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

A summary
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 Ischaemia 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>
</tr>
</tbody>
</table>
Guidelines and Consensus Documents

Every foot ulcer should be examined for the presence of ischaemia.

Trust ABI when low but not when high. An ABI $<0.6$ indicates significant ischaemia 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. Not only rely on ABI. Time is important.

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

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

To prevent a delay in vascular consultation and revascularisation, 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.
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

<table>
<thead>
<tr>
<th>1</th>
<th>Clinical history:</th>
<th>Non-invasive screening tests:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>History to identify symptoms of PAD.</td>
<td>Hand-held Doppler evaluation of flow signals from both foot arteries</td>
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<tr>
<td></td>
<td>Palpation of pulses in the lower limb.</td>
<td>Ankle-Brachial Index (ABI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Toe-Brachial Index when ABI is uncertain</td>
</tr>
</tbody>
</table>

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

2 Assess severity of PAD (wound healing potential)

3

<table>
<thead>
<tr>
<th>Mild PAD:</th>
<th>Severe PAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palpable foot pulses</td>
<td>Significant ischaemia, severely impaired wound healing:</td>
</tr>
<tr>
<td>Toe pressure &gt; 55 mmHg</td>
<td>Toe pressure &lt; 50 mmHg</td>
</tr>
<tr>
<td>tcpO$_2$ &gt; 50 mm Hg</td>
<td>tcpO$_2$ &lt; 30 mm Hg</td>
</tr>
<tr>
<td>ABI &gt; 0.6 *</td>
<td>ABI &lt; 0.6</td>
</tr>
</tbody>
</table>

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

Consider revascularization

*Note: ABI > 0.6 has less predictive value, and in these patients, tcpO$_2$ or toe pressure should be measured*
ESVS
European Society for Vascular Surgery, CLI Guideline Committee

Guidelines for Critical Limb Ischaemia 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, Buerger’s 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>
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<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 tcpO₂ value</th>
<th>Sitting position or under oxygen inhalation tcpO₂ value</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree 1</td>
<td>10 mmHg&lt; forefoot tcpO₂ ≤ 35 mmHg</td>
<td></td>
<td>Best prognosis</td>
</tr>
<tr>
<td>Degree 2</td>
<td>forefoot tcpO₂≤ 10 mmHg</td>
<td>Clear increase in tcpO₂ value (≥ 40 mmHg)</td>
<td></td>
</tr>
<tr>
<td>Degree 3</td>
<td>forefoot tcpO₂≤ 10 mmHg</td>
<td>Inadequate increase forefoot tcpO₂&lt; 30-40 mmHg</td>
<td></td>
</tr>
<tr>
<td>Degree 4</td>
<td>forefoot tcpO₂≤ 10 mmHg</td>
<td>forefoot tcpO₂≤ 10 mmHg</td>
<td>Very poor prognosis</td>
</tr>
</tbody>
</table>
ACC/AHA
American Collage 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, nonhealing 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)

3. Confirmation of PAD

   Decreased post exercise ABI

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

Oxygen Challenge

> 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.

tcpO$_2$ for hyperbaric treatment

- **tcpO$_2$ values in-chamber**

  | Values in-chamber tcpO$_2$ | > 200 mmHg (26.7 kPa) | Benefit from hyperbaric oxygen therapy *likely*
  |---------------------------|-----------------------|---------------------------------------------|
  |                           | < 100 mmHg (13.3 kPa) | Benefit from hyperbaric oxygen therapy *unlikely*

- **tcpO$_2$ values during oxygen challenge test**

  | Values *during* O$_2$ challenge | > 35 mmHg (4.7 kPa) *and* > 50% increase compared to value in air | Benefit from hyperbaric oxygen therapy *likely* |

Summary tcpO₂

- Hear Dr Caroline Fife summarize the information from this document:


ADA
American Diabetes Association

Comprehensive Foot Examination and Risk Assessment, 2008
In patients with diabetes:
Vascular assessment to define overall lower extremity risk status

1. Clinical history:
   Vascular symptoms:
   Claudication, rest pain, nonhealing 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. Assess 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.

