Biofeedback-assisted relaxation training for young adolescents with tension-type headache: a controlled study

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Tension-type headache is common in children and adolescents and is generally treated with medication, but emerging literature suggests that various behavioral treatments may provide efficacious alternatives to medication. Juvenile tension-type headache sufferers were randomly assigned to biofeedback-assisted relaxation or relaxation placebo and followed for 1 year. Following treatment, both conditions led to sizeable headache reductions (approximately 50%). Over time, children receiving biofeedback-assisted relaxation continued to improve and were superior to the control condition at a 6- and 12-month follow-up (86% versus 50%). Biofeedback-assisted relaxation appears to be an efficacious and durable treatment for juvenile tension-type headache and merits further exploration. □ *Childhood headache, electromyographic biofeedback, relaxation training, tension-type headache in children*

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Headache is common in children and adolescents, such that by the age of 15, at least 75% of all juveniles have experienced at least one headache episode (1–3). By the age of 15, approximately 15% of all juveniles experience headaches that are suspected of being tension-type in nature (2). Available data suggest that a sizeable number of juveniles who experience migraines do not outgrow them with time (4). The long-term course of juvenile tension-type headache is unknown, but it is assumed to be similar to juvenile migraine.

As with headaches in adults, pharmacological treatments tend to predominate. However, the empirical data to support the efficacy of medication with pediatric headache are sparse and limited mostly to migraine headache (5–8). Furthermore, medications which are used as prophylactic agents, such as calcium channel blockers, tricyclic antidepressants, beta-blockers, or benzodiazepines, can have side effects which are often unpleasant and may even be dangerous in young people because the long-term effects on development are largely unknown (9, 10). Thus, there is a clear need for other treatment options.

In a series of studies, Larsson and colleagues (11–14) have treated adolescent tension-type headache sufferers with relaxation training, administered in various formats and in different settings, and have compared it with attention placebo and no treatment. Improvement rates for headache activity (the most commonly reported outcome measure) ranged from 17.5% to 40.9% for relaxation treatment, which exceeded reductions for the control conditions (−2.4% to 14.8%). A single case report (15) and a single-group outcome study (16) utilizing electromyographic (EMG) biofeedback-assisted relaxation (BFB/REL) reported much greater levels of improvement, as did two additional single-group outcome studies that employed multiple behavioral techniques, which included BFB (17, 18). These studies, although highly encouraging, contained a number of limitations that inhibit generalization, including small sample sizes, too many components to permit isolation of effects, and/or the absence of important control comparisons. Nonetheless, the improvements noted are encouraging.

The purpose of the present study was to evaluate a more circumscribed treatment for juvenile tension-type headache (BFB combined with relaxation training), to administer the treatment in a straightforward, time-limited manner, to minimize demands on subjects by not requiring extra-clinic home practice, to compare this active treatment with a relaxation pseudotherapy control procedure, and to assess durability of treatment effects over time.

Methods

Subjects

Subjects were the first 35 consecutive patients (17F, 18M) between the ages of 11 and 15 to present to the Headache Center of the Neurological Institute C. Besta who satisfied International Headache Society (19) criteria for episodic tension-type headache, who experienced a minimum of one headache

per week, who had not received preventive pharmacological therapy previously, and whose neurological examination and routine laboratory tests were negative. Nonprescription analgesic use was permitted. Five patients assigned to the control condition (2F, 3M) subsequently dropped out; all ceased participation prior to completion of the first (1-month) follow-up assessment. The analyses to follow are based on the 30 subjects who completed all aspects of the study.

Measures

Each patient kept a daily headache diary for 4 consecutive weeks prior to treatment, throughout treatment, and for the 4 weeks immediately following completion of treatment. Diaries were recorded for additional 4-week periods at 3, 6, and 12 months after treatment completion. The child participants were instructed to record headache severity every hour on a 5-point scale, on which "0" indicated no headache and "4" indicated a very intense headache (one that prevented work or play and necessitated confinement to bed). For each 4-week recording period, a Pain Total Index (PTI) was calculated, in accordance with the following formula, and this served as the primary measure of clinical outcome ([no. of hours at level 1×1] + [no. of hours at level 2×2] + [no. of hours at level 3×3] + [no. of hours at level 4×4]).

