Objective assessment of CLI patients
Hemodynamic parameters

Worth anything in end stage patients?

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Disclosure

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I have the following potential conflicts of interest to report:

- [x] 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
Hemodynamic parameters in CLI

TASC II 2007: Norgren, Hiatt....

“For patients with ulcers or gangrene, the presence of CLI is suggested by an ankle pressure less than 70 mmHg or a toe systolic pressure less than 50 mmHg”

We sometimes neglect what is written in braces!

(It is important to understand that there is not complete consensus regarding the vascular hemodynamic parameters required to make the diagnosis of CLI.)
Hemodynamic parameters in CLI

TIDE-OVER concept

- minimal perfusion pressure to prevent ulcers: appr. 30 mmHg

- minimal perfusion pressure to allow ulcer healing: appr. 80 mmHg
Hemodynamic parameters in CLI

TASC II 2007: Investigations for CLI D 5.2

...Confirmation of the diagnosis and quantification of the arterial flow

- Ankle pressure: In patients with ischemic ulcers the ankle pressure is typically 50-70 mmHg, and in patients with ischemic rest pain it is typically 30-50 mmHg
- Toe pressures: should include toe pressures in diabetic patients (critical level <50 mmHg)
- tcPO2 (critical level <30 mmHg)
- Investigation of microcirculation (usually used as a research tool) CLI is associated with reduced total flow as well as maldistribution of flow and activation of an inflammatory process. A combination of tests to assess healing and quantify flow may be indicated due to the rather poor sensitivity and specificity of the single test.

Tests include:
- Capillaroscopy
- Fluorescence videomicroscopy
- Laser Doppler fluxometry
- Anatomic (Imaging)
Hemodynamic parameters in CLI

Sensitivity and specificity of the ankle–brachial index to diagnose peripheral artery disease: a structured review

- Eight studies comprising 2043 patients (or limbs)
- The result indicated that, although strict inclusion criteria on studies were formulated, different reference standards were found in these studies, and methods of ABI determination and characteristics of populations varied greatly.
- A high level of specificity (83.3–99.0%) and accuracy (72.1–89.2%) was reported for an ABI ≤ 0.90 in detecting ≥ 50% stenosis, but there were different levels of sensitivity (15–79%).
- Sensitivity was low, especially in elderly individuals and patients with diabetes.

Hemodynamic parameters in CLI


- Among patients (N= 89; non invasive testing +angiographic FU) with any ischemic tissue loss, 29% had an ABI between 0.7 and 1.4.
- Overall, the association of TBI with abnormal runoff was not significant (p=0.38)
- In conclusion, in the evaluation of CLI, nearly one-third of patients with any ischemic tissue loss had a normal or mildly reduced ABI.
Hemodynamic parameters in CLI

An analysis of IN.PACT DEEP randomized trial on the limitations of the societal guidelines-recommended hemodynamic parameters to diagnose critical limb ischemia

![Pie chart showing the percentage of patients meeting various hemodynamic parameters.]

**Fig 1.** Status of toe pressure parameter in patients with critical limb ischemia (CLI). Only 40 patients had an available toe pressure. The large pie shows that 24 patients (60%) met the societal guideline-recommended criteria for the toe pressure of <50 mm Hg for patients with Rutherford category 5 or 6 or <30 mm Hg in those with Rutherford category 4. The small pie shows that of those who met the criteria, 3 patients (13%) had calcified vessels, 14 (58%) had an abnormal ankle-brachial index (ABI), and 7 (29%) had a normal ABI.

Hemodynamic parameters in CLI

An analysis of IN.PACT DEEP randomized trial on the limitations of the societal guidelines-recommended hemodynamic parameters to diagnose critical limb ischemia

Hemodynamic parameters in CLI

An analysis of IN.PACT DEEP randomized trial on the limitations of the societal guidelines-recommended hemodynamic parameters to diagnose critical limb ischemia

- Only 14 of 237 patients (6%) had an ABI <0.4.
- Abnormal ankle pressure, defined as <50 mm Hg if Rutherford category 4 and <70 mm Hg if Rutherford category 5 or 6, was found only in 37 patients (16%).
- Abnormal toe pressure, defined as <30 mm Hg if Rutherford category 4 and <50 mm Hg if Rutherford category 5 or 6, was found in 24 of 40 patients (60%) with available measurements. Importantly, 29% of these 24 patients had an ABI within normal reference ranges.

A univariate multinomial logistic regression found no association between the above hemodynamic parameters and the number of diseased infrapopliteal vessels.

However, there was a significant paradoxical association where patients with Rutherford category 6 had higher ABI and ankle pressure than those with Rutherford category 5.

Similarly, there was no association between ABI and pedal arch patency.

