Cranial Application of Low Level Transcranial Electrotherapy vs. Relaxation Instructions in Anxious Patients

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ABSTRACT

A comparative study was conducted using relaxation instructions vs. low level transcranial electrotherapy (Alpha-Stim) as short term treatments for anxiety. Sixty-four subjects reporting feelings of generalized anxiety were randomly assigned to relaxation instuctions, transcranial electrotherapy (TCET), both treatments given simultaneously, or no treatment groups. Subjects were monitored pre- to post-treatment with both subjective (State-Trait Anxiety Inventory) and objective (electromyograph readings of frontalis muscle tension) measures of their anxiety. The results indicate that all three methods of treatment were significantly more effective than placebo in reducing state anxiety and EMG readings of muscle tension. Neither treatment was significantly more effective than the other and pairing the two treatments proved to offer no additive effects.

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The construct of anxiety plays a central role in nearly all therories of psychology. Kutash estimated that approximately 50 million people in the United States suffer from neurotic problems.[1] Anxiety neurosis is the most common of the various neurotic patterns, making up 30 to 40 percent of all neurotic disorders.[2,3,4,5] This disorder is characterized by fears and feelings of apprehensiveness which do not appear to stem from any well defined threat.

Wolpe and Lazarus, have defined the most common symptoms of general anxiety as an inability to concentrate, difficulty in making decisions, extreme sensitivity, discouragement, sleep disturbances, excessive sweating and sustained muscle tension.[6,30] More recently these symptoms have been updated in the DSM III criteria for Generalized Anxiety Disorder (300.02).

For many years numerous researchers have explored nonpharmacological methods to use in the treatment of anxiety. Biofeedback training has shown promise with extensive research.[7,8,9] Biofeedback uses intrumentation to monitor various aspects of physiology, and then feeds such data back to the person, allowing them to learn to control themselves. In addition to the instrumentation approach for biofeedback there is the development of general and progressive relaxation training procedures that work towards a general overall release of muscular tension to reduce anxious feelings and symptoms.[10,11,12,13]

Recent research suggests that the most beneficial effect of all relaxation training procedures is the ability to obtain deep muscle relaxation.[14,15,16] Recent studies indicate that general relaxation procedures can be just as effective as biofeedback.[14,15,17,18]

Advances in electromedical technology also appear to offer a new, short term, treatment for symptoms of general anxiety without the long training efforts of biofeedback. Transcranial electrotherapy, also known as cerebral electrostimulation (CES), "electrosleep" and "alphasleep" is a treatment technique which was developed in the USSR and began to gain some popularity in this country in the 1970's.[19] Rosental reviewed existing literature on TCET and electrosleep, a technique which uses an intermittent low level electrical current (0.4 milliamperes or less) to induce a "relaxed but conscious state" in psychiatric patients.[20] He concluded that this form of treatment is an effective and humane treatment which deserves more thorough exploration. Smith, O'Neill, and Furst list some of the effects which have been attributed to TCET.[21,22,23] These are largely in the catagory of general relaxation, reduction of arousal, or parasympathetic shift.

This study was designed to test the newest electromedical technology (Alpha-Stim) on the market as a treatment modality for subjects with general anxiety and to compare it with the effects of traditional relaxation instructions on the same population.

MATERIALS AND METHODS

Sixty-four subjects completed the study. Nine out of the original 73 subjects were dropped from the study due to failure to meet the study criteria or for failure to show for their treatment sessions. All subjects were non-paid volunteers who responded to advertisements in local newspapers. There were 32 males and 32 females. Each of the four study groups were balanced for males (8) and females (8) for a total of 16 subjects in each group. The subjects ranged in age from 22 to 55 years with a mean age of 36.64.

The State-Trait Anxiety Inventory (STAI) developed by Speilberger, Gorsuch, and Lushene was used as the subjective self-report measurement of feelings of generalized anxiety.[24]

The Bio-Process Systems Model 400 portable EMG biofeedback instrument was employed to monitor the frontalis muscle tension of all subjects. This apparatus offers an "analog output" mode which was interfaced with an Apple II computer to record and analyze the EMG data. The EMG readings were taken via electrodes placed on the frontalis muscle of each individual subject.

