Off-The-Shelf Endovascular Solutions for Complex Thoracoabdominal Aortic Aneurysms

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Off the shelf Solutions for TAAA: Conflict of Interest

- Speaker: Cook, Gore, Medtronic
- Proctor: Cook, Gore, Medtronic
- PI: Gore SSB CTAG
- PI: PS-IDE Medtronic Valiant TAAA branched endograft
- Discussion includes off-label use of endografts

Off the shelf Solutions for TAAA: Commercially available Grafts

- Cook T-branch
  - Anatomic applicability 54-63%
  - Technical success 100%
  - 0% mortality
  - 0% endoleak
  - Re-interventions 10%

Off the shelf Solutions for TAAA: Objective

- Review the available off-label techniques available for endo TAAA repair

Off the shelf Solutions for TAAA: Terrace and Sandwich Techniques

2012 SEMIN VASC SURG
15 patients
Technical success: 92%
Mortality: 20% (2/15), 7.7% elective (1/13), 100% emergent (2/2)
Off the shelf Solutions for TAAA:
Sandwich Grafts

Off the shelf Solutions for TAAA:
Terrace Technique
The “Terrace Technique” – Totally Endovascular Repair of a Type IV Thoracoabdominal Aortic Aneurysm

Off the shelf Solutions for TAAA:
Off the shelf branched grafts

Off the shelf Solutions for TAAA:
PMEG - Fenestrations
Endovascular treatment of thoracoabdominal aortic aneurysm using physician-modified endografts

Off the shelf Solutions for TAAA:
PMEG - Branched Devices

Off the shelf Solutions for TAAA:
USF Octopus Technique
Off the shelf Solutions for TAAA: USF Octopus

Off the shelf Solutions for TAAA: Results

- 14 patients, 7 male since January 2015
- 35% symptomatic
- 2 vessel (abandoned renal) - 2
- 3 vessel - 7
- 4 vessel - 5
- Six celiac arteries sacrificed
- 2 cases TEVAR extension to L SCA
- Radiation exposure: 2318.6 Gy/cm²
- Mean contrast volume: 112 cc
- Median length of stay: 7 days/ ICU 4 days

Off the shelf Solutions for TAAA: Results

- 0% Spinal cord ischemia
- Mortality 14% (30d), 14% 1 year
- Endoleaks
  - 2 early
    - Type III endoleak—endovascular management: 2 (both associated with Type II outflow)
  - 2 late
    - Type II endoleak: observed
    - Type III endoleak (distal aortic cuff attachment, converted with distal bifurcated endograft)
    - Branch patency: 96%
- Endoleaks
  - 2 early
    - Type III endoleak—endovascular management: 2 (both associated with Type II outflow)
  - 2 late
    - Type II endoleak: observed
    - Type III endoleak (distal aortic cuff attachment, converted with distal bifurcated endograft)
    - Branch patency: 96%

Off the shelf Solutions for TAAA: Meta-Analysis

Table A published series of clinical trials for elective and acute TAAA

<table>
<thead>
<tr>
<th>Institution</th>
<th>Study Type</th>
<th>Study Design</th>
<th>Aortic Segment</th>
<th>Arterial Source</th>
<th>Endovascular Management</th>
<th>Type I Endoleaks</th>
<th>Type II Endoleaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MGH</td>
<td>Acute</td>
<td>Randomized</td>
<td>TAAA</td>
<td>Abdominal</td>
<td>Endovascular</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>Acute</td>
<td>Randomized</td>
<td>TAAA</td>
<td>Abdominal</td>
<td>Endovascular</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>Acute</td>
<td>Randomized</td>
<td>TAAA</td>
<td>Abdominal</td>
<td>Endovascular</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
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<td>Randomized</td>
<td>TAAA</td>
<td>Abdominal</td>
<td>Endovascular</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Off the shelf Solutions for TAAA: PMEG - Branched

A novel physiologic thoracic aortic endograft (PTAEG) technique using a novel physiologic thoracic aortic endograft (PTAEG) technique.

