Effects of Frontalis EMG Biofeedback and Diazepam in the Treatment of Tension Headache

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SYNOPSIS

Frontalis EMG biofeedback and diazepam treatments were compared in tension headache patients; headache scores (intensity and frequency) and frontalis EMG were used as control parameters. The study, conducted in a double blind manner, was split in three equal observation periods (4 weeks): baseline, treatment and follow-up. Four patient groups were chosen, two of which received placebo treatment. In both true conditions, biofeedback and diazepam, treatment effects differentiated from placebo groups; with diazepam the strongest results upon headache and frontalis EMG were observed during treatment, which, however, were lost at the follow-up period; biofeedback although with weaker effects during treatment showed, at follow-up, a long lasting reduction of headache scores even when frontalis activity reached baseline levels; in the false biofeedback group some decrease of EMG activity during treatment and of headache intensity at follow-up were also observed. The data suggest that biofeedback is a complex learning situation, where several uncompletely known factors are possibly at work; it also raises the possibility of a complex relation between frontalis muscular activity and headache since a simple linear relation of both variables was not observed.

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INTRODUCTION

Since Sainsbury and Gibson[1] described in 7 patients complaining of tension headache an increased frontalis activity, the relationship between that clinical situation and frontalis muscle tension was thereafter accepted.

Nevertheless, this close relationship has been questioned since migraine sufferers have, on average, higher frontalis activity than tension headache patients.[2,3] Besides, a low correlation between the headache complaint and the level of frontalis EMG was found by several authors.[4,5,6] However, especially after the work of Budzynski[7] all the reasoning about the use of muscle biofeedback (BF) in the treatment of tension headache (TH) continued to rest on the assumption that pain is related to muscle tension. Even if this were true the literature concerning the use of biofeedback seems to be open to several methodological criticisms which render the analysis of the results somewhat difficult. In fact, the relaxation instructions are usually not equal for both the BF and control group; double blindness is not generally employed, though it is well known that 45% of the patients feel benefits from placebo medication;[8] other relaxation techniques are often conjointly used, namely home practice; and even in well designed studies, the adjustment of BF signals by the therapist can lead to spurious effects.

Another missing point concerning the therapeutic power of BF in TH is that, as far as we know, no comparison is available in the literature with standard treatments, for instance, psychoactive drugs. Though miorelaxants are considered ineffective,[9] tranquilizers and antidepressive drugs are commonly used.[10,11,12] So it seems sensible to assess the power of a well tested tranquilizer, the diazepam, against BF, both for clinical and economical reasons.

The aim of the present paper is to try to shed some light on these controversial points in a well controlled design. For that, the definition of TH of the International Ad Hoc Committee and Classification of Headache[13] is strictly relied upon; a double blind trial is set for BF false and true, and, equally in a double blind manner, diazepam is included in the study.

MATERIAL AND METHODS

The experimental design is shown in Fig. 1.

Two Neurologists selected patients, from a Headache Clinic population, obeying to well defined clinical and laboratorial criteria:

a) Ache or sensation of tightness, pressure or constriction frontal and/or suboccipital, with daily frequency;
b) Complaint lasting for one year or more;
c) Normal neurological examination;

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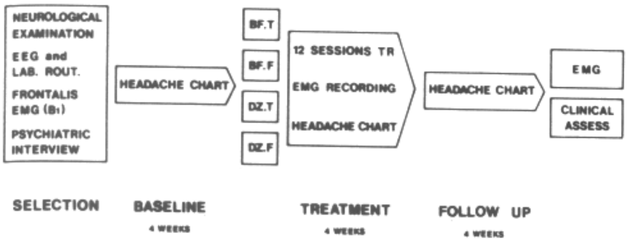


Fig 1.—The experimental design consisted of four different steps: (1) Selection of patients, (2) Baseline, (3) Treatment period and (4) Follow-up. Items 2, 3 and 4 had a duration of 4 weeks.

d) Normal EEG and laboratory routines;
e) Average frontalis EMG, recorded over a period of 5 minutes, above 3.5 uV/min.

