Endoanchor-assisted TEVAR

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Disclosures

Consultant

– Medtronic
– Bolton Medical
– TriVascular
– Lombard Medical
– Aptus
Imaging revolution
catalyst
Treatment revolution
Endoleaks happen

Even with optimal planning

Even with current stent-graft technologies
Endoleak management and postoperative surveillance following endovascular repair of thoracic aortic aneurysms

Joseph J. Ricotta II, MD, Atlanta, Ga

As with endovascular repair of abdominal aortic aneurysms (EVAR), thoracic endovascular aortic repair (TEVAR) has become an accepted and preferred alternative to open surgical repair for the treatment of thoracic aortic aneurysms (TAAs). The incidence of TAAs is approximately 6/100,000 person-years, the risk of rupture for large TAAs is as high as 74% without repair, and >90% of patients do not survive 1 year. TAAs are commonly associated with endoleaks, defined as blood flow outside of the endograft lumen and within the aneurysm sac. An endoleak classification system for endoleaks has been created for endoleaks after both EVAR and TEVAR according to the source of blood flow causing the leak.²,³

ENDOLEAK CLASSIFICATION

An endoleak is defined as blood flow outside of the endograft lumen and within the aneurysm sac. A classification system for endoleaks has been created for endoleaks after both EVAR and TEVAR according to the source of blood flow causing the leak.²,³
Table I. Overall endoleak rate in thoracic endovascular aortic repair

<table>
<thead>
<tr>
<th>First author, y</th>
<th>No</th>
<th>Overall</th>
<th>Early (30-day)</th>
<th>Late (12-mos)</th>
<th>Repair of endoleak (%)</th>
<th>Treated (%)</th>
<th>Success (%)</th>
<th>Early endoleak (%)</th>
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</thead>
<tbody>
<tr>
<td>Orend, 4 2003</td>
<td>74</td>
<td>20.3</td>
<td>NR</td>
<td>NR</td>
<td>86.6</td>
<td>92.9</td>
<td>80</td>
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<tr>
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<td>9.6</td>
<td>4.8</td>
<td>4.8</td>
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<td>75</td>
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<td>Marin, 6 2003</td>
<td>94</td>
<td>25</td>
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<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>4</td>
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<tr>
<td>Czerny, 7 2004</td>
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<td>38.9</td>
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<td>85.7</td>
<td>5.5</td>
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<td>Demers, 8 2004</td>
<td>103</td>
<td>31.1</td>
<td>20.4</td>
<td>21.3</td>
<td>NR</td>
<td>84</td>
<td>NR</td>
<td>16.5</td>
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<tr>
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<td>249</td>
<td>9.2</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<tr>
<td>Parmer, 10 2006</td>
<td>105</td>
<td>29</td>
<td>17.1</td>
<td>11.9</td>
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<tr>
<td>Patel, 11 2006</td>
<td>73</td>
<td>10.9</td>
<td>8.2</td>
<td>2.7</td>
<td>37.5</td>
<td>66</td>
<td>66</td>
<td>2.7</td>
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<tr>
<td>Wheatley, 12 2006</td>
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<td>5.2</td>
<td>5.2</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<tr>
<td>Fattori, 13 2006</td>
<td>457</td>
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<td>NR</td>
<td>18.4</td>
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<td>Rodriguez, 14 2007</td>
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<td>7.4</td>
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<td>2.5</td>
<td>NR</td>
<td>NR</td>
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<td>7</td>
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<td>Dalletto, 16 2007</td>
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<td>16.7</td>
<td>10</td>
<td>6.7</td>
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<td>80</td>
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<td>Leurs, 17 2007</td>
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<td>21.1</td>
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<tr>
<td>Morales, 18 2008</td>
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<td>16.9</td>
<td>9.4</td>
<td>7.5</td>
<td>33</td>
<td>88.9</td>
<td>88.9</td>
<td>11.1</td>
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<tr>
<td>Preventza, 19 2008</td>
<td>249</td>
<td>15.2</td>
<td>8.4</td>
<td>6.8</td>
<td>31.6</td>
<td>94.7</td>
<td>31.6</td>
<td>2</td>
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<tr>
<td>Makaroun, 20 2008</td>
<td>140</td>
<td>12</td>
<td>NR</td>
<td>3.9</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>11.2</td>
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<tr>
<td>Matsumura, 21 2008</td>
<td>160</td>
<td>8.7</td>
<td>4.8</td>
<td>3.9</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>4.9</td>
</tr>
<tr>
<td>Fairman, 22 2008</td>
<td>195</td>
<td>28.3</td>
<td>25.9</td>
<td>12.2</td>
<td>NR</td>
<td>100</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Total (avg)</td>
<td>3002</td>
<td>(18.0)</td>
<td>(10.4)</td>
<td>(9.5)</td>
<td>(46.2)</td>
<td>(85.5)</td>
<td>(74.8)</td>
<td>(8.4)</td>
</tr>
</tbody>
</table>

