DCB in BTK: Why and where should we use it

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Disclosure

Speaker name: Francesco Liistro

I have the following potential conflicts of interest to report:

☒ Consulting: Medtronic
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)
☐ I do not have any potential conflict of interest
Drug-eluting in BTK Intervention: DES vs DCB

- **Elastic Recoil (hours)**
  - DES: -
  - DCB: +

- **F.L. Dissection (dynamic)**
  - DES: -
  - DCB: +

- **Thrombosis**
  - DES: +
  - DCB: ±

- **Drug elution control**
  - DES: +
  - DCB: ±

- **Negative remodeling (months)**
  - DES: -
  - DCB: -

- **Long-term DAT**
  - DES: ±
  - DCB: -
Why do we use DCB in BTK

Elution Control vs Vessel Injury

**Vessel injury**

Stent Inflation and persistent mechanical stress on the vessel wall (months)

**Ballon inflation** (minutes)

**DES**
- Stent mandatory
- +/- Polymer
- Inhomogeneous drug-distribution
- Slow drug release with persistent drug exposure
- Dose: ~ 100-200μg

**DEB**
- Provisional Stent
- No Polymer
- Homogeneous drug-distribution
- Short drug release/exposure
- Dose: ~ 300-600μg
DCB Elution Kinetic
High Drug load for short tissue drug retention

Granada JF. Interventional Cardiology. 2016
Gongora CA. JACC Cardiovasc Interv. 2015
The IDEAS Randomized Controlled Trial

- 50 patients, 25 (25 lesions) DCB, 25 (30 lesions) DES
- Mean lesion length: 148±56 DCB vs 127±46 DES p=0.1
- CTO: 3/25(12%) DCB vs 7/30(23%) DES
- DCB inflation time 1 min

Suboptimal angioplasty

DES: 1.35 ± 0.2
DEB: 1.15 ± 0.3
P = 0.6

DES: 3.6 ± 1.5
DEB: 4.3 ± 1.6
P = 0.16
Why DCB: anatomical issues

Published studies on BTK PTA
Length of the treated lesion

- >300 mm: 37%
- 251-300 mm: 35%
- 201-250 mm: 28%

3683 successfully treated lesion in BTK vessels
### Four Different Paclitaxel Eluting Balloons Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Debate BTK</th>
<th>Registry</th>
<th>Lutonix</th>
<th>Freeway</th>
<th>Litos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Nr</td>
<td>65</td>
<td>31</td>
<td>49</td>
<td>52</td>
<td>39</td>
</tr>
<tr>
<td>Mean age</td>
<td>74±9.4</td>
<td>73±8.7</td>
<td>76±8.5</td>
<td>74±7.4</td>
<td>77±8.9</td>
</tr>
<tr>
<td>Diabetes</td>
<td>65 (100)</td>
<td>28 (90)</td>
<td>44 (90)</td>
<td>41 (78)</td>
<td>39 (100)</td>
</tr>
<tr>
<td>Target Lesion</td>
<td>80</td>
<td>35</td>
<td>55</td>
<td>64</td>
<td>47</td>
</tr>
<tr>
<td>ATA</td>
<td>37 (46.3)</td>
<td>17 (48.5)</td>
<td>34 (61)</td>
<td>35 (54)</td>
<td>28 (59)</td>
</tr>
<tr>
<td>PTA</td>
<td>13 (16.3)</td>
<td>9 (26.5)</td>
<td>11 (20)</td>
<td>16 (25)</td>
<td>10 (21)</td>
</tr>
<tr>
<td>PA</td>
<td>14 (17.5)</td>
<td>5 (14)</td>
<td>7 (14)</td>
<td>8 (13)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>TPT</td>
<td>16 (20.0)</td>
<td>4 (11)</td>
<td>3 (5)</td>
<td>5 (8)</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Tot Occlusions</td>
<td>62 (77.5)</td>
<td>20 (57.1)</td>
<td>39 (70)</td>
<td>45 (70)</td>
<td>34 (72)</td>
</tr>
<tr>
<td>Lesion Length(mm)</td>
<td>128±83</td>
<td>120±93</td>
<td>161±94</td>
<td>173±88</td>
<td>175±112</td>
</tr>
<tr>
<td>RVD</td>
<td>2.91±0.2</td>
<td>2.90±0.34</td>
<td>2.87±0.31</td>
<td>2.84±0.30</td>
<td>2.94±0.39</td>
</tr>
<tr>
<td>Balloon Diameter</td>
<td>2.90±0.39</td>
<td>2.94±0.33</td>
<td>2.88±0.34</td>
<td>2.82±0.32</td>
<td>3.03±0.33</td>
</tr>
</tbody>
</table>

1. Presented by Liistro VEITH 2017
12-month primary patency and lesion length with different DES platforms
DES and lesion Length in BTK

Mean length of the treated lesion

14 studies on Balloon Expandable Drug Eluting Stent (DES)

Mean length of lesion: 38.2 mm (14-127)
Disease location among prox-dist tibial segments

In the last 325 consecutive CLI patients treated in BTK lesions, 40% had vessel reconstitution at the level of the ankle or below!! It is the most frequent cause of screening failure in BTK trial.

