Randomized Trial

Efficacy of Biofeedback in the Treatment of Migraine and Tension Type Headaches

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Background: Biofeedback is an established non-pharmacologic technique commonly used in the treatment of migraine and tension type headaches. Multiple published studies have suggested that biofeedback is effective in reducing the frequency and severity of headaches, often allowing patients to decrease their dependence on medication. Studies have also suggested that biofeedback may effect a decrease in medical utilization.

Objective: Assess the efficacy of biofeedback in reducing the frequency and severity of migraine and tension type headaches.

Design: Randomized, prospective, single blind, single center controlled trial.

Methods: Sixty-four patients with migraine with or without aura and/or tension type headaches, by ICHD-1 criteria, age 18 to 55, who had suffered from headaches for more than one year, were entered into the study. Patients were randomly assigned to receive biofeedback in addition to the basic relaxation instruction or relaxation techniques alone. All patients received instruction in pain theory. Biofeedback training consisted of 10 50-minute sessions utilizing standard EMG feedback from the frontalis and trapezius muscles and temperature from the third finger of the dominant hand. Visual and auditory feedback was provided. Thirty-three patients were assigned to receive biofeedback plus the relaxation techniques and 31, the relaxation techniques alone.

All patients were asked to respond to periodic questionnaires for 36 months. The primary analysis was an intention-to-treat (ITT) analysis. The subsidiary analyses were not and the 11 subjects (7 in the relaxation alone and 4 in the biofeedback group) who received no treatment at all were analyzed and the results were qualitatively the same.

Results: Patients who completed the program with education in pain theory and relaxation techniques showed a statistically significant decrease in the frequency and severity of the headaches in the first 12 months that continued to 36 months. Biofeedback provided no additional benefit, specifically no change in the frequency or severity of the headaches. After 3 months 48% of those in the relaxation group reported fewer severe headaches, while 35% of those in the biofeedback group reported fewer severe headaches; after 6 months, 52% of those in the relaxation group reported fewer severe headaches as compared with 57% reporting fewer severe headaches in the biofeedback group.

The number of medications used by the patients and the utilization of medical care decreased in both groups over 36 months suggesting a regression to the mean.

Limitations: Compliance was an issue throughout the study. Patients dropped out from the outset and that increased over time. Recovery of questionnaires was difficult and fewer were completed at each 3-month interval. Lack of a large control group who did not receive biofeedback or instruction in relaxation techniques.

Conclusion: Biofeedback is an extremely costly and time-consuming treatment modality that, in our study, provided no additional benefit when compared to simple relaxation techniques alone, in the treatment of migraine and tension type headaches in adults.

Key words: Biofeedback, relaxation techniques, tension type headache, migraine, pain program, non-pharmacologic treatment of headache

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I n 1970 Budzynski, Stoyva, and Adler introduced the use of electromyographic (EMG) biofeedback in the treatment of tension type headaches (1). Since that time multiple studies have suggested that EMG biofeedback training administered alone or in combination with relaxation techniques reduced tension type headaches by 40% to 60% (2-6). Subsequent studies using both EMG and temperature biofeedback revealed the techniques to be extremely effective in the treatment of migraine (7-10). In 1984 Seymour Diamond found that 68% of 395 patients with migraine and tension type headaches reported improvement in the severity, duration, and frequency of their headaches using biofeedback and 65% were able to maintain those gains (11). Biofeedback is a technique that combines modern technology and psychology with the precepts of Eastern self-discipline. The basis for biofeedback is operant conditioning. Through biofeedback training, patients develop a physiologic response to certain stimuli. They then acquire a certain degree of control over physiologic functions that contribute to the genesis of head pain. EMG biofeedback promotes a general sense of relaxation of the entire body using an informational feedback system where the patient hears a tone through headphones with the frequency proportional to the EMG activity in the muscle (most often the frontalis in headache) being monitored. As relaxation is achieved the tone decreases. Temperature biofeedback trains the patient to increase finger and hand temperature, in theory, stabilizing the vasomotor responses of migraine. The biofeedback monitor is only a temporary facilitating device and patients who practice the techniques should be able to effect the same changes after they are weaned from the monitor, ultimately decreasing the frequency and severity of their headaches (12). Migraine headaches affect approximately 12% of the population, directly impair the quality of life, and result in reduced work capacity and social activity (13-17). The direct medical and indirect costs of migraine total billions of dollars each year (18). Tension type headaches occur in at least 40% of the population and the impact on health care utilization and decreased productivity is marked as well (19-22). Medication remains the mainstay of treatment for all types of headaches and vast amounts of prescription and over-the-counter medications are used. Side effects frequently occur with medication and at times can be life threatening. The medications themselves often contribute to the reduced productivity

