FEATURED ARTICLE

HBOT TODAY AND VASCULAR SCREENING

Non-Invasive Vascular Testing in the Outpatient Wound Center

By Caroline E. Fife, M.D., CWS

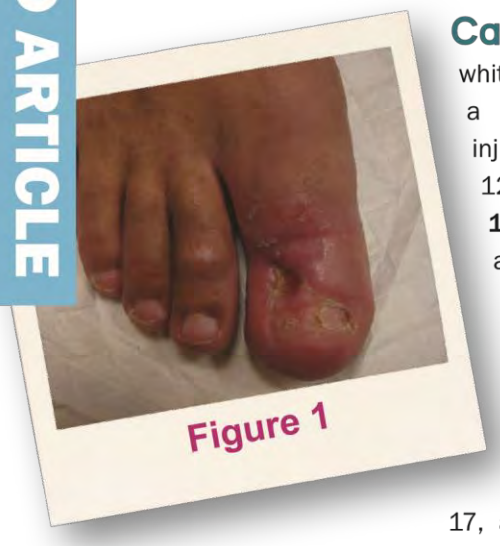
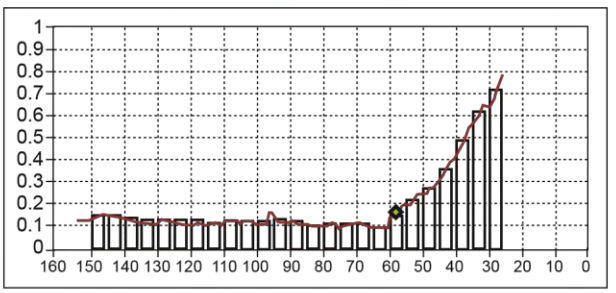


Figure 1

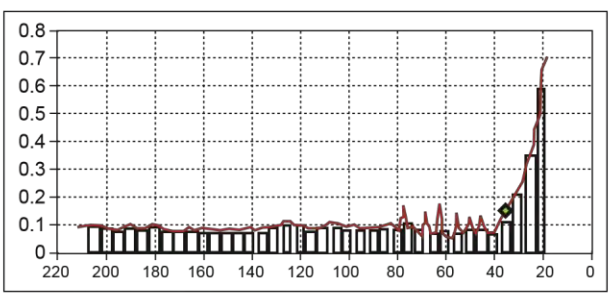
Case: A 30-year-old white male who worked as a machinist suffered an injury to his right great toe 12 months earlier (**Figure 1**). He was treated at another wound center for a year with a variety of topical products, but without improvement. He had smoked a pack of cigarettes a day since the age of 17, and his father died at age 42 of an acute MI. He had no known health problems, and took no medications. A physical exam revealed a normal pattern of hair growth on the leg with a shallow ulcer on the dorsal great toe at the nail bed, and mild erythema of the toe. No DP or PT pulses were palpable.

Our protocol is that all patients with non-healing wounds receive vascular screening. Surprisingly, the transcutaneous oximetry ($TcPO_2$) values on the dorsum of his foot were only 8 and 10 mmHg with no response to sea level oxygen. These readings were so bad for such a young man that I decided to confirm them with a skin perfusion pressure test. His skin perfusion pressure (SPP) was 35 mmHg, which is borderline for wound healing and indicative of arterial disease (Figure 2). Worse, his pulse volume recording (PVR) was almost a flat line (monophasic, Figure 3), indicating that he had almost no pulsatile flow through the large vessels in his calf. I already knew that his father had died of an MI at the age of 42, so I went back in the room to do a better review of systems. I asked more pointed questions about how far he could walk. On careful questioning, he admitted to cramping in his calves when he walked across the machine shop. Sure enough, a magnetic resonance angiogram revealed that only one of the 3 vessels below the knee was open (Figure 4). A few days later, he underwent peripheral bypass surgery, his vascular obstruction not being amenable to angioplasty. **This 30-year-old man had peripheral arterial vascular disease severe enough to prevent him from healing a toe injury.**

