April 11, 2013

Dear UHMS Members,

The recent article by Margolis et al that reports the failure of hyperbaric oxygen in the treatment of diabetic foot ulcers has created major concerns by the hyperbaric community. This article is one of many published on this topic and other articles including several randomized controlled trials have previously shown a benefit for hyperbaric oxygen in achieving healing and preventing amputation.

I have read the Margolis article several times and believe that there are several serious criticisms that can be leveled at the article. First of all, it was not a randomized controlled study. Statistical techniques were applied to the results to compensate for the design not being randomized and controlled, but certainly still fall short of this standard. The study failed to use transcutaneous O2 measurements in the selection process of patients. Many have previously shown the importance of baseline TCPO2 measurements and response to an oxygen challenge for selecting patients appropriate for HBO2 intervention. The authors state that patients were determined to not be ischemic by their treating physicians. No methodology is described and certainly no consistent studies were applied. Certainly, ankle-brachial indices would be appropriate in most patients and even angiographic studies in some. A careful read also shows that one half of the patients received fewer than 29 treatments. Finally, the groups were mismatched in terms of their Wagners scores with the hyperbaric group including 45.7% and the non-HBO group containing only 18.4% of wounds with Wagners grade of 3 or more,

It is important that readers of the hyperbaric literature are equally critical in reading both negative and positive reports. It is also important that clinicians in hyperbaric oxygen carefully select patients likely to respond to treatment by applying selection criteria that have been shown to predict for a successful course of treatment.

A positive study for HBO2 in diabetic foot ulcers consisting of a systematic review was just published in the Mayo Clinic Proceedings. The authors conclude that “quality of life could be improved in selected patients with HBO.” This study consisted of a meta-analysis of 624 patients.

Our Authorization, Utilization, Quality and Reimbursement Committee is preparing a comprehensive review to be posted on the website readily available to our members. Dr. Enoch Huang will be presenting a review of this topic for the UHMS annual scientific meeting in June in Orlando.
Finally, I urge all our member experts to forward letters to the editor of Diabetes Care pointing out these deficiencies and any others detected after a careful and critical review of the paper.

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References:
