International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Operating Publisher
SciFormat Publishing Inc.
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
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ARTICLE TITLE	HYPERBARIC OXYGEN THERAPY IN THE TREATMENT OF DIABETIC FOOT ULCERS: COMPARISON WITH STANDARD CARE AND CURRENT CLINICAL EVIDENCE
DOI	https://doi.org/10.31435/ijitss.1(49).2026.5299
RECEIVED	20 January 2026
ACCEPTED	23 March 2026
PUBLISHED	30 March 2026
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HYPERBARIC OXYGEN THERAPY IN THE TREATMENT OF DIABETIC FOOT ULCERS: COMPARISON WITH STANDARD CARE AND CURRENT CLINICAL EVIDENCE

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ABSTRACT

Background: Diabetic foot ulcers are a common and serious complication of diabetes, associated with high morbidity, higher healthcare costs, and an increased risk of lower limb amputation. Despite advances in standard wound care, a significant proportion of diabetic foot ulcers remain resistant to treatment, prompting interest in adjunctive therapies such as hyperbaric oxygen therapy.
Aim: The aim of this narrative review was to summarize and critically evaluate current evidence comparing HBOT with standard treatment modalities in patients with DFUs.
Material and methods: A structured literature search was conducted using PubMed and Google Scholar to identify randomized controlled trials, systematic reviews, meta-analyses, and clinical guidelines related to the treatment of diabetic foot ulcers and hyperbaric oxygen therapy. Relevant publications were analyzed and synthesized narratively, focusing on wound healing outcomes, amputation rates, and safety considerations.
Results: Evidence from RCTs suggests that HBOT may improve ulcer healing rates in patients with chronic, non-healing DFUs when used as an adjunct to standard care. Several meta-analyses indicate that HBOT is associated with increased rates of complete ulcer healing and a reduced risk of major amputations. However, findings from Cochrane reviews demonstrate that these benefits may be limited primarily to short-term outcomes, with inconsistent evidence regarding sustained long-term efficacy. HBOT was generally well tolerated, with adverse events being infrequent and mostly mild.
Conclusions: Current evidence suggests that HBOT may be beneficial as an adjunctive treatment in carefully selected patients with refractory DFUs. Nevertheless, heterogeneity among studies and methodological limitations preclude definitive conclusions regarding long-term outcomes. Further high-quality, standardized randomized trials are required to clarify the role of HBOT in routine clinical practice.

KEYWORDS

Diabetic Foot Ulcers (DFUs), Diabetic Foot Syndrome, Hyperbaric Oxygen Therapy (HBOT)

CITATION

Joanna Kozak, Agata Pszczółka, Patryk Matuszczak, Kacper Melka, Gabriela Bajor, Mikołaj Szulewski, Wiktoria Jurczyk-Florkiewicz, Zofia Gniadek, Patrycja Machno, Aleksandra Salagierska. (2026) Hyperbaric Oxygen Therapy in the Treatment of Diabetic Foot Ulcers: Comparison with Standard Care and Current Clinical Evidence. *International Journal of Innovative Technologies in Social Science*. 1(49). doi: 10.31435/ijitss.1(49).2026.5299

Introduction

Diabetic foot ulcers (DFUs) are a frequent complication of diabetes and occur in approximately 4–10% of the total diabetic population, with an estimated lifetime risk of 19–34%. The condition represents a significant public health problem, as around 15% of people with diabetes develop foot ulcers at some point in their lives, and around 85% of all lower limb amputations are preceded by a chronic, non-healing diabetic foot ulcer. (Rehman, Khan & Noordin, 2023)

Up to 85% of diabetic foot ulcers are linked to underlying peripheral neuropathy, which results in abnormal plantar pressure distribution. Chronic hyperglycemia induces complex biochemical alterations associated with increased oxidative stress, leading to motor, autonomic, and sensory neuropathy and, consequently, the development of neuropathic diabetic foot ulcers. (Lim, Ng & Thomas, 2017) Peripheral artery disease (PAD) is another key comorbidity in patients with diabetes. The condition is characterized by stenosis or occlusion in the arteries of the extremities, most commonly in the lower extremities, resulting in reduced tissue perfusion. In advanced stages, chronic limb-threatening ischemia develops, where blood flow is insufficient even at rest, with symptoms such as rest pain and/or tissue necrosis, which can contribute to ulcer development. (McDermott, Fang, Boulton, Selvin & Hicks, 2023) Global direct healthcare costs for diabetes amounted to approximately $700 billion in 2019 and are projected to increase to around $825 billion by 2030. Costs related to diabetic foot ulcers are expected to account for approximately one-third of total diabetes care expenditures by that time. (Deng et al., 2023) The aim of this article is to review the literature and compare the effectiveness of hyperbaric oxygen therapy with standard therapies in patients with diabetic foot ulcers.

