COMMENTS AND RESPONSES

Comment on: Margolis et al. Lack of Effectiveness of Hyperbaric Oxygen Therapy for the Treatment of Diabetic Foot Ulcer and the Prevention of Amputation: A Cohort Study. Diabetes Care 2013;36:1961–1966

I read with interest and some disbelief the article by Margolis et al. (1), who conclude that "the usefulness of [hyperbaric oxygen (HBO)] in the treatment of diabetic foot ulcers needs to be reevaluated." Statistical manipulation cannot change the big problem with the study design. Propensity score matching is a technique to be used in situations with substantial overlap between treatment and control groups to account for observed covariates. Factors that affect assignment to treatment but that cannot be observed (e.g., financial gain, clinician preference, lack of vascular surgical input, etc.) cannot be accounted for. It has been argued that this technique may increase hidden bias because matching on observed variables may unleash bias due to hidden unobserved confounders.

Most hyperbaric oxygen therapy (HBOT) facilities first use transcutaneous oxygen measurement to identify those patients with a confirmed hypoxic wound that responds to 100% oxygen at normobaric pressure or failing that, at 2.0–2.4 ATA. If there is no demonstrated oxygen delivery to the site, they need consideration of revascularization not HBOT. The authors simply state they were clinically assessed to determine adequate arterial flow. Since the results come from 83 different private wound facilities (perhaps using different tools, e.g., transcutaneous oxygen measurement, ankle/brachial index, skin color, Doppler, etc.) selection bias cannot be excluded.

Their data show that because of the lack of randomization the HBOT group had the greater number of those with the worst graded ulcers. Only 18.4% of the non-HBOT group had Wagner grade 3 or above compared with 45.7% of the HBOT group. Statistical manipulation cannot change this disproportionate number between groups.

An economic analysis performed by Hailey and colleagues (2) in diabetic patients who received standard wound care versus standard wound care plus HBOT found that "adjunctive HBOT... is cost-effective compared with standard care." Faglia et al. (3) showed in their randomized controlled study a threefold increase in limb amputation rate in the control group compared with the HBOT group.

The authors also comment on the median number of treatments given to the HBOT group. This does not allow a calculation of the percentage of patients who actually received therapeutic HBOT as reported in most studies looking at HBOT effectiveness (i.e., at least 30–40 treatments). From their data, it would appear that at least 25% (but probably more) did not get what would be considered a therapeutic course of treatment. This would effectively render the statement, "to date this is the largest study of HBO" untrue because most did not receive HBOT, and of those who did, many did not receive therapeutic HBOT (potentially 25% of the 12.7% in that group, i.e., at least 200 patients did not receive therapeutic HBOT who were in the HBOT group).

Finally, smoking status was not listed in the basic characteristics table. Smoking is another important variable that may influence outcomes, especially in this group of patients in which amputation rates were an important outcome.

SUSANNAH SHERLOCK, BSC, MBBS, FANZCA

From the Department Anaesthesia and Hyperbaric Medicine, Royal Brisbane and Women's Hospital, Brisbane, Australia.

Corresponding author: Susannah Sherlock, susannah_sherlock@health.qld.gov.au.

DOI: 10.2337/dc13-0607

Acknowledgments—No potential conflicts of interest relevant to this article were reported.

References

1. Margolis DJ, Gupta J, Hoffstad O, et al. Lack of effectiveness of hyperbaric oxygen therapy for the treatment of diabetic foot ulcer and the prevention of amputation: a cohort study. Diabetes Care 2013;36:1961–1966
2. Chuck AW, Hailey D, Jacobs P, Perry DC. Cost-effectiveness and budget impact of hyperbaric oxygen therapy for diabetic foot ulcers. Int J Technol Assess Health Care 2008;24:178–183
3. Faglia E, Favales F, Aldeghi A, et al. Adjunctive systemic hyperbaric oxygen therapy in treatment of severe prevalently ischemic diabetic foot ulcer: a randomized study. Diabetes Care 1996;19:1338–1343