The Importance of Vessel Preparation and How To Do It

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Disclosures

Within the past 12 months, Ralf Langhoff, MD had a financial interest/arrangement or affiliation with the organizations(s) listed below:

- **Advisory**
  - B. Braun, Biotronik SE, Medtronic, Contego Medical, Kardionet

- **Training**
  - Abbott Vascular, Medtronic, Boston Scientific, Biotronik, Alvimedica, Endoscout, BARD, Cordis, Maquet

- **Research**
  - Contego Medical, Biotronik

- **Shares**
  - Contego Medical
Vessel preparation

- Where is vessel preparation essential?
  - Prior to DCB
  - Prior to VMI (Supera Stent)

- Where is vessel preparation probably beneficial?
  - Treatment of occlusions
  - Treatment of complex lesions (Ca++, involving bifurcations,...)

- How to facilitate vessel preparation?
  - PTA
  - Atherectomy
  - Scoring/Cutting balloon
Vessel Preparation For DCB
Vesselpreparation

- A drug coated balloon (DCB) primarily is a drug carrier and not a PTA balloon!

- An undersized PTA balloon should facilitate lumen gain prior to drug application!
Illuminate FIH – Study Design

Two Cohorts

Direct DCB
N=28*

12-Month Follow-up
N=22
  - Withdrew (n=1)
  - Exitd (n=2)
  - Visit missed (n=3)

24-month data collection in process

Pre-dilatation + DCB
N=50

Follow-up through 24 months complete
Illuminate FIH- Direct vs. Pre-Dilatation Patency

FIH Patency (CEC CD-TLR Definition) Through 24 Months (predil) and 12 Months (dDCB)

89.5% at Day 365
77.5% at day 365
80.3% at Day 730
P=0.2270 through 12 months

Days
0 40 80 120 160 200 240 280 320 360 400 440 480 520 560 600 640 680 720 760

Patent (%)
0 10 20 30 40 50 60 70 80 90 100

dDCB predil

37 36 36 35 34 31 28 28 28 21 0
58 56 56 56 55 54 53 51 51 50 46 46 46 45 45 45 44 32 9
Vessel Preparation by Atherectomy prior to DCB
Directional Atherectomy (prepare the vessel) prior to drug delivery could improve outcomes

1. Mechanically re-canalize the vessel without overstretch

2. Remove the perfusion barrier – potential for better and more homogenous drug uptake

3. Reduce the likelihood of bail-out stenting and preserve the native vessel
Addressing the limitations of DCB angioplasty

Limitations of DCB angioplasty..

DCB is based on Angioplasty

Provisional Stent Rate increases with Lesion Length

Calcium May Limit Drug Effect

..addressed by Directional Atherectomy

Mechanically re-canalize the vessel without overstretch

Reduce likelihood of bail-out stent & preserve native vessel

Removes potential barriers for drug uptake
HawkOne™ Directional Atherectomy System

Designed to treat all atherosclerotic plaque efficiently and effectively, including severe calcium

Improved crossing and cleaning capabilities compared to TurboHawk™ platform
DEFINITIVE AR

Pilot study to detect trends in treatment differences between groups and designed to assess the effect of treating lesions with DA followed by DCB (DAART)

DAART: Directional Atherectomy + Anti-Restenotic Therapy

INCLUSION CRITERIA
• RCC 2-4
• $\geq 70\%$ stenosis of SFA and/or popliteal artery
• Lesion Length 7-15 cm
• Reference Vessel $\geq 4$ mm and $\leq 7$ mm

EXCLUSION CRITERIA
• In-stent restenosis
• Aneurysmal target vessel
• Multiple lesions in target limb that require treatment

DEFINITIVE AR: 12-mo Patency via Angio

Same trend:
Potential Advantage Emerging in Long and Severely Calcified Lesions

Results for all patients who returned for angiographic follow-up.

12-Month Patency: DAART RCT Patients

Is it Important to Achieve $\leq 30\%$ Residual Stenosis with Directional Atherectomy Post-Procedure?

DAART resulted in a significantly larger minimum lumen diameter (MLD)
Vessel Preparation prior to Supera Stent
The “3 Keys” for Optimal Supera Implant Deployment

1. Pre-dilate
   - Pre-dilate the lesion to ≥ the outer diameter of the implant.
   - Longer inflation times recommended.

2. Size 1:1
   - Match implant size 1:1 to vessel diameter.
   - Do not oversize the implant.

3. Deploy Slowly
   - Magnify imaging to observe cell geometry.
   - Use short, even throws of the thumb slide.
   - Open the deployment lock and fully advance thumb slide to completely release the implant.
   - Visually confirm implant detachment under fluoroscopy.
   - Retract the tip and lock the thumb slide before withdrawal.
   - Post-dilate as needed.

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New Class of Technology Requires a New Deployment Modality

- Supera is driven out of the delivery sheath by a stent driver near the tip of the delivery system - *the sheath does not retract*
- Stent deployment length depends on lesion preparation and deployment technique

Stent driver advances stent out of sheath

6F delivery system is 0.018” guide wire compatible and hydrophilically coated
Vessel Preparation prior to Supera Stent Implantation

It took 6 ballons to cross and prepare the lesion!!
Conclusions

- Vessel preparation is essential for some dedicated technologies like DCB and VMI technology
- Vessel preparation needs to be done effectively!
- If done with passion Vessel preparation is a driver for better patency
- Combination of atherectomy and DCB is evolving
  - Pilot study of conjunctive directional atherectomy / DCB use (DEFINITIVE AR) yields promising results
  - Current REALITY study may elucidate technical details of DA + DCB
Thank You For Attention!

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