Influence Of Hyperbaric Oxygen Therapy On Diabetic Foot Ulcer Treatment

Oxigenoterapia Hiperbárica Na Taxa De Fechamento E Amputação No Contexto De Úlcera Do Pé Diabético

Influencia De La Terapia Con Oxígeno Hiperbárico En El Tratamiento De La Úlcera Del Pie Diabético

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RESUMO

Introdução: A oxigenoterapia hiperbárica é uma modalidade de tratamento muito empregada no tratamento de feridas de difícil cicatrização. Sua utilização, no entanto, é alvo de debate. A úlcera crônica no pé diabético é um contexto muito prevalente e que carrega elevada morbimortalidade. Objetivo: Avaliar a indicação da oxigenoterapia hiperbárica no manejo das úlceras do pé diabético. Método: Foi realizada pesquisa eletrônica nas bases de dado BVS e SciELO com os termos "oxigenoterapia hiperbárica", "pé diabético" e "tratamento" com operador AND. Resultados: Foram selecionados 19 artigos englobando ensaios clínicos randomizados e revisões sistemáticas com metanálises, evidenciando diferentes graus de evidência e resultados heterogêneos para desfechos primários e secundários, especialmente fechamento total de úlcera e taxa de amputação. Conclusão: Concluiu-se que há espaço na oxigenoterapia hiperbárica após ser evidenciada através dos estudos uma redução na área de lesão, redução na taxa de amputações abaixo do joelho, sem alteração de mortalidade.
Descritores: Oxigenoterapia hiperbárica; Pé diabético; Úlcera diabética.

ABSTRACT

Introduction: Hyperbaric oxygen therapy is a widely used treatment modality for difficult-to-heal wounds. However, its use is subject to debate. Chronic diabetic foot ulcers are a highly prevalent condition with high morbidity and mortality. Objective: To evaluate the indications for hyperbaric oxygen therapy in the management of diabetic foot ulcers. Method: An electronic search was conducted in the BVS and SciELO databases using the terms "hyperbaric oxygen therapy," "diabetic foot," and "treatment" with the AND operator. Results: Nineteen articles were selected, including randomized clinical trials and systematic reviews with meta-analyses, showing varying degrees of evidence and heterogeneous results for primary and secondary outcomes, especially total ulcer closure and amputation rate. Conclusion: The authors concluded that there is a potential for hyperbaric oxygen therapy, as studies demonstrated a reduction in the lesion area and the rate of below-knee amputations, without altering mortality.
Descriptors: Hyperbaric Oxygen therapy; diabetic foot; diabetic ulcer.

RESUMEN

Introducción: La oxigenoterapia hiperbárica es una modalidad de tratamiento ampliamente utilizada para heridas de difícil cicatrización. Sin embargo, su uso es objeto de debate. Las úlceras crónicas del pie diabético son una afección de alta prevalencia con alta morbilidad y mortalidad. Objetivo: Evaluar las indicaciones de la oxigenoterapia hiperbárica en el manejo de las úlceras del pie diabético. Método: Se realizó una búsqueda electrónica en las bases de datos BVS y SciELO utilizando los términos "oxigenoterapia hiperbárica", "pie diabético" y "tratamiento" con el operador AND. Resultados: Se seleccionaron diecinueve artículos, incluyendo ensayos clínicos aleatorizados y revisiones sistemáticas con metaanálisis, que mostraron diversos grados de evidencia y resultados heterogéneos para los resultados primarios y secundarios, especialmente el cierre total de la úlcera y la tasa de amputación. Conclusión: Los autores concluyeron que la oxigenoterapia hiperbárica tiene potencial, ya que los estudios demostraron una reducción en el área de la lesión y la tasa de amputaciones infrarrojas, sin afectar la mortalidad.
Descriptores: Oxigenoterapia hiperbárica; pie diabético; úlcera diabética.

