EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 10
Issue: 2
42-73
Year: 2023

ELECTROMYOGRAPHIC AND TEMPERATURE BIOFEEDBACK AMONG PEOPLE WITH CHRONIC TENSION AND MIGRAIN HEADACHES WHO FAILED STANDARD TREATMENT

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Article Received on 05/12/2022 **Article Revised on 26/12/2022** **Article Accepted on 17/01/2023**

ABSTRACT
Our hypothesis was that utilizing biofeedback along with analgesics for treating uncontrolled chronic Tension and Migraine headaches (Tension Type headaches and Migraines) among patients who failed standard treatment would reduce use of analgesic medication along with the intensity, frequency, and the duration of pain of the headaches as compared to similar patients also failed to be controlled by standard treatment but continued to receive standard therapy consisting of analgesic medication only. This study was completed for the key fact that very few of the studies[1] worked with well diagnosed patients and[2] few worked with patients who had clearly failed other therapies which were shown to have been properly applied. In other words, our study was aimed at showing that biofeedback works with patients meeting set criteria for Migraine and Tension type headaches who failed properly provided standard treatments. Twenty-five patients were randomly selected from the pool of patients in our clinic who failed standard analgesic therapy for Tension type and Migraine headaches. Each was offered the opportunity to receive biofeedback therapy for their headaches along with their medical treatment as part of their regular clinical care. Their information was compared with headache activity of twenty-five similar patients who continued to receive standard medicinal care. Each of the people offered biofeedback and those who would serve as a comparison was provided with a HIPAA and explanation form in which each agreed to the use of their medical data related to headache activity. Each patient receiving biofeedback was given EMG biofeedback for 30 minutes and thermal biofeedback for 10 minutes during each of 10 weekly sessions. Patients in the comparison (treatment as usual) group received their medication as usual but did not receive any placebo biofeedback as this was simply a comparison group rather than a true "control" group. People treated for headaches in our clinic kept 10 week long logs of headache activity and medication as part of normal tracking of headache activity so these data were available to use when comparing people receiving biofeedback in addition to standard care with those simply continuing standard care.

INTRODUCTION
Organization of the Dissertation
This dissertation is organized in five chapters including: Chapter 1 which contains an introduction, equipment and terminology; Chapter 2, which contains a review of the literature; Chapter 3, which contains a description of the study methodology, Chapter 4, which contains the study components, a description of data collection including inclusion and exclusion criteria of participants, Chapter 5 which contains a description of data results which includes measurement models and analysis and an overview and conclusion. References and appendices follow these five chapters.

Primary outcome was reduced use of analgesic medication; further significant effects were along with decrease in intensity, frequency, and the duration of pain of the headaches as compared to the patients who were using analgesic medication only. Reduced muscle tension was observed in electromyographic biofeedback and for Tension-type headache and was more effective along with headache monitoring conditions in 24 out of 25 patients comparing to patients only taking analgesics. Twenty-four out of 25 patients showed decreased muscle tension. These patients learned the task so improved.

The literature clearly shows that pain ratings on the universal pain scale above 50 indicate significant interference with everyday life. At the start of the study, 19 of the 25 patients receiving biofeedback had scores above 50 while 20 of the 25 patients in the ongoing treatment group had scores above 50. By the end of the study, only 3 of the 25 patients receiving biofeedback showed scores above 50 while 15 of those in the ongoing treatment group continued to show scores above 50. This difference was significant with Chi Square showing p

less than 0.0001. An overall statistical difference in universal pain scores with p less than 0.05 between pre, post, and follow-up pain ratings for the two groups was identified using a non-parametric ANOVA so individual Mann-Whitney "U" tests could be run to identify the source of change. Sixteen of 25 patients in the biofeedback group experienced much less headache pain after the biofeedback treatment with a change in ratings from pre to post (Mann-Whitney "U" = 105, p less than 0.05). Twenty-four of 25 patients in the ongoing treatment group also showed a decrease in headache with a change in ratings from pre to post (Mann-Whitney "U" = 74, p less than 0.05). There was clinically important as well as a statistically significant change in analgesic use with the biofeedback group showing a change from pre to post while the treatment as usual group showed no change. Chi Square indicated p less than 0.05.

The results of this study show that the addition of biofeedback to standard analgesic therapy could help to treat uncontrolled chronic headache patients.

