Not So: Endovascular Techniques Have Poor Results In This Setting: Open Bypass Surgery Should be the First Invasive Option

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Disclosures

• None

ISR Classification

• Tosaka Classification
  – Studied 133 ISR lesions after FP stenting
  – Classified according type I, II, or III
  – Rate of recurrent ISR:
    • Class I- 49.9%
    • Class II- 53.3%
    • Class III-84.8%
  – Recurrent Occlusion- Class III-64.6%

Tosaka A. J Am Coll Cardiol. 2012; 80:852-859

ISR

• Endovascular Treatment options
  – Repeat POBA- cutting/scoring balloons
  – High pressure noncompliant balloons
  – Mech. Atherectomy
  – Laser Atherectomy
  – Covered Stents
  – Drug-eluting stents
  – Drug-coated balloon

Laird et al Endovascular Today 2004

DES and ISR

• Largest experience is with drug-eluting stents
  – Zilver PTX multicenter registry
  – 718 patients and 818 lesions treated
  – Subset of 142 ISR lesions
  – Freedom from TLR at 12 and 24 month was 78% and 69%

Dake, M The Zilver PTX randomized trial of paclitaxel-eluting stents for femoropopliteal disease: 24 monht update. Presented at LINC 2011,
**DCB for ISR**

- Virga et al.
  - Prospective registry of safety and efficacy of DCB to treat SFA in-stent restenosis
  - Initial 1 year primary patency results - 92.1%
  - 2 year follow-up and 39 patients
  - Primary patency at 2-year follow-up - 70.3%
  - More complex ISR lesions associated with increased rates recurrence
  - Safe and effective form of therapy

Virga et al. JACC Cardiovasc Interv 2014; 7:411-415

**DEBATE-ISR Study**

- Use of DCB to prevent ISR in diabetic patients
- Prospective all-comers study vs historical controls
- Lesion length
  - 132+/−86 mm in DCB vs 137+/−82 mm in POBA
- Recurrent stenosis at 1 year
  - 19.5% in DCB vs 71.8% in POBA
- Conclusion: DCB led to significant reduction in ISR at 1-year.

Liistro et al. J. Endovasc Ther. 2014; 21:1-8

**DCB for ISR**

- Randomized femoral artery in-stent restenosis trial (FAIR) trial
  - 119 patients over 34 months in 5 German hospitals
  - Randomized to either DCB or POBA
  - Mean lesion length 82.2+/−68.4 mm
  - 34 CTOs and 30 heavily calcified
  - Primary endpoint of recurrent ISR assessed via US at 6 and 12 months

Krankenberg et al. Circulation AHA 2015

**FAIR Trial**

- Results
  - Recurrent ISR 15.4% DCB vs 44.7% POBA at 6 months
  - Freedom of TLR - 96.4% DCB vs 81% POBA at 6 months
  - Freedom of TLR - 90.8% vs 52.6% at 12 months
  - Conclusions DCB associated with less recurrent ISR

Krankenberg et al. Circulation AHA 2015

**IN.PACT Global Study**

- Presented at VIVA 2015
  - Marianne Brodmann, MD
  - Reviewed ISR the IN.PACT Global Study
  - 1538 patients enrolled 64 sites
  - Identified 149 ISR

IN.PACT Global ISR Imaging Cohort
- Lesion length - 17.17 cm
- Primary Patency 88.7% at 1 year (KM)
- Clinically Driven TLR - 7.3%
- Effective form of therapy for ISR
DCB + Laser Atherectomy

- Laser and DCB vs DCB to treat ISR
- 48 patients all with CLI and Diabetes
- All with Tosaka III
- Treated length
  - Laser+DCB 22.4 +/- 9.4 cm
  - DCB 25.9 +/- 8.7 cm
- **12 month Primary Patency:**
  - 66.7% DCB+Laser vs 37.5% DCB

Gandini E et al. J Endovasc Ther. 2013 20:805-34

What about longer follow-up?

- Premature "congratulation"

Well, here are 5 year data

- Presenting an 8 year prospective evaluation of all 130 femoral-popliteal bypasses performed by Sarasota Vascular Specialists using the Gore Propaten® heparin-bonded ePTFE graft and
- Compare it to the prior 4 year experience with 123 standard ePTFE grafts (Gore® and Atrium®)

85.2%

59.6%

Is this the answer?