Combination Therapy
For The SFA
The Evidence For Stent And DCB Choice In This Exciting New Space

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Disclosure
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Drug Coated Balloons Work…

But, on their own they’re not enough to manage REAL WORLD Disease…

Drug Eluting Stents Also Work…

But, they also have drawbacks…

1. "Full-Metal-Jacket"
2. Fracture and metal fatigue
3. No-stent zones

Giacoppo et al. JACC: Cardiovascular Interventions 2016;9(16):1731-42

Dake MD et al. 5-year results of the Zilver PTX randomized trial. Circulation. 2016 Mar 11;CIRCULATIONAHA-115.
ADVANTAGES of Combination Rx

- More extensive drug deposition and transfer
- Limit the length/coverage of stent required
- Limit stents in locations known to be susceptible to extreme biomechanical forces (eg. Popliteal, CFA)

DEBATE SFA Trial (2013)

- Single center RCT
- (DCB & BMS) vs (PTA & BMS)
- Randomised 1:1
- 110 lesions (55 each arm)
- Mean length 94/96mm


What is the Evidence?

- Freedom from restenosis: 83% vs 52.7% (P=0.008)
- Freedom from CD-TLR: 83% vs 66.7% (P=0.07)

Maris Stent (Medtronic)
- 4F
- 0.018"
- Thin struts

InPact Admiral (Medtronic)
- Paclitaxel
- 3.5 µg/mm²
- Urea excipient
RAPID Trial (2016)

• Multi-center RCT
• (DCB & BMS) vs (PTA & BMS)
• Randomised 1:1
• 160 lesions (80 each arm)
• Mean length 156/155 mm

de Vries JP et al. One-year results of the RAPID trial. Presented at: the VERVE Symposium; December 1, 2016; Sydney, Australia.

1st
Legflow (Cardionovum)
• Nanocrystalline Paclitaxel
• Ammonium salt excipient

2nd
Supera Stent (Abbott)
• 6/7F Interwoven
• 0.018”
• Thick struts

@ 12-months
• Freedom from restenosis (PP) 72% vs 61% (P=NS)
• Freedom from CD-TLR

DEBAS Trial (2017)

• Multi-center, Single-arm study
• (DCB & BMS)
• 65 lesions
• Complex Group
• Mean length 187.6 mm
• 96% TASC C & D
• 80.4% CTOs

Mwipatayi BP et al. Presented at: the Leipzig Interventional Course (LINC); January 24–27, 2017; Leipzig, Germany

1st
Pulsar 18 Stent (Biotronik)
• 4F
• 0.018”
• 85x140 µm struts

2nd
Passeo 18 LUX (Biotronik)
• Paclitaxel
• 3.0 µg/mm²
• BTHC excipient

6 mo 12 mo 24 mo
• Freedom from restenosis
  98.0% 94.1% 88.2%
• Freedom from CD-TLR
  96.1% 94.1% 88.2%
DeLoose K et al. DCB + stent in the SFA: 12-month results of the BIOLUX 4EVER trial. Presented at: Charing Cross; April 25–27, 2017; London, United Kingdom.

BIOLUX 4EVER Trial (2017)
- Multi-center, Single-arm study
- (DCB & BMS)
- 120 lesions
- Mean lesion length 83.3 mm
- 33.3% CTOs
- 50% calcified

DeLoose K et al. DCB + stent in the SFA: 12-month results of the BIOLUX 4EVER trial. Presented at: Charing Cross; April 25–27, 2017; London, United Kingdom.

CONCLUSIONS
- Currently, little data exists for “thick-strut” BMS/DCB combinations and early experience using Supera appears less favourable
- Three trials with thin strut BMS combined with DCB have shown encouraging patency rates with Combination Rx
- Using DCB before or after BMS implantation seems to make little difference

DeLoose K et al. DCB + stent in the SFA: 12-month results of the BIOLUX 4EVER trial. Presented at: Charing Cross; April 25–27, 2017; London, United Kingdom.

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