OUTCOMES OF ENDOVASCULAR TAAA REPAIR

Gustavo S. Oderich MD
Professor of Surgery
Director of Aortic Center
Director of Advanced Endovascular Aortic Program
Division of Vascular and Endovascular Surgery
FACULTY DISCLOSURES

• Consulting*
  Cook Medical Inc., WL Gore, GE Healthcare

• Research grants*
  Cook Medical Inc., WL Gore, GE Healthcare

• Investigational, off-label use of devices
  Cook Fenestrated and Branched Grafts, Gore Branched Technology

* All consulting fees and research educations grants paid to Mayo Clinic
1,896 TAAA REPAIRS

A Quarter Century of Organ Protection in Open Thoracoabdominal Repair

Anthony L. Estrera, MD, Harleen K. Sandhu, MD, MPH, Kristofer M. Charlton-Ouw, MD, Rana O. Afifi, MD, Ali Azizzadeh, MD, Charles C. Miller III, PhD, and Hazim J. Safi, MD

Mean age, 64 years-old

30-day mortality:
  - All patients: 15.9%
  - Normal eGFR: 5.2%

Major adverse events
  - Dialysis, 16.6%
  - Stroke, 5%
  - Spinal cord injury, 9.6%
70 yo Iraqi man presented with an extent IV TAAA. He had prior empyema requiring VATS 2 years prior. He is otherwise fit. I would recommend:

A: Open TAAA repair  41%
B: Hybrid open repair (debranching then...  19%
C: Total endovascular repair with custom branched graft.
D: Let him go.  41%
## eTAAA REPAIR

Contemporary results of large aortic centers

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>n</th>
<th>IV/I-III</th>
<th>Mean age</th>
<th>30-day mortality</th>
<th>SCI %</th>
<th>Paraplegia %</th>
<th>Dialysis %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kasprzak et al (2014)</td>
<td>83</td>
<td>30/53</td>
<td>71</td>
<td>7.2%</td>
<td>20%</td>
<td>13%</td>
<td>5%</td>
</tr>
<tr>
<td>Bisdas T et al (2015)</td>
<td>142</td>
<td>12/130</td>
<td>70</td>
<td>2.8%</td>
<td>16%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Dias N et al (2015)</td>
<td>72</td>
<td>17/55</td>
<td>68</td>
<td>6.9%</td>
<td>31%</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>Katsargyris et al (2015)</td>
<td>218</td>
<td>54/164</td>
<td>69</td>
<td>7.8%</td>
<td>10%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Maurel et al (2015)</td>
<td>204</td>
<td>85/119</td>
<td>71</td>
<td>6.9%</td>
<td>4%</td>
<td>1%</td>
<td>5%</td>
</tr>
<tr>
<td>Eagleton et al (2016)</td>
<td>354</td>
<td>0/354</td>
<td>74</td>
<td>4.8%</td>
<td>9%</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Fernandez et al (2016)</td>
<td>133</td>
<td>73/60</td>
<td>71</td>
<td>7.8%</td>
<td>5%</td>
<td>10%</td>
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</tr>
</tbody>
</table>
MOVING TARGET...

• Learning curve: patient selection and team experience
• Strategies to prevent spinal cord injury
• Changes in device design, delivery system, and bridging stents
PATIENT SELECTION

Genetically Triggered Aortic Diseases (GenTADs)

Excessive aortic debris (‘Shaggy Aorta)

Unsuitable target vessel anatomy
MAYO CLINIC F-BEVAR PROGRAM

30-day mortality: 1.5% (8/510)

Year


No. of Patients

7 18 33 22 44 37 54 60 67 71 97
# Learning Curve in 334 Patients Treated by Fenestrated-Branched Endovascular Repair for Complex Aortic Aneurysms

<table>
<thead>
<tr>
<th></th>
<th>All n = 334</th>
<th>Q1 n = 81</th>
<th>Q2 n = 84</th>
<th>Q3 n = 85</th>
<th>Q4 n = 84</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>30 day mortality</strong></td>
<td>2%</td>
<td>6%</td>
<td>2%</td>
<td>1%</td>
<td>0%</td>
<td>0.009</td>
</tr>
<tr>
<td><strong>Any major adverse event</strong></td>
<td>33%</td>
<td>58%</td>
<td>32%</td>
<td>21%</td>
<td>21%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>30-day reinterventions</strong></td>
<td>9%</td>
<td>9%</td>
<td>10%</td>
<td>6%</td>
<td>2%</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Oderich et al (unpublished data)
MOVING TARGET...