of headache sufferers. The purpose of this study was to determine if the noninvasive, non-pharmacologic treatment of biofeedback was unequivocally effective in reducing the frequency and severity of migraine and tension type headaches and as secondary effects, decreasing the need for pharmacologic intervention and direct medical care.

METHODS

Study Design

This was a randomized, prospective, single blind, single center study. The study was approved and diligently monitored by the Harvard Community Health Plan Foundation Clinical Research Committee.

Participants

Sixty-four patients were entered into the study after obtaining written informed consent. Participants ranged in age from 18 to 55 and 52 were female. All of the participants suffered from migraine with or without aura and/or tension type headache, by ICHD-1 criteria, for more than 12 months occurring 2 to 5 times/month (23). Patients with a history of psychosis were excluded. None of the participants suffered from hemiplegic migraine. The groups were similar in age distribution and sex.

Test Methods

All of the participants were referred to the Harvard Community Health Plan Comprehensive Pain Program, a modified group day treatment program of 6 weeks duration for chronic pain of non neoplastic origin. The program emphasized education and training in pain theory including headache. Pain management methods included instruction in relaxation techniques, meditation, self hypnosis, cognitive therapy, and art and movement therapy with a pain clinician. Headache patients received a modified program with emphasis on education and relaxation techniques. From the Pain Program patients were assigned at random to receive biofeedback in addition to the basic relaxation techniques or to just complete the basic relaxation instruction. All patients were followed by a neurologist who had no knowledge of who received the biofeedback treatment. Biofeedback training consisted of 10 50-minute sessions utilizing standard EMG feedback from frontalis and trapezius muscles and temperature from the third finger of the dominant hand. Both visual and auditory feedback was provided. Biofeedback

for all patients was administered by a licensed psychologist with extensive experience in the use of the techniques for the management of headaches. Thirty-three patients were entered into the biofeedback plus Pain Program and 31 into the Pain Program alone.

Data Collection

Patients were asked to complete a questionnaire upon entering the study then at 3, 6, 9, 12, 24, and 36 months. The questionnaire established the total number of headaches, the number of severe headaches (grade 7-10/10) and the number of mild to moderate headaches (grade 1-6/10), in the prior 3 months. Patients who received biofeedback were questioned about the effectiveness of biofeedback techniques in preventing or lessening severe and mild to moderate headaches on a scale of 0 to 4 where 0 was ineffective and 4 completely effective. They were also asked to rate the biofeedback experience using the same scale. Headache medications and the number of medical visits, specifically for headaches, were monitored in the electronic medical record.

Statistical Analysis

Descriptive tables and graphs are presented showing the changing means for the 4 outcome variables over time. The main analysis; however, is a form of longitudinal regression for each of the 4 outcomes. All analyses were done in Stata (various versions) (24). The question of interest in all cases was whether there was a consistent pattern over time (e.g., was there a general trend showing improvement over time) and whether this pattern differed by treatment group. The null hypothesis in each case was that there was no difference between the groups. The structure of the data was that each person was represented by a row of data on each occasion on which they were assessed. This means that rows of data were not independent since people who were assessed more than once were represented by more than one row. This lack of independence would bias the standard errors unless we corrected for this; we used Stata's built-in correction to obtain cluster-adjusted standard errors and those are shown in the table (25). The main analyses were based on intention-to-treat (ITT); the subsidiary analyses, which were not ITT, were repeated after dropping the 11 subjects who received no treatment at all and the results were qualitatively similar. The sample size was too small for multiple imputation.

