The Demise of the Absorb BVS
Why it failed, what we learned from the coronary experience, and is there is a future for bioresorbable scaffolds below-the-knee?

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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, Intervene, Shockwave

- 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
A BVS MAY BE THE BEST OF BOTH WORLDS?

• Mechanical Scaffolding
• Drug Delivery
• Potential Return of Normal Vessel Wall Function
• Then Disappears!
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
<table>
<thead>
<tr>
<th>TIME POINTS</th>
<th>PROC</th>
<th>D/C</th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
<th>12M</th>
<th>2Y</th>
<th>3Y</th>
<th>4Y</th>
<th>5Y</th>
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<td><strong>RUTHERFORD CLASS</strong></td>
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<tr>
<td><strong>Ankle Brachial Index</strong></td>
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<td><strong>DUPLEX ULTRASOUND (PSVR&lt;2.0)</strong></td>
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**ENDPOINTS**

- Binary Restenosis
- Primary Patency
- CD-TLR
- CD-TVIR
• 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)
RESULTS

• 100% Procedural & Technical success

• 18 deaths (38% of cohort) (All Outside 30d)

Mean Follow-Up 28 months
Sustained Clinical Improvement 95%
Assisted primary/secondary patency 100%
Limb salvage 100%
Sustained Clinical Improvement in 95%

Change in Rutherford Category
RESULTS

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

Mean Follow-Up: 28 months
Sustained Clinical Improvement: 95%
Assisted primary/secondary patency: 100%
Limb salvage: 100%
Primary Patency: 89.0%

CD-TLR: 97.2%
Primary Patency & CD TLR

- **CD-TLR**
  - 97.2%
  - 88.1%
- **Primary Patency**
  - 89.0%
  - 78.2%
  - 71.6%

<table>
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<tr>
<th>Patency</th>
<th>N at risk</th>
<th>53</th>
<th>36</th>
<th>24</th>
<th>12</th>
<th>3</th>
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<tbody>
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<td>SE (%)</td>
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<td>3.9</td>
<td>3.9</td>
<td>6.2</td>
<td>8.4</td>
<td>10.2</td>
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<td>Freedom from TLR</td>
<td>N at risk</td>
<td>56</td>
<td>36</td>
<td>24</td>
<td>13</td>
<td>3</td>
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<tr>
<td>SE (%)</td>
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<td>2.0</td>
<td>2.0</td>
<td>5.3</td>
<td>5.3</td>
<td>5.3</td>
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BEFORE:
JUNE 2014

AFTER A SINGLE BVS IN TPT
JUNE 2014
AFTER: JULY 2017
37 MONTHS LATER
So What Happened?

Sept 14, 2017

“Due to low commercial sales, Abbott will stop selling the first-generation Absorb Bioresorbable Vascular Scaffold”
WHY? (It’s all about the Coronaries...)

• DES has very low rates of thrombosis & restenosis A VERY HIGH BAR
• 1\textsuperscript{st} Generation BVS was compared to a 7\textsuperscript{th} generation DES with mature Rx paths
• BVS was rushed to market in Europe & had higher rates of late scaffold thrombosis LIKELY DUE TO POOR DEPLOYMENT TECHNIQUE
• This event can be fatal
A Few Facts about the PAD market...

• Commercial market for PAD is similar to CAD
• Coronaries are contracting, PAD increasing
• Ageing, Obesity and Diabetes
• There is a HUGE unmet need for BTK disease
• Up to 54% of patients undergoing amputation in the US may not have had a vascular assessment! ¹,²

OPPORTUNITIES ARE NEVER LOST; SOMEONE WILL TAKE THE ONES YOU MISS. SEIZE THE MOMENT!

PictureQuotes.com
REVA Enters Peripheral Artery Disease Space With First-Ever CE Mark of a Bioresorbable Scaffold for Below the Knee Therapy

First-ever CE mark of a bioresorbable scaffold for below-the-knee PAD

1st August 2018  
1427
• Coronary results of BVS suffered from a rapid and ill-considered introduction to the market
• Poor commercial sales resulted in withdrawal of Absorb from the market
• A promising technology with distinct patient benefit has been for the Rx of PAD has been lost
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