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Topical hyperbaric oxygen and low energy laser for the treatment of diabetic foot ulcers

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Abstract Fifty patients with chronic diabetic foot ulcers in whom conventional therapy had failed were treated with topical hyperbaric oxygen alone (15 patients) or in combination with a low energy laser (35 patients). Eleven of these patients were treated on an ambulatory basis with topical hyperbaric oxygen. The mean time the ulcer was present before therapy was 9 ± 6.6 months. The mean number of treatments was 25 ± 13, and the mean duration of therapy was 3 ± 1.8 months. Forty-three of the 50 patients were cured. No adverse reactions were noted. Our impression is that topical hyperbaric oxygen alone or in combination with a low power laser are valuable adjuvants to conventional therapy for diabetic foot ulcers.

Introduction

Systemic hyperbaric oxygen therapy has proved to be effective in the treatment of arterial gas embolism, decompression sickness, severe blood loss anemia, and severe carbon monoxide poisoning. Hyperbaric oxygen is also well accepted as an adjunctive therapy for clostridium myonecrosis and for compromised skin grafts and flaps.

The role of systemic hyperbaric oxygen in the treatment of problematic wounds, especially diabetic foot ulcers, is less scientifically established, but many physicians believe that hyperbaric oxygen can be used successfully [10].

Whether topical hyperbaric oxygen has a role in the treatment of leg ulcers remains controversial. Fisher [3] and Ravina et al. [9] have reported favorable results using topical treatment. Leslie et al. [6] in a prospective controlled study reported a lack of efficacy of topical hyperbaric oxygen therapy.

More than three decades ago, the technology of the low energy laser was introduced into clinical medicine, but it has not received enough attention. A low energy laser has a biostimulating effect on cell mitosis [7], keratinocyte motility and proliferation [2], and cytokine production [4]. Animal experimental studies showed an enhancing effect on wound healing [1]. Clinical studies with helium neon (He-Ne) as a source of the laser energy showed a beneficial effect on wound healing [5, 8].

In this study we used topical hyperbaric oxygen alone or combined with a low energy laser for the treatment of patients with chronic diabetic foot ulcers in whom conventional therapy with antibiotics, debridement, and weight reduction had failed.

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Patients and methods

Between May 1995 and May 1996, 50 patients with chronic diabetic foot ulcers were treated in our unit. The patients' characteristics are reproduced in Table 1. There were 28 men and 22 women.

Table 1 Characteristics of patients and effects of treatment for diabetic foot ulcer

Patients	28 men, 22 women
Age (years) mean	59 ± 11
Range	38–88
Diabetes:	
Type 1	14
Type 2	36
Duration of ulcer before beginning of treatment (months)	9 ± 6.6
Range	2–70
Number of treatments	25 ± 13
Range	7–70
Duration of treatment (months)	3 ± 1.8
Range	1–8
Treatment results	
Complete recovery	43
Failure	7

Fig. 1 The polyethylene hyperbaric chamber

The mean age was 59 ± 11 years (range 38–88). The mean time the ulcers were present before the therapy began was 9 ± 6.6 months (range 2–70 months).

All patients were referred to our unit after conventional therapy with systemic antibiotics, debridement, and weight reduction for at least 2 months had failed to cure their ulcers. All patients underwent a physical examination, complete blood count, and biochemistry. The ankle blood pressure was measured, and the ratio (R) of ankle to brachial artery blood pressure was calculated in order to evaluate the vascular supply to the legs. All patients continued to take their medication, and antibiotic treatment was administered according to the sensitivity of the microorganism.

Topical hyperbaric oxygen

The hyperbaric chamber consisted of a disposable polyethylene bag 160 cm long and 60 cm wide. Oxygen in a concentration of 100% was pumped into the bag through a regular car wheel valve. The open end of the bag was sealed by an elastic bandage to the leg above the knee (Fig. 1). Oxygen was allowed to leak around the bandage, and the pressure in the chamber was kept to between 20 and 30 mmHg (1.02–1.03 atm) above atmospheric pressure.

For ambulatory treatment a regular oxygen concentrator (used for patients who suffer from pulmonary disorders) was used as an oxygen source (oxygen concentration 96%).

Low energy laser

For the low energy laser we used Uniluser Scan 60 (Elettronica, Pagany, Italy). The unit had an automatic scanner and provided two sources of laser: He-Ne wavelength 632.8 nm and infrared laser wavelength 904 nm. The power of the He-Ne was 5 mW and that of the infrared laser 60 W. In each treatment 4 J/cm^2 was irradiated to the surface of the ulcer.

Each treatment consisted of 2.5 h of oxygen application and 20 min of concomitant infrared and He-Ne irradiation. These treatments were given 2–3 times a week. Ambulatory hyperbaric oxygen therapy was given 2–3 h daily until a complete cure was effected.

The study was approved by the Helsinki Committee of the Kaplan Hospital and by the Helsinki Committee of the Israel Ministry of Health.