The State-Trait Anxiety Inventory for Children (STAIC) (20), translated into Italian, served as a secondary measure of improvement. The STAIC comprises two separate scales for measuring both State (momentary) and Trait (enduring) anxiety. Scores on both scales range from a minimum of 20 to a maximum of 60 (highest level of anxiety).

BFB instrumentation

A Satem biofeedback instrument was used for treatment and psychophysiological monitoring. After proper skin preparation, three circular metal-Alpaca reusable cup-type electrodes were applied to the forehead (the reference electrode was centered over the bridge of the nose, while the active electrodes were centered directly over each eye) and secured with paper tape. The raw signal was rectified and averaged using a 100 ms time constant. The bandpass was set to 100 – 1000 Hz. An IBM computer recorded and processed the information. The computer interface sampling rate was 20 S/s; the signal was averaged by the computer over 10-sec intervals, with EMG values being recorded every second.

The threshold of the auditory signal feedback to the patient was adjusted by the operator from session to session depending on the level of muscular tension. The operator's task was to shape successively lower thresholds; the subject's task was to go below threshold and turn off the auditory signal completely. With this procedure, subjects learned to reduce their muscle tension progressively. The therapist was instructed to adopt an encouraging attitude initially, but gradually to lessen involvement with subjects' relaxation exercises. The patients were asked to rest with eyes closed during the sessions.

Procedure

Patients were randomly assigned to one of two experimental conditions, BFB/REL or relaxation-placebo (REL/PLAC), with the constraint that subjects be over-sampled in BFB-REL treatment (2:1 ratio) in order to make actual treatment available to as many children as possible.

BFB-REL. Patients assigned to BFB/REL attended two sessions per week, for a total of 10 sessions, with at least 2 days intervening between any consecutive sessions. Patients were seated in comfortable recliners and were encouraged to close their eyes to enhance relaxation effects. The first four sessions were devoted to progressive muscle relaxation training, adapted from the approach of Bernstein and Borkovec (21), which focused primarily on relaxation exercises for eight muscle groups (lower arms, upper arms, legs, abdomen, chest, shoulders, eyes, and forehead). Each relaxation session lasted approximately 20 min. EMG BFB was introduced at the fifth session and this treatment remained the focus for the remaining sessions (6 in all). Each BFB session lasted 21 min and consisted of the following: 7-min baseline (for the purpose of setting the auditory signal threshold), 7 min of auditory feedback, and 7 min of self-control (feedback signal turned off, while subject was instructed to continue attempting to relax). Subjects were instructed not to practice relaxation at home in order to provide a pure test of in-clinic treatment alone.

REL-PLAC. Patients in this control condition also embarked on a 10-session program (2 visits per week for 5 weeks total). Although EMG activity was recorded throughout, no feedback was provided. Subjects were merely instructed to remain calm and attempt to become more and more relaxed, by whatever means possible. This condition was designed to control for attention, expectations for improvement, and effects from sitting quietly for an extended period.

Follow-up. Follow-up sessions were held 1, 3, 6, and 12 months after the treatment completion.

Table 1. Mean PTI values and (standard deviations) for baseline through 12-month follow-up, as well as percentage improvement for each follow-up assessment (figures in bold).

Condition	Baseline	1-month	3-month	6-month	12-month
BFB/REL	142.7	65.4 **54.2%**	59.3 **58.4%**	34.4 **75.9%**	20.0 **86.0%**
	(102.5)	(55.1)	(88.9)	(32.5)	(18.1)
REL/PLAC	221.5	96.3 **56.5%**	80.5 **63.7%**	81.3 **63.3%**	88.8 **60.0%**
	(137.2)	(73.8)	(66.7)	(70.3)	(110.3)

BFB/REL = Electromyographic biofeedback combined with progressive muscle relaxation training.
REL/PLAC = Relaxation placebo.

