

TRANSCRANIAL ELECTROTHERAPY

LOW-INTENSITY TRANSCRANIAL ELECTRO-STIMULATION IMPROVES THE EFFICACY OF THERMAL BIOFEEDBACK AND QUIETING REFLEX TRAINING IN THE TREATMENT OF CLASSICAL MIGRAINE HEADACHE

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Thermal biofeedback and Quieting Reflex training have been shown in many studies to provide effective treatment for classical migraine headache. This study, using the Alpha-Stim 2000 electrostimulation device, shows that the addition of low-intensity cranial electrotherapy stimulation (CES) to thermal biofeedback (TB) and Quieting Reflex training (QR) resulted in faster relief from headache symptoms.

A double-blind group study was employed; 36 female subjects with classical migraine were assigned to groups randomized on the basis of age and severity of headache symptoms.

Statistical comparisons (t-tests) showed that the group treated with combined CES, TB and QR resulted in faster decreases in headache symptoms, particularly during a 3-month follow-up period.

Those groups in this study who did not receive the CES treatment were subsequently treated with the CES. They, in turn, achieved headache reductions comparable to those obtained by the combined CES, TB, and QR group in this study.

The author hypothesizes that CES benefits migraine sufferers through its affect on the hypothalamus, which is thought to regulate and normalize blood flow. The mechanism by which CES affects the hypothalamus is not currently known.

INTRODUCTION

A popular non-pharmacological, electro-medical treatment for classical migraine headache is thermal biofeedback training (TB) enhanced by relaxation techniques as exemplified by the Quieting Reflex (QR) audio cassette program. Many researchers and clinicians report a 70 to 85% success rate using biofeedback for headache treatment.^{1,2,3,4}

The question arises as to whether the addition of certain supplementary techniques to the biofeedback training would lead to further clinical benefits in the treatment of migraine.

Several studies in the literature point out the benefits of low-level CES for various clinical applications.^{5,6,7} Cranial electrotherapy stimulation has been used to reduce pain and is considered beneficial for multiple disorders (e.g., headaches, anxiety syndromes, sleeplessness, and low back pain).

This investigation was undertaken to determine the benefits of the addition of CES to TB and QR treatment of migraine.

BIOFEEDBACK THERAPY

Biofeedback involves the monitoring of body functions and displaying them in such a way that the patient or client can learn to exert voluntary control. The body functions typically monitored and displayed are the electrical activity of the muscles

(EMG) and brainwaves (EEG), peripheral skin temperature, sympathetic nervous system activity (GSR or Galvanic Skin Response), heart or pulse rate, and blood pressure.

The primary biofeedback modality for vascular (migraine) headache treatment is temperature feedback from the hands (hand warming). The hand warming is thought to help control the vascular irregularities in the cranium that result in migraine pain. This may be a hypothalamic mediated effect. The hand warming may affect the hypothalamus which is believed to be intimately involved with the regulation and normalization of blood flow.

Hand warming alone has been the preferred clinical approach for vascular headache ever since Dr. Elmer Green reported the same benefits could be derived from hand warming alone as from the head cooling, hand warming procedure.⁸

A secondary biofeedback modality for vascular headache is electromyography (EMG) from the head area. Here it is assumed that some small part of the migraine pain is due to excess muscle contraction. Electromyographic values were monitored but not fed back to the subjects in the present study.

QUIETING REFLEX TRAINING

An audio cassette program, *Quieting Reflex Training for Adults* (Stroebel, 1982) is widely used by clinicians in conjunction with biofeedback training. It is used for the relief of a variety of stress-related conditions. Quieting Reflex (QR) integrates biofeedback with diaphragmatic breathing exercises, progressive muscle relaxation, autogenic techniques and mental imagery.

REPORTS OF COMBINED THERMAL BIOFEEDBACK, QR AND CES EFFICACY

There are indications in the literature that combined TB, QR and CES training is more effective than any one of the treatments alone.

In a study, J. Whitney Kelley summarizes his finding in the following manner:⁹

"With the over 50 cases in which cerebral electrical stimulation, thermal biomedical feedback and psychotherapeutic relaxation phrases have been used concurrently there is a large enough statistical sample to allow us to infer some trends. Each of the three modalities have therapeutic values individually. Together they seem to synergize each other.

The time necessary to reach therapeutic response seems to be markedly shortened, and the persistence of results appear to be lengthened over the results achieved by either of the modalities alone. The continued use of audio tape cassettes with the therapeutic phrases helps very much.

