36-month Results from the Absorb BTK Study

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Disclosure
Speaker name: Ramon L. Varcoe

- I have the following potential conflicts of interest to report:
  - Receipt of grants/research support
    Details: Abbott Vascular
  - Receipt of honoraria and travel support
    Details: Abbott Vascular, Medtronic, Boston Scientific
  - Employment in industry
    Details:
  - Shareholder in a healthcare company
    Details:
  - Owner of a healthcare company
    Details:
  - I do not have any potential conflicts of interest to report
ADVANTAGES OF STENTING

• TO IMPROVE PATENCY
• MECHANICAL SUPPORT
  • Scaffolding
  • Elastic Recoil
  • Flow Limiting Dissection
ADVANTAGES OF STENTING

• TO IMPROVE PATENCY
• MECHANICAL SUPPORT
  • Scaffolding
  • Elastic Recoil
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• DRUG DELIVERY
DISADVANTAGES OF STENTING

• VESSEL WALL EFFECTS
  • Vasomotion
  • Autoregulation
  • Adaptive Remodelling

• LATE FAILURE
  • Incomplete endothelialisation
  • Fracture
  • Malapposition

• IMPEDIMENT TO FUTURE REVASCULARISATION
A BVS MAY BE THE BEST OF BOTH WORLDS?

- Mechanical Scaffolding
- Drug Delivery
- Potential Return of Normal Vessel Wall Function
- Then Disappears!
• Poly-L-Lactic Acid structure
• Poly-D,L-Lactic Acid polymer
• Everolimus (100µg/cm²)
• 80% (±10%) elutes 28d
• Multilink design
• Circumferential hoops
• Straight connection bridges
• Radio-opaque platinum markers
• 150 µm strut thickness
STUDY DESIGN

• Prospective, Non-Randomised, Single-Center Study

**Inclusion Criteria**

• Chronic lower limb ischemia: RC 3-6
• Life expectancy >1yr
• Single or Multiple De novo lesions; >60%
• Infrapopliteal arteries (distal P3)
• Total Lesion Length ≤5cm (Max 2xBVS)
• Diameters 2.5-4.0mm
### ENDPOINTS

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<td>Ankle Brachial Index</td>
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<td>DUPLEX ULTRASOUND (PSVR&lt;2.0)</td>
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**ENDPOINTS**

- Binary Restenosis
- Primary Patency

- CD-TLR
- CD-TVR
• 48 Patients
  • Male:Female 56:44%
  • Mean Age 82yrs (range 65-97yrs)

• 55 Limbs
  • Left:Right 45:55%
  • CLI:IC 73:27%
• **71 Scaffolds Implanted**
  – Target vessels treated
    • ATA 15
    • PTA 9
    • PA 15
    • TPT 29
    • P3 2

• Mean lesion length **20.1 ±10.8mm** (5-50mm)
• 100% Procedural & Technical success
• 11 deaths (23% of cohort) (All Outside 30d)

Mean Follow-Up 24 months
Sustained Clinical Improvement 93%
Primary patency 63/71 (88.8%)
Assisted primary/secondary patency 100%
Limb salvage 100%
Sustained Clinical Improvement in 93%

Change in Rutherford Category

-5

THE VASCULAR INSTITUTE
PRINCE OF WALES
RESULTS

- 100% Procedural & Technical success
- 11 deaths (23% of cohort) (All Outside 30d)

Mean Follow-Up
- 24 months

Sustained Clinical Improvement
- 93%

Primary patency
- 63/71 (88.8%)

Assisted primary/secondary patency
- 100%

Limb salvage
- 100%
PRIMARY PATENCY 92.2%

CD-TLR 97.2%
CD-TLR 97.2%  CD-TLR 97.2%

PRIMARY PATENCY 92.2%  PRIMARY PATENCY 90.3%

| CD-TLR (%) | 100 | 97.2 | 97.2 | 87.3 |
| SE (%)     | 0   | 2.0  | 2.0  | 5.7  |
| Primary Patency (%) | 100 | 92.2 | 90.3 | 81.1 |
| SE (%)     | 0   | 3.4  | 3.8  | 6.1  |
Table 6. Patency Per Lesion at 3 Year Follow up (Duplex)

<table>
<thead>
<tr>
<th>Modified Intention to Treat Analysis</th>
<th>PTA BMS</th>
<th>DES</th>
<th>p Value†</th>
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<tbody>
<tr>
<td>Lesions with preserved patency</td>
<td>8 (20.5)</td>
<td>20 (37.7)</td>
<td>0.036</td>
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<tr>
<td>Ordinal score</td>
<td>0.18</td>
<td></td>
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<tr>
<td>≤50% stenotic</td>
<td>8 (20.5)</td>
<td>20 (37.7)</td>
<td></td>
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<tr>
<td>&gt;50% stenotic</td>
<td>2 (5.1)</td>
<td>2 (3.8)</td>
<td></td>
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<tr>
<td>Occluded</td>
<td>1 (2.6)</td>
<td>2 (3.8)</td>
<td></td>
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<tr>
<td>Amputation/CI-related death/treatment in interim</td>
<td>28 (71.8)</td>
<td>29 (54.7)</td>
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</table>

3-Year Primary Patency
37.7%
BEFORE: JUNE 2014

AFTER A SINGLE BVS IN TPT JUNE 2014
AFTER: JULY 2017
37 MONTHS LATER
• Vascular restorative therapy with BVS offers several advantages over metal stents

• **Safety** using ABSORB BVS within the tibials has been demonstrated, *now at longer timepoints*

• Excellent 12 & 24-month **patency** has been maintained to “best-in-class” 36-month results
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