Cutting Edge Endovascular Options: Present and Future Options for Vascuropathy

Genius or Madness?

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MD, MMed (Surg), MClinEd, FCS (SA), FRACS
Declaration of Financial Interests or Relationships

Speaker Name: Dr. B. Patrice Mwipatayi

Consultant for Biotronik and Medtronic
Critical limb ischemia (CLI) is growing in global prevalence and is associated with high rates of limb loss (~60-70%) and mortality (~30-50%) within 2-5 years.

Given the fact that many CLI patients have severe comorbidities, the *endovascular-first approach* is most common since it reduces the magnitude of surgical trauma and systemic complications.

Endovascular Results achievable through a Comprehensive Multidisciplinary Diabetic and Foot Service (CMDFS)
Evidence
# Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia

Marcello Romiti, MD, Maximiano Albers, MD, Francisco Cardoso Brochado-Neto, MD, Anai Espinelli S. Durazzo, MD, Carlos Alberto Bragança Pereira, PhD, and Nelson De Luccia, MD, Santos and São Paulo, São Paulo, Brazil

## Table II. Meta-analysis results of crural percutaneous transluminal angioplasty and popliteal-to-distal bypass

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What are we trying to achieve?

Which Outcome Measure?

Late Lumen Loss (LLL) vs. Target Lesion Revascularisation (TLR) vs. Primary Patency vs. Secondary Patency vs. Limb Salvage vs. wound healing

“BASIL trial”
You have to learn the rules of the game. And then you have to play better than anyone else.

“YOU HAVE TO LEARN THE RULES OF THE GAME. AND THEN YOU HAVE TO PLAY BETTER THAN ANYONE ELSE.” - Albert Einstein
Normal Anatomy

Normal Angiosome related arteries
Anterior Tibial Territory

Manzi et al 2011
Peroneal Artery Territory

Lateral calcaneal branch

Manzi et al 2011
Complex-Weight Impact

Normal foot position

Excessive pronation

Weight is on inside edge of sole

© Healthwise, Incorporated
Case Example 1

- Anterior Tibial Angiosome
- Posterior Tibial Angiosome
ANTEGRADE IPSILATERAL COMMON FEMORAL PUNCTURE

Uses:
1. Long sheath (45cm) positioned at or just below the knee (5-6 Fr sheath)
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
- U/S or II guided
- Usually sheathless with support catheter
RETROGRADE TIBIAL PUNCTURES

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ANKLE LEVEL PUNCTURES

- May also be performed through an occluded artery
- Use calcium as a roadmap
Case Example 2

Anterior Tibial Angiosome

Posterior Tibial Angiosome
PEDAL-PLANTAR LOOP TECHNIQUE

Points:
1. Long sheath (45cm) positioned at or just below the knee
2. Antegrade through tibial vessel
3. Through foot (bony landmarks)
4. Retrograde wire through occlusion
PEDAL-PLANTAR LOOP TECHNIQUE

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DRUG COATED TECHNOLOGY
Drug-coated balloons offer Clinician an attractive value proposition for the treatment of lower limb disease

- Encouraging results have been seen in de novo, restenotic lesions, in-stent restenosis and in A-V access stenosis
- Some logical indications might include:
  - “no-stent” zones e.g. CFA lesions
  - Segments prone to restenosis e.g. long AK lesions

Benefits
- Anti-proliferative therapy while leaving nothing behind
- Broad anatomical applicability
- Easily repeatable
- Avoid stent fracture and ISR burden
- Preserve future options
- Matches patient’s quality of life expectations (improvement in walking capacity, Rutherford class)

Limitations
- Not proven in highly calcified lesions
- When provisional stent is required = higher procedural cost
Passeo-18 Lux combines proven technologies for treating lower limb arteries

**Coating Technology**
- Drug: paclitaxel (3.0 μg/mm²)
- Excipient: butyryl-tri-hexyl citrate (BTHC)
- Process: Micro-pipetting