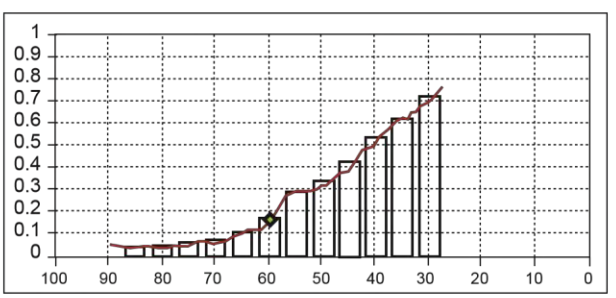
Figure 2



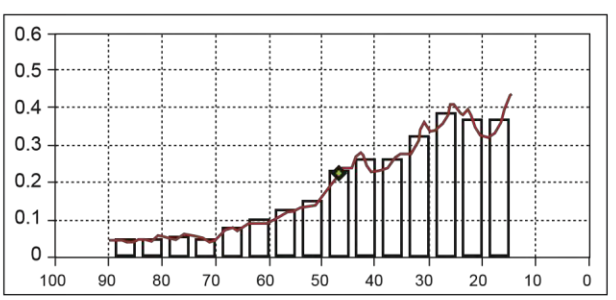
R foot dorsum med 58mmHg



R foot dorsum lat 35mmHg

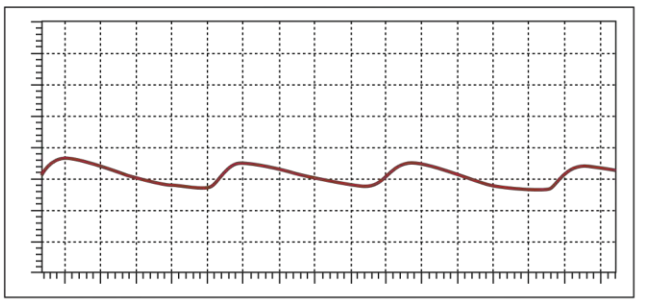


Below R knee med 60mmHg

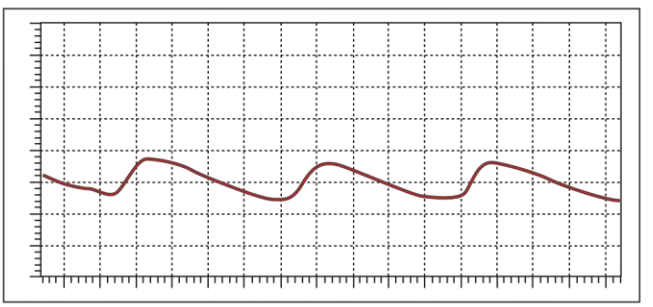


Below R knee lat 47mmHg

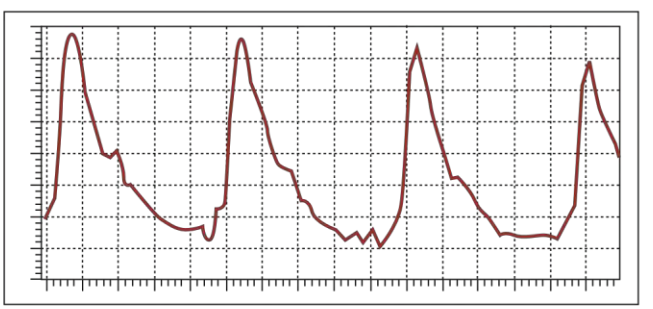
Figure 3



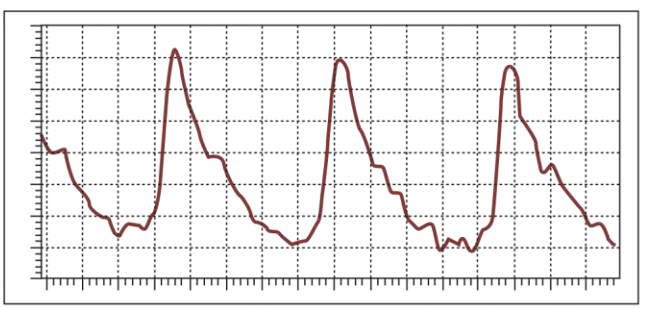
R foot dorsum med 64 mmHg Amp 8.0 mm



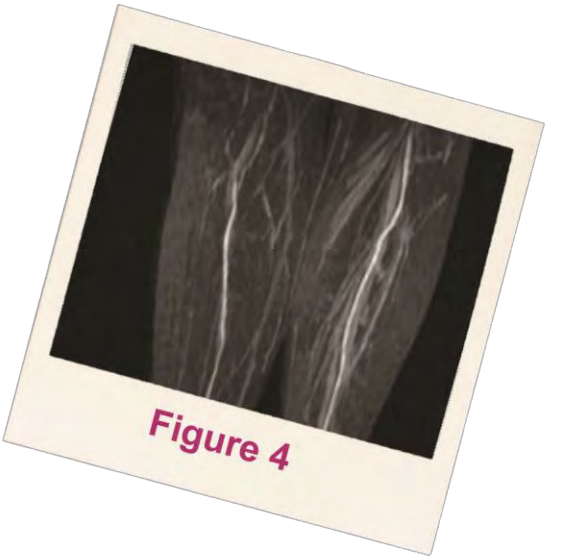
R foot dorsum lat 63 mmHg Amp 11. mm



Below R knee med 63 mmHg Amp 62. mm



Below R knee lat 64 mmHg Amp 61. mm



This case serves as a good example of why vascular screening is advisable for every patient with a chronic non-healing lower extremity ulcer. It also provides an opportunity to discuss the differences between $TcPO_2$ and SPP.

Why Screen for Vascular Disease? The wound center that saw this patient for a year and failed to diagnose his vascular disease committed what may be the cardinal sin in the wound care world—namely, **failure to recognize arterial disease.** When investigators asked Willie Sutton why he robbed banks, he replied, "Because that is where the money is." If anyone were to ask where to find patients with vascular disease, the answer would be, "in the wound center." Why? The patients most likely to have arterial insufficiency are patients with diabetes, who smoke, and who develop non-healing wounds. In other words, they are the patients we see every day in the wound center.

Why is missing peripheral arterial disease the "cardinal sin" of wound care? The 5-year survival of patients after a major amputation is worse than that of most cancers. After a major amputation (below the knee or higher), the 5-year survival rate for non-diabetics is 50%. For a diabetic, the 5-year survival rate is