REVIEW

Introdução

Diabetic foot (DF) is a complex and difficult-to-manage clinical entity, usually requiring treatment by a multidisciplinary team, guiding the course of the disease through lifestyle, pharmacological, physical activity and stomatherapy approaches, to name a few.[1]

Diabetic foot syndrome is a clinical entity resulting from endothelial dysfunction, which eventually progresses to peripheral vascular insufficiency due to diabetic angiopathy. Diabetic angiopathy, in turn, is a complication of diabetes mellitus and occurs due to the glycosylation of endothelial proteins, leading to a chronic decrease in tissue oxygen concentration.[2]

The clinical complexity of diabetic foot ulcers (DFU) results from a disturbance in the physiological order of the healing phases, namely: hemostasis, inflammatory, proliferative, and the final phase, maturation.[3-7]

The underlying pathophysiology of DF results from a pathological alteration in one or more of the aforementioned phases. Some classic factors that justify this condition are glycemic imbalance, diabetic neuropathy, peripheral vascular disease, and secondary infections. It is noted that among the factors mentioned, all have in common a close relationship with decreased oxygen supply to the appendicular regions of the human body.[2]

Hyperbaric oxygen therapy (HBOT) is an adjunctive treatment for chronic wound healing and is crucial for diabetic foot ulcers refractory to standard clinical measures. HBOT consists of inhaling 100% oxygen under conditions of increased atmospheric pressure, either in *single-* or *multi-place chambers.* Inhaling molecular oxygen in its gaseous form under these conditions allows oxygen to be delivered directly to the blood plasma, which then diffuses into the tissues, promoting the expected therapeutic effect. [4-6]

The debate surrounding HBOT in ulcer diagnostics is highly controversial, especially regarding its indication as a first-line or adjuvant therapy, which, in turn, may or may not be associated with a better outcome. There is considerable variability in national protocols, and much of the research presents divergent and biased protocols. There is also a significant need to expand cost-effectiveness research on HBOT as a treatment. This study therefore aims to assess the current scientific consensus regarding oxygen therapy in the diagnostics of this disease.[5, 7, 8]

Physiology of healing and pathophysiology of the ulcer

Healing is a term that encompasses the outcome of the various phases of the body's response to tissue damage. This process aims to preserve the skin's natural barrier and prevent subsequent infections in the event of a dermal rupture, as is the case with most injuries. Effective healing must go through four phases (hemostasis, inflammatory, proliferative, and maturation) cohesively and without any additional complications (infection, inflammation, hypoxia, to name a few). [1,5,3]

The hemostasis phase is the first and most acute of all phases, depending primarily on platelet aggregation, vasoconstriction, and thrombus formation. Its activation triggers the other phases, with growth factors and inflammatory cytokines, as well as proteins associated with tissue damage. It takes minutes to hours to occur. [5]

The inflammatory phase, in turn, is marked by significant inflammatory activity resulting from proteins that activate the hemostatic phase. It is characterized by massive neutrophil infiltration (phagocytosis of invading germs and necrotic tissue). The arrival of macrophages to the injured area initiates a cascade of immunomodulation, which results in relief of local inflammatory symptoms. This phase lasts from day zero to day five post-injury.[2,5]

After the inflammatory phase, the proliferative phase begins, marked by intense replacement of damaged tissue (especially epidermoid and vascular tissues), stimulated by growth factors released by platelets and macrophages. In this stage, new connective tissue, popularly called "granulation tissue," emerges.[5]

The scar maturation (or remodeling) phase occurs as a continuum from the twenty-first day after injury, with contraction of local myofibroblasts aiming to bring greater architectural cohesion to the injured tissue. It is important to note that all these phases occur in a spectrum phase and may overlap.[5]

