2 Staging F/B-EVAR Procedures for Complex TAAAs is a Better Way Than Leaving a Branch to Prevent SCI: Why?

Matthew J. Eagleton, MD
Associate Professor
Walter W. Buckley Endowed Chair
Cleveland Clinic Lerner College of Medicine-CWRU

VEITH 2015
November 20, 2015

Disclosures
- Bolton Medical – Consultant
- Cook Medical - Consultant

Spinal Cord Ischemia (SCI)

• Devastating complication after aortic surgery

• We need to limit this risk if endovascular repair of complex TAAA is to be successful

Evidence Supporting Staged Procedures
Experimental Data

• Porcine model
• Underwent ligation of T13-L5 spinal arteries
• Randomized to...
  — Group 1: Immediate TEVAR
  — Group 2: Staged TEVAR (7 days later)
• 50% of Group 1 animals developed paraplegia
• None in Group 2 developed paraplegia

Bischoff MS et al., Ann Thorac Surg 2011; 92: 138-146

Collateral Network Pressure Outcomes

Baseline CNP was 74 mmHg
↓ to 41-43 mm Hg after ligation

Immediate TEVAR
• ↓ 24 mm Hg after TEVAR
• Returned to baseline by 5 days

Staged TEVAR
• Returned to baseline before second stage
• Only dropped to 54 mm Hg after TEVAR
Collateral Network Orientation

- Increased in diameter 80-100%
- Increased in density of intramuscular paraspinous vasculature
- Re-alignment of paraspinous arterioles to run parallel to the spinal cord

Epidural Arterial Network: (within 5 days)

- Increased in diameter 80-100%
- Increased in density of intramuscular paraspinous vasculature
- Re-alignment of paraspinous arterioles to run parallel to the spinal cord

Took Advantage of...

- Staging potentially mitigates SCI development
- “Built-In” Delay while custom graft is constructed

Staged Repair for Endovascular Therapy

Definitions

| Single Stage | Complete repair performed in a single procedure. No prior aortic surgery |
| 2 Stage | Repair performed in two intentionally separate procedures |
| Unintentionally Staged | Prior aortic surgery (without the intention for further aortic repair) |

Study population

95 (17%) Type II TAAA Repairs with F/B-EVAR (Jan 2008-July 2013)

- Single Stage: N=30
- 2 Stage: N=27
- Unintentionally staged: N=33

Outcomes:
SCI higher in single stage approach

<table>
<thead>
<tr>
<th></th>
<th>Single Stage</th>
<th>Two Staged</th>
<th>Unintentionally Staged</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCI</td>
<td>12 (37.5%)</td>
<td>3 (11.1%)</td>
<td>4 (14.3%)</td>
<td>0.025</td>
</tr>
</tbody>
</table>

Outcomes:
Staging did not alter timing of SCI symptoms

<table>
<thead>
<tr>
<th></th>
<th>Single Stage</th>
<th>Two Staged</th>
<th>Unintent. Staged</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Development</td>
<td></td>
<td></td>
<td></td>
<td>0.13</td>
</tr>
<tr>
<td>- Immediate</td>
<td>5 (42%)</td>
<td>2 (67%)</td>
<td>2 (50%)</td>
<td></td>
</tr>
<tr>
<td>- Delayed</td>
<td>7 (58%)</td>
<td>1 (33%)</td>
<td>2 (50%)</td>
<td></td>
</tr>
</tbody>
</table>

Survival Type II Repairs

Our experience with endovascular repair of extensive TAA disease suggests that intentional staging the repair:

1. Protects against SCI
   - Lower rates of development
   - Less severe symptoms
   - Higher rates of recovery
2. Enhances overall survival

Outcomes:
Intentional staging was associated with less severe symptoms

<table>
<thead>
<tr>
<th>Severity Score</th>
<th>Single Stage</th>
<th>Two Staged</th>
<th>Unintent. Staged</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 1 (Weak v. gravity)</td>
<td>5 (42%)</td>
<td>2 (67%)</td>
<td>1 (25%)</td>
<td>0.025</td>
</tr>
<tr>
<td>- 2 (Weak v. no gravity)</td>
<td>0 (0%)</td>
<td>1 (33%)</td>
<td>1 (25%)</td>
<td></td>
</tr>
<tr>
<td>- 3 (Paralysis)</td>
<td>7 (58%)</td>
<td>0 (0%)</td>
<td>2 (50%)</td>
<td></td>
</tr>
</tbody>
</table>

Is this the best method?

- I don't know
- Potential problems with TEVAR then F/B-EVAR
  - Delay until aneurysm is excluded
  - Cost and potential morbidity – 2 major surgeries
  - May affect device design
  - Limited control over extent of peri-graft exclusion
How Much “Staging Exclusion” is Enough?

What about perfusion branches?
• We have limited experience with perfusion branches
• Potential problems with perfusion branches
  – Delay until aneurysm is excluded
  – May affect device design
  – Unknown effects on aneurysm hemodynamics – potential for pressurization
  – Anecdotal – potential problems with development of low grade DIC (thrombocytopenia, ↑ aPTT, ↑ FDP) which resolved with heparin therapy then sealing branches

Future Questions and Investigations
• What is best method by which to stage?
  – TEVAR then F:BEVAR
  – Perfusion branches
• What is the best timing for staging
• Who needs staging – everyone or selective?
• Why may staging limit SCI?
  – Limit time of each OR
  – Limit degree of embolization
  – Promote spinal collateralization

CRITICAL ISSUES® america
February 12 – 13, 2016
The Biltmore Hotel
Coral Gables, Florida

VEITH SYMPOSIUM
Connecting the Vascular Community