only 30%. If you are a diabetic with renal failure, your chances of being alive 5 years after a major amputation are only 14%. So, major amputation can be considered a "fatal disease." One of the most important jobs we have in the wound center is to diagnose peripheral arterial disease and get patients revascularized if they are candidates. Every limb saved is a life saved.

Guidelines recently published by the Wound Healing Society (WHS) state that all patients with lower extremity ulcers should be assessed for arterial disease *(http://www3.interscience.wiley.com/cgi-bin/fulltext/118605281/PDFSTART).* However, the ideal way to perform non-invasive vascular screening has not been defined by clinical research. A variety of clinical options exist. One can look at the "macro" circulation (the large blood vessels) or the "micro" circulation (the small blood vessels or tissue perfusion/oxygenation). For many years, the most common method of screening was to assess the macro circulation by assessing the Ankle Brachial Index (ABI). The ABI is the ratio of the ankle systolic blood pressure to the brachial systolic blood pressure. It is technically easy to perform, takes only about 15 minutes, and requires only a blood pressure cuff and a handheld Doppler. ABI values of 0.7 or less are considered abnormally low, with values of 0.3 or less representing severe obstruction (ABI is not separately reimbursed; results must be accompanied by printed waveform analysis in order to meet Medicare reimbursement requirements). The problem is that the ABI can be falsely elevated in diabetics due to the incompressibility of their calcified blood vessels, so ABI values correlate poorly with healing prediction in diabetics. We need a better way to assess the vascular supply or healing prediction.

