Why and how to prep the vessel

*Drug elution in the SFA: Leave the right thing behind. Debating evidence to provide an answer*

Erwin Blessing, MD, FESC
SRH Klinikum
Karlsbad-Langensteinbach
Germany
Disclosure

Speaker name:
Erwin Blessing

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company

× Other(s): speakers honorarium: Cook

☐ I do not have any potential conflict of interest
Why and how to prep the vessel?

Limitations of DCB angioplasty

DCB is based on Angioplasty

Provisional Stent Rate increases with Lesion Length

Calcium May Limit Drug Effect

Elastic recoil
High-grade residual stenosis

Prepares the vessel with less/without overstretch

Reduces likelihood of bail-out stent & preserves native vessel

Removes potential barriers for drug uptake
Why and how to prep the vessel?
Optimizing PTA with prolonged balloon inflations reduces dissection severity and rate and need for further intervention

**Peripheral PTA: Effect of Short vs Long Balloon Inflation Times on the Morphologic Results**

<table>
<thead>
<tr>
<th>Inflation Time (sec)</th>
<th>30</th>
<th>180</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major dissection (grades 3 or 4)</td>
<td>16</td>
<td>5</td>
<td>.010</td>
</tr>
<tr>
<td>Minor or no dissection (grades 1 and 2)</td>
<td>21</td>
<td>32</td>
<td>.010</td>
</tr>
<tr>
<td>Further interventions (Stent, repeat dilatation, dilation with larger diameter)</td>
<td>20</td>
<td>9</td>
<td>.017</td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>12</td>
<td>5</td>
<td>.097</td>
</tr>
<tr>
<td>Complication (embolization, thrombosis)</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Mean ankle-brachial index (before, after intervention)</td>
<td>0.66, 0.87</td>
<td>0.65, 0.84</td>
<td></td>
</tr>
</tbody>
</table>

- Inflation times of 180 seconds improve immediate infrainguinal PTA results vs. a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed

Why and how to prep the vessel?
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Case example orbital atherectomy
Why and how to prep the vessel?

Case example directional atherectomy

Restenosis after 2x surgery  Silverhawk™  After Silverhawk™  After In.Pact™ Admiral
Why and how to prep the vessel?

DAART (Definitive AR)

Patency at 12 months

- All Patients: 82.4% (DAART), 71.8% (DCB)
- Lesions > 10 cm: 90.9% (DAART), 68.8% (DCB)
- All Severe Ca++: 58.3% (DAART), 42.9% (DCB)
Why and **how to prep the vessel?**

DEFINITIVE AR | Severe Calcification Combination Therapy Treatment

*TurboHawk LS-C*

- **Initial Angiogram**
  - Severey Calcified SFA Occlusion
- **Fluoroscopic Image**
  - Dense Circumferential Calcium
- **Procedural Angiogram**
  - Post 3x60 & 4x60mm PTA Pre-Dilatation
- **Procedural Angiogram**
  - Post 3 Insertions TurboHawk LS-C
- **Final Angiogram**
  - Post 5 mm DCB PTA

Case Performed by Dr. Marc Husmann | University Hospital Zurich | 3 February 2012
Why and how to prep the vessel?

Case example scoring balloon angioplasty
Why and how to prep the vessel?

Case example scoring balloon angioplasty long lesions

pre  2 atm  4 atm  8 atm
Angiosculpt 5x200
Why and how to prep the vessel?

Case example scoring balloon angioplasty long lesions

post  Stellarex 5x120  Stellarex 5x120  final
Why and how to prep the vessel?

PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Overall cohort

124 lesions

Primary Patency: 91.8%
Secondary Patency: 81.2%
Why and how to prep the vessel?

2x Zilver PTX
6x120 mm
Potential treatment algorithm

The Guide to Drug Elution

- Unsuccessful PTA
- Calcium
- Dissection
- Recoil

- Successful PTA

Vessel prep

POBA

DES

DCB
The ONLY SFA endovascular device with 5-year RCT results

Current pivotal trial data: Duration based on completed follow-up.
Why and how to prep the vessel?

**Advance Enforcer 35**

**FOCAL-FORCE PTA BALLOON CATHETER**

Intended for percutaneous transluminal angioplasty of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and iliofemoral, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Why and how to prep the vessel?

5-year Primary Patency (PSVR < 2.0)
Primary Zilver PTX vs. Provisional Zilver PTX

Provisional stenting:
Stenting only allowed after **failed** PTA
At least **2 min** inflation!
**Adequate** pressure to ensure **full dilatation**!
Conclusions

- DCBs work less well in heavily calcified lesion

- Lesion preparation (prolonged inflation, high pressure dilation, scoring balloon angioplasty, debulking devices etc.) gains increasing recognition

- Lesion preparation with scoring balloons prior DCB (or DES) seems to be an (less expensive) alternative to debulking devices for calcified lesions

- Drug eluting stents as first line treatment after failed PTA (recoil, dissection etc.) despite lesion preparation?

- Already convincing Zilver PTX RCT data might have looked even better with the recent knowledge regarding importance of lesion preparation prior stenting (learning curve)
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