Role of vessel preparation in contemporary DCB practice

Michael K. W. Lichtenberg MD, FESC
Klinikum Arnsberg Vascular Centre
Arnsberg, Germany
### Conflict of Interest - Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Honoraria for lectures:</td>
<td>CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan</td>
</tr>
<tr>
<td>2. Honoraria for advisory board</td>
<td>Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific</td>
</tr>
<tr>
<td>activities:</td>
<td></td>
</tr>
<tr>
<td>3. Participation in clinical</td>
<td>Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow</td>
</tr>
<tr>
<td>trials:</td>
<td></td>
</tr>
<tr>
<td>4. Research funding:</td>
<td>Biotronik, Boston Scientific, Veryan, Veniti, AB medica</td>
</tr>
</tbody>
</table>
Background
Mandate of Endovascular Devices

2 Targets:

1. **Make it Open**
2. **Keep it Open**

- Target 1) necessary but not sufficient to Target 2)
- Measure of success of Target 1 (lumen size, stability, ± presence of dissections may influence degree of success in target 2)
DCB: pre-dilatation + optimal PTA

some DCB can deliver noteworthy primary patency rates as stand-alone therapy with just pre-dil + optimal PTA

DCB randomized Trials with independent Duplex Corelab adjudication

1-year: 89.0%, 87.5%, 73.5%
2-year: 80.3%, 78.8%, 58.6%
3-year: 69.5%

Stellarex | In.Pact | Lutonix

1. M.Brodmann - ILLUMENATE European Randomized Clinical Trial: 12-month Final Results from the Stellarex DCB – oral presentation, AMP 2016
4. P. Krishnan, DCB show superior 3-year outcomes vs. PTA: results from In.Pact SFA randomized trial - oral presentation, VIVA 2016
Vessel prep: role of pre-Dilatation

- Excellent to assess the lesion type beyond just imaging
- Create first tunnel + allows for gradual lumen gain
- Protect DCB coating integrity in general but especially in CTOs and sub-occlusive lesions
- May reduce need for post-dilatation and stenting

Prakash Krishnan – Illumenate FIH pre-dilatation and direct cohorts - VIVA 2015, oral presentation
Role of Optimal PTA

- **Prolonged (3 minutes) PTA inflation**
  - Improves acute result vs. short (30 seconds) inflation
  - Significantly reduces rate of major dissections
  - Shows a modest reduction of residual stenosis

<table>
<thead>
<tr>
<th>Inflation Time (sec)</th>
<th>Major dissection (grades 3 and 4)</th>
<th>Minor or no dissection (grades 1 and 2)</th>
<th>Further interventions</th>
<th>Residual stenosis (&gt;30%)</th>
<th>Complication (embolization, thrombosis)</th>
<th>Mean ankle-brachial index (before, after intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
<td>21</td>
<td>20</td>
<td>16</td>
<td>12</td>
<td>0.66, 0.87</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>32</td>
<td>9</td>
<td>8</td>
<td>5</td>
<td>0.65, 0.84</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>P Value</strong></td>
<td>.010</td>
<td>.010</td>
<td>.017</td>
<td>.097</td>
<td>.097</td>
<td></td>
</tr>
</tbody>
</table>

DCB in complex settings: Ca^{++}

Noteworthy results achievable by some DCBs in trials with highest rates of severe Calcium, however:

do ways exist to improve acute gain (bigger, more stable lumen? to reduce chances of flow-limiting dissections? to make acute success easier and quicker? To potentially enhance drug absorption?

Corelab adjudicated Duplex derived Primary Patency based on PSVR ≤2.4 (▪) or ≤2.5 (▫); KM survival estimates at 360 (†) or 365 (‡) days.