- Learning curve: patient selection and team experience
- Strategies to prevent spinal cord injury
- Changes in device design, delivery system, and bridging stents
Staged endovascular repair of thoracoabdominal aortic aneurysms limits incidence and severity of spinal cord ischemia

Adrian O’Callaghan, MD, Tara M. Mastracci, MD, and Matthew J. Baglione, MD, Cleveland, Ohio

<table>
<thead>
<tr>
<th></th>
<th>1-Stage</th>
<th>2-Stage</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any SCI</td>
<td>38%</td>
<td>11%</td>
<td>.02</td>
</tr>
<tr>
<td>Permanent</td>
<td>16%</td>
<td>0%</td>
<td>.03</td>
</tr>
</tbody>
</table>

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Editor’s Choice — Temporary Aneurysm Sac Perfusion as an Adjunct to Prevention of Spinal Cord Ischemia After Branched Endovascular Thoracoabdominal Aneurysms

P.M. Kasprzak, K. Gallis, B. Cucuruz, K. Pfister, M. Janotta, R. Kopp

Department of Surgery, Vascular and Endovascular Surgery, University Hospital, University of Regensburg, Franz-Josef-Strauss-Allee 13, 93053 Regensburg, Germany

<table>
<thead>
<tr>
<th></th>
<th>No TASP</th>
<th>TASP</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Any SCI</td>
<td>23%</td>
<td>13%</td>
<td>.00</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>21%</td>
<td>3%</td>
<td>.02</td>
</tr>
</tbody>
</table>

Kasprzak et al. Eur J Vasc Endovasc Surg 2014
SPINAL CORD INJURY PREVENTION

- Staged aortic coverage
- Permissive hypertension
- CSF drainage 48-72 hours
- Neuromonitoring
- Early limb reperfusion
- Selective temporary sac perfusion (TASP)
PATIENTS

274 patients enrolled (January 30th, 2018)

232 patients had implantation with > 30-day follow up

42 patients await device implantation

84 pararenal (36%)

62 Extent 4 TAAA (27%)

86 Extent 1-3 TAAA (37%)
## 30-DAY RESULTS

**One (0.5%) 30-day or in-hospital death**

<table>
<thead>
<tr>
<th>Percent</th>
<th>Overall n = 232</th>
<th>Pararenal n = 84</th>
<th>Extent IV n = 62</th>
<th>Extent I-III n = 86</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any MAE</td>
<td>53 (23)</td>
<td>17 (20)</td>
<td>16 (26)</td>
<td>20 (23)</td>
<td>0.72</td>
</tr>
<tr>
<td>EBL &gt;1L</td>
<td>20 (9)</td>
<td>4 (5)</td>
<td>5 (8)</td>
<td>11 (13)</td>
<td>0.17</td>
</tr>
<tr>
<td>eGFR &gt;50%</td>
<td>18 (8)</td>
<td>5 (6)</td>
<td>8 (13)</td>
<td>5 (6)</td>
<td>0.20</td>
</tr>
<tr>
<td>New-onset dialysis</td>
<td>3 (1)</td>
<td>1 (1)</td>
<td>1 (2)</td>
<td>1 (1)</td>
<td>0.96</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>10 (4)</td>
<td>4 (5)</td>
<td>5 (8)</td>
<td>1 (1)</td>
<td>0.12</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>5 (2)</td>
<td>1 (1)</td>
<td>2 (3)</td>
<td>2 (2)</td>
<td>0.69</td>
</tr>
<tr>
<td>Any Spinal Cord Injury</td>
<td>10 (4)</td>
<td>1 (1)</td>
<td>0</td>
<td>9 (10)</td>
<td>0.05</td>
</tr>
<tr>
<td>Permanent Paraplegia</td>
<td>2 (1)</td>
<td>1 (1)</td>
<td>0</td>
<td>1 (1)</td>
<td>0.69</td>
</tr>
<tr>
<td>Major stroke</td>
<td>2 (1)</td>
<td>1 (1)*</td>
<td>1 (2)</td>
<td>0</td>
<td>0.53</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>4 (2)</td>
<td>3 (4)</td>
<td>1 (2)</td>
<td>0</td>
<td>0.2</td>
</tr>
</tbody>
</table>

* Hemorrhagic, spinal drain-related
MOVING TARGET...