A Myotron 220 (Enting Instruments and Systems) was used with electrodes placed on the forehead, the patient lying down with eyes closed. The apparatus amplifies and filters (100-1000 HZ) the raw EMG; the resulting signal is then transformed into a slowly fluctuacting DC voltage which is a measure of muscular activity; this information was provided continuously to the patient in terms of the frequency of a series of clicks. Periodically the device displayed the average value in uV/min, which was used as an indication of muscular tension.[14] Additionally, all patients had a psychiatric interview in order to discard psychiatric disorders as being the main problem. In this way, we selected 36 patients, 27 female, 9 male, with ages ranging from 17 to 59 years, with a mean age of 37.5. Once the selection criteria were met, the patients entered a 4 week baseline period in which they filled up a daily chart for frequency and intensity of headache. At the end of this period a new baseline EMG was made and patients were randomly assigned to one of the 4 following groups:

— Biofeedback True (BF-T)
— Biofeedback False (BF-F)
— Diazepam (DZ-T)
— Diazepam Placebo (DZ-F)

All patients were told that their complaints were related to the increased tension of head muscles and that treatment was aimed to reduce this tension; during it, and the following months they should stop any other form of therapy.

In order to keep constant a majority of placebo factors, namely patient/therapist contact and effects of technology, all patients came three times a week to hospital during a month. BF-T and BF-F patients had 30 minutes treatment sessions in which they were asked to relax and try to decrease the frequency of the clicks which they heard through the headfones (BF-F patients in fact, heard a prerecorded tape). Additionally, during 5 minutes, prior and after treatment, resting frontalis EMG was recorded. DZ-T and DZ-F patients took a similar pill t.i.d. All patients at the end of each session were informed that they were doing quite well. Due to blind requirements the therapist didn't know if patients were in a true or false condition.

During the treatment period and the following month, patients were requested to go on filling their headache chart. One month after the end of treatment, in the follow-up session, resting EMG was recorded in all patients, who were clinically reassessed, what included, naturally, the collection of their Headache Charts.

Two groups of measurements were made:

a) For EMG values, the means of 5 minutes were taken in all patients at baseline sessions (B_1 and B_2) and at the follow-up session (FU). Furthermore, during the 12 treatment sessions and both for BF-T and BF-F groups, the mean of 5 minutes pre (R_1) and post (R_2) BF, and those of the 30 minutes treatment period (TR) were taken. In the DZ-T and DZ-F groups the means of the first 5 minutes resting EMG were also computed, for all the 12 pseudotreatment sessions. Two way ANOVA's with replication were performed to detect effects across sessions and treatments, and one way ANOVA's with replication in the other cases.[15]
b) Headache intensities and frequencies were the means of values charted along 28 days before, during and after treatment. The corresponding indexes were assessed with the non-parametric Mann-Whitney U-test[15] (using the lower bounds for the critical value). The baseline values (B) of the four groups were compared; in each group TR and FU scores were tested against each other and versus B as shown by the half matrices of Fig. 4; all tests had the same number of degrees of freedom (8,8).

RESULTS

The following data are based on 8 patients per group, since in 2 groups there was one drop out and equal sample size was preferred.

The effects of treatment on the resting EMG values — R_1 — are shown in Fig. 2; obviously, this is the only figure where the four groups can be plotted together.

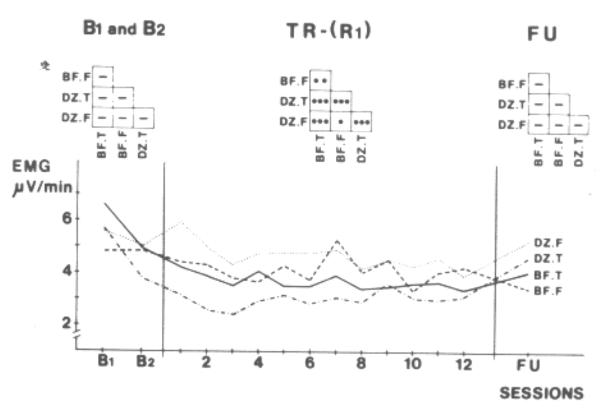


Fig 2.—EMG values of baseline, rest periods and follow-up. The levels, at which differences between groups were obtained, are shown in the half matrices as follows: significant at p<.001 by •••; at p<.025 by ••; at p<.05 by •, and not significant by —.

All 4 groups have similar baseline levels at B_1 and B_2 with no significant statistical differences. It must be noticed that B_2 values are somewhat lower than B_1's, but only in DZ-T group was found a statistical difference ($\rho < .025$).