**SafeGuard Insertion Aid**
- Improves ease of handling
- Protects the user and balloon from contact and damage

**Balloon Platform**
- Passeo-18 Balloon Catheter
  - Ø (mm): 2.0, 2.5, 3.0, 4.0, 5.0, 6.0, 7.0
  - L (mm): 40, 80, 120
Baseline considerations for the development of the Lux coating technology

- Rapid drug transfer into vessel
- Sustained therapeutic effect in local tissue while remaining non-toxic
- Homogeneous drug coating (longitudinal, circumferential, thickness)
- Homogeneous drug concentration throughout the coating
- Minimal drug loss during tracking and inflation
- Balance between coating adhesion and drug transfer
Excipients play a key role in DCB technologies

– The excipient is used to balance coating adhesion and drug release properties

– The excipient aims to ensure a micro-crystalline paclitaxel structure and make the compound more absorbable to the tissue

– The excipient is designed to improve effectiveness and time of drug retention in the arterial tissue
Lux coating technology uses BTHC as the excipient
Biocompatible, safe and effective

- **Excipient**
  - Butyryl-tri-hexyl citrate (BTHC)

- **Characteristics**
  - BTHC is hydrophobic and less soluble in blood and saline/water used during interventional procedures compared to other common hydrophilic excipients

- **Common uses of BTHC**
  - Used in medical devices & cosmetics
  - Additive in blood bags to keep the crystalline structure of the plastic malleable
  - Safe: it is approved to be used in contact with blood and in the body

- **Metabolism**
  - Quickly metabolized by the body and excreted via urine, bile and expired air*
  - Degrades to citric acid and alcohol (n-hexanol*)

* European Commission SCENIHR Report Feb 2008
Passeo-18 Lux – Core Messages

- Clinically proven to reduce restenosis and the need for reinterventions*

- Lux coating technology optimizes drug transfer for maximized efficacy

- Low profile, highly deliverable Passeo-18 balloon platform

- Innovative SafeGuard insertion aid for unrivaled safety and ease of handling

* BIOLUX P-I and BIOLUX P-II Randomized Clinical Trials
Vasculitis resulting from a superficial femoral artery angioplasty with a paclitaxel-eluting balloon

Shannon D. Thomas, FRACS, a Robert R. A. McDonald, FACD, b,c and Ramon L. Varcoe, MS, FRACS, a,d,e
Sydney, New South Wales, Australia

Drug-eluting balloons (DEBs) coated with the antiproliferative agent paclitaxel may improve primary patency by reducing recurrent luminal stenosis. A proportion of the active drug and excipient coating are known to embolize distally, but until now, there have been no reports of adverse events resulting from their use. We report an unusual case of a painful nodular, biopsy specimen-proven vasculitic rash that afflicted the ipsilateral lower limb of a patient after superficial femoral artery treatment with a DEB. This adverse event may have implications for the use of DEB in this and other vascular territories. (J Vasc Surg 2014;59:520-3.)

Fig 1. A, Vasculitic rash confined to the left leg after therapy with a paclitaxel-eluting balloon. B, Nodular, erythematous macules in the distribution of the superficial femoral artery treated with a paclitaxel-eluting balloon. C, Magnified view of the vasculitic rash on the lower leg, demonstrating nonblanching, nonhemorrhagic, nodular, erythematous macules.
New Technology in CLI

Occlusion of ATA / PTA // Disease TPT

Stenting of TPT with DES-Xience Prime
Baseline 2D CT perfusion angiography using i-Flow software (Siemens AG Healthcare). The numbers assigned to each artery represent the time to arrival of contrast after contrast injection via a catheter in the popliteal artery prior to revascularization.

Two-dimensional CT perfusion angiography after revascularization.

Note the time to arrival in the dorsalis pedis artery was measured at 11.7 seconds.

The time to arrival of contrast in the dorsalis pedis artery decreased to 10.6 seconds. The great toe ulcer healed within 6 weeks following revascularization.
Insanity: doing the same thing over and over again and expecting different results.

Albert Einstein

THANK YOU