

Effects of hyperbaric oxygen on postconcussion symptoms in military members

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A clinical trial testing hyperbaric oxygen (HBO) treatment on persistent postconcussion symptoms (PCS) in U.S. military service members showed no benefits over a sham procedure in an air-filled chamber, but symptoms did improve in both the HBO and sham treatment groups compared with a group of patients who received no supplemental air chamber treatment, according to a report published online by *JAMA Internal Medicine*.

Most service members who sustain mild <u>traumatic brain injury</u> (mTBI) fully recover within 30 days but some <u>patients</u> report chronic <u>symptoms</u>, which can include headaches, balance issues, sleep disturbance, forgetfulness and irritability. Some anecdotal evidence suggests HBO treatment can improve PCS. Those anecdotes prompted the Department of Defense and the Department Veterans Affairs to create a clinical research program to evaluate the efficacy and safety of HBO in a series of randomized, sham-control trials.

Researcher R. Scott Miller, M.D., of the Uniformed Services University of the Health Sciences, Bethesda, Md., and colleagues report on the outcomes from one of these preliminary clinical trials. The Hyperbaric Oxygen Therapy for Persistent Postconcussive Symptoms after Mild Traumatic Brain Injury (HOPPS) trial was designed for three groups of patients: patients who received routine PCS care in the Department of Defense, patients with routine PCS care supplemented with HBO for 60



minutes for 40 sessions, and patients who received routine PCS supplemented with 40 otherwise identical sham sessions in an air-filled chamber at a level that masked the pressurization process. Scores on a postconcussion symptoms questionnaire were the primary outcome measure.

The study included 72 military service members at military hospitals in Colorado, North Carolina, California and Georgia. The routine care group had 23 patients, while 24 patients were enrolled in the HBO group and 25 in the sham group. The median age of patients was 31 years old, 96 percent of the patients were male and they had, on average, sustained three lifetime mTBIs.

Findings indicate that no differences were seen between groups for improvement of at least two points (the definition of clinically significant) on part of the symptoms scale (25 percent in the routine care/no intervention group met the prespecified 2-point change as did 52 percent in the HBO group and 33 percent in the sham group). However, compared with the no intervention group (average change score, 0.05), both groups with supplemental chamber procedures showed improved symptoms on a total score (average change score, 5.4 in the HBO group and 7.0 in the sham group). No difference between the HBO group and the sham group was seen. All the chamber sessions were well tolerated.

"Among service members with PCS, HBO showed no benefits over an air sham compression procedure, but symptoms in both groups improved compared with mTBI care without supplemental chamber interventions. This outcome suggests that the observed improvements were not oxygen mediated but may reflect nonspecific improvements related to placebo effects. Taken with results from other concurrent investigations, our study does not support phase 3 trials of HBO for the treatment of PCS at this time," the study concludes.



In a related commentary, Charles W. Hoge, M.D., of the Walter Reed Army Institute of Research, Silver Spring, Md., and Wayne B. Jonas, M.D., of the Samueli Institute, Alexandria, Va., write: "Although this trial was technically a pilot investigation designed to produce data necessary for a pivotal study and will not likely end debate on this topic (given tenacious advocacy by HBO proponents), these results are consistent with two other sham-controlled clinical trials among service members and veterans involving a range of HBO doses. Given the outstanding methods, consistency in results, and lack of dose response across these studies, it is increasingly hard to argue that a phase 3 trial of HBO for the treatment of postconcussion symptoms (or PTSD) is warranted."

"This conclusion is disappointing for service members and veterans experiencing war-related symptoms but offers important lessons and an opportunity to engage in renewed dialogue concerning the priorities for future interventions. This dialogue requires us to begin by acknowledging that no new treatments for persistent blast or impact-related postconcussion symptoms have been identified, despite the extensive investment to date," they note.

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