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Skin Temperature Biofeedback and Migraine Headaches

A Double-Blind Study[1]

Donald Kewman[2]
University of Michigan

Alan H. Roberts
Scripps Clinic and Research Foundation

To assess the relative contribution of specific and nonspecific effects of skin temperature biofeedback upon migraine headache, 11 migraine patients were taught to increase the temperature of their hand. Training to decrease the skin temperature of the hand served as a control for 12 other migraine patients. An additional 11 control subjects were not trained but kept records of migraine activity. Under carefully controlled double-blind procedures, migraine patients who learned to raise finger temperatures showed statistically significant and clinically therapeutic improvement during a 6-week follow-up period. However, they were not significantly better than those trained to lower finger temperatures, those who did not meet a learning criterion, or those receiving no training. While these groups did show some significant improvement when compared to subjects who

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[2]Address all correspondence to Donald G. Kewman, University of Michigan, Department of Physical Medicine and Rehabilitation, University Hospitals, Ann Arbor, Michigan 48109.

learned to decrease finger temperature, the results are most parsimoniously explained through nonspecific rather than specific factors. The necessity of using double-blind procedures in evaluating therapeutic effectiveness is again stressed.

Headaches are among the most frequent of chronic pain problems. Ninety percent of chronic headaches are vascular headaches of the migraine type, muscle tension headaches, or a combination of both (Friedman, 1964).

Migraine headaches are the most extensively studied of the common headache syndromes but the pathophysiology of the disorder is poorly understood. The headache is polysymptomatic, women appear to be more frequently affected than men, and a family history is present in approximately 65% of cases. While the significant family history component of the headache is often presumed to support a partial genetic etiology, recent evidence of the susceptibility of the peripheral vasomotor system to operant learning (cf. Miller, 1978; Roberts, Kewman, & Madconald, 1973; Roberts, Schuler, Bacon, Patterson, & Zimmermann, 1975), as well as evidence of a significant learning component in any chronic pain problem (Fordyce, 1976; Roberts, 1980), suggests that learning may also play an important role.

Generally, migraine is thought to be related to a dysfunction of the cranial arteries, with vasoconstriction of the cerebral arteries prior to the onset of headaches followed by dilation and distension of the external carotid arteries during the headache phase (Schumacher & Wolff, 1941). Most treatment modalities appear to be directed toward the vasodilation phase of the disorder, which is accompanied by pain, rather than the prodromal vasoconstrictive phase. It is possible that various treatments that include relaxation or hand-warming training, by reducing sympathetic arousal, may be effective by reducing vasoconstriction of the cerebral arteries during the preheadache phase, thus reducing the painful hyperemic rebound.

Behavior management treatment programs for migraine have included relaxation training, hypnosis, behavior modification, autogenic training, and hand-warming biofeedback. Hand-warming training for migraine was first used in combination with autogenic training by Sargent, Green, and Walters in 1972. Despite methodological weaknesses in that study, two dozen or more similar studies followed (e.g., Blanchard, Theobald, Willamson, Silver, & Brown, 1978; Friar & Beatty, 1976; Wickramasekera, 1973; Diamond & Franklin, Note 1; Drury, DeRisi, & Liberman, Note 2; Peper & Grossman, Note 3; Turin, Note 4; Zamani, Note 5). In some of these reports autogenic training (Schultz & Luthe, 1959) has been used to supplement the biofeedback training. Most often the

biofeedback has been used to train the subjects or patients to raise their finger temperature. In other reports feedback of pulse amplitude from the extracranial temporal artery is provided (Friar & Beatty, 1976; Zamani, Note 5).

Almost all of the reported behavioral studies, but especially those using hand-warming training, vary substantially in quality from report to report in terms of experimental design, procedures used, subject selection, amount of treatment, and measures of improvement and results. Of the published studies on hand warming, there have been only two using control groups and none have reported double-blind procedures. This is rather surprising in view of the widespread clinical use of this technique.

Despite the many studies seeming to confirm the therapeutic efficacy of finger-warming feedback training in the treatment of migraine headaches, many questions remain unanswered. The lack of adequate experimental controls is a salient feature of nearly all of the studies. In most cases, posttreatment records are compared only with pretreatment baselines, but this offers little information about placebo effects or comparison with alternative therapies. No experimental study to date has shown any relationship between the magnitude of skin temperature changes and therapeutic efficacy. In fact, a clinically significant criterion for the amount of temperature change has not been experimentally established. Another problem in evaluating the results of these studies is the "regression to the mean" phenomenon described by Neal Miller (1978). He points out that symptoms tend to vary in frequency and intensity over time and that patients tend to seek treatment when they are feeling their worst. Therefore, when a patient is treated at that time, any change will most likely be toward the mean and for the better. Miller, among others, also emphasizes the problem of placebo effects in evaluating biofeedback therapies for migriane headaches. He notes that headaches are notoriously susceptible to almost any kind of intervention. This criticism seems especially relevant to finger-warming biofeedback training, which has no easily demonstrable relationship to the pain behaviors generated by migraine headaches. It is important not to underestimate the significance of placebo effects (Katkin & Goldband, 1979). Lance (1974) found that 20–30% of their migraine subjects were treated successfully with inert tablets alone. Sixty percent responded positively when the inert tablets were given together with relaxation therapy.

