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
What are the Problems and Needs in BTK Therapies?

- Small Vessels
- Recoil/Calcium
- Poor Outflow
- Long Lesions
- Inconsistent Drug Delivery
- Reliable Luminal Gain
- Inhibiting Restenosis

- POBA
- Atherectomy
- DCB
- DES
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 S tent in Asian Population Extremity Arterial Revascularization

Accepted J E V T
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>Age, median (IQR) (years)</td>
<td>64 (15)</td>
</tr>
<tr>
<td>Male</td>
<td>23 (56)</td>
</tr>
<tr>
<td>Comorbidities</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>Rutherford category</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% with 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>Total number of scaffolds deployed</td>
<td>69</td>
</tr>
</tbody>
</table>

**Target lesion location (mean±SD[range]) mm**  
22.7±17.2 (4-88)

**Degree of stenosis (median [range]) (%)**  
80 (50–100)

**Total occlusion**  
4 (8)

**Target vessel diameter (median [range]) mm**  
3 (2.5–3.5)

**PARC classification**

- Non: 1 (2)
- Focal: 19 (46)
- Mild: 4 (10)
- Moderate: 7 (17)
- Severe: 10 (24)

**TASC classification**

- A: 25 (61)
- B: 14 (34)
- C: 0 (0)
- D: 2 (5)

**Total patients = 41**
**Limbs = 41**

**No, of Lesions**  
53

**Total number of scaffolds deployed**  
69
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%
Freedom from TLR & US Occlusion

**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
CASE EXAMPLES
Preliminary Results

MAD: 5.4 mm
Rat D: 2.61 mm
% MLA: 45%
% MLA: 85%
Length: 10.13 mm
CF: 0.1395 mm/pix

4 months
R6 – Heel Gangrene

Combination SUPERA and BVS

- 5 x 40 SUPERA
- 3.5 x 28
- 3.0 x 18
- 2.5 x 28
- 2.5 x 28
5.5 years – all stented vessels patent, no repeat interventions
LONG LESION (70MM) WITH 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
Progression of disease in non stented vessel

Upper ATA was normal

Disease segment

Progression of disease in the segment of ATA

BVS segment is disease free

Index Angio 2012 (before BVS)
7 YEAR ANGIOGRAPHIC AND OCT FOLLOW-UP
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 commencement of LIFE BTK Study
12 Month Results of the DISAPEAR Registry (ABSORB BVS in CLTI)

• Single centre retrospective analysis of BVS implanted in Rutherford 4/5/6 CLTI Aug 2012 to June 2017
• 90% DM, 12% Dialysis dependent, 93% R5/6 (tissue loss)
• 53 lesions treated with 69 scaffolds in 41 patients, Rutherford 5 = 56%, Rutherford 6 = 37%
• Lesion length = 22.7±17.2 mm (Range 4-88), Median stenosis = 80%
• Lesion location: TPT 11 (33%), ATA 14 (26%), PTA 11 (21%), Peroneal 6 (11%), Popliteal 5 (9%)
• PARC Classification of calcification: Focal = 50%, Severe = 24%
• Results
  – Technical success 100%
  – Primary patency (DUS PSVR < 2.0) = 95% at 6 months, 86% at 12 months
  – FF CD-TLR = 98% at 6 months, 93% at 12 months
  – FF TLR & US Occlusion = 98% at 6 months, 93% at 12 months
  – AFS = 93% at 6 months, 85% at 12 months
  – Limb Salvage = 98% at 6 and 12 months
  – Complete wound healing = 79.5% at 12 months
  – Median time to wound healing = 4 months
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