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THE ROLE OF THERMAL SELF-REGULATION IN THE BIOFEEDBACK TREATMENT OF MIGRAINE HEADACHE: A CONTROLLED STUDY

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RÉSUMÉ

Le but de l'étude était d'évaluer le rôle de l'autorégulation de la température dans le traitement de la migraine par la rétroaction biologique thermique en la comparant à une procédure tout aussi crédible mais qui ne provoquerait aucun effet significatif sur la température des mains. Vingt-quatre femmes migraineuses ont été assignées à l'une ou l'autre des deux conditions suivantes: la rétroaction biologique thermique ou le TENS (ou stimulation électrique transcutanée). Cette dernière était appliquée de façon à maximiser les attentes thérapeutiques et à minimiser les effets sur la température des mains. La manipulation expérimentale s'est avérée un succès. Cependant, aucune des différences observées entre les groupes au niveau des effets thérapeutiques n'était significative. Il en est de même des corrélations qui furent effectuées entre les changements de température au niveau de la main et l'amélioration thérapeutique. Ainsi, l'hypothèse selon laquelle l'efficacité de la rétroaction biologique serait médiée par l'auto-régulation de la température n'est pas supportée dans cette étude.

ABSTRACT

The aim of the study was to assess the role of thermal self-regulation in biofeedback treatment of migraine headache by comparing it to a procedure that was equally credible but physiologically inert with regard to hand temperature. Twenty-four migraine female patients were assigned to either of two experimental conditions: thermal biofeedback or transcutaneous electrical nerve stimulation (TENS). The TENS procedure was applied such as to maximize therapeutic expectancies and to minimize effects on hand temperature. Results indicated that the experimental manipulation was successful. With regard to treatment outcome, however, no significant between-groups differences were found. Likewise, none of the correlations coefficients between changes in hand temperature and clinical improvement reached statistical significance. Power analyses suggested that, if thermal self-regulation plays some role in the therapeutic mechanism of biofeedback, it is a marginal one.

AVANT-PROPOS

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INTRODUCTION GÉNÉRALE

La migraine est un problème très fréquent dans la population (Adams, Feverstein, & Fowler, 1980). Des études épidémiologiques rapportent une prévalence de 23 à 29% pour les femmes et de 15 à 20% pour les hommes (Waters & O'Connor, 1975).

Parmi les nombreux traitements non pharmacologiques suggérés, la rétroaction biologique thermique est un de ceux qui ont été les plus étudiés pour le soulagement de la migraine (Blanchard & Andrasik, 1982, 1985, 1987). Les études menées jusqu'à maintenant dans notre laboratoire montrent des amélioration thérapeutiques d'au moins 50% pour de 50.0 à 88.2% des personnes migraineuses, dépendemment des variables de migraine considérées (Gauthier, Fradet, & Roberge, 1988; Gauthier, Lacroix, Côté, Doyon, & Drolet, 1985). Même si l'efficacité de la rétroaction biologique thermique est maintenant reconnue pour le traitement de la migraine, le mécanisme par lequel elle opère demeure imprécisé et la spécificité de son effet psychophysiologique, remise en question.

Par le biais de la rétroaction biologique thermique, les personnes migraineuses sont entraînées à augmenter la température de leurs mains. Le rationnel à la base d'un tel entraînement est que l'amélioration thérapeutique serait proportionnelle à l'habileté de la personne à auto-régulariser la température des mains. Toutefois, jusqu'à maintenant aucune étude n'a réussi à démontrer de manière convaincante un tel lien (Blanchard et al., 1983; Gauthier, Doyon, Bois, Leblond, & Drolet, 1982; Gauthier, Doyon, Lacroix, & Drolet, 1983; Gauthier et al., 1985; Kewman & Roberts, 1980; Largen, Mathew, Dobbins, & Claghorn, 1981; Morill & Blanchard, 1989).

La présente étude se proposait de préciser le lien entre l'auto-régulation de la température et l'amélioration thérapeutique obtenue par la rétroaction biologique thermique. Pour ce faire, une comparaison a été effectuée entre la rétroaction biologique et une procédure physiologiquement inerte en terme de changements de température mais tout aussi crédible pour les patientes.

L'étude du mécanisme de la rétroaction biologique thermique est de première importance, en ce sens ou la connaissance de celui-ci permettrait d'optimiser l'efficacité du traitement dans le soulagement de la migraine.