Method

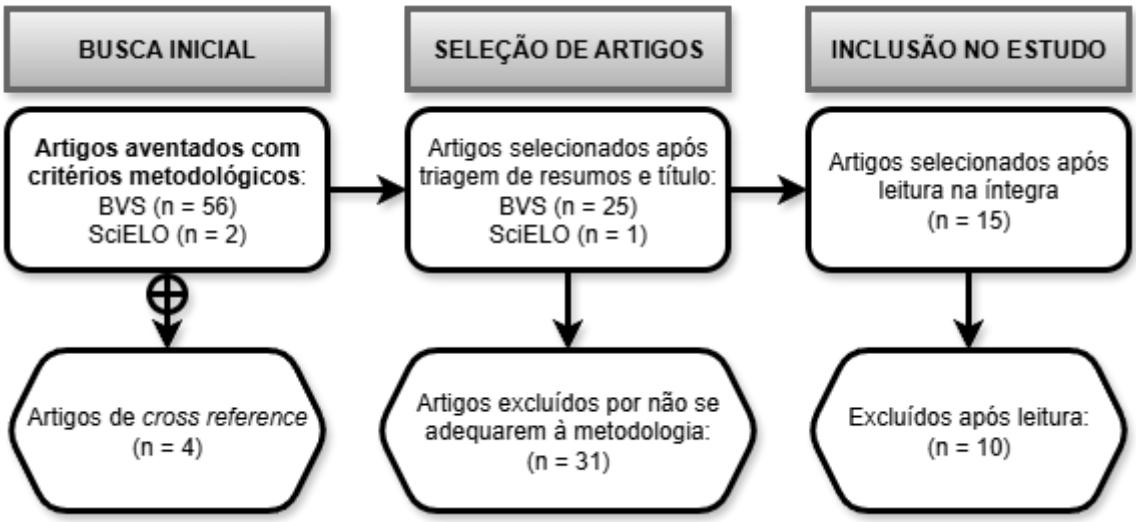
This study is characterized by an integrative review of the literature that seeks to identify the most recent evidence involving the use of hyperbaric oxygen therapy in the treatment of ulcerative complications of diabetic angiopathy, also commonly called diabetic foot in the Brazilian context.

The methodology employed in this study was bibliographic research based on a review of scientific articles, legislation, published academic materials, and online databases. The Scientific Electronic Library Online (SciELO) and the Biblioteca Virtual em Saúde (BVS) databases were used to search for references for this study. The health descriptors "oxigenoterapia hiperbárica", "pé diabético" and "treatment" were used, with the concomitant use of the Boolean operator "AND," defining the time window for results from 2015 to 2025. The types of studies included in the analysis were controlled clinical trials, systematic reviews, and literature reviews.

The first stage of the initial search yielded 56 articles on the BVS platform and 2 on the SciELO platform. The results were initially screened for inclusion or exclusion based on the abstract and the type of study conducted. Studies involving non-human animals, *in vitro studies,* studies that did not encompass the scope and objective of the study, and/or presented results from treatments other than hyperbaric oxygen therapy were excluded.

A total of 31 articles were excluded from analysis due to study designs that did not meet the aforementioned parameters, *in vitro* or non-human animal experiments, duplicate studies among the analyzed databases, and/or studies that did not cover the topic. In cross-reference analysis, especially in search of articles with key concepts for the present analysis, four additional articles were acquired.

Figure 1: Methodological flowchart of encompassed studies



Source: own authors.

Results

This review included 41 studies on the use of HBOT for diabetic foot ulcers, as per the final methodology outlined in **Figure 1.** These studies were read in full and assessed for their fitting with the proposed methodology. Ten studies were excluded at this stage, resulting in a final review of 15 studies: five randomized clinical trials and ten systematic reviews with meta-analysis. Trials were conducted between 2016 and 2025. Systematic reviews with meta-analysis were conducted between 2017 and 2024, as shown in **Table 1.**

Table 1 – Articles used in the integrative review.

AUTHOR (YEAR)	TYPE OF STUDY	DESIGN AND FINDINGS
Mackay *et al.* (2025)	Randomized clinical trial	The study results present theoretical results based on studies of physiology and pathophysiology of diabetic foot ulcers that support HBOT as a potential treatment despite insufficient evidence at the moment.
Chen *et al.* (2024)	Systematic review with meta-analysis	Analysis of 29 randomized clinical trials with outcomes such as time to wound closure and reduced amputation rates compared to control groups. The HBOT group, however, presented a greater number of adverse effects. Finally, there was no reduction in mortality.

