Diagnostic Guidelines for Peripheral Arterial Disease, Critical Limb Ischemia, Diabetic Foot Ulcers and Chronic Wounds

A summary
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Introduction

The aim of this document is to summarize the recommendations and diagnostic guidelines provided by different societies and associations for the assessment of peripheral arterial disease, critical limb ischemia, diabetic foot ulcers and chronic wounds.
## Guidelines and Consensus Documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Society/Association</th>
<th>Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines for Critical Limb Ischemia and Diabetic Foot</td>
<td>ESVS (European Society for Vascular Surgery) CLI Guideline Committee</td>
<td>2011</td>
</tr>
<tr>
<td>Transcutaneous Oximetry in Clinical Practice: Consensus statements from an expert panel based on evidence</td>
<td>Fife CE, Smart DE, Sheffield PJ, Hopf HW, Hawkins G, Clarke D</td>
<td>2009</td>
</tr>
<tr>
<td>Comprehensive Foot Examination and Risk Assessment</td>
<td>ADA (American Diabetes Association)</td>
<td>2008</td>
</tr>
<tr>
<td>Inter-Society consensus for the Management of Peripheral Arterial Disease</td>
<td>TASC II</td>
<td>2007</td>
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</tbody>
</table>
Every foot ulcer should be examined for the presence of ischemia.

Critical Limb Ischemia is a clinical diagnosis but should be supported by objective tests.

Trust ABI when low but not when high. An ABI < 0.6 indicates significant ischemia in respect to wound healing potential, whereas an ABI > 0.6 has little predictive value and, therefore, at least the toe pressure should be measured.

Exclude ischemia. Rely not only on ABI. Time is important.

85% of amputations may be prevented by early detection and appropriate treatment.

To prevent a delay in vascular consultation and revascularization, **early non-invasive vascular evaluation is important** in identifying patients with poor ulcer healing and a high risk for amputation.

In CLI, there is a maldistribution of the skin microcirculation in addition to a reduction in total flow.

All diabetic patients with an ulceration should be evaluated for Peripheral Arterial Disease using objective tests.

Critical Limb Ischemia is a clinical diagnosis but should be supported by objective tests.
IWGDF
International Working Group on the Diabetic Foot

Practical guidelines on the management and prevention of the diabetic foot 2012, 2007
In all patients with diabetes and a foot ulcer, evaluate PAD.

1. Clinical history:
   - History to identify symptoms of PAD.
   - Palpation of pulses in the lower limb.

   Non-invasive screening tests:
   - Hand-held Doppler evaluation of flow signals from both foot arteries
   - Ankle-Brachial Index (ABI)
   - Toe-Brachial Index when ABI is uncertain

2. PAD is likely when:
   - The patient has claudication or rest pain.
   - Both foot pulses are absent to palpation.
   - Absent or monophasic Doppler signals from one or both foot arteries
   - TBI < 0.7
   - ABI < 0.9

3. Assess severity of PAD (wound healing potential)
   - Mild PAD:
     - Palpable foot pulses
     - Toe pressure > 55 mmHg
     - tcpO₂ > 50 mm Hg
     - ABI > 0.6*
   - Severe PAD
     - Significant ischemia, severely impaired wound healing:
       - Toe pressure < 50 mmHg
       - tcpO₂ < 30 mm Hg
       - ABI < 0.6
       - Consider revascularization

   Evaluate the effect of maximum 6 weeks optimal wound care. Reassess perfusion and consider duplex ultrasound or angiography when wound healing response is poor.

*Note: ABI > 0.6 has less predictive value, and in these patients, tcpO₂ or toe pressure should be measured.
ESVS
European Society for Vascular Surgery, CLI Guideline Committee

 Guidelines for Critical Limb Ischemia and Diabetic Foot, 2011
All patients with ulcers and gangrene of the extremity

1. **Look for clinical signs for CLI:**
   - Rest pain, ulcers, prolonged refilling of superficial veins and capillaries on the foot, Buergers test
   - *Note: Ischemic rest pain may be reduced or abolished due to sensory neuropathy.*

2. **Confirm clinical signs** and assess severity with objective tests such as distal pressures and microcirculatory assessment (mainly forefoot tcpO₂).
   - ABI < 0.5
   - Toe pressure < 30 mmHg
   - tcpO₂ < 30 mmHg
   - *Note: ABI is not a reliable parameter in patients with CLI, toe pressure is more reliable.*

3. **Risk stratification to identify the best management for each CLI patient.**
   Forefoot tcpO₂ is probably the best non-invasive method for quantification of ischemia severity and prognostic assessment

<table>
<thead>
<tr>
<th>Supine forefoot tcpO₂ value</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 35 – 40 mmHg</td>
<td>Local prognosis fairly good even with conservative management</td>
</tr>
<tr>
<td>10 – 35 mmHg</td>
<td>Local prognosis is intermediate</td>
</tr>
<tr>
<td>≤ 10 mmHg</td>
<td>Local prognosis is very poor</td>
</tr>
</tbody>
</table>
All patients with ulcers and gangrene of the extremity

Further risk stratification to identify the best management for each CLI patient.

