

Depression & HBOT

Good News for Veterans: Hyperbaric Oxygen Treatment for TBI, PTSD, and Depression.

Posted by Derrick Walker under Advanced Wound Care Systems, Discovery, Dr. Sherman Johnson, Hyperbaric Healing Center, Teri rich

Hyperbaric oxygen therapy (HBOT) appears to be a safe and effective treatment for Traumatic Brain Injury (TBI), Post-Traumatic Stress Disorder (PTSD) and **Depression**. Thanks to the work of the American Association for Health Freedom, and their petition to Congress, it looks as though our veterans will soon be receiving this much-needed treatment.

For each of you who took time to write your representatives regarding this issue – Thank you. The legislation which was passed and signed into law is a start, but this program needs to be funded and sustained.

AAHF Scores a Victory with HBOT for Wounded Veterans

Hope For Traumatic Brain Injury, Diabetic Failure-to-Heal Wounds and More?

On September 30, President Bush signed into law the FY2009 Continuing Resolution that contains the Defense Appropriations bill. In doing so, crucial funding became available to complete a scientific study important to all Americans.

Seventeen years ago, Paul G. Harch, M.D., discovered that hyperbaric oxygen therapy at 1.5 atmospheres of pressure (HBOT 1.5) could repair a chronic traumatic brain injury (TBI). Dr. Harch, director of the Hyperbaric Medicine Fellowship at Louisiana State University's School of Medicine and an AAHF member, has used the therapy on over 700 patients and has taught the technique to hundreds of doctors.

In 2008, Dr. Harch applied HBOT 1.5 to five combat veterans of the current war who have traumatic brain injury and post -traumatic stress disorder (PTSD) from concussive blasts. So far, all of the veterans treated have significant recovery. Eighty percent no longer have PTSD and all are improved.

During this same year, Dr. Harch testified in front of the Surgeon General of the Navy and the Deputy Commandant of the Marine Corps. He told the stories of the five combat veterans he treated with HBOT 1.5; three of those veterans were in the same room.

One of them, a judge who served as a general in the Army Reserves, endured a year of treatment failures at Walter Reed. He is now back on the bench, fully recovered in 120 days, after 80 HBOT 1.5 treatments. The Health Freedom Foundation, sponsored a Marine machine gunner who experienced seven concussive events from roadside bombs during two tours in Iraq. Now, after HBOT treatments, his migraine headaches have disappeared, his sleep is restored , his PTSD is gone. He is now actively employed. He has his life back, as do other veterans who have undergone HBOT treatment.

At Louisiana State University in New Orleans, under an approved study protocol, Dr. Harch is now treating another thirty veterans of the war who have TBI and PTSD. AAHF sought funding from Congress for this important study for the past two years. This year, after nearly 200 visits to members of Congress, funding was finally provided.

In April 2008, the RAND Corporation, a non-profit “think tank” highly respected by the government and NGOs, found that of the 1.6 million veterans of the war, 300,000 have PTSD, 320,000 suffer TBI, and 80,000 have depression. Current treatment costs for each of these conditions, when treated separately, is more than the cost associated with HBOT 1.5.

HBOT 1.5 one-time cost is US \$16,000 (80 treatments at \$200 per session) and appears to treat all three symptoms simultaneously; the earlier a person is treated, the more effective the recovery, and the fewer the treatments needed.

Hyperbaric oxygen therapy at 2.4 atmospheres of pressure is already used 10,000 times a day at over 900 locations for everything from non-healing diabetic wounds and radiation injuries from cancer treatment, to fourteen other Medicare-reimbursable and FDA-approved indications. HBOT 1.5 is a dose of HBOT that clinical experience shows is safe and effective for TBI.

According to Dr. Ted Fogarty, Chairman of Radiology at the University of North Dakota School of Medicine, “Functional neuroimaging shows HBOT revitalizes brain tissues and restores normal brain metabolism in vastly different areas of the brain in ways that other existing treatments cannot. To leave these injured neurons in our brave veterans to wither on the vine seems criminal when HBOT 1.5 is available and works.”

Today a multi-state coordinated effort is under way to treat vets at 78 locations. We expect this AAHF-coordinated effort will result in the necessary scientific proof to establish HBOT 1.5 as the standard of care for acute and chronic neurological injuries, and we hope it will secure reimbursement by the VA, Tri-Care, Medicare and civilian insurance.

The body of scientific evidence indicates that modern medicine has overlooked hyperbaric oxygen as a key tool in the treatment of strokes, diabetic failure-to-heal wounds, and conditions like reflex sympathetic dystrophy. Timely HBOT therapy could reduce the incidence of stroke (the leading cause of disability in the U.S., with over 500,000 reported cases each year) and amputations due to diabetic failure-to-heal wounds. HBOT has sound science, many years of clinical practice and a convincing reason for all of us to seek access when it can be of help.