In the present study, a group of migraine patients was trained to raise digital skin temperature using biofeedback techniques. An attempt was made to assess partially the relative contribution of the specific or active therapeutic factors of the temperature training technique compared to the contribution of nonspecific effects. Therefore, a second group of subjects

was trained to lower finger temperatures, a procedure that should produce nonspecific effects or perhaps even exacerbate migraine activity (Johnson & Turin, 1975). A third group of subjects served as an untreated control group.

In order to control for experimenter bias, the undergraduate assistants who worked with the subjects during training sessions were blind to the subjects' task and naive to our working hypotheses. Neither the subjects nor the undergraduate assistants who treated the subjects were told of the different treatment conditions or whether the subjects were being taught to warm or cool their hands. Rather, subjects were instructed to respond to a feedback tone or meter. A third group of subjects did not receive temperature training and served as an untreated control group to assess changes in migraine activity due to factors other than temperature training. Since even rats can learn to change their skin temperature with biofeedback training, we are not concerned that subjects were reinforced for learning to change skin temperature without being told specifically whether they were being taught to raise or lower it.

An argument could be advanced that the subjects' ignorance of the feedback-relevant response inherent in double-blind studies necessarily leads to inadequate training and therefore might produce negative findings. The success in training animals, obviously unaware of the target response, to control a variety of autonomic functions would seem to invalidate this contention. Furthermore, in recent years a body of literature has been accumulated indicating that what is true for rats also applies to humans. Several experiments designed to compare the performance of subjects who were aware and of subjects who were not aware of the response contingencies were recently reviewed in the report of a Task Force of the Biofeedback Society of America (Carlson, Note 6). While there is no universal agreement, the majority of those studies indicates that knowledge of the feedback-relevant response is unnecessary, if not detrimental, in training humans to control physiological functions like heart rate, EEG patterns, galvanic skin response, and finger pulse volume. It has been shown that subjects can even overcome deceiving information about the target response (Headrick, Feather, & Wells, 1971). There is no experimental evidence indicating that response awareness is essential or even helpful in learning to control peripheral skin temperature. At least two studies have demonstrated that such awareness is unnecessary (Gardner & Keefe, 1976; Sedorow & Masterson, Note 7). The Task Force concluded their review of this issue by noting that "there appears to be no basis for the claim by many clinicians that awareness of the feedback-relevant response is necessary in order to achieve self-control over the response. . . . . In fact, the weight of the evidence to date indicates that non-awareness produces results equal to or better than awareness" (p. 7).

Controlling for experimenter bias or subjects' expectations, if finger warming proved more therapeutic than finger cooling or no treatment, it would appear that some kind of specific effect was involved. If, on the other hand, both finger warming and finger cooling reduced migraine activity, we could then hypothesize that nonspecific factors were involved.

METHOD

Approximately 200 female subjects responded to newspaper press releases and physician referrals asking for migraine volunteers to participate in a research study aimed at teaching them how to bring such headaches under control using biofeedback techniques. Responders were sent a cover letter, a migraine history questionnaire, and a consent form to fill out and return by mail.

Approximatley 150 females returned the history questionnaire and consent form. Fifty subjects who met the following criteria were interviewed: (1) a minimum 3-year history of migraine headache, (2) a minimum history of 72 headaches, (3) a minimum of two headaches per month during the preceding 12 months, (4) a verified diagnosis by their personal physician of migraine headaches, (5) migraine headaches that were unilateral at onset, and (6) a history of nausea or vomiting accompanying the migraine headaches or the prodromal symptoms of the headaches. Forty subjects who met all criteria for inclusion in the study agreed to participate. Five subjects in the control group that kept records of their migraine activity but did not receive temperature training did not complete all 21-weeks of record keeping and were not included in the data analyses. One subject who was assigned to the group being trained to raise finger temperature dropped out of the study before her first training session. Thus 34 subjects completed all phases of the study. They ranged in age from 21 to 75 years, with a mean age of 40 years.

All subjects were given two types of diary forms to complete during the 21 weeks of the study. Instructions were included with the packet of diaries and subjects were contacted by phone to answer any questions they might have concerning the instructions. Subjects were instructed to fill out a migraine diary form each time they experienced a migraine headache. The form included items such as a symptom checklist; time of headache, a rating of impairment, and a listing of the amount and kinds of medication taken.

Each week subjects mailed or returned personally all diary forms filled out during the preceding week. Approximately every 10 days all subjects were reminded by phone or in person to keep filling out and sending in the diaries. At that time they were also provided encouragement for their efforts and any procedural questions were answered by one of the under-

graduate assistants. The 21-week experimental period was divided into three phases: (1) a 6-week pre-treatment period, (2) a 9-week-and-1-day treatment period, and (3) a 6-week posttreatment period. All subjects kept diaries during the entire 21-week period.

