Future of stenting in the current DCB world

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Disclosure slide

Speaker name: Koen Deloose, MD

X I have the following potential conflicts of interest to report:

X Consulting: Medtronic, Spectranetics, Biotronik, Abbott, BD/Bard iVascular, Bentley, Cook, GE Healthcare, Contego medical, Boston Scientific, Cardionovum, B Braun, Terumo

☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
The reality of DCB anno 2019

Evidence supports use in simple & complex lesions.
Performance of DCBs seems to be lesion complexity independent.
Can DCB alone fit it all?

Provisional stenting rate in DCB trial up to 40% in real-world studies

BIOLUX P-III all comers: Tepe G, CIRSE 2017
Lutonix Global: Thieme M. et al, JACC: Cardiovascular Interventions 2017
Lutonix Global Long lesions: Thiem J. et al, JACC: Cardiovascular Interventions 2017

In.Pact SFA: Tepe G. et al, Circulation n. 5, 131, pp. 495–502
Is DCB + BMS as good as DES?

Combining Passeo-18 Lux And Pulsar Shows Good 12-month Outcomes In SFA Compared To DES

BIOLUX 4 EVER: Deloose K., Presented at CX 2017, 12-month data (365 days)

IMPERIAL RCT: Gray WA. Lancet 2018 (Published online Sept 22, 2018)
The problem of DCB + BMS

- Full lesion stenting: full metal jacket
- Chronic physical irritation
- Long length vessel caging
- Fractures
- Intimal Hyperplasia
- In-stent restenosis

LEAVING NOTHING/LESS BEHIND

**BIOLEX 4 EVER**: Deloose K., Presented at CX 2017, 12-month data (365 days)

Therefore, a REACT treatment algorithm

- No Consensus on stent requirement to treat elastic recoil and flow limiting dissection
- No clear definition for flow limiting dissection in peripheral artery
- Should a dissection be treated or observed?
- How to improve procedural hemodynamic assessment and related stenting approach?

POBA
Prolonged Predilation

Acceptable

Satisfactory

Proven DCB
Prolonged inflation 3’

Mission accomplished

Unsatisfactory

BMS
As Less as Reasonably Achievable + post dilatation
## Design

Global Multicenter **Prospective, Pilot Diagnostic Study**

<table>
<thead>
<tr>
<th>Objective</th>
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<tr>
<td>• Evaluation of adjunctive procedural assessments to diagnose post drug-coated balloon flow-limiting dissection/residual stenosis additional to angiography</td>
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<tr>
<td>• Estimation Biotronik <strong>REACT algorithm</strong> clinical performance</td>
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<tr>
<td>• Assessment health care resources</td>
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## Participating centers

<table>
<thead>
<tr>
<th>Country</th>
<th>Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>▪ A.Z. Sint-Blasius, Dendermonde (Dr K. Deloose)</td>
</tr>
<tr>
<td></td>
<td>▪ Onze-Lieve-Vrouwziekenhuis, Aalst (Dr L. Maene)</td>
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<tr>
<td></td>
<td>▪ ZOL Genk (Dr W. Lansink)</td>
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<tr>
<td>France</td>
<td>▪ University Hospital of Nantes (Pr Y. Gouëffic)</td>
</tr>
<tr>
<td>Austria</td>
<td>▪ Medical University, Graz (Pr M. Brodmann)</td>
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<tr>
<td></td>
<td>▪ Medical University Vienna (Pr C. Loewe)</td>
</tr>
<tr>
<td>Germany</td>
<td>▪ Arnsberg Clinic, Arnsberg (Dr M. Lichtenberg)</td>
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<td></td>
<td>▪ Universität Herzzentrum, Freiburg-Bad Krozingen (Pr T. Zeller)</td>
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<td></td>
<td>▪ University Hospital Leipzig Heart Center, Leipzig (Pr D. Scheinert)</td>
</tr>
<tr>
<td>Australia</td>
<td>▪ Royal Perth Hospital, Perth (Pr P.B. Mwipatayi)</td>
</tr>
<tr>
<td>Spain</td>
<td>▪ University Hospital, Guadalajara (Dra M. Guerra)</td>
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</table>

- FPI: September 2018
- 11 subjects enrolled
### Study endpoints

#### Primary Endpoints

- Evaluate the diagnostic performance of (core lab controlled) intra-procedural DUS added to angiography compared to angiography alone:
  - Specificity/Sensitivity will be calculated for various peak systolic velocity ratio (PSVR) values
  - Determination of optimal cut-off via ROC curve

#### Secondary Endpoints (selected)

- Diagnostic performance of IAP+/-IVUS
- Stenting rate, Nb of stents/lesion, stented length (full, spot)
- Primary Patency, cdTLR, MAE
- Health care costs
# Inclusion/Exclusion criteria

<table>
<thead>
<tr>
<th><strong>Inclusion Criteria</strong></th>
<th>De novo, restenotic or (re)occluded lesion(s) post PTA in the native superficial femoral artery and or the proximal popliteal arteries</th>
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<tbody>
<tr>
<td></td>
<td>RC 2-4</td>
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<tr>
<td></td>
<td>RVD ≥ 4 and ≤ 7 mm</td>
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<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>ISR</td>
</tr>
<tr>
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<td>Use of debulking devices during the index procedure</td>
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<tr>
<td><strong>Subgroups</strong></td>
<td>Outcomes will be analyzed by different pre-defined subgroups: lesion length &lt;15 cm vs ≥15 cm; TASC A/B vs C/D; CLI vs non CLI</td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td>150 subjects</td>
</tr>
<tr>
<td><strong>Study duration</strong></td>
<td>Enrollment: 12 months / FUP: 1, 6 and 12 months</td>
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</tbody>
</table>
Final treatment with or without stent based on angiography & adjunctive evaluation findings

Independent Review Committee:
- Dissection grade (A-F)?
- FLD or not FLD?
- stent needed?
- full, spot stenting?

* IAP+/-IVUS will be conducted exclusively at pre-specified trained centers
## Diagnostic performance

### Adjunctive DUS + Angiography  vs Angiography alone

- **Sensitivity**: rate of true positive, based on the subjects with a clear FLD diagnosed by angiography = \( \frac{TP}{TP + FN} \)
- **Specificity**: rate of true negative, based on the subjects with no FLD diagnosed by angiography = \( \frac{TN}{FP + TN} \)

<table>
<thead>
<tr>
<th>Angio+adjunctive DUS or IAP+/-IVUS*</th>
<th>Angiography (independent Committee)</th>
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<tbody>
<tr>
<td></td>
<td>FLD (+)</td>
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<tr>
<td>FLD (+)</td>
<td>True positive (TP)</td>
</tr>
<tr>
<td>FLD (-)</td>
<td>False negative (FN)</td>
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</tbody>
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* IAP+/-IVUS will be conducted exclusively at pre-specified trained centers
BIO REACT case
BIO REACT case

Independent Review Committee:
- Dissection grade (A-F)?
- FLD or not FLD?
- stent needed?
- full, spot stenting?

Intra-operative DUS by operator
BIO REACT case

Stenting middle portion SFA
BIO REACT case
BIO REACT case
Summary

• DCB alone for complex lesions doesn’t work – “leaving nothing behind is a dream”
• Combination DCB + BMS seems to work good and can be benchmarked with DES
• Defining – evaluating – deciding on recoil & flow limiting dissections on angiography alone is extremely difficult and subjective
• BIO REACT pilot study evaluates the extra value of intra-operative DUS, IAP & IVUS to angiography alone, following the REACT strategy
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