RESULTS

Subject Accounting and Demographic

Of the 100 potential subjects who were screened, 64 entered the study and were randomized between the 2 groups (31 into the pain program group and 33 into the biofeedback group). The ages of the subjects ranged from 18 to 55 and 52 were female. All had had migraine and/or tension type headaches for at least 12 months. As Table 1 shows, not all subjects responded to all questions in the survey and some subjects dropped out over time. One patient was lost to follow-up immediately after entering the study and 4 other patients did not complete any of the questionnaires. Note that 2 of the main outcomes (number of headaches and number of severe headaches, each in the preceding 3 months) were measured via the periodic survey. On the other hand, the other 2 outcomes (number of medications and number of medical visits (each over the preceding 12 months) are based on data collected from electronic medical records and virtually no data is missing (with the exception of the one patient who was lost to follow-up at the outset).

Figures 1–4 are graphs showing the mean values at each time point by group. Each graph shows a clear trend toward improvement over time and each

Table 1. *Means, standard deviations, and frequencies of the number of headaches/month in the prior 3 months.*

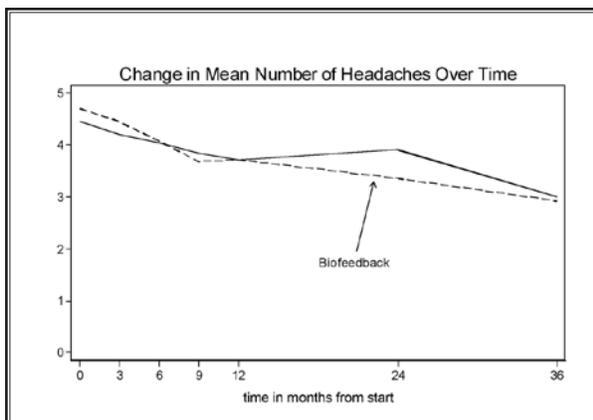| Time in months from start	Pain / Bio PP	BF	Total
0	4.46 ± 0.92 (28)	4.71 ± 0.74 (31)	4.59 ± 0.83 (59)
3	4.21 ± 1.14 (24)	4.46 ± 0.99 (26)	4.34 ± 1.06 (50)
6	4.05 ± 1.21 (22)	4.08 ± 1.13 (26)	4.06 ± 1.16 (48)
9	3.84 ± 1.01 (19)	3.68 ± 1.43 (22)	3.76 ± 1.24 (41)
12	3.71 ± 1.10 (21)	3.71 ± 1.45 (21)	3.71 ± 1.27 (42)
24	3.91 ± 1.04 (11)	3.36 ± 1.65 (14)	3.60 ± 1.41 (25)
36	3.00 ± 1.41 (9)	2.92 ± 1.38(13)	2.95 ± 1.36 (22)
Total	4.00 ± 1.14 (134)	4.00 ± 1.31 (153)	4.00 ± 1.23 (287)

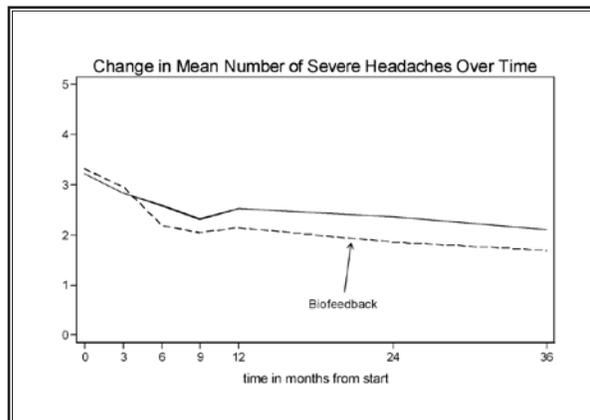Fig. 1. *Change in mean number of headaches over time.*

