Outcome of Zilver PTX stents placed in the infra inguinal outflow for Rutherford criteria >3 and or CLI patients – 1 year ultrasound follow up

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Disclosure

Speaker name: Awais Siddique M.D.

I have the following potential conflicts of interest to report:

☐ Consulting, Cook Medical
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any current potential conflict of interest
How Does Paclitaxel Work

Special Properties of Paclitaxel

• Hydrophobic.
• Lipophilic.
• Antiproliferative.
• 98% of the drug is released with in 72 hours after deployment.
• 100% of the drug in the artery 30 minutes after deployment.
• 0.2% left in the artery at 56 days. (IFU)
The proven drug effect of Zilver PTX

PTX advantage was demonstrated in the Randomized Controlled Trial (RCT) and Single-Arm Study (SAS)

Largest SFA study ever conducted.

- More than 1,000 patients enrolled in the two trials
- Planned for 5-year follow-up (Randomized Control Trial only)
SUMMARY OF THE RCT TRIAL

• Reduction of Re-intervention by 45%.
• Similar results in diabetic and non-diabetics.
• Similar results in lesions ≤ 7 cm and lesions > 7 cm.
• Similar results in lesions ≤ 10 cm and lesions > 10 cm.
• Superior to the standard care in lesions > 10 cm.
• 41% reduction in re-stenosis due to the drug.

4-year results (There was no evidence of late “catch-up”). (Dake et al.)

- 83.2% Zilver PTX
- 69.4% Optimal PTA + BMS

\[ p < 0.01 \text{ log-rank} \]
Overview

• Zilver PTX Single-Arm Study
  – Basically all comers, no length exclusion.
    • 86.2% primary patency rate at 1 year
    • 80.5% freedom from TLR through 2 years
    • Sustained clinical benefit through 2 years
FINANCIAL IMPACT

Significance of Re-intervention.

Initial procedure: $4,150

Re-intervention is costlier. Thus drug elution is a significant advantage.

$11,350

Increase in supply costs: 273%
Patient 1

• 71 year male patient.
• History of CAD. Multiple Co-morbidities (Stage 4 renal disease, COPD, Hx of BPH).
• Smoker, 1.5ppd x 53 years.
• History of 2 months of toe ulcerations.
• Fontaine 4, Rutherford 5.
• CT angiogram could not be performed given the Stage 4 renal disease. CO2 and diluted isosmolar contrast angiograms are performed.
Patient 1
Patient 1
SAFARI
Subintimal Arterial Flossing with Antegrade-Retrograde Intervention (SAFARI) via the AT
Patient 1
Sonographic images at 12 months
Patient 2

• 74 yo male.
• Multiple Co-Morbidities (DM, Smoker, COPD, CAD, PAD, Hx of ETOH use, admitted for back pain).
• Consulted by Orthopedics, for leg evaluation.
• Critical Limb Ischemia.
• Rutherford 6, Fontaine 4.
• CT angiogram demonstrated CTO of the left out flow.
Patient 2
SAFARI via AT
Patient 2
CASE 3

• 73 y old Male.
• Multiple co-morbidities (DM, Smoker 2ppd, CAD, TIA, CHF).
• Non healing ulcerations of the left great toe, digit 4 and 5.
• Rutherford 5 Fontaine 4.
• Patient has had previous BMS placed 3 months prior at an outside facility.
• Ultrasound confirmed occlusion.
US
Shows occlusion of the BMS
Angiography
Our Experience

- 323 stents utilized in approximately 126 limbs in 12 months.
- Approximately 2.56 stents per limb.
- Majority lesions greater than 10cm.
- 58% male, 42% female.
- Approximately 40% DM,
- 77% smokers or previous smokers.
- Approximately 20% diffusely calcified.
- 13% single vessel runoff.
- 94% placed on aspirin and plavix.
- 2 acute limb occlusions in heavily calcified diffuse outflow disease.
- 14 additional late limb occlusions and or symptomatic re-stenosis requiring re-intervention.
- Primary patency rate of 87.3% after 1 year, pSVR< 2.
- If Ultrasound positive then stratified into symptomatic or asymptomatic.
- If symptomatic then intervene.
- If asymptomatic then more frequent ultrasounds.
- High risk patients follow-up ultrasound q 1day-1week, then Strict q3 month follow-up duplex for first year.
- If sonographic stability is demonstrated then recommend evaluation q 6 months. (Possibly q 1 year after 2 year stability)
- Thank you for your attention.
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