A comprehensive approach to diabetic patient Tx

The essentials for BTK procedures: wires, balloons, what else …

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Disclosure

Speaker name: Dai-Do Do

I have the following potential conflicts of interest to report:

X Consulting

- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Vascular features of diabetic foot

Acral gangrene

Heavy calcification

Distal angiopathy

Diabetes mellitus + Renal failure → Revascularization technically demanding!

N. Diehm, S. Rohrer, I Baumgartner, H. Keo, D.D. Do, C. Kalka
Vasa 2008;37(3):256-73

D.D. Do, Bern University Hospital, Switzerland
New Frontiers – Extreme Dilatation

- More experiences
- New techniques/Accesses

- Low profile & OTW long balloon catheter
- CTO dedicated GW

- What else … ?
New Approach - Pedal Loop
Guide Wires

Tip Load & Penetration Power

Tip Load = 4.0g

Tip Diameter = 0.012”

Area of GW Tip

Tip Load / Area of GW Tip

\[ \frac{0.004}{\pi \times 0.06^2} \]

Penetration Power = 40
Guide Wires
- 0.018“ polymer-coated, (Astato 30, V-18 Control, Connect …)
- 0.014 WG, CTO- GW (Astato 20, ….)

Support Catheter:
- 0.018“ CXI (OD 2.6 French)
- 0.018“ CXC (Cook)
- TrailBlazer (Covidien)
- TOTAL across™, Bard ….
79 y-o diabetic male with CLI left leg
79 y-o diabetic male with CLI left leg
Crossing strategies - INTRALUMINAL

Advantages
- It is the standard technique
- More experiences
- It seems more «biological»
- No re-entry problem

Limits
- not always possible to stay intra-luminal in long & calcified lesions
- Usually unsatisfactory results after Balloon PTA
- Dissected irregular lumen

CTO devices:
### Advantages

- Less time consuming, even in cases of flush occlusion
- Smoother lumen
- Probably less distal embolization

### Limits

- Long learning curve
- No controlled re-entry
- Risk of collateral occlusion
- Risk of vessel perforation

### Re-entry Devices:

- SUBINTIMAL crossing strategies
72 y-o diabetic male with CLI right leg
72 y-o diabetic male with CLI right leg
BTK Endo Tx – Angiographic Restenosis

Problem:
High recurrent rates after POBA

Restenosis rates up to 69% @ 3 months

- Bosiers et al. CCR 2009; 32:424-435
- Rand et al. CIR 2006; 29:29-38
- Soder et al. JVIR. 2000;45:751-761
- Schmidt et al. CCI, published online.
Clinically-driven need for secondary interventions after endovascular revascularization of tibial arteries in patients with critical limb ischemia

_Baumann F, et al. JEVTh 2013;20:707–713_

- 2008 – 2010: 128 consecutive infrapopliteal angioplasty procedures
- Prospectively followed
- 2-year data:
  - Mortality: 29.1%
  - Limb salvage: 89.9%
  - TLR: 46.2%

**Re-stenosis is a significant clinical problem in 2-y FU after PTA**
BTK Interventions – Limitations

Strategies to reduce restenosis:

New technologies:

- DEB
- DES

Cre8™ BTK

D.D. Do, Bern University Hospital, Switzerland
Problem of Ballon-PTA: recoil!

Occlusion

POBA 3/40

Angio immediately post PTA: MLD: 2.34

Angio 12 min post PTA: MLD: 1.25

Consecutive series of 30 CLI patients with de-novo tibial lesions, serial angiography 15 minutes post POBA

- Mean lesion length: 83.8 mm
- Elastic recoil (MLD reduction >10%): 96.7%
- Loss of MLD due to elastic recoil: 29.4%
- Bailout stenting in: 33%

Baumann F., Fust J, Engelberger R; Hügel U; Do DD, Willenberg T; Baumgartner I; Diehm N. J Endovasc Ther 2014 Feb;21(1):44-51
DES are worthwhile in BTK lesions

Data from RCT trials

1-Year Patency Rates

- **Yukon a)**: n=161, max. 4.5 cm
- **Destiny b)**: n=140, max. 4.0 cm
- **Achilles c)**: n=200, max. 12.0 cm

<table>
<thead>
<tr>
<th>Year</th>
<th>Patency Rates</th>
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</thead>
<tbody>
<tr>
<td>Yukon</td>
<td>80.6%</td>
</tr>
<tr>
<td>Destiny</td>
<td>55.6%</td>
</tr>
<tr>
<td>Achilles</td>
<td>BMS</td>
</tr>
</tbody>
</table>

P<0.05 all trials

a) Rastan A.  b) Bosiers M.  c) Scheinert D.

