

Development of guidelines for the referral of diabetic problem wounds for hyperbaric oxygen therapy

KEY WORDS

- ▶ Clinical pathway
- ▶ Diabetic foot ulcers
- ▶ Hyperbaric oxygen
- ▶ Hyperbaric oxygen therapy
- ▶ Guidelines

Hyperbaric oxygen therapy (HBOT) can be used as an adjunctive therapy for managing patients with diabetic foot ulcers (DFUs). Guidelines and a pathway were developed to support the referral of patients with DFUs for HBOT from a specialist multidisciplinary clinic.

Guidelines offer support to health professionals and patients when making decisions about care or treatment. Clinical pathways are a tool used more easily in practice when decisions and care must happen swiftly. They allow consistency of treatment. The guidelines described were written using national and international recommendations and consensus. They will be reviewed at a later date, yet to be decided due to coronavirus (COVID-19), to ensure successful implementation and that they meet local and national requirements.

Diabetic foot ulcers (DFU) can be difficult to heal and can lead to amputation. It has been suggested that the 5-year mortality rate for lower limb complications associated with diabetes are similar or worse than for many types of cancer (Armstrong, Wrobel & Robbins 2007). In 2015, Guest et al published the results of a review of patient records from May 2012 to April 2013 and calculated there were 169,000 (8.7%) people with a DFU among the 1,951,000 wounds in the UK with an aetiology assigned. Chronic wounds have been predicted to grow in numbers by 12% annually, therefore the prevalence of DFUs in 2020 can be expected to be much higher (Guest et al, 2017).

Patients with DFUs have increased healthcare needs including GP visits, home visits, emergency department visits and outpatient appointments (Rice et al, 2014). Hyperbaric oxygen therapy (HBOT) can be part of a multidisciplinary approach to the handling of diabetic wounds that have failed to respond to standard wound management.

HBOT involves breathing 100% oxygen, in a specially designed chamber (*Figure 1*), at a pressure greater than that at sea level (approximately 1 atmosphere absolute (ATA)) (Löndahl, 2013). Elementary gas laws and the physiological and

biochemical effects of hyperoxia explain the results seen following a course of HBOT (Löndahl, 2013). These include reduction of inflammatory cytokines, stimulation of growth factor production, reduced oedema, improved white cell function, promotion of angiogenesis, increased fibroblast activity and increased tensile strength (Knighton et al, 1981; Hopf et al, 2005; Milovanova et al, 2009; Zhang & Gould 2014; Eggleton et al, 2015).

Treatment can be given in a multiplace chamber, pressurised on air with more than one patient treated at a time, or in a monoplace chamber, pressurised on oxygen or air with only one patient treated at a time. Where the chamber is pressurised on air, oxygen can be delivered via a mask, head hood or endotracheal tube.

The goal of HBOT is to improve wound healing and to help reduce the incidence of major amputation, but appropriate patient selection is required and it must be used alongside standard care, as an adjunctive therapy. Standard treatment for DFUs is at 2-2.4 ATA (10-14 metres of sea water) for 30-40 sessions; the patient will be required to attend 5 days per week for 6-8 weeks. Review by the referring team often occurs after 20 treatments (4 weeks) to ensure the continuation



Figure 1. A multiplace hyperbaric chamber (suitable for treating multiple patients simultaneously)

of treatment is appropriate and determine whether any other interventions are required.

When delivering an intervention, guidelines offer support to health professionals and patients when making decisions about appropriate care or treatment (Jackson & Feder, 1998). To assist in the delivery of an intervention within guidelines, clinical pathways may be used. These are diagrammatic or written tools providing a link between the best available evidence and clinical practice (Rotter et al, 2010).

Following some concerns about delays in the start of patients' treatment due to lack of information and appropriateness of referral, local guidelines and a clinical pathway were developed for the referral of patients with DFUs for HBOT. Some of the issues experienced were due to time constraints in the multidisciplinary clinic, others were a result of staff changeover or specialists being on leave and their role being filled by someone not routinely involved in that clinic. A health professional from the HBOT centre was often present at the multidisciplinary clinic, but staffing shortages led to the frequency of attendance being reduced. Additionally, a national database for collecting outcome data was being discussed in England, therefore it seemed appropriate to better define and streamline the process for referral. It was hoped this would provide support to health professionals and patients.

