

ONDAMED PILOT STUDY FINDINGS AND PROJECT REPORT

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The following report details the pilot study findings, and outlines information and recommendations that were planned for in the original ONDAMED-JMBCIM proposal. Additional comments and issues have been addressed that have arisen during this period from January 2004 through December 2006. The result is a document that should be helpful for the growth and development of ONDAMED in the US.

I. Phase I and Pilot Phase II Trial of the ONDAMED Biofeedback System in Patients with Pain Disorders

Abstract

Although the ONDAMED Biofeedback System (ONDAMED) has been used internationally for many years as a therapeutic device with many anecdotal reports of benefit, it has not yet been systematically researched. This pilot study was therefore undertaken to: (a) examine the safety of ONDAMED under more controlled circumstances; and (b) collect pilot data regarding the effectiveness of ONDAMED for treating chronic pain.

Eleven subjects with various chronic pain disorders were enrolled in this pilot study. This has included 10 females and 1 male; average age 62.2 years (range 39-68); with pain disorders varying from fibromyalgia syndrome and migraine headaches to inflammatory disorders such as interstitial cystitis and polymyalgia rheumatica, to pain syndromes of the low back, spine, neck and hand, stemming from a variety of causes. For pain management, subjects were taking a variety of medications at specified doses.

There were three ONDAMED therapy sessions for each subject at weekly intervals (approximate treatment duration 30 minutes each). Treatments included standard individualized specific frequencies and 2 pre-set programs, using the specified pulse biofeedback technique.

The results of the subjects' treatments were that there were no outward signs of adverse events in the eight subjects who were treated in the Phase I trial. Also, results for the pilot efficacy study were that 3 of the 11 subjects reported significant improvement in pain levels. These results suggest that the ONDAMED Biofeedback System appears to be safe for the treatment of pain under stable conditions. ONDAMED treatment is also helpful for pain in a percentage of subjects that suggests that it is a viable treatment option. Significant future research is required to: (a) identify those patients who are most likely to benefit from ONDAMED treatment; (b) clarify mechanisms through which ONDAMED is helpful; and (c) develop specific and reliable clinical treatment protocols.

Introduction and Background

Despite optimized pharmacotherapy, millions continue to suffer from chronic pain conditions. Many pain patients explore complementary and alternative medicine (CAM) for pain management.

The National Center for Complementary and Alternative Medicine (NCCAM) of the NIH has identified the domain of Bioelectromagnetic-Based Therapies. These involve the unconventional use of electromagnetic fields, such as pulsed electromagnetic fields (PEMF), magnetic fields, or alternating-current or direct-current fields. Verifying health claims made by providers of alternative therapies remains a high priority of research nationally. The NCCAM Draft Strategic Plan for 2005-2009 has just been published; one research goal is to "accelerate progress in understanding the source and biological effects of putative energy fields." The goal of this pilot study is to confirm safety and tolerability of an alternative biofeedback device, and to gather preliminary data required to design a future study to evaluate efficacy.

Prior research on electromagnetic fields and health has included the study of static magnets [1-4], pulsing electromagnetic fields [5-9] and magnetic field influences on cellular and tissue functions [10-12]. Double-blind, randomized controlled trials have shown that static magnets are helpful for postpolio syndrome pain [1], chronic pelvic pain [2], and knee pain and osteoarthritis [3,4]. Pulsing electromagnetic fields administered by Diapulse, an FDA approved Class III device, has been shown to improve migraine headaches [5], wound healing of pressure ulcers [6,7], and soft tissue injuries of ankles and hands [8,9].

The specific mechanisms by which magnets and electromagnetic fields influence pain are not understood. There is evidence to suggest that electromagnetic fields can affect in vitro growth of cartilage and bone [10,11]. Still other research suggests that magnetic fields may increase peripheral blood flow [12].

The ONDAMED Biofeedback System has been used in clinical practices, primarily in Western Europe, for approximately ten years and on thousands of patients. However, it has never been carefully examined in a controlled, medical environment for a chronic pain population. Anecdotal claims have been made that the device reduces symptoms in chronic pain patients. Because of the rising interest in using the ONDAMED and similar devices in the US, we have conducted this study to: (a) examine the safety of ONDAMED under more controlled circumstances; and (b) collect pilot data regarding the effectiveness of ONDAMED for treating chronic pain.