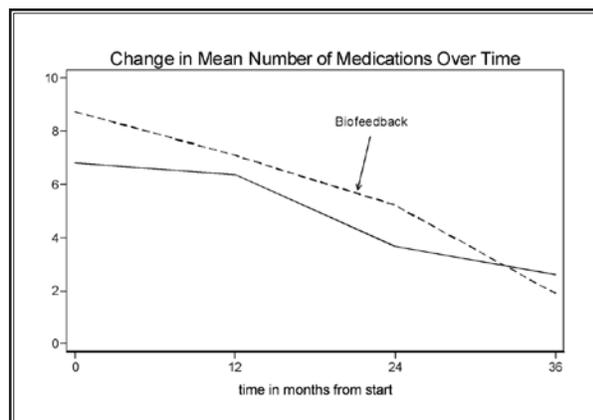Fig. 2. *Change in mean number of severe headaches over time.*

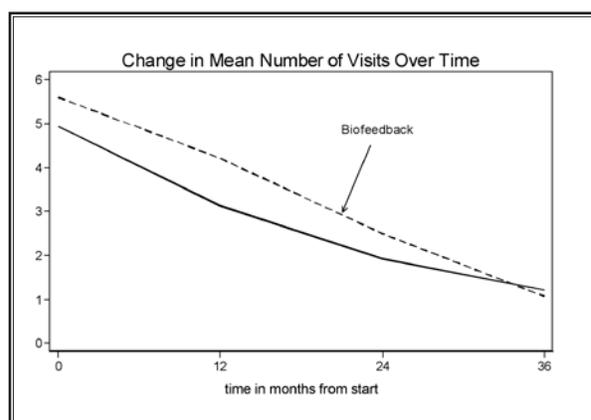Fig. 3. *Change in mean number of medications over time.*

Fig. 4. *Change in mean number of visits over time.*

shows little difference between the groups. We do not think that the differences that are shown are clinically important.

We start with descriptive information for each of the 4 outcomes of interest. Each table shows, in the rows, the time since the start of the subject in the study; the columns are the group: relaxation only (RL) and relaxation plus biofeedback (BF). In each cell are 3 numbers: the mean number of headaches, the standard deviation, and the number of people reporting results. As expected the means at time 0 (start of the study) are very similar. But note that the means continue to be similar at the other time points.

Table 2 shows the mean number of severe headaches/month in the prior 3 months. The means start at the same level and, again, continue to be very similar.

Table 3 shows the number of medications in the preceding 12 months. The table shows that the means differ throughout. At baseline, the biofeedback group were using more medications. This continued through month 24; however, at 36 months, the remaining people in the biofeedback group were using fewer drugs than the remaining people in the relaxation group.

Table 4 demonstrates the number of visits in the preceding 12 months.

Finally, our regression results are summarized in Table 5. The first number in each cell is the coefficient; the *P*-value is shown in parentheses. The rows

Table 2. *Means, standard deviations and frequencies of number of severe headaches/month in prior 3 months.*