The Role of Thermal Self-Regulation in the Treatment of Migraine Headache: A Controlled Study

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ABSTRACT

The aim of the study was to assess the role of thermal self-regulation in biofeedback treatment of migraine headache by comparing it to a procedure that was equally credible but physiologically inert with regard to hand temperature. Twenty-four migraine female patients were assigned to either of two experimental conditions: thermal biofeedback or transcutaneous electrical nerve stimulation (TENS). The TENS procedure was applied such as to maximize therapeutic expectancies and to minimize effects on hand temperature. Results indicated that the experimental manipulation was successful. With regard to treatment outcome, however, no significant between-groups differences were found. Likewise, none of the correlations coefficients between changes in hand temperature and clinical improvement reached statistical significance. Power analyses suggested that, if thermal self-regulation plays some role in the therapeutic mechanism of biofeedback, it is a marginal one.

The Role of Thermal Self-Regulation in the Biofeedback Treatment of Migraine Headache: A Controlled Evaluation.

The therapeutic effects of thermal biofeedback in the treatment of migraine have been widely acknowledged in the literature (Adams, Feverstein, & Fowler, 1980; Blanchard & Andrasik, 1987). Indeed, there is a substantial body of evidence indicating that thermal biofeedback training is therapeutically more effective than headache monitoring or no treatment for controlling migraine. The extend to which its therapeutic effects can exceed those of an attention-placebo, however, is unclear, and, accordingly, some questions about the specificity of its psychophysiological effects on migraine have been raised (Chapman, 1986; Litt, 1986).

Over the years, various attempts have been made to address this issue but none of them have been able to shed much light on it. Two of these attempts have involved the use of nonveridical biofeedback as a possible attention-placebo condition (Mullinix, Norton, Hack, & Fishman, 1978; Reading, 1984). In Mullinix et al. (1978), patients were given either thermal biofeedback with true feedback or thermal biofeedback with feedback that indicated success at the hand-warming task regardless of the actual performance. No significant differences in therapeutic gains were found between the two groups of patients even though the true feedback condition achieved marginally greater temperature change. In Reading (1984), patients were given either true thermal biofeedback for hand warming, true feedback of skin conductance level, true frontal EMG biofeedback, or false EMG biofeedback that showed improvement.

Be it in terms of headache reduction or hand temperature change, no significant between-groups differences were found. In neither of these studies, however, was treatment credibility assessed. Furthermore, in both studies, the lack of significant differences in hand temperature change between groups raises some question about the physiological mechanism. Indeed, in the absence of any relevant information, one wonders about how successful were the biofeedback subjects at increasing their hand temperature and about how physiologically inert was the nonveridical treatment.

Four other attempts have involved comparing thermal biofeedback training in hand warming with thermal biofeedback for hand cooling, with the latter construed as a possible attention-placebo condition (Gauthier, Bois, Allaire, & Drolet, 1981; Jessup, Neufeld, & Stenn, 1976; Kewman & Roberts, 1980; Largen, Mathew, Dobbins, & Claghorn, 1981). None of them found any significant difference in headache relief between the two conditions. However, only two of these clinical trials showed the desired training effect (Gauthier et al., 1981; Largen et al., 1981) and only one of them measured treatment credibility (Gauthier et al., 1981). Moreover, because the hand cooling condition was not physiologically inert, these studies could not rule out the possibility that the stabilization of peripheral vascular activity, rather than a specific directional change (such as vasodilatation or vasoconstriction) was the therapeutic element.

The most recent attempt to address the placebo issue in the thermal biofeedback treatment of migraine has involved the use of pseudomeditation as an ostensible attention-placebo control (Blanchard et al., 1990). In this study,

patients were assigned to one of four conditions: thermal biofeedback (with relaxation as an adjunct), thermal biofeedback (also with relaxation as an adjunct) plus cognitive therapy, pseudomeditation, or headache monitoring. Patients with pseudomeditation were given training in body awareness and mental control with hope that neither of these activities would induce relaxation or increase temperature. Contrary to expectations, results did not reveal any significant differences in treatment outcome and hand temperature change between thermal biofeedback and pseudomeditation. Further analyses suggested that patients in the pseudomeditation group had construed their treatment as a form of relaxation training. Indeed, 90% of the pseudomeditation subjects reported increases in the use of mental relaxation for coping with headaches at posttreatment, and 80% reported an increase on the use of imagining a tension-reducing scene for the same purpose. Obviously, despite no mention of relaxation in the treatment, the pseudomeditation procedure failed to operate as an attention-placebo control for thermal biofeedback. Consequently, the question as to whether thermal biofeedback is superior to a credible, but psychophysiologically neutral, attention-placebo remains unanswered.

