Outcomes and evidence of the covered self-expandable stents for the treatment of critical limb ischemia patients

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Disclosure

Speaker name:
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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
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
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

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 in CLI patients
- 7 participating studies, including 161 limbs treated for CLI
  - 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 commonly used 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

• Endovascular treatment is currently advocated for most femoropopliteal disease

• Heparin-bonded engrafts outperform bare metal stents in long lesions and outcomes are comparable to bypass surgery

• Heparin-bonded endografts provide good clinical and reasonable technical outcomes in patients with CLTI, with low amputation rates

• Re-interventions are common and close surveillance is therefore indicated
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