Dealing with edge stenosis and outcomes of failed endografts

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Disclosure

Speaker name: Michel Reijnen

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Complex Infrainguinal arterial occlusive disease

- Endovascular treatment is replacing the surgical femoro-popliteal bypass for extensive lesions in the superficial femoral artery
- Vulnerable patients with multiple co-morbidities
- Surgery related to a 30-day morbidity rate of 38%
- Endovascular results are improving;
  - PTX-based techniques
  - Covered stents

*Van de weijer et al. Semin Vasc Surg 2015;28:112-121*
Results of nitinol are limited by in-stent re-stenosis
Rationale of covered stents

- Likely to reduce the incidence of re-stenosis
- Focal edge stenosis:
  - incidence independent of lesion length
  - Easier to treat compared to diffuse ISR
Case example
Rationale of covered stents

Prospective Randomized or Prospective Multi-Center (> 2 sites) SFA studies included. Registry studies not included. Patency definitions may vary: where Kaplan-Meier estimates with a PSVR of ≥ 2.5 are available, these were used for comparison. P-values indicate results of t-test on slope of weighted linear regression compared to zero. Note that McQuade et al, 2010 reported stented length, not lesion-length.
Focal edge stenosis are the ‘Achilles heel’ of endoluminal bypasses
Prevention of edge stenosis is key for success

- Proper sizing $\rightarrow$ no or minimal oversizing
- Covering from ‘healthy to healthy’
- No dilatation outside stent-graft
- Low-pressure ballooning at the edges (2 bar)
- Appropriate postoperative medication

VIPER study; Device oversizing assessed by independent Core Lab, data on file
Treatment of edge stenosis

- Three center retrospective study
- Cohort of 341 patients
- Treated between November 2001 and December 2011
- 88 patients with 115 primary edge stenoses
  - Age 66±10 years
  - Male 73%

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Current smoking</td>
<td>43</td>
<td>49%</td>
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<tr>
<td>Hyperlipidemia</td>
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<tr>
<td>Diabetes mellitus</td>
<td>34</td>
<td>39%</td>
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<td>Hypertension</td>
<td>70</td>
<td>80%</td>
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<tr>
<td>Renal Failure</td>
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<td>15%</td>
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<tr>
<td>Pulmonary disease</td>
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<td>19%</td>
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<tr>
<td>Coronary artery disease</td>
<td>37</td>
<td>42%</td>
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<tr>
<td>Cerebrovascular disease</td>
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<td>10%</td>
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</table>

<table>
<thead>
<tr>
<th>Lesion length</th>
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<tr>
<td>TASC-II classification</td>
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</tr>
<tr>
<td>A</td>
<td>11</td>
<td>(13%)</td>
</tr>
<tr>
<td>B</td>
<td>19</td>
<td>(22%)</td>
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<tr>
<td>C</td>
<td>32</td>
<td>(36%)</td>
</tr>
<tr>
<td>D</td>
<td>26</td>
<td>(30%)</td>
</tr>
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Treatment of edge stenosis

- 67% occurred within the first 12 months after insertion of the endograft

- Mean time from insertion of endograft to detection of edge stenosis was $10.7 \pm 8.2$ months

- 41% presented with an occluded endograft

- 63% of edge stenoses were located at the proximal and 37% at the distal edge and no in-stent stenosis observed

Treatment of edge stenosis

Used treatment options:

• PTA in 66% of which 49% presented with an occlusion (treated with thrombolysis)

• Viabahn extension in 13% of which 71% presented with an occlusion (treated with thrombolysis)

• No treatment in 19% due to renal dysfunction, or the wish of the patient, due to lack of symptoms or terminal illness

Treatment of edge stenosis

- 1-year patency rate after treatment
  - PTA 81%
  - Viabahn extension 92%

- The 2-year incidence of re-stenosis and/or occlusion
  - PTA 55%
  - Viabahn extension 43%

- No major amputations required

Treatment of occluded endografts

- Same cohort of 341 patients
- 46 patients with an acute occlusion treated with thrombolysis or thrombectomy
- 89% of thromboses occurred within the first year
- Median time from insertion to primary thrombosis was 3 months (range 0–53)
- Rutherford category:
  - I n=12
  - IIa n=19
  - IIb n=9

Thrombolysis (n=40):
- Complete lysis was achieved in 38/40 patients (95%)
- Treatment time 24 hours (range 3–48)
- No anatomical cause of the occlusion in 23%
- 6 minor complications

Thrombectomy (N=6):
- Successful in 6/6 patients
- Treatment time 90 minutes (range 55–136)
- 6 minor complications
Treatment of occluded endografts

- Thrombolysis at 6 months
  - Primary patency: 56%
  - Secondary patency: 68%

- Thrombectomy at 6 months
  - Primary patency: 67%
  - Secondary patency: 67%

- 3 patients (7%) eventually required a major amputation

Outcome of definitive failure

• 49/341 patients with final failure during FU
• ABI was significantly lower at the time of failure (0.66± 0.19 versus 0.45 ± 0.19)
• Clinical consequences
  – Pre-treatment Rutherford 3.1 ± 1.3
  – Post-failure Rutherford 3.3 ± 0.6
  – 80% presented with the same or even an improved Rutherford category
• 76% needed secondary surgery
  – 25% BK bypass
  – 1-year primary patency rate  55.1%
  – 1-year secondary patency rate 77.7%
• Amputation rate: 4.1% (n=2)

Conclusions

- Failure of endografts could potentially be avoided by:
  - Avoiding excessive oversizing
  - Treat all disease
  - Not ballooning outside the endograft
- Edge stenosis and occlusions mostly occur within the first year and aggressive surveillance is indicated
- Edge stenosis can effectively be treated by PTA and endograft extension
- Endograft extension appears to be more effective but there is room for improvement (DCB?)
- Occlusions do occur and about 65-70% of these endografts can be preserved
- Failures are not related to a high amputation rate
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