The aim of the present study was to assess the role of thermal self-regulation in the biofeedback treatment of migraine by comparing thermal biofeedback training in hand warming with a procedure that would be as credible as thermal biofeedback without having any significant effect on hand temperature. Ideally, of course, the control procedure would have to replicate in as many details as possible the conditions in which the biofeedback treatment

would be administered, if it were to achieve its purpose, which was to control for the nonspecific effects of finger temperature biofeedback training.

Method

Subjects

Research participants were recruited from the general population through local advertisements demanding female volonteers to participate in a non pharmacological treatment study for migraine. Each of the 242 individuals who responded to the invitation were interviewed for possible inclusion in the study using a semi-structured interview schedule adapted from Blanchard, Theobald, Williamson, Silver and Brown (1978). The most critical data from these interviews for the patients included in the study are presented in Table 1.

Insert Table 1 about here

To be included in the study, individuals had to report a minimum of two migraines monthly for a minimum of 2 years and meet three of the following criteria: (a) unilateral and throbbing headaches; (b) nausea and vomiting accompanying headaches; (c) headaches preceded by prodromes; (d) positive family history of similar headaches; or (e) independent diagnosis of migraine by a neurologist. Because of a possible relationship between migraine and hormonal changes (Kudrow, 1975), participation was also limited to nonpregnant

women who were between 18 and 49 years of age, were premenopausal, did not use oral contraceptives and had not undergone ovariectomy or hysterectomy. Furthermore, individuals with a pacemaker were excluded because the control condition was to involve the use of electrical stimulation (Ottoson & Lunderberg, 1988).

Potential subjects were excluded from the study if they described their headaches as occurring almost daily, bilateral and characterized by sensations of tightness and persistent bandlike pain or as a "dull ache". Patients who reported the onset of headaches to follow some form of head trauma were also excluded. Finally, individuals who were taking prophylactic or abortive medication for migraine, and who could not discontinue it or were unwilling to do so were excluded because of the constraints of these drugs in producing reliable data on the parameters under investigation (Gauthier et al. 1981).

All of the headache questionnaires were reviewed by two independent assessors who were responsible for screening out preapplicants who most clearly did not meet any of the selection criteria. A total of 81 applications made it through the initial screening. These applications were then reviewed by the team neurologist who rated each of them for the certainty of a migraine diagnosis as defined by the Ad Hoc Committee on the Classification of Headache (1962) and the Ad Hoc Committee of the International Headache Society on the Classification and Diagnosic Criteria for Headache Disorders, Cranial Neuralgias, and Facial Pain (1985). Applicants who did not receive a maximum certainty rating were excluded, which left 50 patients for further consideration by

the neurologist who went on to interview each of them in person. Another 11 patients were excluded because they did not receive a maximum certainty rating following the interview or because they did not have an EEG and a skull X-ray that were clearly negative. Finally, patients who, after admission in the study, did not have at least two migraine headaches or had headaches almost daily during the pretreatment baseline were excluded. At the end of the 5 weeks of baseline recording, 27 patients were still available.

Pretreatment headache frequency, intensity and duration scores as well as ages of patients were used to form thirteen computer matched pairs of patients and to assign the members of each pair to either of two experimental conditions: thermal biofeedback or transcutaneous electrical nerve stimulation (TENS) which was designed and applied so as to maximize expectancies and to minimize hand temperature changes, as well as potential therapeutic benefits. The patient left over was randomly assigned to the thermal biofeedback group. The computer was programmed so as to identify the assignment of subjects that would secure minimal differences between groups, maximal differences between pairs and homogeneous variances across conditions.

A total of 24 patients completed the study. Three patients dropped out of treatment because their headaches did not seem to improve. Two of them were in the biofeedback group.

Therapists

Therapists were two graduate students in clinical psychology who had been instructed in the use of biofeeback strategies for migraine during the course

of a clinical internship. Both of them treated an approximately equal number of subjects in each condition.

Setting and Apparatus

All sessions were conducted in a sound-attenuated and temperature-controlled (approximately 72° F) room during the spring months. Patients were seated in a padded reclining chair.

In the case of thermal biofeedback, a BioMedical Instrument temperature monitor (Model T5) was used to assist patients in their training. The thermistor was taped onto the volar surface of the distal phalange of the middle finger contralateral to the side of the head usually affected during migraine attacks. If migraine occured equally to either side, the thermistor was placed on the side of the dominant hand.

