Why the Poor Results of Bioresorbable Stents in the Coronary Arteries Should Not Apply to Their Great Potential in BTK and Crural Arteries

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Brian DeRubertis, MD, FACS
Associate Professor of Surgery
UCLA Division of Vascular Surgery

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.

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<th>Company</th>
<th>Affiliation/Financial Relationship</th>
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<td>Abbott Vascular</td>
<td>Scientific Advisory Board</td>
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<td>Consulting agreement</td>
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<td>Speakers fees / Honorarium</td>
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Are the Coronary Outcomes of BVS Relevant to BTK?

- Is there a clinical need and commercial market for BVS below the knee?
- Are there lessons from the coronary circulation that may be relevant to the below knee space?
- Do failures of coronary BVS mean we should curb our enthusiasm for this technology BTK?

Simple answer: Yes! We need better therapies for the below knee space as we continue to utilize balloon angioplasty as the mainstay of treatment for tibial lesions.

Are the Coronary Outcomes of BVS Relevant to BTK?

Is there a clinical need for BVS below the knee?

- Limitations of Tibial Interventions
  - Poor patency rates of PTA
  - Paucity of high quality data to support the variety of atherectomy catheters
  - DES off label, though best evaluated

Simple answer: Yes! We need better therapies for the below knee space as we continue to utilize balloon angioplasty as the mainstay of treatment for tibial lesions.

Are the Coronary Outcomes of BVS Relevant to BTK?

Is there a clinical need for BVS below the knee?

- Limitations of DES:
  - Off-label use
  - Short lengths
  - Implications of permanent impact in CLI population

Simple answer: Yes! We need better therapies for the below knee space as we continue to utilize balloon angioplasty as the mainstay of treatment for tibial lesions.

Are the Coronary Outcomes of BVS Relevant to BTK?

Is there a clinical need for BVS below the knee?

ABSORB GT1 BVS (Abbott)
PLLA Scaffold
- Semi-crystalline poly-L-lactide backbone
- Provides device structure
- Developed to optimize radial strength

Everolimus / PDLLA Matrix Coating
- 2-4μm amorphous (non-crystalline) coating
- Poly-L,D-lactide matrix/Everolimus at 1:1 ratio
- Provides controlled drug release
Are the Coronary Outcomes of BVS Relevant to BTK?

Is there a clinical need for BVS below the knee?

Focal predilatation with non-compliant 3.0x20 balloon

OCT for size assessment of reference vessel diameter

Slow, controlled deployment to nominal diameter

2ATM increase every 5sec

Post-dilate with 3.5x20 non-compliant balloon
38 limbs in 33 patients
50 scaffolds implanted
43 infrageniculate lesions
Mean lesion length 1.9cm
68% CLI, 32% Claudication

Primary Patency (KM)
  - 12mo 96%
  - 24mo 85%

Freedom from CD-TLR
  - 12mo 96%
  - 24mo 96%

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Are there lessons to be learned from the coronary circulation?

- Patency with scaffold diameters <2.25mm
  - Size, and potential for mechanical/compressive forces make BVS unlikely to do well in pedal vessels
- Proper technique is essential to good outcomes
  - Pre-dilatation
  - Appropriate sizing
  - Post-dilatation
  - Adjunctive imaging

Are the Coronary Outcomes of BVS Relevant to BTK?

Is there a commercial market for BVS in the periphery?

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<thead>
<tr>
<th>Scaffold</th>
<th>Company</th>
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<tr>
<td>ABSORB BVS</td>
<td>Abbott Vascular</td>
<td>FDA, CE</td>
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<td>ART Scaffold</td>
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- All approved devices approved are for and marketed toward coronary circulation, following on the success of DES
- PCI market: ~$2.5 billion in U.S. (declining)

Problem for BVS in Coronary circulation:

DES sets extremely high bar for improvement!!!

Are the Coronary Outcomes of BVS Relevant to BTK?

Is there a commercial market for BVS in the periphery?

- Lack of “high bar” or extremely effective Rx in periphery
- Potential for wildly significant levels of adoption
- Global commercial market for PCI is similar to PAD, but decreasing, while the global cost of PAD is staggering high
- At least 30% of amputations are done without prior revascularization.
- This implies that the market for new CLI therapies will increase as access to appropriate care increases

Are the Coronary Outcomes of BVS Relevant to BTK?

Should failures in the coronary circulation deter us from pursuing BVS for the BTK space?

- Answer is overwhelmingly “NO!!!”
- Caution:
  - Pay attention to lessons learned
  - Strut thickness
  - Technique
  - Scaffold sizing
  - Continue to pursue next-generation improvements
Are the Coronary Outcomes of BVS Relevant to BTK?

Should failures in the coronary circulation deter us from pursuing BVS for the BTK space?

- Answer is overwhelmingly “NO!!”
- Enthusiasm:
  - Is a 2-3% difference in late scaffold thrombosis relevant to patient with 50% 5-year mortality and 30-50% likelihood of restenosis with current standard of care?
  - Our industry colleagues need to uncouple the failure of BVS in the coronary circulation from its potential in the BTK space or our patients may suffer from a tremendous missed opportunity for improved outcomes

Summary

- Durable therapies that do not limit potential for surgical options for BTK disease is needed
- Biodegradable technology with drug elution may be the answer to this clinical need
- The market for such a device is large and expanding
- The modest failures in the coronary circulation have little relevance to the great potential for these devices in the BTK circulation

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