Inflation with or without drugs BTK?
Disclosure

Roberto Ferraresi, MD

I have the following potential conflicts of interest to report: consulting, travel reimbursement, teaching courses, training, proctoring:

• Medtronic
• Boston Scientific
• Abbott
• LimFlow
• Terumo
• Cook
• Biotronik
• Asahi
• Shire
• Ivascular
1. The scenario of BTK angioplasty

2. UB POBA published data

3. DCB POBA published data

4. Conclusion
My last 2000 PTA on CLI pts: 3683 successfully treated lesions in BTK vessels
Mean length of the treated lesion

10 studies on BE-BMS
Mean lesion length 27.5 mm (14-52)
Mean length of lesion: 48 mm (33-75)

Published studies on BTK angioplasty
14 studies on DES
Mean length of lesion: 37.0 mm (14-127)
Mean length of the treated lesion

7 studies on UB-POBA
Mean length of lesion: 147.6 mm (115-213)

Published studies on BTK angioplasty
7 studies on DCB-POBA
Mean length of lesion: 160 mm (101-242)
Length of the BTK successfully treated lesion

Published studies on BTK PTA

3683 successfully treated lesions in BTK vessels
Length of the BTK successfully treated lesion

Lesion length ≤ 5 cm

Short proximal BTK lesions: this is the domain of DES.

28%

Published studies on BTK angioplasty
Length of the BTK successfully treated lesion

Lesion length 5-20 cm

Standard long BTK lesions: this is the domain of balloons (UB/DCB).

Published studies on BTK angioplasty
Length of the BTK successfully treated lesion

Lesion length >20 cm

Extra long BTK (and foot!) lesions: this is the *Far West* of CLI-BTK-PTA!!!
1. The scenario of BTK angioplasty

2. UB POBA published data

3. DCB POBA published data

4. Conclusion
Primary patency 64% (Duplex Scan)

Published studies on BTK UB-POBA reporting restenosis rate
No agreement on restenosis rate of UB!

Why?

Primary patency 64% (Duplex Scan)

Published studies on BTK UB-POBA

3 studies on UB POBA
Mean restenosis rate 75% (69-82)

3 studies on UB POBA
Mean restenosis rate 38% (35-41)
Restenosis rate/months FU

Published studies on BTK UB-POBA

Use the correct inflation time!

Prolonged inflation (180 sec) improves the immediate result of BTK angioplasty compared to short dilatation times (30 sec).

Significantly fewer major dissections and a modest reduction of residual stenoses are observed.

Published studies on BTK UB-POBA

<table>
<thead>
<tr>
<th>Year</th>
<th>Study Name</th>
<th>Restenosis Rate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Leipzig Registry-UB</td>
<td>3</td>
</tr>
<tr>
<td>2012</td>
<td>lida-UB</td>
<td>12</td>
</tr>
<tr>
<td>2013</td>
<td>Liistro-Debate-BTK UB</td>
<td>12</td>
</tr>
<tr>
<td>2014</td>
<td>InPact Deep Trial-UB</td>
<td>12</td>
</tr>
<tr>
<td>2015</td>
<td>Biolux P-II UB</td>
<td>6</td>
</tr>
<tr>
<td>2016</td>
<td>Nanocross Study UB</td>
<td>12</td>
</tr>
</tbody>
</table>

Primary patency 64% (Duplex Scan)
Restenosis rate/months FU

Published studies on BTK UB-POBA

No inflation time difference

Use the correct inflation time!

Prolonged inflation (180 sec) improves the immediate result of BTK angioplasty compared to short dilatation times (30 sec)

Significantly fewer major dissections and a modest reduction of residual stenoses are observed
Restenosis rate/length of lesion mm

No lesion length difference
Data on UB-POBA are conflicting!

“…Before running ahead with new devices we should learn when and how to use in BTK the oldest one, the UB”

(Ferraresi, Vascular News 2016)
1. The scenario of BTK angioplasty

2. UB POBA published data

3. DCB POBA published data

4. Conclusion
Restenosis rate/months FU

2 studies on DCB POBA
Mean restenosis rate 27%

3 studies on DCB POBA
Mean restenosis rate 50.7%

Published studies on BTK DCB-POBA
<table>
<thead>
<tr>
<th>Study</th>
<th>Restenosis rate %</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 Leipzig InPact Registry DCB</td>
<td>3</td>
<td>6</td>
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<td>2013 Liistro Debate BTK DCB</td>
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<tr>
<td>2014 Siablis IDEAS DCB</td>
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<tr>
<td>2014 Impact Deep Trial DCB</td>
<td>6</td>
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<tr>
<td>2015 Biolux P-II DCB</td>
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</tbody>
</table>

No agreement on restenosis rate of DCB! Why?