A Staodyn unit (Model 4600) was used to administer the TENS treatment. Electrodes were placed at the junction of the index finger and thumb on the dorsum of the hand. The positive electrode was placed on the side of the head where pain usually occurred and the negative electrode, on the other side. If headaches occured equally to either side, the positive electrode was placed on the side of the dominant hand and the negative, on the other side. In accordance with a recommendation made by Ottoson and Lundeberg (1988) for TENS, the pulse frequency was set at 70Hz and the width at 40μsec. The intensity of the electrical stimulation was set by the patient who was instructed to increase it until a tingling sensation that was neither unpleasant nor painful was felt.

Outcome Measures

Participants were required to record on a headache form adapted from Bakal and Kaganov (1976) the date, time of onset and offset, location and intensity of each migraine attack and all medication taken. The intensity of head pain throughout each attack was rated on a scale from 1 to 5, as defined by Blanchard et al. (1978). These forms were completed at two different periods for 5 weeks each time: immediately before and after treatment. Five-week periods were chosen because of the high probability that each recording period would overlap with at least one complete menstrual cycle. In order to exercise some control over the retrospective completion of those forms, patients were asked to turn in their headache forms every week. The information derived from the headache forms were converted into the following variables:

Intensity of headaches: This variable was a measure of the amount of head pain experienced and represents the total of all intensity ratings.

Duration of headaches: This variable was a measure of the total number of hours spent in a state of migraine.

Number of headache days: This measure was the number of days during which there had been a report of headache

Medication: Because of an overall difficulty in clinically assessing potency and analgesic responses to various classes of medication (for an exhaustive discussion on this question, see Gauthier, Carrier, & Roberge, in press), this measure simply consisted in counting the number of pills. However, in an

attempt to make this variable as meaningful as possible, patients were urged to use the same type of medication throughout the study.

Treatment Procedure

All patients gave informed consent and obtained clearance from their personal physician to participate in the study. In each condition, treatment sessions were administered once a week for a period of 7 weeks. For each patient, the times of appointments were held constant throughout treatment. Missed appointments were rescheduled in the same week. During the first session, which lasted about 90 min, patients were provided with an overview of migraine pathophysiology, a description of the rationale for their treatment, and some explanations about the operation of the setting and apparatus and they also received some treatment.

During the other sessions, once the thermistor or electrodes were attached to the individual, there was a 12-min adaptation phase, followed by a 3-min initial baseline phase and a 20-min treatment phase. The treatment phase involved the administration of either finger temperature biofeedback or TENS. Patients in the biofeedback condition were instruct to increase their finger temperature as much as they could, using mental strategies described to them at Session 1. Patients in the TENS group were given electrical stimulation. It should be noted, however, that the intensity of the stimulation was under their control. Indeed, they were instructed to set (or reset) the intensity of the stimulation at a level that was neither unpleasant nor painful. In order to ensure a minimal amount of electrical stimulation and to increase treatment credibility, they were led to believe they

could derive some benefits from the treatment only as long as they set the unit in such a way as to produce a tingling sensation. During the treatment phase, they were urged to increase the intensity of the stimulation whenever the tingling sensation seemed to decrease.

The treatment rationale given to patients in TENS condition was quite the same as the one given to patients in the other group. Patients were told that electrical stimulation, administered to an acupuncture site, would help to deactivate their sympathetic nervous system. This deactivation would prevent exaggerated vasoconstriction and vasodilatation and, consequently, would prevent migraine attacks. The biofeedback group was given a rationale referring to the same mechanism. However, they were told that the way to deactivate their sympathetic nervous system was to train themselves in handwarming.

Finger temperature was recorded in both treatment conditions at 1-min intervals during the baseline and the treatment phases. In order to facilitate stabilization of physiological responses, patients were requested to be in the waiting room for at least 15 min prior to the time of their appointment. All sessions were administered individually.

Because biofeedback treatment typically involves home practice, patients in the biofeedback condition were encouraged to engage in home practice. Thus, in contrast with those in the TENS condition, they were invited to practice on a daily basis for one 20-min or two 10-min periods whatever strategies they had found to be associated with success in the laboratory. In addition, they were encouraged to utilize their strategy as soon as they became aware of the onset of

a migraine attack. They were also warned that control might be more difficult to achieve in situations where the attacks were severe than in those where they were mild. But should this happen, they would successfully bring the more severe migraines under control as long as they persisted in their efforts. To remind patients of the importance of home practice, inquiries were made at every session as to whether biofeedback strategies were practiced and utilized regularly to control migraine.

