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Treatment of diabetic foot complications with hyperbaric oxygen therapy: A retrospective experience

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ABSTRACT

Background: The aim of this study is to evaluate the role of hyperbaric oxygen in the treatment of diabetic foot ulcers.
Methods: We performed a retrospective observational study of all patients with diabetic foot ulcers treated at the Institution's hyperbaric chamber between January 2010 and August 2012. Patient data was obtained upon patient hospital visit and prospective clinical record consultation.
Results: Twenty-six foot lesions including 13 foot ulcers Wagner grade 2 or greater and 13 amputation stump ulcers were submitted to hyperbaric oxygen therapy between January 2010 and August 2012 in our Institution. Of these, 23 foot lesions completed treatment and complete epithelialization of the primary lesion was achieved in 15 (65%). The mean healing period since the first hyperbaric oxygen therapy session was 16 weeks. Above-ankle amputations were performed in 3 limbs and transmetatarsal amputations in 2 limbs.
Conclusion: Hyperbaric oxygen may be associated with ulcer healing in selected diabetic foot ulcers with impaired cicatrization.

1. Introduction

Diabetic foot complications are responsible for 18% of all hospital admissions directly related to diabetes mellitus (DM) [1]. Approximately 15% of all diabetic patients will present throughout their lives a foot ulcer [3], with an associated 5-year recurrence frequency of 66–70% [4,5]. Complicated diabetic foot ulcers are responsible for two thirds of all non-traumatic amputations [4]. Contemporary management of diabetic foot ulcers combines aggressive wound debridement, pressure off-loading, infection control and prompt revascularization if indicated.

Hyperbaric oxygen therapy (HBOT) is a systemic adjunctive treatment in which oxygen is breathed at a higher pressure than the local atmospheric pressure [6]. The potential benefits of HBOT include reduction of ulcer hypoxia, increased erythrocyte deformability, edema reduction, angiogenesis, increased fibroblastic activity and antimicrobial effects [7–9]. However, despite reports of increased healing rates and decreased amputation rates [10], adjuvant use of HBOT in diabetic foot problems remains a controversial issue.

Currently, HBOT is approved by the Undersea and Hyperbaric Medical Society as an adjunctive treatment in the field of chronic ulcers [11]. Additionally, the European Committee for Hyperbaric Medicine has also issued a type 2 recommendation for the use of HBOT in the treatment of diabetic foot wounds including patients with ischemic wounds without a surgically treatable arterial lesion or as a complement after vascular surgery, in presence of unhealing wounds [12].

Our center serves a population of approximately 150 000 habitants. It is located in the Azores and the estimated prevalence of DM here is 14.3% which is significantly higher than the mean prevalence in Portugal mainland (11.7% in 2009 which has increased to 12.4% in 2011) [1,2]. Between 2007 and 2009, 58% of all amputations performed in our Institution were due to diabetic foot complications. The year 2009 marked the beginning of our Institution's multidisciplinary diabetic foot consult. In that year, 72 amputations were performed in diabetic patients and of these, 33% were above the ankle, in comparison to a 53% proportion of major amputations in the previous two years.

Our hypothesis was that HBOT may be associated with improvement of diabetic foot ulcer cicatrization.

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2. Materials and methods

We performed a retrospective analysis of all diabetic patients with foot complications treated at the Institution's hyperbaric chamber.

2.1. Patient population

All patients with diabetic foot ulcers or below-the-ankle amputation stump complications treated with HBOT between January 2010 and August 2012 were included. Foot ulcers were classified according to Wagner' classification [13]. Patients who were at least 18 years old, presenting a Grade 2 foot ulcer or greater were eligible for HBOT if ulcer-healing had not occurred over a period of 4 weeks. Patients with at-risk amputation stumps performed due to severe infection or ischemic irreversible trophic lesions were also included if wound healing had not been ensured within the expected period or had been complicated by infection. Patients with significant disability, who were unable to attend to own bodily needs without assistance, unable to walk unassisted, required constant nursing care and attention or were bedridden, were excluded from the study.

2.2. Multidisciplinary diabetic foot consult

Each patient was submitted to a first medical evaluation in the Institution's multidisciplinary diabetic foot consult by a vascular surgeon, a general surgeon and an internist. Vascular assessment included routine pulse palpation and ankle-brachial index determinations. Screening for neuropathy was also routinely performed with a Semmes-Weinstein monofilament (size 5.07).

