Initial Experience With Drug-Eluting, Bioresorbable Vascular Scaffolds Below-the-Knee

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Disclosure

Speaker name:

.................... Ramon Varcoe .................................................................

I have the following potential conflicts of interest to report:

- [ ] Consulting: Abbott, Boston, Gore, Covidien
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
DRUG ELUTING STENTS
Primary Patency

Percentage (at 12 months)

<table>
<thead>
<tr>
<th>Trial</th>
<th>YUKON-BTK</th>
<th>DESTINY</th>
<th>ACHILLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES</td>
<td>81</td>
<td>85</td>
<td>78</td>
</tr>
<tr>
<td>BMS</td>
<td>56</td>
<td>54</td>
<td>58</td>
</tr>
</tbody>
</table>

*P=0.004

*P=0.0001

*P=0.019
WHY USE STENTS?

• ELASTIC RECOIL
• TREAT DISSECTION
• DELIVER DRUG TO THE INTIMA TO PREVENT RESTENOSIS
• REDUCE LATE LUMEN LOSS
BIO-RESORBABLE VASCULAR SCAFFOLD
Representative photomicrographs of porcine coronary arteries, 2x, Movat's pentachrome
Transmission Electron Microscopy (TEM)

Smooth Muscle

Phenotypically contractile SMCs

SMC alignment

Restoration of Arterial Integrity and Function

1 Month

36 Month
Gradual disappearance of supportive structure

Mechanical Conditioning

Vessel recovers the ability to respond to physiologic stimuli

Shear stress, pulsatility & cyclic strain

Tissue adaptation

Structure and functionality

• Single centre
• 3 Implanters under special access conditions
• Chronic lower limb ischemia: RC 3-6

• Direct replacement for DES
• De novo lesions; length ≤50mm, diameters 2.5-4.0mm
• Tibial arteries (+P3)
• Sample size: ≥15 patients
ENDPOINTS

• **Safety**: Major adverse events @ 30d
  • Death, target limb loss, major morbidity

• **Feasibility**: Technical success

• **Clinical Improvement**: Rutherford-Becker Class

• **Duplex FU**: 1, 3, 6 & 12mo (PSVR > 2.0)
  • Primary, assisted primary & secondary patency
  • TVR, TLR
PW 60%
WF 50Hz
SV 1.5mm
M2
3.5MHz
2.8cm

Vel 82.7 cm/s
RESULTS

• 22 patients
  – 25 Limbs (CLI 60%:IC 40%)
  – Age range 69-90yo
  – M:F 60:40

• 32 Scaffolds
  – Vessels treated
    • ATA 4
    • PTA 4
    • PA 7
    • TPT 16
    • P3 2

• Mean lesion length **20.2mm** (5-50mm)
• 100% Procedural success
• 1 death (6mo)
• 1 lost to follow up (panc. Ca)
• 1 Acute occlusion
  (day 1: no DAPT)

• Clinical Improvement 88%
• Primary patency 94.4%
• Assisted primary/secondary patency 100%
• Limb salvage 100%
• TLR 5.6%
• TVR 5.6%
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• Clinical Improvement 88%
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• Assisted primary/secondary patency 100%
• Limb salvage 100%
• TLR 5.6%
• TVR 5.6%
• BVS can be implanted safely within the tibial vasculature

• Excellent immediate angiographic results and promising 12-month patency can be achieved

• Dual anti-platelet agents are recommended to prevent thrombosis
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