



Commentary Regarding Off-label Hyperbaric Oxygen Therapy

Although medical science breakthroughs occur at a seemingly breath-taking pace an unfortunate number of conditions continue to thwart the search for curative answers. It is hardly surprising, therefore, that patients and their families for which medical science is considered to have failed them become frustrated and desperate. Some will elect to search elsewhere, in the hope that their physicians have overlooked a therapeutic option that might be of benefit. A therapy, perhaps, that could interrupt disease progression. A therapy that could improve quality of life, maybe even improving the condition itself. And hope above all hope, something that might result in a cure.

In many cases, the internet is that source of hope. It is filled with much credible and useful information. Unfortunately, it is also sprinkled with a disturbing amount of material that is unsubstantiated at best, patently false at its worse. Equally unfortunate is that the internet lacks informational quality controls that otherwise characterize conventional dissemination of medical science. This shortcoming makes it difficult or impossible for the lay public to differentiate fact from fiction, real hope from unmitigated hype.

'Hyperbaric Oxygenation' represents a frequently used internet search term in this regard. Arguably the first medical technology that is still in use today, its origins can be traced back to the 1600's. Today, hyperbaric oxygen (HBO) therapy is recognized as an important therapeutic tool for a small number of acute and chronic conditions. Authoritative organizations such as the Food and Drug Administration and the Undersea and Hyperbaric Medical Society serve as credible sources in terms of which conditions are felt to have the necessary quality of evidence to support the use of HBO therapy. The federal government's Centers for Medicare and Medical Services and essentially every other purchaser of health care uses these resources to guide respective reimbursement policies.

A review of internet sites that are identified by the above noted search term suggests that the number of conditions likely to benefit from HBO therapy is several orders of magnitude greater than those otherwise considered to be medically proven.

These additional conditions are referred to as 'off label' uses. There is certainly nothing unique about the off-label application of a particular medicinal agent. Many within the medical community have considered the potential for a given drug to be helpful for a condition that it was not originally created to address or was approved for its use. What is unique, however, is the establishment of entire medical practices based solely on provision of off-label therapy. And this is precisely what has occurred to HBO therapy in an alarming number of instances. In fact, there is a growing national trend of non-hospital affiliated free-standing off-label hyperbaric medicine facilities.

Even more concerning, it is evident that in many instances those actually responsible for the provision of off-label HBO therapy do not have the necessary medical credentials, training, licensure and clinical experience to effectively evaluate, safely treat, and appropriately manage any related complications. Only fully licensed physicians (MD's or DO's) meet these critically important criteria. A closer look at off-label clinics will, in many instances, turn up situations where chiropractors, podiatrists, physical therapists and a host of other allied health workers have somehow managed to assume this role. Even more concerning, some business opportunists with no health care training at all have recognized the financial potential of a largely gullible patient population and set up shop.

Although considered relatively safe in the right hands, as with essentially every other medical therapy, exposure to hyperbaric doses of oxygen does have risks, both minor and otherwise. These risks range that gamut from simple discomfort to the ears, to changes in vision not always readily reversible, grand mal seizures, and even death, albeit in rare instances.

Proponents of off-label HBO therapy argue their case in one of several ways. They may suggest that it cannot hurt to try. Experience clearly indicates otherwise, including a recent (May 2009) chamber fire resulting in a double fatality, a four year old child and his grandmother. Proponents may offer testimonials culled from a small percentage of the many who have been 'treated' to suggest benefit and that these statements represent proof positive. Proponents may provide written 'evidence' in the form of impressive looking reports that appear to the lay public to be sufficiently authoritative. Yet, they often represent nothing more than handouts or 'Abstracts' from talks that lack commonly accepted scientific research principles and have not undergone the important 'peer review' process inherent in standard medical practice.

Proponents may further argue that there exists something of a conspiracy against their approach to the provision of hyperbaric medicine. That somehow mainstream medicine does not want patients to be helped or cured in this manner because of some obscure and unverifiable rationale. Just think about that. If pediatricians observed marked and sustainable improvement following provision of HBO therapy in otherwise intractable states secondary to the devastating consequences of hypoxic birth injuries, for instance, how could they possibly not demand hyperbaric chamber access to all such children? Their medical journals would be replete with encouraging reports of this exciting medical breakthrough in otherwise incurable conditions. Sadly, these demands do not resonate because improved or enduring clinical outcomes rarely occur and cannot be definitively tied to HBO therapy. The same applies in the adult population where hyperbaric oxygenation is touted for several central nervous disabling conditions in the elderly for which there is presently no effective remedy.

Does this mean that HBO therapy is ineffective to any degree whatsoever across the wide range of 'off-label' uses? No it does not. It is entirely possible that some of these conditions, or at least subgroups of patients with these conditions, could achieve a degree of benefit. But, the reality is that this is presently un-researched and unproven. The way to properly determine whether or not there is any possibility of benefit at all is to formally study each condition in question, as occurs elsewhere in mainstream medicine. It is simply not ethical or otherwise appropriate to offer hope where the current weight of evidence (presently, the majority of such patients not having benefited) does not support a therapeutic role of HBO therapy. Doing otherwise is simply

charging vulnerable patient populations significant fees while essentially experimenting upon them, and invariably with no intention of formally publish results, positive or otherwise.

In the meantime one is advised to carefully balance hope versus hype. This is not just whether or not to commit to an unproven therapy. It should also include consideration of the high costs involved and uncertain therapeutic endpoints. It should further include appreciation of the risks, with particular reference to exactly whom one is placing one's well-being with and the extent, or otherwise, of their credentials to practice medicine.

APPENDIX

Suggested Definitions of Indications: Hyperbaric Oxygen Therapy

1. Approved

Those conditions for which there exists a sufficient body of evidence for authoritative organizations to recommend its use and wide acceptance by those who purchase health care to compensate for its use.

2. Experimental

Those conditions for which there is a growing body of evidence that HBO therapy appears beneficial.

3. Plausible

Those conditions for which there is animal and some anecdotal evidence that HBO therapy may be beneficial.

4. Un-established

Those conditions for which there is good evidence against the use of HBO therapy, or no to very poor supporting evidence.

5. Off-Label

The practice of prescribing HBO therapy for a condition it has not been approved to treat (approval standard commonly referenced to the Federal Drug Administration).