1. T.Zeller – Illumenate Global – oral presentation, LINC 2017
2. S.Lyden - ILLUMENATE Pivotal Stellarex DCB IDE Study 12-month Results - oral presentation, TCT 2016
3. M.Brodmann - ILLUMENATE European Randomized Clinical Trial: 12-month Final Results from the Stellarex DCB – oral presentation, AMP 2016
4. P. Krishnan, DCB show superior 3-year outcomes vs. PTA: results from In.Pact SFA randomized trial - oral presentation, VIVA 2016
Role of Plaque Scoring: AngioSculpt

Nitinol scoring elements increase vessel compliance by breaking circumferential hoop stress:

- Reduce rate and entity of severe dissection
- Increase and stabilize (↓ recoil) lumen gain
- Potentially increase DCB drug uptake
- Confer precision and stability to balloon dilatation

Lengths: 10 to 200 mm
Diameters: 2.0 to 6.0 mm
Intr. Sheath compatibility: 5 / 6 F
Guidewire compatibility: 0.014” / 0.018”

Role of Plaque Scoring: AngioSculpt

Reduced rate of flow-limiting dissections observed with Angiosculpt vs historical PTA benchmarks

DCB in complex settings: ISR

DCB better then PTA @ 1 year, however:

- Tosaka III indep. predictor of re-restenosis and re-occlusion
- Complete catch-up @ 3 years


Laser

Recanalization, Debulking, Plaque Modification

<table>
<thead>
<tr>
<th>Photochemical: Molecular bond break</th>
<th>Photothermal Thermal energy</th>
<th>Photomechanical Kinetic energy</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Photochemical Image]</td>
<td>![Photothermal Image]</td>
<td>![Photomechanical Image]</td>
</tr>
</tbody>
</table>

- Recanalization (Pilot Channel)
- Plaque vaporization
- Limited embolization
- No moving blades
- Only FDA approved Atherectomy for ISR
Laser+DCB in ISR pre-Clinical Insights

Rabbit model of (carotid) CTO ISR by Fogarty Injury and BMS implant

Reduced % stenosis and intimal thickness with Laser+DCB vs. DCB alone at 28 days

<table>
<thead>
<tr>
<th>Sections</th>
<th>Lumen Area (mm²)</th>
<th>Neointimal Area (mm²)</th>
<th>Stenosis (%)</th>
<th>Neointimal Thickness (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA + DCB</td>
<td>6</td>
<td>2.91 ± 0.58</td>
<td>2.82 ± 0.3</td>
<td>49.59 ± 6.74</td>
</tr>
<tr>
<td>Laser + DCB</td>
<td>12</td>
<td>3.6 ± 0.94</td>
<td>2.36 ± 0.54</td>
<td>40.27 ± 11.50</td>
</tr>
</tbody>
</table>

P-value: 0.060 | 0.036* | 0.044* | 0.012*

*Significant based on 1-tailed t-test (p < 0.05)

Laser + DCB in ISR

Single center randomized trial of Laser + DCB vs. DCB in long occlusive ISR

N=48; CLI: 100%; Diabetes: 100%; Occlusive ISR (Tosaka III): 100%
mean ISR treated length: 22.4±9.4 (Laser + DCB) vs. 25.9±8.7 cm (DCB)

• 12-month Prim. Patency* 66.7% vs. 37.5% (p=0.01)
• Significant ↓ of TLR and MAE and improved wound healing in the Laser + DCB arm

* ELA+DCB vs. DCB

Laser + DCB in ISR

SFA-ISR case series treated with Laser + DCB:

N=14
~13 cm ISR length

Laser + DCB resulted in reduced TLR rate (1 TLR: 7%) and reduced time-to-TLR (3 years) vs. initial PTA treatment (8 months)

Conclusions

• Level 1 evidence shows that some DCBs can perform very well in TASC A-B fem-pop lesions. Some DCBs also showed noteworthy outcomes from trials with high rates of Ca++

• Beyond pre-dilatation and optimal PTA, adjunction vessel prep can help to achieve acute success better and easier with larger, more stable acute gain, lower dissection and better predisposition to drug absorption

• Angiosculpt plaque scoring represents a viable solution to easily manage severely calcified lesions

• Laser Photoablation increases DCB effect in ISR, especially if occlusive
Thank you for your attention
Role of vessel preparation in contemporary DCB practice

Michael K. W. Lichtenberg MD, FESC
Klinikum Arnsberg Vascular Centre
Arnsberg, Germany