NR, Not reported.
Challenges in TEVAR

- High anatomical variations
- Deployment challenges & risks, e.g. birdbeaking
- Manipulations near or coverage of critical branches
- Risk of neurologic complications or mesenteric ischemia
- Larger devices in smaller anatomy (higher rate of females)
- Higher risk of access complications
- Beat-to-beat movement
- Risk of migration/leak and progression of TAA

FJ Criado, The TEVAR Landscape in 2012. Dec 2011 Endovascular Today
Securing Endografts in the Thoracic Aorta

- Dynamic environment

- Difference in compliance of aorta

- Pulsating forces
  - Longitudinal
  - Lateral
  - Rotational
Securing Endografts in the Thoracic Aorta
## Most Common Endoleaks in TEVAR are Type I

### Endoleaks Over Time

<table>
<thead>
<tr>
<th>Period</th>
<th>Periop</th>
<th>1 mo</th>
<th>6 mo</th>
<th>12 mo</th>
<th>24 mo</th>
<th>36 mo</th>
<th>48 mo</th>
<th>60 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients available for F/U</td>
<td>81</td>
<td>123</td>
<td>108</td>
<td>103</td>
<td>80</td>
<td>64</td>
<td>57</td>
<td>47</td>
</tr>
<tr>
<td>Patients with endoleaks</td>
<td>7 (8.6%)</td>
<td>10 (8.1%)</td>
<td>7 (6.5%)</td>
<td>4 (3.9%)</td>
<td>5 (6.3%)</td>
<td>2 (3.1%)</td>
<td>3 (5.3%)</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>Type Ia</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Type Ib</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Type II</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Type III</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Type IV</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Image from article: Outcome of endovascular treatment of traumatic aortic transection, Steuer et al. JVS 2012;56*

Re-interventions after TEVAR Remain High

Re-intervention rates not resolved in newer generation grafts

- Re-intervention rate by time period
  - 1997-2001 27%
  - 2002-2006 18%
  - 2007-2010 23%
- Overall reinterventions: 22%

Major indication for re-intervention is Type I EL

- 8.3% type I endoleak related re-interventions

<table>
<thead>
<tr>
<th>Re-intervention Indication</th>
<th>Overall Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I endoleak</td>
<td>8.3%</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>1.5%</td>
</tr>
<tr>
<td>Subclavian steal syndrome</td>
<td>1.5%</td>
</tr>
<tr>
<td>Endograft compression/collapse</td>
<td>1.1%</td>
</tr>
<tr>
<td>Aortobronchial/esophageal fistula</td>
<td>1.1%</td>
</tr>
<tr>
<td>Type III endoleak</td>
<td>0.4%</td>
</tr>
<tr>
<td>Endograft infection</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

1Geisbüsch P. et al. JVS 2011;53:1528. (Heidelberg)
Revision – TAA Proximal Type 1 endoleak
Role of Heli-FX Thoracic EndoAnchor System in TEVAR

- Enhances sealing & fixation of endografts
- Simplifies revisions for endograft migration and Type I endoleak
- Enables tailoring of endograft apposition & fixation to patient anatomy
Primary TAA with Short/Angled Proximal Neck

• 4 EndoAnchors implanted in outer & inner radius of proximal neck

Case images courtesy of Thomas Naslund, MD – Vanderbilt University Medical Center
Multiple Deflection Lengths for Varying Neck Diameters