D.D. Do, Bern University Hospital, Switzerland
84 y-o ♀ w unhealing ulcers & rest pain

Type II diabetic, hypertensive and active smoking
84 y-o ♀ w unhealing ulcers & rest pain
84 y-o ♀ w unhealing ulcers & rest pain

A. popl

Trunc tib.-fib

Cre8™ BTK
Cre8™ BTK: distinctive features

- Abluminal Reservoir Technology
- Amphilimus™ Formulation: Sirolimus + organic acid
- BIS: Bio Inducer Surface
Cre8 for de novo lesions (max 2 in 2 different vessels) in native coronary arteries

*D. Carrié et al JACC, 2012, 59; 1371-76*

**Primary Endpoint:**
6-month in-stent Late Lumen Loss

### Overall Population

- **Cre8 (148 les, 141 pts)**
  - In-stent LLL: 0.14±0.36
  - Late Lumen Loss: 0.34±0.40
  - *P<0.0001*

- **TAXUS Liberté (145 les, 135 pts)**

### Diabetic subgroup

- **Cre8 (42 les, 42 pts)**
  - In-stent LLL: 0.12±0.29
  - Late Lumen Loss: 0.43±0.41
  - *P=0.0002*

- **TAXUS Liberté (38 les, 33 pts)**

- **The Late Lumen Loss in the diabetic subgroup** is comparable to the Late Lumen Loss obtained in the overall population (never seen before!)
NEXT: 36-month clinical results

36-month cumulative MACE
(Cardiac death, all MI, all TLR)

Overall population

Diabetic population

Cre8 has shown that MACE and TLR in the diabetic subgroup are comparable to MACE and TLR obtained in the overall population!
Until today, there are no data available regarding the safety & effectiveness of this novel BRS technology in infrapopliteal lesions.

**Limitation of DES - Lengths BTK Lesions**


<table>
<thead>
<tr>
<th>Artery</th>
<th>Total (n)</th>
<th>Stenotic (n)</th>
<th>Stenoses (mean ±SD, mm)</th>
<th>Occlusions (n)</th>
<th>Occluded (n)</th>
<th>LL (mean ±SD, mm)</th>
<th>P</th>
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<tbody>
<tr>
<td>ATA</td>
<td>47</td>
<td>22</td>
<td>100.7 ± 50.6</td>
<td>12</td>
<td>113 ± 94.1</td>
<td>43.1 ± 13.4</td>
<td>.03</td>
</tr>
<tr>
<td>PTA</td>
<td>11</td>
<td></td>
<td>100.7 ± 50.6</td>
<td>12</td>
<td></td>
<td>93.2 ± 60.0</td>
<td>.01</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

*only 11% (12/105) of the patients had lesions lengths ≤ 35 mm*

Lesions substantially longer than in DES trials!
History of a 96 y-old male with CLI

2009: CLI w rest pain on RT side at the age of 90
History of a 96 y-old male with CLI

26th January 2015: just after PTA at the age of 96:
- still alive w limb
- no more rest pain

D.D. Do, Bern University Hospital, Switzerland
Summary

**Access:** - rather femoral antegrad, Heparin 7‘500, Nitroglycerin
  - Pedal access a/o combined in some cases using
    21 G needle, sheathless,
  - 0.014“ or 0.018“ GW, hydrophlic, CTO GW

**BTK:** - Low profile instrumentarium, rather long OTW balloon and long inflation time

**Revascularization:** „straight-line flow“ to the foot! (wound)

**Patency:** Improvement using
  - DEB
  - adjunctive techniques and optional stenting (DES) if needed

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