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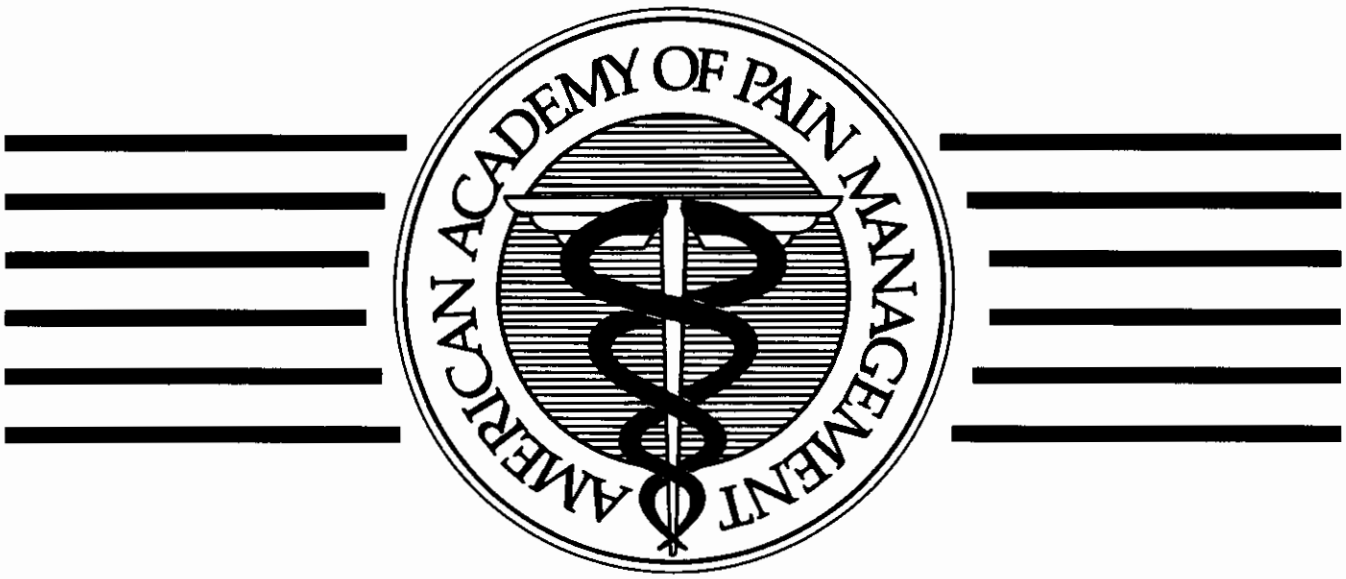

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Submitted to the *American Journal of Pain Management* on January 19, 2000 in response to:

Tan G, Monga T, Thornby J. Efficacy of microcurrent electrical stimulation on pain severity, psychological distress, and disability. *AJPM* 2000; 10(1):35-44.

To the Editor:

The recent study by Tan *et al* reported that there was no efficacy from microcurrent electrical stimulation on pain severity, psychological distress and disability among the patients he studied (1). On the surface, this seems to be a disastrous study outcome to those of us who designed and market microcurrent devices, had the study not been so fatally flawed. Much of the problem may have been due to the loss of 61% of the original randomly assigned patients in the study, which began with 28 and ended with 11. Those 11 had self-selected themselves to remain in the study and, as will be shown below, were no longer randomly distributed.

For example, in his table I (p. 39), the initial pain scores of all active and sham treated patients who remained in the study (plus one, as he lists 12 here) are seen to be significantly different ($t=2.12$, $P<0.05$, two tailed, Excel Data Analysis program) when one interpolates his 5-point pain scale to the more usual 10-point scale. The patients are all in the moderate pain range of 5 (46%) or 6 (50%), with only one scoring as high as 7 on the 10-point scale. One would suspect that an elaborate double-blind controlled pain study would not have been undertaken with a group in no more pain than this, and that the ones scoring 8, 9 and 10 had self-selected themselves out of the study. All of his subsequent, intensive statistical analyses were based on the assumption of randomized groups, which these were not after the 61% dropped out.

