What have we learned after two decades of TEVAR treatment in Type B dissection?

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- **Research/Research Grants, Clinical Trial Support**
  - W. L. Gore
  - Cook Medical

- **Consulting Fees/Honoraria**
  - W. L. Gore
  - Abbott Vascular

- **Equity Interests/Stock Options**
  - NovoStent
  - Vatrix
  - Amaranth
  - CVRx
  - Endoluminal Sciences
  - REVA Medical
  - TriVascular
  - Cytograft Tissue Engineering

- **Officer, Director, Board Member or other Fiduciary Role**
  - VIVA Physicians Group

- **Speaker’s Bureau**
  - None
Aortic Dissection is a Complex Disease

- The most common lethal catastrophe affecting the aorta
- Current incidence is around 30 cases per million population per year
- Characterized by the separation of the lamellae of the aortic wall
Treatment Options

• Medical Management
  • Patient given beta blockers, anti-hypertensives, statins to control symptoms and false lumen growth

• Open Surgical Repair
  • Open thoracotomy, heart and lung bypass and replacement of diseased aorta with surgical graft

• Endovascular Intervention
  • Catheter based delivery of device(s) deployed in the appropriate location in DTA
Type B Dissection Sub-Categories

- Acute Complicated
- Rupture
- Malperfusion
- Uncomplicated
- Identification of “High Risk” patients
- Chronic
- Aneurysm degeneration
- Up to 30% become aneurysmal
  - Imminent rupture or rupture
  - Dissection extension
  - Malperfusion or ischemic events

What we’ve learned:

• Landing zone is important – non-dissected tissue and PET seal
• Device design matters – bare springs and barbs are linked to greater RTAD risk
• Extent of coverage – remodeling versus paraplegia risk; rupture necessitates longer length coverage
• Aortic remodeling leads to better long-term outcomes
• BMT alone is often inadequate for long-term stabilization
• High risk factors may identify uncomplicated dissection patients who will benefit from early TEVAR
• Timing of treatment – delayed treatment may reduce TEVAR complication risk
• Next generation devices offer greater flexibility for treatment
Device Design: Potential Causes of Vessel Trauma

Potential causes of retrograde Type A dissection (RTAD) and stent graft-induced new entry tears (SINEs):

- **Anatomy-related**
  - Aorta fragility, disease progression

- **Procedure-related**
  - Wire and catheter manipulation

- **Device-related**
  - Excessive focal force on anatomy (from stent flares or springs)
  - High spring-back force (tendency of graft to return to its initial straight status)
  - High radial force
## Affect of device features on retrograde Type A Dissection (RTAD)

<table>
<thead>
<tr>
<th>Study</th>
<th>Overall Injury Incidence</th>
<th>Device-Related Incidence</th>
<th>Devices Used for Treatment</th>
<th>SINE Incidence per Device or Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dong 2009 (Zhongshan)</td>
<td>11 cases RTAD (2.5%)</td>
<td>9 cases attributed to device (81.8% of total RTAD incidence)</td>
<td>54% Talent 13% Hercules 3% TX2</td>
<td>3.8% Talent</td>
</tr>
<tr>
<td>Dong 2010 (Zhongshan)</td>
<td>N/A</td>
<td>16 cases attributed to device (2.4% of total implants)</td>
<td>52% Talent 35% Valiant 9% TX2 4% Hercules</td>
<td>1.5% Talent 0.75% Valiant 0.15% Hercules</td>
</tr>
<tr>
<td>Eggebrecht 2009 (Europe Registry)</td>
<td>63 cases RTAD (1.33%)</td>
<td>60% of total RTAD incidence attributed to device</td>
<td>60% Talent 19% Valiant 13% TAG 2% TX2</td>
<td>93% of RTAD cases occurred in pts treated with proximal bare springs</td>
</tr>
<tr>
<td>McCann/Hughes 2012 (Duke)</td>
<td>6 cases (1.9%)</td>
<td>4 cases attributed to device (67% of total RTAD incidence)</td>
<td>66% TAG 14% Talent 18% TX2</td>
<td>0% TAG 4.7% Talent 3.6% TX2</td>
</tr>
</tbody>
</table>
“High Risk” Factors of Uncomplicated Patients: Best Medical Therapy is Often Insufficient