During treatment differences among the four groups were tested by a two way ANOVA with replication, which showed no effect along sessions F = 0.54 (11,168); but demonstrated strong differences between treatments. When pairwise compared DZ-T gave most efficient muscle reduction significantly different from all the other groups $F \geq 11.47$ (1,168; $\rho < .001$); BF-T was next although different from BF-F at lower confidence level, F = 5.75 (1,168; $\rho < .025$), which in turn was slightly different from DZ-F, F = 3.81 (1,168; $\rho < .05$). No differences were detected among the two placebo groups, F = 0.48 (1,168). Effects of treatment were also studied comparing baseline values (B_2) with resting levels at the last treatment session (R_1 (12)) and at follow-up (FU), and no statistical differences were found.

Intratreatment effects, that is, for the periods the patients received "biofeedback", both for BF-T and BF-F groups, are shown in Fig. 3. The curve for BF-T is consistently below the other, and a two way ANOVA revealed significant treatment differences, F = 11.63 (1,168; $\rho < .001$). The same applies to the R_2 periods shown also in Fig. 3, F = 3.87 (1,168; $\rho < .05$). In both cases no effects along sessions were detected.

When the 4 groups are compared at follow-up no significant statistical differences were measured (Fig. 2).

Values for Headache Intensities and Frequencies are shown in Fig. 4 for baseline, treatment and follow-up periods. The four groups started at similar levels; in

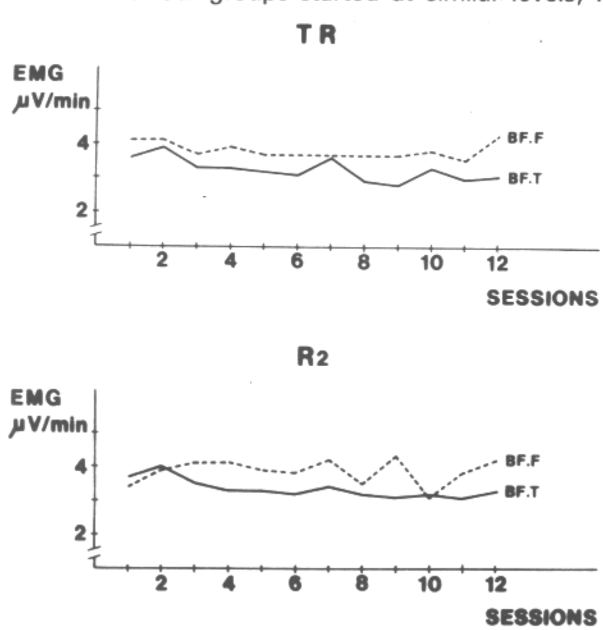
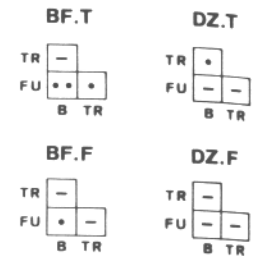


Fig 3.—EMG values of the intratreatment periods (TR) and for Rest 2 (R_2) are plotted along the 12 treatment sessions for BF - T and BF - F groups.

HEADACHE INTENSITY

	B	TR	FU
BF.T	1.64 (0.73)	1.04 (0.74)	0.33 (0.37)
BF.F	1.88 (0.79)	1.06 (0.86)	0.98 (0.69)
DZ.T	1.95 (0.52)	0.88 (0.66)	1.30 (0.70)
DZ.F	2.03 (0.70)	1.51 (0.88)	1.58 (0.89)



HEADACHE FREQUENCY

	B	TR	FU
BF.T	1.21 (0.53)	0.77 (0.50)	0.42 (0.49)
BF.F	2.00 (1.28)	1.52 (1.30)	1.19 (1.19)
DZ.T	1.72 (0.52)	1.00 (0.62)	1.26 (0.81)
DZ.F	2.17 (1.14)	1.61 (1.06)	1.98 (1.29)

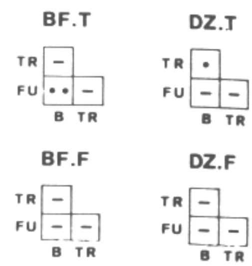


Fig 4.—Headache intensity and frequency scores (mean and Sd) corresponding to B, TR and FU phases. The half matrices indicate the significant levels, when using a Mann Whithney distribution free-test, as follows: p<.01 is presented by ••; p<.05 by •; and non significant values by —.

