Case presentation

The use of DES in CLI

Yann Gouëffic, MD, PhD
Department of vascular surgery, institut du thorax, Nantes, France
Disclosures

Y. Gouëffic reports:

- **Research funding** from Bard, Medtronic, Terumo, WL Gore

- **Personal fees and grants** from Abbott, Bard, Biotronik, Boston Scientific, Medtronic, Terumo, Vygon, WL Gore (medical advisory board, educational course, speaking)
Patient history

Female, 62 y

Symptomatology: CLI of the right foot (Rutherford 5)

Medical history
- Dislipidemia, HTA, active smoking and diabetes
- Peripheral arterial disease
- Coronaropathy
- Chronic renal failure
- Few days ago a transmetatarsal amputation of the first right toe

Duplex scan: popliteal lesions of the right limb

CT scan /MRI: No
Transmetatarsal amputation of the 1st toe without revascularization
Treatment options

Medical treatment alone
Major amputation
Open Surgery
Endovascular therapy
Strategy of endovascular repair

1st: to improve the inflow
   - Iliac and femoral lesions
      - could be sufficient
      - R4

2nd: to treat infrapopliteal lesions
      R5-6

Angiosome is an anatomic unit of tissue fed by a source artery and drained by specific veins.
Angiosome-targeted Lower Limb Revascularization for Ischemic Foot Wounds: Systematic Review and Meta-analysis

F. Biancari *, T. Juvonen
Department of Surgery, Oulu University Hospital, Oulu, Finland

WHAT THIS PAPER ADDS
The efficacy of angiosome-targeted revascularization to achieve healing of ischemic tissue lesions of the foot and limb salvage is controversial. The results of this meta-analysis suggest that, when feasible, direct revascularization of the foot angiosome affected may improve wound healing and limb salvage rates compared with indirect revascularization.

Biancari, Eur J Vasc Endovasc Surg, 2014
Treatment options for P2-P3 and tibial arteries lesions

- POBA
- Primary BMS
- Primary DES
- DCB
- Atherectomy
- Others...
ETAP-Primary Patency at 12 months

Figure 2. Rates of primary patency at 1 year. Shown are patency rates based on the intention-to-treat analysis (ITT: type 1-in.

Patency at 2 years:
64% for primary stent versus
56% for PTA with provisional stent.

25% of PTA group received bailout stents
DCB RCTs have excluded P2-P3 lesions

<table>
<thead>
<tr>
<th></th>
<th>IN-PACT SFA</th>
<th>LEVANT 2</th>
<th>ILLUMINATE RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severe Ca</strong></td>
<td>Exclusion</td>
<td>Exclusion</td>
<td>Exclusion</td>
</tr>
<tr>
<td><strong>Rutherford</strong></td>
<td><strong>2-4</strong></td>
<td><strong>2-4</strong></td>
<td><strong>2-4</strong></td>
</tr>
<tr>
<td><strong>stages</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td>4-18 cm length or occlusion with lengths of ≤10 cm</td>
<td>≤15 cm</td>
<td>3-20 cm</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>Superficial femoral and proximal popliteal arteries</td>
<td>Superficial femoral or popliteal artery*</td>
<td>Superficial femoral or popliteal artery</td>
</tr>
</tbody>
</table>

* terminates distally 2 cm below the tibial plateau AND ≥1 cm above the origin of the TF trunk
DES RCTs have excluded P2-P3 lesions

<table>
<thead>
<tr>
<th></th>
<th>ZILVER PTX</th>
<th>IMPERIAL</th>
<th>BATTLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Ca**</td>
<td>/</td>
<td>Exclusion</td>
<td>/</td>
</tr>
<tr>
<td>Rutherford stages</td>
<td>2-6</td>
<td>2-4</td>
<td>2-5</td>
</tr>
<tr>
<td>Length</td>
<td>≤14 cm</td>
<td>3-14 cm</td>
<td>2-14 cm</td>
</tr>
<tr>
<td>Location</td>
<td>Above-the-knee femoropopliteal artery</td>
<td>Superficial femoral artery or proximal popliteal artery</td>
<td>SFA, the proximal popliteal artery (P1), or both</td>
</tr>
</tbody>
</table>

Available DES diameters for femoropopliteal lesions:
- Zilver® PTX®: 5-8 mm
- Eluvia®: 6-8 mm
Drug coating balloon-RCT: IMPACT DEEP

Paclitaxel coated balloon vs. PTA in patients with CLI and infrapopliteal revascularization

**IMPACT DEEP Multi center Randomized Trial**
- 358 patients
- R3 to 6
- Avg lesion length ~100 to 120-mm
- Ily endpoints: LLL and TLR

No level I evidence for using DCB as a first line of treatment for BTK lesions

**LLL: NS / TLR: NS**

Zeller, JACC, 2014
Randomized Trials for Endovascular Treatment of Infrainguinal Arterial Disease: Systematic Review and Meta-analysis (Part 2: Below the Knee)

S. Jens a,⁎, A.P. Conijn b, M.J.W. Koelemay b, S. Bipat a, J.A. Reekers a

a Department of Radiology, Academic Medical Center, Amsterdam, The Netherlands
b Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands

