The Polemics of Hyperbaric Medicine

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Early History

The history of modern hyperbaric medicine dates back to around 1620, when Drebbel developed a one-atmosphere diving bell. Forty years later, Boyle and Gay-Lussac formulated the General Gas Law.

The modern age of hyperbaric medicine began in 1937, when Benke and Shaw used a hyperbaric chamber to treat decompression sickness (DCS).

It was not until 1955 that interest awakened in using hyperbaric oxygenation therapy (HBOT) for conditions other than DCS. That year, Churchill-Davidson began to use oxygen therapy in a hyperbaric chamber to treat radiotherapy-induced damage in cancer patients. In 1956, Boerema of Holland performed the first reported heart surgery in a hyperbaric chamber. In 1962, Sharp and Smith of Scotland were first to treat carbon monoxide poisoning by HBOT. In 1965, Perrins in the United Kingdom showed the effectiveness of HBOT in osteomyelitis. In 1966, Saltzman et al. in the United States showed the effectiveness of HBOT in stroke patients. In 1970, Boschetty and Cernoch of Czechoslovakia used HBOT for multiple sclerosis. In 1971 Lamm of West Germany used HBOT for treatment of sudden deafness. In 1973, Thurston showed that HBOT reduces mortality in myocardial infarction. ¹

The Undersea Medical Society was formed in the United States in 1967, and added hyperbaric to its name in 1986.

Forgotten Breakthroughs

Most physicians have never heard of these breakthroughs. HBOT has been called the Cinderella of modern medicine. With no large pharmaceutical interest to nurture and protect it, hyperbaric medicine languished.

Since it was not taught in medical schools, knowledge about HBOT was restricted primarily to the fields of diving and aerospace medicine—small niches in the medical community. Even the simple fact that pressure increases the concentration of oxygen in tissues is not widely appreciated. There are no pharmaceutical representatives to offer "free" Continuing Medical Education on the gas laws. In addition, HBOT reaches across all medical specialties and doesn't readily fit into one of the compartments into which medicine has been balkanized since the end of World War II.

In the early 1970s, George Hart, M.D., was asked to chair a committee formed by the Social Security Administration to decide what should and shouldn't receive reimbursement for HBOT therapy. He was a naval officer at the time and received an order from his commanding officer to make sure that "stroke" did not appear as a covered indication, even though there was mounting evidence that HBOT worked for treating stroke patients. The explanation was that it would bankrupt the U.S. Treasury if all the stroke patients in the United States wanted to receive HBOT for neurorehabilitation.

Insurers tend to focus on immediate costs, and often fail to consider long-term savings from a given therapy. For example, the fact that HBOT prevents 75 percent of all major amputations that would otherwise be necessary for diabetic wounds, with all the collateral costs and effect on quality of life, could not be factored into the decision about coverage of HBOT for diabetic foot wounds. The fact that the treatment worked was considered, but not the fact that it is cost-effective.

For a time, cerebral edema was a covered indication, and neurological injury was being successfully treated. This condition was, however, later removed from the Medicare coverage list—as a consequence, it is rumored, of a conflict between two scientists.

In 1980, when the authors formed the American College of Hyperbaric Medicine (ACHM) to foster the ethical advancement and expansion of hyperbaric medicine, it appeared that hyperbaric medicine might be ready to make a major breakthrough. B.H. Fischer, M.D., a tenured professor at New York University, became the principal investigator of a study funded by the Multiple Sclerosis (MS) Society. The MS Society in the United States had great difficulty accepting the results of the work Dr. Fischer had completed, and multiple revisions were required to weaken the conclusions sufficiently to satisfy the editors of the *New England Journal of Medicine*.³

In a double-blind controlled study of patients with advanced chronic disabilities, Fischer found significant improvement in objective measurements, and the treatment effect persisted for at least one year. For reasons hard to explain, this study was never followed up, despite the positive results, and the treatment languished for lack of financial support and sponsorship. Indeed, Fischer lost his position, and his chamber was destroyed.

In 1983, the year that Fischer's study was published, we became founding board members of the American Board of Hyperbaric Medicine.

With the publication of a paper on "idling neurons," a conflict arose within the hyperbaric community because "everyone knew" that neurorehabilitation was impossible. Neurons were simply dead, and could not be reactivated. Certain persons within the UHMS leadership apparently felt that it was their duty to eliminate and discredit both researchers and clinicians involved in using HBOT for neurorehabilitation.

It wasn't until 1996 that this group gained enough momentum to change the UHMS bylaws. Its leaders may have had already had a hand in the relentless persecution by the FDA of David Steenblock, D.O., in California, because he was treating Alzheimer disease, brain trauma, and chronic stroke patients. They wanted to bring the ACHM into their new role as enforcers of how hyperbaric medicine should be practiced, but the college would not join with them.

