

# HYPERBARIC MEDICINE: WHAT OF ITS EVIDENCE?

by Dick Clarke CHT



As many of today's health care professionals readily appreciate, a buzz word amongst academicians and organizations that purchase health care is evidence-based medicine. This concept was reintroduced in the 1980's. It is argued as the best standard by which to evaluate and compare the growing number of diagnostic and therapeutic options for a given disorders. Proponents are of the opinion that this is the most effective method to identify the best balance of medical efficacy, safety, and cost-effectiveness. There are opponents, some with a sense of the extreme! It may not surprise you to learn, however, that the majority of what we do to diagnose and treat our patients is not supported by high levels of evidence.

Evidence-based medicine consists of several levels of evidence, or proof. At the top are the results of high quality randomized clinical trials (CT's), with narrow confidence intervals, termed 'Level I' evidence. Ideally, all medical decision-making would be based upon this standard. In fact, and as noted above, very little is. So, to determine what particular test or intervention is most appropriate, the clinician moves down the hierarchy (or levels) of evidence. Next will be smaller RCT's, then prospective studies, followed stepwise by retrospective studies, case reports and then laboratory data. At the bottom (least evidence) of the list is expert opinion - which once was considered the most important determination of efficacy and effectiveness!

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In all of this, hyperbaric medicine sits squarely under the 'outcomes microscope'. More evidence is demanded of its clinical value; more evidence is demanded of its cost-effectiveness. Although it has been employed in one form or another for more than a century, its practice is largely based upon relatively modest to low levels of evidence. As a consequence, what appears in many cases to be a promising intervention for several acute and chronic conditions remains sidelined on the periphery of mainstream medicine. While many of today's 15 common uses lack sufficient evidence, there are exceptions. The employment of hyperbaric oxygen therapy for carbon monoxide poisoning, for instance, now enjoys Level 1 evidence. Not too far behind is solid (Level II) evidence for its use in diabetic foot lesions, mandibular osteoradionecrosis, radiation cystitis, and prevention of break down of previously irradiated tissue following surgery. This leaves some obvious gaps, of course.

Some are unlikely to be filled. Decompression sickness and cerebral arterial gas embolism are examples. One hundred years of treating divers with hyperbaric oxygen therapy has produced impressive 'outcomes' evidence in terms of effecting cure. It is not close to Level I, but the medical-legal climate and a lack of any viable therapeutic alternatives will likely see these indications 'unchallenged' by controlled trials. To a lesser extent the same applies to clostridial myonecrosis (gas gangrene).

Complicating the hyperbaric research process is a lack of suitable financial sponsorship. Oxygen is the active agent. It is readily available in the atmosphere so its access is not controllable. Anyone with the right equipment can capture it, store and make it available to the consumer. There are, therefore, no pharmacologic companies ready to invest in hyperbaric medicine's scientific advancement. Being able to undertake high level clinical research, then, comes down to a mix of philanthropy, grants from industry, with clinicians and administrators volunteering their time and resources.

Recent events have brought an even sharper focus to hyperbaric's 'evidence' issue. Two regional intermediaries for Blue Cross Blue Shield (Idaho and Hawaii), have relegated several 'currently accepted' hyperbaric indications to an investigational status. Two of these indications stand out, and for different reasons. The first is carbon monoxide poisoning. Completely overlooked in the decision-making process by these intermediaries is a clinical trial published by the New England Journal of Medicine, in 2002. This really is inexcusable, particularly because the reports by BCBS reference later (2004) data elsewhere. One can understand, perhaps, that such a decision-making process may be time-consuming, and that the literature survey was completed some time earlier. For the same policy document to cite a publication in 2004 for a different condition, however, does not argue favorably for the quality of this research analysis. At best it represents sloppy science, at worst the paradigm amongst us see it as bias!

The second relegated condition is late radiation tissue injury. Here, the concern is that this is the most common hyper-

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of a Low Water alarm which sounded as a result of us inadvertently not filling the unit to the proper level.) This will, of course, insure the operator that the proper water level needed to submerge equipment is always maintained. While the unit will work with normal tap water it is suggested that, if the local water is heavily mineralized, distilled, but not de-ionized water, be used. This is due to the fact that the water level sensor requires ionized water to function correctly.