In order to assess treatment credibility and expectancies for improvement, patients were asked to respond to a brief questionnaire (Gauthier et al., 1981) at the end of Sessions 1, 4 and 7. An attempt was made to reduce the influence of social demands on the questionnaire by telling patients that these ratings would not be seen by the therapist. In fact, they were told that the administration of the questionnaire was part of another study conducted by another group of researchers interested in program evaluation. Accordingly, they were instructed to insert their completed questionnaire in an envelope and to seal it themselves before putting it into a box which was located on the door of a different laboratory.

Results

Characteristics of the Study Population

A multivariate analysis of variance (MANOVA) was conducted on the data describing the main characteristics of the study population (see Table 1). Results indicated that the experimental groups did not differ significantly from one another on those variables.

Treatment Credibility

Means at Sessions 1,4, and 7 for the biofeedback group were 23.1 (SD=5.8), 22.4 (SD=5.3), and 24.3 (SD=3.6), respectively. Those corresponding to the same sessions for the TENS group were 24.4 (SD=4.6), 24.9 (SD=3.4), and 24.8 (SD=3.2). Since the possible maximum score was 28, these data indicated that treatment credibility was high in both conditions. A one-way analysis of variance (ANOVA) on the data from Session 1 showed that treatment rationales were equally credible before treatment. Further analyses of the credibility data by means of a two-way ANOVA with repeated measures on one factor indicated that expectancies for improvement were equivalent in both groups throughout treatment without showing any significant changes over time

Physiological Data

Percentages of change in hand temperature during sessions were derived by using the following formula: $[(M_T-M_B)/(98.5-M_B)]$ X100 where M_T represented the mean of the three highest temperature readings during the period following the baseline phase; M_B the mean of the last 3-min of the baseline; and 98.5, the basal temperature of the human body in degrees Farenheit. This formula was chosen because it allowed to take into account the fact that the degree of difficulty involved in producing increases in finger temperature changes as the baseline value approaches the basal body temperature.

Means for the percentages of change in hand temperature at Sessions 1,4, and 7 for the biofeedback group were 20.61 (SD=17.84), 21.82 (SD=22.21),

and 18.05 (SD=19.75), respectively. Those corresponding to the same sessions for the TENS group were 8.57 (SD=27.41), -5.16 (SD=19.61), and 6.73 (SD=15.25). Because the study involved a comparison between a treatment that was physiologically active and one that was physiologically inactive, the temperature data were analyzed separately for each group in order to establish whether or not the treatments were physiologically active if the changes observed in finger temperature differ significantly from zero, and physiologically inactive if they did not.

Analyses of the temperature data for the biofeedback group showed that subjects were able to achieve significant increases in hand temperature at Session 1 [$t(22)=4.00$, $p<.01$], Session 4 [$t(22)=3.40$, $p<.01$], and Session 7 [$t(22)=3.17$, $p,.01$]. In contrast, none of the analyses for the TENS group reached, or even remotely approached, statistical significance, thereby suggesting that the TENS procedure had been quite inert from this physiological viewpoint. Further analyses also indicated that the changes observed in hand temperature in the biofeedback condition were significantly different from those observed in the TENS group [$t(22)=3.16$, $p<.01$].

In order to determine whether the temperature change differences observed between the two experimental conditions had anything to do with differences in baseline values, the following analyses were performed. A mean temperature baseline values were derived for each condition. It was found that the mean for the biofeedback group was 90.6°F (SD=3.48) and 88.2°F (SD=5.84) for the TENS condition. A statistical comparison between these

means did not yield a significant finding. Neither did a Pearson correlation analysis between baseline values and percent temperature scores.

Headache Data

Headache data for both experimental groups at pretreatment and posttreatment appear in Table 2. Because an examination of the raw data revealed that they did not fit a normal distribution they were submitted to various transformations (square root, cube root, logarithm,etc.) until one was found to be satisfactory. The square root provided the most acceptable distribution. Accordingly, each score was transformed by using the square root before proceeding with the analyses.

Insert Table 2 about here

A MANOVA was conducted on the pretreatment scores. Results did not reveal any significant differences between groups. Subsequently, the headache scores were subjected to a two (groups) by two (time of assessment) doubly MANOVA for repeated measures. The only significant effect yielded by this analysis was the "time" effect [$F(4,19)=3.62$, $p<.05$]. Univariate ANOVAs revealed that the main effect of time was significant on each of the headache variables: the intensity of headaches [$F(1,22)=14.92$, $p<.001$], the duration of headaches [$F(1,22)=13.99$, $p<.001$], the number of headache days [$F(1,22)=8.27$, $p<.01$] and the number of pills consumed [$F(1,22)=10.57$, $p<.01$].

