Plaque scoring and DCB: rationale and initial evidence in SFA-ISR

Technical forum

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Disclosure

Speaker name: Erwin Blessing

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s): speakers honorarium: Spectranetics

X I do not have any potential conflict of interest
Lesion preparation in ISR: potential candidates
Treatment options for ISR?

(POBA)

DCB

Atherectomy (plus DCB)

Laser (plus DCB)

BMS

DES

Viabahn

Scoring balloon plus DCB?
Treatment options for ISR?
Atherectomy: off-label indication!

Blessing et al.
Rationale for scoring balloons in ISR

No balloon slippage in fibrotic lesions
Less residual stenosis/recoil?
Less vessel overstretched/barotrauma
Less intimal flap after balloon dilatation?
Less bailout stenting?
Increased penetration depth for DCB?
Neointimal Modification with Scoring-Balloon and Efficacy of Drug-Coated Balloon Therapy in Patients with Restenosis in Drug-Eluting Coronary Stents

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Deutsches Herzzentrum München & I. medizinische Klinik, Klinikum rechts der Isar, Technische Universität München, both Munich; Herzzentrum der Segeberger Kliniken Gruppe, Bad Segeberg; Krankenhaus Landshut-Achdorf, Medizinische Klinik I, Landshut; all in GERMANY

ISAR-DESIRE 4: Intracoronary Stenting and Angiographic Results: Optimizing Treatment of Drug Eluting Stent In-Stent Restenosis 4
Plaque scoring and DCB in coronary ISR

**Study Organization**

**Design**

**DESIGN:** Prospective, randomized, active controlled, multicenter clinical trial

**INCLUSION CRITERIA:**
1. Stenosis > 50% in “limus”-eluting DES
2. Symptoms/signs of ischemia

**EXCLUSION CRITERIA:**
1. Lesion in left main stem
2. Acute STEMI
3. Cardiogenic shock

**FUNDING:** Biotronik

252 patients with DES-restenosis enrolled between June 2012 and December 2014 in 4 centers in Germany

- Scoring balloon plus paclitaxel-coated balloon (N=125)
- Standard balloon plus paclitaxel-coated balloon (N=127)

Angiographic follow-up at 6-8 months in 80.4% (N=203)*

Clinical follow-up at 12 months

*no significant differences across groups

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Study Devices

Spectranetics

Balloon with 3 nitinol spiral “scoring” wires (~0.005”)

Angiosculpt scoring balloon

Biotronik

3 µg paclitaxel/mm²
Butyryl-tri-hexyl citrate (BTHC) excipient

Pantera Lux paclitaxel-coated balloon
Plaque scoring and DCB in coronary ISR

Primary Endpoint

*Diameter Stenosis at Follow-up Angiography*

- Yellow line: Scoring-balloon
- Blue line: Control

P = 0.047

35.0% ± 16.8

40.4% ± 21.4

Cumulative Frequency (%)
Plaque scoring and DCB in SFA ISR
Plaque scoring and DCB in SFA ISR

Angiosculpt 5x200 mm

4 atm  
6 atm  
12 atm
Plaque scoring and DCB in SFA ISR

DCB 6x80 mm

DCB 6x120 mm

DCB 6x120 mm
Plaque scoring and DCB in SFA ISR
Plaque scoring and DCB in SFA ISR
Initial experience

February 2016 – January 2017
19 consecutive ISR cases (19 lesions, 18 patients)
Average age: 72.2 (55-89)
Male/female: 11/7
Rutherford: 3.3 (3-5)
Claudicants: 15
CLI: 3
Plaque scoring and DCB in SFA ISR
Initial experience

Superficial femoral artery: 17 lesions
Common iliac artery: 1 lesion
Popliteal artery: 2 lesion
1 stent fracture
Lesion length 127 mm (20-300 mm) Total occlusions: 5

Scoring balloon:
Angiosculpt 5x40 4 Angiosculpt 6x40 5
Angiosculpt 5x100 2 Angiosculpt 5x200 5
Angiosculpt 6x100 1 Angiosculpt 6x200 2

DCB:
Stellarex 15 InPact 1 Lutonix 1
Plaque scoring and DCB in SFA ISR
Initial experience

Technical success: 100%
Bail-out stenting: 1
Stenosis prior scoring: 91.3%
Stenosis post scoring: 19.5%
Stenosis post DCB: 10.5%
Mean follow up: 6.7 months
Freedom vom TLR: 84%
Drug-coated scoring balloons in ISR?

AngioSculpt®X Drug-Coated PTCA Scoring Balloon:

- Treatment solution combining PLAQUE SCORING and DRUG DELIVERY into a single device
- Potential for higher DRUG UPTAKE
  - 3 scoring elements (0.005” thick)
  - Available diameters: 2.0, 2.5, 3.0, 3.5
  - Available lengths: 10, 15, 20mm
  - GC compatibility: 6F
  - 8 atm Nominal Pressure, 18 atm Peak

Chocolate Touch®:
Changing the Landscape of Drug-Coated Balloons
Conclusions

• Treatment of ISR remains challenging (and expensive)

• Lesion preparation with scoring balloons followed by DCB might be a good (less expensive) alternative to debulking devices for ISR

• Drug-coated scoring balloons offer a potential breakthrough single-device solution
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