BioResorbable, Drug-Eluting Scaffolds in BTK arteries

Update on the ABSORB BTK Project

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Disclosure

Speaker name:

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

I have the following potential conflicts of interest to report:

- Consulting       Abbott, Boston, Gore, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Metal DES are very good, but...

- Late thrombosis rate
- Fixed, rigid blood vessel
- Artefact on imaging (CT, MRI)
- Impediment to future intervention/surgery
• Poly-L-Lactic Acid structure
• Poly-D,L-Lactic Acid polymer
• Everolimus (100µg/cm²)
• 80% (±10%) elutes 28d
• Multilink design
• Circumferential hoops
• Straight connection bridges
• Radio-opaque platinum markers
• 150 µm strut thickness
VASCULAR RESTORATIVE THERAPY

• Reduced late events
• Restoration of vessel function
• Regression of plaque
• Lumenal gain

1. Smits P. EXTEND 3 Year Presentation. Presented at TCT 2014
2. ABSORB Cohort B trial; De Bruyne B, Serruys PW, etal., for the ABSORB Cohort B Investigators, TCT 2014
4. Serruys, PW. ABSORB Cohort B, 2-year results, TCT 2011
5. Serruys PW, ABSORB Cohort B, 3-year results, ACC 2013.
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STUDY DESIGN

- Single centre
- 3 Implanters under special access conditions

**Inclusion Criteria**

- Chronic lower limb ischemia: RC 3-6
- Life expectancy >1yr
- De novo lesions; >60%
- Tibial arteries (distal P3)
- Length ≤5cm,
- Diameters 2.5-4.0mm
- Treated inflow lesion were accepted
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
• 37 Limbs (CLI 73%:IC 27%)
  – 32 patients
  – Age range 65-97yo
  – M:F 51:49

• 48 Scaffolds
  – Vessels treated
    • ATA 11
    • PTA 9
    • PA 8
    • TPT 18
    • P3 2

• Mean lesion length 18.7 ±11.1mm (5-50mm)
• 100% Procedural success
• 1 Acute occlusion (day 1: no DAPT)
• 4 death (12.5%): Outside 30d

• **Sustained Clinical Improvement** 73%
• Primary patency 95.5%
• Assisted primary/secondary patency 100%
• Limb salvage 100%
• TLR 4.5%
• TVR 4.5%
Sustained Clinical Improvement in 73%

Rutherford-Becker Category

At Presentation

At Follow-up

N

RBC0  RBC1  RBC 2  RBC 3  RBC 4  RBC 5  RBC 6
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12-month Primary Patency – Compared With RCTs

- ABSORB-BVS
- IDEAS-DES
- IDEAS-DCB
- DESTINY-DES
- YUKON-DES
- ACHILLES-DES
- RANDON-PTA
- RANDON-BMS
- ACHILLES-PTA
- YUKON-BMS

YUKON. Rastan A et al. European Heart Journal 2011;32:2274-81
IDEAS. Siablis D et al. J Am Coll Cardiol Intv 2014;7:1048-56
BEFORE SEPT 2013

COMPLETION ANGIOGRAM AFTER 2x BVS

14 mo FU
Vascular restorative therapy with BVS offers several advantages over metal DES.

- BVS can be implanted safely within the tibial vasculature.
- Excellent immediate angiographic results and promising 12-month patency can be achieved.
“Leave Nothing Behind”

VS

“The Need for Stent-Like Scaffolding”
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