Methods

This is an unblinded open trial of chronic pain. All subjects were enrolled from the JMBCIM. They were either referred from other center practitioners or saw flyers that were placed in the waiting room. Once subjects were identified and determined to meet the study entry criteria, they were enrolled in the study using a TJU approved consent form.

Dr. Edman was trained in the use of ONDAMED at several sessions with ONDAMED representatives and practiced the required techniques for three to four months before subjects were enrolled and the study began. He specifically learned the pulse biofeedback technique for identifying both individual-specific frequencies and pre-set programs.

There were three ONDAMED therapy sessions for each subject at weekly intervals (approximate treatment duration 30 minutes each). Treatments included standard individualized specific frequencies and 2 pre-set programs, using the specified pulse biofeedback technique.

Eleven subjects with various chronic pain disorders were enrolled in this pilot study. This has included 10 females and 1 male; average age 62.2 years (range 39-68); with pain

disorders varying from fibromyalgia syndrome and migraine headaches to inflammatory disorders such as interstitial cystitis and polymyalgia rheumatica, to pain syndromes of the low back, spine, neck and hand, stemming from a variety of causes. For pain management, subjects were taking a variety of medications at specified doses.

Results

The experience and results of the first eight enrolled subjects was considered the Phase I Trial. Since there were no significant adverse effects reported, ONDAMED treatment can be considered safe under stable circumstances.

For the pilot Phase II trial of therapeutic effectiveness, 3 of 11 subjects reported significant improvement in their pain level. Also, each of the 3 subjects who reported improvement felt less pain at each of the 3 treatment sessions. One of eight subjects who did not report improvement with ONDAMED treatment, dropped out after the second treatment.

Discussion

This research is one of the first studies to objectively evaluate the ONDAMED Biofeedback System under controlled circumstances in the US. The importance of this investigation is to begin a thorough and scientific approach to the use of ONDAMED, which will hopefully lead to a more clear understanding for how to most effectively apply the treatments and to better appreciate how it works.

ONDAMED treatments appear to be safe, although there are two cautions. First, there were no biological markers assessed that could more sensitively measure beneficial or adverse effects. For example, this might include inflammatory markers or cellular function measures. Secondly, this was a small study covering a range of chronic pain syndromes - although unlikely, it is possible that larger studies evaluating a range of pain disorders could identify a disorder or circumstances in which greater caution is required. As we better understand bioelectromagnetic fields and their influence on physiology and health, it will be easier to determine if there are any risks for ONDAMED treatment.

The size and design of this pilot study makes it difficult to truly determine how effective ONDAMED treatment is for people with chronic pain disorders. Because 3 of 11 subjects reported significant improvement in pain levels, ONDAMED is a viable option for pain therapy. It is interesting to note that all 3 subjects who reported benefit from the treatments had immediate improvement at each visit. In contrast, there were no subjects who had beneficial effects after initially seeing no effect. It is possible that if 10 to 15 treatments or more were given (two times per week), that the ONDAMED therapy could have produced more significant improvements or responses in more subjects. At this point it is not known what the optimal number of treatments would be or if there is a greater advantage to applying more individual frequencies or pre-set programs for specific disorders or circumstances. This would require an examination of larger numbers of subjects with specific pain diagnoses.

For practitioners of the ONDAMED system who have seen significant benefits from the treatments, it is possible that they would have expected a higher percentage of responses. While this may have resulted from subjects only receiving 3 treatment sessions, it could also have occurred because using ONDAMED in clinical practice often applies ONDAMED therapy as part of an overall integrative medicine treatment program that may include

dietary guidelines, nutritional supplements, exercise, stress management, massage, acupuncture and/or other modalities. While this clearly is the correct approach to take in clinical practice, this makes it more difficult to determine how much improvement resulted from ONDAMED treatment and how much benefit resulted from one or more of the other approaches.

It also must be noted that there is a significant amount of subjectivity in the application of ONDAMED therapy and the use of the pulse biofeedback technique to identify frequencies and programs. In addition, there are no reliable markers of the influences of the ONDAMED System since it is not well understood whether biomagnetic fields are influenced, what other mechanisms may be affected and/or what impact this may have on physiology and health. While this lack of understanding may not adversely affect treatment benefits in clinical practice, these are significant challenges that will slow the progress of scientific and medical acceptance because this will make it very difficult to establish validity and reliability of the equipment and its use.

These challenges contribute to another important issue to consider, which is practitioner training and inter-practitioner reliability. It is possible that practitioner skill can be an important factor in study outcomes, because there seems to be no objective ways to assess practitioner skills other than positive clinical effects. While this may again not be a problem for clinical practice or application, it does present a challenge for continued effective clinical research.