The group systematically proceeded to destroy the relationship between the UHMS and the college. We said we would never consent to be a member of any organization that established itself as an "enforcer" of the group's self-created "approved" standard. Ironically, the group's efforts accelerated just as the National Institutes of Health announced that work on canaries and gorillas showed that neurons could indeed regenerate, although no one knew how. It has been hoped that stem cells might be the answer. Perhaps that will prove to be true, but we already know that HBOT can bring about the recovery of idling neurons and cause neural pathways to regenerate.

In 2000, Paul Harch, M.D., director of the Hyperbaric Fellowship Program at Louisiana State University (LSU), presented to the UHMS the "pro" argument for endorsing the treatment of traumatic brain injury (TBI) with HBOT. By then, multiple studies had shown that HBOT reduces cerebral edema and decreases intracranial pressure in TBI patients.⁶

Rigorously controlled, randomized human clinical studies showed as much as 60 percent reduction in total mortality in TBI patients receiving HBOT, compared with standard intensive care without HBOT. A follow-up study showed the effects of HBOT, at 1.5 atmospheres absolute (ATA) daily for 5 to 7 days after surgery, on brain metabolism. HBOT improved the cerebral metabolic rate for oxygen and decreased CSF lactate, especially in patients with reduced cerebral blood flow (CBF) or with ischemia; normalized the coupling of CBF and cerebral metabolism; exerted a persistent effect on CBF and metabolism; and reduced levels of ICP and CBF. Notably, the recoupling of flow and metabolism by HBOT is the only demonstration of such in the history of science. Rockswold and coworkers recommended that shorter (30 minutes), more frequent (every 8 hours, as in their first study) treatments would optimize the effects.

One study showed a 450% increase in complete recovery with TBI patients receiving HBOT vs. standard intensive care without HBOT.⁸

Using the American Heart Association classification, the evidence for the efficacy of HBOT in TBI is Class I, meaning that

one or more Level 1 studies exist, with consistently positive and compelling results. This included a double-blind comparison with currently accepted therapeutic agents vs. HBOT.⁷ Paul G. Harch, M.D., had presented a number of studies concerning the treatment of neurologic injuries, among other conditions, at the UHMS's own meetings.⁹⁻¹¹

By UHMS's established criteria, brain injury should have been accepted without hesitation. Both the data and the scientific rationale are strong and support/demand low-pressure HBOT in acute severe traumatic brain injury. Some of the studies suggest that even a few treatments can have a profound effect. While the most desirable regimen, especially beyond the first two weeks, is uncertain, the need for further research does not justify withholding treatment. The UHMS, however, confronted with scientific evidence that HBOT was a treatment for brain injury, changed its acceptance criteria on the spot and rejected the "pro" argument that had just been presented.

Apparently, the inability to accept new information—that brain cells can recover from trauma or hypoxia—prevents consideration of evidence that contradicts firmly held preconceptions. Actual clinical experience of physicians, who obtain consistent results if they follow the suggested treatment regimens, is simply disregarded. Thousands of patients who have experienced the benefits want to make sure that others can have the same opportunity.

Changes in the Clinical Scene

Hyperbaric medicine has been dominated by large institutions since the 1960s, when the National Institutes of Health built hyperbaric research centers at academic centers such as Duke and Stanford Universities. Technology changed, however, and soon, in addition to large multiplace chambers that required investments of millions of dollars, small monoplace chambers became possible.

Today, most treatment in the United States is conducted in monoplace chambers. This has made it practical for smaller hospitals to have hyperbaric facilities, and has even given rise to separate clinics not controlled by the partisans who dominate the UHMS.

In 2002, diabetic foot wounds because the first new indication for HBOT¹ to gain approval in 18 years, owing to Harch's congressional testimony as President of the International Hyperbaric Medical Association, with the assistance of Dr. William Duncan, a House Appropriations Committee Associate, and Congressman Istook (R-OK). As a result, many physicians have

The UHMS accepted indications for HBOT are: (1) air or gas embolism; (2) carbon monoxide poisoning; (3) clostridial myositis and myonecrosis; (4) crush injury, compartment syndromes, and other acute traumatic ischemias; (5) decompression sickness; (6) enhancement of healing in selected problem wounds; (7) exceptional blood loss; (8) intracranial abscess; (9) necrotizing soft tissue infections; (10) refractory osteomyelitis; (11) delayed radiation injury; (12) compromised skin grafts and flaps; (13) thermal burns.

become aware of this treatment and are taking a new look at what it can do for their patients.

Who Will Define the "Standard of Care"?

Unfortunately, resistance to the expansion of hyperbaric medicine has not ended. In 2004, partisans took control of the executive committee of the ACHM. Their agenda was clear and straightforward: to expunge "off-label" treatment by expelling physicians who prescribed it.

ACHM bylaws prohibited any change in those bylaws without a two-thirds membership vote, but members were never told of a proposed change, and there was never a vote. The executive committee simply moved the ACHM from Texas and reincorporated in another state, with new bylaws and new officers.