fact no differences were observed when intensities were compared, but for headache frequency the BF-T group is different from DZ-F at $\rho < .05$ (U = 47). Although all groups showed a tendency to decrease the intensity and frequency of headaches during treatment, significant levels were only reached in the DZ-T group (U = 45; $\rho < .05$). Comparison of post-treatment (FU) data in relation to baseline (B) data shows different results; in fact the initial decrease observed in the DZ-T group disappears and both biofeedback groups are effective during this period: BF-T reduces both intensity (U = 41; $\rho < .01$) and frequency (U = 46; $\rho < .05$) of headaches and BF-F only decreases their intensity (U = 48; $\rho < .05$). Besides comparing treatment (TR) and follow-up (FU) headache scores, a further significant decrease in their intensity was found in the BF-T group (U = 47; $\rho < .05$). It must be stressed that, in all the above comparisons, statistically meaningful effects were never obtained for the DZ-F group (see Fig. 4).

DISCUSSION

The purpose of this work was centered around two main questions: which is the value of Biofeedback in the absence of spurious effects, and whether it is a better treatment than a standard pharmacological approach. Furthermore, some of our data raise questions in the discussed relation between muscle tension and head pain in TH patients.

Even under the strict experimental conditions used, BF-T proved more efficient than its placebo, although in both situations a significant reduction of frontalis tension was observed during the treatment period, and both acted upon headaches at follow-up with a stronger effect for the true condition. A linear decay of EMG along treatment sessions was not detected, a fact that could imply the absence of learning effects during training; the lack of linear regression of our data could be explained by the difficulty in reducing EMG when the initial values are somewhat low; however, they are in the same range of others referred in the literature with more obvious decays;[3,16] other explanations could be offered by the absence of home practice and the inexistence of shaping during treatment, condition requested by the double blindness used. However, even without a linear EMG decay along BF treatment, headache levels decreased at follow-up; this fact observed and discussed by others,[5] has no clear explanation.

The parallelism of action between the two biofeedback groups (true and false), the inexistence of learned control of frontalis EMG, and the improvement of headaches at follow-up could imply that the effect of biofeedback could be considered as a result of a complex learning situation in which factors other than pure effect in muscle tension, namely cognitive ones, are most important. Both treatments used, Diazepam and Biofeedback, were effective in tension headache patients although with different timings. Diazepam, most powerful during treatment, both in pain scores and EMG levels, worsens its effectiveness when stopped: frontalis tension approaches baseline levels and headache scores are in between baseline and treatment indexes, weighing the advantages of each treatment is at the moment a matter of choice between a rapidly efficient drug with short lasting results and a time consuming treatment with long lasting effects; it may be expected that the treatment option will be based on individual indications rather than medical capabilities, but the lack of studies on this subject makes any choice a matter of rough probabilities; however it may be assumed that a continued combination of an instructional set of relaxation with Diazepam might attain the best long term results in decreasing muscle tension and reducing pain complaints, such as was found by Lavallée[17] in Chronic Anxiety Patients.

The questionable relation between EMG and headache in T.H. is also raised by some of our data; namely, during Baseline, the BF-T group although having the highest frontalis tension, presents the lowest headache indexes, which in relation to headache frequency reached statistical significance. The same reasoning applies to follow-up values once at that phase no differences in frontalis tension were observed among the four groups, although BF-T and BF-F present significantly lower headache scores. Meanwhile a clear temporal relation between this two variables appears in the DZ-T group with a simultaneous decrease of both. Therefore it is possible that although a strict linear relation between frontalis tension and headache does not exist, this two parameters are probably linked in a more complex relationship where other pathogenic factors also intervene; namely, psychological parameters that appeared to bear a stronger relation with frontalis EMG than head pain.[6] Meanwhile some organic factors with an obscure role in Tension Headache pathogeny may be hypothesized as intervenients in headache and/or muscular activity. Among these must be mentioned a permanent state of vasoconstriction in the temporal artery,[18] the lower levels of platelets 5-hidroxitryptamine,[19] and the moderate incidence of anomalies in the computarized axial tomography[20] of TH patients.

To understand treatment results in Tension Headache an adequate knowledge of pathogenic mechanisms is needed; the relative paucity of research on this field prevents a broad and clear conception of this clinical entity.

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