Further analyses of the headache data were conducted to determine the degree to which the power of the comparisons between the experimental conditions had been affected by the small sample sizes. For all headache variables (intensity, duration, headache days and medication), estimation of effect sizes using d (Cohen, 1977) yielded values ranging from .40 to .64. Given the sample sizes (paired comparisons) and the significance criterion set at .05, the power to detect these effects in the present study were ranged from .15 to .33. Thus, the probability to conclude by mistake that there were no significant differences between treatments (Type II error) varied from .07 to .84. For a conventional desired power value set at .80 (Cohen, 1977), it will be noted that the minimal number of subjects that would have been required in each condition to demonstrate a significant difference between both groups at the 5% level (assuming, of course, that these differences really exist in the general population) would have ranged from 39 to 45 for three of the headache variables (intensity, duration, and number of headache days) and would have been 99 for the remaining variable. The values of Omega-Square (Plutchick, 1974) corresponding to those of d indicated that the amount of variance that these differences would have accounted for would have ranged from .04 to .09.

Clinical Improvement Data

In order to test further the differences between the two experimental conditions, the clinical meaningfulness of headache reductions at posttreatment were taken into consideration. Accordingly, percent improvement scores were computed for all headache variables using the following formula: [(pretreatment-

posttreatment)/pretreatment] X 100. Then, subjects who improved 50% or more were classified as Successful whereas subjects whose improvement was less than 50% were classified as Unsuccessful. These data are summarized in Table 3. A series of Binomial tests on the percentages of Successful or Unsuccessful did not reveal any significant differences between groups.

Further analyses of the clinical improvement data were conducted to determine the degree to which the power of the comparisons between the experimental conditions had been affected by the small sample sizes. For all of the headache variables, estimation of effet sizes using h (Cohen, 1977) yielded values ranging from .00 to .55. Given the sample sizes (paired comparisons) and the significance criterion set at .05, the power study ranged from .00 to .39. For a conventional desired power value set at .80 (Cohen, 1977) the minimal number of subjects that would have been required in each condition to demonstrate a significant difference between both groups at the 5% level (assuming, of course that these differences really exist in the general population) would have been more than 1,237 for the headache medication variable and would have ranged from 41 to 77 for the remaining variables. Again, the values of Omega-Square indicated that the amount of variance that these differences would have accounted for would have been less than 10%.

Insert Table 3 about here

Credibility Ratings Versus Clinical Improvement

In order to assess the extend to which treatment was related to expectancies for improvement, credibility ratings were correlated with percent improvement scores by means of Pearsons-rank correlation coefficients. None of the correlational values reached statistical significance.

Changes in Hand Temperature Versus Clinical Improvement

The specificity of the therapeutic effects of learned temperature control on migraine was further evaluate, as recommended by the Task Force Report on the Biofeedback Treatment of Vascular Headache (Blanchard & Andrasik, 1987), by conducting correlational analyses with the percent clinical improvement scores and the percent temperature change scores at Sessions 1, 4, and 7. None of the Pearson correlational coefficients were found to be statistically significant (the correlational values ranged from -.23 to .21). It may be also noteworthy that none of the correlational analyses between the temperature baseline values or the level of fingertip temperature achieved at Sessions 1,4, and 7 and the percent clinical improvement scores yielded significant results.

Discussion

The major purpose of the study was to assess the role of thermal self-regulation in biofeedback treatment of migraine. In order to do so, the effects of thermal biofeedback were compared with those of a control procedure involving the use of TENS. Given the purpose of the study, it was essential to demonstrate before anything else that the control procedure was as credible as biofeedback, but physiologically inert from a temperature viewpoint. With regard to this issue,

the present results do indicate that the experimental manipulation was successful. Indeed, the TENS procedure was found to generate therapeutic expectancies similar to those observed in the biofeedback condition. Furthermore, it was found not to have any significant impact on finger temperature.

Contrary to expectations, results pertaining to treatment outcome did not reveal any significant differences between groups. In fact, the control procedure seemed to be just as effective as thermal biofeedback for hand warming in reducing migraine. Of course, absence of significant differences between two variables is not necessarily evidence of absence of differences, and this was clearly confirmed by the power analyses. Furthermore, one cannot ignore the fact that there was a tendency for the biofeedback treatment to generate more improvement in migraine than the control condition on nearly all of the headache variables. However, an examination of the sample sizes that would be needed to detect those differences and a consideration of the percentages of variance that they would account for suggest that they could hardly be construed as clinically meaningful. Thus, it would seem that the ability to self-regulate does not play a major role in determining the effects of biofeedback on migraine. Again, this is not to say that it does not play a role at all. However, if it does play a role, it would seem to be a marginal one. It may be noteworthy that our results are consistent with most of the literature which has found very little support for a dose-response relationship between any specific measure of hand-warming (or hand-cooling) and headache improvement (Blanchard et al., 1983; Gauthier,

Doyon, Bois, Leblond, & Drolet, 1982; Gauthier, Doyon, Lacroix, & Drolet, 1983; Gauthier, Lacroix, Côté, Doyon, & Drolet,1985; Kewman & Roberts, 1980; Largen et al., 1981; Morill & Blanchard, 1989).

