Drug-coated balloons: also the primary solution for long lesions? Pro

Francesco Liistro
Chief of Cardiovascular Intervention
Arezzo, Italy
Disclosure

Speaker name:
Francesco Liistro

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 potential conflict of interest
Long SFA Lesion and Restenosis

- Occlusion > stenosis
- Sub-intimal recanalization with long dissection
- Calcified segment with high residual stenosis
- Ostial lesion difficult to treat
- Re-entry point often in popliteal artery
For “metal believers”…

Interwoven Nitinol Supera 500 registry

No drug delivery: diffuse intimal hyperplasia

Mean 223mm
IN.PACT vs. DES in Long SFA lesions
Zeller T. J Endovasc. Ther 2014

228-Patients Retr. propensity score Analysis
• Non significant difference between IN.PACT DEB and Zilver PTX in long SFA lesions
• prov. Stent rate post DEB = 18.3%

Lesions ~19 cm

12-month freedom from death and TLR

12-month freedom from loss of Primary Patency (PSVR < 2.4)
For those who look forward....

**DCB as first line treatment**

- Homogeneous drug delivery for the entire length of the lesion, mostly inside the vessel structure (subintimal recanalization)
- Stenting rate is low and for short segment
- Drug delivery beyond lesion margins in CF or PIII segments for ostial SFA or popliteal disease
- No need for double antiplatelet treatment
- Restenosis is often focal and asymptomatic
DCB in long SFA Lesion: Available data....

Shmidt A. LINC 2013

Lesion Length: 24.0 ± 10 cm
Total occlusion: 65%
Stenting rate: 23%

Mean lesion length: 25.7 ± 7 cm
Total occlusion: 49.5%
Stenting rate: 10.5%

Micari A. PCR 2015

Lesion Length: 26.40 ± 8.61 cm
Total occlusion: 60.4%
Stenting rate: 40.7%

In.Pact Global Long Lesions
Sheinert D. PCR 2015
DCB: first line treatment in long SFA
DCB: first line treatment in long SFA

Baseline

DCB in CF artery

Post

In.Pact DCB
5x120mmx3

LL340mm

Post

12-month

12-month
DCB disadvantages

✓ Need of stent in case of suboptimal result (recoil, flow limiting dissection)
✓ Limited drug penetration in calcified segments

SOLUTIONS

✓ DCB + stent
✓ DCB+Debulking device
DCB+stent

Left SFA PTA+ Maris Stent 6X120mm

Right SFA DEB+ Maris stent 6X120mm

DCB prior to stent yields to macroscopic LLL reduction
Tailored approach to SFA long Occlusion using DCB:
Stent if dissection is “flow limiting”
Tailored approach to SFA long Occlusion using DCB Stent, if dissection is flow limiting.
DCB disadvantages

- Need of stent in case of suboptimal result (recoil, flow limiting dissection)
- Limited drug penetration in calcified segments

SOLUTIONS

- DCB + stent
- DCB + Debulking device
Limited drug penetration in calcified segments
Not only DCB problem:
Directional Atherectomy + DCB: DEFINITIVE AR

Zeller T, Tepe G.: ClinicalTrials.gov Identifier: NCT02363894
Orbital Atherectomy + DCB:

Primary lesion treatment with an orbital atherectomy system enhances paclitaxel deposition in calcified peripheral arteries

Euro Intervention

Five fresh human limbs
SFA-POP-Tibial calcified artery
OAS segments vs control segments
Infused with Radiolabeled $^{14}C$ or
Fluorescent paclitaxel

Paclitaxel deposition $\uparrow$ 50%

Paclitaxel deeper $20-40\mu\text{c}$ vs $100-300\mu\text{c}$ diffusion

DIAMONDBACK 360®

Classic crown (tibial)

Macro crown (distal pedal/tibial)

Tungsten solid crown (SFA/POP)

Euro PCR 2015
Lithoplasty

DISRUPT PAD*: Multicenter single arm registry
35 patients with calcified vascular stenosis of the SFA-POP
Success 100% (<50% residual DS)
6-month outcome:
  TLR 0%
  PP (duplex) 83%

✔ Electromechanical Lithotripsy breaks both superficial and deep calcium
✔ No damage to surrounding tissue
✔ Electrodes are built directly into the center of the balloon
✔ No physical movement of the device in the vessel.
✔ POBA or DEB ultimate the procedure after calcium barrier has been ruptured.

*Andrew Holden MBChB; Charing Cross 2105
DCB as primary solution for long SFA occlusion?

Yes: alone, with stents or debulking device in a tailored approach.
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