PATIENT CASES

Diabetic ulcers and critical limb ischemia – is ABI enough?

THE VASCULAR LAB
Peripheral Arterial Disease (PAD) can influence the outcome of a wound or the fate of a limb. The most common way to diagnose PAD is to measure the Ankle-Brachial Index (ABI). The question is, is ABI enough to accurately diagnose PAD and exclude ischemia in all patients?

Patients suffering from diabetes, renal disease or Critical Limb Ischemia (CLI), often show falsely elevated ABI values due to arterial calcifications. Moreover, they often have impaired microcirculation and ABI will not reflect the microvascular status. As an option to ABI, several guidelines recommend measuring toe pressures (or Toe-Brachial Index, TBI) and transcutaneous oxygen (tcpO₂) as alternative objective vascular tests in these particular patients. Toe pressure measurements are similar to ankle pressures but the risk for falsely high values, due to incompressible arteries, is lower. A TBI < 0.25 confirms severe CLI. An absolute toe pressure < 30 mmHg in a patient with rest pain or < 50 mmHg in a patient with ulcers, also indicates CLI. Monitoring tcpO₂ is a non-invasive way, to evaluate the microvascular status of the patient by measuring the oxygen released from the skin through the capillaries. A tcpO₂ value < 40 mmHg indicates impaired wound healing. The technique has also proven useful for risk stratification of patients with CLI and is frequently used for qualification for hyperbaric oxygen therapy and determination of amputation level.

In this document, we present several clinical cases in which the evaluation of the patient was reinforced by performing toe pressures and tcpO₂, in addition to, or instead of, an ABI.

References:
2. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASCII), Eur J Vasc and Endovasc Surgery, Vol 33 suppl 1 2007
CASE 1 - Critical Limb Ischemia

Female born 1940. Diabetic patient with bilateral ulcers, rapidly progressing on the right foot. Unreliable ankle pressures. Toe pressures required to evaluate suspected ischemia before referral to Vascular Surgery.

CLINICAL HISTORY

Diabetes Type 1 since childhood
Ex-smoker, stopped in 1997
Mechanical heart valve
Bilateral neuropathy in feet

VASCULAR EXAMINATION

Tests performed: Brachial blood pressure 110/70
Bilateral toe pressure
Bilateral tcpO₂ baseline and oxygen (O₂) challenge*

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
<th>O₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT FOOT</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>LEFT FOOT</td>
<td>45</td>
<td>103</td>
</tr>
</tbody>
</table>

* tcpO₂ measurement during 100 % oxygen inhalation (oxygen challenge) will distinguish low values due to a reversible barrier to oxygen diffusion (edema and/or inflammation) from macrovascular disease (PAD). Expect values > 100 mmHg and/or > 100% increase from baseline.

COMMENTS AND CONCLUSIONS

Right side: Low toe pressure, well below the threshold value for CLI (30 mmHg).
Extremely low tcpO₂. No response to oxygen challenge.

Right foot critical limb ischemia with severely affected microcirculation.

Left side: Low toe pressure, borderline CLI.
Slightly reduced tcpO₂ just above the threshold value for wound healing (40 mmHg).
Good response to oxygen challenge.

Beneficial conditions for spontaneous healing on the left side.

Courtesy of Dr. Rosfors, Södersjukhuset, Stockholm, Sweden
CASE 2 - Non-ischemic ulcer

Male born 1940.
Diabetic patient with pain in the feet, particularly in the left foot. Infected ulcer on the left big toe.
Normal ankle pressures, no palpable foot pulses, decreased sensitivity for vibration. Is the ankle pressure falsely elevated? Toe pressures required to investigate possible ischemia.

CLINICAL HISTORY
Insulin-dependent diabetes Type 2
Ex-smoker, stopped in 2001
Angina

VASCULAR EXAMINATION
Tests performed: Brachial blood pressure 150/90
Bilateral toe pressure
Bilateral tcpO₂ baseline

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT FOOT</td>
<td>76</td>
</tr>
<tr>
<td>LEFT FOOT</td>
<td>78</td>
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</table>

<table>
<thead>
<tr>
<th>Toe Pressure (mmHg)</th>
<th>RIGHT</th>
<th>LEFT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>139</td>
<td>140</td>
</tr>
</tbody>
</table>

COMMENTS AND CONCLUSIONS
Right side: Normal toe pressure.
Normal tcpO₂.