If one looks at the pre to post treatment scores of all the patients, one finds that the treated patients did indeed improve significantly ($t=4.59$, $P<.0001$), but surprisingly, so did the controls who were supposedly not provided treatment by the study protocol ($t=7.83$, $P<.00000008$). An outcome with this unusually high level of statistical significance is most surprising in that Tan's patients were classified as "chronic treatment failures," having been treated unsuccessfully by "a combination of surgeries, Physical Medicine and Rehabilitation, Anesthesiology, Neurology, Rheumatology, and Primary Care to no avail" (p.42). Yet now, when analyzed this way, it can be seen that these patients who were highly refractory to treatment, have experienced significant improvement by participating only as sham patients in this study. A different perspective of this is that in graduate schools students of science are taught that any time their untreated control group improves significantly they have lost control of their study and it is over.

This was a crossover design, however, in which cranial electrotherapy stimulation (CES) was used in the treatment phase. It has long been known that one can not use crossover designs in research with CES, since the effect of very little CES treatment can carry over for days, weeks, or yes, even months. Tan reports this fact on page 37 in his procedure section. We were warned about this as early as 1985 when a reviewer noted that four of five crossover design CES research projects he had found, had failed (2). This was most recently seen last year when a doctoral dissertation research project used a crossover design and originally ended up with almost nothing to show for a great deal of

work. It was later discovered that in every instance, the subjects who had CES prior to their control EEG had pretest scores significantly different from the pretest scores of those controls who had not previously had CES (3). I would have checked for this carry over effect with Tan's data in his table I, but he gave no indication how many, if any, of the 11 (or 12) patients remaining had participated in the crossover or to what extent. It may well be that every one of those reported as sham-treated had already been treated with CES and were still improving from the carry over effect of that treatment. Something had made them much better but we can not tell if it was the sham treatment because his design did not control for any placebo effect from the sham treatment condition.

Tan did note that during sham treatment, "brief electrical stimulation was provided in a random order" (p.37). He gives no additional information on the intensity or duration of this stimulation, but Jacobson reviewed studies in which a very tiny amount of current (3 picotesla) was very effective in the treatment of seven different types of chronic pain (4).

In summary, before any clinician turns his back on what, in my experience, has proven to be a highly potent, non-drug pain treatment, he might want to replicate this study. That will be exceedingly difficult under the circumstances, since even though in his method section Tan refers the reader to his design section for study details, in fact, no design section appeared in the report, so we do not know how many minutes of treatment were given over what period of time, at what intensity of current and so forth. In other words, we are not told what his treatment parameters were, but only that he found no positive results from microcurrent stimulation, to include CES on the head and electrodes at unspecified places on the body.

Those wishing more controlled insight into the effects of microcurrent CES on severe pain patients might get a copy of Lichtbroun's recent double-blind, placebo-controlled study in which 30 patients in his rheumatology practice, whose average entering pain was at or above 7 on a 10-point self-rated pain scale, were given three weeks of CES, one hour per day, at a current of 100 microamperes. The CES treated patients improved significantly, and there was no placebo effect from sham treatment (5).

A more complete review of studies involving the use of microcurrent electrical stimulation in the treatment of chronic pain patients will be available soon (6).

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Electromedicine

EFFICACY OF MICROCURRENT ELECTRICAL STIMULATION ON PAIN SEVERITY, PSYCHOLOGICAL DISTRESS, AND DISABILITY

Gabriel Tan, PhD, Trilok Monga, MD, and John Thornby, PhD

Abstract. *The purpose of this study was to assess the efficacy of microcurrent electrical stimulation on pain severity, psychological distress, and disability using a double-blind controlled crossover design. Subjects with primarily neuromuscular pain of at least 6 months duration were recruited from a tertiary care teaching hospital. All subjects received both active and sham treatment conditions with two-month washout periods following each treatment condition, but the order of the treatment assignment was randomized. Eleven of the 28 subjects completed all phases of the study*

The results indicated the absence of a significant finding on all measures tested as well as the absence of a statistically significant difference between the effects of the active versus the sham treatment. Because of the small sample size, the model of stochastic curtailed testing for interim analyses by Johnson (1990) was adapted to determine if doubling the sample size could have increased the probability of a significant finding. It was concluded that the data in this study did not support the efficacy of microcurrent electrical stimulation on pain severity, psychological distress, and disability. It was further concluded that even if the sample size was doubled, the likelihood of finding a significant difference between the active and the sham treatment would be quite low.

Descriptors. *disability, electrical stimulation, pain, psychological adjustment*

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Microcurrent electrical stimulation (MES), also referred to as cranial electrostimulation (CES), employs low-level electrical signals applied to the head and body to treat a variety of conditions. Interest in CES dates back to the early-1900s. Investigators theorized that weak impulses of direct current applied transcranially would induce a sleeplike response and lead to a calming effect on the central nervous system.