Biofeedback is a process of gaining greater awareness of many physiological functions for patients looking for a lifelong way to control headache beyond medications. Biofeedback allows the patient to play an active and integral role in maintaining his or her health. Within the last 35 years, continued research has shown biofeedback to be a viable therapeutic tool in the treatment of many disorders, including headache, high blood pressure, Raynaud's disease, muscle spasm, chronic anxiety, neuro-muscular dysfunction, epilepsy, insomnia, asthma and numerous other conditions (Yucha, 2002). Biofeedback is a non-drug therapy that patients use every day to control headache symptoms and reduce headache frequency. It is an acquired skill that can be applied on demand to change specific responses of the body and diminish or even stop headache pain.

Biofeedback teaches you how to control bodily functions, such as heart rate, blood pressure and muscle tension, which once were considered to be beyond voluntary control. Decades of research have proven that, with daily practice, patients can be taught this voluntary control and how to use it effectively (https://migraine.com/migraine-treatment/natural-remedies/biofeedback, May 2021).

Body temperature and muscle tension are affected by stress and strain. Biofeedback training provides you with instant information on how these involuntary processes react to stress. By tracking these reactions, one can observe and even change your body's reaction to stress. Specifically, patients who can recognize and reduce muscle tension and/or warm the temperature of their hands experience fewer and less severe headache attacks.

Various types of instruments monitor bodily response — muscle tension or skin temperature — as the patient attempts to affect that response. With a sufficient amount of effort and practice, and the help of a qualified professional trainer, the patient gradually learns physiological sensations and body cues that allow the instruments to be removed. Once that happens, the technique can be used at any time and in any place.

When the patient is receptive to this type of therapy and willing to make the commitment to practice it regularly, the results can be significant. In some studies, patients saw a reduction of 45% – 60% in migraine and tension headache - equivalent to that provided by certain drugs (e.g., beta blockers for migraine and tricyclic antidepressants for tension headache) (Nestoriuc, 2008).

Migraine and Tension-type headaches are the two most prevalent and disabling headache conditions in adults (Rasmussen, Jensen, Schroll & Olsen, 1991) as well as in children and adolescents (Kroener-Herwig, Heinrich & Morris, 2007). In North America migraine is experienced by 18% of women and 7 % men, with at least one attack per year (Lipton, Stewart, Daimond & Reed, 2001). The more common but less disabling episodic Tension-type Headache (ETTH) is estimated with a one-year prevalence of 38%, while prevalence of Chronic Tension-type Headache (CTTH) defined as having a frequency of at least 15 days per month, is estimated at 2-3% (Schwartz, Steward, Simon and Lipton, 1998). Significant negative social and economic impact resulting from these headache conditions have been reported which consists of low quality life because of suffering with disabilities. Headache patients frequently experience deteriorated functional levels at home, work, and school (Molarious & Tegelberg 2006).

The intense pain of a headache can last anywhere from a few hours to several days (www.ninds.nih.gov, May 2021). Headache symptoms include: intense, pulsating pain, nausea, dizziness, vomiting, sensitivity to light, sensitivity to sound, experiencing blind spots, and seeing flashing lights or lines. Symptoms can come on suddenly or can be preceded by an aura. An aura basically refers to the sensory or visual distortions that can accompany migraines, such as blind spots or flashing lights. An aura serves to warn of an impending migraine, and disappears with initial pain of the headache itself (NHF).

There are automatic functions in our body that occur outside of our conscious awareness. For instance, an individual does not think about the process of breathing or having to breathe in and out every few seconds, they just naturally do so. In a similar fashion, other functions such as heart rate and skin temperature work on an automatic basis. Biofeedback is a means for gaining control of your body processes to increase relaxation, relieve pain, and develop healthier, more comfortable life patterns" (http://www.bio-medical.com/homeuse-home.cfm, May 2016). Essentially, biofeedback equipment allows an individual to monitor their body's automatic activities, particularly their reactivity to stress. The idea behind biofeedback is that once an individual

learns how to monitor their body's reactions, they can learn how to alter them. For example, the individual can consciously learn how to monitor and change their heart rate and skin temperature.