**Operational Analysis:** The Mini-Pasteumatic is exceedingly easy to use. It has only 4 controls. The written instructions are also simple and clear consisting of photos illustrating each step of the process. As previously noted the start-up process was just about an hour. From that point the pasteurizer maintains its heat until the power is shut off. This means that it is always "ready to go".

**Miscellaneous:** We asked for the standard information and literature packet and received a collection of very informative materials including CDC and APIC guidelines. The instruction manual, as mentioned previously, is well designed, easy to understand and had lots of white space for note taking.

**Benefits:** This is a low cost method of decontaminating equipment that can tolerate submersion in moderately hot water. There are no chemical or radiation disposal or hazardous problems associated with the process. Special personal protection devices other than, perhaps gloves and goggles are also, not needed. There is a thirty minute turn around time from the time the lid closes until it is ready for opening.

Naturally, it is not to be used with electronic or electrical devices such as spirometers, respirometers, gas analyzers, etc. Parts and equipment should also be washed and rinsed of particulate matter prior to pasteurization and drained and dried after the process is finished. (Olympic makes washers and drying cabinets for these purposes, as well.)

**Recommendation:** The Olympic Medical Mini-Pasteumatic is an ideal, low cost, effective solution for providing high level disinfection at sites with low to moderate levels of equipment usage. It would be a good choice for respiratory therapy departments, outpatient clinics, sleep labs, public health clinics, pulmonary and stress labs. The unit has an excellent track record and there have been no problems or recalls in the field. Again, the company itself is a proven organization with an excellent 40 year history of manufacturing high quality devices covered by excellent warranties and top-notch service. This table-top disinfection unit can be just the ticket for many settings. We recommend you look into it as a possible solution to your equipment disinfection needs. The company can be contacted at 800-426-0353. Their website is found at [www.olymed.com](http://www.olymed.com).

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baric referral indication in North America. Should the position taken by these two intermediaries be adopted by the larger health insurance community, the practice of hyperbaric medicine as we know it today might cease to exist.

It is interesting in that the principal reason for a change in reimbursement policy was a lack of Level 1 evidence. We see clearly that poor methodology (a blunder) not lack of adequate science resulted in the carbon monoxide decision. A failure to understand the concept of evidence-based medicine likely contributed to the radiation necrosis decision.

As noted earlier, evidence-based medicine involves a hierarchy process. The idea here is that one begins at the top. If no Level 1 evidence is available one moves to level 2, and so on. Eventually, one will come across one or more tests or therapies that represent 'best' evidence. It appears that these BCBS representatives failed to grasp this concept. Take radiation cystitis for example. Therapeutic options include a variety of surgical and medical options, including hyperbaric oxygen therapy. More are supported by Level 1 evidence. Moving down the evidence trail we arrive at Level 2. What is it? Why, hyperbaric oxygen therapy? So, the decision not to reimburse for hyperbaric medicine on the basis of lack of evidence implies that no other intervention should be covered. This, of course assumes that the same standards that are applied to hyperbaric medicine apply elsewhere.

What, then, is the hyperbaric medicine discipline to do? Three options spring to mind. The first is to hope that present position by BCBS remains limited, and not embraced by the other major purchasers of health care. A head in the sand approach, and not the smart thing to do. Next, and already underway, is a lobbying effort. To argue some of the points made above; to say that evidence was missed in one case and that no better evidence than hyperbaric oxygen therapy exists in another. While this latter option is not exactly arguing the negative it is perhaps not a strong enough an argument for some policy-makers to accept. A third option? To undertake clinical research that will hopefully generate the type of evidence (Level 1) that resolves efficacy questions.

This is not as tall an order as it might seem. Several randomized trials are already underway, and several others in the planning stages. Such trials are time-consuming both to design and implement, particularly when a reasonable degree of follow-up is incorporated. Not only must one show efficacy. One must also demonstrate an enduring response. It is one thing to cure a case of radiation cystitis for \$15,000.00: an entirely different matter to demonstrate that such a cure is not short-lived and therefore a good financial investment.

Hopefully, resulting supportive evidence will become available before reimbursement is more widely affected.



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