The SVS VQI/ FDA TEVAR for Type B Dissection Project


DISCLOSURES

- Chairman SVS/VQI TEVAR for Dissection Project

Vascular Quality Initiative®

Background

- VQI is an AHRQ designated Patient Safety Organization
  - Allows data collection for quality purposes without specific consent
  - Device safety and effectiveness monitoring is central to our mission
- Two TEVAR devices approved by FDA for use in dissection after trial use in complicated dissection presentations (rupture, malperfusion). Industry Sponsorship
- Post-market approval studies
  - Typically expensive and difficult to enroll
  - Do not represent real world device usage

Use of VQI for Post Approval Surveillance

- Aligns with FDA recommendations to use registries to collect real world data for post approval surveillance
  - “FDA believes that device registries should serve as the foundation of our National Medical Device Postmarket Surveillance System.”

Objectives

- 400 pts
  - 200 Acute Arm (n=204)
    - 60 Device A
    - 60 Device B
  - 200 Chronic Arm (n=194)
    - 60 Device A
    - 60 Device B

Enrollment Objectives

- Innovative postmarket device evaluation using a quality registry to monitor thoracic endovascular aortic repair in the treatment of aortic dissection
- Determine the effectiveness of TEVAR for treating type B dissection (TBD)
- Describe the project cohort and 30-day outcomes of TEVAR for both acute (AD) and chronic dissection (CD) patients

Enrollment Objectives

- 200 Acute Arm (n=204)
  - ED Device A ✓
  - ED Device B ✓
  - Chronic, 164, 60%
  - Acute, 164, 14%

- 200 Chronic Arm (n=194)
  - ED Device A ✓
  - ED Device B ✓
  - Chronic, 164, 60%
  - Acute, 164, 14%
**TEVAR Dissection Project Enrollment Rate**
Existing Network of VQI Centers and Processes Allowed Rapid Enrollment

---

**Methods**
- Consecutive type B aortic dissection treated with TEVAR
- Acute Dissection (AD) <30 days
- Complicated = Malperfusion/Rupture
- Compare AD vs. CD
- Uncomplicated AD compared
  - <14 days
  - ≥14 days

**Device Breakdown**

![Device Breakdown Chart]

**Complete F/U**
- Visit N %
  - Procedure 398 100%
  - 30 D 351 93%

**Results – Procedural Outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Acute (N=204, 51%)</th>
<th>Chronic (N=194, 49%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malperfusion</td>
<td>67 (33.5)</td>
<td>13 (7.1)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Rupture</td>
<td>28 (14.0)</td>
<td>5 (2.7)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Primary entry tear zone*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0 (0.0)</td>
<td>3 (1.6)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4 (2.0)</td>
<td>2 (1.0)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>42 (21.0)</td>
<td>42 (21.0)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>135 (67.5)</td>
<td>91 (49.7)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>17 (8.5)</td>
<td>41 (22.4)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>2 (1.0)</td>
<td>4 (2.2)</td>
<td>.0002</td>
</tr>
<tr>
<td>Distal zone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>62 (31.0)</td>
<td>55 (30.0)</td>
<td></td>
</tr>
<tr>
<td>6+</td>
<td>138 (69.0)</td>
<td>128 (69.9)</td>
<td>.832</td>
</tr>
<tr>
<td>Max aortic dia (Mean [SD]; [range])</td>
<td>42.3 (11.1)</td>
<td>51.5 (12.8)</td>
<td>.0001</td>
</tr>
</tbody>
</table>

*Definition of Type B dissection was by location of primary entry tear in Ishimaru zones 2-5; type B dissection with retrograde dissection into the arch were included.
Vascular Quality Initiative®

Results

<table>
<thead>
<tr>
<th></th>
<th>Acute complicated (N=93)</th>
<th>Acute uncomplicated treated ≤14d (N=78)</th>
<th>Acute uncomplicated treated ≥14d (N=21)</th>
<th>Chronic complicated (N=18)</th>
<th>Chronic uncomplicated (N=165)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissection-related</td>
<td>10 (12.0)</td>
<td>4 (6.7)</td>
<td>1 (6.2)</td>
<td>6 (4.8)</td>
<td>0.389</td>
<td></td>
</tr>
<tr>
<td>Death within 30 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraplegia</td>
<td>4 (4.3)</td>
<td>1 (1.3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.037</td>
<td></td>
</tr>
<tr>
<td>Any SCI</td>
<td>6 (6.5)</td>
<td>2 (2.6)</td>
<td>1 (4.8)</td>
<td>1 (5.6)</td>
<td>2 (2.4)</td>
<td>0.108</td>
</tr>
<tr>
<td>Related re-intervention</td>
<td>4 (4.3)</td>
<td>1 (1.3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.153</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 (10.8)</td>
<td>2 (3.6)</td>
<td>2 (9.5)</td>
<td>1 (5.6)</td>
<td>6 (3.6)</td>
<td>0.123</td>
</tr>
</tbody>
</table>

Mean (SD)

Conclusions

A registry-based device surveillance project can be used to rapidly accrue patients/procedures for analysis.
Not surprisingly, AD patients have a higher 30-day mortality and lower freedom from additional intervention compared to CD patients. 5-year follow-up data informs practice.
At the 30 days, there were no apparent differences in the acute uncomplicated patients with respect to acuity of intervention (>14 days<).
The FDA cites this project as great success in using registries for post-market surveillance.