Approaching the challenge of the complex SFA lesion – a data driven approach

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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
What do the guidelines say?

**ESVS guidelines**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>An endovascular-first strategy is recommended in short (i.e. &lt;25 cm) lesions.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Primary stent implantation should be considered in short (i.e. &lt;25 cm) lesions.</td>
<td>IIa</td>
<td>A</td>
</tr>
<tr>
<td>Drug-eluting balloons may be considered in short (i.e. &lt;25 cm) lesions.</td>
<td>IIb</td>
<td>A</td>
</tr>
<tr>
<td>Drug-eluting stents may be considered for short (i.e. &lt;25 cm) lesions.</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td>Drug-eluting balloons may be considered for the treatment of in-stent restenosis.</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td>In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥ 25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is &gt; 2 years.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein.</td>
<td>IIa</td>
<td>A</td>
</tr>
<tr>
<td>In patients unfit for surgery, endovascular therapy may be considered in long (i.e. ≥ 25 cm) femoro-popliteal lesions.</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

Surgery is only recommended in lesions longer than 25 cm in patients not at high operative risk.
Endovascular strategies

• Plain balloon angioplasty

• Nitinol stents

• Paclitaxel-based therapy;
  • Drug-coated balloons
  • Drug-eluting stents

• Self-expandable covered stents
Why using SE covered stents?

- Avoid the occurrence of in-stent re-stenosis
- Reduce re-stenosis to a focal edge stenosis:
  - Easy to treat
  - Incidence independent of lesion length
- Clinical data are encouraging
VIPER trial

- Prospective single arm trial
- 119 patients included
- Mean lesion length: 19cm
- CTO: 56%

Results
- 12-month primary patency: 73%

Sizing is Critical
- Primary patency is significantly better when IFU sizing is not exceeded at the proximal edge

VIASTAR trial

- Prospective, physician-initiated trial
- Randomized VSX vs BMS
- Patients enrolled: 72 vs 69
- Mean lesion length: 19cm vs. 17cm
- CTO: 79% vs 70%

Significantly higher primary patency results using covered compared to BMS. This improvement is even greater in long, complex lesions

SUPERB trial

- Prospective, randomized trial
- VSX vs Open surgery (vein/prosthetic)
- Patients enrolled 63 vs. 62
- mean lesion length 23cm vs. 23cm
- CTO: 75% vs 80%

Results
- Less morbidity
- Similar technical results
- Quicker improvements in QOL

Additional insights:
- Time to first TVR 3.0 (1-10) months in surgical vs. 7.0 (2.5-14.5) months in endoluminal group (p=0.035)
- Concomitant endarterectomy, was a significant but modest predictor for prevention of occlusion

Similar patency and TLR rates compared to the femoro-popliteal bypass through 24 months FU
RELINE trial

- Prospective, Randomized trial
- Comparing VSX vs PTA
- 39 vs 44 patients included
- Mean lesion length: 17cm vs 19cm
- CTO: 23% vs 25%

Superior primary patency in the Viabahn Endoprosthesis group compared to PTA
RELINE trial

- Prospective, Randomized trial
- Comparing VSX vs PTA
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Superior primary patency in the Viabahn Endoprosthesis group compared to PTA

Japanese experience

**Japan IDE study**
Single-arm, prospective, multicenter study

- 103 patients
- Follow-up out to 5 years

**Vanquish**
Single-arm, Physician initiated, prospective, multicenter study

- 371 patients
- Follow up out to 1Y

**Japan Post Market Study**
Single-arm, prospective, multicenter, post-market surveillance study

- 321 patients
- Follow up out to 1Y

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Japan IDE trial

- Single-arm, prospective
- 103 patients
- Mean lesion length: 22 cm
- CTO: 66%

- Used learnings from VIPER for sizing recommendations
Japan IDE trial

79.1% freedom from TLR at 5-years

- Through 5-years:
  - 79.1% freedom from TLR
  - 100% limb salvage with no acute limb ischemia, amputations or stent fractures

- Proper technique, including appropriate sizing, drives good outcomes

Data on file 2020; W. L. Gore & Associates, Inc.; Flagstaff, AZ.
5 Year manuscript accepted by JVS May 2021
VANQUISH trial

