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<u>What You Never Knew About Multiple Sclerosis and</u> <u>Hyperbaric Oxygen</u>

R. A. Neubauer, M.D.

Having begun hyperbaric oxygenation treatments (HBOT) in the early 1970s under the tutelage of Dr. Edgar End, I encountered several patients suffering simultaneously from chronic refractory osteomyelitis, and multiple sclerosis (MS). The signs and symptoms of MS had been improving during exposures to hyperbaric oxygenation so in 1978 I published several case reports in the *Journal of the Florida Medical Association*(1). By 1980 I had accumulated data on 250 patients with multiple sclerosis and once again published in the *Journal of the Florida Medical Association*, concluding the following: 1) this is not a cure; 2) it is dose sensitive; 3) it takes repeated treatments over the long term; and, 4) it alters the natural history of the disease favorably(2). In that 1980 paper, I reported on minimal to dramatic improvement in 91 percent of 250 patients treated with hyperbaric oxygen at pressures of between 1.5 and 2.0 atmospheres absolute (ATA).

In 1970 Boschetty and Cernoch of Romania reported small transient improvement in 16 of 26 patients treated with hyperbaric oxygen at a pressure of 2.0 ATA(3). In 1978 Baixes of Toulon, France reported improvement in 11 patients treated with hyperbaric oxygen.(4) Positive results were again reported in 1980 in a detailed study by Dr. Formai in Italy, who first used hyperbaric oxygen because of clinical similarities between the decompression sickness and multiple sclerosis.(5) In that same year, Dr. Pallotta of Italy independently reported substantial improvement with hyperbaric oxygen in six patients with multiple sclerosis.(6)

Because of those published observations and other sporadic suggestions that hyperbaric oxygenation might be beneficial to treat MS, the National Multiple Sclerosis Society became furious. They went to Dr. Boguslav Fischer, a professor of neurology at New York University Medical School, who was also an experienced physician in hyperbaric oxygenation, and, awarded Dr. Fischer a \$250,000 grant to silence such claims. Dr. Fischer conducted an exceptionally well designed double-blind study, as difficult as this may be with multiple sclerosis, and much to the surprise and apparent chagrin of the National MS society, his positive results were published in 1983 in the *New England Journal of Medicine*(7). However, that original paper was delayed in publication and watered down significantly, under pressure from the National MS society. Consequently, upon publication, Dr. Fischer was asked to seek employment elsewhere.

Those early reports all have several things in common. There was remarkable

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agreement and uniformity of positive observations, although the studies had been conducted independently by different researchers at widely separated locations around the world. It became obvious that hyperbaric oxygen therapy might well be beneficial in the treatment of MS, especially considering the lack of harmful side effects. Prior to Dr. Fischer's study, they had all been conducted without controls, and only the Neubauer study utilized an established disability scale as a point of reference(2).

I contacted Dr. Boschetty in Romania and it had become very clear to him and to me in clinical practice that repeated long-term treatments were mandatory for sustained benefit. It also came to my attention that Dr. Jacque Baixe in Toulon, apparently had also been treating MS with hyperbaric oxygenation plus carbon dioxide, and had not published all of his data. Dr. Fischer's and mine were the first studies published in peer-reviewed journals.

In the interim, Dr. Charles Shilling introduced me to Dr. Philip James in England. Dr. James had brilliant ideas on the etiology of MS and was a proponent of treatment with hyperbaric oxygenation. He was one of the first to note that microscopic lesions in the spinal cord of MS patients and that of decompression illness were identical. He is currently preparing a book on hyperbaric oxygenation for MS.

In 1982, my wife and I were invited to the United Kingdom to lecture to a lay organization sponsoring research into Multiple Sclerosis. This consisted of a wonderful group of patients who had banded together for self-help and to investigate all new possibilities for improvement. As a result, in the United Kingdom there are now 110 hyperbaric oxygen chambers treating 12,000 cases of multiple sclerosis, in some cases for as long as 16 years. This has been entirely because of the pioneering work of Dr. P. B. James and Dr. David Perrins. Their resulting massive amount of clinical data could never have otherwise been reproduced at any price. Yet, it was denied publication by *Lancet* and the*British Medical Journal* because it was not considered a controlled study. Those journals completely ignored the excellent longitudinal data, which fulfilled criteria of the Schumacher dictum(8) (if a patient receiving any type of therapy for MS has not become worse after two years, the therapy is considered a success).

In 1985, a review article critical of HBOT in treatment of MS appeared in *Lancet* by Drs. Barnes and Bates.(8) This was preceded by a news release in the *London Times* stating that hyperbaric oxygenation was not indicated or effective in MS and caused side effects. When one reads the article, however, it became obvious that the author(s) had never read Fischer's work completely and had never looked beyond the study title. A dose of 2.0 ATA was mentioned. The original Neubauer work indicated a dose of between 1.5 and 2.0 ATA(2). Fischer measured arterial oxygen pressures while in a multi-place chamber and with the patient breathing oxygen through a mask(7). Because of mask administration, his measured arterial oxygen pressure was equivalent to only 1.3 ATA.

Barnes and Bates described in their *Lancet* publication using a pressure of 2.0 ATA, with possible slight side effects and lack of reported benefit. They treated

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the patients at 2.0 ATA (33-feet equivalent), but ran the controls to 3-feet and said that there were no side effects at 3-feet. They seem to have partially misinterpreted their own data, possibly because of preconceived ideas. They did observe improvement in bladder and cerebellar function and felt that further study was warranted(11) Those same authors subsequently published a more positive report in the *Journal of Neurology, Neurosurgery and Psychiatry* showing beneficial cerebellar effects(12).

Following the Barnes and Bates article in *Lancet*, 12 other papers appeared. A careful review showed that all of those subsequent reports were seriously flawed for lack of proper patient selection, lack of appropriate treatment pressure; and poor protocol. The follow-up data on some of those studies were of such poor quality that they should never have been published. Dr. Sheldon Gottlieb and I published a detailed review of those severely flawed papers in the *Journal of Hyperbaric Medicine(13)*.

Under the direction of Dr. P B. James and Dr. David Perrins, treatment with hyperbaric oxygenation continued to be a mainstay of therapy for MS in the United Kingdom.

I had been invited to lecture in many medical centers in Europe, but my first US professional forum was an invitation in 1984 by Dr. Sheldon Gottlieb, a physiologist, who was then president of the Gulf Coast Chapter of the Undersea Medical Society. I spoke at that chapter's annual meeting, in Auburn, Alabama. Since that time Dr. Gottlieb and I have worked closely together. His basic science background has been very helpful in the preparation of future studies.

While the use of hyperbaric oxygenation in MS might accurately be described as controversial, it has by no means been proved ineffective. On the contrary, a vast amount of clinical experience and a number of published reports have shown that HBOT has great potential for MS patients.

A serious double standard has been applied by the National MS Society: it approves of exorbitantly expensive drug therapies that cause many serious adverse effects, and with only limited effectiveness—primarily by reducing the frequency of the exacerbations in the relapsing-remitting form of this disease. On the other hand, patients are routinely denied information about the reported improvements in longstanding MS symptoms using HBOT, as reported in a number of published clinical trials, and with an exceptionally good history of safety.

More studies are greatly needed to scientifically document the improvements we have been observing for decades in a clinical setting.

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