The relevance of vessel-patency for optimal outcomes and approaches to achieve it

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Disclosure

Speaker name:
Enrico Maria Marone MD

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)

Speaker: Abbott, Alvimedica
Introduction

In vascular surgery the patency of infragenicular bypass is directly proportional to the patency of distal vessels (run off)
Introduction

This statement is well known in nature..
Introduction

..and an alteration of this system can have devastating consequences

This is the result of the occlusion of the river..
Introduction

..and this is the result of the occlusion of bypass due to bad runoff
Gold standard

GSV bypass

Patency of tibial vessels
Diabetic patients

“Coronary collateral vessels are poorer in patients with diabetes mellitus”

A. Abaci et al. Circulation 1999
Diabetic patients

- Unavailability of veins
- Infection/gangrene site of anastomosis
- Absence of landing zone
Hybrid procedure

- Male 71, diabetes
- CLI, major tissue loss
- CFA stenosis
- SFA, ATA and PTA occlusion
Hybrid procedure

Femoral TEA

Femoro-popliteal AK bypass
Hybrid procedure
Hybrid procedure

Anterior TA recanalization
Hybrid procedure

Post. TA recanalization
Hybrid procedure

4 months

8 months
Advantages of endovascular revascularisation

- Less invasive
- Repeatable
- Extension to the foot vessels
Angiosome concept

“When feasible, direct revascularization of the foot angiosome may improve wound healing and limb salvage”

F. Biancari, T. Juvonen, EJVES 2014
Complete revascularisation

- In case of large diabetic foot lesions, revascularization should be as more aggressive as possible.
How to improve vessel patency?

Technical features (long inflation PTA)

Unconventional technique
   Transcollateral
   Double approach
   Plantar pedal loop

Selective use of DES (spot stenting)
## Drug eluting stents

**Bosiers M. et al., J Vasc Surg 2012**

<table>
<thead>
<tr>
<th></th>
<th>DES</th>
<th>BMS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency rate</td>
<td>85%</td>
<td>54%</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>91%</td>
<td>66%</td>
<td>= .001</td>
</tr>
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</table>

> “Treatment of the infrapopliteal occlusive lesions of critical limb ischemia with everolimus-eluting stents reduces restenosis and the need for reintervention”

DES indications

- Flow-limiting dissection
- Heavily calcified lesions with residual stenosis
- Focal restenosis post POBA with recoiling
Cre8™ BTK: distinctive features

- Abluminal Reservoir Technology
- Amphilitmus™ Formulation: Sirolimus + organic acid
- BIS: Bio Inducer Surface
Abluminal Reservoir Technology

Proprietary polymer-free drug release system (Abluminal Reservoir Technology) constituted by reservoirs on the stent's outer surface.

Cre8 BTK drug release kinetic:
- Peak tissue concentration during the first days
- 50% drug elution in approximately 18 days
- 65%-70% drug elution within 30 days
- Complete drug elution within 90 days

* Cre8 implants in rabbit model
Cre8™ BTK employs a permeation enhancer (fatty acid) in its formulation.

1) Fatty acids are used to improve transdermal and skin delivery of many different drugs.*
   * Drug Delivery, 15:373-379, 2008

2) Cardiac fatty acid uptake is double in diabetic mice model.**

** Cardiac fatty acid uptake and metabolism in db/+ and db/db mice. Curr Cardiol Rev. 2008
BIS: Bio Inducer Surface

**During Drug Release**
- Sirolimus
- Organic Acid

**Amphilimus™ Formulation**
- Sustained drug elution
- Modulated drug bioavailability

**After Drug Release**
- BMS covered with Bio Inducer Surface (BIS)
- Pure carbon coating
- Excellent haemo/biocompatible features
- No late inflammatory stimuli inside treated segment
Residual stenosis post PTA

TPT stenosis

2 Pilot 200 0.14” + Sleek 2.5x100 mm

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Residual stenosis post PTA

TPT and PT stenting

CRE8 3 x 31 mm
Residual stenosis post PTA

CULOTTE TECHNIQUE

Maverick Quantum 2 x 20 mm + 3 x 30 mm
Flow limiting dissection

ATA, PTA, PA occlusion
Flow limiting dissection

ATA recanalization

Pilot 200 0.14” + Trailblazer Crossing Cath
ATA recanalization

Flow limiting dissection

Pilot 200 0.14” + Trailblazer Crossing Cath
Flow limiting dissection

ATA Angioplasty

2.0 x 150mm Amphirion Deep PTA Balloon
Flow limiting dissection
Flow limiting dissection

ATA Angioplasty

2.0 x 150mm Amphirion Deep PTA Balloon (10 min inflation time)
Flow limiting dissection
Resistant PTA dissection
Flow limiting dissection

ATA stenting

2.5 x 25 mm  CRE8 BTK DES Stent

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Flow limiting dissection

Final Angiography Results
# Clinical Results

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>1 month Follow up</th>
<th>12 months Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td>14</td>
<td>14/14 (100%)</td>
<td>12/14 (86%)</td>
</tr>
<tr>
<td><strong>Stents</strong></td>
<td>16</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>TVR</strong></td>
<td>-</td>
<td>0/14 (0%)</td>
<td>4/12 (33%)</td>
</tr>
<tr>
<td><strong>TLR</strong></td>
<td>-</td>
<td>0/14 (0%)</td>
<td>3/12 (25%)</td>
</tr>
<tr>
<td><strong>Stent thrombosis</strong></td>
<td>0/11</td>
<td>0/16 (0%)</td>
<td>1/14 (7%)</td>
</tr>
<tr>
<td><strong>Restenosis</strong></td>
<td>0/11</td>
<td>0/16 (0%)</td>
<td>2/14 (14%)</td>
</tr>
<tr>
<td><strong>Primary patency</strong></td>
<td>-</td>
<td>14/14 (100%)</td>
<td>9/12 (75%)</td>
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Mean follow up: 18±5 months
Conclusions

• Angiosome vs complete revascularization tailored depending on the status of the patient

• The use of DES in BTK arteries is feasible and safe (spot stenting)

• Endovascular techniques cardiac derived should be applied to the tibial vessels
Leonardo da Vinci
Limb salvage: the Italian way
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