Much of the early work using CES was conducted in the former Soviet Union and Eastern Europe. Researchers claimed success in treating diverse disorders, including depression, anxiety, insomnia, and psychosis. Attention to CES in the West was stimulated by the International Symposium for Electrotherapeutic Sleep and Electroanesthesia which was held in Austria in 1966 and 1969 (1,2). However, poor study design, lack of controls, and the nature of the outcome measures generated skepticism about the claims of success (2,3).

A meta-analysis of randomized controlled trials of CES concluded that CES as a treatment for anxiety was significantly more effective than sham ($p < 0.5$) and that pooling did not affect the results that were individually

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positive (headache and pain under anesthesia) or negative (brain dysfunction and insomnia) (4). The authors indicated that in all but two trials, the therapist/experimenter was not blinded and knew which patients were receiving CES or sham treatment. The authors concluded the report by strongly urging that future trials of CES report complete data and incorporate therapist blinding to avoid possible bias. A double-blind controlled study on the use of CES to treat alcoholism showed that although both the active and the sham groups improved significantly, the CES active group showed additional benefits in reducing weekend alcohol consumption and two psychological measures (depression and stress symptoms index), but not in general drinking behavior (5).

Studies which investigated the effectiveness of CES on pain reduction are relatively scarce despite the staggering economic loss and untold human suffering due to pain, particularly chronic pain. Low back pain, for example, occurs in 50-80% of the general population of industrial societies (6). It is estimated that 97 million Americans suffer from some kind of pain, at a total cost of about 79 billion dollars per year in terms of lost work days and health care expenditures (6,7). Fortunately, a majority of acute pain episodes remit without physicians' consultations. The remainder, however, report persistent pain and prolonged disability.

Various treatment approaches have been described including acupuncture, hypnosis, biofeedback, and transcutaneous electrical nerve stimulation (*e.g.*, 8,9). Reported success rates vary from placebo levels (less than 3%) to as high as 95%. Many of these studies have methodological problems, which makes it difficult to reconcile these variations.

Recently, cranial electrical stimulation (CES) has been used in management of acute dental pain (10), pain in cancer patients (11), and chronic pain (12,13). The wave form in CES is a varying biphasic, rectangular shape of alternating current supplied by a battery with intensity of stimulation in the micro amperage range, and the best frequency is between 0.5 and 8 Hertz.

The use of CES in 23 chronic pain patients and 11 patients with long-standing depression of more than 2 years has been reported (12). Results were compared with 14 non-smoking adults with no known illnesses. Improvement in pain and depressive symptoms was noted in 44% and 60% of the patients. The authors concluded that CES may be of therapeutic value in depression and in chronic pain. No side effects were reported.

In a multicenter double-blind study of the use of CES in tension headaches, approximately 35% reduction in pain intensity in the active treatment group as compared with 18% reduction in placebo group was reported (13).

Alpha-Stim® technology was used at the Cleveland Veterans Affairs Medical Center on patients with severe head and neck cancer pain, and pain reduction in three cases was reported (11).

The mechanism of action of CES is not clear, but the manufacturer of the equipment claims that it is quite different from transcutaneous electrical nerve stimulation (TENS). It has been suggested that the significant reduction in pain and depression could be attributed to the increased production or release of endorphins after the application of CES (12).

The need for a double-blind controlled design to evaluate the efficacy of a treatment cannot be overemphasized. For instance, the research on the effectiveness of TENS, a modality somewhat similar to CES and one which has been widely used and accepted as among the standard armamentarium for the treatment of pain, when subjected to rigorous evaluation using a controlled trial, was found to be no more effective for low back pain than placebo (14). Other smaller, well-blinded trials of TENS for painful chronic conditions also showed similar negative findings (15,16). Placebo effect of TENS may also be assumed in studies showing short-term efficacy with little long-term benefits (17,18).

The present study employed a double-blind control design to examine the benefits of microcurrent electrical stimulation (MES) which includes delivery of microcurrent directly to identified pain sites in addition to the traditional CES where the current is passed through the brain. Since emotional and psychosocial effects are often associated with chronic pain, these effects were included in the outcome measures in addition to pain intensity/severity. It is hypothesized that the application of MES would lead to a significant reduction in self-

rated pain severity, psychological distress, and disability. The effects of this treatment on functional status and medication use has been reported elsewhere (19).

