Select Type I and III Endoleaks at the Completion of Fenestrated EVAR are Safe to Observe

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Disclosures

Abbott, Cook, Endologix, Medtronic, Silk Road
Background

• Endoleak after EVAR
  – Type I and III endoleaks
    • Associated with conversion to open repair, rupture, and mortality
  – Technical Failure
    • SVS Reporting Standards classify type I and III endoleaks on completion angiogram as a technical failure
  – Common
    • 3 – 16% of EVAR
    • The majority resolve spontaneously
Endoleaks after FEVAR

- Type Ia
- Type Ic
- Type IIIa
- Type IIIb
Aims

• Characterize the natural history of completion type I and III endoleaks after FEVAR

• Identify patient characteristics associated with completion endoleak
  – Demographics / comorbidities
  – Anatomic
  – Graft design
Methods

• Study Design:
  – Retrospective cohort study
  – Single-center experience
  – All patients undergoing FEVAR with the Zenith Fenestrated AAA Endovascular Graft (ZFEN; Cook Medical, Bloomington, IN)
  – Exposure variable: presence of type I or III completion endoleak
ZFEN Device

Fenestrated Component
- Scallop
- Sealing Stent
- Small Fenestration
- Tapered Stent
- Overlap Stents

Bifurcated Component
- Overlap Stents
- Contralateral Limb
- Ipsilateral Limb

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Methods

• Endoleak Management
  – Small, slow type I and III endoleaks routinely observed
  – Large, brisk endoleaks undergo further intervention
    • Remolding
    • Iliac extension
    • Placement of aortic cuff
Methods

• Outcomes:
  – Primary Outcome: Presence of type I or III endoleak on initial postoperative CTA

• Secondary Outcomes:
  – Perioperative mortality/complications
  – Late/recurrent type I or III endoleaks
  – Reintervention rate
  – Sac regression at one-year
Results

• Patients
  – 53 patients from 2013 to 2018

• Graft design
  – 146 visceral vessels targeted
    • 103 fenestrations and 43 scallops
    • 100 renal arteries, 46 superior mesenteric arteries
  – 145 / 146 target vessels successfully incorporated
    • One main right renal artery lost secondary to cannulation of an accessory renal artery
Results

• Completion Endoleaks
  – 31 (60 %) type I or III endoleaks after implantation of all devices
    • Further intervention in 12 patients
    • 3 endoleaks resolved completely
  – 28 patients (54 %) with type I or III endoleak on completion angiogram
## Results

- **Source of completion endoleak**

<table>
<thead>
<tr>
<th>Location</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main body and bifurcate or bifurcate and iliac limb</td>
<td>13</td>
<td>46</td>
</tr>
<tr>
<td>Ia or main body and renal</td>
<td>9</td>
<td>32</td>
</tr>
<tr>
<td>Bifurcate and iliac limb</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Ib</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>1a or main body and renal AND main body AND bifurcate</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Ic (from large unstented renal fenestration)</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>
### Demographics and Comorbidities

<table>
<thead>
<tr>
<th></th>
<th>Completion Endoleak N = 28</th>
<th>No Completion Endoleak N = 24</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>75.4 ± 8.9</td>
<td>75.0 ± 7.5</td>
<td>.57</td>
</tr>
<tr>
<td>Male</td>
<td>68 %</td>
<td>83 %</td>
<td>.20</td>
</tr>
<tr>
<td>White Race</td>
<td>92 %</td>
<td>91 %</td>
<td>.93</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.8 ± 5.3</td>
<td>27.8 ± 5.3</td>
<td>.26</td>
</tr>
<tr>
<td>Hypertension</td>
<td>89 %</td>
<td>79 %</td>
<td>.31</td>
</tr>
<tr>
<td>GFR (mL/min/1.73m²)</td>
<td></td>
<td></td>
<td>.51</td>
</tr>
<tr>
<td>&gt;60</td>
<td>61 %</td>
<td>75 %</td>
<td></td>
</tr>
<tr>
<td>30 – 60</td>
<td>32 %</td>
<td>25 %</td>
<td></td>
</tr>
<tr>
<td>&lt; 30</td>
<td>4 %</td>
<td>0 %</td>
<td></td>
</tr>
<tr>
<td>Dialysis-dependent</td>
<td>4 %</td>
<td>0 %</td>
<td></td>
</tr>
<tr>
<td>Smoking Status</td>
<td></td>
<td></td>
<td>.09</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>25 %</td>
<td>29 %</td>
<td></td>
</tr>
<tr>
<td>Former Smoker</td>
<td>57 %</td>
<td>71 %</td>
<td></td>
</tr>
</tbody>
</table>
# Procedural Characteristics