This method is pleasant to the patient, has practically no risk, has none of the bad side effects and is far less expensive to the patient than conventional treatments. Hospitalization generally can be avoided."

EQUIPMENT USED

The CES equipment used was the Alpha-Stim Model 2000GL (supplied by Electromedical Products, Inc. and distributed by Biofeedback Instrument Company, New York). The CES equipment is calibrated in microamperes. The wave type of the Alpha-Stim unit is a unique biphasic direct current with positive and negative interacting phases. The frequency is variable from 0.5 to 320 Hz and the output current from 25 to 500 microamperes. Only the 0.5Hz frequency was used for the CES treatment in this study.

The Bio Comp 2001, a full-featured computerized biofeedback system, was used for all the biofeedback training. Both audio and color monitor visual feedback of bilateral finger temperature was provided to the subjects. The temperature measurements were calibrated in degrees Fahrenheit (the Bio Comp 2001 has an accuracy of plus or minus 0.01°F), and the EMG in RMS (root mean square) microvolts.

SUBJECTS

Thirty-six female subjects ages 18-40 diagnosed as having "classical migraine, ICD-9-CM 346.0" (clear prodromata, cold extremities, scintillating scotoma or blurred vision prior to headache pain, etc.) were assigned to three similar groups based on age and severity of headache symptoms.

METHOD

All groups received thermal biofeedback training. One group also received QR, but placebo CES (Group 1), another received both QR and active CES (Group 2), and the third active CES, but no QR (Group 3) (Table 1). The application of CES was performed in a double blind manner by advancing the intensity control of the CES instrument, with the audio off, to the point where "pin pricking" sensations were experienced, and then reducing the level until no pricking sensations were felt; for the placebo CES subject, the instrument

TABLE 1. TREATMENT RECEIVED BY 3 STUDY GROUPS

GROUP 1	GROUP 2	GROUP 3
TB	TB	TB
QR	QR	CES
PLACEBO CES	CES	

TABLE 2. RESULTS OF t-TESTS BETWEEN GROUPS 1 (PLACEBO CES) AND 2 (ACTIVE CES) ON F×I SCORES

VARIABLE	MEAN DIFF.	t _{obt}	SIG AT 0.10 (ONE-TAIL TEST)
1 F×I Session 8	-0.17	0.08	No
2 F×I 1 Month	1.42	1.49	Yes
3 F×I 2 Months	1.25	1.63	Yes
4 F×I 3 Months	0.50	1.36	Yes

RESULTS OF t-TESTS BETWEEN GROUPS 2 (QR) AND 3 (NO QR) ON F×I SCORES

VARIABLE	MEAN DIFF.	t _{obt}	SIG AT 0.10 (ONE-TAIL TEST)
1 F×I Session 8	-1.83	0.88	No
2 F×I 1 Month	-6.50	3.83	Yes*
3 F×I 2 Months	-8.42	4.40	Yes*
4 F×I 3 Months	-8.58	4.31	Yes*

Note: All results involve df = 22
 * Also significant at alpha = 0.05

TABLE 3. DESCRIPTIVE STATISTICS ON DEPENDENT VARIABLE F×I

VARIABLE	GROUP 1	GROUP 2	GROUP 3
1 Mean F×I Initial	15.33	14.42	14.00
2 SD F×I Initial	6.62	6.26	4.56
3 Mean F×I Sess 8	4.33	4.50	6.33
4 SD F×I Sess 8	4.46	5.30	4.38
5 Mean F×I 1 Mo	2.42	1.00	7.50
6 SD F×I 1 Mo	2.75	1.53	5.42
7 Mean F×I 2 Mo	1.67	0.42	8.83
8 SD F×I 2 Mo	2.43	0.76	6.30
9 Mean F×I 3 Mo	0.58	0.08	8.67
10 SD F×I 3 Mo	1.19	0.28	6.60

was turned off by an assistant without knowledge of the clinician or subject.

It was statistically determined that all three groups were adequately randomized so that the groups did not differ initially in terms of age, headache onset age, headache monthly frequency, headache intensity, baseline frequency intensity product and medication levels.

Both audio and color monitor visual feedback of finger temperature from the dominant hand were provided to the subjects.

The CES device was set at a 0.5Hz frequency with the current set as above.

The groups received eight treatment sessions and three follow-up sessions. First session finger temperature baselines of 70°-73°F were recorded for all groups. The subjects of each group (on average) were able to achieve 95° finger temperature values by the eighth treatment session.

