Long term effects of paclitaxel releasing balloon dilatation catheters for AVF stenosis: the evidence to date

LINC, Leipzig. 23rd January 2019

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Consultant vascular radiologist, Leeds, UK
Declarations

• Supported by Cardionovum to attend LINC 2019
• Paid speaker at Industry Symposium at BSIR 2018
## DCBs

<table>
<thead>
<tr>
<th>Dose (µg/mm²)</th>
<th>Coating</th>
<th>RBP (atm)</th>
<th>Max diameter (mm)</th>
<th>Min shaft (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Sorbitol and polysorbate</td>
<td>10-12</td>
<td>12</td>
<td>40</td>
</tr>
<tr>
<td>3.5</td>
<td>Urea</td>
<td>14</td>
<td>7</td>
<td>40</td>
</tr>
<tr>
<td>3.0</td>
<td>Safepax amorphous</td>
<td>18-20</td>
<td>10</td>
<td>40</td>
</tr>
<tr>
<td>3.0</td>
<td>Butyryl tri-hexylcitrate</td>
<td>12-15</td>
<td>7</td>
<td>90</td>
</tr>
<tr>
<td>2.0</td>
<td>TransPax</td>
<td>12-14</td>
<td>8</td>
<td>80</td>
</tr>
<tr>
<td>2.0</td>
<td>Polyethylene glycol</td>
<td>12-20</td>
<td>6</td>
<td>80</td>
</tr>
</tbody>
</table>
Some non randomized data

**InPact Admiral**
In stent recurrent stenoses
Controls: same patient before DCB

- f-TLR @ 1y
  - DCB: 69%, POBA: 19%. OR: 3.6

**InPact Admiral**
Historical controls.

- f-TLR @6 months
  - DCB: 90%, POBA: 61%. OR: 1.5
- f-TLR @1y
  - DCB: 77%, POBA 29%. OR: 2.7
Descriptive cohort study, Italy, 4 centres, 2014-17

- **n**: 217
- **recruitment time**: 39 months
- **device**: Aperto OTW
- **mean fistula age**: 50% <1y
- **type**: 50:50 fistulae and grafts
- **prior intervention**: 75%
- **endpoint time**: f-TLR 6, 12 & 24 months
  - 21 month mean FU
- **f-TLR DCB**: 6/12: 88%
  - 1y: 64%
  - 2y: 40%

Better patency with first interventions
Published RCTs for DCBs in fistulae

as at 01.2019

2013  2014  2015  2016  2017  2018

0  1  2  0  1

0  1  2  0  1  4
<table>
<thead>
<tr>
<th>RCTs</th>
<th>n</th>
<th>time</th>
<th>device</th>
<th>site</th>
<th>predilated</th>
<th>sham</th>
<th>age</th>
<th>matching</th>
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</thead>
<tbody>
<tr>
<td>Terotola 2018</td>
<td>285</td>
<td>10</td>
<td>Lutonix</td>
<td>Fist</td>
<td>✓</td>
<td>✓</td>
<td>38</td>
<td>✅</td>
</tr>
<tr>
<td>Irani 2018</td>
<td>119</td>
<td>16</td>
<td>In.Pact</td>
<td>Fist, Graft</td>
<td>✓</td>
<td>✓</td>
<td>45</td>
<td>□</td>
</tr>
<tr>
<td>Björkman 2018</td>
<td>39</td>
<td>30</td>
<td>In.Pact</td>
<td>Fist</td>
<td>✓</td>
<td>✓</td>
<td>6</td>
<td>✅</td>
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<tr>
<td>Maleux 2018</td>
<td>64</td>
<td>33</td>
<td>In.Pact</td>
<td>Fist</td>
<td>✓</td>
<td>✗</td>
<td>36</td>
<td>✅</td>
</tr>
<tr>
<td>Kitrou 2017 [CVs]</td>
<td>40</td>
<td>20</td>
<td>Lutonix</td>
<td>Central</td>
<td>✓</td>
<td>✗</td>
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<tr>
<td>Kitrou 2015</td>
<td>40</td>
<td>17</td>
<td>In.Pact</td>
<td>Fist</td>
<td>✗</td>
<td>✗</td>
<td>30</td>
<td>□</td>
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<tr>
<td>Kitrou 2015b</td>
<td>40</td>
<td>10</td>
<td>In.Pact</td>
<td>Fist, Graft</td>
<td>✗</td>
<td>✗</td>
<td>30</td>
<td>□</td>
</tr>
<tr>
<td>Lai 2014</td>
<td>20</td>
<td>12</td>
<td>Coronary DCB</td>
<td>Fist</td>
<td>✓</td>
<td>✗</td>
<td>26</td>
<td>✅</td>
</tr>
</tbody>
</table>
Trials – 6 month outcomes

- Terotola 2018
- Irani 2018
- Björkman 2018
- Maleux 2018
- Kitrou 2017 [CVs]
- Kitrou 2015
- Kitrou 2015b
- Lai 2014
- Non randomized studies
Trials – 6 month & 1y outcomes

- Terotola 2018
- Irani 2018
- Björkman 2018
- Maleux 2018
- Kitrou 2017 [CVs]
- Kitrou 2015
- Kitrou 2015b
- Lai 2014
- Non randomized studies

Graph showing outcomes comparing DCB and POBA favorability.
Aperto registry

- Terotola 2018
- Irani 2018
- Björkman 2018
- Maleux 2018
- Kitrou 2017 [CVs]
- Kitrou 2015
- Kitrou 2015b
- Lai 2014
The future

In.PACT AV access IDE study
330 patients

PAVE
211 patients, recruitment complete 2018

Aperto trial
161 patients, recruitment complete 2018, 6m FU data expected Feb 2019

UK DeVA
186 patients, recruiting
Aperto AVF trial China

Prospective multicentre RCT
OHICHO II balloon ± APERTO

F-TLR @6/12

Superiority design
A note of caution
Summary

• Long term outcomes after fistula intervention are poor

• Stenoses recur in perhaps half to two-thirds by 1y

• No good evidence of DCB efficacy at the moment but perhaps a signal of a small effect

• More trials on the way

• Consensus that vessel preparation is important: advantage of a high pressure DCB.
Thank you for your attention

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