Subjects were assigned to one of three experimental conditions. Eleven subjects who were obviously not naive about biofeedback treatment of migraine headaches and subjects who had scheduling conflicts were assigned to a group that kept records of their migraine activity for the 21-week period but did not receive finger temperature training. Subjects with knowledge about skin temperature biofeedback training were excluded from treatment groups to minimize the likelihood of their breaking the double-blind through discovery and communication of the direction and hypothesized therapeutic significance of skin temperature changes. The remaining subjects were assigned to one of two training conditions on a random basis. The three groups did not differ significantly with respect to pretreatment levels of any of the dependent variables.

One group of 11 subjects received training to raise finger temperature, and a second group of 12 subjects received training to lower finger temperature in 10 weekly laboratory sessions during the 9-week treatment period.

Subjects were told in the cover letter and consent form that the experiment involved training them to voluntarily control finger temperature for the treatment of migraine. They were told that similar forms of treatment were used with considerable success in many clinics and that subjects chosen for temperature training would be randomly assigned to one of two learning conditions in order to compare the therapeutic effects of two conditions. Subjects were instructed that they would not be told which condition they were in or the difference between the two conditions. They were also instructed not to discuss their training with other subjects and to avoid reading about biofeedback from independent sources during this study. They were instructed that if the results showed that one group received greater therapeutic benefit at the conclusion of the study, members of the other treatment group would be given the opportunity to learn the more effective procedure.

Subjects were not told whether they were being trained to increase or decrease finger temperature. Rather, they were simply told to respond to a tone, a meter, or both, which registered relative changes in finger temperature with no information regarding whether they were being trained to increase or decrease temperature.

Two undergraduate research assistants served as primary therapists. The subjects worked individually with one of the two assistants who were blind as to what the two experimental conditions were and to which

condition subjects were assigned. During training sessions the undergraduate assistants attached the electrodes to the subjects and sat with them in the isolated treatment room during the session. They conversed with the subjects regarding the subjects' performance based on the feedback meter, which they could also observe.

One of two graduate student experimenters sat in a separate room and operated the monitoring and temperature feedback equipment. These graduate experimenters had no contact with the subjects during training except to signal the beginning and end of trials and to greet subjects when they arrived and to say good-bye as they left the isolated experimental room.

For each condition, the graduate student experimenter flipped a switch that changed the sign or direction of the feedback. Therefore, when the subjects being conditioned to raise finger temperature actually increased their finger temperature, the stereo tone and the meter went up and to the right. When their temperature decreased, the meter and tone went to the left. For subjects being conditioned to decrease finger temperature, the direction of the tone and meter was reversed. The result of this switch was that feedback appeared the same for both groups although one group was being trained to increase and the other group was being trained to decrease finger temperature.

The auditory and visual feedback was readjusted to a neutral or centered position at the beginning of each 10-minute training period. When a subject exceeded the range of the tone or meter, it was also automatically recentered by the graduate experimenters and the subject continued with the training. In a neutral position, the needle on the visual meter would appear in a straight up-and-down position in the center of the scale. When the stereo tone was in a neutral position, a medium-pitch sound could be heard equally in both ears. If the subject's temperature changed in the desired direction, the pitch of the tone would become higher and it would become louder in the right ear and softer in the left. If the subject's temperature went in the opposite direction, the pitch would become lower and the tone would become louder in the left ear and softer in the right.

Each subject worked with the same undergraduate assistant for the entire study. The undergraduate assistants were instructed to maximize positive expectations and to give copious verbal reinforcements to all subjects. Each undergraduate assistant worked with approximately equal numbers of subjects from the group trained to increase finger temperature and the group trained to decrease finger temperature. Following the 10 training sessions, the undergraduate assistants maintained contact with their subjects, reminded them to send in their diaries, and reinforced them for their efforts. Subjects were instructed to practice at home and at the onset of migraine symptoms.

The procedure used in this study is an analogue of procedures used in pharmacological studies where the individuals administering the therapy regimen are blind to the nature of the substance that they are administering. It is presumed that the positive expectations of the subject and experimenter toward the treatment and other aspects of the interpersonal relationship are significant factors in this study just as they have been demonstrated to be important in double-blind studies in pharmacology.

After completion of data collection for all subjects, undergraduate experimenters contacted subjects by telephone and asked several questions about the study. One subject in the decrease temperature group could not be reached; therefore a total of 22 subjects were interviewed. In order to assess how much subjects knew about temperature direction, a general and then a more specific question was asked. Subjects were first asked, "What did it mean or what was your finger temperature doing when the tone and meter went to the right and up?" In the group being trained to raise finger temperature, 36% of the subjects indicated that they thought their temperature was going up, while the rest of the subjects did not know or gave an answer that was not related to finger temperature changes. In the group being trained to decrease temperature, only 1 subject answered correctly that skin temperature was decreasing when the tone went up and to the right. Thirty-six percent of the subjects in this group replied incorrectly that their skin temperature was going up when the tone and meter went to the right and up. Forty-five percent of the subjects in this group did not know or gave responses not related to temperature direction.

