Efficacy of Hyperbaric Oxygen Therapy for PTSD and TBI

One of the principal researchers behind HBOT is Dr. Paul Harch, a Louisiana-based medical researcher who began looking into HBOT as a way to treat both PTSD and traumatic brain injuries (TBI) in veterans. In 2007, Harch conducted one of the first serious experiments involving HBOT, testing the procedure on lab rats. His findings were encouraging. A 40-day series of 80 low-pressure HBOTs <u>caused</u> "an increase in contused hippocampus vascular density and an associated improvement in cognitive function." In other words, the rats could think better. In a <u>subsequent three-year study</u> on veterans, Harch discovered the therapy was successful on humans as well. According to the study, the therapy <u>helped the vast majority of the soldiers cope</u> with headaches, sleep disruption and mood swings. It also boosted their IQ and blood flow in the <u>brain</u>, and reduced PTSD symptoms and suicidal thoughts. Though the FDA <u>has not yet approved</u> HBOT, the new option does offer a bit of hope for soldiers suffering from PTSD and TBI.

"Literally, during the first two hyperbaric oxygen therapy treatments, I found parts of my brain waking up and the fogginess becoming less intrusive," <u>said Edward Lucarini</u>, a veteran who suffered a traumatic brain injury in Iraq in April 2003 when an ammunition bunker exploded nearby. "By the time I finished 80 treatments, I had rediscovered the ability to enjoy reading a book again for the first time in five years! Writing this simple statement would have taken me three or four hours before treatment, but now a matter of 15 minutes. (excerpt taken from Vocativ Online:The New Frontier of PTSD Treatments: Hyperbaric Oxygen Therapy)

A few Study abstracts for your review

A Phase I Study of Low-Pressure Hyperbaric Oxygen Therapy for Blast-Induced Post-Concussion Syndrome and Post-Traumatic Stress Disorder

Paul G. Harch, Susan R. Andrews, Edward F. Fogarty, Daniel Amen, John C. Pezzullo, Juliette Lucarini, Claire Aubrey, Derek V. Taylor, Paul K. Staab, and Keith W. Van Meter. Journal of Neurotrauma. January 1, 2012, 29(1): 168-185. doi:10.1089/neu.2011.1895.

This is a preliminary report on the safety and efficacy of 1.5 ATA hyperbaric oxygen therapy (HBOT) in military subjects with chronic blast-induced mild to moderate traumatic brain injury (TBI)/post-concussion syndrome (PCS) and post-traumatic stress disorder (PTSD). Sixteen military subjects received 40 1.5 ATA/60 min HBOT sessions in 30 days. Symptoms, physical and neurological exams, SPECT brain imaging, and neuropsychological and psychological testing were completed before and within 1 week after treatment. Subjects experienced reversible middle ear barotrauma (5), transient deterioration in symptoms (4), and reversible bronchospasm (1); one subject withdrew. Post-treatment testing demonstrated significant improvement in: symptoms, neurological exam, full-scale IQ (+14.8 points; p<0.001), WMS IV Delayed Memory (p=0.026), WMS-IV Working Memory (p=0.003), Stroop Test (p<0.001), TOVA Impulsivity (p=0.041), TOVA Variability (p=0.045), Grooved Pegboard (p=0.028), PCS symptoms (Rivermead PCSQ: p=0.0002), PTSD symptoms (PCL-M: p<0.001), depression (PHQ-9: p < 0.001), anxiety (GAD-7: p = 0.007), quality of life (MPQoL: p = 0.003), and self-report of percent of normal (p < 0.001). SPECT coefficient of variation in all white matter and some gray matter ROIs after the first HBOT, and in half of white matter ROIs after 40 HBOT sessions, and SPECT statistical parametric mapping analysis (diffuse improvements in regional cerebral blood

flow after 1 and 40 HBOT sessions). <u>Forty 1.5 ATA HBOT sessions in 1 month was safe in a military cohort with chronic blast-induced PCS and PTSD. Significant improvements occurred in symptoms, abnormal physical exam findings, cognitive testing, and quality-of-life measurements, with concomitant significant improvements in SPECT.</u>

Hyperbaric Oxygen Therapy Treatment of Chronic Mild-Moderate Blast-Induced Traumatic Brain Injury/Post Concussion Syndrome with Post Traumatic Stress Disorder: Pilot Trial

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Objectives

Mild-moderate blast-induced traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) affect 11-28% and 13-17%, respectively, of U.S. combat troops returning from Iraq and Afghanistan. Protracted treatment for PTSD exists, but there is no effective treatment for the post-concussion syndrome (PCS) of mild-moderate TBI nor the combined diagnoses of PCS and PTSD. Based on previous case experience with PCS and an animal model we investigated the effect of hyperbaric oxygen therapy (HBOT 1.5) on symptoms, cognition, and SPECT brain blood flow in military veterans with blast-induced TBI/PCS with/without PTSD.

