Facing the Future with a Look 10 Years Forward

The Breakthrough in Complex Tibial and Pedal Revascularization Will Be......

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Disclosure

Speaker name: John R. Laird

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cordis, Medtronic
- Employment in industry
- Stockholder of a healthcare company: Syntervention, Shockwave, Eximo, Reflow, PQ Bypass
- Owner of a healthcare company
- Other(s)
The Past Ten Years Have Been Pretty Amazing!

- Distal and multivessel intervention
- Angiosome guided intervention
- Pedal and tibial access
- Better guidewires and CTO devices
- Advanced CTO techniques (CART/Reverse CART)
- Recanalization through collaterals
- Plantar arch recanalization
Access Technique
1. Fluoroscopy guided (follow the Ca²⁺)
2. Angio guided
3. Ultrasound guided
Retrograde Access

• 61 yo AAF with DM, CAD s/p CABG, and ESRD on dialysis
• CLI with rest pain and ischemic ulcers of medial distal lower leg
• Subtotal popliteal occlusion and infra-popliteal disease
• No usable vein
Angiosome Based Treatment
PTA Through Collaterals
Plantar Arch Not Intact
PTA of Plantar Arch
Meta-Analysis of DES Below the Knee

• Five studies, 611 patients

• Median lesion length 27 mm

• Reference vessel diameter 2.9 mm

• Lower rates of restenosis, TLR, and major amputation among patients treated with DES

Fusaro et al, J Am Coll Cardiol Intv 2013;6:1284-1293
**Meta-Analysis of DES Below the Knee**

### Amputation

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>DES Events</th>
<th>Total</th>
<th>Control Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHILLES</td>
<td>11</td>
<td>80</td>
<td>17</td>
<td>85</td>
<td>61.7%</td>
<td>0.64 [0.28, 1.46]</td>
<td></td>
</tr>
<tr>
<td>BELOW</td>
<td>2</td>
<td>10</td>
<td>8</td>
<td>28</td>
<td>13.8%</td>
<td>0.63 [0.11, 3.61]</td>
<td></td>
</tr>
<tr>
<td>DESTINY</td>
<td>1</td>
<td>74</td>
<td>2</td>
<td>66</td>
<td>7.2%</td>
<td>0.44 [0.04, 4.95]</td>
<td></td>
</tr>
<tr>
<td>YUKON-BTK</td>
<td>2</td>
<td>82</td>
<td>9</td>
<td>79</td>
<td>17.3%</td>
<td>0.19 [0.04, 0.93]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>246</strong></td>
<td></td>
<td><strong>258</strong></td>
<td></td>
<td><strong>100.0%</strong></td>
<td><strong>0.50 [0.26, 0.97]</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td><strong>16</strong></td>
<td></td>
<td><strong>36</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: \( \tau^2 = 0.00; \chi^2 = 1.82, df = 3 (P = 0.61); I^2 = 0\%

Test for overall effect: \( Z = 2.06 (P = 0.04) \)

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Fusaro et al, J Am Coll Cardiol Intv 2013;6:1284-1293
Bioresorbable Scaffolds Below the Knee
Bioresorbable Scaffolds

Varcoe et al, J Am Coll Cardiol Intv 2016;9:1721-1728
Novel Approaches
LimFlow Clinical Example: Restored Perfusion*

LimFlow Patient #5
* Videos courtesy of Dr. S. Kum, Changi Hospital, Singapore
Where Will the Next Breakthrough Be?

• Better plaque modification techniques for tibial intervention?
• Better drug eluting technologies?
• Novel approaches?
• Better ways to assess the results/guide tibial interventions (tissue oxygen microsensors)?
• Regenerative therapies?
• Better wound care methodologies?
Drugs and Devices!!
Is the Answer a Drug Coated Lithoplasty Balloon?
Lesion modification using lithotripsy in a balloon

Sonic Pressure Waves are Tissue-selective:
- Hard on hard tissue, soft on soft tissue

Waves, unfocused and spherical in shape, travel outside balloon:
- Designed to disrupt both superficial, deep calcium

- Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation
- Effective lesion expansion with minimized impact to healthy tissue
- Familiar Balloon-based endovascular technique
- “Front-line” balloon strategy (.014” compatible)
Part of the Answer will be a better DES for BTK use
A Better DES for BTK Use?

- Useful for focal disease or for treatment of flow limiting dissection or elastic recoil
- Self-expanding or hybrid design
- Longer lengths
- Fracture resistant

Modified Eluvia™ Stent?
The Breakthrough Will Need to Be?

- A drug/device combination (separate or combined in one)
- Simple to use and time efficient
- Safe (low risk of distal embolization or perforation)
- Combined with techniques to better assess effectiveness/completeness of revascularization
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