In summary, ONDAMED treatment represents a novel and potentially useful therapy that will hopefully be well researched in the years ahead so that many of these questions and concerns can be resolved. It is likely also that insights will be gained from a variety of research on biomagnetic field devices which will lead to a better understanding of the impacts that they may have on human health and disease.

II. General Information and Recommendations

A. Background Scientific Literature

Every year, more and more research is being done to evaluate energy medicine modalities in general and specifically the use of biomagnetic fields. This is important because it suggests that there is a steady and broad effort to examine and validate energy medicine and magnetic field therapy. As a result, many people will become familiar with these therapies. There will also be more anecdotal reports of benefits from these treatments and an accumulation of scientific reports showing benefits as well as mechanisms that may be involved. The following areas of research have been identified that can be very helpful to ONDAMED because they support the use of electromagnet therapies:

1. Magnets – static magnets. The number of studies using magnets is steadily growing. They have examined a range of disorders from arthritis to post-polio syndrome to pelvic pain (1-3).
2. Diapulse – a class III device, this is the only FDA registered electro-magnetic field device that is being used in the US as far as I know. There are several published studies (4-6). Advantages and disadvantages of Diapulse: The major advantage is that it is not operator dependent and is more objective.

The probable disadvantage is that it possibly is not as specific as ONDAMED and not as effective, but this remains to be seen.

3. Transcranial Electromagnetic Stimulation and other such devices – these just add to the general approach and general mechanisms. Still need to determine how ONDAMED compares with this and other techniques regarding how it actually works and its biophysical parameters.
4. Acupuncture and Homeopathy – support general influence of energy flow or energy influence on health.
5. Biomagnetic or Electromagnetic Field mechanism studies can be very helpful and important depending upon the audience. It is definitely important to begin from what is known and understood, and to progress slowly from there. There appear to be more devices being developed and used clinically, which may be studied and shown to be helpful.

For scientists and academic settings it may also be better to say that exact mechanisms are still being examined, rather than discussing processes or providing explanations that do not seem plausible. Some specific mechanisms are also better understood than others so these should be emphasized over others depending on the audience.

Literature searches should be conducted periodically to identify new research being done – maybe every 6 months; also to identify terms or terminology that will quickly identify studies.

B. Concise Documentation of ONDAMED Therapeutic Cases and Pilot Research Data

In this Phase I and Pilot Phase II trial conducted at the Jefferson Myrna Brind Center of Integrative Medicine (JMBCIM) there was one subject with a diagnosis of polymyalgia rheumatica that showed significant improvement when treatment options are limited and not very effective. This is an example of the kinds of cases that should be clearly documented and archived by ONDAMED. In fact, it might be useful to have an award or financial prize for the most dramatic and well-documented case or cases that a practitioner submits.

C. Subjectivity in ONDAMED Training and Treatments

ONDAMED is very operator dependent as described in the discussion section – it would be great to find a way to make this more objective. This could slow the scientific acceptance, but it also runs the risk of not producing as positive effects for clinicians as possible, and not getting as good results with research as might otherwise be possible.

This is a topic that should be revisited periodically. It may also be helpful to identify effective practitioners and trainers to get significant input and feedback that would help to address this issue.

D. Outline of Future Research

It is highly recommended to form a scientific advisory board that would meet 1-2 times per year (by phone or in person) to review what has been accomplished and what needs to be done. This is largely dependent upon the review of ongoing research for ONDAMED and general biomagnetic field research, as well as collected case reports.

Questions about how ONDAMED works, the reproducibility of it and the steady progression of the range of steps that are needed that would be important to address.

E. Summary of Recommendations to Consider

ONDAMED has made significant progress over the last few years. The following are some recommendations to consider, as well as issues that could be helpful:

- i. Try to find ways to introduce more objectivity into the use of ONDAMED.
- ii. Once or twice per year, carefully evaluate new devices and research on biomagnetic fields. What was done, how does it compare to ONDAMED, what impact might it have in general and in relation to ONDAMED treatment?
- iii. Collect effective case reports to put into your newsletter and to archive. Offer financial incentives for the best and most well documented cases, but also review them carefully from a scientific standpoint as well as interviewing the patient/subject.
- iv. Convene a scientific advisor board meeting one to tow times per year by phone or in person, perhaps at the ONDAMED meetings or conferences.

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