- Learning curve: patient selection and team experience
- Strategies to prevent spinal cord injury
- Changes in device design, delivery system, and bridging stents
STENT DESIGNS

Off-the-Shelf
Cook t-Branch®
Gore TAMBE®
Medtronic
Jotec

Patient Specific
Cook platform
- Any design with fenestrations ± branches
PRE-LOADED WIRE SYSTEM
**VBX® BALLOON EXPANDABLE STENT**

<table>
<thead>
<tr>
<th></th>
<th>Viabahn</th>
<th>VBX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length</strong></td>
<td>5, 7.5, 10-cm</td>
<td>39, 59, 79 mm</td>
</tr>
<tr>
<td><strong>Diameter</strong></td>
<td>6-9 mm</td>
<td>5-9 mm</td>
</tr>
<tr>
<td><strong>Sheath</strong></td>
<td>7-9 Fr</td>
<td>7-8 Fr</td>
</tr>
</tbody>
</table>

What are the state-of-the-art results...after overcoming the learning curve of F-BEVAR?
MANUSCRIPT IN PREPARATION (UNPUBLISHED DATA)
• 10 ongoing prospective, non-randomized physician-sponsored investigational device exemption trials
US IDE CONSORTIUM

- Prospective, non-randomized PS-IDE study
  - External auditing, FDA auditing
  - Clinical Event Committee/ DSMB
  - Independent radiological review of imaging
- Off-the-shelf or patient-specific fenestrated/branched endograft devices
- Modern, preloaded, lower-profile designs
- Novel bridging stent-grafts (Viabahn, VBX)
- Does not include “learning curve”
- Large numbers in shorter period (True ‘state-of-the-art’ contemporary experience)
Branch Vessel Durability After Branched and Fenestrated Endovascular Repair of Pararenal and Thoracoabdominal Aortic Aneurysms in the US IDE Experience

Darren B. Schneider MD, Mark A. Farber MD, Andres Schanzer MD, Adam Beck MD, Carlos H. Timaran MD, Matthew P. Sweet MD, Emanuel Tenorio MD, PhD and Gustavo S. Oderich MD

On behalf of the US Branched and Fenestrated IDE Consortium

Outcomes of endovascular repair of post-dissection and degenerative thoracoabdominal aortic aneurysms using fenestrated-branched stent-grafts

Emanuel Tenorio MD, PhD, Gustavo S. Oderich MD, Mark Farber MD, Darren B. Schneider MD, Carlos Timaran MD, Andres Schanzer MD, Adam Beck MD, Matthew Sweet MD

On behalf of the United States Fenestrated-Branched Research Consortium

Abstracts submitted for presentation
661 patients enrolled (January 1\textsuperscript{st}, 2018)

All patients had implantation with > 30-day follow up

- 232 pararenal (36%)
- 221 Extent 4 TAAA (33%)
- 208 Extent 1-3 TAAA (31%)
<table>
<thead>
<tr>
<th></th>
<th>Overall n = 661</th>
<th>Pararenal n = 232</th>
<th>Extent IV n = 221</th>
<th>Extent I-III n = 208</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n (Percent) or Mean ± Standard Deviation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age (years ± SD)</td>
<td>73±8</td>
<td>75±7</td>
<td>72±8</td>
<td>73±8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age &gt; 80 years old</td>
<td>148 (23)</td>
<td>74 (32)</td>
<td>34 (15)</td>
<td>40 (19)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male gender</td>
<td>465 (70)</td>
<td>181 (78)</td>
<td>170 (77)</td>
<td>114 (55)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td>500 (76)</td>
<td>169 (73)</td>
<td>181 (82)</td>
<td>150 (72)</td>
<td>0.03</td>
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<tr>
<td>Hypertension</td>
<td>605 (92)</td>
<td>206 (89)</td>
<td>217 (90)</td>
<td>199 (96)</td>
<td>0.02</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>476 (80)</td>
<td>173 (75)</td>
<td>155 (79)</td>
<td>148 (71)</td>
<td>0.54</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>321 (49)</td>
<td>115 (50)</td>
<td>119 (54)</td>
<td>87 (42)</td>
<td>0.04</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>282 (43)</td>
<td>96 (41)</td>
<td>91 (41)</td>
<td>95 (46)</td>
<td>0.57</td>
</tr>
<tr>
<td>Chronic Kidney Disease III-V</td>
<td>283 (44)</td>
<td>97 (43)</td>
<td>98 (46)</td>
<td>88 (43)</td>
<td>0.93</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>91 (14)</td>
<td>27 (12)</td>
<td>34 (15)</td>
<td>30 (14)</td>
<td>0.48</td>
</tr>
<tr>
<td>Prior aortic repair</td>
<td>288 (44)</td>
<td>57 (25)</td>
<td>91 (41)</td>
<td>140 (68)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>92 (14)</td>
<td>34 (15)</td>
<td>32 (14)</td>
<td>26 (13)</td>
<td>0.77</td>
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<tr>
<td>Stroke</td>
<td>77 (12)</td>
<td>27 (12)</td>
<td>26 (12)</td>
<td>24 (12)</td>
<td>0.99</td>
</tr>
<tr>
<td>Chronic Dissection TAAA</td>
<td>38 (6)</td>
<td>0</td>
<td>7 (3)</td>
<td>31 (15)</td>
<td>&lt;0.001</td>
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## 30-DAY OUTCOMES

