Re-interventions after TEVAR: How often does it occur and what are procedures most commonly utilized to treat these issues?

Pacific Northwest Endovascular Conference
Seattle, WA
June 15, 2018
DISCLOSURE

Ronald Fairman

• No relevant financial relationship reported
Background: Challenges of analyzing TEVAR Outcomes in regard to re-interventions

- Heterogenous patient populations
- Expanding indications for diverse thoracic aortic pathologies: Degenerative DTA Vs PAU Vs TBAD Vs BTAI
- Elective Vs Emergency indications for both Acute Vs Chronic pathologies
- Changes in device iterations / technology over time
  - Lower profile $\rightarrow$ less peripheral vascular complications
  - Improved conformability $\rightarrow$ less Type I endoleaks
Pathology-specific secondary aortic interventions after thoracic endovascular aortic repair

Salvatore T. Scali, MD, Adam W. Beck, MD, Khayree Butler, MD, Robert J. Feezor, MD, Tomas D. Martin, MD, Philip J. Hess, MD, Thomas S. Huber, MD, PhD, Catherine K. Chang, MD

Journal of Vascular Surgery
Volume 59, Issue 3, Pages 599-607 (March 2014)
DOI: 10.1016/j.jvs.2013.09.050

![Diagram A: Initial TEVAR indications]

- CTBAD + Aneurysm: 14%
- Acute Dissection: 13%
- Other: 5%
- Penetrating ulcer: 12%
- Post-surgical: 4%
- Traumatic Transection: 6%
- TAA: 46%

![Diagram B: Rate of SAI by TEVAR Indication]

- Acute dissection: 21.3
- Post-surgical: 20
- CTBAD + Aneurysm: 16.7
- Other: 14.8
- TAA: 10.8
- Traumatic transection: 8.1
- Penetrating ulcer: 1.5
**Pathology-specific secondary aortic interventions after thoracic endovascular aortic repair**

Salvatore T. Scali, MD, Adam W. Beck, MD, Khayree Butler, MD, Robert J. Feezor, MD, Tomas D. Martin, MD, Philip J. Hess, MD, Thomas S. Huber, MD, PhD, Catherine K. Chang, MD

*Journal of Vascular Surgery*

Volume 59, Issue 3, Pages 599-607 (March 2014)

DOI: 10.1016/j.jvs.2013.09.050

---

SAI did not negatively affect long-term survival. Aortic pathology did!
The SUMMIT registry includes aggregated data of 521 TEVAR patients from five prospective, multicenter trials evaluating thoracic endografts of the Zenith platform.

Acute and Chronic TBAD are associated with a higher risk for re-intervention compared to BTAI, DTAA, and PAU.

Case complexity predictive of re-interventions

- Intraop contrast
- Blood transfusion
Single center series (192 patients) of TEVAR for DTAA (non-syndromic) with adherence to the IFU
- Mean follow-up of 69 ± 44 months
- Endovascular re-intervention in 14 patients (7.3%) for Types I, II, and III endoleak – all resolved.
- No open re-interventions required
- Late TEVAR durability (12 years) established for DTAA
- Outcomes not device related
5 year outcomes for DTAA

Secondary procedures were performed in 10 patients (7.5%), with seven procedures to correct Ia endoleak and one surgical conversion
5 year outcomes for DTAA

- **Re-intervention rate 7% (11 patients)** with 9 procedures for type I endoleak, 3 for aneurysm expansion, and 1 for rupture.

- Average time to re-intervention was **900 days**; all but one were performed after at least one year follow-up.
VALOR I Vs VALOR II trials for DTAA: TALENT Vs VALIANT devices
Endoleak Primary Reason for Secondary Procedures in Both Trials

- **VALOR I**: 21 of 25 secondary procedures (84%) attributable to endoleak (any type)
- **VALOR II**: 5 of 8 secondary procedures (63%) attributable to endoleak (any type)
Type I Endoleaks Most Frequently Led to Secondary Procedure in Both Trials

- **VALOR I**: 12 of 21 (57%)
- **VALOR II**: 4 of 5 (80%)
Incidence of all type Endoleaks Over 3 Years