METHOD

Participants. Subjects were recruited from the Houston VA Medical Center, a tertiary care teaching hospital in a metropolitan region. Inclusion criteria included patients with primarily neuromuscular pain of at least 6 months duration. Except for medications, these patients were not receiving and were told not to seek other treatment for pain during the duration of the study. Exclusion criteria excluded pregnancy, fibromyalgia, use of pacemaker, inaccessible surgical scar, history of significant exposure to electricity, and chronic psychiatric problems as the predominant complaint.

A total of 28 patients enrolled in the study, but only 11 completed it, primarily due to the length of the study (see design section). For those who completed the study, the average age was 55.6 (range 45-65 years); 91% were male; 73% were White; 64% were married and 36% separated or divorced; 82% had at least a high school education; 73% were either unemployed or retired; and about one-half were receiving disability assistance due to a pain condition. Sixty-four percent had reported multiple pain sites with back pain being the most prevalent. The mean duration of pain was 15 years (ranging from 4 to 45 years), and at least 36% had prior pain-related surgeries. A double-blind, control, crossover design was used.

PROCEDURE

After signing an informed consent, each subject was randomly assigned to receive either the active or the sham treatment first, followed by a two-month wash out period, then the other treatment condition followed by another two-month wash out period. All subjects received both treatment conditions (active and sham), but the order was randomly assigned. The sham treatment was made possible by having the treatment delivered via a "black box" with two possible selections: "B" or "C". One of these selections led to receiving the active treatment, while the other choice led to receiving the sham treatment.

The treatment frequency was selected based on pragmatic considerations (*e.g.*, many patients had to travel long distances to the site), consultation with the equipment manufacturer, and a review of the literature. Although a majority of previous CES studies utilized a daily treatment frequency, several studies on pain (*e.g.*, 11,20,21) have shown that subjects did respond positively and rather dramatically, at times, to a very limited exposure of microcurrent electrical stimulation; these results did hold up over time when the patients were followed by the researchers. For instance, 40 patients who were given either real or sham MES/CES treatment for their chronic low back pain reported significant pain reduction (*i.e.*, 74% post treatment, 72% in two-week follow-up, and 67% at two-month follow-up) when given an average of 3.2 minutes of treatment, three times a week for two weeks (21). Other recommendations call for a treatment time of 20 to 40 minutes, no more than every other day (22).

Treatment conditions were of the same frequency and duration. Patients were informed that the treatment might be "sham" or real. The Alpha-Stim® 100 microcurrent stimulator (Electomedical Products International) was used as per instructions provided by the company. This equipment uses a battery to deliver 10 to 600 microamperes of adjustable current at selected frequencies of 0.5, 1.5, or 100 Hertz. For this study, 0.5 Hertz was the selected frequency used. This equipment can be used for both surface electrode applications using probes or CES application. The manufacturer modified the equipment so that the two treatment conditions could be provided independently. In the sham (placebo) condition, brief electrical stimulation was provided in a random order.

Each treatment session consisted of applying surface probe electrodes to scar tissues first (if present), followed by probe treatment of identified pain sites, then 20 minutes of CES applied by attaching electrodes to the ear lobes. There were no limits to the pain sites to be treated, but for measurement purposes, subjects were asked to rate only changes in three most painful sites as well as

overall change in pain intensity. In order to standardize the treatment delivered to the sites, standard protocols were developed and followed for each site, and the clinician providing the treatment was instructed not to solicit or provide feedback regarding any effect the treatment might have on the patient.

MEASURES

Subjects were assessed on 5 different occasions – prior to and after the first treatment condition, at two months post-first treatment follow-up, after the second treatment condition, and at two months, post-second treatment follow-up. Subjects also rated pain intensity on a scale of 0 to 5 on a Visual Analog Scale before and after each treatment session. The assessment instruments were Multidimensional Pain Inventory (MPI) and the Sickness Impact Profile-Roland Scale (SIPR) in addition to the Visual Analog Scale.

The Pain Severity Scale of the MPI measured pain severity. Psychological distress was measured by three sub-scales of MPI – Affective Distress, Life Interference, and Life Control. Increased Affective Distress and Life Interference scores and decreased Life Control score constituted psychological distress. The Sickness Impact Profile-Roland Scale and the General Activity Level of the MPI measured disability.

