12 Month Results of the DISAPEAR Registry
BVS IN CLTI

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Disclosure

Speaker name:

Steven Kum

I have the following potential conflicts of interest to report:

- [x] Consulting  *Abbott Vascular*
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Primary Patency Favors DES

- Scaffold and reliable luminal gain
- Reliable drug delivery even in calcification
- Prolonged drug delivery
- No toxic effects (systemic and distal)
Metallic implants may be problematic in reintervention.
Abbott Vascular ABSORB

- Poly-L-Lactic Acid structure
- Poly-D,L-Lactic Acid polymer
- Everolimus (100μg/cm²)
- 80% (±10%) elutes 28d

Not available commercially
DISAPEAR Registry in CLTI - Singapore

Drug
Impregnated Bioabsorbable Stent in Asian Population Extremity Arterial Revascularization
Inclusion criteria
• Chronic Infraopliteal lesions
• Rutherford 4, 5 and 6
• De novo lesions - Stenosis >50% or Occlusion
• 8 cm above ankle joint

Exclusion criteria
• BVS across the ankle joint
## Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total patients, n=41; Limbs, n=41</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, median (IQR) (years)</strong></td>
<td>64 (15)</td>
</tr>
<tr>
<td>Male</td>
<td>23 (56)</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
<td></td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>24 (59)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>37 (90)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>36 (88)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>37 (90)</td>
</tr>
<tr>
<td>Dialysis-dependent renal failure</td>
<td>5 (12)</td>
</tr>
<tr>
<td>Smoking history</td>
<td>16 (48)</td>
</tr>
<tr>
<td><strong>Rutherford category</strong></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>2 (4.87)</td>
</tr>
<tr>
<td>5</td>
<td>24 (58.5)</td>
</tr>
<tr>
<td>6</td>
<td>15 (36.5)</td>
</tr>
</tbody>
</table>

95 % Tissue Loss
## Lesion/Scaffolds

<table>
<thead>
<tr>
<th>Target lesion location</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tibioperoneal trunk</td>
<td>17(33)</td>
</tr>
<tr>
<td>Anterior tibial artery</td>
<td>14(26)</td>
</tr>
<tr>
<td>Posterior tibial artery</td>
<td>11(21)</td>
</tr>
<tr>
<td>Peroneal artery</td>
<td>6(11)</td>
</tr>
<tr>
<td>Popliteal artery</td>
<td>5(9)</td>
</tr>
<tr>
<td><strong>Target lesion length (mean±SD[range]) mm</strong></td>
<td><strong>22.7±17.2 (4-88)</strong></td>
</tr>
<tr>
<td><strong>Degree of stenosis (median [range]) (%)</strong></td>
<td><strong>80 (50–100)</strong></td>
</tr>
<tr>
<td><strong>Total occlusion</strong></td>
<td>4 (8)</td>
</tr>
<tr>
<td><strong>Target vessel diameter (median [range]) mm</strong></td>
<td><strong>3 (2.5–3.5)</strong></td>
</tr>
<tr>
<td><strong>PARC classification</strong></td>
<td></td>
</tr>
<tr>
<td>Non</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Focal</td>
<td>19 (46)</td>
</tr>
<tr>
<td>Mild</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 (17)</td>
</tr>
<tr>
<td>Severe</td>
<td>10 (24)</td>
</tr>
<tr>
<td><strong>TASC classification</strong></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>25 (61)</td>
</tr>
<tr>
<td>B</td>
<td>14 (34)</td>
</tr>
<tr>
<td>C</td>
<td>0 (0)</td>
</tr>
<tr>
<td>D</td>
<td>2 (5)</td>
</tr>
<tr>
<td><strong>No, of Lesions</strong></td>
<td>53</td>
</tr>
<tr>
<td><strong>Total number of scaffolds deployed</strong></td>
<td>69</td>
</tr>
</tbody>
</table>
RESULTS
Primary Patency

6 month = 95%
12 months = 86%

DUS PSVR < 2.0
Freedom from CD-TLR

**FF CD-TLR**

6 month = 98%

12 month = 93%
FF TLR & Occlusion

6 month = 98%
12 month = 93%
AFS

6 month = 93%
12 month = 85%
Limb Salvage & Wound Healing

- Limb salvage = 98% @ 6 and 12 months
- Complete wound healing (R5/6) = 79.5% @ 12 months
- Median time to wound healing = 4 months
R6 – Heel Gangrene

Combination SUPERA and BVS
5.5 years – all stented vessels patent, no repeat interventions
4 year Angiographic Follow up

Aug 2012 pre implantation

Aug 2012 post implantation

Oct 2016 Control Angiogram

BVS
3 x 28
3 x 28
3 x 18

Total Stented Length
= 70mm
4 year Angiographic Follow up

- Upper ATA was normal
- Disease segment
- Progression of disease in the segment of ATA
- BVS segment is disease free

Index Angio 2012 (before BVS) → 2016
7 year Angiographic + OCT
Combined 3 centre BVS experience - *Interim*

3 Centre Experience (Varcoe, Kum, Shah)

189 scaffolds in 125 patients

**Primary Patency**
- 12 months: 91.1%
- 24 months: 88.6%

**TLR**
- 12 months: 96.6%
- 24 months: 94.5%
Summary

• BTK lesions are associated with recoil, high restenosis and high reintervention when treated with standard POBA
• There may be a role for Scaffold and Drug elution for reliable lumen gain and consistent drug elution
• Our experience in the DISAPEAR registry is encouraging with good patency, low TLRs, and high limb salvage / wound healing rates
• We eagerly await the next generation BVS dedicated for BTK interventions
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