Tao *et al.* (2024)	Systematic review with meta-analysis	A study evaluated the outcome of complete closure of diabetic foot ulcers and the amputation rate. The relative risk for closure was 3.59 with $p < 0.001$, with no statistical significance for the amputation rate.
Jiang *et al.* (2018)	Systematic review with meta-analysis	The aim of this study was to assess the consensus regarding the indication of HBOT for DFU. The main finding was that most studies presented low to moderate quality information, highlighting a greater need for further studies in this area.
Zhang *et al.* (2022)	Systematic review with meta-analysis	Twenty randomized clinical trials were selected, evaluating clinical outcomes of wound closure speed and amputation rate. Clinically significant results were presented, with accelerated closure with a risk ratio of 1.901 ($p<0.0001$) and a lower amputation rate compared to the control, with a risk ratio of 0.518 ($p<0.01$).
Wenhui *et al.* (2021)	Systematic review with meta-analysis	Comprising 11 systematic reviews, the study highlighted the success of HBOT for patients with ischemic DFU. It demonstrated a reduction in the amputation rate, but highlighted the need for further robust studies in this area.
Sharma *et al.* (2021)	Systematic review with meta-analysis	Comprising 14 studies totaling 768 patients with complete DFU closure, presenting a statistically significant result with an OR of 0.29. Lower efficacy when compared to smaller DFUs. It did not show a significant reduction in mortality.
Lalieu *et al.* (2020)	Systematic review with meta-analysis	Comprising seven studies, two of which were randomized clinical trials. Two studies showed no significant change in the amputation rate. Five studies showed no reduction in recovery time. In patients without peripheral angiopathy, the efficacy of HBOT in reducing the risk of amputation and improving the cure rate is inconclusive.

Brouwer *et al.* (2020)	Systematic review with meta-analysis	A review of 11 studies, totaling 729 patients, analyzed the primary outcomes of amputation rate, amputation-free survival, complete improvement in DFU, and mortality. The meta-analysis showed a lower amputation rate. Conflicting results were found regarding complete improvement in DFU. There was no statistical significance for mortality rate or amputation-free survival.
Golledge *et al.* (2019)	Systematic review with meta-analysis	Study encompassing 9 randomized clinical trials totaling 585 patients. The intervention group showed a greater chance of complete wound closure (RR 1.95, $p < 0.001$) and a lower need for major or minor amputation (RR 0.54 & RR 0.68).
Salama *et al.* (2019)	Randomized clinical trial	Clinical trial with 30 patients evaluating HBOT *versus* usual care. The HBOT group was exposed to 20 to 40 sessions. The primary outcome was complete closure of the ULN. Secondary outcomes were ulcer improvement rates at 4 and 8 weeks. In the HBOT group, 5/15 patients presented complete closure at 8 weeks, while in the control group, 0/15 ($p < 0.014$).
Zhao *et al.* (2017)	Systematic review with meta-analysis	This study included nine randomized clinical trials with a total of 526 patients. No statistically significant differences were found in the outcomes of DFU healing, major or minor amputation, or adverse effects. A decrease in ulcer area was identified, along with a reduction in the area of ulcer lesions ($p < 0.04$).
Li *et al.* (2017)	Randomized clinical trial	Clinical trial evaluating quality of life outcomes at the end of treatment. The study did not show statistically significant data on patients' self-assessed quality of life at the end of treatment.

Chen *et al.* (2017)	Randomized clinical trial	A randomized clinical trial involving 38 patients divided into groups receiving HBOT with conventional treatment and control groups receiving only conventional treatment. The study observed complete ulcer closure in 25% of the HBOT group, compared with 5.5% of the control group (p = 0.10). The HBOT group showed statistically significant improvements in inflammatory indicators, blood perfusion, and improved quality of life.
Fedorko *et al.* (2016)	Randomized clinical trial	A trial involving 157 patients, divided into groups receiving HBOT and standard treatment, and a control group receiving only standard treatment. The study found statistical insignificance when measuring the primary outcome of amputation rate.