Transcutaneous Oximetry ($TcPO_2$)

Transcutaneous oximetry measures the oxygen partial pressure in the skin ($TcPO_2$). The technology is old (1960s). The device consists of a heating element and a sensor attached to the skin via a gas permeable membrane in contact with an electrolyte solution. The electrode is heated, usually to 44 or 45 degrees centigrade, dilating the blood vessels and allowing oxygen to diffuse to the electrode. When a constant polarizing voltage is applied to the gold cathode, oxygen molecules at the cathode are reduced, the silver in the anode becomes oxidized, and a current is generated in proportion to the number of oxygen molecules in solution. This means that the machine is measuring the actual number of oxygen molecules (PO_2) in the periwound area, not oxygen saturation. In fact, before pulse oximetry was available, TCOMs were used as a way to non-invasively monitor arterial PO_2 in babies. $TcPO_2$ is not a way to determine arterial PO_2 in adults because of the thickness of adult skin, among other reasons. However, it can provide an estimate of arterial perfusion to the area. **The results are reported in "mmHg" just like an arterial blood gas.** The machine has to be calibrated, the seal has to be airtight, and there is a steep "learning curve" for the technologists. It is an "artsy" test. Examples of devices are those manufactured by Radiometer (Denmark) and Perimed (Stockholm, Sweden).

15 studies (1,137 patients) have demonstrated that $TcPO_2$ provides better overall predictive capability than Doppler studies, ABI, segmental pressures, or laser fluximetry. However, many factors can cause $TcPO_2$ to be low besides arterial disease. Anything that creates a barrier to diffusion of oxygen will lower $TcPO_2$. Callous, edema, skin diseases such as scleroderma and scar tissue, or placing the electrode over a bony prominence may decrease the readings. Factors that decrease cutaneous blood flow may also decrease $TcPO_2$ such as hypotension, dehydration, or vasoconstriction due to cold. Arterial hypoxia will decrease the reliability of the findings, and infection may cause them to be increased or decreased as a result of local oxygen consumption or vasodilatation.

$TcPO_2$ has some serious limitations. It cannot be used on most digits because the electrodes are 9 mm wide and thus will not "seal" around most toes. Reliability is affected by callous, so it may not be useful on the plantar foot. It cannot be used in the wound bed itself since the seal around the electrode must be airtight (otherwise the electrode will read the oxygen molecules in the air). It is an estimation of the oxygen supply to the periwound. Patients who are on supplemental oxygen probably cannot have meaningful $TcPO_2$ studies. $TcPO_2$ values are best thought of as "mapping" the extremity (the more values the better). It is important to have more than two sites to use for decision-making, and the more electrodes the better. This can get expensive because the equipment is not cheap.