WHAT THIS PAPER ADDS
Endovascular treatment of patients with critical limb ischemia should preferably be done using balloon angioplasty with optional bailout stenting for below-the-knee arterial lesions. The use of drug-eluting balloons in these patients, especially diabetic patients, seems promising, but more studies focusing on clinical outcomes are needed before this strategy can be implemented into standard clinical care. Bare stents, when bailout stenting is indicated, are recommended over drug-eluting stents, as trials have not shown clinically significant differences.
Primary stenting versus POBA

### 6 mo TLR

<table>
<thead>
<tr>
<th>Study</th>
<th>BS Events</th>
<th>BS Total</th>
<th>PTA Events</th>
<th>PTA Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bosiers 2009</td>
<td>23</td>
<td>74</td>
<td>12</td>
<td>75</td>
<td>76.7%</td>
<td>1.94 [1.05 to 3.61]</td>
</tr>
<tr>
<td>Tepe</td>
<td>1</td>
<td>9</td>
<td>2</td>
<td>8</td>
<td>23.3%</td>
<td>0.44 [0.05 to 4.02]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>83</td>
<td></td>
<td>83</td>
<td></td>
<td>100.0%</td>
<td>1.38 [0.41 to 4.68]</td>
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<tr>
<td>Total events</td>
<td>24</td>
<td></td>
<td>14</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Heterogeneity</td>
<td>Tau² = 0.41; Chi² = 1.60, df = 1 (p = 0.21); I² = 37%</td>
<td></td>
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<tr>
<td>Test for overall effect: Z = 0.51 (p = 0.61)</td>
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### 6 mo binary restenosis

<table>
<thead>
<tr>
<th>Study</th>
<th>BS Events</th>
<th>BS Total</th>
<th>PTA Events</th>
<th>PTA Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bosiers 2009</td>
<td>30</td>
<td>44</td>
<td>21</td>
<td>50</td>
<td>91.8%</td>
<td>1.62 [1.11 to 2.38]</td>
</tr>
<tr>
<td>Tepe</td>
<td>6</td>
<td>9</td>
<td>2</td>
<td>8</td>
<td>8.2%</td>
<td>2.67 [0.74 to 9.65]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>53</td>
<td></td>
<td>58</td>
<td></td>
<td>100.0%</td>
<td>1.69 [1.17 to 2.44]</td>
</tr>
<tr>
<td>Total events</td>
<td>36</td>
<td></td>
<td>23</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity</td>
<td>Tau² = 0.00; Chi² = 0.54, df = 1 (p = 0.46); I² = 0%</td>
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<tr>
<td>Test for overall effect: Z = 2.80 (p = 0.005)</td>
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Jens, Eur J Vasc Endovasc Surg, 2014
Popliteal stenting and angioplasty of the anterior tibial artery and tibio-fibullar trunk

Lifestent® (Bard): 5-120mm

Angioplasty by a 3-20mm RX-balloon
DESTINY

- RCT (1:1)
- Polymer everolimus eluting metal stent (Xience®) vs BMS (Vision®)
  - Primary patency @ 12 months
  - Lesion length ≤ 40mm
  - Sample size: 140 patients

Bosiers, J Vasc Surg 2012

YUKON

- RCT (1:1)
- Polymer-free sirolimus eluting stent vs BMS
  - Event-free survival @ 1,100 days
  - Lesion length ≤ 45mm
  - Sample size: ?

Rastan, JACC, 2012
DESTINY
140 pts
Mean target lesion length: 15.9mm (DES)

YUKON
161 pts
Mean target lesion length: 31.9mm

Amputation rates were 2.6% and 12.2% in SES and BMS respectively (p=0.03)

Freedom from target lesion revascularization 91% for Xience V vs 66% for Vision (P=0.001).

Bosiers, J Vasc Surg 2012

Rastan, JACC, 2012
The use of drug eluting stents in infrapopliteal arteries: an updated systematic review and meta-analysis of randomised trials.

« Stents coated in sirolimus analogues were more effective than paclitaxel. »
1 month later
Limitations

P2-P3 lesions
- DES trials have excluded P2-P3 lesions
- Availability of 5-mm DES

Tibial arteries
- No head to head comparison POBA/DES
- Not proven for long lesions (>45-mm)
- Clinical improvement to demonstrate
The DES BTK Vascular Stent System vs PTA in Subjects With Critical Limb Ischemia (SAVAL trial)
(ClinicalTrials.gov Identifier: NCT03551496)

Phase A: A global, prospective, multicenter, 2:1 randomized superiority trial evaluating the safety and effectiveness of the DES BTK Vascular Stent System compared to standard percutaneous transluminal angioplasty to treat infrapopliteal artery lesions in subjects with critical limb ischemia (CLI) (201 patients)

Primary outcome measures: primary patency at 6-month

Total lesion length up to 140-mm

Nitinol self-expanding stent and PTx drug coating (PBMA/PVDF)

PI: J. Mustapha

Sponsor: Boston Scientific
Case presentation

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