Tan, Gabriel, Monga, Trilok, and Thornby, John. **Efficacy of microcurrent electrical stimulation on pain severity, psychological distress, and disability.** American Journal of Pain Management, 10(1):35-44, 2000.

Unedited Published 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 preliminary 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 randomize. 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 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 sham treatment would be quite low.

Rebuttal:

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 (see The Science Behind Cranial Electrotherapy Stimulation , pages 123-126, Comments on Followp-Up From All CES Research Studies). 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).

REFERENCES

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