What are the Options for Treating Type III and IV TAAA’s and When Should They be Used?

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No Financial Compensation or Conflicts
Advisory Board: Medtronic/ WLGore
National PI for the TAMBE early Feasibility trial
National PI for the US IDE InCraft study

Thoraco-Abdominal Aneurysms: Modified Crawford

Options for Complex AAA / Type IV

Selection of Treatment Option Depends on:

- Physiologic risk and Life expectancy (Frailty Index):
  - Cardio-pulmonary
  - Renal Insufficiency
  - Previous procedures (colostomy, Aortic...)
- Acceptable Seal Zones
- Emergency nature of the procedure
- Availability of endo components (country - IDE)
- Operator skill and familiarity
- Access vessels both Ileo-Femoral and Axillary
- Anatomy of visceral vessels...

Disclosures

Options for Type III and IV TAAA

Caution: Investigational devices / Limited by US Law to Investigational Use
Debranching and Hybrid

- Same Limitations as Direct Open Repair
  - Pulmonary Insufficiency
  - Previous Thoracic Aortic Surgery
  - Lack of Suitable Complete Endovascular Options


<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Patients</th>
<th>Mortality</th>
<th>Morbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee</td>
<td>2005</td>
<td>17</td>
<td>24%</td>
<td>25%</td>
</tr>
<tr>
<td>Resch</td>
<td>2006</td>
<td>13</td>
<td>23%</td>
<td>46%</td>
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<tr>
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<td>2006</td>
<td>22</td>
<td>13%</td>
<td>54%</td>
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<tr>
<td>Chiesa</td>
<td>2007</td>
<td>13</td>
<td>23%</td>
<td>31%</td>
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<tr>
<td>Bockler</td>
<td>2008</td>
<td>28</td>
<td>14%</td>
<td>59%</td>
</tr>
<tr>
<td>Quinones</td>
<td>2008</td>
<td>20</td>
<td>0</td>
<td>32%</td>
</tr>
</tbody>
</table>

Options for Complex AAA / TAAA

- Chimneys
  - Best Suited and Acceptable in High Risk Emergency Situations
  - Used successfully in Elective repairs when no other Options
  - Advantage: Suitable in a wide variety of Anatomies

- CHIMNEY
  - No Standardization and many question marks
    - Balloon expandable?
    - Self expanding?
    - Length of overlap?
    - Configuration?
    - Crushed stents and patency?
    - Gutters and endoleaks?
    - Biopolymer sac seal with Nellix?

Literature review of CHIMNEY results

<table>
<thead>
<tr>
<th>World Literature Review</th>
<th>CHIMPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (Abdominal)</td>
<td>234 (176)</td>
</tr>
<tr>
<td>30-Day Mortality</td>
<td>5.1%</td>
</tr>
<tr>
<td>Type I Endoleak</td>
<td>11.5%</td>
</tr>
</tbody>
</table>

NO MEDIUM OR LONG-TERM DATA

Options for Complex AAA / TAAA

- Fenestrated
  - Commercial product in US is a Good option for short necks
  - Custom made (3-5 weeks). Off the shelf in Phase II trials.
  - Durable repair with good landing zone in visceral aorta
  - Wider options OUS and with IDE
  - Many exclusions (nearly 60% in US trial)
Options for Complex AAA / TAAA
Fenestrated

Exclusions from Fenestrated
Neck Too Angulated

RG 69
BH 64
MB 70

Exclusions from Fenestrated
Aorta Too Large/Aorta Too Small

DC 69
JH 73
JS 62

Exclusions from Fenestrated
Poor Access

MB 70
JH 73
CL 79

Exclusions from Fenestrated
Poor Renal/Neck Anatomy

Multiple Renals
Renal Stenosis
Thrombus+2 Renals
Heavy Calcifications

Literature Review of Fenestrated Results

Open repair versus fenestrated endovascular aneurysm repair of juxtarenal aneurysms

Robert Ren, DSC, Timotea R. A. Lane, MBBS, Sir J. Franklin, FRCSEng(Surg), and
Kim H. McAneney, DSC, MBBS, London, United Kingdom

1947-2013 Lit Review  FEVAR  OPEN  P
Number 2326 Patients  751  1575
Perioperative Mortality  4.1%  4.1% NS
Post-Op Complications  15.7%  25% <.001
Post-Op Renal Insufficiency  11.4%  13.9% NS
Renal Failure During FU  19.7%  7.7% <.0001
Secondary Interventions  12.7%  4.9% <.0001
5-Yr Survival KM  55%  73% .09
**Options for Complex AAA / Type IV**

**BRANCHED SYSTEMS**

Zenith T Branch and Gore TAMBE

*Caution: Investigational devices / Limited by US Law to Investigational Use*

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**Options for Complex AAA / Type IV**

**BRANCHED SYSTEMS**

Probably the future for most Type IV and Type III TAAA

Pros
- Anatomic reconstruction
- Can be off the shelf
- Early results suggest durable repair
- Allows the selection of best landing Zones

Cons
- Limited in Availability
- Requires advanced skills in planning and implantation
- Long Procedures
- Anatomic limitations (access, angulations, anatomic variability, stenosis...)

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**T Branch Reports Appearing**

Endovascular repair of thoracoabdominal aortic aneurysm using the off-the-shelf multibranched t-Branch stent graft

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**TAMBE® Early Feasibility Study (AAA 13-02)**

National PI: Michel Makaroun MD
University of Pittsburgh Medical Center

Preliminary Data: Technical Success

- Death: 0
- Stroke: 0
- Myocardial Infarction: 0
- Bowel Ischemia: 0
- Paraplegia: 0
- Respiratory Failure: 0
- Renal Failure: 0
- Procedural Blood Loss > 1000 ml: 4

All excessive blood loss was from the 12 Fr brachial sheath valve leaking around the multiple catheters and wires

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**WL Gore TAMBE® Early Feasibility Study**

Preliminary Data: 30 Days Primary Safety

- Death: 0
- Stroke: 0
- Myocardial Infarction: 0
- Bowel Ischemia: 0
- Paraplegia: 0
- Respiratory Failure: 0
- Renal Failure: 0
- Procedural Blood Loss > 1000 ml: 4

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<table>
<thead>
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<th>Summary</th>
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<tbody>
<tr>
<td>Many options exist for complex AAA/Type IV TAAA</td>
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<tr>
<td>Decision depends heavily on the anatomy and risk profile of the patient</td>
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<tr>
<td>Open repair and hybrids limited to good risk patients</td>
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<tr>
<td>Parallel grafts are useful in emergency situations</td>
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<td>Fenestrated endografts offer advantages but have a limited applicability and delayed availability</td>
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<td>Branched systems with off the shelf design may prove best endovascular option for device durability</td>
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