The Sickness Impact Profile-Roland Scale (SIPR) is a 24-item scale derived from the Sickness Impact Profile (23) which was later adapted for the assessment of disability associated with back pain (24). Research has supported the validity and reliability of this scale for assessing dysfunction and disability associated with pain in a variety of sites (25,27).

The Multidimensional Pain Inventory (MPI) is a 56-item measure divided into 3 sections to assess the impact of pain on the patient's life, the patient's view of how significant others respond to the communication of pain, and the patient's general activity level (28). The validity and reliability of the MPI has been well-established (29). In support of concurrent validity, correlation with the Beck Depression Scale, and the McGill Pain Questionnaire have been moderate to high (28,29).

DATA ANALYSIS

Change scores between pre- and post-pain ratings were calculated for each of the 12 sessions and for the average of all sessions separately for the sham and active treatments for all patients. Repeated-measures analyses of variance (ANOVA) were then applied to compare the effects of treatment on the pre/post changes for each session and overall. In addition to the effects of treatment, these analyses also accounted for differences due to patients and order of treatment in the crossover design. Effects were considered statistically significant if the test statistics were significant at the 5% level or less.

In addition, the differences (changed scores) in pain severity, psychological distress, and disability between the active and sham treatment conditions were compared using repeated-measures ANOVA. In the face of negative findings, the model of stochastic curtailed testing as proposed by Johnson for interim analyses (30) was adapted and applied to determine if doubling the sample size would have made a difference.

RESULTS

Of the 28 subjects who agreed to participate in the study, only 11 completed all phases of the study. The primary reasons cited for premature withdrawal included length of the study, scheduling conflicts, and inability to comply with the requirements of not receiving other treatments for pain (except medication) throughout the course of the study.

Table I summarizes the results of the analysis of variance which compared the effects of treatment on the pre/post changes of the Visual Analog Scale for each session and overall, as determined by the interaction between pre/post-treatment. Note that there were no significant differences in pain ratings pre/post changes between the active and sham groups. The ANOVA also indicated no significant effect due to the order of treatment.

Table I. Effects of active versus sham on changes in pain rating by treatment sessions.

Session #	Treatment conditions	Mean ± Standard Deviation Pre	Post	Change	F (1, 8)	P - Value
1	Active	2.60 ± 1.15	2.40 ± 1.20	-0.20 ± 0.65		
	Sham	3.02 ± 1.00	2.55 ± 1.39	-0.47 ± 0.97	1.49	0.26
2	Active	2.75 ± 1.11	2.52 ± 1.23	-0.23 ± 0.34		
	Sham	2.77 ± 1.06	2.40 ± 1.32	-0.37 ± 0.79	0.50	0.50
3	Active	2.98 ± 1.11	2.40 ± 1.33	-0.58 ± 0.89		
	Sham	2.85 ± 0.96	2.68 ± 1.13	-0.17 ± 0.66	2.72	0.14
4	Active	3.05 ± 1.09	2.45 ± 1.43	-0.60 ± 0.85		
	Sham	2.93 ± 1.17	2.68 ± 1.33	-0.25 ± 0.77	4.83	0.06
5	Active	2.72 ± 1.36	2.07 ± 1.58	-0.65 ± 0.79		
	Sham	3.05 ± 1.39	2.53 ± 1.53	-0.52 ± 0.84	0.27	0.62
6	Active	2.97 ± 1.18	2.30 ± 1.55	-067 ± 0.72		
	Sham	3.10 ± 1.15	2.82 ± 1.24	-0.28 ± 0.45	1.87	0.21
7	Active	3.13 ± 1.05	2.77 ± 1.44	-0.36 ± 0.66		
	Sham	2.90 ± 1.28	2.67 ± 1.44	-0.23 ± 0.42	0.41	0.54
8	Active	3.52 ± 1.18	2.92 ± 1.49	-0.60 ± 0.78		
	Sham	3.00 ± 1.40	2.67 ± 1.36	-0.33 ± 0.52	0.95	0.36
9	Active	3.10 ± 1.40	2.62 ± 1.72	-0.48 ± 0.63		
	Sham	2.90 ± 1.35	2.48 ± 1.34	-0.42 ± 0.47	0.03	0.87
10	Active	3.32 ± 1.10	2.83 ± 1.52	-0.49 ± 0.63		
	Sham	2.92 ± 1.27	2.68 ± 1.29	-0.24 ± 0.34	1.00	0.35
11	Active	3.20 ± 1.01	2.82 ± 1.28	-0.38 ± 0.76		
	Sham	2.87 ± 1.23	2.50 ± 1.47	-0.37 ± 0.54	0.05	0.82
12	Active	3.08 ± 1.00	2.88 ± 1.24	-0.20 ± 0.47		
	Sham	3.02 ± 1.34	2.48 ± 1.50	-0.54 ± 0.73	2.97	0.12
All 12	Active	3.03 ± 1.02	2.58 ± 1.35	-0.45 ± 0.55		
	Sham	2.94 ± 1.14	2.60 ± 1.27	-0.34 ± 0.48	0.62	0.45