Materials and methods

This narrative literature review was conducted using structured searches of PubMed and Google Scholar. Search terms included: “diabetic foot syndrome”, “diabetic foot ulcers”, “diabetic foot treatment”, “hyperbaric oxygen therapy”. RCTs, systematic reviews, meta-analyses and clinical guidelines for diabetic foot ulcers treatment were included. References in the articles were also manually reviewed to identify additional relevant studies. Data on clinical outcomes and therapeutic interventions was collected, systematically organized, and integrated into a narrative synthesis summarizing the current evidence. AI-assisted language tools were used in the preparation of the manuscript to improve grammatical precision, clarity, and overall coherence. Their use was limited to linguistic and stylistic editing and had no impact on the conclusions drawn in this review. No formal quality assessment or meta-analysis was performed due to the narrative nature of this review.

Standard Treatment Modalities in Diabetic Foot Ulcers

The main objectives in the treatment of diabetic foot ulcers are to promote tissue healing, preserving limb function and weight-bearing capacity for walking. Management is based on the appropriate treatment of invasive infection with antibiotic therapy, combined with surgical debridement or amputation of nonviable tissue, as well as reduction of plantar pressure until complete healing. Patient education regarding foot care and the use of appropriate footwear is essential and should not be neglected. (Bellomo et al., 2022)

Wound infection should be diagnosed on clinical grounds, based on signs of inflammation or purulent discharge, and graded according to severity. Wounds with clinical evidence of infection require antibiotic treatment. Initial empirical antibiotic therapy should be guided by clinical judgment and local epidemiological patterns, while targeted treatment should be tailored according to microbiological culture results obtained from infected tissue. (Lipsky et al., 2012)

Wound debridement consists of the complete removal of necrotic tissue incompatible with the healing process, and also peripheral callus. This intervention promotes granulation tissue formation and re-epithelialization, in addition to reducing plantar pressure in hyperkeratotic areas. Debridement is also essential for infection control. Surgical debridement is preferred over topical methods, such as autolytic dressings or biological debridement. (Everett & Mathioudakis, 2018).

There is no single type of dressing that is ideal for all lesions. Maintaining a moist environment is considered beneficial for cell migration and extracellular matrix formation. Dressings should protect the wound bed and, at the same time, be able to adequately manage excess exudate. (Braun, Kim, Margolis, Peters & Lavery, 2014)

The development of many foot ulcers is also influenced by biomechanical factors; therefore, off-loading high-pressure areas is important in both treatment and prevention of recurrence in diabetic foot ulcers. Effective pressure-relief strategies include the use of walking aids, modified footwear, custom orthotic insoles, therapeutic diabetic shoes, and total contact casts. (Braun, Kim, Margolis, Peters & Lavery, 2014).

Hyperbaric Oxygen Therapy

Hyperbaric oxygen therapy (HBOT) is a therapeutic modality that involves the administration of pure oxygen under higher than normal atmospheric pressure. The origins of HBOT date back to 1662, when British physician Henshaw first used compressed air in therapy. The world's first hyperbaric chambers began to appear in the 19th century, and in 1937, hyperbaric oxygen was successfully used to treat decompression sickness. Since then, HBOT has been used to treat many conditions. (Edwards, 2010).

Nowadays, in hyperbaric oxygen therapy, the patient enters an airtight chamber and inhales 100% oxygen. The partial pressure of oxygen inside the chamber, as well as the exposure time, are adjusted according to the individual clinical condition. HBOT sessions can range from a few minutes to about two hours, with pressure gradually returning to normal at the end of the procedure. (Sen & Sen, 2021)

The therapeutic effects of HBOT are based on three main mechanisms: inhaling 100% oxygen creates a beneficial pressure gradient, promoting the diffusion of oxygen from hyperoxygenated lungs to hypoxic tissues; increased ambient pressure raises the concentration of oxygen dissolved in the blood; and elevated pressure reduces the volume of gas bubbles in the circulation. (Ortega et al., 2021)

HBOT promotes wound healing by increasing oxygen gradients at the margins of ischemic lesions and stimulating oxygen-dependent collagen matrix synthesis, which is essential for angiogenesis. In addition, HBOT has been shown to reduce leukocyte adhesion to ischemic tissues, attenuating the release of proteases and reactive oxygen species associated with tissue damage. The therapy also helps preserve ATP production after ischemic episodes and decrease lactate accumulation in affected tissues. (Gill & Bell, 2004).

