DEPARTMENT OF THE ARMY
DEFENSE CENTERS OF EXCELLENCE
FOR PSYCHOLOGICAL HEALTH AND TRAUMATIC BRAIN INJURY
2345 CRYSTAL DRIVE, CRYSTAL PARK 4, SUITE 120
ARLINGTON VA 22202

INFORMATION PAPER

MCMR-DCV-ADR
12 June 2015

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

Hyperbaric oxygen therapy (HBO_2) 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, HBO_2 may initiate protective and regenerative processes that prevent further damage and enhance repair mechanisms at the cellular level. For example, HBO_2 may benefit the healing process in cases where ischemia or hypoxia drives disease progression. Currently, HBO_2 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 HBO_2 mitigates neurological damage (edema, hypoxia, and ischemia) by ensuring a surplus of oxygen for reparative mechanisms. A recent meta-analysis of HBO_2 randomized controlled trials on TBI patients of all severities concluded that HBO_2 may reduce the risk of death and improve the level of consciousness in TBI patients. However, there is no evidence that HBO_2 improves their quality of life. The FDA issued a statement in 2013 admonishing that HBO_2 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 HBO_2 as a candidate therapy for TBI.

Some clinical studies have demonstrated the effectiveness of HBO_2 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 HBO_2 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 HBO_2 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 HBO_2 literature. The goal was to determine the current state of the science on the efficacy of HBO_2 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 HBO_2 is no better than shams as a treatment for TBI. It acknowledges that HBO_2 does improve some symptoms, but this may be due to a placebo effect. Accordingly it does not recommend HBO_2 as a treatment. Finally, the review comments there are many unknowns in the literature. If HBO_2 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.

Dr. Felicia Qashu / MCMR-DCV-ADR | 301-295-2717
Felicia.m.qashu.civ@mail.mil

APPROVED BY: COL Sidney Hinds| DVBIC National Director