Subjects were than asked directly whether their finger temperature was increasing or decreasing when the meter or tone was going up. Ninety-one percent of the subjects in the increase temperature group replied correctly, while only 18% of the subjects in the decrease temperature group gave the correct response. Fifty-five percent of the subjects in the decrease temperature group replied incorrectly that their temperature was going up when the meter or tone was going up, and 27% of the subjects in this group did not know. It appears that subjects based their assumptions on guesses regarding temperature direction on several factors. Although an attempt was made to choose subjects for the study who were naive regarding biofeedback for migraine, some subjects may have come into contact with information that led them to believe that biofeedback treatment for migraine headaches involves raising skin temperature. Subjects then assumed, either correctly or incorrectly, that they were being trained to raise skin temperature. Another group of subjects may not have been cognizant of the issue of temperature direction and only guessed the correct response when a specific question regarding temperature direction was asked at the end of the study. A third group of subjects may have been able to sense actual skin

temperature changes and therefore accurately identified the direction of temperature training. The fact that no subjects dropped out of the decreased temperature group suggests that subjects in that group did not interpret this procedure as a control condition that would result in less therapeutic efficacy.

Following completion of data collection, the undergraduate assistants were interviewed to ascertain their knowledge of group assignment. They were unable to distinguish subjects' group assignments beyond chance levels. The fact that some subjects were able to correctly guess the direction of skin temperature changes apparently did not influence the experimental assistants' judgments because they were specifically instructed to avoid discussion or references regarding temperature or temperature direction during this study. Instead, discussion was solely related to the feedback changes and other nonspecific properties of the experience, such as relaxation. The experimental assistants indicated that they entertained many hypotheses during the study regarding exactly what was being measured and what subjects were receiving feedback for. One of the experimental assistants thought that subjects might be receiving feedback for differences between hands, and the other experimenter thought that subjects might be receiving EMG feedback even though subjects were informed they would be receiving feedback for temperature changes.

Following 6 weeks of migraine diary record keeping, subjects were scheduled for 10 weekly training sessions. Sessions were approximately 7 days apart, with the first session occurring on the 1st day of the 9-week period and the last session on the last day of the 9-week period for a total of 10 laboratory training sessions. Each session lasted approximately 1 hour. Subjects were asked to arrive at the laboratory at least 10 minutes before each session to acclimate to the inside temperature. Subjects were then escorted into the treatment room and electrodes and thermistors were attached to the subjects during the next 10 minutes. Recorders were then started and a 5-minute baseline was taken, which was followed by the first 10-minute training period. Subjects were then given a 5-minute baseline before the second training period. This was followed by another 5-minute baseline before the final 10-minute training period was begun. Thus there were three 10-minute training periods per session, with 5-minutes between periods, for a total of 30 training periods per subject. Subjects lay in a semi-recumbent position on a hospital bed in a sealed, temperature-controlled room. The undergraduate assistant sat in a chair 3 feet away. The ambient temperature of the room was 22 plus or minus 1 degree centigrade.

Skin temperature was measured by Yellow Springs thermolinear components with a Type 727 surface temperature probe. A thermistor was taped to the center of the distal pad on each index finger. However, subjects only

received feedback for temperature changes on the index finger of their dominant hand. Analogue feedback was provided to the subjects by means of the visual meter that the subject could see while lying on a bed in the temperature-controlled room and simultaneously by a stereophonic tone that increased in one earphone and decreased in the other depending upon the direction and degree of temperature change in the dominant index finger.

Temperature changes were recorded on an eight-channel Gould model 481 recorder with Gould preamplifiers as well as on a 3 1/2-digit panel meter. This allowed absolute temperatures to be read with a resolution of plus or minus 1/10 of 1 degree centigrade.

Outcome measures were derived primarily from the diary forms filled out by each subject. A diary was completed for each migraine headache. Dependent variables included frequency of migraine headache per week; minutes of migraine headache per week; number of symptoms per week checked by a subject on each migraine diary (the symptom checklist had 16 items including such things as loss of appetite, vomiting, drowsiness or fatigue, mood changes, increased sensitivity); amount of impairment reported on a scale ranging from 0 to 5, with 0 being "no interference in activities," 3 being "retired to bed," and 5 being "hospitalized"; and type and amount of medication taken.

Medications were divided into five categories (opiates and related substances; salicylics; ergot compounds; miscellaneous symptomatic medication, most generally sedatives; and propranolol and methysergide maleate). For the purposes of the analyses reported here, pentile scores were derived for each of the five medication categories separately, using the average amounts of medication taken by each subject per week using the pre- and posttreatment periods. A frequency distribution was generated from which pentile scores of 1 through 5 were computed, with 1 representing relatively low amounts of medication taken and 5 representing high amounts. Twenty percent of the medication scores above 0 were in each pentile. The pentile score within each of the five medication categories was averaged for each subject to obtain a composite medication score for analysis. The results of the composite medication use analyses were similar in most respects to findings from analyses of the five medication categories analyzed separately (Kewman, 1977).

An analysis of variance was performed on each outcome measure using a repeated-measure method design taking into account cells with unequal numbers of subjects. The differences between the pre- and posttreatment scores of subjects were analyzed by making orthogonal comparisons.