Hyperbaric oxygen therapy in diabetic foot ulcers treatment

Current guidelines do not recommend the use of HBOT in the treatment of diabetic foot ulcers, unless as part of a clinical trial, (*National Institute for Health and Care Excellence*, 2023) however, there are promising reports suggesting the benefits of adding such therapy to standard treatment. A growing body of clinical evidence supports the use of hyperbaric oxygen therapy (HBOT) as an adjunctive treatment for diabetic foot ulcers (DFUs), particularly in patients with chronic, non-healing wounds that are refractory to standard care. The evidence comes from randomized controlled trials (RCTs), systematic reviews, and meta-analyses evaluating wound healing outcomes and amputation rates. (Kranke et al., 2015; Löndahl, Katzman, Nilsson & Hammarlund 2010; Moreira Da Cruz, Oliveira-Pinto & Mansilha 2022; Sharma, Sharma, Mudgal, Jelly & Thakur 2021; Stoekenbroek et al., 2014; Vahabi et al., 2023; Zhang, Zhang, Xu & Liu 2022; Zhang, Zhou, Jia, Wang & Meng, 2023)

Randomized controlled trials provide basic evidence for the potential benefits of HBOT. The Hyperbaric Oxygen Therapy in Diabetic Foot Ulcers (HODFU) study showed a significantly higher rate of complete ulcer healing in patients receiving additional HBOT therapy compared to the control group. After one year of follow-up, complete healing was observed in 52% of patients treated with HBOT compared to 29% in the group receiving standard care ($p = 0.03$). Importantly, adherence to treatment recommendations influenced outcomes, as patients who completed more than 35 HBOT sessions achieved a cure rate of 61% compared to 27% in the control group, indicating a possible dose-response relationship. (Löndahl et al., 2010)

The results of RCT studies have been confirmed by several meta-analyses synthesizing data from clinical trials. Although a Cochrane systematic review including meta-analyses of selected outcomes demonstrated that adjunctive HBOT significantly improved short-term healing of diabetic foot ulcers, this benefit was not sustained at long-term follow-up, and no statistically significant reduction in major amputation rates was observed. (Kranke et al., 2015) However, the latest meta-analyses show more promising results.

An updated meta-analysis of 20 studies and 1,263 participants showed that HBOT almost doubles the likelihood of ulcer healing compared to standard treatment alone (relative risk [RR] = 1.90; 95% confidence interval [CI], 1.48–2.43; $p < 0.0001$). In addition, HBOT significantly reduced wound healing time by an average of 19.36 days (95% CI, -28.75 to -9.97; $p < 0.001$) and reduced the risk of major amputation (RR = 0.52; 95% CI, 0.32–0.83; $p < 0.01$), however did not reduce the risk of minor amputation. (Zhang et al., 2022)

Another smaller meta-analysis of 14 studies involving 768 patients also confirms these findings, showing improved treatment outcomes and a significant reduction in the number of major amputations among patients undergoing HBOT (RR = 0.60; 95% CI, 0.39–0.92). However, fewer adverse events were reported in the group receiving standard treatment (RR = 1.68; 95% CI 1.07–2.65; I2 = 0%). (Sharma et al., 2021)

A systematic review focusing exclusively on data from randomized trials further confirmed these results, showing a reduced risk of major amputation (odds ratio [OR] = 0.53; 95% CI, 0.32–0.90) and a significantly increased likelihood of complete ulcer healing (OR = 4.00; 95% CI, 1.54–10.44) in the HBOT group. (Moreira et al., 2022)

The differences between the Cochrane review and subsequent meta-analyses likely reflect differences in methodological rigor, heterogeneity of the studies included, and evolving clinical practice. Although short-term therapeutic benefits appear consistent, the extent of long-term efficacy remains uncertain.

Despite these promising results, recent systematic reviews highlight considerable heterogeneity in studies in terms of patient selection, ulcer severity, HBOT protocols, and outcome definitions. Methodological limitations and potential sources of bias limit the certainty of conclusions regarding long-term efficacy. (Kranke et al., 2015; Moreira Da Cruz et al., 2022; Sharma et al., 2021; Stoekenbroek et al., 2014; Zhang et al., 2022) Nevertheless, the overall evidence suggests that HBOT may improve wound healing and reduce the risk of major limb amputation in carefully selected patients with refractory diabetic foot ulcers when used as part of a comprehensive, multidisciplinary wound care program.

