ⅰ</td>
<td>42.5% (37/87)</td>
</tr>
<tr>
<td>Ⅱ</td>
<td>44.8% (39/87)</td>
</tr>
<tr>
<td>Ⅲ</td>
<td>21.8% (19/87)</td>
</tr>
<tr>
<td>Ⅳ</td>
<td>5.6% (5/87)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>branch artery tortuosity</th>
<th>数量 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>低</td>
<td>40.2% (35/87)</td>
</tr>
<tr>
<td>高</td>
<td>59.8% (52/87)</td>
</tr>
</tbody>
</table>

Baseline Anatomy

Core Lab reported

<table>
<thead>
<tr>
<th>Vessel Diameter (mm)</th>
<th>数值 (mean ± standard deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. Common Iliac</td>
<td>9.3 ± 2.5</td>
</tr>
<tr>
<td>Max. Aneurysm Diameter</td>
<td>55.7 ± 13.1</td>
</tr>
<tr>
<td>Aneurysm Length (mm)</td>
<td>113.1 ± 71.5</td>
</tr>
<tr>
<td>Prox. Neck Length (mm)</td>
<td>58.0 ± 46.1</td>
</tr>
<tr>
<td>Distal Neck Length (mm)</td>
<td>99.0 ± 68.0</td>
</tr>
<tr>
<td>Access Vessels (mm)</td>
<td>数值 (mean ± standard deviation)</td>
</tr>
<tr>
<td>左</td>
<td>右</td>
</tr>
<tr>
<td>Min. External Iliac</td>
<td>7.7 ± 1.9</td>
</tr>
<tr>
<td>Min. Femoral</td>
<td>7.5 ± 1.7</td>
</tr>
</tbody>
</table>

Access Artery Calcification

<table>
<thead>
<tr>
<th>严重程度</th>
<th>数量 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>无</td>
<td>8.1%</td>
</tr>
<tr>
<td>轻</td>
<td>54.7%</td>
</tr>
<tr>
<td>中</td>
<td>31.3%</td>
</tr>
<tr>
<td>重</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

Tortuosity Indices per Core Lab (N=87)

- Access Artery Tortuosity
- Thoracic Aorta Tortuosity
**Procedural Results**

- **FreeFlo**: 74.7% (65/87) as Proximal Piece
- **CoverSeal**: 25.3% (22/87) as Proximal Piece

<table>
<thead>
<tr>
<th>Procedure Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LSA Complete Coverage</td>
<td>21.8% (19/87)</td>
</tr>
<tr>
<td>% of Pts Revascularized</td>
<td>94.7% (18/19)</td>
</tr>
<tr>
<td>Duration of Procedure (min)</td>
<td>88.7 ± 53.4</td>
</tr>
<tr>
<td>Percutaneous Access</td>
<td>50.6% (44/87)</td>
</tr>
<tr>
<td>Estimated Blood Loss (cc)</td>
<td>94.0 ± 147.1</td>
</tr>
<tr>
<td>Volume of Contrast (ml)</td>
<td>96.2 ± 52.8</td>
</tr>
<tr>
<td>Total Fluoroscopic Time (min)</td>
<td>12.2 ± 8.8</td>
</tr>
</tbody>
</table>

- **No Access or Deployment Failures**

**Key Clinical Endpoints**

- **Peri-operative Mortality through 30 Days**: 2.3% (2/87)
  - Secondary Procedures through 30 Days: 2.3% (2/87)
  - Endoleaks at 30-day visit:
    - Type Ia: 1.2% (1/87)
    - Type II: 1.2% (1/87)
  - Major Adverse Events (MAE) through 30 Days: 28.7% (25/87)

- **2 Deaths through 30 Days**
  - (1) Retrograde type A dissection at day 1
  - (1) Non-device related death at day 24

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**Type to Endoleak**

- No adverse event associated, no interventions performed, and no aneurysm expansion

30d overall endoleak rate less than that observed in VALOR II trial

2.5% vs 18%

**Key Clinical Endpoints**

- **Major Adverse Events (MAE) through 30 Days**: 28.7% (25/87)
  - Cardiac Complications: 17.2% (15/87)
  - Neurological Complications: 5.7% (5/87)
  - Stroke (1 CVA / 2 Emboli / 1 Ischaemic): 4.6% (4/87)
  - Spinal Cord Ischaemia (resolved day 20): 1.1% (1/87)
  - Vascular Complications: 5.7% (5/87)
  - Aortic Dissection (1 RTAD; 1 distal): 2.3% (2/87)
  - Aortic Rupture (due to sepsis): 1.1% (1/87)
  - Femoral Artery Occlusion (post-index, perc case): 1.1% (1/87)
  - Peripheral Ischaemia (left hand, resolved): 1.1% (1/87)

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MAE rate within 30d less than that observed in VALOR II trial

28.7% vs 38.1%
Valiant Navion Summary

- Design enhancements of Valiant Navion improve upon current generation TEVAR
- Acute performance is encouraging:
  - No access or deployment failures in tortuous anatomy
  - Low procedure and fluoro times; majority percutaneous
  - Endoleaks were rare with low rates of 2nd procedures
  - Major Adverse Events are within expected range for TEVAR
- US FDA & European CE approved
- Trial subjects will be followed through five years

Major adverse events through 30 days

Neurological Complications

- Cerebrovascular Accident: Zone 2 landing, intentional partial LSA coverage, no revasc
- Embolic Stroke: Zone 2 landing, intentional complete LSA coverage, no revasc
- Embolic Stroke: Zone 4 landing
- Ischemic Stroke: Zone 2 landing, intentional complete LSA coverage, LCCA-LSA bypass and LSA embolization pre-op
- Spinal Cord Ischemia: Day 0; resolved day 20

Vascular Complications

- Aortic Dissection: RTAD day 1; distal neck dissection day 1 (no intervention)
- Aortic Rupture: Day 28, due to septicemia
- Femoral-Artery Occlusion: not during index procedure; percutaneous
- Peripheral Ischemia: left hand ischemia post-op; improved with medication; resolved at 30 day visit