TEVAR for Uncomplicated Type B Dissections: A RCT is Not Needed

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Disclosures

• Company: Silk Road Medical
• Relationship: Consulting

The Problem Defined

The Landscape

New Era of FDA Approval

Conformable stent graft for the treatment of acute, complicated type B dissection: Multicenter clinical trial

• 50 cTypeB pts with TEVAR – all with rupture/malperfusion
• 8% 30-day mortality
• NO paraplegia
• Issues are stroke/reinterventions/proximal dissection events

FAVORABLE 5 YEAR CLINICAL/ ANATOMIC RESULTS
INSTEAD – TEVAR IMPROVES ANATOMIC OUTCOMES AND LATE SURVIVAL

TEVAR vs Med Rx → ANATOMY

Late Outcomes

MGH Series

Houston Data- Anatomic Predictors

MGH Data- Anatomic Predictors

Predictors of late aortic interventions in patients with medically treated type B aortic dissection

• 245 pts with uTBD managed medically with mean f/u of 6.8 yrs!
• 38% required intervention in f/u
  → Entry tear > 10mm (OR 2.1)
  → Total Ao diameter >40mm (OR 2.2)
  → Flumen diameter > 20 mm
• Complete Flumen thrombosis → protective
**Objectives**

- Innovative project to serve as a pilot program for registry-based post-approval surveillance in collaboration with industry and the FDA
- 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

**Methods**

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

**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>Dissection-related death within 30 days</td>
<td>15 (7.5)</td>
<td>7 (3.8)</td>
<td>.325</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>6 (3.0)</td>
<td>0 (0)</td>
<td>.031</td>
</tr>
<tr>
<td>Any SCI</td>
<td>9 (4.5)</td>
<td>3 (1.6)</td>
<td>.145</td>
</tr>
<tr>
<td>Retrograde extension of dissection</td>
<td>1 (0.5)</td>
<td>2 (1.4)</td>
<td>.582</td>
</tr>
<tr>
<td>Dissection-related additional intervention</td>
<td>15 (7.5)</td>
<td>7 (3.8)</td>
<td>.325</td>
</tr>
</tbody>
</table>

**Outcomes from the Core Global Registry for Endovascular Aortic Treatment in patients undergoing thoracic endovascular aortic repair for type B dissection**

- 264 Type B TEVAR patients (2010-16)
- 30-day mortality (2.3%) + SCI very low
- Significantly better late survival for UTBD patients!
Conclusion

- Use of TEVAR in acute TBD reduces early and late complications \[\rightarrow\] Improved Survival

- Readily available anatomic features predict need for later intervention and should figure in clinical decision-making

- RCT neither Needed Nor Practical

And we've been to Washington with a thumbs down