Limitations and adverse effects of hyperbaric oxygen therapy

Despite the suggested benefits of hyperbaric oxygen therapy in diabetic foot ulcers, it is important to consider the side effects and limitations of this therapy. In terms of safety, HBOT is generally considered a well-tolerated intervention. Nevertheless, adverse events were observed more frequently in patients receiving additional HBOT than in the group treated with standard therapies alone. The most commonly reported adverse events include ear barotrauma and transient visual disturbances. Serious adverse events such as oxygen-induced seizures or cardiopulmonary complications are rare, but the possibility of their occurrence emphasizes the need for adequate monitoring of the patient during therapy. It should also be noted that serious adverse

reactions seem to occur more frequently in patients with pre-existing medical conditions, such as congestive heart failure. (Zhang et al., 2023) Data from studies involving patients with diabetic foot ulcers indicate that adverse reactions occur in a small number of cases (approximately 6%), are usually mild, and rarely require discontinuation of treatment. The role of educating patients about the early signs of adverse effects and teaching them maneuvers to reduce the risk, such as the Valsalva maneuver, was also emphasized. (Vahabi et al., 2023) A correlation was also observed between the frequency of adverse events and the number of sessions and pressure in the chamber. In the group of patients who underwent more than 10 sessions of HBOT, the frequency of adverse events was higher, as was the case in the group where pressure above 2.0 ATA was used. (Zhang et al., 2023)

In summary, these results highlight the importance of careful patient selection, standardized treatment protocols, and further high-quality studies to better define the safety profile and optimize the benefit-risk ratio of HBOT in this population. (Heyboer et al., 2017; Vahabi et al., 2023; Zhang et al., 2023)

Discussion

Diabetic foot ulcers are a multifactorial complication of diabetes resulting from the interaction of peripheral neuropathy, ischemia, infection, and impaired wound healing mechanisms. Standard treatment strategies such as infection control, surgical debridement, offloading, and appropriate dressings remain the most important part of the management of DFUs. Despite the use of these methods, some ulcers do not heal, highlighting the need for adjunctive therapies to improve tissue oxygenation and accelerate healing.

Hyperbaric oxygen therapy has been proposed as a complementary method due to its ability to increase oxygen delivery to hypoxic tissues and stimulate angiogenesis. This review shows that evidence from randomized controlled trials, such as the HODFU study, supports the beneficial effect of HBOT on ulcer healing rates, particularly in patients with chronic, non-healing ulcers. Furthermore, the observed dose-response relationship suggests that adherence to treatment recommendations and protocol intensity may influence outcomes.

Systematic reviews and meta-analyses provide additional evidence for the effectiveness of HBOT, showing an increase in the percentage of complete ulcer healing and a reduction in the incidence of major amputations. However, these results should be interpreted with caution. The Cochrane review emphasized that the improvement in healing is mainly short-term and may not be sustained over longer periods of time. Evidence for a reduction in the incidence of major amputations also remains inconsistent. Differences in study design, patient populations, ulcer severity, and HBOT protocols likely contribute to these discrepancies.

Safety issues are an important aspect of HBOT use. Although HBOT is generally well tolerated, it is associated with adverse events such as ear barotrauma and transient visual disturbances. Serious complications are rare. Evidence suggests that higher chamber pressures and prolonged treatment cycles may increase the risk of adverse events, highlighting the importance of careful patient selection and standardized treatment protocols.

Overall, differences between earlier systematic reviews and more recent meta-analyses may reflect the evolution of clinical practice, improved patient selection, and methodological differences. The presence of these factors warrants further research focusing on well-defined patient subgroups, standardized outcome measures, and long-term follow-up to better define the role of HBOT in the treatment of DFU.

Conclusions

Hyperbaric oxygen therapy appears to offer potential therapeutic benefits as an adjunct to standard care for patients with chronic, non-healing diabetic foot ulcers. Evidence suggests improved short-term wound healing and a possible reduction in the rate of major amputations in selected populations. However, the long-term efficacy of HBOT remains uncertain due to study heterogeneity and methodological limitations. Currently, HBOT should be considered mostly for carefully selected patients as part of a multidisciplinary treatment approach. Further high-quality randomized controlled trials are needed to establish standard protocols, clarify long-term outcomes, and determine the optimal role of HBOT in the treatment of diabetic foot ulcers.

Disclosure
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Receiving funding: not applicable

All authors have read and agreed with the published version of the manuscript.
Funding Statement: This research has not received any special funding.
Acknowledgements: This research has not received any administrative or technical support.
Conflict of Interest: The authors declare no conflict of interest.

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