Balloon Angioplasty of Infrapopliteal Arteries: A Proposed Algorithm for Optimal Endovascular Treatment

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Disclosure

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I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Boston Scientific, Cardiovascular Systems, Gore, Medtronic, Philips, PQ Bypass, Shockwave

  Employment in industry

- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Limitations of Balloon Angioplasty

• Balloon angioplasty is foundation of infrapopliteal endovascular intervention.

• Mechanism of balloon angioplasty is:
  • Subtotal rupture of artery to adventitial layer
  • Dissection of plaque off medial/adventitial interface
  • NOT compression of plaque (impossible)
Dissections Are Common and Are Often Severe

Up to 42% of PTA (POBA or DCB) results in a dissection ≥ Grade C\textsuperscript{1,2}

<table>
<thead>
<tr>
<th>Dissection Severity\textsuperscript{1}</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td>16%</td>
</tr>
<tr>
<td>A</td>
<td>19%</td>
</tr>
<tr>
<td>B</td>
<td>23%</td>
</tr>
<tr>
<td>C</td>
<td>5%</td>
</tr>
<tr>
<td>D</td>
<td>24%</td>
</tr>
<tr>
<td>E</td>
<td>9%</td>
</tr>
<tr>
<td>F</td>
<td>4%</td>
</tr>
</tbody>
</table>

Real World Registry

<table>
<thead>
<tr>
<th>Registry</th>
<th>Stent Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix\textsuperscript{3} Registry</td>
<td>25.2% All Patients</td>
</tr>
<tr>
<td></td>
<td>35.7% Lesions 140-500mm</td>
</tr>
<tr>
<td>IN.PACT\textsuperscript{4} Admiral Registry</td>
<td>24.7% All Patients</td>
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<tr>
<td></td>
<td>40.4% Lesions ≥150mm</td>
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<tr>
<td></td>
<td>46.8% Total Occlusions</td>
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</tbody>
</table>

\textsuperscript{1} Fujihara, J Endovasc Ther 2017
\textsuperscript{2} Kobayashi, Circ Cardiovasc Interv 2016
\textsuperscript{3} Thieme, J Am Coll Cardio Interv, 2017
\textsuperscript{4} Micari, J Am Coll Cardio Interv, 2018
• 30 patients undergoing infrapopliteal balloon angioplasty.

• Angiograms obtained immediately and 15 minutes later.

• 97% had elastic recoil, with mean recoil 29%.
  • More pronounced effect in diabetics.

Baumann et al, JEV 2014;21:44-51
Elastic Recoil
What are the Patency Rates After Tibial Artery Angioplasty?

• Angioplasty in 77 tibial arteries.
  • Average lesion length 184 mm
  • 65% occlusions

• At 3 months, clinical improvement in 76% of patients.

• Angiographic follow-up
  • Reocclusion in 38%
  • Stenosis > 50% in 31%

Schmidt et al, CCI 2010;76:1047-1054
Proposed Algorithm for Infrapopliteal Balloon Angioplasty

Step 1: Assess Lesion Calcification
- Consider using IVUS or EVUS to determine calcification extent and location
- If moderate/severe calcium, consider use of adjunctive atherectomy, intravascular lithotripsy, or specialty balloons

Step 2: Select Balloon Diameter and Length
- Size balloon 1:1 or 1.1:1 to reference vessel (typically 3.0-4.5 mm)
- Size balloon 0.5-1.0 mm larger diameter than visual estimate
- Strongly consider IVUS or EVUS for optimal diameter measurement
- Use tapered balloon for long (e.g., >200 mm) lesions

Step 3: Optimize Balloon Inflation Technique
- Slow balloon inflation (1 atm every 5-10 seconds)
- Inflaate balloon to nominal pressure (4-8 atm)
- Inflaate balloon for at least 3 minutes

Step 4: Assess Dissection and Recoil
- Utilize multiple angiographic views
- Repeat angioplasty in cases of severe dissection or recoil >30%
- Implant bailout scaffolds for continued dissection
Step 1: Lesion Calcification

• Angiography underestimates the severity and extent of lesion calcification.
  • IVUS is a useful adjunct for determining calcification severity

• Calcification is more common in the infrapopliteal arteries.

• Atherectomy or intravascular lithotripsy may help minimize dissections and need for bail-out stenting.
Step 2: Balloon Diameter and Length

• Select a balloon diameter sized 1:1 or 1.1:1 relative to the vessel diameter.

• IVUS optimizes sizing – consistently 0.5-1.0 larger diameter than angiographic visual estimate.

• Use a long balloon – consider tapered balloons for very long lesions.
88 vessels treated with IVUS vs. 242 vessels treated with angiography alone

Mean balloon size with IVUS was 0.3-0.5 mm larger on average.

No difference in TLR, but improved rate of wound healing with IVUS guidance
Step 3: Balloon Inflation Duration

• Inflate balloon slowly.

• Goal is minimal pressure that optimizes balloon expansion.

• Inflate balloon for at least 3 minutes.
Prolonged balloon dilation >3 minutes associated with lower rates of severe dissection

Additional balloon dilation was more often required if initial dilation was for shorter duration
Step 4: Assess Dissection and Recoil

• Utilize multiple angiographic views.

• In cases of dissection or residual stenosis, consider repeat balloon angioplasty.

• In cases of continued dissection, place a tack or stent.
Tack Device For Severe Dissection
Tack Device For Severe Dissection
Summary and Conclusions

• Balloon angioplasty remains the mainstay of therapy for infrapopliteal lesions but has important limitations.

• Careful attention to technique has the potential to improve acute outcomes and potentially long-term patency.

• New purpose-built implants will help improve outcomes.