

# Hyperbaric Oxygen in the Management of Chronic Diabetic Foot Ulcers

Andrew J. M. Boulton

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## Trial

Londahl M, Katzman P, Nilsson A, Hammarlund C: Hyperbaric oxygen facilitates healing in chronic foot ulcers in patients with diabetes mellitus. *Diabetes Care* 2010, in press.

## Rating

- Of importance.

## Introduction

Foot lesions remain the most common cause of hospital admissions among diabetic patients in Western countries. The cost of diabetic foot disease in the United States in 2007 was estimated to be a staggering \$30 billion, of which \$19 billion was due to foot ulceration and \$11 billion to amputations [1]. Whereas neuropathy, deformity, and trauma represented the most common triad of component causes in the pathway to foot ulceration until recently [2], a multicenter study from Europe and other similar studies suggest that the combination of neuropathy, ischemia, and trauma now represents the most common pathway to ulceration [3]. Whereas effective therapies proven by randomized controlled trials (RCTs), such as offloading, exist for neuropathic ulcers [2], there are few proven

therapies for ischemic or neuroischemic ulcers. One possible exception is the use of low molecular weight heparin in neuroischemic ulcers, which has been supported by one RCT [4]: results of a larger, ongoing multicenter trial of this therapy are therefore awaited with interest.

Hyperbaric oxygen (HBO) has been promoted as an effective therapy for diabetic foot ulceration and is widely, and sometimes inappropriately, used in the United States [5]. Until recently, HBO has been advocated for diabetic foot wounds based on case series, nonrandomized and few randomized trials, most of which have methodologic flaws. The current study from Sweden is therefore of major interest.

## Aims

To evaluate the effects of HBO in the management of chronic diabetic foot ulcers.

## Methods

A single-center, randomized, double-blinded, placebo-controlled trial in which 88 diabetic patients with foot ulcers of more than 3 months' duration were randomized to HBO ( $n=47$ ), or hyperbaric air ( $n=41$ ), for 85 min a day, 5 days a week for 8 weeks (maximum, 40 treatment sessions).

## Results

In the intention-to-treat analysis, complete healing of the index ulcer was achieved in 37 patients at 1 year's follow-

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A. J. M. Boulton (✉)  
Manchester Diabetes Centre,  
193 Hathersage Road,  
Manchester M13 0JE, UK  
e-mail: ABoulton@med.miami.edu

up in the HBO group (53%) and 12 in the placebo group (29%;  $P=0.03$ ). In a subanalysis of those patients completing more than 35 HBO treatments, the figures were 61% healing on HBO versus 29% on placebo ( $P=0.009$ ). Adverse events were infrequent.

## Conclusions

The authors concluded that as an adjunctive therapy, HBO facilitates the healing of chronic diabetic foot ulcers.

## Comments

HBO has been widely used for diabetic foot ulcers of diverse etiologies over the past two decades, particularly in the United States where it is frequently reimbursed [5, 6]. Promoters of the use of HBO therapy in diabetes state that it has an antimicrobial effect as well as increasing oxygenation in hypoxic foot ulcer tissue [6]. These effects, in turn, enhance neutrophil killing ability, stimulate angiogenesis, and enhance fibroblast activity and collagen synthesis. The “counterpoint” view by Berendt [7] concluded that “it is time that the advocates of HBO for diabetic foot ulcers organized large RCTs with placebo control to provide definitive answers to the question.” Whereas a *Cochrane* systematic review concluded that HBO may improve healing and reduce amputation risk, it also suggested that the results be interpreted with caution because of the small number of studies and patients as well as methodologic and reporting inadequacies [8].

Therefore, the current study provides further evidence from a well-designed trial that HBO may have a place in certain chronic, ischemic foot ulcers, and supports the previous, although smaller study from the United Kingdom that provided similar results in a properly designed trial [9]. It must be emphasized that all patients in the current Swedish study had been assessed by a vascular surgeon who had recommended that further vascular intervention was not indicated. Thus, although HBO may be helpful in

infected, neuroischemic or ischemic ulcers, it is still not indicated for the management of the vast majority of diabetic foot wounds.

As concluded in the accompanying editorial [5], this study puts HBO on firmer ground for diabetic patients with chronic foot ulcers who do not respond to standard therapy and in whom vascular reconstruction is not possible; as well as a need for further trials, firm criteria as to when to consider HBO therapy are now needed.

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