Vessel preparation in the SFA before PTA or Stenting – the role of optimal balloon angioplasty, high pressure and focal force balloons

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Disclosure

Speaker name:
Erwin Blessing

I have the following potential conflicts of interest to report:

X Consulting: Medtronic
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
X Other(s): Honorarium: Medtronic

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

Challenges with Endovascular Treatment

Provisional Stenting

12-Month Data from DCB RCTs and Registries

DCB use in real-world registries enrolling more complex disease is associated with increased provisional stenting

Provisional stent rates of 40-47%
Why and how to prep the vessel?

**CALCICUM BURDEN ASSESSMENT AND IMPACT ON DCB**

**IN.PACT™ DCB and Calcium Registry (n=60) – 12 month results**

- Ca²⁺ distribution and severity affect late lumen loss (LLL) and primary patency
- Ca²⁺ represents a barrier to optimal drug absorption

Calcium distribution evaluation by CTA (circumf.) and DSA (longitud.); “a” <3cm and “b” >3cm

Debulking (plaque removal) prior to drug delivery could improve outcomes:

1. Mechanically re-canalize the vessel without overstretch

2. Remove the perfusion barrier – potential for better and more homogenous drug uptake

3. Reduce the likelihood of bail-out stenting and preserve the native vessel
Why and how to prep the vessel?
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></th>
<th>Inflation Time (sec)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30</td>
<td>180</td>
</tr>
<tr>
<td>Major dissection (grades 3 or 4)</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>Minor or no dissection (grades 1 and 2)</td>
<td>21</td>
<td>32</td>
</tr>
<tr>
<td>Further interventions (Stent, repeat dilatation, dilation with larger diameter)</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Complication (embolization, thrombosis)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mean ankle-brachial index (before, after intervention)</td>
<td>0.66, 0.87</td>
<td>0.65, 0.84</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?

Images: Blessing
Why and how to prep the vessel?

Provisional stenting:
Stenting only allowed after failed PTA
At least 2 min inflation!
Adequate pressure to ensure full dilatation!
Why and how to prep the vessel?

PROPER SIZING, PREPARATION, AND DEPLOYMENT TECHNIQUE RESULT IN EXCELLENT PATENCY RATES

High patency rates are demonstrated in cases where appropriate implant selection, vessel preparation, and deployment technique are used.

**Primary Patency (K-M) by Percent Compression/ Elongation at 12 months**

- **Moderate** (21-40%) - 83.3% (p=0.480)
- **Minimal** (11-20%) - 81.8% (p=0.268)
- **Nominal** (+/- 10%) - 90.5% (p=0.026)
- **Minimal** (11-20%) - 73.7% (p=0.029)
- **Moderate** (21-40%) - 74.4% (p=0.029)
- **Severe** (>40%) - 57.7% (p=<.001)

Source: US Supera Peripheral Stent System Instructions for Use
This data is from a post-hoc analysis.
**Why and how to prep the vessel?**

**Plaque Scoring in calcified SFA**

*Insights form the PANTHER Registry*

**Supporting the role of plaque scoring for vessel prep in calcific lesions and the hypothesis that degree of calcium does not predict patency**

- ASC Technical Success* = 100% (w/out pre-dil)
- Overall Primary Patency = 81.2% (69/85)

* successful scoring = ability to cross the lesion and inflate ASC at least at NP w/out balloon rupture

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*Primary Patency (KM) per treatment strategy*

*Primary Patency (KM) per degree of calcification*

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*Results from the Heidelberg PANTHER registry. Vasa. 2017 Nov 8:1-7*
Why and how to prep the vessel?

CHOCOLATE™ BAR STUDY\textsuperscript{1,2}

Outcomes

<table>
<thead>
<tr>
<th>Procedural Success</th>
<th>ATK\textsuperscript{**} (n = 262)</th>
<th>BTK (n = 226)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Flow Limiting Dissections* (Site Reported)</td>
<td>97.7%</td>
<td>99%</td>
</tr>
<tr>
<td>Freedom from Flow Limiting Dissections* (Adjudicated)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Achieved &lt;30% Diameter Stenosis (Adjudicated)</td>
<td>85.1%</td>
<td>84.6%</td>
</tr>
<tr>
<td>Freedom from Bail-Out Stenting</td>
<td>98.4%</td>
<td>99.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Outcomes (Kaplan Meier)</th>
<th>ATK\textsuperscript{**} (n = 262) 12 months</th>
<th>BTK (n = 226) 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Target Lesion Revascularization</td>
<td>78.5%</td>
<td>88.9%</td>
</tr>
<tr>
<td>Freedom from Major Unplanned Amputation</td>
<td>97.2%</td>
<td>96.7%</td>
</tr>
<tr>
<td>Freedom from All-Cause Mortality</td>
<td>93.3%</td>
<td>97.1%</td>
</tr>
</tbody>
</table>

*Flow Limiting Dissections defined as: Type E- Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen and Type F- Filling defect accompanied by total occlusion
** many ATK patients had concurrent BTK disease

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
Clinical Data: Chocolate™ plus DCB

68 patients, 82 lesions
Chocolate™ followed by DCB (Ranger)
Average lesion length
Stenoses: $64.9 \pm 30$ mm
Occlusions: $186.14 \pm 82$ mm
Bail-out stenting rate 9.5%
12 month: fTLR 95.7%

Sirignano P et al, CVIR 2017;e-Pub
Why and how to prep the vessel?
Why and how to prep the vessel?
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Conclusions

- Angioplasty of long lesions is plagued by high bail-out stent rates
- DCBs work less well in heavily calcified lesions
- Lesion preparation crucial prior placement of interwoven stents (and drug eluting stents)
- Debulking plus DCB is an attractive treatment option in selected cases („no stent zones“, bifurcations, young patients, severely calcified lesions etc.)
- Specialty balloons and intravascular lithotripsy might offer a (less complex) alternative to debulking devices
- Limited data from RCTs available for most „lesion preparation devices“
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