As recommended by the Task Force Report on the Biofeedback Treatment of Vascular Headache (Blanchard & Andrasik, 1987), subjects' ability to achieve significant changes in the response system being targeted was assessed. Results indicated that biofeedback subjects were indeed able to bring about some significant increases in hand temperature throughout their training. They also showed that the physiological changes observed in the biofeedback group exceeded those observed in the TENS condition. Consequently, one cannot suggest that the lack of significant differences in treatment outcome in the present study has something to do with the lack of ability to self-regulate finger temperature. Concerning this issue, it may be worth pointing out that the levels of thermal self-regulation achieved in the present study were also comparable to those found in some of our earlier studies where the application of thermal biofeedback for hand warming had led to significant reductions in migraine. In Gauthier et al. (1985), for example, improvement ranged from 62.5% to 87.5%, depending on the variable being considered, and the increase achieved in finger temperature was most often at the level of 20%.

Given subjects' ability to warm volitionally their hand in the present study, clinical improvement in the biofeedback condidtion was expected to be within the range of what had been obtained in our previous studies (e.g., Gauthier et al., 1981; 1983; 1985). This expectation, however, was not fulfilled. Indeed,

comparisons of clinical improvement between studies indicated that subjects in the present study had derived less benefits from biofeedback than usual. Further comparisons between the studies were done in order to find some explanation. These comparisons revealed that patients in the present study had less severe migraine headache. Because there is some evidence showing that the more severe cases of migraine tend to respond more favorably to biofeedback (Gauthier, Fradet, & Roberge, 1988), a question arises as to whether or not chances to find some significant differences between groups would have been significantly enhanced if the study had involved more severe cases of migraine. The answer to this question is fairly simple if one considers regression toward the mean. This phenomenon has been observed with many clinical populations and treatment modalities (Agras, Taylor, Kraemer, Southam, & Schnelder, 1987; Chesney, Black, Swan, & Ward, 1987; Gauthier et al., 1988; Richter et al., 1986) and there is no reason to believe that the control subjects in the present study would not have responded more favorably to the TENS procedure if they had been subjects with more severe migraine headache. Consequently, it is doubtful that the use of more severe cases would have led to significant findings.

In the attempt to reach some understanding of what happened in the present study, it is important to reflect on the control condition. It may have been physiologically inert in that it did not produce any significant changes in hand temperature. However, this is not to say that it did not have any physiological impact whatsoever. Indeed, TENS involves electrical stimulation and, in the present study, subjects had to keep the stimulation at a level corresponding to a

tingling sensation. Thus, a question arises as to whether or not TENS as used in the present study was an active treatment. In order to generate therapeutic expectancies, real electrical stimulation was used. It was also set in accordance with some recommendations by Ottoson and Lunderberg (1988) for the application of TENS so that it would be more realistic and more honest. However, the site of stimulation had very little to do with the clinical application of TENS for the management of headaches. Indeed, concerning the placement of the electrodes for the treatment of headaches, the recommendation (Ottoson & Lunderberg, 1988) and the practice (Hay, 1982; Jay, Brunson, & Branson, 1989; Solomon & Guglielmo, 1985) has been to place the electrodes on or around the pain area, not on the dorsum of the hand. Furthermore, the amount of exposure to TENS was kept to minimal. In fact, all of the treatment outcome studies on TENS and headaches have used more treatment sessions (Hay, 1982; Jay et al., 1989, Solomon & Guglielmo, 1985) than the present study, and home applications up to twice a day for periods ranging from 10 to 15 min were sometimes added to the treatment sessions (Jay et al., 1989).

Although the present study did not reveal any significant differences in treatment outcome between the biofeedback and the control condition at posttreatment, it does not mean that differences would not have emerged at follow-up if a follow-up had been conducted. Indeed, at the end of treatment, some anecdotal observations revealed that patients in the TENS condition were wondering about what would happen to them in the long run. Biofeedback patients did not seem to have this preoccupation. Perhaps it was because they

were taking their therapeutic strategies with them at home. In contrast, patients in the TENS condition did not have this kind of "security blanket" that they could use at home whenever they liked. In fact, none of them was given a TENS apparatus to use at home and cost made it prohibitive for most of them to buy one. Obviously, following-up this cohort of patients might shed some light on the therapeutic mechanism of biofeedback for migraine headache.