RESULTS/DISCUSSION

Figure 1 shows the change over time of F×I, a measure of headache symptoms, where F is the frequency and I the intensity of the migraine. The values for F×I are those charted during the week prior to the sessions. Figure 1 shows that the TB, QR, and active CES (Group 2) demonstrated faster relief from headache symptoms than the other groups, particularly at follow-up months 1, 2 and 3. Table 2 shows significant differences between groups 1 and 2 and groups 2 and 3; Table 3 shows comparison of the means of F×I.

Faster relief can be a positive motivating factor in that it may deter the headache sufferer from seeking an increase in medication levels during the follow-up period (prior to receiving the full headache reduction effects of the treatment).

The QR groups both demonstrated greater persistence of training effects than the no-QR groups. That is, F×I was lower in those two groups even after the QR training had "stopped" (cf. Table 2, particularly the mean F×I values reported during the follow-up sessions). Biofeedback and active CES without QR may not offer adequate cognitive-restructuring cues to perpetuate headache reduction effects. The results of this study suggest that QR adds some of these cognitive-restructuring cues, while CES augments the learning of these cues.

It was observed that only the active CES/QR group demonstrated a fast rise to high temperatures (over 95°), and maintained those high temperature values for the remainder of the eighth session. The active CES/no-QR group also demonstrated a fast rise to 95°, but did not maintain those values. The placebo CES group took most of the session time to reach 95°.

As stated above, the initial baselines for all three groups varied from 70° to 73°F. It was noted that by the eighth session, only the groups that received CES showed significant carry-over effects in terms of finger temperature, that is, by the eighth

session, only Groups 2 and 3 raised their finger temperature baselines significantly (to 86° and 81°, respectively). It is probable that the members of the active CES groups reached a new homeostasis in terms of their ability to maintain warmer finger temperatures. The TB, QR, placebo CES group did not show the carry-over effect. According to Charles Stroebel, Ph.D., M.D., author of *The Quieting Reflex for Adults*, QR training generally takes up to six months to produce finger temperature carry-over effects.¹⁰

Cranial electrotherapy stimulation may contribute to both the rapid rise in finger temperature during each session and homeostatic rise in finger temperature through its effect on the hypothalamus. The mechanism by which CES affects the hypothalamus is currently not known, but hypotheses do exist.¹¹ The hypothalamus is believed to be intimately involved with the regulation and normalization of blood flow.

SUBSEQUENT TREATMENT

Those groups which did not receive the CES treatment were subsequently treated with CES. They, in turn, achieved headache reductions comparable to those obtained by the combined TB, QR, CES group in this study.

SUMMARY

The results of this study lend support to the conclusion that CES is beneficial as an adjunct to thermal biofeedback in the treatment of classical migraine headache. The addition of cranial electrotherapy stimulation therapy to thermal biofeedback and Quieting Reflex Relaxation Training provided significantly faster relief from headache symptoms. □

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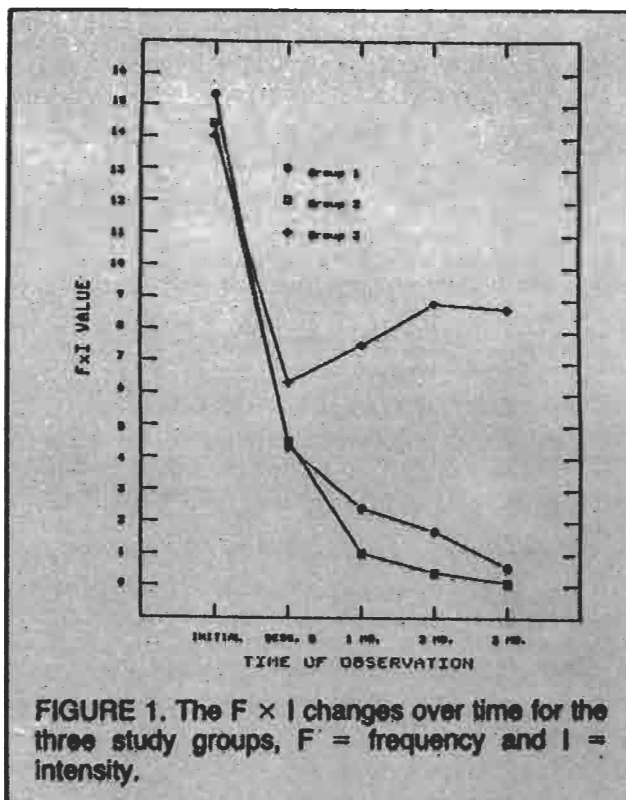


FIGURE 1. The $F \times I$ changes over time for the three study groups, F = frequency and I = intensity.

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