IRAD: International Multicenter Prospective Registry
Circulation 2003; 108 [Suppl II]: II312-II 317
Acute Dissection Treatment Can Offer Good Long-Term Survival Outcomes

1 yr = 89%
2 yr = 85%
3 yr = 76%

1 yr = 94%
2 yr = 94%

Acute Complicated Dissection IDE Trial

Acute Type B Dissections in GREAT
Initial Presentation:

- Primary entry tear diameter $\geq 10$ mm
- Primary entry tear location
- Total aortic diameter $\geq 4$ cm
- False lumen diameter $\geq 22$ mm
- Partial false lumen thrombosis
- Fusiform index $\geq 0.64$
Timing of Treatment: Acute-delayed treatment may reduce intervention risk

Impact of timing on major complications after thoracic endovascular aortic repair for acute type B aortic dissection

Nimesh D. Desai, MD, PhD, Jean-Paul Gottret, MD, Wilson Y. Szeto, MD, Fenton McCarthy, MD, Patrick Moeller, BS, Rohan Menon, BS, Benjamin Jackson, MD, Prashanth Vallabhajosyula, MD, Grace J. Wang, MD, Ronald Fairman, MD, and Joseph E. Bavaria, MD

Acute-Early < 48 hrs
Acute-Delayed 48 hrs to 14 d
Subacute 14 days to 6 w

Patient Demographics and Reason for intervention

- Frank Rupture
- Contained rupture
- Impending Rupture
- Clinical Malperfusion
- Radiographical Malperfusion
- Other

% of Cases

- Acute-Early intervention (70)
- Acute-Delayed intervention (44)
- Subacute Intervention (18)
Timing of Treatment:
Acute-delayed treatment may reduce intervention risk

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Acute-Early Intervention (N = 70)</th>
<th>Acute-Delayed Intervention (N = 44)</th>
<th>Subacute Intervention (N = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>8.6</td>
<td>6</td>
<td>4.5</td>
</tr>
<tr>
<td>Mortality at 30 d</td>
<td>12.7</td>
<td>9</td>
<td>6.8</td>
</tr>
<tr>
<td>Any paralysis</td>
<td>7.0</td>
<td>5</td>
<td>4.5</td>
</tr>
<tr>
<td>Paralysis (permanent)</td>
<td>1.4</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Any stroke</td>
<td>5.6</td>
<td>4</td>
<td>4.6</td>
</tr>
<tr>
<td>Stroke (permanent)</td>
<td>1.4</td>
<td>1</td>
<td>2.3</td>
</tr>
<tr>
<td>New renal failure</td>
<td>8.5</td>
<td>6</td>
<td>6.8</td>
</tr>
<tr>
<td>Retrograde type A dissection</td>
<td>8.5</td>
<td>6</td>
<td>6.8</td>
</tr>
<tr>
<td>Overall major complication</td>
<td>38.7</td>
<td>27</td>
<td>27.3</td>
</tr>
</tbody>
</table>

*Retrograde Type A dissection occurred in a repeat TEVAR performed in the subacute period for a proximal type 1 endoleak in a patient previously stented for clinical malperfusion with complex arch anatomy. This was excluded, as it was from a repeat TEVAR procedure. |

Desai et al 2015

- Acute-Early: < 48 hrs
- Acute-Delayed: 48 hrs to 14 days
- Subacute: 14 days to 6 wks
Timing of Treatment:
Acute-delayed treatment may reduce intervention risk

Acute-Early  < 48 hrs
Acute-Delayed  48 hrs to 14 days
Subacute  14 days to 6 wks
Next Generation Devices

Zone 2

Zone 1

Zone 0

Investigational Device only
Gore Aortic Arch Multi-Branch – Total Arch

A system for off the shelf endovascular repair of aortic aneurysm, dissection and transection with branch vessel involvement

CAUTION: Investigational device, limited by law (US) to investigational use only
Conclusion

• Management of aortic dissections is trending towards greater TEVAR intervention

• Best practices for treatment will continue to evolve based on:
  • Assessment of literature and randomized studies
  • Society recommendations
Thank you
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