Evolving Approaches to Accurately Determine the Adequacy of Revascularization in CLI Patients

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Challenge of Assessing Adequacy of Revascularization in CLI

What’s Wrong with the ABI in CLI?

Does not tell the entire story in the CLI patient:
- Lower accuracy in intrinsic pedal artery disease
- Lower accuracy in multilevel disease (*almost all CLI patients*)
- Not everyone performs toe pressures/waveforms
An analysis of IN.PACT DEEP randomized trial on the limitations of the societal guidelines-recommended hemodynamic parameters to diagnose critical limb ischemia.

- Met criteria for toe pressure: 40% (60%)
- Ankle-brachial index >1.4: 29%
- Normal Ankle-brachial index: 13%
- Ankle-brachial index <0.9: 58%
• 5mm biocompatible oxygen microsensor (MOXY) hydrogel permanent implant; contains a oxygen-sensitive phosphorescence molecule
• MOXY injected into areas of interest and one in the arm to serve as a control
• A light emitting detector placed on the skin in the area of the MOXY and “excites” the oxygen sensitive molecule, which emits a signal back to detector
A case study of dynamic relative oxygen indices (DROIDS) vs time during endovascular therapy shows the relationship of delivered therapy on local tissue oxygen in the foot. On the far right side of the image is a topographic descriptor of where the sensors were placed in the patient’s foot. The Supplementary Fig (online only) demonstrates quick changes in tissue oxygen levels after delivery of therapy in patients with popliteal-tibial disease.
The Basic Principles: Pedal BOLD Assessment

Kos, et al., Invest Radiol 2009; 44: 741-747

T1 Gradient Echo (7,17,27,37 msec) Dynamic T2* map
Overshoot

Dynamic range

Reserve

Cuff inflated

Time to Peak

Cuff release
Potential for pre-procedural planning based on regional tissue perfusion and post-procedure follow-up
## Pedal BOLD MR in PAD – A Case Study
(Baseline vs. 30d Follow-up)

<table>
<thead>
<tr>
<th></th>
<th>Overshoot</th>
<th>Reserve</th>
<th>Dynamic range</th>
<th>Time to peak</th>
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</thead>
<tbody>
<tr>
<td>01-002</td>
<td>Baseline</td>
<td>3.07%</td>
<td>4.43%</td>
<td>7.50%</td>
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<tr>
<td></td>
<td>30 days</td>
<td>10.51%</td>
<td>4.29%</td>
<td>14.80%</td>
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TP=33

TP=89
Baseline & 30d PEDAL BOLD
Evolving Approaches to Accurately Determine the Adequacy of Revascularization in CLI Patients

• Non-invasive diagnostics, beyond toe pressures, to assess pedal perfusion are essential to the care of CLI patients

• Both MOXY and pedal BOLD hold the potential, with further iteration and validation, to provide surrogates of pedal perfusion
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