Method

Fifteen symptomatic U.S. military veterans with blast-induced PCS(2) or PCS/PTSD(13), diagnosed by military and/or civilian neuropsychologists and neurologists, who were average: 29.7y (21-45), 2.6y (1.24-4.75) post injury, 1 minute (13 subjects; 2 subjects 4.5 & 9h) loss of consciousness, with 3 blast TBI's (1-8) completed the study. All subjects completed cognitive testing, symptom and quality of life questionnaires, and affective measures pre and immediately post a course of forty bid, 5d/week, 1.5ATA/60 minute hyperbaric oxygen therapy treatments (HBOT). Subjects underwent SPECT brain blood flow imaging (Picker Prism 3000, 25mCi Ethyl Cysteinate Dimer) pre and post a single HBOT and post 40 HBOT's. SPECT was analyzed with Osirix software; relative standard deviation of the mean on a histogram analysis of counts in left centrum semiovale region of interest was taken pre/post Rx. Paired Student t test and Wilcoxon Signed-Ranks test (non-normally distributed data) were used for all cognitive/questionnaires.

Results

All subjects reported symptomatic improvement in the 35 day study period. Pre, post, difference, confidence interval, and p values for cognitive tests and questionnaires were: FSIQ: 95.8+/-8.4; 110.6+/-10.3, 14.8+/-7.4, 10.7-18.9, <0.001; Wechsler Memory Scale (WMS) IV delayed memory: 97.7+/-13.3, 106.9+/-15.4, 9.2+/-14.3, 1.3-17.1, =0.026; WMS Working Memory: 97.0+/-13.6, 106.9+/-13.1, 9.9+/-10.3, 4.1-15.6, =0.003(np); Stroop Color/Word: 84.3+/-12.2, 95.3+/-12.8, 11.1+/-9.2, 6.0-16.2, <0.001; TOVA variability: 64.4+/-28.7, 75.3+/-24.6, 10.9+/-20.2, -0.2-22.1, =0.045(np); Rivermead Post Concussion Symptom Questionnaire: 39.7+/-6.0,

24.1+/-12.6, -15.6+/-12.8, -22.7-(-8.5), =0.002(np); PTSD Checklist Military: 67.4+/-10.5, 47.1+/-16.0, -20.3+/-18.2, -30.4-(-10.2), <0.001; Modified Perceived Quality of Life: 81+/-37, 114+/-36, 33+/-36, 13-53, =0.003; Personal Health Questionnaire 9-Depression Index: 16.6+/-4.9, 8.2+/-4.7, -8.4+/-7.4, -12.5-(-4.3), <0.001; GAD-7 Anxiety Rating: 12.7+/-5.8, 7.9+/-5.3, -4.8+/-5.8, -8.0-(-1.6), =0.007; Percent Back to Normal: [Cognitive: 49.6+/-17.6, 67.0+/-19.4, 17.4+/-17, 7.5-27.2, =0.002], [Physical: 46.8+/-23.0, 66.3+/-18.6, 19.5+/-16, 10.3-28.7, <0.001], [Emotional: 32.5+/-20.6, 61.3+/-19.8, 28.8+/-20.9, 16.7-40.9, <0.001]. SPECT analysis on the first 5 subjects showed a reduction in the standard deviation of the mean on counts in the left centrum which corresponded to a pattern shift from heterogeneity (abnormal) to homogeneity (more normal).

Conclusions

A thirty-day course of forty 1.5 ATA HBOT's demonstrated significant symptomatic, cognitive, and affective improvements in 15 U.S. military veterans with chronic blast-induced post-concussion syndrome and post-traumatic stress disorder. These findings were reinforced by quantitative and qualitative SPECT improvements.

Problem With the Wolf Study-which is being used to show that HBOT doesn't work

The Effect of Hyperbaric Oxygen on Symptoms after Mild Traumatic Brain Injury

George Wolf, David Cifu, Laura Baugh, William Carne, and Leonardo Profenna. Journal of Neurotrauma. November 20, 2012, 29(17): 2606-2612. doi:10.1089/neu.2012.2549.