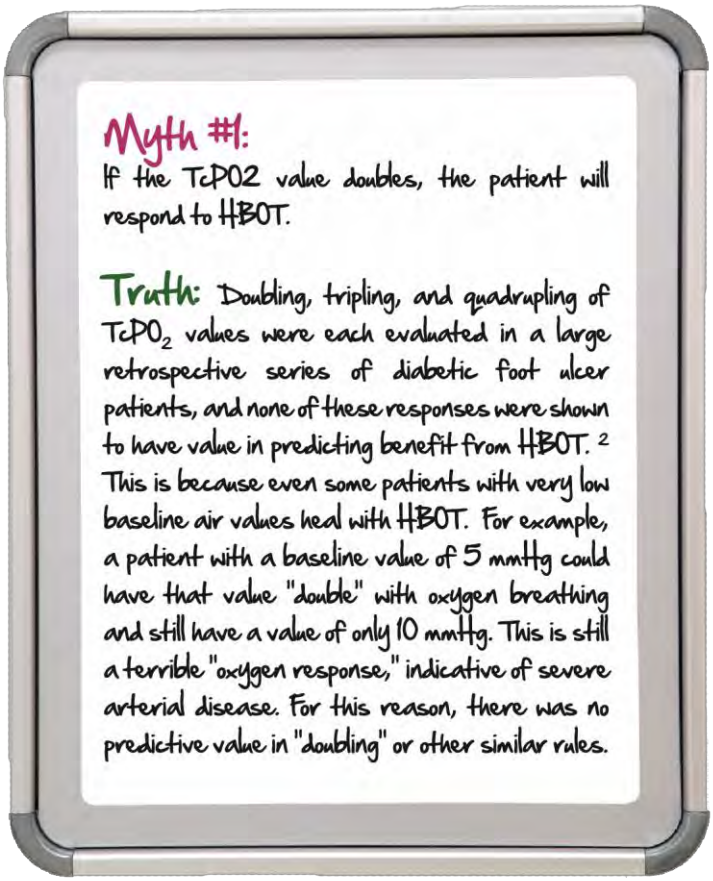
The Oxygen Challenge

To determine whether a low $TcPO_2$ value is due to a diffusion barrier, the patient is allowed to breathe 100% oxygen via a tight-fitting face mask. **Some sort of "challenge" is absolutely necessary as a method of determining whether a low value is due to arterial disease or a diffusion barrier.** If you are not using some sort of a challenge, you have not done a complete test. Oxygen is the most commonly used challenge, but leg elevation is also used as a test for arterial disease (if values decrease with elevation, then arterial disease is likely). If the $TcPO_2$ values increase to >100 mmHg with sea level oxygen breathing, the patient is not likely to have arterial disease. If the $TcPO_2$ values fail to increase significantly with oxygen breathing, the patient likely has large vessel disease.

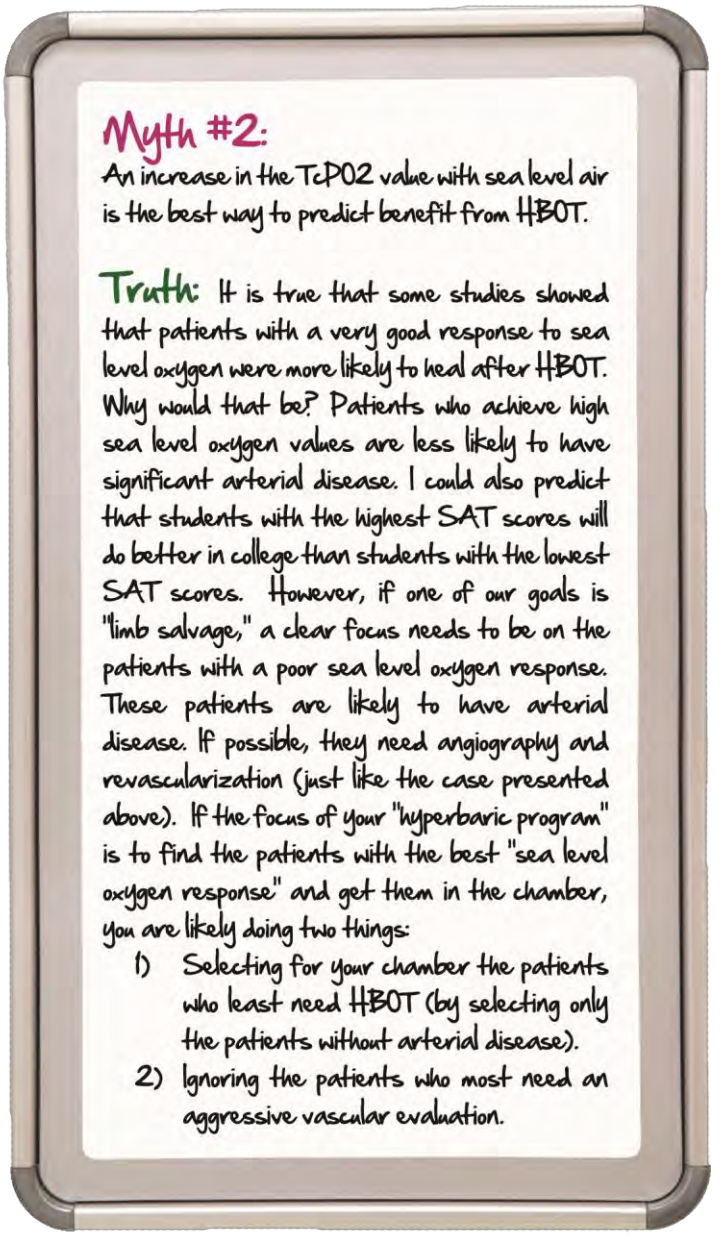
Baseline air $TcPO_2$ values can be diminished for reasons other than arterial disease, but this does not mean the $TcPO_2$ values are "false." A patient with a venous ulcer who has a value of 10 mmHg is not likely to heal spontaneously, but if values increase to 200 mmHg with sea level oxygen breathing, the treatment is edema reduction with compression, not arterial revascularization.

