5-year results from the ABSORB BTK study

BIORESORBABLE SCAFFOLDS FOR THE TREATMENT OF TIBIAL ARTERY STENOSIS

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Disclosure

Speaker name:

........Ramon L. Varcoe..........................................................

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Medtronic, Boston Scientific, Intact Medical, Surmodics, Intervene
A BVS MAY BE THE BEST OF BOTH WORLDS?

• Mechanical Scaffolding
• Drug Delivery
• Potential Return of Normal Vessel Wall Function
• Then Disappears!
Porcine Coronary Artery 1 Month Post BVS Implant
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

- CD-TLR
- CD-TVR

MEDICATION CHECK

PHYSICAL EXAMINATION

RUTHERFORD CLASS

ANKLE BRACHIAL INDEX

DUPLEX ULTRASOUND (PSVR<2.0)

ENDPOINTS
- Binary
- Restenosis
- Primary Patency
ENDPOINTS

- **48 Patients**
  - Male:Female 56:44%
  - Mean Age 82yrs (range 65-97yrs)

- **55 Limbs**
  - Left:Right 45:55%
  - CLI:IC 73:27%
Results

- **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)
Results

• 100% Procedural & Technical success
• 18 deaths (38% of cohort)
  • (All Outside 30d)

• Mean Follow-Up
  35.0 months
• Sustained Clinical Improvement
  95%
• Assisted primary/secondary patency
  100%
• Limb salvage
  100%
SUSTAINED CLINICAL IMPROVEMENT IN 95%
Results

• 100% Procedural & Technical success
• 18 deaths (38% of cohort)
  • (All Outside 30d)

• **Mean Follow-Up** 35.1 months
• Sustained Clinical Improvement 95%
• **Assisted primary/secondary patency** 100%
• **Limb salvage** 100%
1-Year Results

Primary Patency 89.2%
Freedom from CD-TLR 97.2%

N at Risk

PP
71 54
FF CD-TLR
71 59

### 3-Year Results

**Primary Patency**: 80.3%

**Freedom from CD-TLR**: 90.7%

<table>
<thead>
<tr>
<th>N at Risk</th>
<th>PP</th>
<th>CD-TLR</th>
</tr>
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<tbody>
<tr>
<td>PP</td>
<td>71</td>
<td>54</td>
</tr>
<tr>
<td>FF CD-TLR</td>
<td>71</td>
<td>59</td>
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</table>

5-Year Results

Primary Patency

72.9%

Freedom from CD-TLR

90.7%

N at Risk

<table>
<thead>
<tr>
<th>PP</th>
<th>71</th>
<th>54</th>
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<th>28</th>
<th>20</th>
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<td>71</td>
<td>59</td>
<td>47</td>
<td>32</td>
<td>21</td>
<td>10</td>
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</tbody>
</table>

Time (months)
ABSORB vs PADI

5-Year Results

Primary Patency 72.9%
Freedom from CD-TLR 90.7%

Table 10. Patency Per Lesion at 5-Year Follow-up (Duplex)

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>PTA-BMS</th>
<th>DES</th>
<th>P Value*</th>
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</thead>
<tbody>
<tr>
<td>Lesions with preserved patency</td>
<td>n=35*</td>
<td>n=43*</td>
<td>0.67</td>
</tr>
<tr>
<td>Ordinal score</td>
<td></td>
<td></td>
<td>0.52</td>
</tr>
<tr>
<td>≤50% stenotic</td>
<td>3 (8.6)</td>
<td>5 (11.6)</td>
<td></td>
</tr>
<tr>
<td>&gt;50% stenotic</td>
<td>1 (2.9)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Occluded</td>
<td>0</td>
<td>2 (4.7)</td>
<td></td>
</tr>
<tr>
<td>Amputation/CLI-related death/treatment in interim</td>
<td>31 (88.6)</td>
<td>36 (83.7)</td>
<td></td>
</tr>
</tbody>
</table>

BEFORE:
JUNE 2014

AFTER A SINGLE BVS IN TPT
JUNE 2014
AFTER: JULY 2017

37 MONTHS LATER
The First-generation ABSORB BVS has achieved excellent long-term patency and freedom from TLR rates in the tibial arteries.

This proof-of-concept facilitates the next generation of BVS devices and a larger evaluation in the form of a multicenter RCT.
Investigation of safety and efficacy of BRS treatment—Below The Knee

Prospective, randomized multicenter, US and OUS single-blind, trial
225 patients randomized 2:1 ESPRIT™ BTK vs. PTA

Safety Endpoint: MALE+POD
Efficacy Endpoint: Primary Patency+Limb Salvage

5-YEAR FOLLOW-UP

Trial Leadership:
Ramon Varcoe MBBS, MS, FRACS, PhD; Sahil Parikh MD, FACC, FSCAI; Brian DeRubertis MD, FACS,
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