Time in months from start	Pain / Bio PP	BF	Total
0	3.22 ± 1.22 (28)	3.32 ± 1.25 (31)	3.28 ± 1.23 (58)
3	2.83 ± 1.43 (24)	2.96 ± 1.48 (26)	2.90 ± 1.45 (50)
6	2.59 ± 1.26 (22)	2.19 ± 1.20 (26)	2.38 ± 1.23 (48)
9	2.32 ± 1.016 (19)	2.05 ± 1.09 (22)	2.17 ± 1.07 (41)
12	2.52 ± 1.08 (21)	2.14 ± 1.20 (21)	2.33 ± 1.14 (42)
24	2.36 ± 1.12 (11)	1.86 ± 0.95 (14)	2.08 ± 1.04 (25)
36	2.11 ± 1.45 (9)	1.69 ± 0.95 (13)	1.86 ± 1.17 (22)
Total	2.66 ± 1.25 (133)	2.45 ± 1.32 (153)	2.55 ± 1.29 (286)

Table 3. *Means, standard deviations and frequencies of number of medications in prior 12 months.*

Time in months from start	Pain / Bio PP	BF	Total
0	6.80 ± 8.35 (30)	8.76 ± 12.04 (33)	7.83 ± 10.41 (63)
12	6.37 ± 12.33 (30)	7.09 ± 9.16 (33)	6.75 ± 10.70 (63)
24	3.68 ± 6.29 (28)	5.22 ± 9.09 (32)	4.50 ± 7.88 (60)
36	2.61 ± 3.82 (23)	1.89 ± 4.79 (28)	2.22 ± 4.36 (51)
Total	5.03 ± 8.61 (111)	5.90 ± 9.50 (126)	5.49 ± 9.09 (237)

Table 4. *Means, standard deviations, and frequencies of number of visits in prior 12 months.*

Time in months from start	Pain / Bio PP	BF	Total
0	4.93 ± 4.91 (30)	5.61 ± 6.37 (33)	5.29 ± 5.69 (63)
12	3.13 ± 5.49 (30)	4.21 ± 4.90 (33)	3.70 ± 5.18 (63)
24	1.93 ± 3.31 (28)	2.50 ± 3.71 (32)	2.23 ± 3.51 (60)
36	1.22 ± 1.44 (23)	1.07 ± 1.90 (28)	1.14 ± 1.70 (51)
Total	2.92 ± 4.40 (111)	3.44 ± 4.86 (126)	3.20 ± 4.65 (237)

are interpreted as follows: biofeedback group gives the difference between the 2 groups, shown as biofeedback minus relaxation; thus, for example, the 0.24 under number of headaches says that the mean number of headaches in the biofeedback group was 0.24 higher than the mean for the relaxation group. The other rows show the various time points — each is compared to the baseline measure (i.e., at randomization and before treatment); all the coefficients are negative showing that each measure declines over time compared with the baseline value. Ninety-five percent confidence intervals are shown for the group predictor (which was coded 0 for "relaxation only" group and 1 for those who were in the "biofeedback also" group). Note that medications and visits are only measured at annual assessments and thus the rows for the 3, 6, and 9-month values are blank in these columns. In addition, we checked for an interaction between time and group (pain program or biofeedback) for each of the 4 outcomes; in no case was there a statistically significant interaction, with *P*-values ranging from > 0.1 to > 0.9. Thus, there is no evidence that there was any difference either over time or at any single time between the 2 groups.

The results are similar in structure for each of the 4 outcomes: there is a general trend showing improvement over time and this trend does not differ by treatment group. Recall that each coefficient shows the predicted mean change in outcome when comparing people in a row to relaxation people; for the time oriented rows (e.g., 3 months, 6 months), the comparison is to the time 0 (baseline) measure. For example, the coefficient of 0.24 for biofeedback under number of headaches means that those in the biofeedback group suffered, on average, 0.24 more headaches during the prior 3 months than did the relaxation group; similarly, they suffered approximately 0.2 fewer severe headaches, use almost one more medication, and just over half an additional visit when compared to the relaxation group. On the other hand, all the coefficients for the time variables are negative meaning that headaches, severe headaches, medications, and visits all decreased over time.

Finally, *P* values calculated by unequal variance 2-sample t-tests are as follows. Number of headaches: 0.2678; number of severe headaches: 0.7584; number of medications: 0.4532; number of visits: 0.6390. Each of the 4 *P*-values is larger than 0.05 so we cannot reject the null hypothesis.