Left side: Normal toe pressure.
Normal tcpO₂.

Non-ischemic ulcer. Neuropathy.

Courtesy of Dr. Rosfors, Södersjukhuset, Stockholm, Sweden
CASE 3 - Critical Limb Ischemia

Female born 1927.
Non-diabetic patient with rest pain and small ulcer on the left heel. No palpable pulse in left groin.
Evaluation of ischemia before referral to Vascular Surgery.

CLINICAL HISTORY

No diabetes
Smoker, trying to stop
Previous bilateral surgery for intermittent claudication

VASCULAR EXAMINATION

Tests performed: Bilateral ankle pressure, ABI
Bilateral toe pressure
Bilateral tcpO₂ baseline

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT FOOT</td>
<td>74</td>
</tr>
<tr>
<td>LEFT FOOT</td>
<td>4</td>
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<table>
<thead>
<tr>
<th>ABI</th>
<th>Ankle Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT</td>
<td>0.51</td>
</tr>
<tr>
<td>LEFT</td>
<td>0.16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toe Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT</td>
</tr>
<tr>
<td>LEFT</td>
</tr>
</tbody>
</table>

COMMENTS AND CONCLUSIONS

Right side: Reduced ankle pressure and ABI, but not critical. Reduced toe pressure, but not critical. Normal tcpO₂.

*Right foot slightly reduced pressures, far from critical.*

Left side: Low ankle pressure and ABI, well below the threshold value for CLI (50 mmHg). Low toe pressure, well below the threshold value for CLI (30 mmHg). Extremely low tcpO₂, well below the threshold value for wound healing (40 mmHg).

*Critical limb ischemia.*

After duplex scanning at the vascular surgery department, an occluded stent in the common iliac artery and an occluded femoral artery on the thigh were observed. Percutaneous Transluminal Angioplasty (PTA iliac) and bypass (fem-pop) were performed on the patient.

Courtesy of Dr. Rosfors, Södersjukhuset, Stockholm, Sweden
Male born 1930. Diabetic patient with non-healing wounds on both legs for eight months. Referral from vascular surgeon. Evaluation to determine if the patient is a potential candidate for hyperbaric oxygen (HBO) therapy.

**CLINICAL HISTORY**

Insulin-dependent diabetes Type 2  
Hypertension  
Deep vein thrombosis  
VNUS, VSP and VSM

**VASCULAR EXAMINATION**

Tests performed: Bilateral ankle pressure, ABI  
Bilateral toe pressure  
Right side tcpO₂ baseline and oxygen challenge under normobaric and hyperbaric conditions.

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
<th>O₂ (Normobaric*)</th>
<th>O₂ (Hyperbaric**)</th>
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</thead>
<tbody>
<tr>
<td>RIGHT site 1</td>
<td>31</td>
<td>180</td>
<td>664</td>
</tr>
<tr>
<td>RIGHT site 2</td>
<td>46</td>
<td>298</td>
<td>1236</td>
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</tbody>
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<table>
<thead>
<tr>
<th>ABI</th>
<th>Ankle Pressure (mmHg)</th>
<th>TBI</th>
<th>Toe Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT</td>
<td>1.1</td>
<td>178</td>
<td>0.79</td>
</tr>
<tr>
<td>LEFT</td>
<td>0.91</td>
<td>143</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>ABI</th>
<th>Ankle Pressure (mmHg)</th>
<th>TBI</th>
<th>Toe Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFT</td>
<td>0.87</td>
<td>136</td>
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</table>

* tcpO₂ measurement during 100 % oxygen inhalation. Expect values > 100 mmHg and/or > 100% increase from baseline.  
** tcpO₂ measurement in-chamber. Expect values > 200 mmHg for benefit from HBO therapy.

**COMMENTS AND CONCLUSIONS**

Right side: Normal ankle pressure, ABI, toe pressure and TBI.  
Borderline tcpO₂. Good response to oxygen challenge and in-chamber measurement.

Left side: Normal ankle pressure, ABI, toe pressure and TBI.

Ankle and toe pressure values indicate that there is no severe macrocirculatory disturbance. The miccirculation is suppressed but responds well to hyperbaric oxygen. Patient was treated with HBO therapy with good results.

Courtesy of Dr. Onno Boonstra, Instituut voor Hyperbare Geneeskunde, Rotterdam, Netherlands
CASE 5 - Borderline CLI

Male
Diabetic patient with painful left foot. All toes amputated on the left foot.