POBA is the only possible treatment in BTK vessel and DCB is the drug eluting technology we can use most
Where to use DCB

Long Lesion: Green Light for DCB

BASELINE

6-MONTH AFTER DCB
Where to use DCB

Complex long Lesions with BTA reconstitution:

baseline
baseline
3.0x300 mm DCB
Where to use DCB

Complex long Lesions with BTA reconstitution:
Stent fracture and compression in distal BTK intervention

Karnabatidis D: Journal of Endovascular Therapy 16(1):15-22 · February 2009

GAME OVER
Long Tibial Occlusion
Subintimal Recanalization + DCB is The optimal Strategy

Subintimal recanalization (long occlusion)
- More dissection = more risk of mechanical reocclusion
- High vascular trauma ↑ higher restenosis in POBA
- DCB: The drug is delivered directly into the media = more paclitaxel at the target site means more antiproliferative effect

Intraluminal recanalization (long lesions)
- Less dissection = low risk of mechanical reocclusion
- Less vascular trauma ↓ vascular response
- DCB: The drug is delivered into the intima and has to migrate into the media: calcification and plaque burden my limit the absorption = less paclitaxel at the target site means less antiproliferative effect
Long Tibial Occlusion and subintimal recanalization with DCB

Popliteal Trifurcation
Blunt Occlusion
Distal filling of PTA

∅ 3.5mm
Retrograde wire as guide to antegrade recanalization

Aggressive pre-dilatation with 3.5mm balloon in POP-TPT and 3.0mm balloon in PT artery

Residual Spiral dissection but Direct flow to plantars

3.5x120mm +3.0x120mm DCB

SPIRAL DISSECTION BUT NOT FLOW LIMITING
8-month Outcome
Full vessel patency
Dissection healed

OPTIMAL BLUSH IN THE FOOT
Subintimal recanalization and Spiral Dissection

PRE Retrograde DCB 3x300m
POST
POST
POST
Subintimal angioplasty via retrograde recanalization
Entry and Re-entry points
Things may change early

Post procedure 2 weeks later
Mechanical TLR: Repeat Revascularization Due to Early Reocclusion Caused by Dissection-Recoil-Thrombosis Not Restenosis

2 weeks post procedure
Stent in TP
Post MTLR
6-month
Is the proximal segment the target for DES?
Is the proximal segment the target for DES?
In proximal stenosis be aggressive because you are intraluminal: Use Duplex guidance

3.0x80mm
Difining optimal balloon angioplasty: Duplex guidance

In the ACOART BTK study restenosis rate is <20% for lesion located in the first 80mm of tibial arteries.
# ACOART BTK

## Patients Clinical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>LITOS</th>
<th>POBA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients Nr</strong></td>
<td>51</td>
<td>53</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Mean age</strong></td>
<td>75.6±8.6</td>
<td>74.6±8.8</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Male gender</strong></td>
<td>39(76)</td>
<td>42(79)</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>51(100)</td>
<td>49(93)</td>
<td>0.1</td>
</tr>
<tr>
<td><strong>Ever smoked</strong></td>
<td>24(47)</td>
<td>28(53)</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>41(80)</td>
<td>47(89)</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Dyslipidemia</strong></td>
<td>26(51)</td>
<td>32(60)</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>Renal Failure</strong></td>
<td>20(39)</td>
<td>21(40)</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Number of limb</strong></td>
<td>54</td>
<td>54</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Rutherford class</strong></td>
<td>3(5)</td>
<td>3(5)</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>51(95)</td>
<td>49(95)</td>
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</table>
# Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>LITOS DCB</th>
<th>POBA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Vessel</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATA</td>
<td>36(61)</td>
<td>41(64)</td>
<td>0.9</td>
</tr>
<tr>
<td>PTA</td>
<td>10(17)</td>
<td>11(17)</td>
<td></td>
</tr>
<tr>
<td>PA</td>
<td>4(7)</td>
<td>5(8)</td>
<td></td>
</tr>
<tr>
<td>TPT</td>
<td>9(15)</td>
<td>7(11)</td>
<td></td>
</tr>
<tr>
<td><strong>N.Lesion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De Novo</td>
<td>56(92)</td>
<td>60(90)</td>
<td>0.6</td>
</tr>
<tr>
<td>Restenotic</td>
<td>5(8)</td>
<td>7(10)</td>
<td>0.6</td>
</tr>
<tr>
<td>CTO</td>
<td>43(70)</td>
<td>47(70)</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Lesion Length</strong></td>
<td>150-200</td>
<td>150-200</td>
<td></td>
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</table>
## Preliminary Angiographic Outcome at 6 Months

<table>
<thead>
<tr>
<th>Pat/lesion</th>
<th>LITOS</th>
<th>POBA</th>
<th>p value</th>
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</thead>
<tbody>
<tr>
<td>Death before 6 month</td>
<td>3pts(3les)</td>
<td>2pts(3les)</td>
<td>0.5</td>
</tr>
<tr>
<td>Lost from Angio F.UP</td>
<td>2pts(2les)</td>
<td>1pts (1/les)</td>
<td></td>
</tr>
<tr>
<td>Angio Fup in 2019</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Angio F.up completed</td>
<td>54/61(89)</td>
<td>59/67(88)</td>
<td>0.4</td>
</tr>
<tr>
<td>TL Reocclusion</td>
<td>7/54(13)</td>
<td>32/59(54)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>TLR</td>
<td>6/54(11)</td>
<td>27/59(46)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

### Reocclusion
- Δ 41%
- RRR 76%
Conclusion

• DCB is a valid drug-release treatment for BTK
• In 2019 solid data will confirm it
• DCB should be used after optimal balloon angioplasty
• DCB has the most advantage in occluded vessel, long lesion, preferring an aggressive subintimal approach with final and short term functional flow assessment
• DCB can be also used in short stenosis but the advantage might be less.
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