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The Role of Hyperbaric Oxygen Therapy in Ischaemic Diabetic Lower Extremity Ulcers: a Double-blind Randomised-controlled Trial

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Objective: *ischaemic lower-extremity ulcers in the diabetic population are a source of major concern because of the associated high risk of limb-threatening complications. The aim of this study was to evaluate the role of hyperbaric oxygen in the management of these ulcers.*
Method: *eighteen diabetic patients with ischaemic, non-healing lower-extremity ulcers were recruited in a double-blind study. Patients were randomly assigned either to receive 100% oxygen (treatment group) or air (control group), at 2.4 atmospheres of absolute pressure for 90 min daily (total of 30 treatments).*
Results: *healing with complete epithelialisation was achieved in five out of eight ulcers in the treatment group compared to one out of eight ulcers in the control group. The median decrease of the wound areas in the treatment group was 100% and in the control group was 52% ($p = 0.027$). Cost-effectiveness analysis has shown that despite the extra cost involved in using hyperbaric oxygen, there was a potential saving in the total cost of treatment for each patient during the study.*
Conclusion: *hyperbaric oxygen enhanced the healing of ischaemic, non-healing diabetic leg ulcers and may be used as a valuable adjunct to conventional therapy when reconstructive surgery is not possible.*

Key Words: Hyperbaric oxygenation; Peripheral arterial diseases; Wound healing; Diabetes mellitus; Randomised controlled trial.

Introduction

At anytime about 5–7% of the diabetic population are estimated to have a lower-extremity ulcer of varying severity.[1,2] These ulcers are a source of major concern because of the high risk of developing serious limb threatening complications.[3,4] Several well-accepted risk factors predispose diabetic patients to ulceration. The most important include peripheral arterial disease (PAD) and peripheral neuropathy.[5,6] PAD is a major contributing factor in 60% of the lower-extremity ulcers in diabetic patients.[1,7] In these ulcers, bacterial infection is common and wound hypoxia is well documented.[8–10]

Hyperbaric oxygen therapy has been demonstrated to have an antimicrobial effect and to increase oxygenation of the hypoxic wound tissues. This enhances the neutrophil killing ability, stimulates angiogenesis, and enhances fibroblasts activity and collagen synthesis.[11–14]

Despite the seriousness of complications arising from lower-extremity diabetic ulcers, the international medical community has not accepted hyperbaric oxygen therapy as an adjunctive treatment because of the poor quality of reports supporting its use and the relatively high cost of the treatment.[15,16] In view of this we conducted a double-blinded, randomised-controlled study to examine the role of hyperbaric oxygen therapy in the treatment of diabetic lower-extremity ulcers in patients with PAD. The study objective was to determine whether hyperbaric oxygen, as compared to control, could have any therapeutic effect on these ulcers. Secondary objectives included the influence of hyperbaric oxygen on quality of life measures and a limited economic evaluation of its use.

Patients and Methods

Participants

Diabetic patients presenting to Hull Royal Infirmary with ischaemic lower-extremity ulcers were recruited

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