Early PS-IDE experience with the off-the-shelf Valiant™ Thoracoabdominal Device

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I have the following potential conflicts of interest to report:

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

I do not have any potential conflict of interest
Thoracoabdominal Aneurysm Repair

- Endovascular approaches to thoracoabdominal aneurysm repair offers several advantages over open surgery.

- Current endovascular options highlight opportunities for improvement:
  - With today’s devices, complex procedures best suited only for experienced operators.
  - These devices aren’t readily available ‘off-the-shelf’ and time delay can lead to increased risk for patient.
  - Requirement for anatomical alignment can lead to offset between custom device and vessel ostium.
  - Distal perfusion impeded during procedure, increasing vascular bed/physiologic stress.
  - Current iterations aren’t easily stageable, when needed.
Valiant™ Thoracoabdominal Aneurysm Device

Advantages of modular endovascular device

- **In situ** anatomical alignment
  - Broad patient applicability
- Off-the-shelf and stageable throughout
  - Urgent/emergent use
  - Stageability = surgical bailouts, as needed
- Favorable flow characteristics
  - To increase branch patency
  - Reorganization of flow
- Unimpeded distal perfusion
- Intuitive and less complex

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PS-IDE Investigational Design

6 US sites with access to this device under PS-IDE approval

- **Study Design:**
  - Each PS-IDE is designed as a Prospective, single center, nonrandomized, multi (or single)-arm study with 5 year follow-up
  - All PS-IDE sites are using similar protocols with similar data point outcomes
The NYU Approach to Endo TAAA Repair
A Multi-Disciplinary Team

• Vascular Surgery
• Neurosurgery: pre-op drain and post-op management
• Neuro Interventional: spinal angiography
• Neurology: stroke team, intra-op neuro monitoring (MEP)
• Dedicated lead anesthesiologist
• Dedicated Nursing team: operative and post-op
• Critical care intensivists: patients recover in NeuroICU

An Experienced, Multi-Disciplinary Team – pre, intra, and post-op – Is Paramount to Ensuring Optimal Outcomes for These Patients
Overall, 39 Subjects Enrolled To Date

<table>
<thead>
<tr>
<th>PS-IDE Site/Investigator</th>
<th>Primary Arm</th>
<th>Expanded Selection Arm + CU/EU</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Total</td>
<td>20</td>
<td>19</td>
<td>39</td>
</tr>
</tbody>
</table>

- 23% (9/39) Staged procedures

### Extent

- **Type I**: 10%
- **Type II**: 46%
- **Type III**: 28%
- **Type IV**
  - Type IV*: 13%
  - Type IV includes Pararenal / paravisceral / juxtarenal
- **Type V**: 3%

1 Reasons for Expanded Selection Arm
- Emergent/urgent/rupture
- Renal insufficiency
- Visceral vessel diameter <5mm
## Baseline Data

<table>
<thead>
<tr>
<th></th>
<th>Overall n=39</th>
<th>Primary Arm n=20</th>
<th>Expanded Selection Arm n=19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years ± SD)</td>
<td>71 ± 7</td>
<td>70 ± 8</td>
<td>72 ± 6</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>13 (33%)</td>
<td>2 (10%)</td>
<td>11 (58%)</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>7 (18%)</td>
<td>4 (20%)</td>
<td>3 (16%)</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>17 (44%)</td>
<td>8 (40%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>COPD</td>
<td>18 (46%)</td>
<td>9 (45%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>Creatinine (≥ 2.0 mg/dL)</td>
<td>5 (13%)</td>
<td>0 (0%)</td>
<td>5 (26%)</td>
</tr>
<tr>
<td>Any Prior Aortic Repair</td>
<td>24 (62%)</td>
<td>9 (45%)</td>
<td>15 (79%)</td>
</tr>
<tr>
<td>Thoracic Only</td>
<td>7 (18%)</td>
<td>3 (15%)</td>
<td>4 (21%)</td>
</tr>
<tr>
<td>Infrarenal Only</td>
<td>8 (21%)</td>
<td>3 (15%)</td>
<td>5 (26%)</td>
</tr>
<tr>
<td>Both (Thoracic + Infrarenal)</td>
<td>9 (23%)</td>
<td>3 (15%)</td>
<td>6 (32%)</td>
</tr>
</tbody>
</table>