Elimination of first sentence. The rationale behind biofeedback as a treatment for headaches is embedded in the vascular theory; that headaches are a result of the processes of vasoconstriction and vasodilation mentioned earlier. This theory further suggests that the blood flow during headaches has been increased to certain areas in the head and decreased to the extremities. Therefore, if a headache sufferer can modify the temperature of another body part (e.g. their hands) through biofeedback, then the blood flow will automatically increase to the extremities and decrease to the "strained" vessels in the head. When the vasodilation/swelling of the blood vessels begins to diminish, the throbbing, pulsating, head pain disappears (Webster, 2001) and the treatment has proven effective.

There are many different types of biofeedback. EMG biofeedback provides information regarding muscle tension, whereas thermal biofeedback (referred to as temperature biofeedback and hand warming biofeedback, interchangeably) and blood flow biofeedback both provide information regarding blood flow. The latter two methods of biofeedback are suggested treatments for headache sufferers. Essentially, regardless of the type of biofeedback implemented, training in this treatment begins with the equipment. An individual is hooked up to sensors, which depict their body's physiology on a computer screen. This then allows the individual to monitor their automatic processes on the screen. Eventually, the individual will be able to recognize/become aware of their body's reactions without the equipment.

Temperature biofeedback assumes that the colder the temperature of the skin, there is less blood flowing to this area. For this form of biofeedback, a temperature wire (thermistor) is attached to one of the individual's fingers. Then, the patient concentrates on warming their hands, in an attempt to increase blood flow to this area. By practicing this form of biofeedback, the vascular system can actually be retrained, potentially preventing future headaches.

Hans Selye's (1956) groundbreaking research on stress demonstrated that the human response to stress is an adaptive biological response with impact on the entire body system. Cognitive attention to an approaching threat triggers an alarm and mobilization response preparing the body for emergency action. The stress response activates the limbic or emotional brain, and the hypothalamus, which then stimulate large portions of the sympathetic nervous system and the endocrine system. The result is a flood of stress hormones (including ACTH), elevated blood sugar, and hyper arousal of many internal organs and functions. The individual will notice elevated heart rate, tense musculature, rapid respiration, and a variety of intense emotional states. This adaptive response prepares the individual to flee or fight the threat. In ideal circumstances the threat passes and the individual can return to a more relaxed psycho-physiological state.

In modern human society, however, the individual is exposed to chronically stressful work and family environments, the individual perseverates in thinking about the problems, and neither mind nor body return to the original resting state. This is the basis for many functional medical and psychiatric disorders. The body and mind enter a state of fatigue, exhaustion, and loss of adaptability. Many of specific components in the stress response have a temporary adaptive effect, but a debilitating effect over time. Under stress, for example, the pituitary releases vasopressin, which contracts the walls of the arteries, raising blood pressure. Over time this vasoconstriction contributes to chronic and life threatening hypertension. The immune system also can become depleted and unable to protect one from disease.

More recent research has shown that the so-called stress response is really more complex than first recognized. The autonomic nervous system does not respond as one single unit; rather a variety of divergent patterns occur in different individuals, some for example, affecting the cardio-vascular system in various ways, others affecting the upper or lower gastrointestinal tract, and others the musculoskeletal system. Both sympathetic and parasympathetic nervous system activation patterns play a role in the multiple forms of the human stress response (Gevirtz, 1996).

Herbert Benson (1975) established that just as there is a human *stress response*, with negative effects on the body, there is also a *relaxation response* with a healing or restorative impact on the human physiology and mind.

Electrophysiological Equipment

The equipment used for this study has been purchased by the office from J&J Engineering. The Equipment includes I-330-C2+ 12 Channel with capabilities of EMG, EEG, ECG, HRV, RESP, SR and TEMP (Figure 1). Each channel necessary to complete these tests came with initial system setup and software. There are many seemingly small items which are needed for biofeedback including disposable pre-jelled SEMG sensor pads, breathable tape used to attach temperature leads, conductive jell for reducing impedance, and adhesive removal pads.