Why Hyperbaric Oxygen Therapy Works for Chronic Brain Injury & PTSD

The International Hyperbaric Medical Foundation has launched the NBIRR-01 "Mild to Moderate TBI & PTSD HBOT 1.5" study at numerous sites across the nation, effective October 1, 2009. As each site is approved, their contact information will appear on www.clinicaltrials.gov. 1,000 patients will be treated. Progress can be followed at www.nbirr.com. To date all casualties have had some improvement and about 80% of veterans treated have been able to return to duty, work, or school. The NBIRR team saved the federal government over \$6.3 million in recruiting and retraining costs for just five active duty personnel treated, for a cost of \$62,500 in treatment costs. Effective TBI and PTSD treatment is available now. This is a culmination of 20 years of positive clinical results.

This memorandum outlines the scientific basis for why casualties of the current war treated with Hyperbaric Oxygen Therapy at 1.5 ata (HBOT 1.5) have experienced significant recovery. These casualties have suffered from Persistent Post-Concussion Syndrome (PPCS) caused by Traumatic Brain Injury (TBI) with or without PTSD. A recent study of Fort Lewis Washington war veterans exposed to blast showed 98% had PPCS symptoms. HBOT uses oxygen as a drug to cause biological repair and regeneration of damaged tissue, a fundamentally different healing process from the "symptom relief" usually prescribed. In the NBIRR pilot study, instead of "symptom relief," these patients have experienced a biological repair, demonstrated by a 37% reduction in Persistent Post-Concussion Syndrome, a 15 point IQ jump, a 28% reduction in PTSD symptoms, as well as improving on neurological imaging and quality of life measures, just in the first 1/2 of the protocol over 35 days. HBOT 1.5 is also low risk. Current "standard of care" on-label & off-label drug treatments are helping to drive the suicide epidemic which is believed to be as high as 17 per day in these untreated⁴ war casualties.

HBOT is the use of oxygen in an FDA-cleared medical device, a pressure chamber that uses oxygen at greater than atmospheric pressure as a medication to treat injury and disease processes. There are currently thirteen "indications" or standards of care for which the FDA and Medicare has approved the use of hyperbaric therapy, including three for neurological injuries (decompression illness, carbon monoxide poisoning, and brain abscess). Most of these treatments are done at 2.0 - 2.8 ata (a measurement of oxygen dose). The brain is more sensitive to oxygen⁶ and has responded better to HBOT 1.5, in cumulative repeated treatments.

Nature of the Crisis:

The RAND Report (April 2008) estimated approximately 33% of all who have been deployed to Iraq or Afghanistan have one of three conditions; PTSD, major depression or TBI. That is 541,200 war veterans as of April, 2008. National Guard injury rates were expected to be higher. A new report issued by DoD on March 4, 2009, indicates that 20% of the 1.8 million who have served, or 360,000 service members have suffered wartime brain injuries. Of those retention is a major concern of both the military command and policy makers. Barracks across the nation are filled with injured war veterans who are not receiving treatment to biologically repair their injuries. Instead the effort and expense are to mitigate the symptoms of their injuries.

Of all exposed to blast during combat in a recent Fort Lewis study, 98% suffered from Persistent Post Concussion Syndrome. Today recent reports put the IEF/OEF war veteran unemployment number at 185,000. In addition, the suicide rate was reported at 17 per day in this population in 2005⁹, and reports have indicated that rate may have increased. We have seen a surge of county jail inmates from this war, reported at 10% in several counties, and one of our small cities saw a surge from 35 in November 2008 to nearly 200 just a few months after 3,000 Iraqi war veterans returned to the state. The divorce rate for this population is reported at 80-90%, personality changes are common, and the rate of disability, substance abuse and homelessness is high. About 154,000 veterans are homeless. This is with the current "standard of care" medical practices. Compassionate use reimbursement for HBOT 1.5 should be authorized by government third party payers as quickly as possible.

The practice of not treating brain insults with an effective biological repair therapy has resulted in trillions of dollars of unnecessary expenditures for disability, incarceration, substance abuse, homelessness, domestic violence, special

education and mental illness. Untreated brain insults are the single most expensive cause of expenditures in any government's budget. Trillions in savings will be realized when this treatment is fully implemented for acute and chronic brain insult patients. Even a single episode of loss of consciousness from trauma has been shown to cause permanent injury to the brain. The sooner someone is treated with HBOT after an injury, the greater the recovery. Even decades after an injury benefit can be derived. HBOT is a medical treatment that saturates the body with 100% pure oxygen under pressure. It is also the only FDA-approved non-hormonal treatment that stimulates repair and regeneration of non-healing wounds. This NBIRR observational study is to determine whether successive HBOT 1.5 treatments generate improvement in cognitive function and other symptoms in patients suffering from TBI and/or PTSD.

