

Note 1: Indicators

- Lower extremity wound
- Diabetes
- History c/w risk for PVD
- Physical findings c/w PVD

Note 2: Define level of suspected hypoxia

- Identify unsuspected hypoxia
- PtcO2 >40 mmHg, no significant baseline hypoxia
- PtcO2 <40 mmHg, clinically significant hypoxia
- A higher value may be more reasonable,
 <50mmHg, in diabetics and patients with renal failure
- The lower the value below 40 mmHg the more significant the degree of hypoxia
- Critical limb ischemia PtcO2 < 30 mmHg

Note 3: Performed to differentiate PVD from edema, assess potential to respond to HBO, quality of runoff re success of possible revascularization

- > 100 mmHg considered an adequate response indicating likelihood of responding to HBO (not evidence based)
- > 10 mmHg rise above air baseline considered in one study to be reflective of positive HBO response (not evidence based)

Note 4: The higher the PO2 value the more likely a therapeutic response to HBO will occur.

Note 5: S/S of large vessel disease???

- Ischemic rest pain
- Claudication
- Abnormal pulse exam
- Prior vascular surgery

Note 6: >20% drop on elevation from air baseline = significant PVD

Measurement of tissue oxygenation (superficial dermal capillary plexus PO2) is an essential aspect in the evaluation of non or poorly healing wounds, particularly if adjunctive hyperbaric oxygen treatment is being considered as an interventional modality. The application of this technology in problem wound evaluation and management dates back some 30 years. Essentially, transcutaneous PO2 (PtcO2) measurement involves the application of a specially configured Clark oxygen electrode to the surface of the skin which is locally heated to maximize vasodilation and oxygen diffusion to the electrode surface. This provides for an **estimate** of tissue oxygenation (superficial dermis and epidermis) by measuring the diffusion of extracellular oxygen into the heated sensor (electrode) on the surface of the skin. We typically assume that the PtcO2 measured accurately reflects wound tissue oxygenation, however, that may not always be true. In fact, in some cases, PtcO2 may overestimate the tissue oxygen availability within the wound. Several studies have addressed the "normal value" for PtcO2 measurements of the skin. These values in four published studies range from 50 to the mid 70s and are remarkable consistent from day to day in the absence of underlying vascular or local tissue pathology.

Transcutaneous PO2 measurements are used to:

- 1. predict healing of wounds and ulcers
- 2. predict the success of planned surgical procedures
- 3. predict or define the severity of symptoms of ischemia
- 4. predict the level of amputation that will heal without supportive intervention
- 5. predict the success of vascular interventions

Summarizing the available data on the use of PtcO2 measurements in the management of problem wound patients...PtcO2 can be used before revascularization or hyperbaric oxygen treatment to define the target tissue's level of hypoxia and to assess if this level of oxygenation is adequate or inadequate to support primary healing or after intervention to assess if the intervention produced a sufficient increase in tissue oxygenation to allow healing to occur.

- 1. Wound hypoxia exists when the PtcO2 values is ≤ 40 mmHg, in some cases ≤ 50 mmHg (patients with diabetes, renal failure, Smart DR, et al, 2006)
- 2. 38 studies since 1982 suggest that hypoxia is defined as PtcO2 < 40 mmHg. In diabetics and renal failure patients, tissues may behave as hypoxic up to 50mmHg. Thus, sea level AIR PtcO2 values can be used to predict which wounds will not heal spontaneously. Hypoxic PtcO2 values measured during air breathing are a good predictor of healing failure but are not useful predictors of response to various interventions, including hyperbaric oxygen treatment or revascularization.
- 3. Multiple studies have shown PtcO2 to be a more accurate predictor of outcome and to a lesser extent the presence of peripheral arterial occlusive disease than ABI measurements, (Hanna GP, 1997) although potentially less accurate than skin perfusion pressure in a recent study in patients undergoing hemodialysis (Okamoto K, 2006).
- 4. Critical limb ischemia currently defined by a PtcO2 value ≤ 20-30 mmHg. Patients with critical limb ischemia, (rest pain, gangrene, or an arterial ulcer) will almost always have PtcO2 <30 mmHg and usually less than 20 mm Hg. However, low AIR values may be caused by a diffusion barrier such as edema, excess consumption caused by inflammation, or reversible vasoconstriction caused by cold exposure, dehydration, or pain. Sea level air PtcO2 values need to be evaluated in conjunction with the clinical history and conditions present at the time of testing. It is also possible that low air values are caused by microvascular disease such as seen in diabetes. Isolated low values in periwound tissue (with normal distal values) may be caused by local vasoconstriction or lack of angiogenesis, or some other process confined to the wound.
- 5. Elevation of the lower extremity during PtcO2 measurement increases the sensitivity of the test in identifying lower extremity peripheral arterial occlusive disease and unmasking hypoxia adversely affecting wound healing (Hauser CJ, et al, 1993; Bacharach JM, et al, 1992).
- 6. An increase in PtcO2 >30 mmHg during AIR breathing after revascularization (by surgery or endovascular procedure) is a significant improvement and is usually associated with subsequent healing. PtcO2 values can continue to increase for as long as 28 days after revascularization. The literature suggests that post revascularization PtcO2 studies should not be performed until at least three days following the procedure and preferably more than a week.

