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Title: UHMS Position Statement: Topical Oxygen for Chronic Wounds

Abstract:

There is a growing incidence of chronic wounds and recognition from the medical community of the complexity involved in caring for these patients. The prevalence of chronic wounds is estimated to be as high as 2% of the US population [1, 2]. While chronic ulcers and non-healing wounds encompass a wide range of etiologies including trauma, diabetes, venous disease, ischemia, neuropathy and infection, localized ischemia is often a contributing factor [3]. Oxygen is necessary for more than aerobic respiration. It has an essential and well-established role in collagen crosslinking, re-epithelialization, angiogenesis and leukocyte killing of bacteria, as well as reactive oxygen species in cellular signaling [4-6]. In tissues with a deficit of the necessary partial pressure of oxygen these required processes for wound healing are arrested [7].

In addition to localized basic wound care, adjuvant methods are often used to aid the delivery of oxygen to promote healing of chronic wounds. Hyperbaric oxygen (HBO2) treatment is a widely recognized systemic treatment where the patient is entirely enclosed in a pressure vessel and intermittently breathes oxygen at elevated pressure, typically greater than 1.4 atmospheres absolute (ATA) [8]. One indication for HBO2 treatment is the management of selected wounds where localized hypoxia is part of the pathophysiology of failed healing [9]. Systemic mechanisms of HBO2 treatment which promote healing include increased mobilization of stem cells, improved cellular signaling, and restoration of adequate oxygen content necessary for angiogenesis and collagen formation [7].

An alternative strategy to HBO2 is to topically deliver oxygen to the wound bed, avoiding systemic delivery. Topical oxygen therapy is a local treatment, and therefore these strategies must be distinguished from the administration of HBO2, with all its unique systemic effects. Various methods have been developed to attain this goal. These include localized delivery of oxygen at or near 1 ATA, generating oxygen adjacent to the wound and a multitude of dressings and topical medications designed to provide oxygen directly to the wound surface [10]. With the latter approach, oxygen may be released through the degradation of hydrogen peroxide, or micro/nanobubbles contained within perflurocarbon or polyacrylamide polymers, among others. These wound dressings are available in different forms, including hydrogels, films, and microfluidic bandages [10]. Topical oxygen emulsions can also be used with dressings to directly deliver oxygen to the wound bed. These dressings all aim to optimize localized wound bed environments and are used as part of an overall wound care strategy.

Regarding devices used to deliver local topical oxygen, there are several systematic reviews that have evaluated the efficacy of topical oxygen therapy for the treatment of lower grade diabetic foot ulcers [12-15]. These reviews reported relative risks for wound healing ranging from 1.53 to 1.94, with confidence intervals that support clinically significant findings. One systematic review reported a number needed to treat of 5.33, suggesting that topical oxygen

therapy increased the likelihood of DFU healing [12]. Collectively, the available systematic reviews support the potential use of topical oxygen therapy as an adjunctive therapy for selected lower grade diabetic foot ulcers. Current evidence supports consideration of topical oxygen therapy as an adjunct to standard wound care for chronic Wagner grade 1 and 2 diabetic foot ulcers in patients with adequate perfusion and without active infection [13]. Topical oxygen therapy appears to be generally well tolerated and is associated with improved healing outcomes in this patient population [14]. However, additional research is needed to determine its effects on amputation rates and its overall cost-effectiveness [12].

Conclusions and Recommendations:

1) Devices, wound dressings, and topical medication designed to increase external wound exposure to oxygen should not be termed hyperbaric oxygen therapy. Doing so intentionally or unintentionally suggests that topical oxygen delivery methods are equivalent or identical to hyperbaric oxygen. Any report on methods and devices providing increased topical oxygen delivery to wounds should clearly state that topical oxygen and not hyperbaric oxygen is being delivered.

2) Hyperbaric oxygen therapy provides mechanisms of action and physiological effects which are distinct from those of devices, wound dressings, and topical medication that provide topical oxygen. Study results concerning hyperbaric oxygen should not be used to support topical oxygen therapy.

3) Oxygen containing and oxygen generating wound dressings aim to address localized wound bed environments and are part of overall wound care strategies to optimize local conditions. They are a local treatment and lack the systemic effect of HBO2 therapy. These treatments are distinct from HBO2 as they lack the systemic effects of HBO2 therapy. Hyperbaric oxygen literature should not be used in support of their use, and it should be clear that they are not HBO2.

4) It is our recommendation that topical oxygen devices be considered as an adjunct to standard-of-care treatment for lower grade chronic Wagner grade 1 and 2 diabetic foot ulcers that demonstrate inadequate healing despite appropriate standard wound care. Adequate perfusion should be confirmed, and wounds should have no active infection at the initiation of topical oxygen therapy. Available evidence does not support routine use of topical oxygen therapy for nonhealing higher grade Wagner grade 3, 4, or 5 diabetic foot ulcers. Topical oxygen therapy should not be considered as a replacement for hyperbaric oxygen therapy when hyperbaric oxygen therapy is otherwise clinically indicated. Systematic reviews have demonstrated improved diabetic foot ulcer healing with topical oxygen therapy, with reported relative risks ranging from 1.53 to 1.94; however, there is no evidence demonstrating a reduction in amputation rates. Further research is needed to better define the patient populations most likely to benefit from topical oxygen therapy and to evaluate its effects on amputation rates, long-term outcomes, and cost-effectiveness.

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