METHODS

Draft guidelines and a referral pathway were developed with input from the local diabetes and vascular teams. The draft was shared with the diabetes, vascular, orthopaedic, podiatric and

orthotic teams involved in the joint foot clinic for comments and suggestions.

Further amendments were made to the guidelines as seen fit by those involved and the final draft was issued.

RESULTS

The written guidelines were successfully developed and agreed on before a clinical pathway in the form of a flow chart was added to support the guidelines. Although the guidelines were only two pages long, the flow chart (*Figure 2*) provided a clear pathway and allowed for quick easy reference when decision making in the multidisciplinary foot clinic. It provided a definitive guide to what action to take and what information to gather if HBOT is being considered for the patient. It also indicated which patients meet the criteria for referral in line with best available evidence.

Recommendations for HBOT frequently use the Wagner grading system to select DFUs suitable for treatment, but SINBAD (site, ischaemia, neuropathy, bacterial infection, area, depth) classification is more commonly used locally (*Figure 3*). Therefore, reference to both has been made in the guidelines and a quick reference guide provided on the pathway.

Review of the guidelines and pathway was planned for one year post implementation, which was in June 2019. but due to delays in referral and treatment as a result of the coronavirus pandemic, a new review date is yet to be decided. Evaluation will include looking at referral date compared with treatment start date, information provided upon referral and patient feedback forms (completed as standard upon completion of a course of treatment.