Off the shelf Solutions for TAAA: PS-IDE Medtronic Valiant

Medtronic Valiant TAA (Pat Kelly Device) Restricted to PS-IDE (7 sites nationally)
**Off the shelf Solutions for TAAA: PS-IDE Medtronic Valiant**

- **Key features of Valiant TAAA**
  - TEVAR Main body – 2 lumens
  - Visceral manifold
  - Visceral endo branches
  - Distal modified Endurant

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 the intent to pool data

Expanded arm for
  - Emergent/urgent/rupture
  - Renal insufficiency
  - Visceral vessel diameter < 5 mm

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**Study Arm**

<table>
<thead>
<tr>
<th>Study Arm</th>
<th>Total</th>
<th>Type I</th>
<th>Type II</th>
<th>Type III</th>
<th>Type IV</th>
<th>Pararenal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Study Arm</td>
<td>18</td>
<td>2</td>
<td>9</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of Staged Cases</td>
<td>5</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
| Expanded Selection + 
  OA/EU               | 14    | 3      | 5       | 3        | 0       |           |
| Number of Staged Cases | 1    | 0      | 0       | 1        | 0       |           |
| Program Total       | 32    | 5      | 12      | 11       | 3       | 3         |

(100%) (88%) (38%) (34%) (19%) (19%)

**Index Procedure time (Minutes)**

<table>
<thead>
<tr>
<th></th>
<th>Overall n=32</th>
<th>Primary Arm n=18</th>
<th>Expanded Selection Arm = O/EU n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time</td>
<td>352±13.8</td>
<td>356±13.7</td>
<td>345±9.6</td>
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<tr>
<td>(Median: 314)</td>
<td>(Median: 325)</td>
<td></td>
<td>(Median: 302)</td>
</tr>
</tbody>
</table>

**Estimated Blood Loss (mL)**

<table>
<thead>
<tr>
<th></th>
<th>Overall n=32</th>
<th>Primary Arm n=18</th>
<th>Expanded Selection Arm = O/EU n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Loss</td>
<td>60±873</td>
<td>67±954</td>
<td>51±273</td>
</tr>
<tr>
<td>(Median: 408)</td>
<td>(Median: 575)</td>
<td></td>
<td>(Median: 450)</td>
</tr>
</tbody>
</table>

**Pre-Op CSF drain**

<table>
<thead>
<tr>
<th></th>
<th>Overall n=32</th>
<th>Primary Arm n=18</th>
<th>Expanded Selection Arm = O/EU n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSF drain</td>
<td>23±114</td>
<td>14±78</td>
<td>9±64</td>
</tr>
<tr>
<td>(Median: 162)</td>
<td>(Median: 450)</td>
<td></td>
<td>(Median: 203)</td>
</tr>
</tbody>
</table>

**Technical success**

<table>
<thead>
<tr>
<th></th>
<th>Overall n=32</th>
<th>Primary Arm n=18</th>
<th>Expanded Selection Arm = O/EU n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>30 (94%)</td>
<td>16 (89%)</td>
<td>14 (100%)</td>
</tr>
</tbody>
</table>

**Cumulative ACM**

<table>
<thead>
<tr>
<th></th>
<th>Subjects Enrolled</th>
<th>Subject Deaths</th>
<th>0 – discharge</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative ACM ALL</td>
<td>32</td>
<td>3</td>
<td>3 (9%)</td>
<td></td>
</tr>
<tr>
<td>Cumulative ACM Primary Study Arm</td>
<td>18</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Cumulative ACM Expanded Selection Arm</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**Total M/A to 30d (or re-hospital n=2)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with 1 or more M/A</td>
<td>11 (59%)</td>
</tr>
<tr>
<td>All Cause Mortality</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Acute Renal Failure Mortality</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>MI</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Permanent Neurologia</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>10 (51%)</td>
</tr>
<tr>
<td>Tracheostomy</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>
Off the shelf Solutions for TAAA: Conclusions

- Endovascular techniques show early promise for thoracoabdominal aortic aneurysm repair
- While we await broader availability of branched/fenestrated technologies, a unique opportunity exists for exploration of individual surgeons creativity