Will DCB ever work effectively in BTK and Crural Occlusive Disease: Size Matters: How Ultrasound Help and How to predict Performance

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Disclosures
• Dr Micari is consultant for:
  – Bard
  – Medtronic
  – Boston
  – Astra Zeneca
  – Terumo

Determinants to Early angioplasty failure
• Inappropriate vessel sizing and balloon dilatation
• Immediate Recoil
• Flow limiting dissection
• Thrombosis
• Restenosis (ineffective drug elution....)

DEB: IN.PACT DEEP
Failure to meet Primary Efficacy Endpoint

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<tr>
<th>Primary Efficacy</th>
<th>DEB</th>
<th>PTA</th>
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Are DCB dead? Have you looked at average DCB size used???

How big are Tibial arteries?
• Angio
• Duplex
• IVUS
• CT

Duplex Measurements
Golden Rules for Intraprocedural Duplex

- Select a preloaded peripheral setting
- Optimize the grey scale
- Decrease depth to have a large image
- Set the colour box in appropriate direction
- Reduce the colour scale (you will have low flow at tibial level)
- Adjust the PW angle to 60
- Reduce the sample size of PW

When measuring the vessel size: Zoom enough the image and measure orthogonally the artery from external wall to opposite external wall.

External to External

Internal to internal

Not orthogonal

Procedural data

<table>
<thead>
<tr>
<th>Item</th>
<th>Value</th>
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<tr>
<td>Antegrade approach (%)</td>
<td>331 (65.8%)</td>
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<tr>
<td>Presence of severe calcification (%)</td>
<td>307 (61%)</td>
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<tr>
<td>Presence of thrombus (%)</td>
<td>9 (1.8%)</td>
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<td>Atherectomy performed (%)</td>
<td>3 (0.5%)</td>
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<td>DEB used (%)</td>
<td>108 (21.5%)</td>
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<td>Stent deployed (%)</td>
<td>25 (5%)</td>
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<tr>
<td>Contrast used (ml)</td>
<td>97.2 ± 47.1</td>
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<tr>
<td>Procedural time (min)</td>
<td>91.6 ± 40.0</td>
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How can we transfer drug into the wall?

Is it restenosis/hyperplasia or early mechanical failure?

Selective Angiography of left limb (through antegrade femoral approach)

- Heavily Calcified Occlusion of Posterior Tibial Artery

CO2 Injection

Iodine

Heavy Calcifications: impossible balloon crossing of the lesions

Step #1

- Measures to increase Back-up

- Guidewire in Anterior Tibial Artery through Pedal Plantar Loop

- Support of a 6F-Coronary Guiding Catheter JR4

Step #2

- Heavy Focal Calcifications prevented balloons from dilating adequately

- Coronary Non-Compliant Balloons

  Ineffective, associated with rupture of balloons at pressure > 26 ATM

- Coronary Cutting Balloons

  Ineffective because of incomplete balloon dilation in the site of heaviest calcifications

Step #3

- Heavy Focal Calcifications prevented balloons from dilating adequately despite high pressure and aggressive balloons

- Rotational Atherectomy (Burr 1.5 mm)
If injury needs to be, can we make this injury more controllable, more predictable, more effective? We can break a glass in different ways.

97% of tibial dilatation show early recoil: ~29% lumen narrowing @ 15 minutes post intervention

If DCB....
We should touch the wall and drug overcome calcified bareer.

CONCLUSIONS
Vessel sizing is still an issue. Use of small Balloon size is more frequent than expected.

Vessel preparation is very important in Tibials due to high grade of calcification.

Early recoil, especially, in calcified vessels, makes the way to patency very cumbersome.

Uniform and effective drug elution is the target.