The impact of intravascular ultrasound on femoro-popliteal artery endovascular interventions - a randomised controlled trial

Dr. Phil Puckridge
Head of Unit
Department of Vascular and Endovascular Surgery
Southern Adelaide Local Health Network,
Flinders Medical Centre, Adelaide, Australia
Flinders University, Adelaide, Australia
Disclosure

Speaker name:
Dr. Phillip J Puckridge

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
Intravascular ultrasound (IVUS)

- Axial 360° image of the vessel lumen and wall
- High frequency ultrasound real time assessment
- Cross sectional images
- Stacking of the images provides longitudinal assessment
- Ability to identify the arterial wall layers
Impact of intravascular ultrasound on femoro-popliteal artery endovascular interventions

• Prospective
• Investigator initiated
• Single Centre Randomised Controlled Trial (Flinders Medical Centre)
• Investigate effect of availability of IVUS information on binary restenosis rates at 12 months
• In endovascular treatment of the femoro-popliteal arterial segments
Study design

• Parallel-group design with balanced randomization
• Control group (angiography information only available)
• Treatment group (angiography and IVUS available)
• Minimal exclusion criteria
  • unable to give informed consent (language difficulties, or physical and/or mental incapacity)
  • under 18 years of age
  • iodine-based contrast allergy
  • life expectancy <6 months.

• Real-world sample
Recruitment

Treatment plan based on angiography recorded

Treatment plan based on IVUS recorded
Enrollment and Imaging Analysis

• Volcano s5 IVUS (Philips Healthcare) for majority
  • RVD proximal and distal recorded
  • Lesion length estimated with IVUS under fluoroscopy
  • 100cm radiopaque ruler assisted comparison

• Angiographic images obtained in usual fashion
  • RVD and Lesion length measured using quantitative vessel analysis software

• 161 patients recruited and 150 randomised
  • Intervention group 76
  • Control Group 74
Outcome measures

• Primary Outcome
  • Binary restenosis within 12 months of the index procedure
    • >50% stenosis on duplex ultrasound
    • PSV ≥2.4

• Secondary Outcomes
  • Periprocedural complications
  • Major Adverse Events (MAE) within 12 months
    • major complications within 30 days, major target limb amputation, MI, stroke, death
  • Disagreement in imaging findings between IVUS and angiography
  • Changes to treatment plan due to IVUS
  • Clinically directed target lesion revascularization (cdTLR) within 12 months
Results

- No significant difference in baseline patient characteristics
- No significant differences in vessel and lesion characteristics between groups
- One difference in treatment parameters between groups:
  - Larger DCB size in treatment group
Primary Outcome

- IVUS imaging improved outcomes
- Significantly less binary restenosis at 12 months
- Freedom from binary restenosis 72.4% with IVUS vs 55.4% using angiography alone (P=0.008)
Secondary Outcomes

• Use of IVUS was safe
  • No difference in MAE between treatment and control

• No difference in cdTLR rates at 12 months

• IVUS availability significantly increased mean DCB size

• DCB outcomes significantly improved with IVUS
  • Binary restenosis 9.1% in treatment group vs 37.5% in the control group (P = 0.004)
Imaging findings differ in majority cases

- Disagreement in 123/150 patients
- 185 total disagreements
  - 151 prior to treatment
  - RVD, lesion length, plaque eccentricity, cause of stenosis, stent appearance
- 34 post treatment
  - Severity of dissection, degree of residual stenosis, adequacy of stent expansion
Differences in Angiography vs IVUS

Reference vessel diameter and lesion length

<table>
<thead>
<tr>
<th></th>
<th>Angiography</th>
<th>IVUS</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean RVD, mm (SD)</td>
<td>5.10 ± 0.85mm</td>
<td>5.60 ± 0.87mm</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Median lesion length, mm (IQR)</td>
<td>120 (IQR: 50-200) mm</td>
<td>140 (IQR: 80-270) mm</td>
<td>0.017†</td>
</tr>
</tbody>
</table>

- IVUS RVD larger 86% and smaller in 10.7%
  - IVUS identifies negative arterial remodelling
- RVD IVUS and angiography agreement in only 3.3%
- IVUS measurement of the lesion almost always demonstrated a longer segment of disease
Impact of IVUS on treatment

• Treatment plan changed in 78.9% (60/76)
• 83 specific changes to planned therapy due to IVUS

<table>
<thead>
<tr>
<th>Treatment change (n=83)</th>
<th>Number of occasions</th>
<th>% of total treatment changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes to initial plan - total</td>
<td>65</td>
<td>78.3%</td>
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<tr>
<td>Increase in treatment length</td>
<td>32</td>
<td>38.6%</td>
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<tr>
<td>Increase in treatment device size</td>
<td>21</td>
<td>25.3%</td>
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<tr>
<td>Change in initial treatment modality</td>
<td>7</td>
<td>8.4%</td>
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<tr>
<td>Decrease in treatment length</td>
<td>3</td>
<td>3.6%</td>
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<tr>
<td>Decrease in treatment device size</td>
<td>2</td>
<td>2.4%</td>
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<tr>
<td>Changes after initial treatment - total</td>
<td>18</td>
<td>21.7%</td>
</tr>
<tr>
<td>Additional angioplasty due to IVUS</td>
<td>10</td>
<td>12.1%</td>
</tr>
<tr>
<td>Adjunctive stenting due to IVUS</td>
<td>7</td>
<td>8.4%</td>
</tr>
<tr>
<td>Repeat atherectomy due to IVUS</td>
<td>1</td>
<td>1.2%</td>
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</tbody>
</table>
Conclusions

• The first prospective RCT evidence demonstrating benefit from IVUS in femoro-popliteal interventions
  • IVUS changes treatment
  • Improves outcomes by reducing binary restenosis
  • IVUS guided accurate vessel sizing in DCB use

• IVUS provided greater information about the target vessel versus angiography alone

• Further research required for long-term outcomes
The Impact of Intravascular Ultrasound on Femoropopliteal Artery Endovascular Interventions
A Randomized Controlled Trial

Richard B. Allan, BHMSc (Hons), PhD,1,a,⁎ Phillip J. Puckridge, MBBS,1,a,⁎ J. Ian Spark, MBCiB, MD,1,c
Christopher L. Delaney, BMBS, PhD1,a,⁎

JACC: Cardiovascular Interventions, 2022, Volume 15 (5):536-546