During each follow-up session subjects received their respective treatment and were readministered the STAIC. Prior to each appointment, subjects maintained daily headache diaries for 4 weeks.

Results

Demographics

The treated group comprised 20 subjects (10F, 10M) whose mean age was 11.1±2.6 years. Mean onset of headache occurred at 8.1±2.7 years and mean headache duration was 2.6±2.0 years. The control group comprised the 10 children (5M, 5F) who provided data throughout the study period. Control subjects had a mean age of 13±1.5 years. Mean headache onset occurred at 10.5±2.8 years, while mean duration of headache activity was 2.7±2.0 years. The general characteristics of the groups did not differ significantly (*t*-test, n.s.). Analgesic consumption, ASA principally, was under five tablets per month for both groups. Since this was such a low overall level and no child was taking daily medications, no further analysis was conducted for medication.

Clinical outcome

Mean monthly values for the primary outcome measure (PTI) are presented in Table 1, along with mean percentage improvement for each follow-up interval. In order to provide the most sensitive statistical test possible, these values were subjected to a 2 (group: treatment vs control) × 4 (trials: 1-, 3-, 6-, and 12-month follow-up) ANCOVA, wherein baseline values served as the covariate. This analysis revealed a significant effect for group only ($F(1,25)=4.68$, $p=0.04$). Follow-up contrasts, comparing the two groups at each follow-up assessment, revealed statistically significant differences at 6 months ($F(1,15)=7.86$, $p=0.01$) and 12 months ($F(1,25)=6.79$, $p=0.02$). Thus, effects became more pronounced over time. These findings are depicted in Fig. 1, wherein the PTI values have been adjusted for the covariate.

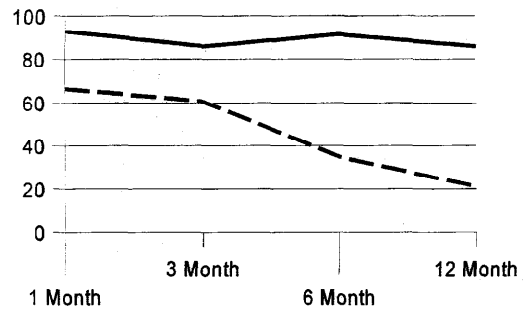

Fig. 1. Mean Pain Total Index scores (covariate adjusted) for BFB-REL (- - - -) and REL-PLAC (—) during follow-up.

Mean values for State and Trait anxiety scores are presented in Table 2. Separate ANCOVAs, of the form indicated above, revealed the following. No significant effects occurred for any factor for State anxiety. The ANCOVA for Trait anxiety revealed a significant effect for follow-up period only ($F(3,72)=2.99$, $p=0.04$). Inspection of the mean values reported in Table 2 suggests that although the changes over time were statistically significant they are not of great clinical importance.

Psychophysiological measure

Mean EMG resting values obtained at the start of each treatment session (see Table 3) were analyzed using the same ANCOVA model. This analysis yielded significant effects for group ($F(1,17)=6.58$, $p=0.02$), trials ($F(3,51)=3.19$, $p=0.03$), and the interaction of groups with trials ($F(4,51)=7.48$, $p=0.001$). Follow-up contrasts revealed that the source of the significant interaction was attributable to the increased EMG activity displayed by the control condition relative to the treated condition at 12-month follow-up ($F(1,17)=12.22$, $p=0.003$). The two groups did not differ at any other follow-up period. Inspection of individual subject data revealed one child in the control condition with extremely elevated EMG data. It is likely that this one aberrant value skewed the

Table 2. Mean State and Trait anxiety scores and (standard deviations) for baseline through 12-month follow-up.

