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Control groups in hyperbaric trials

Dear Editor,

I read with interest Dr Bennett's excellent recent appraisal of the study by Londahl and colleagues.[1–4] However, there are some concerns with respect to the trial design that I would like to highlight. Londahl et al's study on the addition of hyperbaric oxygen to specialised wound care for chronic diabetic foot ulcers uses a questionable "sham" treatment method, which has been employed by the same research team previously.[5] The paper by Londahl et al was also included in the recently updated Cochrane review of hyperbaric oxygen therapy for chronic wounds and appraised as having a low risk of bias, exclusively owing to the inclusion of a control group.[6]

What has not been commented on is whether their choice of control (sham) was appropriate. Londahl et al compared the effect of hyperbaric oxygen at 254 kPa in patients with diabetic foot ulcers with a sham group where patients breathed air at 254 kPa. In real terms, therefore, sham was equivalent to breathing 50% O_2 under normobaric conditions, which is not a true control. It could be argued that breathing 100% O_2 at normobaric pressure may have produced the same differences between the two groups. To better discern the effects of hyperbaric oxygen at 254 kPa a better control group would have been air at 1.0 ATA. Such an approach would confirm beyond doubt that the wound-healing effects are entirely attributable to hyperbaric oxygen.

There is also lack of discussion regarding the possible risk of decompression illness (DCI) in the control group since they are exposed to 90 mins of air at 254 kPa. This also raises ethical issues as the 'control' group is being exposed to a risk that the experimental group is not subject to. There were no reports of any adverse effects in the control arm, but the study only analysed 90 patients and the relative risk may be low, but still real. Conducting research in hyperbaric medicine is very difficult because of the problems of delivering sham treatments and Londahl and colleagues have improved substantially on previous published studies. For instance, the study by Annane et al gave hypoxic gas mixtures under pressure to their control group to ensure they received the same oxygen dose equivalent to a patient breathing air at normobaric pressure.[7] This was confirmed by blood gas analysis and the control group was therefore not only exposed to a potentially lethal gas mixture if pressurisation failed, but also the dual risks of arterial puncture and decompression sickness.

In order to undertake well-designed RCTs in hyperbaric medicine there has to be careful thought given to the appropriate control treatment group/sham, which should carry with it a negligible risk. Hyperbaric research needs to be promoted internationally and intervention trials should be designed with high methodological rigour. I disagree with Dr Bennett's assertion that this trial satisfied that principle.

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