- 7. The sea level oxygen challenge is the best way to determine whether low air values are due to a reversible diffusion barrier such as edema or inflammation rather than an oxygen delivery problem. A PtcO2 value breathing 100% oxygen at sea level which is <30 mmHg is consistent with severe arterial disease. Sea Level AIR PtcO2 may assist in identifying which patients will not heal spontaneously (e.g. without HYPERBARIC OXYGEN TREATMENT or revascularization). Sea level AIR PtcO2 values cannot be used to predict benefit of subsequent HYPERBARIC OXYGEN TREATMENT. This is because patients with very low sea level air values, even as low as 5 mmHg, have subsequently healed with HYPERBARIC OXYGEN TREATMENT, and because HYPERBARIC OXYGEN TREATMENT has been shown to progressively correct hypoxia in ischemic tissue.</p>
- 8. A PtcO2 ≥ 100 mmHg or rise in PtcO2 ≥ 10 mmHg during an oxygen challenge (100% oxygen by hood for face mask, requires high flow oxygen delivery) at one atmosphere may identify patients who will respond favorably to hyperbaric oxygen treatment (**Smart DR**, **et al**, **2006**; **Grolman RE**, **et al 2001**). In normal subjects breathing 100% **oxygen at sea level**, PtcO2 values on the extremity always increase to a value >100mmHg. Such an oxygen response indicates that significant macrovascular disease is unlikely. The one atmosphere 100% oxygen challenge is a less accurate predictor of favorable response to hyperbaric oxygen treatment than is a measurement made during hyperbaric oxygen treatment. Some patients respond to hyperbaric oxygen treatment to a degree much greater than would be anticipated based upon their response to one atmosphere 100% oxygen breathing, therefore, patients should not be excluded from hyperbaric oxygen treatment in limb threatening situations without a trial of treatment with inchamber measurements made (**H01.02 Selecting Wound Patients for HBO**).
- 9. When changing from sea level air to 100% oxygen at sea level, if the increase in PtcO2 is < 10mmHg, or if PtcO2 <u>decreases</u>, then benefit from HYPERBARIC OXYGEN TREATMENT is highly unlikely (89% HYPERBARIC OXYGEN TREATMENT failure rate).
- 10. Several published cases since 1977, using both PtcO2 and invasive oxygen tension measurements in a variety of wound types (e.g. radiation and diabetes), have shown that baseline AIR oximetry values increase in response to HYPERBARIC OXYGEN TREATMENT. In his RCT, Faglia demonstrated that ischemic diabetic foot ulcer patients completing HYPERBARIC OXYGEN TREATMENT had a statistically significant increase in baseline air PtcO2 values compared to non-HYPERBARIC OXYGEN TREATMENT controls. However, an increase in baseline air PtcO2 has never been used as a predictor of clinical HYPERBARIC OXYGEN TREATMENT success. In diabetic foot ulcers, in-chamber PtcO2 values are the most reliable way to predict benefit from HYPERBARIC OXYGEN TREATMENT. If wound is hypoxic breathing air, and a PtcO2 >200 mmHg is achieved breathing HYPERBARIC OXYGEN TREATMENT, then this is the single best predictor for success of subsequent HYPERBARIC OXYGEN TREATMENT for diabetic foot ulcers. This test is 74% reliable. Conversely, in-chamber PtcO2 values <100 mmHg are closely associated with failure of HYPERBARIC OXYGEN TREATMENT in diabetic foot ulcers. The authors note that although several studies have suggested that an ulcer with a PtcO2 of less than 200mmHg while breathing hyperbaric oxygen is unlikely to heal, due to the variety of etiological and treatment modalities used in these studies, a definitive statement regarding healing prediction cannot be made based on in-chamber PtcO2 alone. As a general guide given the limitations discussed above:</p>
 - In-chamber PtcO2 < 100 mmHg, failure rate with hyperbaric oxygen treatment between 41-90%. In-chamber PtcO2 < 50 mmHg is predictive of failure.
 - b. In-chamber PtcO2 > 200 mmHg is the best predictor of a positive outcome (74-88% reliable).