In patients with ABI > 1.3:
   Toe pressure
tcpO2

ABI > 0.9 normal
ABI < 0.8 claudication
ABI < 0.4 tissue necrosis
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
- \( \text{tcpO}_2 \)
  - < 30 mmHg

* In addition: PVR, VWF, Duplex imaging
Some facts...
Facts

- 50% of all patients with diabetes and foot ulcers have PAD
- PAD is the most important factor relating to the outcome of the diabetic foot ulcers
- Role of PAD is underestimated in patients with diabetes
  - Rest pain and intermittent claudication is masked by neuropathy, diagnosis of ischemia is delayed
  - Arteriovenous shunting may cause an ischemic foot to appear pink and warm, even though impaired perfusion exists
- Every foot ulcer should be examined for the presence of ischemia
- ABI > 0.6 has less predictive value, and in diabetic patients, tcpO₂ or toe pressure should be measured
- 30% – 40% of all diabetic patients with an ulcer present falsely high ABI values (ABI>1.3)
- Due to falsely elevated ABI, the importance of toe pressures and tcpO₂ measurements cannot be underestimated
- Both macrovascular disease and microvascular dysfunction impair the perfusion of the diabetic foot, only “macrovascular methods” are not good enough
- To prevent a delay in vascular consultation and revascularization, early, non-invasive vascular evaluation is important in identifying patients with poor ulcer healing and high risk for amputation
- Up to 85% of amputations may be prevented by early detection and appropriate treatment

Ref. Documents listed on page 3 of this ppt.
Diagnostic methods
Macro- and Microcirculation

- Vena cava: 340 mm²
- Larger vein: 28 mm²
- Aorta: 240 mm²
- Larger artery: 20 mm²
- Venules: 0.008 mm²
- Arterioles: 0.002 mm²
- Capillaries: 0.00005 mm²

Laser Doppler
\( tcpO_2 \)
Macrocirculation
Ankle Pressure, Ankle-Brachial Index

• Simple and cheap
• First line evaluation test most commonly used
• Risk for falsely high ABI values due to calcified vessels
  – Common in diabetics, end-stage renal disease patients
  – May result in underestimation of PAD/CLI
• Macrocirculatory measure only
  – Skin microcirculation important factor for wound healing, macrocirculation is not enough
Toe pressure - TBI

- More reliable than ankle pressure in patients with calcified vessels (ABI > 1.40)
  - 30%-40% of patients with diabetes show falsely high ABIs
  - ABI > 0.6 has low predictive value for patients with calcified vessels

- Requires sensitive technique such as Laser Doppler
  - Sensitive at low pressures
  - Solution for cold, ischemic feet – in-built local heating
Pulse Volume Recording - PVR

- Measures changes in pressure reflecting arterial pulsatility (air plethysmography)
- Aid in localizing significant occlusive lesions in limbs
- Not affected by calcified vessels as the ABI

![Graph showing healthy, mild, moderate, and severe arterial disease examples]
Segmental pressures

- Similar to toe pressure, but different positioning of the cuff
- Provide an initial indication of anatomical location of arterial occlusive lesions
- Often combined with segmental pulse volume recordings (PVR).
Microcirculation
Microcirculation

Transcutaneous oxygen (tcpO₂)

- Measures **local oxygen** tension deriving from the local capillary (nutritive) blood perfusion
- Predicts wound healing potential
- Evaluates benefit from HBO treatment
Microcirculation

Heat-Controlled laser Doppler

- Measures the *total local blood perfusion* in the tissue - capillaries, arterioles, venules and shunts
- Combined with heat, measures wound healing potential

Spontaneous healing likely
- Max during heat >20 PU
  (>100 PU if inflammation)
- % increase during heat >150%

Baseline

Heat induced vasodilatation
Skin Perfusion Pressure- SPP

- Similar to toe pressure, but detecting probe underneath cuff
Why restrict yourself to one test?
The Vascular Lab

One instrument, one software-
Several tests

- Toe- and ankle pressure, TBI/ABI
- Pulse Volume Recording (PVR)
- Transcutaneous oxygen (tcpO2)
- Heat controlled laser Doppler
- Skin perfusion pressure (SPP)
- Segmental pressures
- Flap/graft monitoring
- Raynaud
Work flow

1. Patient Set-Up
2. Follow Instructions
3. Automatic Report
The Vascular Lab

Several tests in parallel! One example:

- Ankle pressure → Toe pressure → PVR → Heat-controlled LD
- \( T_{cpO_2} \) -baseline → provocations (leg elevation, oxygen inhalation)
- One Report

Macrocirculation
Microcirculation
Report

One example:
Thank You!

Please visit

www.perimed-instruments.com