<table>
<thead>
<tr>
<th></th>
<th>Overall n = 661</th>
<th>Pararenal n = 232</th>
<th>Extent IV n = 221</th>
<th>Extent I-III n = 208</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n (Percent)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Mortality</td>
<td>13 (2)</td>
<td>3 (1)</td>
<td>5 (2)</td>
<td>5 (2)</td>
<td>0.82</td>
</tr>
<tr>
<td>Any MAE</td>
<td>97 (15)</td>
<td>26 (11)</td>
<td>33 (15)</td>
<td>38 (18)</td>
<td>0.11</td>
</tr>
<tr>
<td>EBL &gt;1L</td>
<td>29 (5)</td>
<td>6 (3)</td>
<td>9 (4)</td>
<td>14 (7)</td>
<td>0.10</td>
</tr>
<tr>
<td>Acute Kidney injury</td>
<td>36 (5)</td>
<td>7 (3)</td>
<td>14 (6)</td>
<td>15 (7)</td>
<td>0.11</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>12 (2)</td>
<td>4 (2)</td>
<td>7 (3)</td>
<td>1 (0.4)</td>
<td>0.11</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>20 (3)</td>
<td>2 (1)</td>
<td>10 (5)</td>
<td>8 (4)</td>
<td>0.053</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>11 (2)</td>
<td>1 (0.4)</td>
<td>1 (0.4)</td>
<td>9 (4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>12 (2)</td>
<td>3 (1)</td>
<td>4 (2)</td>
<td>5 (2)</td>
<td>0.68</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>22 (3)</td>
<td>5 (2)</td>
<td>10 (5)</td>
<td>7 (3)</td>
<td>0.37</td>
</tr>
</tbody>
</table>
PATIENT SURVIVAL

Mean age, 74 years-old
43% CKD Stage III to V

Stage I: 88±2
Stage II: 80±2
Stage III: 76±3
Stage IV


At risk (no.)
Follow-up (years)
623 331 181 50
AORTIC RELATED DEATH

Freedom from aortic related death (%)

At risk (no.)

Follow-up (years)

624
331
181
50

98±1
TARGET VESSEL INSTABILITY

Any target vessel related death, rupture, occlusion or secondary intervention

Freedom from target vessel instability (%) at different follow-up years:
- 0 years: 97 ± 4%
- 1 year: 96 ± 5%
- 2 years: 93 ± 1%
- 3 years: 93 ± 1%

At risk (no.): 2,428, 1,239, 679, 191
SECONDARY INTERVENTIONS

Freedom from secondary intervention (%)

Follow-up (years)

At risk (no.)

- 95% minor, endovascular
- 3% major, endovascular
- 2% major, open surgical

83±2
74±2
66±3

653 278 137 32
TREATMENT TRENDS & OUTCOMES OF OPEN VERSUS ENDOVASCULAR TAAA REPAIR IN A SINGLE CENTER

Ying Huang MD PhD, Gustavo S. Oderich MD, Mauricio Ribeiro MD PhD, Thomas C. Bower MD, Alberto Pochetino MD, Manju Kalra MBBS, Randall DeMartino MD, Stephen Cha MS and Peter Gloviczki MD
AORTIC REINTERVENTION

Freedom from reintervention (%)

OSR

F-BEVAR

Year

No. at risk

OSR

F-BEVAR

86 ± 3.

5

81 ± 3.

4

84 ± 3.

8

68 ± 5.

4

P = .01

0.0

0.5

1.0

1.5

2.0

0

10

20

30

40

50

60

70

80

90

100

127

58

39

160

63

26

MAYO CLINIC
NON-AORTIC REINTERVENTION

Freedom from reintervention (%)

- OSR
- F-BEVAR

No. at risk
- OSR: 127
- F-BEVAR: 160

Year

P < .001

94±2. 93±2.
80±3. 80±3.

0 3
4 8
CONCLUSIONS

• Outcomes of eTAAA repair continue to improve as a reflection of team experience and adoption of specific protocols to prevent spinal cord injury.

• The technique is safe, effective, and has the potential to significantly reduce morbidity and mortality compared to open surgical repair.

• Important considerations are learning curve, need for optimal imaging and familiarity with advanced endovascular techniques.

• Unquestionably, a 71-year Iraqi male with a large TAAA and suitable anatomy should have endo TAAA repair, and not an open repair…
MAYO CLINIC
150 Years
SERVING HUMANITY