Update of bioresorbable scaffolds in the coronary arteries: Is there hope for the future - in coronary or peripheral arteries?

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Disclosures
• Chairman of the ABSORB global clinical trial program (uncompensated)

Why We Need Bioresorbable Scaffolds in 2019

Metallic DES result in...
• Ongoing risk of very late events (lifelong)
• Suboptimal outcome in special situations:
  STEMl and NSTEMI (high stent thrombosis rates)
  Bifurcations (jailed side branches)
  Diffuse disease (full metal jacket)
  Treatment of in-stent restenosis (layer on layer)
• Permanent implant not desirable for many pts

Fully Bioresorbable Scaffolds (BRS)
• Designed to provide the mechanical support and drug delivery functions of metallic DES within the first year, and then completely resorb within 2-4 years, removing the nidus for very late adverse events

Full Bioresorption of Absorb Within ~3 Years

Metallic DES vs. Absorb BVS

Representative Human images at 5 Years

The Promise of BRS

Individual Patient Data Pooled Analysis
4 Absorb RCTs, 3,384 pts at 301 centers

<table>
<thead>
<tr>
<th>ClinicalTrials.gov</th>
<th>ABSORB II</th>
<th>ABSORB Japan</th>
<th>ABSORB China</th>
<th>ABSORB III</th>
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<tbody>
<tr>
<td>N centers</td>
<td>46</td>
<td>38</td>
<td>24</td>
<td>193</td>
</tr>
<tr>
<td>N randomized pts</td>
<td>501</td>
<td>400</td>
<td>487</td>
<td>2,008</td>
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<tr>
<td>- assigned to BVS</td>
<td>335</td>
<td>296</td>
<td>241*</td>
<td>1,322</td>
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<tr>
<td>- assigned to EES</td>
<td>168</td>
<td>134</td>
<td>239*</td>
<td>686</td>
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<td>1 or 2</td>
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<tr>
<td>N study vessels***</td>
<td>1 or 2</td>
<td>1 or 2</td>
<td>1 or 2</td>
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</table>

*3 pts randomized to BVS and 2 pts randomized to BVS withdrew consent immediately after enrolment and were de-registered.
**Maximum 1 lesion per vessel.

Pooled analysis of 4 BVS vs. EES RCTs (n=3,384 pts)

5-Year TLF (with 3-Year Landmark)

P = 0.004
HR: 1.42 [95% CI: 1.12, 1.80]

BVS 2,161
Number at risk:
2,030 1,985 1,929 1,884 1,829 1,777 1,713 1,658 1,580 1,568

EES 1,223 1,168 1,142 1,114 1,094 1,065 1,046 1,013 985 941 933

0 5 10 15 20
Time (Months)

Target lesion failure (%)

BVS EES

5-Year Device Thrombosis

P = 0.002
HR: 2.87 [95% CI: 1.46, 5.65]

BVS 2,161
Number at risk:
EES 1,223

0.8% 2.5%
Device thrombosis (%)
**ABSORB: 5-year Outcomes**

Pooled analysis of 4 BVS vs. EES RCTs (n=3,384 pts)

5-Year Device Thrombosis (with 3-Year Landmark)

<table>
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<tr>
<th>Time (Months)</th>
<th>BVS</th>
<th>EES</th>
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<tbody>
<tr>
<td>0</td>
<td>2,161</td>
<td>1,223</td>
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<tr>
<td>6</td>
<td>2,030</td>
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<td>12</td>
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<td>60</td>
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**ABSORB 5-Year Meta-analysis**

Conclusions and Implications

- Adverse ischemic events through 5 years were more common with the first-generation BVS compared with EES
- However, the period of excess risk ends at 3 years
- These data provide mechanistic insights into the timing of adverse events after BVS and identify the hurdles that need to be overcome for BVS technology to provide enhanced patient benefit
- Specifically, if new generation scaffolds are demonstrated to have comparable results to metallic DES prior to the time point of their complete bioresorption, BVS technology might be an acceptable or even preferred alternative to metallic DES for many patients with CAD

**Next Generation Absorb**

"Esprit"

- Absorb GT1
  - 157 um strut thickness
- Esprit
  - <100 um strut thickness

**LIFE-BTK:** 235 pts randomized to Esprit vs. PTA