The Alpha-Stim 350 manufactured by Electromedical Products, Inc. was selected for use in the study because it uses a microampere, randomized biphasic direct current through remote electrodes. The short-term (10 to 20 minutes) "alpha conditioning" mode of this unit is recommended for inducing relaxation.[25]

PROCEDURE

Research subjects were scheduled for an interview/treatment session at which time they filled out an information form, informed consent, and a pre-treatment STAI. Subjects scoring 50 or above on the state anxiety scale (that is, on standard deviation above the mean) were considered as "anxious" and thus qualified for inclusion in the study. Subjects, matched by gender, were then randomly assigned to one of the four groups: relaxation instructions, TCET, both treatments simultaneously, or a no treatment control group.

Each subject had an individual session with the experimenter. All subjects in all groups were monitored by baseline, pre-treatment, and post-treatment readings using frontalis EMG with three electrodes placed on the forehead area. All subjects in all groups also had the Alpha-Stim electrodes attached bilaterally to their ear lobes. Preliminary pilot studies had shown no interference from the Alpha-Stim on frontalis EMG readings.

Treatment sessions consisted of subjects listening to 20 minutes of relaxation instructions played on a tape recorder, receiving TCET treatment, or both simultaneously. The control group listened to 20 minutes of a neutral tape with the TCET off. The subjects receiving the TCET treatment for relaxation were unaware of the current since the treatment is below the level of sensation when the unit is properly set at 0.5 Hz frequency and 50 microamperes intensity as it was for this study. All subjects then filled out a post-treatment STAI.

RESULTS

Table 1 displays the summary of the means of the state anxiety raw scores for the three experimental groups and the control group. The mean difference score indicates a clear pre-treatment to post-treatment decrease in state anxiety scores across the treatment groups with only a slight change in the control group.

Table 1. Summary of the Means of the State Anxiety Raw Scores for the 3 Experimental Groups and the Control Group

Groups	Pre-test	Post-test	Main Difference
Relaxation	52.88	32.19	20.69
Alpha Conditioning	52.31	30.06	22.25
Both Treatments	53.69	30.44	23.25
Control Group	53.25	51.94	1.31

Table 2 summarizes the results of the Analysis of Variance for state anxiety among the four groups. The variance over time (pre- to post) was highly significant ($p < .001$). This suggests that there is a significant difference between the pre-treatment and post-treatment measures within the subject sample as a whole. The significant group X time interaction term indicates that the change over time differs among groups. The significant change occurred in the three treatment groups but not in the control group.

Table 3 shows the summary of means of the EMG scores taken pre-treatment to post-treatment for all 4 groups. There are obvious pre- to post downward changes in the three treatment groups with the minimal increase in the control group.

Table 4 verifies that these are significant changes. The Analysis of Variance for EMG scores among the groups shows highly significant F-ratios for the time variance term and the group X time interaction term.

Specific group vs. group comparisons were carried out by using Tukey tests for pair-wise comparisons (Table 5). This table again shows that all 3 treatment groups have significantly greater change then the control group. Table 5 also shows that none of the treatments was significantly more effective than the other two and that pairing the two treatments did not offer any significant additive effect.

DISCUSSION

The core purpose of the study was to examine the possible efficacy of TCET treatment and compare it to an established behavioral therapy (relaxation instructions). The null hypothesis of the study was that there would be no significant difference between any of the four groups. This hypothesis

Table 2. Summary of the Two Way Analysis of Variance with One Repeated Measure for State Anxiety Among the Four Groups

Source	SS	df	MS	F
Between Subjects	5338.87			
Groups	2760.44	3	920.15	21.41**
Error	2578.44	60	42.97	
Within Subjects	12842.00			
Time	9112.50	1	9112.50	488.42**
Group × Time	2610.06	3	870.02	46.63**
Error	1119.44	60	18.66	
Total	18180.87	127		

**P<.001

Table 3. Summary of the Means of the EMG Raw Scores for the 3 Experimental Groups and the Control Group

Groups	Pre-test	Post-test	Main Difference
Relaxation	15.64	11.10	4.54
Alpha Conditioning	17.12	11.17	5.95
Both Treatments	17.41	9.77	7.64
Control Group	14.14	14.47	−.33

