SUBJECT: Hyperbaric Oxygen for Mild Traumatic Brain Injury (mTBI)

Hyperbaric oxygen therapy (HBO₂) involves implementing an artificial environment where the percentage and pressure of oxygen are raised above that of the normal atmosphere. This condition increases the concentration of oxygen in the blood and bodily tissues to supraphysiological levels. As a treatment for injury and disease, HBO₂ may initiate protective and regenerative processes that prevent further damage and enhance repair mechanisms at the cellular level. For example, HBO₂ may benefit the healing process in cases where ischemia or hypoxia drives disease progression. Currently, HBO₂ treatment is approved by the Food and Drug Administration (FDA) for a number of conditions, including decompression sickness, carbon monoxide poisoning, gas gangrene, thermal burns, and crushing injuries.

Hyperbaric oxygen therapy has also been proposed as an alternative therapy for traumatic brain injury (TBI). It’s been hypothesized that HBO₂ mitigates neurological damage (edema, hypoxia, and ischemia) by ensuring a surplus of oxygen for reparative mechanisms. A recent meta-analysis of HBO₂ randomized controlled trials on TBI patients of all severities concluded that HBO₂ may reduce the risk of death and improve the level of consciousness in TBI patients. However, there is no evidence that HBO₂ improves their quality of life. The FDA issued a statement in 2013 admonishing that HBO₂ treatment has not been proven clinically effective for treating TBI. Additionally, professional organizations such as the American Academy of Neurology, the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and the Brain Trauma Foundation, do not consider HBO₂ as a candidate therapy for TBI.

Some clinical studies have demonstrated the effectiveness of HBO₂ therapy for reducing post-concussion symptoms months to years after mild TBI. The results of these studies must be interpreted with caution. The lack of subject randomization, treatment group blinding, and control groups weaken their scientific rigor and potentially allow experimenter and selection bias. Recent randomized controlled trials on mild TBI patients provide no evidence that HBO₂ treatment ameliorates post-concussion symptoms compared to shams, either immediately or three months post-intervention. Complicating the interpretation of these findings is the possibility of a placebo effect. Placebo effects involve intense or invasive drugs/interventions/devices, such as HBO₂ treatment, that induce a benefit because patients believe they are effective. Factors that can affect the ability to detect an interventional effect over placebo in randomized controlled trials include spontaneous improvement of symptoms; fluctuation of symptoms in chronic patients; and improvement in patient outcomes due to expectation,
conditioning, and/or the psychosocial context of treatment (i.e., clinician-patient interactions).

The Department of Defense contracted the Samueli Institute to conduct a rigorous, transparent, high quality systematic review of the HBO₂ literature. The goal was to determine the current state of the science on the efficacy of HBO₂ as a treatment for TBI (with an emphasis on the level of evidence for mild TBI). As part of this effort, a steering committee composed of a diverse group of subject matter experts provided high level scientific oversight and guidance for the literature review. The Samueli Institute completed their analysis in March 2015. The review concludes that HBO₂ is no better than shams as a treatment for TBI. It acknowledges that HBO₂ does improve some symptoms, but this may be due to a placebo effect. Accordingly it does not recommend HBO₂ as a treatment. Finally, the review comments there are many unknowns in the literature. If HBO₂ has any utility as a therapy, placebo or not, further research is necessary to understand how variables like percent oxygen, pressure, and duration interact with disease state to affect clinical outcomes.

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