How Do I Determine the Minimum Necessary End Point of an Endovascular CLI Procedure – When is Enough?

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

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<th>Affiliation/Financial Relationship</th>
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<tr>
<td>• Grant/Research Support</td>
<td>• WL Gore, Medtronic</td>
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<td>• Consulting Fees/Honoraria</td>
<td>• Abbott Vascular, Bard Peripheral Vascular, WL Gore, Boston Scientific, Medtronic</td>
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The fundamental question...

• On a cellular level, in an individual patient, what level of perfusion is needed for wound healing?
Angiographic pattern

Tissue pattern

Wound Resolution
Angiographic endpoints

- Unobstructed flow in anticipated angiosome = “straight line pulsatile flow” = classic endpoint
- Patent angiographosome = angiographically mediated flow
- Patent pedal loop

**Watershed perfusion**
Importance of Plantar Arch Integrity

- Presence of complete plantar arch is strongly associated with lower major amputation rate ($p=0.012$)
  - Limb salvage rate: 88.1%
- Regardless of direct or indirect angiosomal revascularization

Dr Kiang Hiong TAY (MBBS, FRCR, FAMS, FSIR)
DEFINING PERFUSION → NO SUBSTITUION FOR CLINICAL RESULTS!!!
We got it ... right?
Kinda...
Tissue patterns

- Wound blush
- Indigocarmine/methylene blue angiography
- Perfusion angiography
- nIR / tissue oxygenation imaging
Impact of wound blush as an angiographic end point of endovascular therapy for patients with critical limb ischemia

Makoto Utsunomiya, MD, Masato Nakamura, MD, Mami Nakanishi, MD, Takurou Takagi, MD, Hidchiko Hara, MD, Kiyoshi Onishi, MD, Tetsuro Yamada, MD, and Kaoru Sugiyama MD, Tokyo, Japan

Objectives: Several reports have been published of the acceptable patency and limb salvage rates after infrapopliteal interventions for the treatment of critical limb ischemia (CLI). However, the optimal angiographic end point of endovascular therapy (EVT) remains unclear. This study assessed the relationship between the appearance of wound blush as an angiographic end point and the limb salvage rate in patients with CLI.

Methods: “Wound blush” was defined as contrast opacification of the vessels around the wound in digital subtraction angiograms obtained immediately after EVT through the catheter introduced into the popliteal artery. We analyzed the data of 77 consecutive patients (93 limbs) with ischemic ulcers, classified as Rutherford category 5 or 6, who underwent EVT without bypass surgery. Patients were divided into two groups depending on whether wound blush was seen in the angiogram obtained immediately after the procedure. The freedom from amputation rate was compared between the two groups.

Results: The overall limb salvage rate was 81.7%. The limb salvage rate was significantly higher in the wound blush positive group than in the wound blush negative group, remaining at least 3 years after the EVT (96.4% vs 56.8%, P < .001).

Conclusions: Presence of wound blush after EVT is associated with higher skin perfusion pressure, both of which are associated with higher rates of limb salvage. Wound blush as an angiographic end point in EVT may be a novel predictor of limb salvage in patients with CLI. (J Vasc Surg 2012;55:113-21.)
METHYLENE BLUE ANT TIB INJECTION
The First-in-Man “Si Se Puede” Study for the use of micro-oxygen sensors (MOXYs) to determine dynamic relative oxygen indices in the feet of patients with limb-threatening ischemia during endovascular therapy

Miguel F. Montero-Baker, MD, Kit Yee Au-Yeung, PhD, Natalie A. Winnicki, PhD, Soya Gamscy, PhD, Luis Morelli-Alvarez, MD, Joseph L. Mills Sr, MD, Marianella Campos, MD, and Kristen L. Helton, PhD, Tucson, Ariz; South San Francisco, Calif; and San José, Costa Rica.

J Vasc Surg 2015; 61:1501-10

Summary of First-In-Man Study Results

- **48 sensors** were injected into a total of **14 people** for a cumulative exposure time of 336 subject-days

- Primary endpoint was successfully met; the **positive sensor detection rate was 97.2%** (n=212)

- There were no reported adverse events (AE) related to the research materials. **A total of 26 AEs reported; 18 of which were mild bruising** related to the sensor injection.
Pedra’s Non-Invasive Real-Time Deep Tissue Perfusion Monitor

Allows for simultaneous perfusion monitoring at up to 4 sites.
Levels of angiographic success:

- Level 1: restoration of uninterrupted flow to ischemic tissue
  a. Straight line flow (level 1A)
  b. Flow via non-collateral branches (level 1B)
  c. Flow via pedal loop (level 1C)

- Level 2: restoration of flow to collateral supply to ischemic tissue
  a. WITH wound blush (level 2A)
  b. WITHOUT wound blush (level 2B)

- Level 3: Procedural success without restoring flow directly to ischemic tissue
  a. Flow to “non-target” vessel (i.e. no direct flow to ischemic tissue or collaterals supplying ischemic tissue, no wound blush) (level 3A)
  b. Flow to collateral outflow only (i.e. no major named vessels) (level 3B)

- Level 4: Procedural failure – unable to restore flow in target lesion or level
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