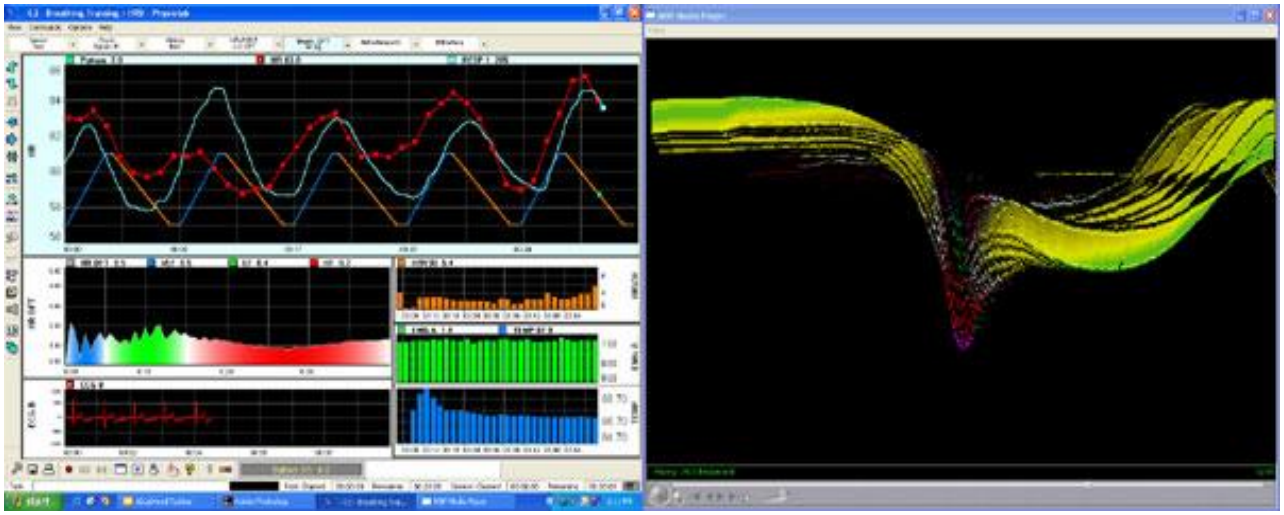


Figure 1: JJ Engineering Monitor.

Types of Headaches

Figure 2: Types of Headaches.

Tension-Type Headaches

Tension-type headache (TTH) has been known as muscle contraction headache, psychomyogenic headache, ordinary headache, idiopathic headache and even psychogenic headache. This makes no sense since so many of us have TTH and we do not differ psychologically from people without TTH. Therefore, we are in agreement that all these types of names should be commonly referred to as TTH. The International Headache Society described tension-type headache as infrequent episodes of headache that last minutes to days. The pain is usually bilateral in location with a pressing or tightening quality. Tension-type headache does not usually worsen with physical activity and may not cause disability. Nausea is usually not a symptom, but light sensitivity (photophobia) or sound sensitivity (phonophobia) may be present.

Table 1: Diagnostic Criteria for Infrequent Episodic Tension-type.

Diagnostic Criteria for Infrequent Episodic Tension-type
A. At least 10 episodes occurring on <1 day per month on average (<12 days per year) and fulfilling criteria B-D below
B. Headaches lasting from 30 minutes to 7 days
C. Headache has at least two of the following characteristics
a. Bilateral location
b. Pressing/tightening (nonpulsatile) quality
c. Mild or moderate intensity
d. Not aggravated by routine physical activity such as walking or climbing stairs
D. Both of the following:
a. No nausea or vomiting (anorexia may occur)
b. No more than one of photophobia or phonophobia
Not attributed to another disorder

Indent Tension type headache is the most common type of headache and as many as 30% to 78% of the general population experience at some time during their lifetime. Studies further suggest that there is a biological mechanism underlying these types of headaches and they are not psychogenically based. The exact mechanisms are not known, but peripheral pain mechanisms are most likely involved.

Tension-type headaches occurring frequently or even daily are classified as chronic tension-type headaches and are a serious condition that is associated with headache-induced disability and significantly impacts quality of life. Pain mechanisms peripherally and centrally may be involved in chronic tension-type headache, making treatment more challenging.

Migraine Headaches

Migraine headaches are less common than tension-type headaches. Nevertheless, migraines afflict about 28 million people in the United States alone. As many as 6% of all men and up to 18% of all women (about 12% of the population as a whole) experience a migraine headache at some time. Roughly three out of four migraine sufferers are female. It is important to recognize that children also get migraine and it affects between 5-10% of children under the age of 18 years (https://migraine.com/migraine-treatment/natural-remedies/biofeedback, May 2016).