Data expressed as n-value (%)
# Key Procedural Data

<table>
<thead>
<tr>
<th></th>
<th>Overall n=39</th>
<th>Primary Arm n=20</th>
<th>Expanded Selection Arm n=19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Index Procedure time</strong> (min)</td>
<td>351 ± 142</td>
<td>355 ± 149</td>
<td>348 ± 137</td>
</tr>
<tr>
<td><strong>Contrast Vol</strong> (mL)</td>
<td>105 ± 67</td>
<td>108 ± 61</td>
<td>102 ± 74</td>
</tr>
<tr>
<td><strong>Estimated Blood Loss</strong> (mL)</td>
<td>631 ± 700</td>
<td>710 ± 942</td>
<td>547 ± 291</td>
</tr>
<tr>
<td><strong>Fluoroscopy Time</strong> (min)</td>
<td>111 ± 57</td>
<td>103 ± 41</td>
<td>120 ± 70</td>
</tr>
<tr>
<td><strong>Pre-Op CSF drain</strong></td>
<td>25 (64%)</td>
<td>14 (70%)</td>
<td>11 (58%)</td>
</tr>
<tr>
<td><strong>Technical success</strong>¹</td>
<td>35 (90%)</td>
<td>17 (85%)</td>
<td>18 (95%)</td>
</tr>
</tbody>
</table>

¹ Reasons for technical failures (N=4):
- Physician was unable to successfully debranch renal arteries due to severe aortic tortuosity
- Unsuccessful deployment of iCast in the right renal artery
- Physician unable to successfully debranch visceral vessels due to severe LSA stenosis and complete heart block.
- Physician unable to successfully debranch L Renal artery at index procedure.
## Key Clinical Outcomes through 1 Year

<table>
<thead>
<tr>
<th>Completed Procedures n=34*</th>
<th>0 – 30d</th>
<th>31 – 180d</th>
<th>181 – 365d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Branch vessel occlusion (m/n)</td>
<td>0/124</td>
<td>0/118</td>
<td>3/96*</td>
</tr>
<tr>
<td><strong>Endoleaks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type Ia endoleaks</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Type Ib endoleaks</td>
<td>0</td>
<td>1†</td>
<td>0</td>
</tr>
<tr>
<td>Type Ic endoleaks</td>
<td>0</td>
<td>1†</td>
<td>0</td>
</tr>
<tr>
<td>Type IIIb endoleaks</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Aneurysm size increase &gt;5mm</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Reinterventions</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Only subjects with completed TAAA procedure are represented; staged procedures at time of data cut not included in this analysis.

Data expressed as number of subjects with events.

- * 2 Subjects had 3 occlusions total (One had celiac and SMA occlusions; One had a renal artery occlusion)
- † 1 Subject had a Type Ib and Type Ic endoleak
Key Clinical Outcomes through 1 Year

Key Clinical Takeaways:

- **8% ARM (all w/in 30d) with 23% ACM through 1 year**
- **3 early permanent paraplegias. SCI screening protocol implemented with no further events thereafter.**
  - Type III, not staged, POD 0, rescue maneuvers unsuccessful (CSF drain, ↑ MAP)
  - Type IV, not staged, POD 0, rescue maneuvers unsuccessful
  - Type II, staged (celiac BMS), Rt renal artery disruption and sacrifice with persistent hypotension, rescue maneuvers unsuccessful
- **Very high freedom from branch vessel occlusion through 1-Year: 98% (only 3 of 124 treated vessels)**
- **Decreasing/Stable maximum aortic diameters: 96% (6mo) and 90% (1-Year)**
- **Low need for reinterventions in high-risk patients: 4 patients (requiring 5 reinterventions):**
  - 0-30 Day: Aortic Dissection repair; Type Ia endoleak repair
  - 31-180 Day: Type Ib and Ic endoleak repair (same subject)
  - 181-365 Day: Limb Occlusion
Case Example

- 79 year old female
- 6cm Type III TAAA
- Emphysema on home O2
- HTN, hyperlipidemia
- Afib
- 42 pack smoking history, quit 20 yrs ago
Celiac injection with endoleak through open stent

Celiac injection distal to bare metal stent

Celiac with proximal and distal atrium stents bridged with zilver stent
Stage 2 @ 1 month

Celiac accessed from brachial – endoleak noted

9mm X 10 cm balloon inflated in celiac X 30 min
Celiac relined with additional 9mmX59mm Atrium

DC home post op day 1
Key Clinical Conclusions
Valiant™ Thoracoabdominal Device

- The Valiant TAAA device addresses key limitations of existing technologies
  - Anatomical alignment not required,
  - Off-the-shelf and user friendly,
  - Constant distal perfusion,
  - Easily stageable
- Multi-disciplinary institutional infrastructure is critical for success
- Through 1-year, very good clinical outcomes in high-risk population
- Due to length of aortic coverage required by this design, a next generation device is in development for treatment of extent IV anatomy
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Thank You
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