How The Petticoat Technique Is Better Than Standard TEVAR For TBAD Patients: Update On The STABLE I And II Trials

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On behalf of STABLE investigators

Disclosure

- The STABLE trials are sponsored by Cook Medical
- Educational grants from Cook Medical

STABLE I (feasibility study)
- Type B aortic dissection warranting surgical intervention or not responding well to medical management (within 90 days of symptom onset)
- Prospective, multicenter study in US, Australia and Europe

STABLE II (pivotal study)
- Acute (≤14 days), complicated type B aortic dissection with rupture and/or malperfusion
- Prospective, multicenter study in US and Japan

Enrollment of 86 patients was completed in 2012
- 55 with acute dissection (≤14 days); 31 with non-acute dissection
- Primary endpoint: 30-day mortality
- Follow-up through 5 years is ongoing; results through 1 year and 2 years were published1,2
- Results through 4 years (as of June, 2015) are presented here: 4-year follow-up available for 77% of eligible patients


STABLE Studies

Zenith Dissection Endovascular System

- Dual component system

1. Proximal covered stent-graft for primary tear coverage
2. Distal bare stent for true lumen support

Caution - Investigational device. Limited by Federal (or United States) law to investigational use
STABLE I Study - Devices

- Dissection stent was placed in 93% of patients
- A majority of patients received only 1 TX2 component (79%)
- Successful device deployment in all patients, with 100% patency

Mortality Within 30 Days

- 30-day mortality
  - Acute dissection: 5.5% (3/55)
  - Non-acute dissection: 3.2% (1/31)
  - Overall group: 4.7% (4/86)
  - 4 year dissection related mortality 11% (9/86)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Days to death</th>
<th>Cause of death</th>
<th>CEC adjudication of relationship to dissection repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>5</td>
<td>Stroke</td>
<td>Related</td>
</tr>
<tr>
<td>Acute</td>
<td>11</td>
<td>Stroke</td>
<td>Related</td>
</tr>
<tr>
<td>Acute</td>
<td>11</td>
<td>Aortic rupture</td>
<td>Related</td>
</tr>
<tr>
<td>Non-acute</td>
<td>29</td>
<td>Unknown</td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

False Lumen Thrombosis

Descending thoracic aorta (LCC to celiac trunk)
- Complete thrombosis: Pre-op 1-year 2-year 3-year 4-year
  - Acute dissection: 0% 38% 47% 53% 67%
  - Non-acute dissection: 0% 25% 32% 47% 39%
- No patients with patent false lumen (i.e., false lumen was either partially or complete thrombosed) at 6 months and beyond

Abdominal aorta (celiac to aortic bifurcation)
- Complete thrombosis: Pre-op 1-year 2-year 3-year 4-year
  - Acute dissection: 2% 12% 11% 8% 12%
  - Non-acute dissection: 0% 4% 10% 17% 14%
- Patent false lumen: 58% (pre-operative) to 0% (4 years)

Changes in Aortic Diameter

- Freedom from secondary intervention at 4 years
  - 68% for acute dissections; 71% for non-acute dissections
- 24 patients (16 acute, 8 non-acute) underwent 32 secondary interventions
  - 9 of 32 (28%) secondary interventions were open surgical repair for type A/retrograde dissection or aneurysmal progression
WHATS THE DIFFERENCE?

**PETTICOAT vs TEVAR Alone**

- Maximum TL expansion in both the Thoracic and Abdominal Aorta

**PETTICOAT vs TEVAR Alone**

- Reintervention & sealing reentry tears easier with bare stent

**STABLE vs TEVAR**

- Aortic volumes: True lumen and false lumen after STABLE or TEVAR alone

- Patients
  - Acute, complicated type B aortic dissection
  - Available CTA imaging at pre-procedure and 12 months

- Two groups
  - TEVAR, 45 patients treated at 3 European institutions
  - STABLE, 39 patients from STABLE I study

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**Favorable Mortality and paraplegia rates with PETTICOAT**

<table>
<thead>
<tr>
<th>30-day event</th>
<th>STABLE I Acute (N = 55)</th>
<th>White 2011 Pooled SVS dataset Acute, complicated (N = 85)</th>
<th>Fattori 2013 Pooled results on TEVAR Acute (N = 2,359)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>5.5%</td>
<td>10.6%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Stroke</td>
<td>10.9%</td>
<td>9.4%</td>
<td>4.9%</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>1.8%</td>
<td>0.6% Paraplegia/paraparesis</td>
<td>4.2%</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>1.6%</td>
<td>3.5%</td>
<td>Not reported</td>
</tr>
<tr>
<td>Renal failure</td>
<td>10.9%</td>
<td>9.4%</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

**STABLE vs. TEVAR: Thoracic Remodeling**

**STABLE (Petticoat)**
- + Aortic Growth

**TEVAR Alone**
- No Aortic Growth

**STABLE vs. TEVAR: Abdominal Aortic Remodeling**

**STABLE (Petticoat)**
- + Total Aortic Growth

**TEVAR Alone**
- + Total Aortic Growth

**Aortic Growth after TEVAR**

<table>
<thead>
<tr>
<th>Study</th>
<th>Dissections</th>
<th>Thoracic Aorta (&gt;5mm increase)</th>
<th>Abdominal Aorta (&gt;5mm increase)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resch 2006</td>
<td>N = 74 (mixed acute and chronic)</td>
<td>28%</td>
<td>Not reported</td>
</tr>
<tr>
<td>Sobocinski 2013</td>
<td>N = 52 (all acute)</td>
<td>25% at 1 year</td>
<td>33% at 12 months</td>
</tr>
<tr>
<td>Fattori 2013 IRAD registry</td>
<td>N = 276 (all acute)</td>
<td>28% at 1 year</td>
<td>33% at 2 years</td>
</tr>
<tr>
<td>Lombardi 2013 STABLE Trial</td>
<td>N = 86 acute and chronic</td>
<td>29% at 1 year</td>
<td>33% at 1 year</td>
</tr>
<tr>
<td></td>
<td>STABLE / Petticoat</td>
<td>29% at 2 years</td>
<td>47% at 3 years</td>
</tr>
<tr>
<td>Brunkwall Adsorb trial 2014</td>
<td>N = 30 (acute uncomplicated)</td>
<td>37% @ 1 year</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

**Long Term Considerations**

**Reapproximation & TL Expansion**

**Conclusions**

- TEVAR & Petticoat for Type B aortic dissection are effective treatment modalities.
- STABLE 1 demonstrates promising 4 year mortality rates.
- Petticoat technique also shows more favorable remodeling of the abdominal aorta with more options for secondary intervention when needed.
- Long term failure in the abdominal aorta will be the next frontier in the management of TBAD.