For these outcome measures, two main analyses were performed. First, data were analyzed according to group assignment. Subjects being trained to raise finger temperature were compared to subjects being trained to lower finger temperature and to subjects who kept records of their migraine activity

but did not participate in temperature training. However, all subjects who received training did not learn to control their finger temperature and some subjects did not produce reliable and consistent changes in the assigned direction. Therefore, data were reanalyzed by regrouping and comparing subjects according to a learning criterion. This regrouping by the learning criterion was done independently of the subjects' feedback condition.

In the second analysis, the following four groups were compared: (1) subjects who consistently raised their finger temperature, (2) subjects who consistently lowered their finger temperature, (3) subjects who received biofeedback training but did not meet the learning criterion, and (4) subjects who kept records of their migraine activity but did not receive biofeedback training. Eight subjects in the group originally being trained to increase skin temperature and three subjects in the group trained to lower skin temperature met the criterion for subjects who were able to raise their skin temperature on a consistent basis. Three subjects in the group being trained to decrease skin temperature and two subjects in the group being trained to raise skin temperature met the criterion for subjects who decreased their skin temperature on a consistent basis. One subject from the group being trained to raise skin temperature and six subjects from the group being trained to lower skin temperature did not change their skin temperature in any consistent direction and therefore were considered "nonlearners" for purposes of reanalysis.

RESULTS

Analyses According to Original Group Assignment

Subjects being trained to raise finger temperature ($N = 11$) were compared with subjects being trained to lower finger temperature ($N = 12$) and with subjects who kept records of their migraine activity but did not participate in temperature training ($N = 11$).

The results shown in Table I indicate that the group being trained to raise finger temperature and the group being trained to lower finger temperature, as well as the group not receiving temperature training, all showed significant improvement in number of symptoms experienced during a headache ($p < .02$), ratings of amount of impairment ($p < .01$), and the composite score of medications taken to treat the migraine symptoms ($p < .001$). There was no significant change in the frequency or minutes of migraine episodes per week, although all three groups showed a tendency toward fewer headaches. Most importantly, there were no significant differences between groups (treatment effects) for any of the dependent measures.

Table I. Mean Headache Symptomatology and Composite Medication Use per Week before, during, and after Training for Experimental and Control Subjects

Symptom		Temperature Increase ($N = 11$)			Temperature decrease ($N = 12$)			Records only ($N = 11$)		
		Pre	During	Post	Pre	During	Post	Pre	During	Post
Frequency	$\bar{X}$	.98	1.0	.85	.68	.79	.54	1.23	.86	1.0
	SD	.74	1.05	1.72	.47	.56	.38	1.28	.91	1.57
Duration (minutes)	$\bar{X}$	664	508	367	884	691	512	757	691	401
	SD	330	362	353	667	444	414	729	601	554
Number of symptoms	$\bar{X}$	3.2	3.0	2.0	2.6	3.1	2.7	2.5	1.7	1.1
	SD	1.67	2.69	2.52	1.00	1.45	1.76	1.77	.81	1.39
Impairment rating	$\bar{X}$	1.12	1.04	.68	.88	.94	.69	.65	.44	.43
	SD	.62	.92	.89	.47	.58	.53	.52	.29	.52
Composite medication rating	$\bar{X}$	2.25	1.73	1.36	1.97	1.69	1.33	1.70	1.48	1.20
	SD	.98	1.11	1.32	1.13	.83	.83	1.12	.84	1.27

Analyses According to Learning Criteria

Learning criteria were derived by counting the number of learning periods during which a subject changed her finger temperature in one direction or another. The average temperature for the last 5 minutes of each 10-minute learning period or trial was compared to the average temperature for the preceding 5-minute baseline period. Subjects who raised their temperature at least 19 of the 30 learning periods were assigned to the "raise temperature" group. Subjects who lowered their temperature at least 19 of the 30 learning periods were assigned to the "decrease temperature" group. Subjects who received temperature training but neither raised nor lowered their finger temperature at least 19 of the 30 learning periods were assigned to the "no learning" group. The criterion yielded 11 subjects in the raise temperature group, 5 subjects in the decrease temperature group, and 7 subjects who were not able to consistently decrease or increase finger temperature.

An analysis of variance was computed on the average temperature of the index finger of the dominant hand for the last 5 minutes of each trial compared to the preceding 5-minute baseline. Subjects who met the criterion for the raise temperature group showed the largest average increase from baseline. From an average baseline temperature of 30.7° C, they increased their temperature to an average of 31.4° C for the last 5 minutes of each trial. The subjects who did not meet the learning criterion showed a somewhat smaller average increase from baseline. From an average baseline temperature of 30.5, the nonlearners increased their temperature to an average of 30.8 for the last 5 minutes of each trial. Subjects who met the criterion for the decrease temperature group had an average baseline temperature of 31.6° C compared to an average temperature of 30.9 during the last 5 minutes of each trial.

The difference between the temperature changes of the group that increased finger temperature and the group that decreased temperature was statistically significant ($p < .01$). The difference between the temperature changes of the group that decreased temperature and the nonlearners reached borderline significance ($p < .1$). There was no statistically significant difference between the group that increased temperature and the nonlearners, although the average temperature increase for the group that met the criterion was greater.