The literature listed reveals a debate within the hyperbaric medicine community regarding the patient profile that will most benefit from this treatment in the management of diabetic foot ulcers. The most frequently assessed outcomes were mortality, complete ulcer closure, lesion area, amputation rate (major or minor), and quality of life. [6,17,18,19]

Profile of the patient who is a candidate for HBOT in the treatment of DFU

A meta-analysis of the global prevalence of diabetic foot ulcers presented the prevalence according to demographics and continental group of the diabetic population. Currently, the prevalence of diabetic foot in the diabetic population is 6.3% (95% CI 5.4-7.3%), with a slight predominance in males, 4.5% (95% CI 3.7-5.2%) when compared to females (3.5%; 95% CI 2.8-4.2%). [4]

There is a higher prevalence of DFU in patients with type 2 diabetes (6.4%) compared to type 1 (5.5%). This finding is due to the greater lack of glycemic control in this population, in addition to the longer duration of subclinical dysglycemia before diagnosis. [3, 4]

Influence of HBOT and complete closure of ulceration

The meta-analyses discussed presented cohesive results regarding the outcomes of complete ulcer closure, showing a positive association between patients undergoing HBOT and early DFU closure compared to control groups. [6,7,9,11,14,15]

In a trial specifically targeting clinical data from the subgroup of patients with non-ischemic DFU, a sample of 30 patients (15 control, 15 HBOT) showed that 33% of patients undergoing treatment achieved complete ulcer closure in 8 weeks under a protocol of 20 to 40 sessions, compared to the usual treatment that did not achieve closure. [15]

The pattern of results is conflicting, but some studies stand out for their greater rigor and data quality, which shed light on HBOT, such as that of Sharma and Zhang, who identified earlier ulcer closure and reduced ulcer recurrence. [9, 11]

Influence of HBO on amputation rate

Amputation, in the context of diabetic foot ulcers, is due to a triad of etiologies, all complications arising from chronic diabetes: neuropathy, peripheral angiopathy, and persistent glycemic dyscontrol. In the context of diabetic foot, it is estimated that 85% of amputations are preceded by a previous clinical context of DFU, highlighting this complication in the individual prognosis. [5]

A study with 729 patients in total identified a reduction in the rate of major amputations (above the ankle) with a risk difference of -15%, but without significant findings for a reduction in the rate of amputations below this anatomical landmark. [13]

Two studies, with 157 and 526 patients, evaluated the amputation rate in patients from a representative group of the diabetic population who presented with this condition. No statistically significant variability was identified for this finding, with the HBOT and placebo groups presenting 20% and 22% amputation rates in both groups at the end of 12 weeks. However, a reduction in the lesion area was identified at the end of the analysis.[14, 15, 16]

Effectiveness of oxygen therapy according to randomized clinical trials

The general limitations of clinical trials were the quantitatively insufficient sample sizes for obtaining better data quality, as well as the lack of representativeness of the populations the studies proposed to analyze. In turn, these limitations make them more vulnerable to bias, especially due to the wide variability of ulcers, which can present with varying degrees of severity and other factors related to peripheral perfusion.[5, 11]

Conclusion

The literature addressed in this study presents great divergence regarding the indication or not of hyperbaric oxygen therapy as a standard treatment in the management of diabetic foot ulcers. However, the pattern of improvement in groups exposed to HBOT, especially regarding earlier closure and lower rate of minor amputations, is notable.

All studies suggest the need for a more robust theoretical framework to better understand the pathophysiological aspects, given the diversity of diabetic foot ulcer presentations, and to better define and recommend this therapy. A constant throughout the literature is the lack of robust studies that can both confirm or deny the true impact of hyperbaric oxygen therapy on treatment and delineate the profile of the patient who will benefit most. Many variables leave something to be desired in obtaining concise results, the main ones being lesion staging according to the Wagner scale, disease duration, and concomitant comorbidities.[12, 19]

However, the reduction in mortality appears to be a consensus among studies, with no significant reduction being reported as the primary outcome. The plethora of

factors involved in the clinical history of diabetic ulcers supports this finding, as HBOT preferentially adopts an adjuvant approach and identifies predictors directly associated with mortality.

Even with so many review studies, the limitation of this study is precisely the need for more qualitative and quantitative research, especially randomized clinical trials with a large sample size, that present consolidated statistical data on the efficacy of this therapeutic modality. The widespread availability of cohesive research protocols in hyperbaric medicine is a motivating factor for research in this area. [8]

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