Selecting Patients for Hyperbaric Oxygen Therapy

Transcutaneous oximetry has many hundreds of references to support its use, including randomized controlled trials. It is often found in facilities that offer hyperbaric oxygen therapy (HBOT) because it is often used as a way of predicting which patients will benefit from HBOT. An evidence-based guide to $TcPO_2$ interpretation has been published,[1] but there is still much misunderstanding about how to use $TcPO_2$ for HBOT patient selection.



The "poor sea level oxygen responders" need further arterial work-up. Besides that, it is the "in-chamber" $TcPO_2$ value that will really "tell the tale" of whether HBOT will work. The most reliable way to predict benefit from HBOT



is the in-chamber $TcPO_2$. Diabetic patients whose values during HBOT are >200 mmHg have a significant likelihood of benefiting from hyperbaric oxygen therapy. Even patients with very poor sea level oxygen response may have an excellent in-chamber value.

Although patients whose "in-chamber" values are <50 mmHg are not likely to benefit from HBOT, it does not mean that you should not give HBOT a try, particularly since they have few other options. [2] If $TcPO_2$ values increase at least 30 mmHg after revascularization (endovascular or surgical), this suggests that the revascularization procedure was successful. These patients have a high likelihood of subsequently healing an open wound.

Skin Perfusion Pressure (SPP)

Another non-invasive vascular screening option is the measurement of the capillary opening pressure after occlusion. This involves using a cuff to occlude blood flow, and then slowly deflating the cuff, allowing the gradual return of blood flow. The maximal velocity of the returning blood flow is the "skin perfusion pressure," as measured by a laser device that senses the first blood cells moving through the capillaries. This measurement is also in mmHg but in this case, it is a unit of pressure similar to blood pressure. An example of this device is the SensiLase System (Vasamed, Eden Prairie, MN), but the Perimed $TcPO_2$ device has a SPP unit as an option as well.

SPP technology has a number of advantages in that it is not affected by vessel calcification, it is not affected by edema (much), can be used on the plantar foot and the digits, is not affected by callus or thickened skin, and no calibration of the machine is required.

