The influence of balloon inflation time in femoro-popliteal and BTK angioplasty: a systematic review

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Disclosure

Speaker name:

Olaf J Bakker

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)

X I do not have any potential conflict of interest
Introduction

• Numerous studies have investigated the effect of DCB, BMS or DES in fempop and BTK angioplasty

• Only 3 studies have investigated the effect of prolonged balloon inflation\textsuperscript{1-3}

• Current guidelines lack a recommendation on balloon inflation time

\textsuperscript{1}Manninen ‘97; \textsuperscript{2}Soder 2002; \textsuperscript{3}Zorger 2002
Study Question

• What is the effect of balloon inflation time on outcomes in fem-pop and BTK angioplasty?
Methods

• Systematic review of the literature & meta-analysis
  Scopus, Pubmed, Embase, Cochrane, ClinicalTrial.gov

• Inclusion: - fempop / BTK angioplasty (POBA or DCB)
  - inflation time

• Exclusion: - studies not written in English, German or Dutch
  - < 10 patients
Inclusion Flowchart

- Scopus: 9,331 results
- Pubmed: 6,032 results
- Embase: 8,725 results
- Cochrane: 521 results
- ClinicalTrials.gov: 193 results

Combined: 24,802 studies

Duplicates: 12,422 studies

Title / Abstract screening: 12,380 studies

Excluded: 11,559 studies
Inclusion Flowchart (2)

Full-text screening: 821 studies

Series < 10 patients: 17 studies
Language restrictions: 81 studies
Conference abstracts: 130 studies
Full-text not retrievable: 79 studies

Retrospective studies: 269 studies
Not reporting balloon inflation: 217 studies
Included retrospective: 52 studies

Prospective studies: 245 studies
Not reporting balloon inflation: 176 studies
Included prospective: 69 studies
Balloon Inflation Time over the years
# Baseline

<table>
<thead>
<tr>
<th></th>
<th>&lt; 150 sec</th>
<th>&gt; 150 sec</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>957</td>
<td>1389</td>
<td></td>
</tr>
<tr>
<td>Balloon inflation (mean, sec)</td>
<td>112.0</td>
<td>183.8</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Follow-up (mean, months)</td>
<td>16.0</td>
<td>14.4</td>
<td>0.35</td>
</tr>
<tr>
<td>Lesion length (mean, mm)</td>
<td>98.7</td>
<td>97.5</td>
<td>0.95</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>46.0</td>
<td>52.4</td>
<td>0.48</td>
</tr>
<tr>
<td>Rutherford 0-3 (%)</td>
<td>74.4</td>
<td>72.7</td>
<td>0.92</td>
</tr>
<tr>
<td>Rutherford 4-6 (%)</td>
<td>25.6</td>
<td>27.3</td>
<td>0.93</td>
</tr>
</tbody>
</table>
Need for stent placement
Target Lesion Revascularization
Multivariable Linear Regression Analysis

- Adjusted for use of DCB
- Adjusted for vessel segment (fem-pop-BTK)

Stent placement

- Inflation time: OR = 0.59 (p < 0.01)
Multivariable Linear Regression Analysis

- Adjusted for use of DCB
- Adjusted for vessel segment (fem-pop-BTK)

12-month TLR

- Inflation time: OR = 0.67 (p = 0.04)
- DCB use: OR = 0.63 (p < 0.01)

>> non-significant difference DCB vs. Inflation Time
Summary

• Prolonged inflation is correlated with reduced need for stent placement and target lesion revascularization

• In reducing need for TLR, prolonged inflation is equally as effective as DCB use
Limitations

• Inflation time was not primary goal of included studies

• Overall, few studies report balloon inflation time (14 out of 514)

• Results mostly applicable to non-complex lesions
Conclusion

• Prolonged balloon inflation is associated with improved procedural and long-term outcomes in fem-pop and BTK angioplasty

• If recoil or dissection occurs after primary angioplasty, prolonged inflation should be the next step
Thank you

- Olaf Bakker
- Rutger Welling
- Frans Moll
- Gert Jan de Borst
- Andrej Schmidt
- Dierk Scheinert
Methods (2)

Outcome measures:
• Technical success
• Bail-out stent placement
• 12-month amputations
  • Minor
  • Major
• 12-month angiographic restenosis
• 12-month TLR
### Baseline (2)

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>&lt; 150 seconds</th>
<th>&gt; 150 seconds</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>957</td>
<td>1389</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>69.8%</td>
<td>68.0%</td>
<td>0.75</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>68.7</td>
<td>69.0</td>
<td>0.59</td>
</tr>
<tr>
<td>Hypertension</td>
<td>80.5%</td>
<td>81.0%</td>
<td>0.63</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>57.8%</td>
<td>77.0%</td>
<td>0.03</td>
</tr>
<tr>
<td>Diabetes</td>
<td>46.0%</td>
<td>52.4%</td>
<td>0.48</td>
</tr>
<tr>
<td>Current or history of smoking</td>
<td>36.6%</td>
<td>62.5%</td>
<td>0.09</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>28.9%</td>
<td>44.2%</td>
<td>0.19</td>
</tr>
<tr>
<td>Rutherford 0-3</td>
<td>74.4%</td>
<td>72.7%</td>
<td>0.92</td>
</tr>
<tr>
<td>Rutherford 4-6</td>
<td>25.6%</td>
<td>27.3%</td>
<td>0.93</td>
</tr>
</tbody>
</table>
Results – Exact Time – Correlations (1)

• Sample Size weighted Pearsons’ correlation.

• Non-significant correlations;
  • Technical success
  • Angiographic restenosis
  • Minor amputations
  • Major amputations
Limitations

• Inflation time was not primary goal of included studies
• Few studies report balloon inflation time
  • 23.5% in method section (121 out of 514)
  • 2.7% as outcome (14 out of 514)
• No comparison to primary stenting studies possible
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