Hemodynamic parameters in CLI

Lack of Association Between Limb Hemodynamics and Response to Infrapopliteal Endovascular Therapy in Patients With Critical Limb Ischemia

- Prospective, single-center study of consecutive CLI patients \( (N = 100) \) who underwent infrapopliteal endovascular revascularization in the Peripheral Registry of Endovascular Clinical Outcomes (PRIME) registry.
- Patients underwent clinical examination and noninvasive limb hemodynamic measurements, including ABI, TBI, and TP prior to revascularization and within 3 months post intervention on the affected limb.
- Hemodynamic measures were obtained after subjects rested supine for 5 minutes.
  - Systolic pressures were measured in both arms (brachial artery) and at the dorsalis pedis and posterior tibial arteries using a MultiLab Series 2-CP (Unetixs Vascular) or Dopplex D900 Doppler waveform analyzer (Huntleigh).
  - ABI was calculated as the ratio between the higher of the ankle pressures and the higher brachial pressure.
  - Systolic TP was evaluated at the hallux using a MultiLab Series 2-CP (Unetixs Vascular) or Vista Doppler waveform analyzer (Wallach Surgical Devices) by photoplethysmography.
  - TBI was calculated as the ratio between toe pressure and the higher brachial pressure.

J.A. Mustapha et al. J INVASIVE CARDIOLOGY 2017;29(5):175-80
Hemodynamic parameters in CLI

Lack of Association Between Limb Hemodynamics and Response to Infrapopliteal Endovascular Therapy in Patients With Critical Limb Ischemia

When comparing patients based on hemodynamic diagnostic eligibility, there were no observable differences in baseline characteristics or in response to infrapopliteal endovascular therapy.

Baseline ABI and TBI were not different in patients with treatment success or treatment failure.

In the multivariate logistic regression model, only lower Rutherford class (odds ratio, 19.8; 95% confidence interval [CI], 5.5-71.6; P<.001) was associated with treatment success.

### Table 3. Logistic regression: predictors of treatment success (defined as procedure success, freedom from amputation, and clinical success).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unit of Measure</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
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<tbody>
<tr>
<td>Univariate model</td>
<td></td>
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<tr>
<td>Rutherford class</td>
<td>4 vs 5/6</td>
<td>19.8</td>
<td>5.5-71.6</td>
<td>&lt;.001</td>
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<tr>
<td>Diabetes</td>
<td>No vs Yes</td>
<td>3.9</td>
<td>1.4-10.5</td>
<td>&lt;.01</td>
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<td>Glomerular filtration rate</td>
<td>Per 10 mL/min/1.73m² increase</td>
<td>1.3</td>
<td>1.1-1.6</td>
<td>.01</td>
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<tr>
<td>Hemoglobin</td>
<td>Per 1 g/dL increase</td>
<td>1.3</td>
<td>1.0-1.7</td>
<td>.02</td>
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<tr>
<td>Ankle-brachial index</td>
<td>Per 0.1 unit decrease</td>
<td>1.1</td>
<td>1.0-1.2</td>
<td>.20</td>
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<tr>
<td>Toe pressure</td>
<td>Per 10 mm Hg increase</td>
<td>1.1</td>
<td>1.0-1.2</td>
<td>.23</td>
</tr>
<tr>
<td>Age</td>
<td>Per 5 year increase</td>
<td>1.1</td>
<td>0.9-1.4</td>
<td>.24</td>
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<tr>
<td>Toe-brachial index</td>
<td>Per 0.1 unit increase</td>
<td>1.1</td>
<td>0.9-1.3</td>
<td>.31</td>
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<td>Smoking</td>
<td>No vs Yes</td>
<td>1.4</td>
<td>0.6-3.2</td>
<td>.44</td>
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<td>No. diseased vessels</td>
<td>Per 1 vessel decrease</td>
<td>1.1</td>
<td>0.7-1.8</td>
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<td>Body mass index</td>
<td>Per 5 kg/m² increase</td>
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<td>0.7-1.4</td>
<td>.81</td>
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<td>Sex</td>
<td>Male vs female</td>
<td>1.1</td>
<td>0.5-2.6</td>
<td>.84</td>
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<td>Final multivariate model</td>
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<tr>
<td>Rutherford class</td>
<td>4 vs 5/6</td>
<td>19.8</td>
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CI = confidence interval.

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How should we proceed?

- Revascularization is the cornerstone of management for CLI: Objective visualization of diseased arteries
- The current recommended hemodynamic measurements by the societal guidelines are not consistent and have significant limitations in patients with critical limb ischemia.
- Toe pressure, rather than ABI or ankle pressure alone, may be a better measure of perfusion in all patients with CLI
- New methods for proof of impaired blood flow to the wounds and consecutive improvement