Non-evidence based suggestions:

There were speakers at the 2007 UHMS Annual Scientific Session pre-meeting on transcutaneous PO2 measurement who made suggestions in the use of PtcO2 which were not based on published literature but which are of interest for consideration:

Evidence that a series of HYPERBARIC OXYGEN TREATMENT treatments can result in an increase in sea level <u>air</u> oximetry values was first
demonstrated by Sheffield as early as 1977. Conference speakers (2007) suggested that it might be possible to predict benefit from HYPERBARIC
OXYGEN TREATMENT if an increase in AIR PtcO2 is noted after a brief series of hyperbaric treatments. As yet, there are no published data to support
the assertion that an increase in baseline AIR PtcO2 can reliably be used to define a successful HYPERBARIC OXYGEN TREATMENT course (i.e., an
indicator that treatment may be discontinued) <u>prior</u> to visible clinical response. We anticipate such data will be forthcoming from a large series of
hyperbaric patients.

- 2. In analyzing PtcO2 values, it has been suggested that adjacent PtcO2 values can be averaged. To date, the largest publication relating ouPtcO2e to PtcO2 values used the LOWEST leg value and thus some data exist regarding the reliability of this method. There are no data to determine whether "averaged values" are more or less accurate in predicting ouPtcO2e than "lowest value" data. Studies are needed to evaluate the reliability of averaged data in comparison to lowest value data in relation to ouPtcO2e and/or vascular disease prediction.
- 3. With regard to HYPERBARIC OXYGEN TREATMENT ouPtcO2e prediction, we agree that even in patients with in-chamber values <100 mmHg (and thus a low likelihood of HYPERBARIC OXYGEN TREATMENT benefit), the reliability of this test is still only 75%. Thus, a trial of HYPERBARIC OXYGEN TREATMENT continues to be a reasonable approach, if there are no other options for the patient, on a case-by-case basis. A reasonable trial of HYPERBARIC OXYGEN TREATMENT is regarded as 15- 20 treatments.
- 4. There are some data to suggest that leg elevation might be a better indicator of vascular disease than failure to respond to sea level oxygen. However, since sea level oxygen is useful for other things such as predicting amputation healing and confirming that arterial disease is NOT present, and there is nothing to suggest that adding limb elevation adds to/enhances PtcO2 data, one might argue that sea level oxygen it is a more versatile test.
- 5. The regional perfusion index has been used in the past to help determine whether a low PtcO2 value is a local or central problem, i.e. whether tissue hypoxia is due to arterial hypoxemia. However, the regional perfusion index appears to have little use in the hyperbaric evaluation process. Furthermore, a predicable percentage of patients have an abnormally low chest reference value, perhaps due to previous sternotomy, etc. An abnormally low chest reference will create a spuriously high RPI. Thus, the value of RPI in determining vascular disease is also questionable. Moreover, the absolute value of wound oxygen is probably more important in predicting healing potential.
- 6. It was emphasized that a "best practice" would be to check oxygen saturation at the time of PtcO2 testing in all patients. Since the purpose of the chest reference is to ensure that the patient does not have arterial hypoxemia, oxygen saturation may be an easier and more accurate way to assess this, thus freeing a PTCO2 electrode for extremity measurements. (This "best practice" but not evidence-based recommendation is not at this time being implemented by Diversified Clinical Services, RW.)
- 7. A low air value followed by a response to sea-level oxygen > 100mmHg may indicate that the patient has minimal arterial disease and that any low air values are due to a diffusion barrier. A search for a correctable diffusion barrier should be undertaken prior to consideration for HYPERBARIC OXYGEN TREATMENT.
- 8. Skin perfusion pressure can be used as an adjunct to determine whether low PtcO2 values are due to poor tissue perfusion, and the pulse volume recording can be used to assess large vessel status. The combination of these technologies may be useful in diagnosing the cause of a low PtcO2. SPP may also be useful in evaluating whether revascularization has led to increased arterial inflow. The increase in tissue oxygen may be delayed after successful revascularization, but it remains useful to know if inflow was increased acutely. (It is our experience within Diversified Clinical Services that the time required to perform transcutaneous oximetry has been an impediment to its application as a screening tool for PAD. We are therefore aggressively evaluation skin perfusion pressure (SPP) measurement as an alternative screening method to identify PAD focusing transcutaneous oximetry on the identification of reversal hypoxemia as described above in patients with abnormal SPP or normal SPP but persistently impaired wound healing, RW.)

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The identical clinical practice guideline is also included under the section Wound/Ulcer as W05.01.2 TRANSCUTANEOUS PO2 (PtcO2) INTERPRETATION.