The group of nonlearners can be viewed as a biofeedback placebo group. If they show improvement in migraine symptoms without having produced reliable changes in finger temperature, it can be argued that control of finger temperature may not be the primary variable responsible for therapeutic change.

Table II. Mean Headache Symptomatology and Composite Medication Use per Week before, during, and after Training for Subjects Regrouped According to Learning Criteria

Symptom		Increase temperature (N = 11)			Decrease temperature (N = 5)			No learning (N = 7)			Records only (N = 11)		
		Pre	During	Post	Pre	During	Post	Pre	During	Post	Pre	During	Post
Frequency	$\bar{X}$	.89	.86	.54	.83	1.40	1.30	.71	.65	.48	1.23	.86	1.03
	SD	.51	.49	.52	1.05	1.57	1.54	.46	.38	.45	1.27	.91	1.57
Duration (minutes)	$\bar{X}$	672	529	319	593	600	778	1079	723	397	757	691	401
	SD	360	318	298	358	512	486	768	493	335	729	601	554
Number of symptoms	$\bar{X}$	3.4	3.5	2.3	1.7	2.4	3.0	2.9	3.0	2.0	2.5	1.7	1.1
	SD	1.58	2.61	2.65	.70	1.91	1.26	.90	1.20	1.85	1.78	.81	1.39
Impairment rating	$\bar{X}$	1.06	1.11	.65	.59	.71	.68	1.20	1.01	.76	.65	.44	.43
	SD	.53	.80	.73	.36	.69	.42	.59	.74	.91	.52	.29	.52
Composite medication rating	$\bar{X}$	2.14	1.61	1.25	1.70	1.65	2.10	2.36	1.89	.96	1.70	1.48	1.20
	SD	1.00	1.11	1.21	1.02	1.17	.84	1.19	.54	.77	1.12	.84	1.27

Again there were no significant differences among the four groups with respect to pretreatment means on any of the dependent variables. Analyses of the data shown in Table II showed that there was a significant reduction in ratings of duration of headache, ($p < .04$) and the amount of medication consumed ($p < .005$) for the combined groups.

Treatment effects were found for several dependent variables. Orthogonal comparisons between the subjects who met the criterion for decreasing temperature and the other groups combined were significant for frequency of migraines ($p < .01$), number of symptoms per week ($p < .05$), minutes of headache per week ($p < .05$), and medication consumed ($p < .05$). These analyses showed that subjects who decreased temperature did not get better compared to the subjects in the other three groups, all of whom showed significant improvement.

DISCUSSION

The results of this study do not support the specific effectiveness of hand temperatute biofeedback for the treatment of chronic migraine headache. Number of symptoms experienced during headache, ratings of impairment, and amount of medications used to treat migraine symptoms all decreased significantly during the study for all groups, including the group that simply stayed at home and kept records.

Even when subjects were regrouped according to a learning criterion, analysis of changes in migraine activity did not yield statistically significant effects among subjects who raised their finger temperature, subjects who did not meet the learning criterion, and subjects who did not receive any temperature training whatsoever, although all three of these groups improved significantly on some measure of migraine activity. The failure to decrease migraine activity by subjects in the group that decreased temperature cannot be interpreted as demonstrating a specific effect when the data from the study are taken as a whole since the nonspecific factors are at least as powerful as those that might be attributable to temperature training.

It is interesting to note that subjects who were able to decrease their skin temperature on a consistent basis had a higher initial baseline temperature, although this difference is nonsignificant. It is conceivable that these subjects were successful in decreasing skin temperature on a consistent basis because of their higher initial baseline. This higher baseline could conceivably be attributable to a conditioning effect whereby subjects would arrive at the session with higher initial skin temperature in order to achieve reinforcing effects of feedback in the correct direction.

It could be argued that the failure to find specific treatment effects might be attributed to the finding that very few subjects actually learn to

produce large and reliable increases in hand temperature. It should be remembered, however, that difficulty in learning to raise peripheral skin temperature is not at all peculiar to this study. The same finding has been reported in normal subjects (Surwit, Shapiro, & Feld, 1976; Alberstein, Note 8; Lynch, Hama, Kohn, & Miller, Note 9; Packer & Selekman, Note 10; Reynolds, Note 11; Turin, Note 12) as well as in patients with Raynaud's disease (Surwit, Pilon, & Fenton, 1978; Guglielmi & Roberts, Note 13). Surwit recently concluded (1978) that "a review of the experimental literature produces only equivocal evidence for the ability of humans to learn to voluntarily vasodilate with the use of temperature feedback alone" (p. 10).

The decrease in skin temperature found in those subjects who did not decrease migraine activity may simply be reflecting the general factor of increased sympathetic arousal. Price (1976) has reported that relaxation is just as effective as biofeedback in producing vasodilation. It is likely that the various behavioral treatment modalities that have been reported to be effective in controlling migraine headache activity such as autogenic training, biofeedback training, relaxation training, and hypnosis all share in common the reduction of sympathetic arousal. Vascular headaches, particularly migraine, tend to occur in individuals who are tense, active, hardworking, and otherwise prone to sympathetic nervous system arousal. Most medical treatments for these headaches are directed toward the painful hyperemic state of a psychophysiological chain that is preceded by vasoconstriction possibly activated by sympathetic arousal.