- Total endoleak incidence (all types) through 3 years; VALOR I vs VALOR II

Through 1-month visit to 12-month visit

- VALOR I: 16.4%
- VALOR II: 17.9%
- VALOR II: 17.7%

>12-month visit to 24-month visit

- VALOR I: 12.0%
- VALOR II: 6.7%

>24-month visit to

- VALOR I: 14.7%
- VALOR II: 4.3%

* P<0.05

Incidence of all type Endoleaks Over 3 Years
Freedom from Secondary Procedures
VALOR I (3 year) and VALOR II (3 year)

\[ P = 0.03 \]
Composite-Freedom (Secondary Procedures, Surgical Conversions, and Ruptures): VALOR I vs VALOR II

\[ P = 0.02 \]
Conclusions

- Evolving commercial devices have the potential for reduced re-intervention rates for DTAA pathology:
  - Most dramatic improvements have occurred in first year
  - Endoleak (Type I) remains primary reason for re-intervention following TEVAR.
  - Lower profile devices and improved conformability may explain reduced re-intervention rates following TEVAR for DTAA,
  - Current device technology continues to yield higher re-intervention rates for acute and non-acute TBAD than DTAA, BTAI, and PAU; indicating the need for further evolution in pathology driven commercial technology.
The Journal of Thoracic and Cardiovascular Surgery

The mode of endograft failure was endoleak (n = 45, 61%). In 7 patients, 2 patients had a distal chimney endograft technique to the superior mesenteric artery, an infected aortic homograft in 1 patient, an arch chimney endograft stent (Cordis Corp, Miami Lakes, Fla) in the proximal landing zone for endoleak in 1 patient, and deployment of an Amplatz device in the arch for type II endoleak in 1 patient. In 2 patients, and deployment of a bare metal PALMAZ coil embolization for type II endoleak in 3 patients, proximal repair with frozen elephant trunk in 30-day mortality according to the mode of endograft failure are listed in Table 1.

### Table 1. Preoperative patient demographics

<table>
<thead>
<tr>
<th>Patient demographics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At index TEVAR</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>68 ± 13</td>
</tr>
<tr>
<td>Aortic pathologic features</td>
<td>680</td>
</tr>
<tr>
<td>Descending thoracic aortic aneurysm</td>
<td>381 (56%)</td>
</tr>
<tr>
<td>Type A dissection repair with FET</td>
<td>52 (8%)</td>
</tr>
<tr>
<td>Acute type B dissection</td>
<td>77 (11%)</td>
</tr>
<tr>
<td>Chronic type B dissection</td>
<td>34 (5%)</td>
</tr>
<tr>
<td>Arch hybrid repairs</td>
<td>46 (7%)</td>
</tr>
<tr>
<td>Traumatic transection</td>
<td>37 (5%)</td>
</tr>
<tr>
<td>Infection (mycotic, A-B-E fistula)</td>
<td>10 (1%)</td>
</tr>
<tr>
<td>Penetrating atherosclerotic ulcers</td>
<td>25 (4%)</td>
</tr>
<tr>
<td>Other</td>
<td>18 (3%)</td>
</tr>
</tbody>
</table>

The preoperative patient characteristics and indications for endograft repair, the procedures included additional open surgical repair in 20. In the 60 patients who underwent endovascular repair, the procedures included repair of retrograde type A aortic dissection in 34, respectively (7/80). The reintervention and early outcomes were required. The modes of endograft failure are listed in Table 1.
Reintervention Rate by Type of Index Procedure

<table>
<thead>
<tr>
<th>Index pathologic indication for TEVAR</th>
<th>Reintervention rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All causes</td>
<td>80/680 (11.7%)</td>
</tr>
<tr>
<td>Descending thoracic aneurysm</td>
<td>46/381 (12%)</td>
</tr>
<tr>
<td>Type A dissection</td>
<td>13/52 (25%)</td>
</tr>
<tr>
<td>Acute type B dissection</td>
<td>11/77 (14%)</td>
</tr>
<tr>
<td>Chronic type B dissection</td>
<td>4/34 (12%)</td>
</tr>
<tr>
<td>Arch hybrid</td>
<td>1/46 (2%)</td>
</tr>
<tr>
<td>Traumatic transaction</td>
<td>2/37 (5%)</td>
</tr>
<tr>
<td>Infection (mycotic, A-B-E fistula)</td>
<td>2/10 (20%)</td>
</tr>
<tr>
<td>PAU</td>
<td>0/25 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>1/18 (6%)</td>
</tr>
</tbody>
</table>
Reason for Re-Intervention (80/680)