• Physician initiated, prospective, multicenter study

• Enrolled 424 limbs of 371 patients treated with a Viabahn stent-graft placement in the Femoro-popliteal artery

• Purpose:
  • 1-year patency outcomes in real-world setting
  • Evaluating the role of hypercoagulability

<table>
<thead>
<tr>
<th>Angiographic assessment</th>
<th>TASC II class</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>8 (1.9)</td>
</tr>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>27 (6.4)</td>
</tr>
<tr>
<td></td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>174 (41.1)</td>
</tr>
<tr>
<td></td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>214 (50.6)</td>
</tr>
</tbody>
</table>

| Proximal RVD, mm        | 5.7±1.0      |
| (missing data)          | 15 (3.5)     |
| Distal RVD, mm          | 5.1±0.9      |
| (missing data)          | 13 (3.1)     |
| Lesion length, cm       | 26±11        |
| Chronic total occlusion | 303 (71.6)   |
| Occlusive length, cm    | 13±14        |
| (missing data)          | 1 (0.2)      |

VANQUISH trial

- A full-coverage stent-graft was selected in 343 limbs (81.1%), whereas the remaining 80 limbs (18.9%) underwent spot implantation.
  
<table>
<thead>
<tr>
<th>1-year primary patency</th>
<th>Full-coverage group 80.3%</th>
<th>Spot-coverage group 68.0% (p=0.025)</th>
</tr>
</thead>
</table>

- A smaller vessel size was significantly associated with loss of patency.
- The prothrombotic state was not associated with loss of patency.
Japan PMS

- A prospective, multicenter, post-market surveillance study
- 321 patients
- Mean lesion length: 23.6 cm
- CLI: 26.5%
- CTO: 70%

12M primary patency: 85.6%
12M fTLR: 92.3%
Most studies focus in intermittent claudication

Viastar trial 14%
SuperB trial 31%
Viabahn in chronic limb threatening ischemia

Design and baseline data

- Individual patient data meta-analysis
- Heparin-bonded Viabahn for femoropopliteal disease treated for CLI
- **7 participating studies**, including **161 limbs**
  - Rutherford 4  n=59 (37%)
  - Rutherford 5  n=86 (53%)
  - Rutherford 6  n=16 (10%)
- Age 75±9 years and 65% with male gender
- Anatomical characteristics
  - Lesion length  28 cm (IQR 25-33 cm)
  - CTO  83%
  - TASC C/D  93%
Viabahn in chronic limb threatening ischemia

Procedural data and clinical outcomes

- Technical success 93%
- Most patients treated with 1 or 2 endografts with 6 mm the most common diameter
- Hospital stay 3 days (IQR 2-7 days)
- 30-day mortality 2%
Viabahn in chronic limb threatening ischemia

Survival and reinterventions


2-year survival 78%

2-year freedom from reinterventions 62%
Viabahn in chronic limb threatening ischemia

Technical and amputation outcomes

2-year patency rates:
- Primary 60%
- Assisted primary 63%
- Secondary 86%

2-year freedom from:
- Minor amputation 95%
- Major amputation 99%

Summary

• Self-expanding covered stents perform well in complex and long SFA lesions

• Smaller vessel size, excessive oversizing and spot stenting negatively impact the outcomes

• Studies have demonstrated;
  • A better performance compared to bare metal stents
  • A similar technical outcome compared to femoro-popliteal bypass surgery with faster recovery

• Self-expanding covered stents can also be safely used in patients with chronic limb threatening ischemia
Literature-based best practices

Device sizing considerations
- Treat all of the disease (stent “normal to normal”)
- Overlap devices by at least 1 cm
- Avoid excessive oversizing (> 20 percent)

Procedural considerations
- Ensure adequate inflow and outflow
- Post dilate
- Do not use balloon angioplasty outside of the device
- Place device at the SFA origin if proximal SFA disease is present

Follow-up considerations
- Regular duplex ultrasonography follow-up
- Prescribe appropriate antiplatelet therapy
- Treat progressing disease
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