CLINICAL HISTORY
Insulin-dependent diabetes Type 2

VASCULAR EXAMINATION
Tests performed: Brachial blood pressure 120
Right side ankle pressure, ABI
Right side toe pressure
Bilateral tcpO₂ baseline

<table>
<thead>
<tr>
<th>ABI</th>
<th>Ankle Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT</td>
<td>1.22</td>
</tr>
<tr>
<td></td>
<td>146</td>
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</table>

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT FOOT</td>
<td>43</td>
</tr>
<tr>
<td>LEFT FOOT</td>
<td>42</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFT FOOT</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

COMMENT AND CONCLUSIONS
Right side: Normal ankle pressure and ABI, questionable if reliable.
Low toe pressure, below the threshold value for CLI (50 mmHg).
Borderline tcpO₂.

Similar toe pressure and tcpO₂ values indicate macrovascular disease only.
No CLI, since tcpO₂ values are above threshold (30 mmHg).

Left side: Incompressible arteries resulting in unreliable ABI and ankle pressure.
All toes amputated.
Borderline tcpO₂.

Low tcpO₂, but no CLI as values are above the threshold (30 mmHg).

Courtesy of Dr. Rosfors, Södersjukhuset, Stockholm, Sweden
Male born 1946. Diabetic patient with problematic wound healing on both feet. Referral from vascular surgeon. Evaluation to determine if the patient is a potential candidate for hyperbaric oxygen (HBO) therapy.

**CLINICAL HISTORY**

Insulin-dependent diabetes Type 2  
Crohn’s disease  
Transmetatarsal amputation of the left hallux  
Amputation of dig IV right  
Pre-renal insufficiency

**VASCULAR EXAMINATION**

Tests performed:  
- Bilateral ankle pressure, ABI  
- Left side toe pressure  
- Left side tcpO₂ baseline and oxygen (O₂) challenge (normobaric and hyperbaric)

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
<th>O₂</th>
<th>O₂</th>
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<tbody>
<tr>
<td>LEFT FOOT</td>
<td>41</td>
<td>238</td>
<td>982</td>
</tr>
<tr>
<td>ABI</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ankle Pressure (mmHg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIGHT</td>
<td>0.41</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>LEFT</td>
<td>0.55</td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>TBI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toe Pressure (mmHg)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>LEFT</td>
<td>0.16</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

* tcpO₂ measurement during 100 % oxygen inhalation. Expect values > 100 mmHg and/or > 100% increase from baseline.

** tcpO₂ measurement in-chamber. Expect values > 200 mmHg for benefit from HBO therapy.

**COMMENTS AND CONCLUSIONS**

Right side: Reduced ankle pressure and ABI.

Left side: Reduced ankle pressure and ABI. Severely reduced toe pressure and TBI. Borderline tcpO₂ with good response to oxygen.

Results indicate both macro- and microcirculatory problems. Good response to hyperbaric oxygen challenge. To avoid amputation, treatment with HBO therapy was started and the wounds responded well.

Courtesy of Dr. Onno Boonstra, Instituut voor Hyperbare Geneeskunde, Rotterdam, Netherlands
CASE 7 - Severe CLI, No HBO Candidate

Female born 1967. Diabetic patient with problematic wound healing of the right leg after bypass surgery 4 months ago (PTA femoro popliteal right and PTA arteria femoralis superficialis right). Referral from vascular surgeon. Evaluation to determine if the patient is a potential candidate for hyperbaric oxygen (HBO) therapy.

CLINICAL HISTORY

Insulin-dependent diabetes
End stage renal insufficiency
Kidney transplant with interstitial rejection
CVA
PTA’s with stents left and right leg

VASCULAR EXAMINATION

Tests performed: Bilateral ankle pressure, ABI
Right side tcpO₂ baseline and oxygen (O₂) challenge

<table>
<thead>
<tr>
<th>tcpO₂ (mmHg)</th>
<th>BL</th>
<th>O₂ Normobaric*</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT above knee</td>
<td>45</td>
<td>86</td>
</tr>
<tr>
<td>RIGHT below knee</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

* tcpO₂ measurement during 100 % oxygen inhalation. Expect values > 100 mmHg and/or > 100% increase from baseline.

COMMENTS AND CONCLUSIONS

Right side: Severely low ankle pressure and ABI.
Borderline tcpO₂ and slight response to oxygen challenge above the knee.
Severely low tcpO₂ and no response to oxygen challenge below the knee.

