Do Drug Eluting Balloons And Stents Promise Anything Extra Compared To Plain Old Balloon Angioplasty For Wound Patients?

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SESSION 18: VASCULAR INTERVENTIONS IN WOUND CARE
Veith Symposium
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No disclosures

‘Critical limb ischaemia’
Definition and problems in the foot in diabetes

TASC II
“should be used for all patients with chronic ischaemic rest pain, ulcers or gangrene attributable to objectively proven arterial occlusive disease”

In any patient with diabetes and ulceration of the foot PAD is likely to be only one aetiological factor

Issues for Endovascular Revascularisation

• Cross the lesion
• Create a lumen
• Maintain patency

Heal the wound and prevent amputation

Revascularisation in general
UK vascular practice

• St George’s Vascular Institute 16 months
• 342 patients CLI undergoing revascularisation
• 19.9% (68/342) iliac disease
• 61.4% (201/342) femoropopliteal
• 22.2% (76/342) crural
• 3.2% (11/342) pedal

Overall 257 (75.1%) underwent angioplasty on their first admission

Technical feasibility of angioplasty in patients with diabetes and CLI


Faglia E. Eur J Vasc Endovasc Surg. 2005;29:420-7
**Infrapopliteal angioplasty**

- Technical success 89%
- 1 month
  - 1st patency 77.4%
  - 2nd patency 83%
  - Limb salvage 93.4%
- 36 months
  - 1st patency 48.6%
  - 2nd patency 62.9%
  - Limb salvage 82.4%

**Limb salvage and wound healing following revascularisation in diabetes**

- **Limb salvage**
  - 1-year 85% (80-90%) open surgery
  - 1-year 76% (72-78.5%) endovascular

- **Wound healing poorly reported**
  - >80% at 1-year in all studies

**PTA versus stenting below the knee**

Two randomized controlled trials failed to show the superiority of primary infrapopliteal stenting over balloon angioplasty alone


**Drug eluting technology**

- Local delivery of anti-proliferative drugs to the vessel wall
  - Sirolimus / everolimus
  - Paclitaxel

- Drug eluting stents (DES)
- Drug eluting balloons (DEB)

**What is the evidence for drug eluting technology?**

- January 2013
- 26 studies (different technologies / indications)
- 11 RCTs
- 2 cohort with controls
- 2407 limbs

**Studies**

- Drug eluting balloon
  - Infraoplitreal
  - Femoropopliteal

- Drug eluting stent
  - Infraoplitreal
  - Femoropopliteal
Infrapopliteal DEBs
- 1 study (RCT)
- 109 limbs, 83% CLI
- 77% occlusions, mean length 176mm
- Procedural success 96%
- 3 months
- Primary patency 73%
- Limb salvage 96%
- Wound healing 74%

Femoropopliteal DEBs
- 4 studies
- 242 limbs
- 91% technical success
- 11 months follow-up
- TLR 8%
- Limb salvage meaningless (claudication)

Femoropopliteal DES
- 5 studies
- 1174 limbs
- 93% technical success
- 11 months follow-up
- TLR 10%
- Limb salvage 89% (of those with CLI)

Meta-analysis DEBs versus PTA

Binary re-stenosis

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<thead>
<tr>
<th>Odds Ratio</th>
<th>M-H Fixed, 95% CI</th>
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<td>0.21 [0.11, 0.44]</td>
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Major amputation

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<th>Odds Ratio</th>
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<td>1.32 [0.80, 2.19]</td>
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Meta-analysis DES versus BMS

Binary re-stenosis

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<th>Odds Ratio</th>
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Amputation

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<th>Odds Ratio</th>
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<td>0.69 [0.33, 1.44]</td>
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Are we going to get the evidence we need in BTK with DEBs?

- **Debate-BTK** (November 2013)
  - Binary restenosis; interim results 27% DEB versus 56% SPTA
- **IN.PACT DEEP** (August 2017)
  - Primary restenosis rate at 3 months 31% DEB versus 69% SPTA
- **EUROCANAL** (temporarily stopped recruiting)
  - Primary outcome measure amputation free survival

Conclusions - drug eluting technology

- Early angiographic results suggest beneficial effects of drug eluting technology
- Not reflected in clinical outcomes yet (wound healing)
- **NICE** – only as part of a clinical trial
- Larger more carefully designed trials needed
  - When drug eluting technology is best utilised
  - DES v DEB
  - Anti-platelet therapy?