<table>
<thead>
<tr>
<th>Modes of failure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoleak</td>
<td>45 (56%)</td>
</tr>
<tr>
<td>Type I</td>
<td>24</td>
</tr>
<tr>
<td>Type II</td>
<td>5</td>
</tr>
<tr>
<td>Type III</td>
<td>9</td>
</tr>
<tr>
<td>Multiple or unclear origin</td>
<td>7</td>
</tr>
<tr>
<td>Proximal aortic events</td>
<td>11 (14%)</td>
</tr>
<tr>
<td>Retrograde type A dissection</td>
<td>9</td>
</tr>
<tr>
<td>Aneurysmal degeneration</td>
<td>2</td>
</tr>
<tr>
<td>Distal aortic events (dissection/expansion)</td>
<td>15 (18%)</td>
</tr>
<tr>
<td>Multiple failure modes</td>
<td>4 (5%)</td>
</tr>
<tr>
<td>Endograft infection</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Other (carotid occlusion, stent collapse)</td>
<td>2 (3%)</td>
</tr>
</tbody>
</table>
Re-Interventions

1. Endovascular TEVAR (n=55)
   - 52 adjunct TEVAR
     - 1 aortic bare metal stent
     - 1 TEVAR LCC “Snorkle” endograft
     - 1 TEVAR with additional amplatz to LSC, simultaneous EVAR

2. Open repair (n=18) 22%
   - 16 open re-operations incorporating new or prior stent graft
     - 9 Retrograde Type A Repairs (hemi or total arch sewn to stent)
       - 1 Arch Debranching w/ Additional TEVAR
       - 1 Total Arch replacement sewn to stent graft
     - 3 Visceral artery Debranchings w/ new TEVAR graft
     - 2 Distal TAAA w/ dacron graft sewn to previous stent graft

3. Other (n=7)
   - 1 Amplatz device
   - 3 Branch artery coil embolization
   - 2 Re-ballooned TEVAR graft
   - 1 ascending aorta to Left Common Carotid bypass
Outcomes By Open Vs Endo Reintervention

<table>
<thead>
<tr>
<th>Complication</th>
<th>Total (n = 80)</th>
<th>Open (n = 20)</th>
<th>Endovascular (n = 60)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-d Mortality</td>
<td>7 (8.7%)</td>
<td>3 (15%)</td>
<td>4 (6.7%)</td>
<td>.35</td>
</tr>
<tr>
<td>Reoperation for bleeding</td>
<td>2 (2.5%)</td>
<td>1 (5%)</td>
<td>1 (1.7%)</td>
<td>.43</td>
</tr>
<tr>
<td>Permanent paraplegia/paraparesis</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Temporary paraplegia/paraparesis</td>
<td>2 (2.5%)</td>
<td>0 (0%)</td>
<td>2 (3.3%)</td>
<td>1</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (1.3%)</td>
<td>0 (0%)</td>
<td>1 (1.7%)</td>
<td>1</td>
</tr>
<tr>
<td>Renal failure</td>
<td>7 (8.7%)</td>
<td>3 (15%)</td>
<td>4 (6.7%)</td>
<td>.35</td>
</tr>
<tr>
<td>Renal failure requiring dialysis</td>
<td>4 (5%)</td>
<td>3 (15%)</td>
<td>1 (1.7%)</td>
<td>.04</td>
</tr>
</tbody>
</table>
Overall Survival

Re-interventions
No Re-intervention

N at risk
80
59
31
17
1
4

P=.29  No statistical difference
Conclusions

- Re-intervention after TEVAR is not uncommon (11% in our series)
- Does not negatively impact on long term survival.

- Although most secondary interventions will be endovascular, a variety of open techniques will be indicated for definitive repair.
  - Stent graft incorporation
  - Stent graft explant