To conclude, the present results suggest that thermal self-regulation does not play a major role in the mechanism of biofeedback for migraine. They also suggest that it would be premature to reduce biofeedback to a mere placebo.

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Table1

Characteristics of the Study Population

		Biofeedback (n=12)		TENS (n=12)	
		M	Range	M	Range
Age (years)		38.25	(31-47)	37.50	(29-47)
Chronicity (years)		14.67	(04-33)	20.50	(04-31)
		n	%	n	%
Civil status	-Married	10	83.3	9	75.0
	-Single	1	8.3	3	25.0
	-Divorced	1	8.3	0	0
Occupation	-At work	9	75.0	9	75.0
	-At home	2	16.7	3	25.0
	-At school	1	8.3	0	0
Migraine diagnostic	-Classic	0	0	2	16.7
	-Common	12	100.0	10	83.3
Family history		9	75.0	11	91.7
Unilaterality		12	100.0	12	100.0
Pulsative		6	50.0	4	33.3
Prodromes		4	33.3	2	16.7
Nausea		12	100.0	9	75.0
Vomiting		9	75.0	6	50.0
Hormonal influence		7	58.3	8	66.7

Table 2

Means and Standard Deviations for Each Headache Variable for Each Group During Each Experimental Phase

		Pretreatment		Posttreatment	
Headache Variable	Group	M	SD	M	SD
Intensity	Biofeedback	90.8	25.2	47.1	38.7
	TENS	103.9	45.1	79.3	55.4
Duration	Biofeedback	69.7	23.9	40.3	31.4
	TENS	80.5	38.8	63.0	34.3
Number of days	Biofeedback	7.5	2.5	5.6	4.2
	TENS	8.1	3.1	7.5	4.8
Medication	Biofeedback	18.3	7.8	11.0	12.3
	TENS	16.4	15.0	12.4	19.7

Table 3

Number and Percentage of Subjects Who Improved 50% or More (Successful) or Less than 50% (Unsuccessful) on Each Headache Variable

		Unsuccessful		Successful	
Headache variables	Group	n	(%)	n	(%)
Intensity	Biofeedback	5	(41.7)	7	(58.3)
	TENS	9	(75.0)	3	(25.0)
Duration	Biofeedback	7	(58.3)	5	(41.7)
	TENS	11	(91.7)	1	(8.3)
Number of days	Biofeedback	8	(66.7)	4	(33.3)
	TENS	11	(91.7)	1	(8.3)
Medication	Biofeedback	7	(58.3)	5	(41.7)
	TENS	7	(58.3)	5	(41.7)

CONCLUSION GÉNÉRALE

Le but de cette étude était de comparer les effets de la rétroaction biologique à ceux obtenus avec une procédure physiologiquement inerte en terme de changements de température. Cette comparaison devait clarifier le rôle de l'auto-régulation de la température dans le traitement de la migraine par la rétroaction biologique thermique.

La procédure contrôle utilisée était la stimulation électrique transcutanée (TENS). Étant donné le but de l'étude, il était essentiel de prouver que cette procédure générait autant d'attentes thérapeutiques chez les patientes que la rétroaction biologique. Aussi, il importait de démontrer que la procédure de TENS ne provoquait aucun effet significatif sur la température. Cette manipulation expérimentale s'est avérée un succès. Cependant, aucune des différences observées entre les groupes au niveau des effets thérapeutiques n'était significative. De même, aucune corrélation significative ne fut trouvée entre les changements de température au niveau de la main et l'amélioration thérapeutique. Enfin, les analyses de puissance démontrent qu'un très grand nombre de sujets supplémentaires aurait été requis pour détecter une différence significative entre les deux conditions.

Ces résultats suggèrent que l'habileté des patientes à auto-régulariser la température de leurs mains n'est pas un bon prédicteur de la diminution des migraines quand traitées avec la rétroaction biologique thermique. Toutefois, on ne peut pas conclure que l'effet de la rétroaction biologique n'est qu'un effet placebo ou un effet des attentes thérapeutiques. En effet, aucune corrélation significative ne fut trouvée entre la crédibilité de traitement et l'amélioration thérapeutique. De plus, même si la procédure de TENS était inactive à produire des changements de température, il n'est pas certain qu'elle était inactive par rapport à d'autres paramètres physiologiques.

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