Restenosis rate/months FU

- 2 studies on DCB POBA
  - Mean restenosis rate 27%
- 3 studies on DCB POBA
  - Mean restenosis rate 50.7%
Restenosis rate/length of lesion mm

No lesion length difference

Published studies on BTK DCB-POBA
Restenosis rate/mean balloon diameter

Key point: balloon diameter?

Published studies on BTK POBA
Drug-Coated Balloons for Revascularization of Infrapopliteal Arteries
A Meta-Analysis of Randomized Trials

Salvatore Cassese, MD, PhD, Gjin Ndrepepa, MD, Francesco Liistro, MD, Fabrizio Fanelli, MD, Sebastian Kufner, MD, Ilka Ott, MD, Karl-Ludwig Laugwitz, MD, Heribert Schunkert, MD, Adnan Kastrati, MD, Massimiliano Fusaro, MD

TABLE 1 Main Characteristics of Patients Enrolled Among Trials Included in the Study

<table>
<thead>
<tr>
<th>Trial (Ref. #)</th>
<th>Patients, n</th>
<th>Age, yrs</th>
<th>Men, %</th>
<th>Diabetes, %</th>
<th>CKD, %</th>
<th>CLI, %</th>
<th>Lesion Length, mm</th>
<th>Diameter Stenosis, %</th>
<th>Severe Calcification, %</th>
<th>Occlusion, %</th>
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</thead>
<tbody>
<tr>
<td>BIOLUX PII (9)</td>
<td>72</td>
<td>71.3</td>
<td>79</td>
<td>67</td>
<td>28</td>
<td>78</td>
<td>114.1</td>
<td>72.3</td>
<td>5</td>
<td>NR</td>
</tr>
<tr>
<td>DEBATE BTK (6)</td>
<td>132</td>
<td>74.5</td>
<td>80</td>
<td>100</td>
<td>11</td>
<td>100</td>
<td>130.0</td>
<td>97.2</td>
<td>27</td>
<td>80</td>
</tr>
<tr>
<td>DEBELLUM* (7)</td>
<td>30</td>
<td>66.5</td>
<td>73</td>
<td>52</td>
<td>NR</td>
<td>52</td>
<td>77.0</td>
<td>86.5</td>
<td>18</td>
<td>21</td>
</tr>
<tr>
<td>IDEAS (8)</td>
<td>50</td>
<td>71.5</td>
<td>76</td>
<td>70</td>
<td>54</td>
<td>100</td>
<td>137.5</td>
<td>86.0</td>
<td>47</td>
<td>17</td>
</tr>
<tr>
<td>IN.PACT DEEP (10)</td>
<td>358</td>
<td>72.5</td>
<td>73</td>
<td>72</td>
<td>11</td>
<td>100</td>
<td>115.0</td>
<td>85.2</td>
<td>21</td>
<td>42</td>
</tr>
</tbody>
</table>

Overall mean values are reported. *Patients presenting with infrapopliteal lesions only.

BIOLUX PII = First-in-Man Study to Compare the Passeo-18 Lux DRB Against POBA in Infrapopliteal Arteries; CKD = chronic kidney disease; CLI = critical limb ischemia; DEBATE BTK = Drug Eluting Balloon in Peripheral Intervention for Below the Knee Angioplasty Evaluation; DEBELLUM = Drug-Eluting Balloon Evaluation for Lower Limb Multilevel Treatment Drug Eluting Stents; IDEAS = Infrapopliteal Drug Eluting Angioplasty Versus Stenting for the Treatment of Long-Segment Arterial Disease; IN.PACT DEEP = IN.PACT Amphirion™ Drug Eluting Balloon vs. Standard PTA for the Treatment of Below the Knee Critical Limb Ischemia; NR = not reported.
CONCLUSIONS

The results of our meta-analysis suggest that in patients with infrapopliteal artery disease, percutaneous intervention with DCBs compared with uncoated balloons or DESs displays similar clinical efficacy and favorable angiographic outcomes at 1-year follow-up.
Favorable Angiographic Outcome After Treatment of Infrapopliteal Lesions With Drug-Coated Balloons Without Clinical Benefit

What We Learn From a Meta-Analysis*

Thomas Zeller, MD,a Michael R. Jaff, DOb
First of all, are the angiographic findings correct? Are DCB really superior in terms of LLL over UB and DES? Interestingly, only the 3 uncontrolled studies using the IN.PACT Amphirion DCB resulted in superior LLL outcomes whereas both independently core laboratory adjudicated and fully industry funded studies found identical LLL outcomes for the DCB and UB cohorts suggesting a lack of biological efficacy of both DCB brands examined in those 2 studies.
In summary, despite the superior angiographic outcome defined as LLL in this meta-analysis the performance of DCB in infrapopliteal lesions remains controversial.
I need something to treat the vast majority of BTK lesions (5-35 cm).

I believe in DCB on the basis of:

• Personal experience
• Friends advise

But today we have not any real scientific support to use DCB!