The Altura Double D Endograft Device For EVAR: Advantages, Limitations And 4-Year Results

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Disclosure

I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Limitations Of Current EVAR

**Anatomical**
- Length/shape of neck
- Angulation
- Complex procedures

**Procedural**
- Unpredictable and time consuming
- Gate cannulation, Snaring, Polymer
- Complex procedures

**Economical**
- Throughput / efficiency
- Device costs

ALTURA Design Goal: Address current EVAR limitations with a simple, low profile system

ALTURA System Concept

**Stent Graft**
- “D” endografts (aortic)
- Flexible Nitinol braid
- Ribbed woven polyester outside the stent
- Suprarenal anchors
- Telescoping Iliac endografts

**Delivery System**
- Low profile (14F) and flexible
- Controlled braid deployment
- No Gate Cannulation
- Contrast injection capability

Bringing Braided Stent Flexibility to EVAR...

Top-Down Aortic Deployment

- Offset deployment
- Repositionability

Bottom-Up Iliac Deployment

- Retrograde deployment
- Preservation of hypogastrics

ALTURA Clinical Trial Experience – METHODS

**AAA**

- Aneurysm Ø > 4.5 cm
- Infrarenal neck Ø 18-28mm
- Neck angulation < 60
- Infrarenal neck length > 15mm
- Iliac artery Ø 8-18mm
- Iliac artery seal length > 15mm

90 Subjects pooled under protocols with identical endpoints 2011-2015

- Independent Clinical Events Committee
- Core laboratory reviewed CT images
- CT follow-up and clinical evaluation at:
  - 30 days and 6 months
  - Annually post-implant up to 5 years
ALTURA Clinical Trial Experience Results

Demographics & Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Gender (%)</td>
<td>87.8</td>
</tr>
<tr>
<td>Age, Years, Mean, Range</td>
<td>72.8 ± 8.3</td>
</tr>
<tr>
<td>History of Coronary artery disease (%)</td>
<td>41.6</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>62.8</td>
</tr>
<tr>
<td>Family history of AAA (%)</td>
<td>7.3</td>
</tr>
</tbody>
</table>

| Mean AAA Sac Diameter, cm          | 5.4 ± 0.6 |
| Mean Neck Vessel Diameter, mm      | 22.0 ± 8.5 |
| Mean Neck Length, mm               | 22.3 ± 7.4 |

Mean Follow-up 2.7 years
2 Years: n = 70
3 Years: n = 50
4 Years: n = 26

ALTURA Clinical Trial Experience Results

Procedural / In-Hospital Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural Technical Success, N</td>
<td>89/90 (99%)*</td>
</tr>
<tr>
<td>Mean Fluoroscopy Time, min</td>
<td>26 ± 12</td>
</tr>
<tr>
<td>Mean Total Procedure Time, min</td>
<td>117 ± 46</td>
</tr>
<tr>
<td>Vessel Access Type percutaneous (%)</td>
<td>56.8</td>
</tr>
<tr>
<td>Anesthesia Type (%)</td>
<td></td>
</tr>
<tr>
<td>Regional/Spinal</td>
<td>73.3</td>
</tr>
<tr>
<td>Local</td>
<td>5.6%</td>
</tr>
<tr>
<td>General</td>
<td>21.1</td>
</tr>
<tr>
<td>Post-procedure ICU, N</td>
<td>7/89</td>
</tr>
<tr>
<td>Time to Hospital Discharge, days</td>
<td>2.9 ± 1.4</td>
</tr>
</tbody>
</table>

* 1 Gen1 device not inserted

Evaluation

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>30 Days (N=85)</th>
<th>1 YR (n=75)</th>
<th>2 YRS (n=50)</th>
<th>3 YRS (n=50)</th>
<th>4 YRS (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA Rupture</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-AAA mortality*</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Device Migration*</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Endoleak – Type I</td>
<td>1 (1.2%)</td>
<td>2 (2.6%)</td>
<td>3 (6.0%)</td>
<td>6 (12.0%)</td>
<td>5 (19.2%)</td>
</tr>
<tr>
<td>Endoleak – Type II</td>
<td>13 (15.8%)</td>
<td>13 (17.3%)</td>
<td>12 (24.0%)</td>
<td>8 (16.0%)</td>
<td>6 (23.1%)</td>
</tr>
<tr>
<td>Endoleak – Type III</td>
<td>0</td>
<td>1 (1.3%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sac Expansion</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Back Migration*</td>
<td>1 (1.2%)</td>
<td>1 (1.4%)</td>
<td>1 (1.4%)</td>
<td>3 (6.0%)</td>
<td>1 (3.8%)</td>
</tr>
<tr>
<td>Fracture or Fatigue</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Rate of Secondary Procedures</td>
<td>4 (4.7%)</td>
<td>0</td>
<td>1 (2%)</td>
<td>2 (7.7%)</td>
<td></td>
</tr>
</tbody>
</table>

* Patient rejected intervention to treat expanding sac.
* All Gen1 devices in LATURA
* Majority of device migration were associated with undersized grafts in the proximal neck.
* Rate of secondary procedures is directly associated with chronic Type II endoleak.
* Sac expansion and type IA endoleak are associated with Type I endoleak.

Surveillance Appearances

Majority of patients had sac shrinkage

ALTURA Clinical Trial Experience

IA endoleak (Calcium nodule in proximal neck)
Present at 30 days, disappeared at 1 year.

Aneurysm sac shrinkage with no endoleak at years 1 - 4
Is it worth highlighting the regional / spinal anesthesiа figure here and the subsequent potential for day case....?
Natalie Hayes, 11/1/2018
ALTURA Clinical Trial Experience
IB endoleak (Treated with coils)

Small distal aorta – Secondary Procedure
PTA of iliac stent

“D” Endograft Stability
No septal endoleaks

Conclusions
- Novel Altura endograft concept has potential to play major role in mainstream EVAR cases:
  - Potential benefits include:
    - Predictable, precise and easy to use
    - Offset renals – maximum use of neck length
    - Low profile overcomes current anatomic limitations
      - Tortuous iliacs
      - Narrow aortic bifurcations
    - Accurate proximal and distal placement
    - No gate cannulation

  - Offers option for EVAR day surgery and rAAA patients
  - Encouraging early clinical experience

Thank You