Drug-Eluting Balloon will be most Promising in Infrainguinal Arterial Disease

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Randomized Trials
DEB vs. Conventional Balloon

Werk et al. CIRSE 2011
THUNDER-Long-Term Results (5 Years)

Freedom from TLR

Tepe, LINC 2012
Drug-Eluting Devices CE-marked in Europe

**DEB:**
- Cotavance (CE approved)
- Freeway (CE approved)
- Elutax (SFA, BTK, AVF, Renal, CE approved)

**DES:**
- Zilver-PTX (COOK)

**MEDTRONIC**
- IN.PACT Range
  - Admiral 0.035” SFA
  - Pacific 0.018” SFA/BTK
  - Amphirion 0.014” BTK
- All CE approved
RCTs POBA vs. Stenting SFA

12 months restenosis vs. lesion length

- PTA + provisional stent
- Stent
- DEB

Data from randomised trials

Modified from Prof. Schillinger, EURO-PCR 2008
Recoil after Balloon-Angioplasty

Bailout-stenting rate up to 40% (Resilient)
Case from Thunder-Trial

Intervention 8 / 2004
2 PTX-coated balloons;
5 x 100 mm and 4 x 40 mm

3 / 2005
3 / 2006

Tepe et al., *NEJM* 2008;358:689-99
**The Value of DEB for SFA Lesions**

- In 4 RCTs DEB was significantly superior to non-coated balloons in SFA-lesions with regard to LLL.

<table>
<thead>
<tr>
<th>Device</th>
<th>Mean lesion length</th>
</tr>
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<tbody>
<tr>
<td>Thunder</td>
<td>7.5 cm</td>
</tr>
<tr>
<td>FemPac</td>
<td>5.7 cm</td>
</tr>
<tr>
<td>Levant I</td>
<td>8.1 cm</td>
</tr>
<tr>
<td>Pacifier</td>
<td>7.0 cm</td>
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</tbody>
</table>

TASC A and B lesions
DEB or DES for Long SFA-Lesions

SFA reocclusion

3 x DEB 5.0/120
DEB or DES for Long SFA-Lesions

3-months result

9 months after DEB
DEB or DES for Long SFA-Lesions

Subintimal reca with Outback

3 x DEB 5.0/120

15 months result
DEB or DES for Long SFA-Lesions

Outback-recanalisation

2 x 5.0/120mm DEB

Bare-metal stents

23 mo FU
Zilver-PTX for Long SFA-Lesions
Data from the single arm registry

Lesions > 15 cm

Cirse 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency</td>
<td>94.3%</td>
<td>77.0%</td>
</tr>
<tr>
<td>Lesions (at risk)</td>
<td>116</td>
<td>90</td>
</tr>
</tbody>
</table>

Patent (PSVR < 2.5)
DEB or DES for In-Stent-Restenosis?

After balloon-angioplasty
Treatment of In-Stent-Restenosis

After ballooning

In-stent stenting
Zilver-PTX for ISR
Data from the Single-Arm Registry
Primary Patency (PSVR < 2.5)

Primary Patency

87%
80%

Zilver PTX
No in-stent restenosis

Zilver PTX
In-stent restenosis

Bosiers, Cirse 2010
DEB for ISR of the SFA

39 ISR SFA, mean stent-length 181mm

One year clinical outcome

- Target Lesion Revascularization: 3/38
- Target Limb Revascularization: N = 4/38

Stabile, LINC 2012
Highly Calcified SFA-Lesions

- Cutting-balloon ?
- Scoring-balloon ?
- Atherectomy ?

Atherectomy + DEB ?

Standard nitinol-stent
DEB for SFA-Lesions

- Multicentric, italian registry
- PTA of femoropopliteal lesions \( n = 114 \)
- In.Pact Admiral (Medtronic)

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<table>
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<tbody>
<tr>
<td>Lesion-length</td>
<td>76.3 ± 38.3 mm</td>
</tr>
<tr>
<td>Severe calcification</td>
<td>16.7 %</td>
</tr>
<tr>
<td>Moderate calcification</td>
<td>50.0 %</td>
</tr>
<tr>
<td>Stent-implantation</td>
<td>12.3 %</td>
</tr>
<tr>
<td>TLR at 12 months</td>
<td>8.7 %</td>
</tr>
<tr>
<td>Primary Patency at 12 months</td>
<td>83.7 %</td>
</tr>
</tbody>
</table>

A. Micari and G. Biamino PCR 2011
How to Treat the SFA?

Drug-eluting devices have proven to be superior compared to their non-coated counterparts.

DEB or DES? Comparative trials are needed

DEB for shorter lesions

DES for more complex lesions
Comparative Trial of DES vs. DEB needed

ISR / occlusions can be difficult to treat
Follow-up should be long enough to recognize potential disadvantages of early SFA-stenting.
Angioplasty with Uncoated Balloons (POBA)

Occlusion ATA, Stenosis PA

After POBA both arteries

3-mo re-occlusion
3-Months Angiographical FU after POBA of long BTK-Lesions

- 58 CLI-pts. / 62 limbs
- Mean length of BTK-lesions: 183 mm
- Restenosis > 50 % after 3 months: 68.8 %

A. Schmidt et al., *Catheter Cardiovasc Intervent* 2010
In.Pact Amphirion for BTK-Lesions

Prospective registry of long BTK-lesions + DEB

104 patients, 109 limbs, 114 lesions
Critical ischemia in 82.6 %
Mean lesion-length 173 mm

Follow-up schedule:
Angiography at 3 months
Clinical FU 3, 6 and 12 months

Schmidt et al. J Am Coll Cardiol 2011;58:1105-9
CLI right, Poor Run-Off

2.0/120 + 2.5/120mm In.Pact Amphirion
3-Mo FU after DEB of the Peroneal Artery
9-Mo FU after DEB of the Peroneal Artery
<table>
<thead>
<tr>
<th></th>
<th>POB BTK</th>
<th>DEB BTK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion-length</td>
<td>183 mm</td>
<td>173 mm</td>
</tr>
<tr>
<td>Restenosis &gt;50 % @ 3 Mo</td>
<td>69 %</td>
<td>27 %</td>
</tr>
<tr>
<td>TLR-rate at 12-15 mo</td>
<td>50 %</td>
<td>17 %</td>
</tr>
</tbody>
</table>

61% restenosis reduction
65% TLR-rate reduction

A. Schmidt et al., *Catheter Cardiovasc Intervent* 2010
Schmidt et al. *JACC* 2011
IN.PACT™ in BTK / CLI / Diabetics

- Preliminary results from a single center RCT of IN.PACT Amphirion™ vs PTA BTK in CLI diabetic patients
- Significant reduction in angiographic restenosis rate at 12 mo

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<tr>
<th></th>
<th>In.Pact</th>
<th>PTA</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td># Patients</td>
<td>48</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>121</td>
<td>116</td>
<td>0.07</td>
</tr>
<tr>
<td>12m RR (Angio)</td>
<td>27%</td>
<td>66%</td>
<td>0.0004</td>
</tr>
<tr>
<td>12m re-occlusion</td>
<td>16%</td>
<td>53%</td>
<td>0.0006</td>
</tr>
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F.Liistro, TCT 2011
Will DEB Play a Role in BTK-Arteries?

- No competitor for DES

- First angiographical results are very promising

- Clinical endpoints are more important, TLR-rate is one of them.