CHANGING PARADIGMS AND FUTURE CONCEPTS IN PERIPHERAL INTERVENTIONS

How Far Have We Come?

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Sydney, Australia
Disclosure

Speaker name:
.........Ramon Varcoe..................................................

I have the following potential conflicts of interest to report:

- Consulting   Abbott, Boston, Gore, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
CRITICAL LIMB ISCHAEMIA

- Multi-Level
- Tibial Involvement
- CTOs
- Calcification
Vascular Involvement in Diabetic Subjects with Ischemic Foot Ulcer: A New Morphologic Categorization of Disease Severity

L. Graziani,1,2 A. Silvestro,1 V. Bertone,2 E. Manara,3 R. Andreini,4 A. Sigala,5 R. Mingardi5 and R. De Giglio2

Table 1. Morphologic Classification of Below-The-Groin arterial lesions distribution, based on 7 Classes of progressive involvement severity

<table>
<thead>
<tr>
<th>Class</th>
<th>Angiographic Finding</th>
<th>Patients, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Isolated, one vessel tibial or peroneal artery obstruction</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>2a</td>
<td>Isolated femoral/popliteal artery or two below knee arteries obstructed but with patency of one of the two tibial arteries</td>
<td>12 (3%)</td>
</tr>
<tr>
<td>2b</td>
<td>Isolated femoral/popliteal artery or two below knee tibial arteries obstructed but with patency of the peroneal artery</td>
<td>23 (5%)</td>
</tr>
<tr>
<td>3</td>
<td>Isolated, one artery occluded and multiple stenosis of tibial/peroneal and/or femoral/popliteal arteries</td>
<td>58 (14%)</td>
</tr>
<tr>
<td>4</td>
<td>Two arteries occluded and multiple stenosis of tibial/peroneal and/or femoral/popliteal vessels</td>
<td>151 (36%)</td>
</tr>
<tr>
<td>5</td>
<td>Occlusion of all tibial and peroneal arteries (below knee cross-sectional occlusion)</td>
<td>47 (11%)</td>
</tr>
<tr>
<td>6</td>
<td>Three arteries occluded and multiple stenosis of tibial/peroneal and/or femoral/popliteal arteries</td>
<td>114 (27%)</td>
</tr>
<tr>
<td>7</td>
<td>Multiple femoro-popliteal obstructions with no visible below the knee arterial segments</td>
<td>3 (1%)</td>
</tr>
</tbody>
</table>
IMPROVING OUTCOMES IN CLI
LIMB SALVAGE

TECHNICAL SUCCESS

PATENCY

WOUND CARE
TECHNICAL SUCCESS
DEDICATED CTO DEVICES
CROSSING/RE-ENTRY DEVICES
**RETROGRADE TIBIAL PUNCTURES**

Points:
1. Long sheath (45cm) positioned at or just below the knee
2. Multiple options for puncture site
3. Retrograde wire passage, then through wire, then track catheter, then reverse wire

**ANKLE LEVEL PUNCTURES**

- All 3 vessels suitable
- Useful for long tibial CTOs
- Usually sheathless with support catheter
Primary Patency

Percentage (at 12 months)

Trial

YUKON-BTK

DESTINY

ACHILLES

DES

BMS

DES

BMS

DES

PTA

81

56

85

54

78

58

P=0.004

P=0.0001

P=0.019
BIO-RESORBABLE VASCULAR SCAFFOLD
95.5% 
12 months

ABSORB
BTK
**12-month Primary Patency – Compared With RCTs**

- **95.5% 12 months**

- ABSORB
  - BTK

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YUKON. Rastan A et al. European Heart Journal 2011;32:2274-81
POBA in BTK: Restenosis and TLR rates

1. D. Scheinert, J Am Coll Cardiol 2012;60:2290–5
5. F. Liistro, TCT 2012 oral presentation
6. A. Schmidt, Catheter Cardiovasc Intervent 2010;76:1047-54
IN.PACT in BTK: Restenosis and TLR rates

3. F Liistro – TCT 2012
Drug-Eluting Balloon Versus Standard Balloon Angioplasty for Infrapopliteal Arterial Revascularization in Critical Limb Ischemia
12-Month Results From the IN.PACT DEEP Randomized Trial

- 2014, JACC
- Prospective, multicentre, RCT
- 358 Patients with BTK disease & CLI
- DEB vs PTA
- Mean LL 10-13cm
- Independent, blinded CEC
POBA in BTK: Restenosis and TLR rates