<table>
<thead>
<tr>
<th>Graft Design</th>
<th>Completion Endoleak N = 28</th>
<th>No Completion Endoleak N = 24</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenestrated Graft Diameter (mm)</td>
<td>30.0 ± 3.4</td>
<td>29.7 ± 3.3</td>
<td>.72</td>
</tr>
<tr>
<td>Number of target vessels</td>
<td>3 [3-3]</td>
<td>3 [3-3]</td>
<td>.54</td>
</tr>
<tr>
<td>Right renal stent diameter (mm)</td>
<td>6.1 ± 0.5</td>
<td>6.3 ± 0.6</td>
<td>.24</td>
</tr>
<tr>
<td>Left renal stent diameter (mm)</td>
<td>6.2 ± 0.5</td>
<td>6.3 ± 0.5</td>
<td>.39</td>
</tr>
<tr>
<td>Degree of oversizing (%)</td>
<td>18 ± 9</td>
<td>18 ± 6</td>
<td>.88</td>
</tr>
<tr>
<td>On Instructions for Use</td>
<td>58 %</td>
<td>70 %</td>
<td>.36</td>
</tr>
</tbody>
</table>
## Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Completion Endoleak (n = 28)</th>
<th>No Completion Endoleak (n = 24)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anatomy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck length (mm)</td>
<td>9 ± 7</td>
<td>11 ± 8</td>
<td>.34</td>
</tr>
<tr>
<td>Neck diameter (mm)</td>
<td>26 ± 3</td>
<td>25 ± 3</td>
<td>.57</td>
</tr>
<tr>
<td>Alpha angle (degrees)</td>
<td>23 ± 12</td>
<td>19 ± 12</td>
<td>.29</td>
</tr>
<tr>
<td>Beta angle (degrees)</td>
<td>30 ± 14</td>
<td>21 ± 17</td>
<td>.84</td>
</tr>
<tr>
<td>Extensive Neck Calcification</td>
<td>23 %</td>
<td>23 %</td>
<td>.98</td>
</tr>
<tr>
<td><strong>Procedural Anticoagulation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ACT (sec)</td>
<td>249 ± 25</td>
<td>248 ± 18</td>
<td>.95</td>
</tr>
<tr>
<td>Final ACT (sec)</td>
<td>258 [229 – 279]</td>
<td>258 [233 – 274]</td>
<td>.73</td>
</tr>
</tbody>
</table>
Results

• Endoleak Resolution
  – 27 of 28 completion endoleaks resolved spontaneously
    • One completion type Ia/III endoleak persisted on the initial postoperative CTA
    • Underwent continued observation
    • Type Ia/III endoleak resolved on the 6-month scan
      – Persistent type II endoleak
      – Sac diameter: 61 mm to 57 mm
Results

• Endoleak Resolution
  – One patient without a completion endoleak had a type Ia endoleak on initial postoperative CTA
    • Graft infolding
    • Treated with placement of a Palmaz stent and endoanchors
Results

• Outcomes
  – Perioperative mortality: 1.9 %
  – Any Perioperative complication: 19 %

• No difference between patients with and without completion endoleaks
Mid-term Results

- Median Follow-up: 269 days
- No late/recurrent type I or III endoleaks
- Reintervention
  - 8 Reinterventions
  - No difference between groups in 1-year freedom-from reintervention
    - Completion endoleak: 91%
    - No completion endoleak: 85%
Mid-term Results

• Sac Status
  – Sac regression at 1-year: no difference
    • Completion endoleak: 47%
    • No completion endoleak: 35%
  – One patient with sac expansion at 3-years secondary to type II endoleak
    • No evidence of type I or III endoleak
    • Underwent transcaval embolization, stabilized
Limitations

• Single-center, high volume experience
• Subjective endoleak evaluation
  – No technique for intraoperative quantification
  – Future research/develop
  – Possible roll for on-table cone-beam CT
• Limited long-term follow-up
Conclusions

• Select completion type I and III endoleaks following FEVAR resolve spontaneously
  – If properly selected, these endoleaks are safe to observe

• Late/recurrent type I and III endoleaks are potentially dangerous
  – Most require prompt treatment
  – These patients require consistent long-term follow-up with routine surveillance