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In this single-center, double-blind, randomized, sham-controlled, prospective trial at the U.S. Air Force School of Aerospace Medicine, the effects of 2.4 atmospheres absolute (ATA) hyperbaric oxygen (HBO₂) on post-concussion symptoms in 50 military service members with at least one combat-related, mild traumatic brain injury were examined. Each subject received 30 sessions of either a sham compression (room air at 1.3 ATA) or HBO 2 treatments at 2.4 ATA over an 8-week period. Individual and total symptoms scores on Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT[®]) and composite scores on Post-traumatic Disorder Check List-Military Version (PCL-M) were measured just prior to intervention and 6 weeks after completion of intervention. Difference testing of post-intervention means between the sham-control and HBO₂ group revealed no significant differences on the PCL-M composite score (t=-0.205, p=0.84) or on the ImPACT total score (t=-0.943, p=0.35), demonstrating no significant effect for HBO₂ at 2.4 ATA. PCL-M composite scores and ImPACT total scores for sham-control and HBO₂ groups revealed significant improvement over the course of the study for both the sham-control group (t=3.76, p=0.001) and the HBO₂ group (t=3.90, p=0.001), demonstrating no significant HBO₂ effect. Paired t-test results revealed 10 ImPACT scale scores in the sham-control group improved from pre- to post-testing, whereas two scale scores significantly improved in the HBO₂ group. One PCL-M measure improved from pre- to post-testing in both groups. This study showed that HBO2 at 2.4 ATA pressure had no effect on post-concussive symptoms after mild TBI.

Rebuttle to This Article by Dr. Harch-showing the flaw in the study

Hyperbaric Oxygen Therapy for Post-Concussion Syndrome: Contradictory Conclusions from a Study Mischaracterized as Sham-Controlled

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Dear Editor,

The recent study by Wolf and associates 1 <u>has affirmed the effectiveness</u> of hyperbaric (oxygen) therapy in the treatment of patients with mild traumatic brain injury (mTBI)/post-concussion syndrome (PCS) and post-traumatic stress disorder (PTSD). This affirmation emerges from analysis of the study data, rather than from the study's stated conclusions. Mischaracterized as a sham-controlled (placebo implied) design, the study errs in concluding that "HBO2at 2.4 ATA pressure had no effect on post-concussive symptoms after

mild TBI." A reconsideration of the science of hyperbaric therapy reveals that the study by Wolf and colleagues is neither a sham nor placebo-controlled study. Rather, it is a Phase II study of two composite doses of hyperbaric therapy that demonstrated significant improvements in PCS and PTSD symptoms at the 2.4 atmospheres absolute (ATA) pure oxygen dose as well as the low-pressure 1.3 ATA air/oxygen dose.

Hyperbaric (oxygen) therapy (HBOT) is a combination product of increased pressure and increased pressure of oxygen above ambient atmospheric pressure, according to scientific principles and current Food and Drug Administration understanding. Although traditionally misdefined as a treatment for diseases based on the increased oxygen component alone (>1.4 ATA oxygen),² it is a treatment with hyperbaric pressure and hyperoxia for disease processes^{2.3} whose primary targets are oxygen and pressure sensitive genes.⁴⁻⁶

Evidence for this dual component nature of hyperbaric therapy is found in the 351-year history of hyperbaric air therapy^Z and the recent 60-year history of animal, human tissue, and human experiments that have documented biological effects of pressure, especially in the micropressure range^{8.9} of the Wolf and coworkers¹ "sham" control group and the control groups of the Department of Defense (DoD) HBOT TBI studies. ¹⁰ Examples of this literature are listed in <u>Tables 1</u> and <u>2</u>. ^{11–28} Pressures from 1.21–1.26 ATA delivered to human ^{29–31} and 1.0015–1.015 ATA to animal endothelial cells, ³² and 1.10 and 1.20 ATA to human platelets ^{33, 34} for 15 min or longer have caused the elaboration or suppression of vasoactive substances, ^{29–31} and the elaboration of growth factors, ³² inflammatory mediators, ³³ oxidation products, ³⁴ and cell proliferation. ³² This literature and biological effects from a 1-min exposure to 1.09 ATA or 3 min at 1.04 ATA ¹⁷ inform the symptomatic improvements noted in the Wolf and associates ¹ "sham" group, as do benefits of hyperbaric air on spinal function and PTSD in spinal cord injured veterans during a SCUBA diving training course. ²⁸

*Full Article Has Been Included *