Table 4. Summary of the Two Way Analysis of Variance with One Repeated Measure for EMG Scores Among the Four Groups

Source	SS	df	MS	F
Between Subjects	1290.38			
Groups	18.92	3	6.31	.298
Error	1271.48	60	21.19	
Within Subjects	1242.14			
Time	634.43	1	634.43	116.85**
Group × Time	281.93	3	93.98	17.31**
Error	325.78	60	5.43	
Total	2532.51			

**P<.001

Table 5. Summary of Tukey Tests for Pair Wise Comparison

Groups Compared	State Anxiety	EMG
1 vs. 2	1.0199	.6514
1 vs. 3	1.6827	2.6310
1 vs. 4	12.6889**	5.1701**
2 vs. 3	.6628	1.9796
2 vs. 4	13.7087**	5.8215**
3 vs. 4	14.3715**	7.8011**

**P<.01
Group 1 = Relaxation Group
Group 2 = Alpha Conditioning Group
Group 3 = Both Treatments Group
Group 4 = Control Group

was rejected since all three treatment procedures were significantly effective in reducing the subjective and physiological correlates of anxiety in a subject population reporting symptoms of generalized anxiety. It was further noted that none of the three active treatment procedures proved to be significantly more effective than the other two.

How can mild electrical stimulation to the cranial area bring about feelings of relaxation? Several possible explanations can be hypothesized from the extensive research in the use of TENS units in pain treatment. Recent pain research has shown that electro-stimulation of cerebral structures may involve the endorphinergic system as an analgesic mechanism.[26] Sjolund and Erikson were able to identify the rise of the endorphin levels in the cerebral spinal fluid after electro-

acupuncture treatment.[27] The question is, can the endorphins be therapeutically released via electro-stimulation in subjects not suffering from pain? The answer appears to be yes. Saler, Job, Mingrino, Bossio and Trabucci found that transcutaneous electrical stimulation may induce an analgesic effect by modulating the activity of the endorphinergic system in non-pain subjects.[28] It is therefore possible that the type of electrotherapy used in this study may have triggered the release of brain endorphins in the subject population.

Another possible explanation is suggested by Newland.[25] He proposed that alternating current from an electromedical device may produce a rhythmic pacemaking effect on brain-wave patterns, changing them to an alpha brainwave range. He labeled this effect the "alpha conditioning" treatment.

In 1965 Melzack and Wall postulated their gate theory by nerve path transmission of pain.[29] The gate theory proposed that the non-pain carrying myelinated A-fibers can block transmission of pain by the non-myelinated C-fibers. This is produced by synaptic inhibition. Later, a second "gate" was postulated to exist at a higher level in the brain stem. Various stimuli may be blocked from input to the brain through the use of electical stimulation to the descending reticular activating system which plays a role in controlling the arousal level.

Regardless of the specific mechanisms, the results of this study indicates that the Alpha-Stim may be a useful adjunctive therapy for short term treatment of symptoms of anxiety. The treatment appears to have about the same efficacy as the same amount of time of relaxation instructions, but is easier to administer.