Table II provides a comparison of the pre/post scores of the MPI and SIPR scales for each of the active and sham treatment conditions. The results of the repeated-measures ANOVA indicated no significant differences on any of the variables measured for either the active or sham conditions. Comparisons of the pre/post differences between the active and sham treatment conditions are shown in Table III. Note that on all the variables assessed, there were no significant difference found between the active and the sham treatment.

DISCUSSION

The results of this double-blind controlled study on the efficacy of MES on chronic pain clearly indicated negative findings across all the variables assessed. A major issue concerns the small sample size used which would question the validity of the findings. Increasing the sample size would have been a viable option if there had not been logistic difficulty in recruiting and maintaining participation of the subjects in this design which had required an average of 10 months to a year per subject to complete. Since this was a labor and time-intensive pilot study, it was decided to first determine statistically if increasing the sample size could result in a different finding. Therefore, the following additional analyses were conducted.

Pain intensity and negative findings. Failure to detect statistically significant effects could be due to insufficient numbers of patients in the study. Therefore, the study may not have adequate power to detect meaningful differences between treatment conditions. One way to assess the adequacy of the study design is to calculate confidence intervals for the *true difference* between treatments with respect to their pre/post change scores.

Table II. Comparison of change scores between active and sham treatments.

Variable	Treatment Condition	Pre		Post		Change		P - Value of Change Score*
		Mean	SD	Mean	SD	Mean	SD	
Pain severity	active	5.00	0.54	4.55	0.00	-0.45	0.86	0.12
	sham	4.91	0.63	4.55	1.18	-0.36	0.93	0.18
Life control	active	4.91	0.79	4.87	0.78	-0.04	0.57	0.91
	sham	5.05	0.87	4.94	1.17	-0.11	0.72	0.68
Life interference	active	3.11	0.90	3.00	0.87	-0.11	0.72	0.63
	sham	3.08	0.98	2.91	0.90	-0.17	1.27	0.52
Affective distress	active	3.73	0.90	3.58	1.27	-0.15	1.10	0.62
	sham	3.48	1.33	3.42	1.53	-0.06	0.87	0.83
General activity level	active	1.64	0.63	1.84	0.53	0.20	0.63	0.30
	sham	1.88	0.61	1.98	0.76	0.10	0.87	0.71
Disability	active	15.76	3.98	15.27	3.32	-0.45	1.63	0.42
	sham	15.00	4.56	15.00	4.96	0.00	1.26	0.97

* repeated-measures ANOVA was used.

As an example of this, the 95% confidence interval for the difference between treatments at the 12th session was:

$$(\text{Active - Sham}) = 0.33 + 0.49 = (-0.16, 0.82)$$

That is, with 95% confidence, the pre/post improvement for the *active* treatment was at most 0.16 units greater than that of the *sham* treatment and 0.82 units less than that of the sham treatment. Likewise the most likely outcome was that the active treatment is 0.33 units worse than the sham treatment. Comparable results were obtained for the other sessions and overall.

The authors wondered what the chance might be of finding significant differences between treatments by doubling the number of patients. To explore this question, the model of stochastic curtailed testing for interim analyses was adapted (27). We hypothesized that the true pre/post improvement of active treatment as compared to that of sham was equal to 10% of their combined pre-treatment mean value. We also assumed that the true random error standard deviation was as calculated in the paired difference t-test analysis. Then, based on this hypothesis and assumption, the approximate probabilities of finding a significant difference between the active and the sham treatments were computed and the results shown in Table IV. Note that for every assessment measure used, the probability of finding a significant difference between the two treatment conditions is quite low. It is, therefore, concluded that even if we were to double the sample size to N = 22 (which is quite substantial for a crossover design) and assuming a true difference of 10% between the active and sham treatments as defined above, the likelihood of finding a significant difference between the treatments would remain quite low. It was decided that continuing this study by increasing the sample size would not have been cost effective given the low probability of finding a significant difference.

