Latest Techniques and Results in BTK interventions

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Regional Center of Reference for Diabetic Foot Treatment
**DISCLOSURE:**

Marco Manzi, MD

<table>
<thead>
<tr>
<th>Company</th>
<th>Position</th>
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<tr>
<td>Abbott Vascular</td>
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<td>Angiodroid</td>
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<td>CID/ALVIMEDICA</td>
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<td>COOK</td>
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<td>Boston Scientific</td>
<td>Proctor</td>
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<tr>
<td>Medtronic</td>
<td>Consultant/Proctor</td>
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<td>TERUMO</td>
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Italian Flowchart of Strategies and Techniques

Step-by-step crossing strategy

# Antegrade approach
1. Endoluminal approach
2. Subintimal approach

# Retrograde approach
1. Pedal-Plantar Loop Technique
2. Trans-collateral approach
3. Retrograde percutaneous puncture
BTK HOT Topics

• Debulking + DEB when Ca+++;
• DEB ;
• DES;
Debulking + DEB

- 21 PTS (LLC 18, CLI 3);
  DA + DEB (InPact Admiral/Pacific Medtronic/Invatec)
- Primary Patency @ 12 months = 95%
  @ 18 months = 90%
- Secondary Patency = 100%

Rationale: Thrombus and calcium plaques removal in order to facilitate drug absorption into the vessel’s wall
Debulking + DEB

- Aggressive Debulking when Ca+++;
- Rotational or Directional;
- DEB one to one;
Drug-coated balloon angioplasty for the management of recurring infrapopliteal disease in diabetic patients with critical limb ischemia☆☆☆

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ABSTRACT

Objective: To describe the 1-year outcomes of recurring infrapopliteal disease after endovascular revascularization with the Lutonix drug-coated balloons (LDCB) in diabetic patients with critical limb ischemia (CLI), and to benchmark our findings with previously published objective performance goals (OPG) addressing safety and efficacy of new catheter-based therapies for CLI.

Methods: The present study was a retrospective, single-center, and single-arm trial of symptomatic diabetic patients with CLI, who underwent LDCB-angioplasty for recurring infrapopliteal disease. Acute procedural and technical success were recorded. TcPO2 metrics variations at baseline and follow up were analyzed. Freedom from clinically driven target lesion revascularization (CD-TLR) was calculated using Kaplan-Meier analysis, and outcomes compared with previously published OPG for infrapopliteal interventions.

Results: 21 patients (15 men; mean age 66.6 ± 11.2 years) were followed-up for 356.5 ± 159.2 days and 90.47% had 12-months follow up data available for analysis. TcPO2 increased (14.3 ± 11.6 mm Hg to 35.8 ± 11.7 mm Hg; p < 0.05). Limb salvage rate was 100%, and 90.4% of patients achieved the combined endpoint of reduction in ulcer size/depth or complete healing. LDCB had superior efficacy (MALE + post-operative death, amputation free survival, freedom from re-intervention, limb salvage and survival rates), while attaining superior or equivalent safety (Major Adverse Limb Events, major adverse cardiovascular events and Amputation) endpoints for the overall, modified clinical and anatomical high-risk groups.

Conclusions: Lutonix DCB is safe and effective for recurring infrapopliteal disease. It outperforms the OPG for CLI patients with clinical and anatomical high-risk features.

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Percutaneous Transluminal Angioplasty and Drug-Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia (PADI) Trial.

Abstract

BACKGROUND: Endovascular infrapopliteal treatment of patients with critical limb ischemia using percutaneous transluminal angioplasty (PTA) and bail-out bare metal stenting (BMS) is hampered by restenosis. In interventional cardiology, drug-eluting stents (DES) have shown better patency rates and are standard practice nowadays. An investigator-initiated, multicenter, randomized trial was conducted to assess whether DES also improve patency and clinical outcome of infrapopliteal lesions.

METHODS AND RESULTS: Adults with critical limb ischemia (Rutherford category ≥4) and infrapopliteal lesions were randomized to receive PTA ±BMS or DES with paclitaxel. Primary end point was 6-month primary binary patency of treated lesions, defined as ≤50% stenosis on computed tomographic angiography. Stenosis >50%, retreatment, major amputation, and critical limb ischemia-related death were regarded as treatment failure. Severity of failure was assessed with an ordinal score, ranging from vessel stenosis through occlusion to the clinical failures. Seventy-four limbs (73 patients) were treated with DES and 66 limbs (64 patients) received PTA±BMS. Six-month patency rates were 48.0% for DES and 35.1% for PTA±BMS (P=0.096) in the modified-intention-to-treat and 51.9% and 35.1% (P=0.037) in the per-protocol analysis. The ordinal score showed significantly worse treatment failure for PTA±BMS versus DES (P=0.041). The observed major amputation rate remained lower in the DES group until 2 years post-treatment, with a trend toward significance (P=0.066). Less minor amputations occurred after DES until 6 months post-treatment (P=0.03).

CONCLUSIONS: In patients with critical limb ischemia caused by infrapopliteal lesions, DES provide better 6-month patency rates and less amputations after 6 and 12 months compared with PTA±BMS.

Clinical Trial Registration: URL: http://www.clinicaltrials.gov. Unique identifier: NCT00471289.

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Focal calcified lesion scaffolding

RCT Bail out scaffolding DES vs BMS = better 6 months patency and less amputations @ 6 and 12 months
Complex Lesion involving Bifurcations: Maintaining Good In-flow: focal calcificated lesion scaffolding
POBA: Recanalization through Collaterals - Foot

P.L., 62 yo
Type 2 DM, Ischemic Neuropathy, Hypertension;
Right I Toe TUC 2C lesion; TcPO2=7 mmHg;
Pre-medication: Nitrate 200 microg/2ml
0.014 Asahi Fielder + Tokai Microcath Cornelian
New Studies are required for BTK:

Atherectomy + Deb;

Scoring + DEB;

Lytho +DEB;

High pressure Non Compliant + DES ;

Of Course when we have a transmission failure only (BAD) with a good outflow in the foot
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Details</th>
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<tr>
<td>08:45</td>
<td>SESSION I</td>
<td>Introduction</td>
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<td>LIVE CASE #1</td>
<td>SFA</td>
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<td>- What happens when endo is not possible?</td>
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<td>- Is there any space for Hybrid procedures in SFA?</td>
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<td>- Practical indications from my experience</td>
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<td>SESSION II</td>
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<td>Popliteal artery</td>
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<td>Focus on CTOs in Popliteal artery</td>
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<td>LIVE CASE #3</td>
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<td>- The most frequent bad acute outcome:</td>
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<td>- no reflux: What to do?</td>
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<td>- CA++ Tibials: Non compliant balloons</td>
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<td>- Direct antegrade tibial puncture: alternative routes</td>
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<td>Different closure devices: use it or avoid it?</td>
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<td>17:30</td>
<td>Closing remarks</td>
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Different techniques will be performed during live cases to treat the patient and improve outcomes:
- BMS - DES - Covered stents - DCR - Skiving Balloon - Meniscus tech - Thrombolysis - Thrombectomy - Atherectomy.
THANKS FOR YOUR ATTENTION
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