Status Of Bioresorbable DES For Treating BTK Arteries

Though They Failed In The Coronary Arteries They Show Promise In The Leg: The ABSORB BTK Trial 4-Year Results Show Why

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Disclosure
Speaker name: Ramon L. Varcoe

I have the following potential conflicts of interest to report:

- Receipt of grants/research support
  Details: Abbott Vascular
- Receipt of honoraria and travel support
  Details: Abbott Vascular, Medtronic
- Employment in industry
  Details:
- Shareholder in a healthcare company
  Details:
- Owner of a healthcare company
  Details:
- I do not have any potential conflicts of interest to report

A BVS MAY BE THE BEST OF BOTH WORLDS?

- Mechanical Scaffolding
- Drug Delivery
- Potential Return of Normal Vessel Wall Function
- Then Disappears!

STUDY DESIGN

- Prospective, Non-Randomised, Single-Center Study

Inclusion Criteria

- Chronic lower limb ischemia: RC 3-6
- Life expectancy >1yr
- Single or Multiple De novo lesions; >60%
- Infrapopliteal arteries (distal P3)
- Total Lesion Length ≤5cm (Max 2xBVS)
- Diameters 2.5-4.0mm

ENDPOINTS

- MEDICATION CHECK
- PHYSICAL EXAMINATION
- RUTHERFORD CLASS
- Ankle Brachial Index
- DUPLEX ULTRASOUND (PSVR<2.0)

ENDPOINTS

- Binary Restenosis
- Primary Patency
- CD-TLR
- CD-TVR

PATIENTS

- 48 Patients
  - Male:Female 56:44%
  - Mean Age 82yrs (range 65-97yrs)
- 55 Limbs
  - Left:Right 45:55%
  - CLI:IC 73:27%
• 71 Scaffolds Implanted
  – Target vessels treated
    • ATA 15
    • PTA 9
    • PA 15
    • TPT 29
    • P3 2
  • Mean lesion length $20.1 \pm 10.8$mm (5-50mm)

• 100% Procedural & Technical success
• 18 deaths (38% of cohort)
  (All Outside 30d)

Mean Follow-Up 28 months
  Sustained Clinical Improvement 95%
  Assisted primary/secondary patency 100%
  Limb salvage 100%

Sustained Clinical Improvement in 95%

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<tr>
<th>Time in Months</th>
<th>Freedom from TLR</th>
<th>Patency</th>
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CD-TLR 97.2%
Primary Patency 89.0%

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So What Happened?

Sept 14, 2017

“Due to low commercial sales, Abbott will stop selling the first-generation Absorb Biodegradable Vascular Scaffold”

WHY? (It’s all about the Coronaries...)

• DES has very low rates of thrombosis & restenosis A VERY HIGH BAR
• 1st Generation BVS was compared to a 7th generation DES with mature Rx paths
• BVS was rushed to market in Europe & had higher rates of late scaffold thrombosis LIKELY DUE TO POOR DEPLOYMENT TECHNIQUE
• This event can be fatal
A Few Facts about the PAD market...

• Commercial market for PAD is similar to CAD
• Coronaries are contracting, PAD increasing
• Ageing, Obesity and Diabetes
• There is a HUGE unmet need for BTK disease
• Up to 54% of patients undergoing amputation in the US may not have had a vascular assessment! 1,2


CONCLUSIONS

• Coronary results of BVS suffered from a rapid and ill-considered introduction to the market
• Poor commercial sales resulted in withdrawal of Absorb from the market
• A promising technology with distinct patient benefit has been for the Rx of PAD has been lost