Left side: Low ankle pressure and ABI.

Very low ABI on the right side. Not hypoxic above the knee but very little response to oxygen challenge. Extremely low tcpO₂ below the knee and no response to oxygen challenge, indicating critical arterial insufficiency. The poor macrocirculation and lack of response to the oxygen challenge predict no benefit from HBO therapy.

Courtesy of Dr. Onno Boonstra, Instituut voor Hyperbare Geneeskunde, Rotterdam, Netherlands
GUIDELINES FOR DIAGNOSIS

Several organizations and committees have published guidelines and recommendations concerning the diagnosis of peripheral arterial disease (PAD) and/or critical limb ischemia (CLI), some of which are summarized below:

**Peripheral Arterial Disease**

- **Ankle/Brachial Index (ABI)**
  - > 1.40
  - 0.91-1.40
  - ≤ 0.90

- **Claudication symptoms - ABI treadmill test**
  - 15%-20% decreased post-exercise ABI

To assess the severity of disease, an ABI < 0.6 indicates significant ischemia, but an ABI > 0.6 has less predictive value. In these cases toe pressure and/or tcpO₂ should be measured.

**Critical Limb Ischemia**

- **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

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

**Wound Healing**

- **tcpO₂**
  - > 40 mmHg
  - < 40 mmHg

- **Spontaneous healing likely**

- **Oxygen Challenge**
  - < 30 mmHg
  - > 100 mmHg

- **Severe arterial disease**
  - No significant vascular disease

**Amputation Level**

- **tcpO₂**
  - > 40 mmHg
  - < 40 mmHg

- **Spontaneous healing likely**

- **Amputation failure likely**

- **Amputation healing likely**

**Hyperbaric Treatment**

**Normobaric Oxygen Challenge**

Expect values > 100 mmHg and/or > 100% increase from baseline.

**Hyperbaric (In-Chamber) Oxygen Challenge**

Expect values > 200 mmHg for benefit from HBO therapy.

References

European Society for Vascular Surgery, CLI Guideline Committee Guidelines for Critical Limb Ischaemia and Diabetic Foot, 2011
Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASCII). Eur J Vasc and Endovasc Surgery, Vol 33 suppl 1 2007
Transcutaneous Oximetry in Clinical Practice: Consensus statements from an expert panel based on evidence. C E FIFE et al., J Undersea and Hyp Med Vol. 36, No. 1 p 43-53, 2009
## The Vascular Lab – Common configurations

### Diagnostic value
- **Basic Vascular Lab**: Advanced PAD diagnosis including micro- and macrocirculation. Accurate wound healing and amputation level assessments. All functionalities in a compact system. One leg at the time. One site tcpO₂.
- **Multi-Channel Vascular Lab**: Advanced PAD diagnosis including micro- and macrocirculation. Accurate wound healing and amputation level assessments. Perfect for the high volume environment. Both legs and reference arm simultaneously. Several sites tcpO₂.
- **Bilateral Toe Pressure System**: Extended macrocirculatory PAD assessment including toe pressures/TBI as well as ABI, segmental pressures and PVR. Complete solution for distal pressures. Bilateral pressure assessment. Reference arm value entered separately.
- **Transcutaneous Oxygen**: Well established microvascular assessment for wound healing potential, amputation level determination, HBO evaluation and more. Ideal for Wound Care and Hyperbaric clinics. Flexible number of sites.

### Measurements

<table>
<thead>
<tr>
<th></th>
<th>Toe/Ankle Pressure*</th>
<th>ABI/TBI</th>
<th>PVR</th>
<th>Segmental Pressures</th>
<th>tcpO₂</th>
<th>SPP</th>
<th>Tissue response to local heating</th>
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<tbody>
<tr>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>1 site simultaneously</td>
</tr>
<tr>
<td><strong>Multi-Channel Vascular Lab</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>2 sites simultaneously</td>
</tr>
<tr>
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<td>✓</td>
<td>✓</td>
<td>2 sites simultaneously</td>
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<tr>
<td><strong>Transcutaneous Oxygen</strong></td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>–</td>
</tr>
</tbody>
</table>

*To simplify measurement in cold ischemic feet, all described configurations include local heating at the measurement point.

Due to its modular design, additional configurations are possible. Please contact Perimed for more information.

The PeriFlux System 5000 Vascular Lab is operated using PSW ExM software. PSW ExM is DICOM compatible.