Lo and colleagues compared SPP and $TcPO_2$ in terms of ability to predict healing outcome in 100 patients with lower extremity wounds. A threshold of <30 mmHg was selected as the cut-off below which the test was considered significantly abnormal and indicative of a wound unlikely to heal. SPP alone successfully predicted outcome in 87% of the patients, compared to $TcPO_2$ at a rate of 64% ($P< 0.0002$). Skin perfusion pressure was more sensitive in its ability to predict wound healing relative to $TcPO_2$ (99% vs. 66%).[3] SPP is also highly reliable in the prediction of healing after amputation, and it can be used to diagnose limb ischemia [4] and thus select patients who need further vascular testing. In addition to the uses above, SPP testing may be useful for planning foot and ankle surgery and ensuring that the patient can tolerate compression therapy for venous ulcers.

SPP Interpretation Guideline (in mmHg)

30 or less = chronic limb ischemia (CLI), wound healing unlikely

30 to 40 = gray zone in wound healing/likely to moderate ischemia

40+ = wound healing probable/ mild to moderate ischemia

40-50 = mild ischemia

50 or more = normal skin perfusion

SPP has some minor disadvantages. Blood flow occlusion by the cuff may be painful, and the area measured must be an area over which a cuff can be placed, so the face or the trunk cannot be assessed. Such areas are more amenable to $TcPO_2$ assessment. For SPP assessment, patients must be placed supine and must be able to extend their legs, so patients with severe contractures or patients who are not able to lie supine may not be able to be tested with SPP. It is often reported that SPP can be performed more quickly than transcutaneous oximetry. However, if multiple sites are evaluated up and down the leg, I have found that the time to perform SPP and TCOM can be comparable.

Do $TcPO_2$ and SPP Measure the Same Thing?

Many people find it confusing that both of these technologies report their results in the same units of measure. However, transcutaneous oximetry measures oxygen molecules (rather like a blood gas) and SPP measures pressure, rather like blood pressure. Both are reported in mmHg but they do not measure the same thing. This is why the man in the case presented could have different values for his $TcPO_2$ and his SPP. Different things were being measured. My patient's oxygen partial pressure to the skin was only 8-10 mmHg. However, he had probably developed small collateral vessels, which kept his skin perfusion pressure at 35 mmHg. There was one more piece of information that the SPP device was able to provide which helped me understand what was really happening to the large vessels, and that was the pulse volume recording (PVR) of the wave forms.

A plethysmograph is an instrument for measuring changes in volume within an organ (usually resulting from fluctuations in the amount of blood it contains). Each time the blood pulses through the leg (or the toe), the volume of the leg changes slightly. The cuff can detect these tiny volume changes and provide information on the pulsatility of this wave form. We are all familiar with the "triphasic" or three "hills" seen in a healthy pulse wave form on an arterial catheter. A less healthy wave form has two phases, and a pulse with only one phase suggests even poorer flow. There are also observable changes within the waveform itself such as steepness of upstroke, shape of the peak, steepness of downstroke, and presence/absence of the dichrotic notch. If no wave form can be detected, it is because so little flow enters the organ that the volume inside the cuff has not changed significantly. That was the case with my patient whose flow to the foot was so poor there was no pulsatile wave form at all (flat line).

Complementary Technologies

I have more than 20 years of experience with $TcPO_2$ and more than 10 years of experience with SPP. I find the two technologies are highly complementary. I use both devices every day, often selecting one over the other for a given patient, and occasionally using one to check the results of the other as I did in the example cited above. Frankly, SPP is the easier technology to learn and implement. It will not be useful in determining which patients will benefit from HBOT. For a clinic just beginning to perform non-invasive testing, the most logical approach may be to initially screen with SPP, reserving $TcPO_2$ for in-chamber testing. However, I find I need both technologies.

Coverage Policy: Which Patients, How Often, and By Whom?

Although they measure different things, both SPP and $TcPO_2$ are billed using CPT codes 92922 and 93923. **I am not a reimbursement expert and am not qualified to provide advice regarding billing and coding. Therefore, I can only point out some potential problems that the reader needs to research further with a reimbursement expert.** For example, there are regional variations regarding which Medicare beneficiaries can undergo vascular screening and unfortunately, they do not necessarily correlate with evidence-based guidelines for screening. You need to review your local carrier coverage policies.