Aptus Heli-FX Thoracic EndoAnchor System

Aptus Heli-FX EndoAnchor System

18Fr OD, 90cm working length

22, 32, 42mm Tip Lengths

22 & 28mm Tip Lengths

16Fr OD, 62cm working length
Limitations of EndoAnchors

• Mural thrombus >2mm thick and 180° of circumference
• Porcelain aorta (severe circumferential calcification)
• Loss of graft apposition with resulting gap
• Attaching endograft layers without aortic wall penetration
Early Published European TEVAR Experience

- Kasprzak et al. used EndoAnchors to repair incomplete sealing and non-alignment of TAA/TAAA grafts
  - 4 pts - revision setting
  - 2 pts - primary setting for acute complications
  - Indications: type Ia/Ib EL, graft migration, graft infolding
- EndoAnchor implantation and fixation successful in all patients
  - No EndoAnchors misdeployed
  - No other adjunctive maneuvers needed after EndoAnchors
- Favorable follow-up in mean 11-month
  - No stent-graft migration, type I endoleak or EndoAnchor dislocation observed

TEVAR + Endoleaks

Aortic Arch

Distal Segment

Treatment

Prevention
“Commit to the curve”
Why Endostapling in this Case?

Preventive

• “Gothic Arch”
• Type III arch
• Short proximal neck
• Avoid “windsocking” of graft while ballooning proximal neck
• Prevent graft migration
• Prevent neck dilation?
EndoAnchor Clinical Experience in TEVAR

• >200 total TEVAR cases with EndoAnchors since June-2013 launch
  – Majority cases in Primary setting
  – No reported late Anchor Dislocations, Fractures or Fistula
• Hostile necks in Primary and Type I endoleaks in Revision are most common cited reasons for EndoAnchoring

<table>
<thead>
<tr>
<th>PRIMARY SETTING</th>
<th>REVISION SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason</td>
<td>Frequency*</td>
</tr>
<tr>
<td>Short neck</td>
<td>47.9%</td>
</tr>
<tr>
<td>Angulated neck</td>
<td>15.5%</td>
</tr>
<tr>
<td>Wide neck</td>
<td>15.5%</td>
</tr>
<tr>
<td>Conical neck</td>
<td>12.7%</td>
</tr>
<tr>
<td>Acute type 1</td>
<td>8.5%</td>
</tr>
</tbody>
</table>

Breakdown of TEVAR cases*

- Revision 32%
- Primary 68%

Types of Grafts*

- Gore TAG 27%
- Medtronic Valiant 56%
- Cook TX2 14%
- Other 3%

1 Per data on file at Aptus
2 Reflects EndoAnchor TEVAR use in the US
EndoAnchors: When to Consider?

Primary

Severe Angulation

Difficult landing

Revision

Migration/ Type 1 Leak

Birdbeaking

Case images courtesy of P. Kasprzak MD, Regensburg and JM Panneton, Eastern Virgina Medical
Lower image from R. Kolvenbach et al. J Vasc Bras. 2009;8(4)

Type 1 Leak image courtesy of P. Kasprzak MD, Regensburg, birdbeaking image from Tadros et al, JVS 2011:53
65-year-old white male

Prior open AAA repair

6.5 cm aneurysm of lower descending thoracic aorta

5 cm aneurysm of proximal descending thoracic aorta
Celiac artery
Valiant 44 x 100 proximal main graft

Valiant 46 x 100 distal main graft
Valiant 44 x 100 proximal main graft

Valiant 46 x 100 distal main graft
Conclusions

– Strong need for EndoAnchors in TEVAR
  • Addresses major cause of complications by potentially reducing neck dilatation and realignment risks
  • Treats seal complications and may mitigate risk of further complications
  • Provides a solution for challenging anatomy and often compromised seal zones

– Clinical experience (>200 pts) confirms EndoAnchor use is safe
  • No reported late Anchor Dislocations, Fractures or Fistula

– Preliminary results show promise in preventing and treating seal-related complications
  • Primary TEVAR: challenging proximal and/or distal neck, acute type I endoleak
  • Revision TEVAR: late type I endoleak, graft migration, graft in-folding
Endoanchor-assisted TEVAR

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