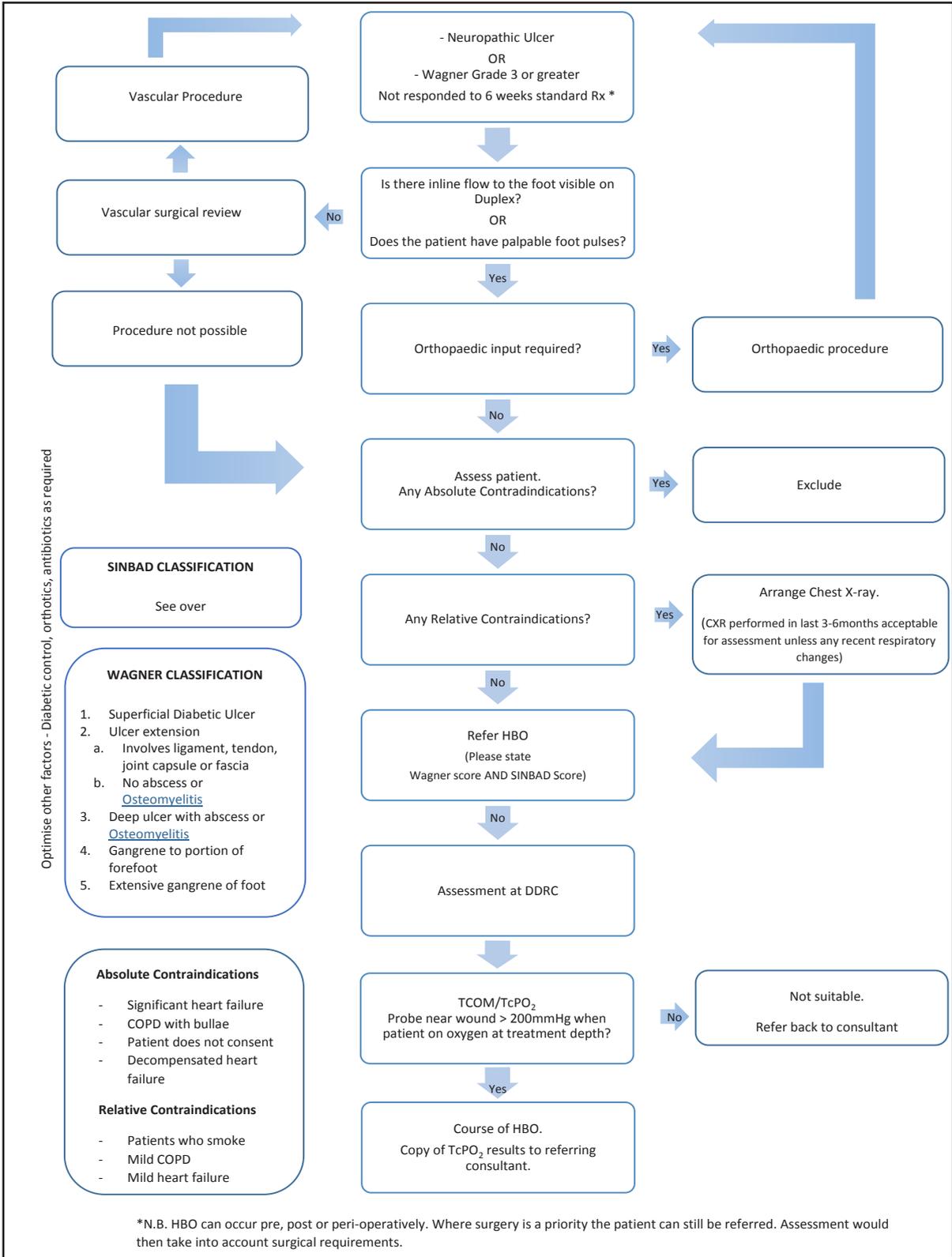


Figure 2. Diabetic foot ulcer (DFU) referral pathway for hyperbaric oxygen therapy (HBOT)

The SINBAD system for classifying and scoring foot ulcers		
Category	Definition	SINBAD score
Site	Forefoot	0
	Midfoot and Hindfoot	1
Ischaemia	Pedal blood flow intact: at least one pulse palpable	0
	Clinical evidence of reduced pedal blood flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial Infection	None	0
	Present	1
Area	Ulcer<1cm ²	0
	Ulcer>1cm ²	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total Possible score		6

*N.B. HBO can occur pre, post or peri-operatively. Where surgery is a priority the patient can still be referred. Assessment would then take into account surgical requirements.

Figure 3. Diabetic foot ulcer (DFU) referral pathway for hyperbaric oxygen therapy (HBOT) (page 2)

A review of whether each of the key steps has been completed will also be conducted. The pathway will also be discussed with the clinicians using it, to gain their assessment of it as a tool.

DISCUSSION

Guidelines should be simple, patient specific and user friendly (Jackson & Feder, 1998). First introduced to healthcare in the 1980s in the US (Vanhaecht et al, 2010), Rotter et al. (2010) surmised that clinical pathways are linked to reduced complications in hospitals. In clinical practice, it can be difficult to ensure all the criteria are met for patients requiring certain interventions or care with many pressures upon time.

The guidelines and pathway developed here were written using recommendations from both the European consensus (Mathieu et al, 2017) and the Undersea and Hyperbaric Medical Society (UHMS) list of indications (Weaver, 2014). They also meet the advice given in the tissue, inflammation/ infection, moisture, edge, regeneration, social factors (TIMERS) document (Atkin et al, 2019). They ensure referral is appropriate, standardised and supports the multidisciplinary team in making their decision. With clear contraindications listed,

health professionals can quickly see whether there are any reasons why treatment would not be possible. In the past, it was often a few key consultants and the hyperbaric clinical team who advised about when referral was not suitable and the patient had often already been informed that treatment was a possibility.

The guidelines recommend treatment for neuropathic ulcers and ulcers assessed as Wagner grade 3 and above that have failed to respond to standard therapy for 6 weeks. The European consensus advises that Wagner grade 3 or Texas classification B3 or worse ulcers that have failed to respond to adequate wound care after 4 weeks (Mathieu et al, 2017). National Institute for Health and Care Excellence (NICE) guidelines (2019) recommend SINBAD or the University of Texas Classification system are used. Locally, SINBAD scoring is used and as Wagner grading is internationally recognised, both were included on the referral pathway and are used at assessment. NICE (2019) state that Wagner grading should not be used to clarify the severity of a DFU, presumably as it is a very basic assessment of the ulcer.

