Is There a Future for Bioresorbable Stents in the Coronary Tree or Elsewhere?

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship
- Grant/Research Support
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Company
- Boston Scientific
- Biotronik
- Biosensors
- Astra Zeneca
- Chessi
- Medtronic Vascular
- Abbott Vascular
- Amgen
- Boston Scientific
- Biotronik
- Biosensors

Potential Benefits of Bioresorbable Scaffolds over Standard DES

Absence of Permanent Rigid Metallic Cage
- Restoration of vasomotion
- Elimination of ISR
- Late luminal enlargement
- Preservation of targets for CABG
- Freedom from long-term polymer exposure
- Appeal to physician/patient

So far no evidence that BRS will improve patient outcomes?

Metallic DES vs. Absorb BVS: Representative Human Images at 5 Years

Absorb-Treated Artery

Where did Absorb go wrong? – complex patients and lesions

The device was not ready for the Challenge

Real-world registries in all-comers patients with lesions in small vessels started before being aware of the pre-clinical characteristics of the device

<table>
<thead>
<tr>
<th>GHOST-EU real-world registry</th>
<th>30-day follow-up</th>
<th>6-month follow-up</th>
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</thead>
<tbody>
<tr>
<td>TLF</td>
<td>2.2%</td>
<td>4.4%</td>
</tr>
<tr>
<td>TVF</td>
<td>2.3%</td>
<td>4.9%</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>0.6%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Target-vessel MI</td>
<td>1.1%</td>
<td>2.0%</td>
</tr>
<tr>
<td>TVR</td>
<td>1.6%</td>
<td>4.0%</td>
</tr>
<tr>
<td>TLR</td>
<td>1.1%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Definite/probable ST</td>
<td>1.5%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

Risk of thrombosis with BVS is 3.7x higher compared with Xience
Extended DAPT should be considered after implantation of BVS
Where did Absorb go wrong? – implantation technique

Despite a strut thickness and radial strength resembling the ones from first generation DES, the implantation technique was not modified early enough to adapt to the technology.

PSP implemented in November 2016

Prolonged DAPT duration to 3 years

DAPT duration should be given according to the resorption time of the device, for Absorb this means at least 3 years.

1-Year Device Thrombosis

ABSORB IV vs. ABSORB III

AGBSORB IV (n=2604)
1-year Device Thrombosis (%)

HR [95%CI] =
2.08 [0.78, 5.55]
P interaction = 0.53

ABSORB III (n=1308)

HR [95%CI] =
2.28 [0.70, 7.40]

HR [95%CI] =
1.72 [0.41, 7.21]
P interaction = 0.59

HR [95%CI] =
4.02 [0.45, 35.95]

1918/2604 pts (73.7%) enrolled in ABSORB IV were “ABSORB III-like”; 686 (26.3%) were not (23.9% troponin+ ACS, 0.5% 3 target lesions treated, 2.1% thrombus).

Data are Kaplan-Meier rates

The ESC guidelines August 2018: what happened?

The guidelines in a nutshell

- Randomized trial data are available only with the Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular).
- Absorb BVS is associated with a significantly increased risk of target lesion revascularization and device thrombosis, with numbers needed to harm of 40–60.
- In patients who have been treated with BRS, prolonged-duration DAPT for 3 years or longer may be considered.
- Available evidence on the magnesium scaffold is limited to small observational studies. Initial results appear encouraging, but further evaluation is needed.

How to Improve BRS Outcomes Prior to Their Complete Bioresorption

- Improve the Technique
  - PSP
  - Imaging
  - Prolonged DAPT
- Improve the Device
  - Thinner struts
  - Improved mechanical properties
Magnesium Resorbable Scaffold

Bioresorbable Scaffolds: Rapidly thinning

Emerging BRS from China

ESPRIT: Bioresorbable Scaffold in Peripheral Lesions

Final Thoughts

- The unmet need for Bioresorbable scaffolds remain despite improvement of second generation DES
- The first generation BRS are inferior to best in class DES and not suitable for all patients and lesions and requires meticulous technique.
- Randomized clinical trials of BRS to DES are mandatory for adoption
- Second generation BRS technology are on their way to make BRS great again