Critical limb-threatening ischemia and BTK interventions:
New approaches for assessment of procedural outcomes and surveillance

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Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

☒ 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
Revascularization is the key element to restore adequate tissue perfusion in CLI

- But how to determine if this was successfully achieved?
- Angiogram alone not reliable
- When does tissue perfusion increase to a certain threshold which is critical for tissue maintenance?
CLI/BTK interventions: Assessment of EVT and surveillance

- Improving the ability to evaluate foot perfusion would benefit patients with CLI during EVT and FU
  - assisting with the etiology of a non-healing wound
  - identifying patients with poor perfusion in the angiosome of interest who might benefit from revascularization
  - identifying patients with seemingly adequate perfusion who may not require revascularization
  - selecting a target vessel for revascularization
  - providing insight when revascularization is sufficient
  - facilitating surveillance for patency

CLI/BTK interventions: Assessment of EVT and surveillance

- Two dimensional (2D) perfusion-angiography software analysis package
  - measurement of parameters of contrast delivery to a region of interest in the foot
  - no additional radiation, intra-procedural time, or contrast
CLI/BTK interventions: Assessment of EVT and surveillance

- Two dimensional (2D) perfusion-angiography

  The REPEAT study (Reproducibility and rEliability of Perfusion angiography and prEdiction of wound healing in criTical limb ischaemia)
  - Prospective single centre study investigating 2DPA
  - Study investigates the reliability of 2DPA and the correlation between perfusion changes measured with 2DPA and clinical outcomes

Eg; Region of interest

After and before revascularisation

Daniel A.F. van den Heuvel et al; Eur J Vasc Endovasc Surg (2021) 61, 980e987
CLI/BTK interventions: Assessment of EVT and surveillance

- Two dimensional (2D) perfusion-angiography

**Available evidence**
- Majority of patients increase in perfusion was observed after revascularization
- ABI correlated well to time-to-peak and peak density ratios
- Improvement in 2D angiographic perfusion parameters was observed following revascularization

**Benefit**
- Practical, as it can be incorporated into a standard angiogram
- ‘Angiosome specific’, providing information of regional foot perfusion
- Theoretically could guide revascularization decisions in real time

**Limitation**
- No evidence on longitudinal outcomes associated with 2D perfusion parameters
- Modality not standardized
  - Technique would need to be the same across operators and institutions so that the data generated would be generalizable to patient care.

Miguel Montero-Baker et al; Vascular Medicine 2020, Vol. 25(3) 235–245
CLI/BTK interventions: Assessment of EVT and surveillance

- Indocyanine green angiography
  - Water-soluble contrast agent quickly bound to plasma proteins
  - Visualization of local-regional blood flow by a charge-coupled camera to detect the fluorescence emitted after excitation by a laser light source of a specific wavelength

To obtain the objective fluorescence intensity curves to assess foot perfusion in the patient with CLI, a single area of the foot is analyzed and there must be virtually no movement of either the foot or the camera once recording begins. However, looking in this single view may limit subjective visualization of regional perfusion variations in the entire foot. 

![Image](image-url)
CLI/BTK interventions: Assessment of EVT and surveillance

- Indocyanine green angiography

**Available evidence**
- Ingress (the increase in fluorescence intensity from baseline) and Ingress rate (the increase in intensity over the time to maximum intensity) have shown some correlation with ABI and toe pressure\(^1\)
- Able to detect severe ischemia, based on the Wound-Ischemia-foot-Infection (WIfI) classification, with reasonable accuracy\(^2\)
- Parameter of time to half-maximal intensity to detect response to revascularization\(^3\)

**Benefit**
- appear to show promise for providing incremental information

**Limitation**
- Need for intravenous access
- Contraindication in previously documented iodinated contrast allergies
- Specialized equipment
- Inability to assess perfusion deeper than 5 mm
CLI/BTK interventions: Assessment of EVT and surveillance

- Oxygen Microsensors

  - injectable oxygen microsensors to directly monitor oxygen in the subcutaneous tissue in vivo

  - Soft biocompatible hydrogel sensor injected into subcutaneous space

  - Fluorescence chemistry on hydrogel responds based on analyte concentration

  - Reader collects emissions and data sent to cloud
CLI/BTK interventions: Assessment of EVT and surveillance

- **Oxygen Microsensors**

  **Available evidence**
  - Healthy volunteer study provided validation of the ability of oxygen microsensors to reliably detect changes in tissue oxygen confirmed by TcPO2, with data over 3 months after sensor injection.¹
  - FIH/10 CLI: patients average tissue oxygen in the affected foot increased after EVR.²
  - Post-market Registry study (OMNIA): Increases in oxygen levels assessed during endovascular revascularization procedures were associated with wound healing 3 months following the procedure.³,⁴

  **Benefit**
  - Sensitivity to both arterial insufficiency and microvascular impairment (e.g. diabetics)
  - Treatment planning and long-term monitoring
  - Prediction of wound healing

  **Limitation**
  - Limited data available

³ Brodmann M. Interventional course (LINC), Leipzig, Germany, 2019
CLI/BTK interventions: Assessment of EVT and surveillance

- Single photon emission computed tomography (SPECT)

Prognostic Value of Radiotracer-Based Perfusion Imaging in Critical Limb Ischemia Patients Undergoing Lower Extremity Revascularization

- Prospective single center study/25 patients
- SPECT/CT perfusion imaging of the feet before and after revascularization.

CLI/BTK interventions: Assessment of EVT and surveillance

Impact in CLI patients

Proper diagnosis
Identification of differences related to sex and ethnicity
Reduction of major amputation
Identification of procedural failures or incomplete revascularization
Potential for telemedicine to reduce disparities in CLI
Potential cost savings in the care of patients with CLI
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