Patients had wound dressing changes 3–4 times every week and in the office wound debridement was performed whenever necessary. Specimen-cultures were obtained if infection was clinically suspected and antibiotic susceptibility testing guided further treatment. Contact casting and cast boots were tailored to ensure adequate off-loading.

According to Institutional protocol, patients with active ulcers were weekly followed at the multidisciplinary diabetic foot consult where dietetic recommendations and metabolic control were addressed. Preventive foot care measures and hygienic attitudes were also discussed with the patient. Revascularization procedures, off-loading casts and wound debridement were performed upon indication.

Amputations were not postponed due to HBOT treatment, and were performed initially once indication presented.

2.3. Hyperbaric oxygen treatment protocol

Each patient was observed in the hyperbaric medicine consult prior to treatment. Treatment issues were discussed with the patient and written informed consent was obtained once contra-indications were excluded (untreated pneumothorax, acute superior respiratory infection, pulmonary emphysema, previous thoracic surgery, pregnancy, active neoplasm, regular use of doxorubicin, cisplatin, disulfiram or mafenide acetate) [9,10].

Hyperbaric oxygen was administered 5 days a week in a multi-seat hyperbaric chamber (Haux-Starmed 2200). During each session, patients breathed pure oxygen at 2.4 absolute atmospheres (ATA) during 3 periods of 30 min (overall 90 min) intercalated by 5 min intervals, according to a standardized protocol [14]. Any in-chamber adverse reactions were noted. Unless hospitalization was required due to a diabetic foot complication with indication for intravenous antibiotics or amputation, or any other medical comorbidity, HBOT was administered in an ambulatory setting.

2.4. Data management

Patient data was obtained upon patient hospital visit and prospective clinical record consultation. Patient comorbidities such as hypertension, dyslipidemia, chronic obstructive pulmonary disease, smoking habits, retinopathy and surgical procedures (revascularization interventions and amputations) were recorded. Glycosylated hemoglobin was registered if available.

2.5. Definitions

The index ulcer was defined as the ulcer with the largest area if the patient presented multiple foot lesions. Healing was defined as complete coverage of the ulcer by epithelial regeneration with no clinical signs of infection.

Infection was defined by a positive culture obtained from an ulcer aspiration or biopsy in the presence of clinical signs of infection (such as purulent exsudate, hyperemia, aggravated pain or fever).

Severe macroangiopathy was defined as absence of both distal pulses of that limb or by an ankle-brachial index <0.9.

Follow-up time was calculated from the last HBOT treatment session until the most recent recorded observation of the patient in the clinical file.

2.6. Endpoints

The primary study endpoint was complete epithelization and/or scar healing with no residual ulcer or infection. Secondary endpoints were time elapsed until complete healing and freedom from amputation. Additional variables were assessed for association with the primary endpoint.

2.7. Statistical analysis

Categorical variables are presented as count and percentage and were compared using the χ^2 test. Continuous variables are presented as mean, standard deviation, median, interquartile range and range. Differences between groups were analyzed using Mann–Whitney U test for independent samples with non-normal distributions. Outcome variables were assessed by univariate Cox-hazards regression models. Confidence intervals of 95% were used and statistical significance was considered if $P < 0.05$. All statistical analysis was performed using dedicated statistical software (Statistical Package for Social Sciences 21.0, IBM Inc., Chicago, IL, USA).

3. Results

3.1. Patient characteristics before hyperbaric oxygen therapy

Twenty-five patients with 26 foot lesions were submitted to HBOT. One patient presented a contralateral foot ulcer several months after healing a first ulcer and was thus statistically treated as two separate lesions. Two patients dropped-out after 1 and 14 sessions and were excluded from further statistical analysis. One patient with a known history of coronary artery disease, who had previously declined a coronary artery bypass suffered a fatal myocardial infarction after 19 sessions of HBOT and was also excluded.

Of the remaining 23 foot lesions, 11 were diabetic foot ulcers (Wagner 2–4) and 12 were foot amputation stump ulcers. Patient characteristics before HBOT are depicted in Table 1. Most lesions were infected and many lesions were associated with macroangiopathy (Table 2). Of the 11 primary diabetic foot ulcers, 9 (82%) were classified as Wagner grade 3 or 4. Mean follow-up time since the last HBOT treatment session was 10.4 months. Only 13 foot