Table III. Comparison of the effects of active versus sham treatment.

Variable	Active*	Sham**	Difference	F (1,9)	P - Values
Pain severity	-0.45	-0.36	-0.09	0.01	0.93
Life control	-0.04	-0.11	0.07	0.25	0.63
Life interference	-0.11	-0.17	0.06	0.12	0.74
Affective distress	-0.15	-0.06	-0.09	0.05	0.83
General active level	0.20	0.10	0.10	0.07	0.79
Disability	-0.45	0.00	-0.45	0.53	0.49

* pre/post changes in mean scores for the active treatment.
** pre/post changes in mean scores for the sham treatment.

Negative findings in the primary outcome measures. Alternate data analyses for the outcome measures in this paper would neglect treatment order, use baseline-to-post-treatment change score for each treatment as the raw data, and compare the active versus sham treatments by two-tailed paired difference t-tests. For example, the mean change scores for Pain Severity were -0.45 and -0.36 for active and sham treatments respectively, favoring the active treatment by 0.09 units. The paired difference t-test would result in t = 0.25 (p = 0.81), similar to that of the ANOVA, clearly a non-significant difference between treatments.

Table IV. Probability of significant findings by doubling the sample size.

Variable	Difference score from Table III	Hypothesized true difference*	Probability of findings significant difference **
Pain severity	-0.920	-0.5	0.10
Life control	-0.065	-0.5	0.41
Life interference	0.053	-0.3	0.03
Affective distress	-0.900	-0.4	0.04
General active level	0.104	0.2	0.02
Disability	-0.455	-1.5	0.50

* hypothesized true superiority of active over sham treatment was approximately 10% of the pre-treatment values.

** based on a two-tailed t-test. This value may be interpreted as one would the power statistic (a value less than 0.80 would be considered weak).

Generalizability to other population. The results of this study should be generalized with caution, since the sample consisted of a primarily White male veteran population. A factor, which might have biased the results towards negative findings, may be the chronicity of the pain conditions. About three-quarters of the subjects were unemployed or retired; half were receiving disability; 64% had multiple pain sites; the mean duration of pain was 15 years; and at least 36% had prior pain-related surgeries. Moreover, a majority of the subjects could be classified as *chronic treatment failures*, a finding that has typically been assessed and treated by a combination of surgeries, Physical Medicine and Rehabilitation, Anesthesiology, Neurology, Rheumatology, and Primary Care to no avail. The issue of prognosis with variability among chronic pain patients has been discussed and showed that education, employment, previous surgeries, narcotics, and favorable personality profiles could significantly influence treatment outcomes as well (28).

Efficacy versus effectiveness. It is important to draw a distinction between the efficacy and the effectiveness of a treatment. It is generally well-known and accepted in the practice of medical science that the effectiveness of any treatment is closely tied to the practitioner-patient relationship and the expectation of cure/symptom relief on the part of the patient. The double-blind controlled nature of this study may have interfered with the development of this patient-clinician relationship. For instance, in normal clinical application, the probe treatment of the pain site would be varied in location, frequency, and intensity, depending on the feedback received from the patient. Furthermore, acknowledging and verbally reinforcing any feedback of positive change often lead to increased expectation of treatment efficacy. None of these practices was allowed in this study.

All except one of the previous studies on pain using MES/CES which were reviewed in this paper would fit the category of clinical application or research, rather than a double-blind controlled studies. Thus, the positive or promising findings may have been partially influenced by the factors previously discussed.

The results of this study merely question the efficacy of MES as a sole treatment for chronic, debilitating, and refractory pain. However, they do not negate the possibility or probability that in the hands of a skilled clinician, the use of MES/CES could lead to reported benefits and positive outcomes. As has been previously pointed-out

in this paper, a similar situation currently exists with the use of transcutaneous electrical stimulation (TENS). That is, it is clinically useful and relevant yet lacking in efficacy when scrutinized by a double-blind controlled format.

Future research could utilize a less chronic pain population representing a broader range of demographics including ethnicity, gender, age, and employment status. Selecting subjects based on personality variables may also be relevant (29).

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