Condition	Baseline	1-month	3-month	6-month	12-month
A. State Anxiety					
BFB/REL	30.1 (3.4)	28.1 (3.49)	28.5 (2.9)	28.9 (2.9)	27.8 (2.3)
REL/PLAC	30.1 (5.1)	29.2 (5.1)	29.4 (4.4)	28.2 (3.0)	29.1 (1.4)
B. Trait Anxiety					
BFB/REL	34.0 (5.9)	31.8 (4.9)	32.6 (6.2)	31.7 (5.3)	31.0 (5.8)
REL/PLAC	31.9 (6.6)	32.7 (7.0)	35.0 (8.5)	31.1 (7.5)	35.8 (5.9)

distribution enough to account for this significant finding.

Discussion

At the 1-month follow-up, headache activity had improved by approximately 55% in each condition. However, from 6 through 12 months of additional follow-up, the BFB-REL group continued to improve, achieving a reduction of approximately 85% at 1 year. The REL-PLAC condition showed no further improvement beyond that obtained immediately after treatment was completed. Thus, sitting quietly on a regularly scheduled basis, which was intended to serve as a credible attention placebo, led to marked improvement and may constitute a meaningful, easy to implement intervention. It needs to be reiterated that the five dropouts from this condition were omitted from analysis because of insufficient data. Inclusion of these five subjects might have led to different results. Also, the resultant sample size for the REL/PLAC condition was small, which raises questions about representativeness and maximizes the impact of outliers.

The enhanced effects for BFB-REL for months 6 through 12 were both statistically and clinically significant when compared to the control condition, which suggests that this additional treatment was useful. Since this group of patients received a different form of relaxation and another entirely different treatment as well, it is not possible to determine the incremental contributions of relaxation and BFB. Why the additional effects were delayed in onset is not clear. This may be due in part to our decision not to incorporate home practice. With concurrent daily practice at home, headache improvement may have peaked more quickly and effects would likely have been more substantial overall. We purposely omitted extra-therapy practice in order to provide a test of a treatment that placed minimal demands on participants. Thus, our active treatment condition may provide a lower-bound estimate of effects that one can expect when employing BFB-REL training with this age range of participants.

Muscle tension levels before treatment were similar for both groups and did not change significantly during the study (with the exception of the apparent aberrant finding for relaxation placebo at 12 months). Our decision to omit home practice in the BFB-REL condition may account in part for the nonsignificant reductions in EMG levels in this condition. Two prior studies (16, 22) found a relationship between symptom change and physiological change, particularly between muscle tension reduction and tension-type headache improvement in children. However, this relationship did not appear in the present study. In research with adult tension-type headache patients, similar inconsistent findings have been found (e.g., 23–25). As with adults, the role of muscle tension in the etiology of tension-type headache and in the mediation of relaxation-based treatments is complex and warrants further exploration.

Minimal changes occurred with respect to anxiety. There may have been several reasons for this. One possibility concerns floor effects; the baseline values were not clinically elevated and had little room for change. Another concerns the scale itself. The psychometric integrity of the Italian translation has not been fully explored, and, consequently, the scale may not be as precise a measure of the construct as intended. Research addressing a broader spectrum of psychological variables suggests other constructs (such as depression) may be important in understanding and treating child headache patients (26–30). Consideration needs to be given to exploring similar constructs with children who are experiencing tension-type head-

Table 3. Mean resting EMG levels (microvolts) for baseline through 12-month follow-up.

Condition	Baseline	1-month	3-month	6-month	12-month
BFB/REL	2.4 (1.1)	2.4 (1.5)	2.2 (0.9)	2.0 (0.6)	2.1 (0.6)
REL/PLAC	2.9 (1.2)	2.3 (0.9)	2.5 (1.0)	2.4 (0.9)	5.1 (2.7)

ache. We were unable to examine other potentially important psychological variables because of the unavailability of translated scales or comparable Italian versions.

To summarize, BFB combined with relaxation may be an optimal therapeutic alternative in juvenile tension-type headache, because it leads to pronounced clinical benefits, produces improvements that endure, is quickly and easily learned by children, and prevents the unknown and potentially even dangerous side effects that can be caused by pharmacologically based therapies. Effects obtained for the combination of BFB and relaxation appear to be greater than those obtained for relaxation alone in previous research. This supports prior observations that children may be especially good candidates for BFB treatment (31).

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