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>12m Angio</th>
<th>10m Angio</th>
<th>6m Angio</th>
<th>12m Angio</th>
<th>3m Angio</th>
<th>12m Angio</th>
<th>3m Angio</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHILLES [1]</td>
<td>101</td>
<td>75.4%</td>
<td>41.9%</td>
<td>16.5%</td>
<td>2.7%</td>
<td>35.6%</td>
<td>3.8%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Soder 2000 [2]</td>
<td>60</td>
<td>53.0%</td>
<td>2.7%</td>
<td>3.8%</td>
<td>2.7%</td>
<td>35.6%</td>
<td>3.8%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Bauman 2011 [3]</td>
<td>33</td>
<td>42.0%</td>
<td>40.0%</td>
<td>29.4%</td>
<td>13.0%</td>
<td>42.0%</td>
<td>5.9%</td>
<td>3.8%</td>
</tr>
<tr>
<td>DEBELUM [4]</td>
<td>11</td>
<td>74.3%</td>
<td>52.9%</td>
<td>47.0%</td>
<td>47.0%</td>
<td>29.4%</td>
<td>7.4%</td>
<td>2.7%</td>
</tr>
<tr>
<td>DEBATE BTK [5]</td>
<td>67</td>
<td>82.1%</td>
<td>74.3%</td>
<td>45.3%</td>
<td>45.3%</td>
<td>29.4%</td>
<td>7.4%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Schmidt 2010 [6]</td>
<td>58</td>
<td>69.0%</td>
<td>64.9%</td>
<td>50.0%</td>
<td>18.4%</td>
<td>69.0%</td>
<td>18.4%</td>
<td>64.9%</td>
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1. D.Scheinert, J Am Coll Cardiol 2012;60:2290–5
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DCBs are not all the same

With courtesy C. I. Mena
Ex Vivo Administration of Fluorescent-Labeled PTX to Excised Porcine Artery

10% Oregon green labeled PTX incorporated into Lutonix DCB coating

Segment-to-segment variability ± 4.0 %

Lutonix coating uniformity allows uniform drug delivery
Does Drug Coating Matter?

**Data obtained from two data sets. Virmani preclinical animal data on file. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.***
# Lutonix BTK Trial Summary

| PRIMARY ENDPOINTS | Safety at 30 days  
Limb salvage & primary patency at 12 months |
<table>
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<tr>
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<tbody>
<tr>
<td><strong>NUMBER OF PATIENTS/SITES</strong></td>
<td>480 patients at 55 global sites</td>
</tr>
</tbody>
</table>
| **FOLLOW-UP** | **Clinical:** 1, 6, 12, 24, and 36 Months  
**Duplex Ultrasound (DUS):** 0–30 days, 6, 12, 24, & 36 months  
**Angiography in subset of patients:** 12 months  
**Telephone:** 48 and 60 Months |
| **NATIONAL PRINCIPAL INVESTIGATORS** | **Patrick Geraghty:** Washington University, St. Louis, MO  
**Jihad Mustapha:** Metro Health Hospital, Wyoming, MI  
**Marianne Brodmann:** Medical University Graz, Austria |
| **SPONSOR** | Lutonix Inc., Minneapolis, MN |
Inflow Treatment
If needed

PTA Pre-Dilatation
With Uncoated Balloon

Successful PTA with Outflow
Randomize 2:1

Test Arm:
Dilatation of ALL target lesions with Drug Coated Balloon

Control Arm:
Dilatation of ALL target lesions with Uncoated Balloon

Suboptimal PTA
Absence of above ankle reconstitution
>75% residual stenosis

Treat per standard practice
30 day follow-up for safety
8 Data Monitoring Committee meetings so far

273 randomized patients:
- 184 have completed 6 month follow-up
- 134 have completed 12 month follow-up

Only 11 major amputations (3% of enrolled pts) recorded

Only approved and ongoing BTK trial in the US
The Bullfrog® Micro-Infusion Device (Mercator MedSystems)
Bullfrog Device Features

• Microneedle is 34 Ga (0.007”) diameter; smaller than most suture needles, so insertion does not injure the vessel

• Balloon self-adjusts to a range of vessel diameters (2-4 mm, 3-6 mm or 4-8 mm)

• Contrast co-delivered with drug confirms real-time procedural success
CONCLUSION

• TECHNICAL SUCCESS
  – CTO devices
  – Retrograde techniques
  – Persistence

• PATENCY OPTIMISATION
  – Know your options
  – Future technology appears promising
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