REFERENCES

1. Kutash, S.: *Psychoneuoses.* In: B.B. Wolman (Ed.), Handbook of Clinical Psychology. New York: McGraw-Hill, 1965.
2. Eiduson, B.T.: "The two classes of information in Psychiatry." *Archives of General Psychiatry,* 1965, 18, 404-419.
3. Goodwin, D.W., Guze, S.B. and Robbins, E.: "Follow-up studies in obsessional neurosis." *Archives of General Psychiatry,* 1969, 20, 182-187.
4. Kenyon, F.E.: "Hypochondriasis: A survey of some historical, clinical and social aspects." *Intl. J. Psych.,* 1966, 2, 308-325.
5. Marks, I. and Lader, M.: "Anxiety states (anxiety neurosis): A review." *Journal of Nervous and Mental Diseases,* 1973, 156, 3-18.
6. Wolpe, J.: *Psychotherapy by Reciprocal Inhibition.* Stanford: Stanford University Press, 1958.
7. Brown, B.: *Stress and the Art of Biofeedback,* New York: Harper and Row, 1977.
8. Budzynski, T.G.: "Biofeedback procedures in the clinic." *Seminars in Psychiatry,* 1973, 5, 537-547.
9. Mulholland, T.B.: "Biofeedback as scientific method." In G.E. Schwartz and J. Beatty (Eds.), *Biofeedback Theory and Research.* New York: Academic Press Inc., 1977.
10. Benson, H.: *The Relaxation Response.* New York: William Morrow & Co., Inc., 1975.
11. Bernstein, D.A. and Borkevec, T.D.: *Progressive Relaxation Training: A Manual for the Helping Professions.* Chicago: Research Press, 1973.
12. Jacobson, E.: *"Progressive Relaxation."* Chicago: The University of Chicago Press, 1938.
13. Jacobzon, E.: *Anxiety and Tension Control: A Physiologic Approach.* Philadelphia: J.B. Lippincott Company, 1964.
14. Cott, A.: "The long term therapeutic significance of the addition of electromyographic biofeedback to relaxation training in the treatment of tension headaches." *Behavior Therapy,* 1981, Vol. 12, 4, 556-559.
15. Burish, T.G. and Hendrix, E.M.: "Importance of relaxation instructions in the EMG biofeedback training package." *Journal of Psychosomatic Research,* 1980, 24, 137-145.
16. Lehrer, P.M. and Shapiro, S.: "Psychophysiologic effects of autogenic training and progressive relaxation." *Biofeedback and Self-Regulation,* 1980 (Jun.), 5, 249-255.
17. Sisson, R.W.: "The effect of three relaxation procedures on tension reduction and subsequent drinking of inpatient alcoholics." *Dissertation Abstracts International,* 1981, 42, 2085B-2086B.
18. Chavous, A.S.: "Biofeedback assisted relaxation and relaxation alone: Effects on headache symptoms, affect and cognitions." *Dissertation Abstracts International,* 1982, 42, 2086B.
19. Brown, C.C.: "Electroanesthesia and electrosleep." *American Psychologist,* 1975, 30, 402-410.
20. Rosenthal, S.H.: "Electrosleep as a therapeutic treatment." *Comments on Contemporary Psychiatry,* 1971, (Jul.), 1, 25-33.
21. Smith, R.B.: "The use of cerebral electrostimulation in the treatment of alcohol addiction: a review." Reported in E. Weingarten, The effect of cerebral electrostimulation on the frontalis electromyogram. *Biological Psychiatry,* 1981, 16, p.61.
22. Smith, R.B. and O'Neill, L.: "Electrosleep in the management of alcoholism." *Biological Psychiatry,* 1975, 10, 675-680.
23. Furst, W.: "Use of the neuromod transcutaneous nerve stimulation in psychiatry: An electrical alternative to acupuncture?" *Research Communications in Psychology, Psychiatry & Behavior,* 1976, 1(1), 143-148.
24. Spielberger, C.D., Gorsuch, R.L. and Lushene, R.E.: *STAI Manual for the State-Trait Anxiety Inventory.* Palo Alto: Consulting Psychologists Press, Inc., 1970.
25. Newland, A.J.: *Electro-medical Therapeutics: A Guide to its Clinical Application.* Century Medical Distributors, 1977.
26. Hosobuchi, Y., Adams, J.E. and Linchitz, R.: "Pain relief by electrical stimulation of the central gray matter in humans and its reversal by naloxone." *Science,* 1977, 197, 183-186.
27. Sjolund, B. and Erikson, M.: "Electro-acupuncture and endogenous morphines." *Lancet,* 1976, 1085.
28. Salar, G., Job, I., Mingrino, S., Bosio, A. and Trabucchi, M.: "Effect of transcutaneous electrotherapy on CSF B-Endorphin content in patients without pain problems." *Pain,* 1981, 10, 169-172.
29. Melzack, R. and Wall, P.D.: "Pain Mechanisms: A new theory." *Science,* 1965, 150, 971-979.
30. Lazarus, A.: "The results of behavior therapy in 126 cases of severe neurosis." *Behavior Research and Therapy,* 1963, 1, 69-79.