Evidence-based guidelines from every wound healing society agree that all patients with non-healing leg ulcers should be screened for arterial disease. Unfortunately, many carriers will not cover vascular screening for patients with chronic venous stasis ulcers, even though a high percentage of these patients also have arterial disease and arterial screening is required before venous compression can be initiated. Pre-operative screening prior to elective surgery may also be a medically justifiable reason to perform non-invasive arterial studies, but is often not covered by third-party payors and Medicare. There are also Medicare limits on the *frequency* of non-invasive screening. Follow-up testing to assess the success of vascular interventions or to predict the success of HBOT may fall outside the payment guidelines, depending on how soon it is performed after the initial study.

In the past, **some regions have allowed certified hyperbaric technicians (CHTs) to perform transcutaneous oximetry testing, since this is part of their CHT training.** If SPP training is not part of the CHT certification, it could be argued that CHTs may not be able to perform SPP evaluations, even though the same procedure code is used to bill both tests. This seems like an issue that could easily be remedied.

The American Medical Association (AMA) has recently edited the Healthcare Common Procedure Coding System (HCPCS) code 93923, defined as the following: **Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels** (e.g., for lower extremity). It lists:

- Ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels
- Ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography, at 3 or more levels
- Ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements, at 3 or more levels
- Single level study with provocative functional maneuvers (e.g., measurements with postural provocative tests, or measurements with reactive hyperemia)

Although I emphasize that I am not an expert at coding matters, the use of the word "or" in the above definition indicates to me that provocative functional maneuvers (e.g. reactive hyperemia) meets the definition. Thus, transcutaneous oximetry using an oxygen challenge meets the criteria for 93923, as long as it is performed at 3 or more levels. The American Medical Association (AMA) is considering a new CPT®* code pertaining to $TcPO_2$ screening for hyperbaric patients.

The Bottom Line

Appropriate non-invasive vascular screening can reduce unnecessary amputations and help clinicians make better use of advanced technology, thus saving money and lives. The problem is that even if clinicians are committed to screening, payors may not cover it for the patients who most need it, and the technical component may not be billable if performed by the staff who are trained to do it if their credentials do not meet payor requirements. The equipment is relatively expensive, and purchase may only be justified if the test is reimbursable. Clinicians may be left with choosing between what is right and what is covered. Clinicians should work with their regional carriers for better coverage policies regarding non-invasive testing.

A Rational Approach to Non-Invasive Vascular Screening in the Wound Center

1. **Vascular screening is clinically indicated for all patients with non-healing lower extremity wounds (whether screening is billable is a separate issue).**
2. **Patients with low baseline $TcPO_2$ values breathing air should be challenged with 100% oxygen. Patients whose values increase dramatically upon respiring sea level oxygen are unlikely to have large vessel disease. Patients with a low SPP but a normal PVR likely have microvascular disease.**
3. **Patients whose $TcPO_2$ values fail to increase with sea level oxygen or who have a low SPP in the presence of a dampened PVR can be referred for anatomical studies to determine whether correctable disease is present.**
4. **After vascular status is maximized, $TcPO_2$ or SPP should be performed again. Patients who still have low baseline values should undergo in-chamber $TcPO_2$ testing to determine whether HBOT is likely to be of benefit.**

If not used properly, **$TCPO_2$ (or even SPP) can be unintentionally misused as a way to select patients with the best vascular status for HBOT,** rather than a way to reduce amputation rates. Following the above stepwise decision tree will ensure that no patients with significant peripheral arterial disease are overlooked. This is what happened to the patient in the case presented here, who was followed for a year in a wound center without benefiting from therapy because he had undiagnosed ischemia. Patients who are not candidates for revascularization or who remain ischemic after revascularization (a common occurrence) can undergo HBOT. In this way, HBOT becomes part of a limb salvage program, reducing the rate of amputation among patients most at risk for it.

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