European recommendations are for HBOT to be considered after 4 weeks of standard

wound care (Mathieu et al, 2017). Locally, it was decided to extend that for 6 weeks as this better fits with review dates in the joint foot clinic and is considered a reasonable time for any wound improvement to be visible before a referral is considered. Wounds requiring surgical intervention can also be referred and timing and number of treatments will be dependent upon the planned intervention. NICE (2019) specify that standard treatment includes one or more of the following:

- Offloading
- Control of foot infection
- Control of ischaemia
- Wound debridement
- Wound dressings.

NICE (2019) have stated that HBOT must not be used unless part of a clinical trial. NHS England no longer fund HBOT for DFUs as standard. However, locally we have an agreement to treat patients meeting the referral criteria. Patients are treated as at no direct cost to the NHS as part of a research-based data collection registry which will further the understanding of the effects of HBOT on DFUs by gathering outcome data, including wound size at start and end of treatment and whether surgery was needed.

The guidelines developed recommend transcutaneous oxygen monitoring (TCOM) during patients' first HBOT to ensure treatment is suitable. During TCOM a sensor is gently applied to the skin and continuously measures the oxygen diffusing in that area. If a sensor placed close to the wound measures greater than 200 mmHg while on 100% oxygen at treatment pressure, the wound is highly likely to heal following treatment (Moon et al, 2016). Therefore, within the pathway developed, patients will be classed as unsuitable for treatment if this level is not achieved. Work has been conducted to demonstrate that TCOM readings less than 20–30 mmHg on room air indicate a wound will not heal without additional intervention or care and a measurement of 30–40 mmHg suggests an element of hypoxia (Arsenault et al, 2011; Fife et al, 2009). Those with a reading of 40–50 mmHg may struggle to heal in the presence of any comorbidities, such as diabetes or renal failure (Fife et al, 2007). In these circumstances HBOT referral may be indicated. However, in the local joint foot clinic, TCOM is

not a routine component of assessment, most likely (in the author's opinion) due to logistical and time factors with other assessment methods taking priority.

Due to lack of information on the referral from the multidisciplinary foot clinic, usually because of limited knowledge of what detail was required, a delay was often experienced between referral and treatment start. This was to allow necessary investigations, such as chest x-ray, to be undertaken or information about patient history to be requested. The referral pathway specifies consideration of these things in advance, so HBOT should commence much quicker. Initial signs are that this is indeed the case. The standard hospital referral form requires only very minimal detail about the patient and historically delays starting treatment have occurred.

A systematic review of the guidelines and clinical pathway at a later date should establish the success of linking best evidence and recommendations to clinical practice. As there is currently no data in the UK regarding adherence to the recommended referral criteria, such a review would provide a benchmark for future audits. The guidelines and pathway will be revisited before implementation of the NHS supported, countrywide database. Not only will this ensure that consistency with national requirements is maintained, but it will allow patients referred via the pathway to be reviewed, assessing whether they meet the criteria specified and whether each step was followed. Discussion with the referring consultants and the specialist teams involved will also be necessary to ensure the pathway continues to support them in following the guidelines effectively.

Developing these guidelines took longer than initially expected. This was due to the involvement of representatives from all the disciplines involved in the joint foot clinic and the determination to ensure a robust pathway. It is anticipated that these guidelines, intended to support referral of patients with DFUs for HBOT, will ensure appropriate and timely referral and lead to optimum outcome and experience for patients. Ultimately, standardised referral criteria should lead to better continuity and satisfaction for the patient with more informed choice about the process.

CONCLUSION

Guidelines and clinical pathways are now well established in healthcare. They support health professionals and patients when deciding upon treatment or care required and ensure this is consistent with the best evidence. Documents need to be easy to follow and understand and future review and follow up is essential to ensure they do not become out dated or fail to be effective for clinicians and patients alike. **WUK**

Declaration of Interest: None

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