Below-the-ankle angioplasty in patients with critical limb ischemia: A systematic review and meta-analysis

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Speaker name: MA Schreve

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
Introduction

In patients with Critical limb ischemia:
- direct blood flow to the wound
  - New materials
  - BTK angioplasty technically successful

BTA lesions: remaining obstacle for uninterrupted blood flow to the wound

Do we need to open the below-the-ankle lesions?
Below-the-ankle angioplasty in patients with critical limb ischemia: A systematic review and meta-analysis

Aim of this study

1. Angioplasty in BTA lesions
   • Safety?
   • Effectiveness?

2. Additional BTA angioplasty after BTK improve clinical outcomes?
Methods

- Literature search: June 1964 - March 2018 (Pubmed, Embase, Cochrane)
- **In- and exclusion criteria**
  - Studies that reported clinical outcomes of BTA angioplasty
  - Published in English
  - Human studies
  - Full text available
  - Any type of balloon/stent was possible
- **Quality assessment (MINORS score)**
Methods

Primary outcome:
• Limb salvage at 12 months

Secondary outcomes:
• Technical success
• Complications
• Amputation free survival (AFS)
• Survival
• Freedom from reintervention
Records identified through database searching
- MEDLINE: 1379
- EMBASE: 1679
- COCHRANE: 120
- Total: 3178

Additional records identified through other sources
- n = 4

Total records identified
- n = 3182

Duplicates removed
- n = 804

Records screened based on title or abstract
- n = 2378

Titles and abstracts excluded
- Intrapopliteal only: 1027
- Conference abstracts: 239
- Irrelevant studies: 710
- Overlapping data: 4
- Study design: 359
- Total: 2339

Full text articles assessed for eligibility
- n = 39

Excluded studies
- No distinction BTK and BTA: 6
- Article type: 20
- Language: 1
- Abstract only: 1
- Overlapping data: 1
- Total: 29
10 studies

Published 2004-2017

• 524 ischemic limbs (478 patients)
• 44 (R4), 420 (R 5,6), 60 not defined

Lesions:

• Dorsalis pedis artery, inframalleolar posterior tibial artery and the plantar artery

Treatment:

• POBA (9), DEB (1)
• Stents (2)
### MINORS Score

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<td>1. A clearly stated aim</td>
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<td>2. Inclusion of consecutive patients</td>
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<td>3. Prospective collection of data</td>
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<td>4. Endpoint appropriate to the aim of the study</td>
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<td>5. Unbiased assessment of the study endpoint</td>
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<td>6. Follow-up period appropriate to the aim of the study</td>
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<td>7. Loss to follow-up less then 5%</td>
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<td>8. Prospective calculation of the study size</td>
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**Validity assessment**

- Item 9-12 only for comparative studies
- An adequate control group
- Contemporary groups
- Baseline equivalence of groups
- Adequate statistical analysis

**Total MINORS score**

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<td>Minimum possible score</td>
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<td>Maximum possible score</td>
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**Moderate quality**

- 3 studies comparative: BTK only versus additional BTA
- All studies: moderate quality
# Results (BTA angioplasty)

## Studies

<table>
<thead>
<tr>
<th>Studies</th>
<th>Estimate (95% C.I.)</th>
<th>LS/BTA</th>
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<tbody>
<tr>
<td>Abdelhamid et al 2010</td>
<td>0.810 (0.691, 0.928)</td>
<td>34/42</td>
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<tr>
<td>Kawarada et al 2011</td>
<td>0.925 (0.843, 1.000)</td>
<td>37/40</td>
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<tr>
<td>Manzi et al 2009</td>
<td>0.861 (0.798, 0.924)</td>
<td>99/115</td>
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<tr>
<td>Nakama et al 2016</td>
<td>0.929 (0.794, 1.000)</td>
<td>13/14</td>
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<tr>
<td>Nakama et al–1 2017</td>
<td>0.886 (0.833, 0.938)</td>
<td>124/140</td>
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<tr>
<td>Palena et al 2014</td>
<td>0.987 (0.952, 1.000)</td>
<td>38/38</td>
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<tr>
<td>Teymen et al 2018</td>
<td>0.976 (0.911, 1.000)</td>
<td>20/20</td>
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<tr>
<td>Zhu et al 2009</td>
<td>0.947 (0.889, 1.000)</td>
<td>54/57</td>
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<tr>
<td>Zhu et al–1 2011</td>
<td>0.944 (0.795, 1.000)</td>
<td>8/8</td>
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<td><strong>Overall (I^2=65.18%, P=0.003)</strong></td>
<td><strong>0.924 (0.884, 0.964)</strong></td>
<td><strong>427/474</strong></td>
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92% limb salvage (12 months)
Results (BTA angioplasty)

- Amputation-free survival: 78% (12 months)
- Overall survival rates: 71-100% (7 studies)
Results

Technical success BTA angioplasty: 63-95%

Complications (6 studies)
- Vessel perforation (n=7)
- Subacute occlusion (n=12)
- Balloon rupture (n=3)
- Puncture hematoma (n=7)
- Retroperitoneal hematoma (n=1)
- Heart failure (n=1)
- Stroke (n=1)

Freedom from BTA reintervention: 40-94% (4 studies)
BTK only – additional BTA

3 comparative studies

Additional BTA
• Operator decision: bad outflow

Severe pedal artery disease in the additional BTA group
(Type 3 Kawarada artery disease)
• 79% vs 40% in Nakama [2016]
• 53% vs 33% in Nakama [2017]
BTK only - additional BTA

12 months limb salvage

OR: 1.23    95% CI: 0.61–2.49

12 months afs

OR: 1.58    95% CI: 0.95–2.64

Wound healing: 38-60% (BTK only) versus 59-93% (BTA)
Conclusion

BTA angioplasty

Safe

Feasible

No benefit limb salvage and AFS additional BTA angioplasty

Possible benefit wound healing
Thank you for your attention

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