<table>
<thead>
<tr>
<th>Severity of CLI</th>
<th>Supine tcpO$_2$ value</th>
<th>Sitting position or under oxygen inhalation tcpO$_2$ value</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree 1</td>
<td>10 mmHg &lt; forefoot tcpO$_2$ ≤ 35 mmHg</td>
<td></td>
<td>Best prognosis</td>
</tr>
<tr>
<td>Degree 2</td>
<td>forefoot tcpO$_2$ ≤ 10 mmHg</td>
<td>Clear increase in tcpO$_2$ value (≥ 40 mmHg)</td>
<td></td>
</tr>
<tr>
<td>Degree 3</td>
<td>forefoot tcpO$_2$ ≤ 10 mmHg</td>
<td>Inadequate increase forefoot tcpO$_2$ &lt; 30-40 mmHg</td>
<td></td>
</tr>
<tr>
<td>Degree 4</td>
<td>forefoot tcpO$_2$ ≤ 10 mmHg</td>
<td>forefoot tcpO$_2$ ≤ 10 mmHg</td>
<td>Very poor prognosis</td>
</tr>
</tbody>
</table>


ACC/AHA
American College of Cardiology
American Heart Association

ACC/AHA 2005 Guidelines for the Management of Patients with Peripheral Arterial Disease: Executive Summary, Update 2011
Diagnosis of PAD

**1. Resting ABI should be measured in both legs in patients with exertional leg symptoms, non-healing wounds, age 65 years and older, or 50 years and older with a history of smoking or diabetes.**

**Ankle/Brachial Index (ABI) in both legs**

- **> 1.40**
- **0.91 - 0.99**
- **≤ 0.90**

**2. Measure ABI after treadmill**

(TBI, segmental pressures, duplex ultrasound examination)

- **Decreased post exercise ABI**

**3. Confirmation of PAD**

___

Leg segmental pressures are useful to establish the lower extremity PAD diagnosis when anatomic localization of lower extremity PAD is required to create a therapeutic plan.

Vascular laboratories could use segmental pressures, Doppler waveform analysis, pulse volume recording, or ABI with duplex ultrasonography (or combinations of these methods) to document the presence and location of PAD in the lower extremities.
Expert panel:
Fife, Smart, Sheffield, Hopf, Hawkins, Clarke

Transcutaneous Oximetry in Clinical Practice: Consensus statements from an expert panel based on evidence, 2009
tcpO₂ for wound healing and amputation level

Assessing:
Wound Healing

- tcpO₂
  - > 40 mmHg: Spontaneous healing likely
  - < 40 mmHg: Oxygen Challenge
    - < 30 mmHg: Severe Arterial Disease
    - > 100 mmHg: No Significant Vascular Disease

Amputation Level

- tcpO₂
  - > 40 mmHg: Spontaneous healing likely
  - < 40 mmHg: Amputation failure likely
    - < 10 mmHg increase: Amputation failure likely
    - > 10 mmHg increase: Amputation healing likely

An increase in tcpO₂ > 40 mmHg after revascularization is also associated with improved wound healing. Note that tcpO₂ should not be performed < 3 days after surgery.

tcpO₂ for hyperbaric treatment

• tcpO₂ values **in-chamber**

<table>
<thead>
<tr>
<th>Values in-chamber tcpO₂</th>
<th>&gt; 200 mmHg (26.7 kPa)</th>
<th>Benefit from hyperbaric oxygen therapy <em>likely</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 100 mmHg (13.3 kPa)</td>
<td></td>
<td>Benefit from hyperbaric oxygen therapy <em>unlikely</em></td>
</tr>
</tbody>
</table>

• tcpO₂ values **during oxygen challenge test**

<table>
<thead>
<tr>
<th>Values <em>during</em> O₂ challenge</th>
<th>&gt; 35 mmHg (4.7 kPa) <em>and</em> &gt; 50% increase compared to value in air</th>
<th>Benefit from hyperbaric oxygen therapy <em>likely</em></th>
</tr>
</thead>
</table>

Summary tcpO₂

- Hear Dr. Caroline Fife summarize the information from this document:
  
  http://www.perimed-instruments.com/diagnosing-PAD#tcpo2
In patients with diabetes:
Vascular assessment to define overall lower extremity risk status

1 Clinical history:
Vascular symptoms:
Claudication, rest pain, non-healing ulcer.

2 Vascular foot exam:
Palpation of posterior tibial and dorsalis pedis

3 In patients with absent pulses or signs/symptoms of vascular disease,
   In all diabetic patients over 50 years:
   Ankle-Brachial Index (ABI)

4 Assign foot risk category
   Apart from vascular status, other parameters such as
   neurological assessment are included in the risk assessment.

Note: ABI may be misleading in diabetes because of incompressible arteries resulting in falsely elevated ABI.
TASC II

Inter-Society consensus for the Management of Peripheral Arterial Disease, 2007
Objective testing is recommended in all patients:
- Age 50-69 years diabetics and/or smokers
- Age > 70 years
- Leg symptoms with exertion or reduced physical function
- Abnormal leg vascular exam
- Assessment of cardiovascular risk

Diagnosis should be supported by objective tests:
- **Ankle Pressure**
  - Patients with ischemic ulcers < 70 mmHg
  - Patients with ischemic rest pain < 50 mmHg

- **Toe Pressure**
  - Patients with ischemic ulcers < 50 mmHg
  - Patients with diabetes < 50 mmHg
  - Patients with ischemic rest pain < 30 mmHg

- **tcpO₂**
  - < 30 mmHg

*In addition: PVR, VWF, Duplex imaging*
Thank You!

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www.perimed-instruments.com