The first action of the newly reconstituted ACHM was to announce that all those physicians who had been board certified by the American Board of Hyperbaric Medicine (ABHM) were now illegitimate, incorrectly citing a legal case to justify this deed. New bylaws mysteriously appeared on the college's website—bylaws giving them the right to discipline a member who practiced off-label.

The new regime determined the ABHM to be unnecessary, and thought that it would be destroyed in the changeover. ABHM is, however, a separate corporation, and we, as the last recorded members of the board of directors, were able to rescue it—the oldest hyperbaric medicine board in the U.S.

Today the ABHM has become affiliated with the American Board of Physician Specialties (ABMS), which is one of the nation's largest recognized physician multispecialty certifying bodies, providing board certification to thousands of physicians, both allopathic and osteopathic. The ABHM is an active corporation in good standing with the state of Texas that continues to honor, defend, and offer board certification in hyperbaric medicine, as it has since its inception on June 10, 1983.

Physicians Fight for Professional Autonomy

A group of hyperbaric physicians, also affiliated with the ABHM, has formed the new American Academy of Hyperbaric Medicine (AAHM). The Academy is also becoming affiliated with the American Association of Physician Specialists, and the Academy's establishment has the mission of fulfilling the original intent of the ACHM. Specifically, the AAHM will assert the right of every hyperbaric physician to practice medicine in a free, openminded, and unrestricted fashion without the threat of repercussions.

The objective is to develop an Institutional Review Board-based Treatment Registry at Oklahoma University and an executive fellowship in hyperbaric medicine. This fellowship will provide continuing medical education, taught by LSU medical faculty, leading to board certification in hyperbaric medicine approved by both the ABPS and ABHM.

We believe that the use of hyperbaric medicine to treat the problem wound, whether the wound is found on the foot or in the brain, is a divine gift. It was never meant to be owned by a small group with the power to deny it to patients who might benefit from it. We must work to improve access to treatment, and to expand research from the narrow channels in which it has been confined because of the tight control held by government, third parties, and pharmaceutical companies over funding sources.

We believe that great advances in this field are on the horizon. If these come to fruition, the story will be a powerful example of the need for independent physicians with the right to prescribe according to the best of their knowledge and judgment, rather than the dictates of a self-appointed elite.

If physicians do not defend their autonomy, who knows how many life-saving and life-enhancing advances in medicine will be kept from American patients for many years or decades.

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REFERENCES

- ¹ Jain KK, ed. *Textbook of Hyperbaric Medicine*. 4th ed. Ashland, Oh.: Hogrefe & Huber; 2004.
- ² Freels D. Medicare's noncovered conditions: a conversation with Dr. George B. Hart. *Hyperbaric Medicine Today* 2003;2(2):7-12.
- Fischer BH, Marks M, Reich T. Hyperbaric-oxygen treatment of multiple sclerosis: a randomized placebo-controlled, double-blind study. New Engl J Med 1983;308:181-186.
- Neubauer RA, Gottlieb SF, Kagan RL. Enhancing "idling neurons." *Lancet* 1990;335:542.
- Salaman MK. Hyperbaric oxygen therapy denied to doctor, embraced by government. *Health Freedom News* 1999;17(4):1-5,8.
- ⁶ Rockswold SB, Rockswold GL, Vargo JM, et al. Effects of hyperbaric oxygenation therapy on cerebral metabolism and intracranial pressure in severely brain injured patients. *J Neurosurg* 2001;94:403-411.
- Rockswold GL, Ford SE, Anderson DC, Bergman TA, Sherman RE. Results of a prospective randomized trial for treatment of severely braininjured patients with hyperbaric oxygen. *J Neurosurg* 1992;76:929-934.
- ⁸ Holbach KH, Wassmann H, Kolberg T. Verbesserte Reversibilität des traumatischen Mittelhirnsyndromes bei Anwendung der Hyperbaren Oxygenierung. (Improved reversibility of the traumatic midbrain syndrome following the use of hyperbaric oxygenation.) *Acta Neurochir* 1974;30:247-256 [German].
- ⁹ Harch PG, Kriedt CL, Weisend MP, Van Meter KW, Sutherland RJ. Low pressure hyperbaric oxygen therapy induces cerebrovascular changes and improves cognitive and motor function in a rat traumatic brain injury model. *Undersea Hyperb Med* 1996;23(Suppl):48.
- Harch PG, Van Meter KW, Gottlieb SF, Staab P. HMPAO SPECT brain imaging of acute CO poisoning and delayed neuropsychological sequelae (DNSS). *Undersea Hyperb Med* 1994;21 (Suppl):15.
- ¹¹ Harch PG, Gottlieb SF, Van Meter KW, Staab P. HMPAO SPECT brain imaging and low pressure HBOT in the diagnosis and treatment of chronic traumatic, ischemic, and anoxic encephalopathies. *Undersea Hyperb Med* 1994:21 (Suppl):30.