Any treatment that decreases the "fight–flight" responses mediated by the sympathetic nervous system may tend to decrease the frequency and intensity of these headaches. These factors combined with other nonspecific factors such as placebo and regression to the mean effects are sufficient to account for the finding of this study as well as the many clinical studies reporting the alleviation of headaches through the use of biofeedback techniques. As Miller (1978) has pointed out, there are many powerful general factors that may lead to exaggerated impressions of therapeutic effectiveness unless all of them are controlled in experimental designs.

The interview with subjects following the completion of data collection indicated that 81% of the subjects felt that they had satisfactory or better control of the feedback. Only four subjects, or approximately 18%, felt that they had little or no control. Ninty-one percent of the group being trained to decrease temperature felt that they had satisfactory or better control of the feedback, while 72% of the group being trained to raise skin temperature felt that they had satisfactory or better control. This observation suggests the possibility that the feeling of mastery or control may be as important as actual control and may be one nonspecific factor playing an important role in the clinical efficacy of biofeedback treatment.

Since this study was completed, the findings have been replicated in a bidirectional study by Jessup (Note 14) that included autogenic training as a variable. A study by Waters and O'Connor (1971) reported migraines declining simply during self-monitoring. Cohen, Rickles, and McArthur (Note 15) trained four groups of migraine subjects in either EMG frontalis muscle relaxation biofeedback, EEG alpha enhancement biofeedback, temporal area scalp artery pulse amplitude biofeedback, or finger-warming biofeedback. All groups showed a decrease in the frequency of headaches per week and headache reduction was not related to the ability to learn a procedure or other physiological measures. Other reports indicate that the experimental literature produces only equivocal evidence for the ability of human subjects to vasodilate beyond baseline temperatures (Surwit, 1978), that individuals with migraine headaches are not different from individuals without headaches in their baseline skin temperatures (Boudewyns & Cornish, 1978), and that headache improvement can occur with vasoconstricted fingers (Friar & Beatty, 1976).

Four conclusions appear warranted. First, there is a "clinical" effect of biofeedback training; large numbers of subjects improved during training in this study. Many clinicians have commented that there is a positive therapeutic "effect of training" involved in biofeedback for migraine, which includes the relationship between the clinician and subject or patient. Our findings fully support this point. Since a majority of our patients showed clinical improvement, there must be, in fact, an effect generated by biofeedback training. However, our second conclusion is that dramatic therapeutic improvements in migraine headaches with hand temperature biofeedback is not due to a specific property of skin temperature alterations but rather is due to nonspecific effects of clinical procedures employed. The results of this double-blind study are negative, not because the treated group failed to improve but because the two control groups improved as much as the treated group did. Third, headache diary keeping and attention from therapists and experimenters are likely to be a part of these nonspecific effects. Finally, there can be no definitive evaluation of the specific effects of biofeedback training in alleviating any disorders without the use of careful double-blind procedures. We believe that there are justifiable criticisms that may be leveled at the present study, but they are best answered by better designed research studies employing multiple control groups with careful attention paid to the collection of clinical outcome and physiological data.

REFERENCE NOTES

1. Diamond, S., & Franklin, M. *Intensive biofeedback therapy in the treatment of headache.* Paper presented at the Biofeedback Research Society meetings, Monterey, California, 1975.

2. Drury, R. L., DeRisi, W., & Liberman, R. *Temperature feedback therapy for migraine headache: A controlled study.* Paper presented at the Biofeedback Research Society meetings, Monterey, California, 1975.
3. Peper, E., & Grossman, E. R. *Thermal biofeedback training in children with headache.* Paper presented at the Annual Meeting of the Biofeedback Research Society, Colorado Springs, 1974.
4. Turin, A. *Biofeedback for migraines.* Paper presented at the Biofeedback Research Society meetings, Monterey, California, 1975.
5. Zamani, Reza. *Treatment of migraine headache: Bio-feedback versus deep muscle relaxation.* Reports from the Research Laboratories of the Department of Psychiatry (PR-75-2), University of Minnesota, 1975.
6. Carlson, J. G. (Ed.). *Biofeedback as a research tool* (Task Force Study Section Report). Denver: Biofeedback Society of America, 1978.
7. Sedorow, L. M., & Masterson, J. *Effects of knowledge of target response, feedback, and direction of change on self-control of fingertip temperature.* Unpublished manuscript, 1977.
8. Alberstein, B. Biofeedback and skin temperature control. *Psychophysiology,* 1977, *14,* 115. (Abstract)
9. Lynch, W. C., Hama, H., Kohn, S., & Miller, N. E. *Instrumental learning of vasomotor responses: A progress report.* Paper presented at the Annual Meeting of the Biofeedback Research Society, Colorado Springs, 1974.
10. Packer, L. E., & Selekman, W. L. *Within-subjects control in EMG and thermo-biofeedback training: The baseline effect.* Paper presented at the Annual Meeting of the Biofeedback Society of America, Orlando, 1977.
11. Reynolds, A. *Patterns of vasomotor activity during temperature and photoplethysmograph feedback training for peripheral vasodilation.* Paper presented at the Annual Meeting of the Biofeedback Society of America, San Diego, 1979.
12. Turin, A. C. *Biofeedback and suggestion in finger temperature training: An effect for the control but not for the "treatments."* Paper presented at the Annual Meeting of the Biofeedback Society, Orlando, 1977.
13. Guglielmi, S., & Roberts, A. H. *Biofeedback for Raynuad's disease: A double blind study.* Paper presented at the meetings of the Society for Psychophysiological Research, Madison, Wisconsin, 1979.
14. Jessup, B. *Autogenic feedback for migraine: A bidirectional control group study.* Unpublished paper, University of Western Ontario, 1978.
15. Cohen, M. J., Rickles, W. H., & McArthur, D. L. *Four modalities of biofeedback training for migraine headache.* Paper presented at the Annual Meeting of the Society for Behavioral Medicine, San Francisco, 1979.