Discussion

We initiated this study to provide scientific evidence validating the use of biofeedback techniques in the treatment of migraine and tension type headaches. Biofeedback is virtually free of untoward side effects and if effective for preventative and abortive treatment of headaches would obviously be preferable to the use of medication. Our study, however, failed to reveal a beneficial effect. Compliance with this type of study is always a limitation and the patients were asked to complete multiple questionnaires so that a sufficient number would be returned allowing us to complete a valid statistical analysis. We were able to track medical utilization in all but one patient over the 3-year period using an electronic medical record. The data that we obtained allowed us to reach our goals and clearly showed that completion of the modified pain program, which incorporated education in pain theory and instruction in simple relaxation techniques, resulted in a statistically significant decrease in the frequency and severity of the migraine and tension type headaches in the first 12 months that continued to 36 months. Biofeedback provided no additional benefit and did not satisfy the primary endpoint which was, specifically, an additional reduction in the frequency and severity of the headaches. The patients who received biofeedback training reported a subjective improvement in their headaches but the objective data did not support their perception.

The secondary endpoints were a reduction in the total number of medications used and the utilization of medical care. Patients in both the relaxation and biofeedback groups showed a decrease with regard to both parameters over the 36 months. Eleven patients either did not commence treatment or dropped out before completing treatment and their results, with regard to medication use and medical utilization, did not differ from the groups that received the treatment modalities. One alternative hypothesis that cannot be ruled out without additional data is whether this general trend toward improvement is an artifact of regression to the mean. Given that 11 people received no treatment of any kind, and that the results do not differ to a statistically significant extent between those who received and those who did not receive treatment, this alternative must be taken seriously. However, since only 11 people received no treatment, this comparison has little statistical power and we cannot distinguish between regression to the mean and improvement based on treatment.

Headaches are a major health problem in the United States because of direct medical costs, increased health care dependency, and loss of productivity (14,17,18,20). Optimal treatment for headaches, and in fact any disorder, would be effective in reducing or eliminating symptoms with no or few side effects. Non-pharmacologic treatments have been utilized by practitioners for many years in the hope of reaching those goals. However, controlled studies to demonstrate efficacy of those treatment modalities are lacking (26). Biofeedback has been a mainstay of headache treatment for decades and is offered at many of the major pain and headache clinics throughout the United States. It is expensive and time consuming and while it may have a beneficial effect in the treatment of migraine and tension type headaches, our study found it to be no more effective than simple relaxation techniques.

Table 5. Summary of regression results.

Predictor	# headaches	# severe	Medications	Visits
Biofeedback group	0.24 (.926) CI: -.49, .54	-0.19 (.471) CI: -.73, .34	0.95 (.618) CI: -2.85, 4.75	0.58 (.522) CI: -1.22, 2.38
3 months	-0.25 (.045)	-0.38 (.042)		
6 months	-0.53 (.001)	-0.90 (<.001)		
9 months	-0.84 (<.001)	-1.10 (<.001)		
1 year	-0.88 (<.001)	-0.95 (<.001)	-1.08 (.230)	-1.59 (.001)
2 years	-0.99 (.001)	-1.19 (<.001)	-3.33 (.001)	-3.06 (<.001)
3 years	-1.64 (<.001)	-1.40 (<.001)	-5.63 (<.001)	-4.16 (<.001)

Conclusion

In conclusion, non-pharmacologic treatment, specifically simple relaxation techniques and education in pain theory, should remain an integral part of the treatment program for migraine and tension type headaches. Instruction in relaxation can be accomplished in a few visits and does not require a prolonged course of treatment (27). Biofeedback, however, should no longer be universally accepted as standard treatment for these disorders in adults as the addition of this treatment modality, in our study, did not provide additional therapeutic benefit.

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