Early insights from the clinical trial for Valiant Navion™: how Medtronic’s new low-profile TEVAR device expands therapeutic options

Prof. Fabio Verzini, MD, PhD, FEBVS
University of Turin, Italy
Disclosure

Speaker name:

...............Fabio Verzini............... 

I have the following potential conflicts of interest to report:

- Consulting for Cook, Gore, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
- European P.I. Valiant EVO Trial
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. Precise deployment mechanisms
   - Expanded applicability will introduce more complex anatomy/pathology
     - Increasingly narrow, calcific, tortuous access vessels and aortas overall

3. Better TEVAR configuration options
   - Expanded size matrix (broader diameter range / extended lengths / enhanced tapering)
     - Proximal device with / without bare metal exposed
Lower Profile to Increase Patient Applicability

- **Up to a 4Fr reduction in outer diameter profile**

Valiant Captivia

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Fr Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>46-42 mm</td>
<td>25 Fr</td>
</tr>
<tr>
<td>40-34 mm</td>
<td>24 Fr</td>
</tr>
<tr>
<td>32-22 mm</td>
<td>22 Fr</td>
</tr>
</tbody>
</table>

Valiant Navion

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Fr Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>46-40 mm</td>
<td>22 Fr</td>
</tr>
<tr>
<td>37-28 mm</td>
<td>20 Fr</td>
</tr>
<tr>
<td>25-20 mm</td>
<td>18 Fr</td>
</tr>
</tbody>
</table>
## Delivery System Enhancements

### Valiant Captivia
- **Fr**:
  - 25 Fr
- **Dimensions**:
  - 46-42 mm

### Valiant Navion
- **Fr**:
  - 22 Fr
- **Dimensions**:
  - 46-40 mm

**Up to a 4Fr reduction in outer diameter profile**

**Lengths reduced ≥ 10 mm**
- 18Fr
- 20Fr
- 22Fr

- 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

Valiant Captivia

- 25 Fr
- 24 Fr
- 22 Fr
- 46-42 mm
- 40-34 mm
- 32-22 mm

Valiant Navion

- 22 Fr
- 20 Fr
- 18 Fr
- 46-40 mm
- 37-28 mm
- 25-20 mm

- 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)
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

59.8% (52/87) enrolled at 18 US centers
40.2% (35/87) enrolled at 13 EU / CND centers
Demographics & Primary Indication

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>37.9%</td>
<td>33/87</td>
</tr>
<tr>
<td>Age (years)</td>
<td>70.8 ± 8.7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Indication for TEVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusiform TAAs</td>
</tr>
<tr>
<td>Saccular TAAs</td>
</tr>
<tr>
<td>PAUs</td>
</tr>
</tbody>
</table>

ASA Class Distribution:
- ASA Class I: 6.9% (6/87)
- ASA Class II: 21.8% (19/87)
- ASA Class III: 44.8% (39/87)
- ASA Class IV: 26.4% (23/87)
Tortuosity Indices per Core Lab (N=87)

Access Artery Tortuosity
- Mild: 10.5%
- Moderate: 18.6%
- Low: 70.9%
- High: 14.3%

Thoracic Aorta Tortuosity
- Low: 85.7%
- High: 14.3%
### Procedural Results

#### FreeFlo
- % of Pts Revascularized: 74.7% (65/87) as Proximal Piece

#### CoveredSeal*
- % of Pts Revascularized: 25.3% (22/87) as Proximal Piece

<table>
<thead>
<tr>
<th>Metric</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>

*Reported as closed web within the clinical study

- **No Access or Deployment Failures**

---

---
**Key Clinical Endpoints**

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peri-operative Mortality through 30 Days</td>
<td>2.3% (2/87)</td>
</tr>
<tr>
<td>Secondary Procedures through 30 Days</td>
<td>2.3% (2/87)</td>
</tr>
<tr>
<td>Endoleaks at 30-day visit</td>
<td></td>
</tr>
<tr>
<td>Type Ia</td>
<td>1.2% (1/81)</td>
</tr>
<tr>
<td>Type II</td>
<td>1.2% (1/81)</td>
</tr>
<tr>
<td>Major Adverse Events (MAE) through 30 Days</td>
<td>28.7% (25/87)</td>
</tr>
</tbody>
</table>

MAE rate within 30d less than that observed in VALOR II trial
28.7% vs 38.1%
- Female, 83 y.o.
- Hypertension
- Hypercholesterolemia
- Type 2 diabetes mellitus
- Persistent atrial fibrillation under anticoagulant and antiarrhythmic therapy
- COPD

Left vocal cord paralysis

Persistent coughing and dysphonia
Distal aortic arch saccular aneurysm on penetrating aortic ulcer
1 stage: L carotid-subclavian bypass, 2 stage: TEVAR w Rapid pacing
Prevertebral subclavian embolization

Amplatzer Vascular Plug II 10 mm
Post-procedural angiogram

30 days post-op CTA
• Male, 59 y.o.
• Hypertension
• Hypercholesterolemia
• Type 2 diabetes mellitus
• Obesity
• COPD
• Renal Insufficiency

• 6 cm Thoracic Aneurysm
1 stage: L carotid-subclavian bypass, Amplatzer LSA embolization
2 stage: TEVAR w Rapid pacing

Right femoral surgical cut-down

Left percutaneous fem:
- vein access for Cardiac rapid pacing
- Artery for Angio
Conclusion

- Design enhancements of Valiant Navion improve upon current generation TEVAR:
  - Applicability: 0% access failure, 50.6% percutaneous
  - Trackability: 85.7% High tortuousity
  - Deployment accuracy: 100% deployment success
  - Conformability: only 1 Type 1a endoleak
Early insights from the clinical trial for Valiant Navion™: how Medtronic’s new low-profile TEVAR device expands therapeutic options

Prof. Fabio Verzini, MD, PhD, FEBVS
University of Turin, Italy