

Topical Hyperbaric Oxygen for Treatment of Diabetic Foot Ulcers

Leslie et al. (1) conclude in their study that the healing of diabetic foot ulcers was not accelerated by topical hyperbaric oxygen (THO). This conclusion is unreasonable.

THO was applied to their patients by a THO leg chamber, in which the pressure cycled every 20 s between 0 and 30 mmHg (1.0 and 1.04 atm absolute pressure). Although this is certainly topical application of oxygen, it is barely hyperbaric. The THO leg chamber involves, in effect, the intermittent application of a 30-mmHg tourniquet, a potentially hazardous procedure in patients with already compromised circulation. In addition, this method will only increase the oxygen tension of the wound surface and not that of the wound base because of the limited diffusion of oxygen through any fluid (diffusion coef = 2.1×10^{-5} cm²/s in water at 37°C calculated from the value at 18°C; 2). This study contrasts with another recently reported in *Diabetes Care* (3), in which hyperbaric oxygen was applied systemically and a highly significant benefit was demonstrated for gangrenous ulcers in diabetic patients.

The major finding of Leslie et al. (1) was that "small and superficial ulcers tended to heal proportionally better than the more extensive ones." They showed that the effect of either increasing ulcer area or depth on the outcome of the ulcers was significant ($P < .05$). Although patients were randomly assigned to the THO and control groups, remarkably there was no apparent effort to establish that the two groups were comparable with respect to original ulcer size. From Table 5 in ref. 1, the THO patients appear to have had ulcers that were originally larger and deeper than those in the control patients. By our calculations, the difference in area was not significant because of the very large standard deviation, but the original ulcers were significantly deeper in the THO group ($P < .025$). It follows that, despite the random assignment of patients, the two groups were not comparable; therefore, the conclusion that THO did not affect outcome has not been established.

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Reply

We thank Dr. Gorman and his colleagues for comments regarding our recent article on the utilization of topical hyperbaric oxygen (THO) for the treatment of diabetic foot ulcers (1). As they point out, topically administered oxygen may not diffuse well into the foot ulcer's base, and if excessive pressures are applied, the leg chamber could cause a tourniquet effect. To circumvent these theoretical concerns, we decided to use the same range of THO pressures that were identified as being harmless and beneficial in previous studies by others (2,3). In our randomly controlled study, THO did not accelerate healing of diabetic foot ulcers.

Dr. Gorman et al. incorrectly assert that, despite the random assignment of patients, our two study groups were not comparable because "the original ulcers were significantly deeper in the THO group ($P > .025$)" (1). On the contrary, as we were careful to emphasize in our report, the original mean ulcer area and depth were somewhat greater in the THO group than in the control group, but such differences were not statistically significant ($P > .05$ for both dimensions).

Finally, we do not have sufficient experience with the use of systemic hyperbaric oxygen in the treatment of diabetic gangrene as reported by Baroni et al. (4); therefore, we cannot comment in regard to its value. Nonetheless, note that, to date, there have been no prospective randomized studies demonstrating the effectiveness of this modality in the treatment of diabetic foot infections. This subject deserves further investigation.

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Hypertension and Nephropathy in the Diabetic Patient

This symposium was presented in conjunction with the American Diabetes Association's 35th Postgraduate Course, 12 January 1988, Palm Desert, California.

Funding for this symposium was provided by an educational grant from E.R. Squibb & Sons, Inc.