Results

Fifteen patients were treated with topical hyperbaric oxygen alone. There was no significant clinical difference between them and those who were treated with a combination of hyperbaric oxygen and laser. In fact, the decision for treatment with hyperbaric oxygen alone was based on logistic considerations. Eleven of these patients were treated on an ambulatory basis because of lack of space in our unit, and the rest had difficulties in mobilization: status post-cerebrovascular accident and hemiplegia, and after amputation of one limb. All 15 were cured.

Thirty-five patients were treated with a combination of hyperbaric oxygen and a low power laser. The mean number of treatments was 25 ± 13 (range 7–70), and the mean

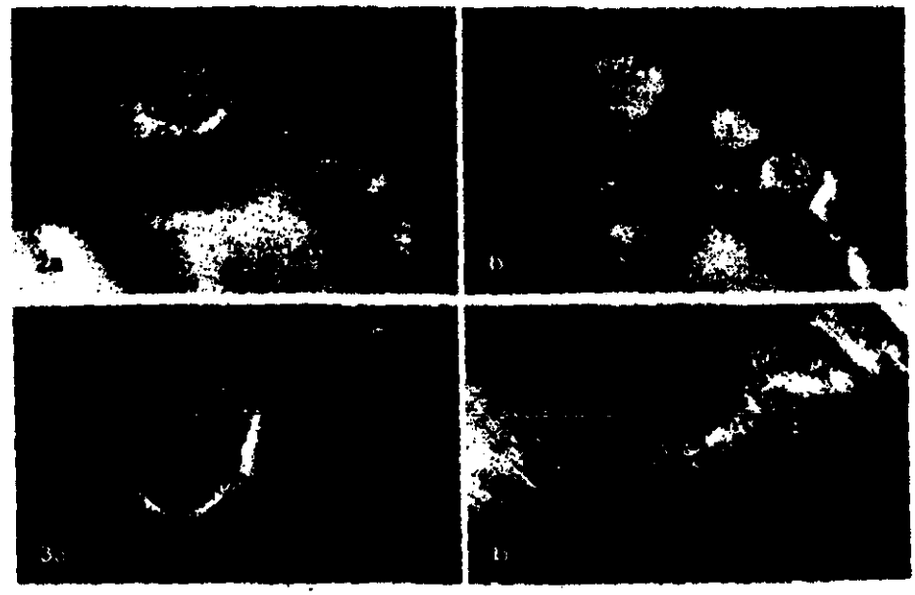

Fig. 2 Diabetic foot ulcer before (a) therapy and 2 months later (b)

Fig. 3 Diabetic foot ulcer before (a) therapy and 7 months later (b)

time until complete healing was 3.1 ± 1.8 months. Figures 2 and 3 show diabetic foot ulcers before and after treatment.

Among the 50 patients with a diabetic foot ulcer, 43 were cured and 7 not. All patients in whom the treatment failed and a limb or finger had to be amputated had severe peripheral vascular disease, ankle pressure below 100 mmHg, and R < 0.4. No recurrence of ulcers was noted during the follow-up of 1 year.

In the group of patients with concomitant laser irradiation, pain reduction and decrease of leg edema appeared faster than in those who did not receive laser therapy.

There were no adverse reactions during and after the therapy either in the hyperbaric oxygen group or in the combination therapy group.

Discussion

In this study two modalities (topical hyperbaric oxygen combined with low power laser, or topical hyperbaric oxygen alone) were used to treat patients with chronic diabetic foot ulcers who had not responded to conventional therapy.

The rationale of treating diabetic foot ulcer with hyperbaric oxygen was to use the lethal effect of the oxygen on the anaerobic bacteria which are part of the flora of diabetic foot ulcers, and as expected, the foul odor of anaerobic bacteria disappeared after a few treatments. Nevertheless, hyperbaric oxygen has more effect than just being antiseptic. It is known that hyperbaric oxygen stimulates fibroblast growth, increases collagen formation, promotes rapid growth of capillaries, and promotes healing in problematic wounds, and through these effects stimulates wound healing.

In most of the patients who received combined treatment, some effects could be attributed to the laser alone: the skin around the ulcer which was irradiated changed in colour to pink, probably due to the vasodilatation in the irradiated skin. Edema and pain ceased more rapidly in patients treated with laser compared to those who had hyperbaric oxygen alone, even though the time until complete cure was not different in the two groups. This fact might be attributed to differences in size, the chronicity of the ulcers, and the variation in the circulation to the legs.

Even though this study is not controlled, it seems that the combination of a low power laser and topical hyperbaric oxygen have additive effects compared with conventional methods. This suggestion is compatible with an observation in four patients who developed an acute new ulcer while on hyperbaric oxygen therapy, in whom immediate laser application cured their lesions very quickly.

The use of polyethylene bags as the hyperbaric chamber has several advantages: they are cheap, disposable, and do not require sterilization. They are flexible and enabled us to treat 2–4 patients sitting on chairs in one room and ambulatory patients.

No adverse reactions to the oxygen or to the lasers were noticed during the study.

In conclusion, topical hyperbaric oxygen combined with a low power laser or topical hyperbaric oxygen alone are attractive modalities which should be considered in the treatment of chronic diabetic foot ulcers.

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