HBOT's mechanisms of action are well understood and HBOT is already FDA-cleared, is safe, and available throughout the nation. This treatment is a low-risk procedure that is already approved for non-healing wounds in the body. Indication number 6 is "problem, non-healing wounds." These non-healing brain wounds respond to the correct oxygen dose in the same manner as diabetic foot wounds, approved by Medicare after the IHMA's request and submission to CMS for a National Coverage Determination, in 2003. This Memorandum justifies an observational study, where all patients receive real treatment, to track pre and post testing of patients to provide evidence to policy makers rapidly. This will shorten the time for scientific proof from 2 ½ years for an RCT to six months with FDA-approved scientific validity at a fraction of the cost. The lack of such a Level I study has inhibited the wide-spread adoption and use of HBOT 1.5 for TBI & PTSD. Because all patients in the observational study receive real treatment, 3rd party payment is justified, especially when there is independent evidence of recovery. Thus HBOT 1.5, a legal and ethical treatment already available, will be able to meet the national emergency presented by these war casualties.

The NBIRR team, led by Dr. Paul Harch at LSU in New Orleans, has treated over 40 combat veterans. Over thirty eight were treated with HBOT 1.5 for neurological injuries and two veterans treated for broken vertebrae, off-label, with the wound care protocol HBOT 2.0 for 90 minutes. A total of 30 will have been treated for "blast only" injuries when the LSU IRB-approved HBOT 1.5 pilot study is completed. They will have clinical evaluation; imaging and most will have an extensive battery of pre and post neuropsychological testing.

Hyperbaric oxygen therapy has proven to be an effective treatment for the pain caused by RSD/CRPS. A patient is placed inside a hyperbaric chamber where he/she will breathe pure oxygen at an increased pressure. This allows more oxygen to get into the body's system and promotes faster healing and reduces swelling.

The use of HBOT in Treating Mental Patients Resistant to Psychopharmacotherapy

127 patients were observed: 65 schizophrenic patients and 62 patients with vascular mental disorders. The treatment by hyperbaric oxygenation (HBO) was applied in such patients to overcome resistance to psychopharmacotherapy. A positive clinical effect was marked in 72.5% of cases (in 67.4% of schizophrenic patients and in 77.4% of patients with vascular diseases). The conclusion was made that HBO enabled to shorten the time of hospital treatment as well as to improve both clinical and social prognosis.

Clinical Effectiveness of HBOT in the Combined Treatment of Patients with Schizophrenia.

Hyperbaric oxygenation (HBO) was employed in 50 schizophrenic patients showing resistance to the conducted drug therapy. Thirty-two patients had shift-like and 18, sluggish, moderately and slowly progressive forms of schizophrenia. HBO treatment was always combined with psychopharmacotherapy. The results of the study have shown the advisability of inclusion of HBO into the multiple-modality treatment of patients with asthenic and apathetic depressions encountered during a shift-like or sluggish, schizophrenia with hysterical-hypochondriac disturbances and obsessions. The maximum therapeutic effect was observed after 10-12 sessions of HBO.

Personality Change

During the course of therapy, there may be some unpredictable neurological effects. In many brain injuries a part of the brain may be damaged in such a way that upon therapy it may demonstrate a different rate and extent of healing than other parts of the brain. In turn, these differences in rate of healing may bring about imbalances in the brain's delicate system of checks and balances. For example, those brain injured patients who have mood swings and changes in temperament, such as temper tantrums and crying, between eight and 25 treatments as they proceed through a healing phase toward return to their pre-injury temperament and personality. Stopping therapy at this point may have unpredictable and potentially serious consequences. At the same time Patients with irritability, impatience, and mood swings, resulting from their brain injury have experienced a calming effect in the same range of treatments as they returned to their pre-injury state. Some individuals report a decrease in temper tantrums and inappropriate outburst.

Please be aware that the vast majority of patients that are treated with Hyperbaric Oxygen Therapy throughout the world are people with diabetes who at the same time may have other ailments such as Heart, Kidney, brain, vascular and metabolic disease. Complications associated with HBOT are exceedingly rare. In approximately one quarter of the brain injured patients, however, there is another effect that has been noticed in New Orleans and other HBOT free standing centers, namely a change in emotional state usually occurring during the first two to four weeks of treatment. Patients, who, after their injury, became very quiet, can have tantrums, loss of emotional control, and wide mood swings of mood, indicating a change in brain function. In all likelihood this change, (personality change) represents an improvement in nerve cell function brought about by an oxygen-induced increase in blood flow with its improvement of local oxygen delivery and removal of metabolic waste products. It has been observed that this emotional change is temporary and improves with further treatments in the next few weeks. Based on our experience, we strongly recommend against discontinuing treatment during this period.

In contrast to the above stated mentioned quiet patients, it has been observed that those patients who, after injury, became more uninhibited and aggressive tended to regain control. This change tended to be more of a permanent effect, which persisted beyond the discontinuation of HBOT.