REFERENCES

Blanchard, E. B., Theobald, D. E., Williamson, D. A., Silver, B. V., & Brown, D. A. Temperature biofeedback in the treatment of migraine headaches: a controlled evaluation. *Archives of General Psychiatry,* 1978, *35,* 581-588.

Boudewyns, P., & Cornish, R. Finger temperature norms for migraine sufferers. *Behavior therapy,* 1978, *9,* 689.

Fordyce, W. E. *Behavioral methods for chronic pain and illness.* St. Louis: C. V. Mosby, 1976.

Friar, L. R., & Beatty, J. T. Migraine: Management by operant control of vasoconstriction. *Journal of Consulting and Clinical Psychology,* 1976, *44,* 46-53.

Friedman, A. P. Reflection on the problem of headache. *Journal of the American Medical Association,* 1964, *190,* 445-447.

Gardner, E. T., & Keefe, F. J. The effects of knowledge of response on temperature biofeedback training. *Biofeedback and Self-Regulation,* 1976, *1,* 314. (Abstract)

Headrick, M. W., Feather, B. W., & Wells, D. T. Unidirectional and large magnitude heart-rate changes with augmented sensory feedback. *Psychophysiology,* 1971, *8,* 132-142.

Johnson, W. G., & Turin, A. Biofeedback treatment of migraine headache: A systematic case study. *Behavior Therapy,* 1975, *6,* 394-397.

Katkin, E. S., & Goldband, S. The placebo effect and biofeedback. In R. Gatchel & K. Price (Eds.), *Clinical applications of biofeedback: Appraisal and status.* New York: Pergamon Press, 1979.

Kewman, D. G. *Voluntary control of digital skin temperature for treatment of migraine headaches* (Doctoral dissertation, University of Texas at Austin, 1977). (Ann Arbor, Michigan: University Microfilms No. 77-29053)

Lance, J. W. The pathophysiology and treatment of migraine. *New Zealand Medical Journal,* 1974, *79,* 954-960.

Miller, N. E. Biofeedback and visceral learning. *Annual Review of Psychology,* 1978, *29,* 373-404.

Price, K. P. Vascular reactivity of migraineurs and non-migraineurs: A comparison of responses to self-control procedures. *Headache,* 1976, *16,* 210-217.

Roberts, A. H. The behavioral treatment of pain. In J. M. Ferguson & C. B. Taylor (Eds.), *A comprehensive handbook of behavioral medicine.* New York: Spectrum, 1980.

Roberts, A. H., Kewman, D. G., & Macdonald, H. Voluntary control of skin temperature: Unilateral changes using hypnosis and feedback. *Journal of Abnormal Psychology,* 1973, *82,* 163-168.

Roberts, A. H., Schuler, J., Bacon, J. G., Patterson, R., & Zimmermann, R. L. Individual differences and autonomic control: Absorption, hypnotic susceptibility, and the unilateral control of skin temperature. *Journal of Abnormal Psychology,* 1975, *84,* 272-279.

Sargent, J. D., Green, E. E., & Walters, E. D. The use of autogenic feedback training in a pilot study of migraine and tension headaches. *Headache,* 1972, *12,* 120-125.

Schultz, J. H., & Luthe, W. *Autogenic training.* New York: Grune and Stratton, 1959.

Schumacher, G. A., & Wolff, H. G. Experimental studies on headache. *Archives of Neurology and Psychiatry,* 1941, *45,* 199-214.

Surwit, R. S. Peripheral vasomotor: Raynaud's disease. *Behavioral Medicine Newsletter,* 1978, *1*(3), 9-11.

Surwit, R. S., Pilon, R. N., & Fenton, C. H. Behavioral treatment of Raynaud's disease. *Journal of Behavioral Medicine,* 1978, *1,* 323-335.

Surwit, R. S., Shapiro, D., & Feld, J. L. Digital temperature auto regulation and associated cardiovascular changes. *Psychophysiology,* 1976, *13,* 242-248.

Waters, W., & O'Connor, P. Epidemiology of headache and migraine in women. *Journal of Neurology, Neurosurgery and Psychiatry,* 1971, *34,* 148-153.

Wickramasekera, I. E. Temperature feedback for the control of migraine. *Journal of Behavior Therapy and Experimental Psychiatry,* 1973, *4,* 343-345.

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