Migraine is described as a recurrent headache lasting 4-72 hours and often has unilateral pulsating pain, moderate to severe intensity pain, nausea and/or photophobia. The pain of migraine can be aggravated by routine physical activity.

About one in five migraine sufferers experiences an aura prior to onset of a migraine headache. Auras are neurologic symptoms that may occur before during and after a migraine. There are many different types of either visual or other sensory auras and they may differ between attacks.

Table 2: Classification Criteria for Migraine.

Classification Criteria for Migraine
A. At least 5 attacks fulfilling criteria B-D below
B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
C. Headache has at least two of the following characteristics:
1. unilateral location
2. pulsating quality
3. moderate or severe pain intensity
4. aggravation by or causing avoidance of routine physical activity (*eg*, walking or climbing stairs)
D. During headache at least one of the following:
1. nausea and/or vomiting
2. photophobia and phonophobia
E. Not attributed to another disorder

Differentiating between Tension-Type Headaches and Migraine Worksheet

Columns A and B show the symptoms commonly seen in these two headache types. Some people have both of these types of headache. Many headache sufferers experience both types of headaches. Learning to distinguish between the two headache types may help direct appropriate treatment.

Table 3: Differentiation Between Tension Type Headache and Migraine.

Symptom	**Tension**	**Migraine**
Intensity, Duration and Quality of Pain		
Mild or moderate pain intensity	√	√
Severe		√
Duration of headache 30 min – 7 days 4-72 hours	√	√
Intense pounding, throbbing and/or debilitating		√
Distracting but not debilitating	√	
Steady ache	√	
Location of Pain		
One side of head		√
Both sides of head	√	√
Associated Symptoms		
Nausea/vomiting		√
Sensitivity to light and/or sounds		√
Aura before onset of headache such as visual symptoms		√

Cluster Headaches

Cluster headaches occur in about 1% of the population and are distinct from migraine and tension-type headaches on several levels. Most of the cluster headache sufferers are men with onset between ages of 20-40 (where most migrainers are women with onset following the start of menstruation).

- These attacks are characterized by severe, unilateral pain that is around the eye or along the side of the head.
- Headache attacks last from 15 to 180 minutes and occur once every other day to up to 8 times daily.
- Attacks are associated with tearing on the same side of the head that the pain is located. Patients may also experience nasal congestion, runny nose, forehead and facial sweating, dropping eyelids or eyelid swelling.
- During an attack, patients may be restless or agitated due to excruciating pain.

Table 4: Classification Criteria for Cluster Headache.

Classification Criteria for Cluster Headache
A. At least 5 attacks fulfilling criterial B-D
B. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes if untreated
C. Headache is accompanied by at least one of the following
a. Ipsilateral conjunctival injection and/or lacrimation
b. Ipsilateral nasal congestion and/or rhinorrhea
c. Ipsilateral eyelid edema
d. Ipsilateral forehead and facial sweating
e. Ipsilateral miosis and/or ptosis
f. A sense of restlessness or agitation
D. Attacks have a frequency from one every other day to 8 per day
E. Not attributed to another disorder

Biofeedback Terms

Active - one of the two electrodes in a differential measurement. Generally, on the head, it is the location you are interested in measuring and training.

DC - direct current. A signal containing energy at 0 Hz, i.e. a steady potential. Since the potential is considered too slowly change, a working bandwidth of 0.000-0.03 Hz, for example, may be considered "DC."

Differential amplifier - an electronic amplifier that measures the difference in potential between two electrode locations.

Electrode - a metallic device used to make a connection to the scalp or body, to measure electrical potential.

EMG: Electromyograph(y) refers to a process whereby through the use of biofeedback equipment, you can become consciously aware in real time of electrical changes in muscle activity.

Frequency - the rate at which a signal is changing or vibrating. EEG frequency is measured in cycles per second. Typical frequency ranges are Theta: 4-7, Alpha: 8-12, SMR or Low Beta: 12-15, Beta: 15-20, and High Beta: 20-30. Exact frequency ranges used for EEG training vary with the practitioner and protocol.

GSR: Galvanic Skin Response measures electrical conductance in the skin, which is associated with the activity of the sweat glands. A very slight, unnoticeable electrical current is run through the skin.

HRV- A metric often computed by a biofeedback machine to determine the regularity of a heartbeat. It compares the time between each beat, to determine how steady your heart performs. Psychophysiological models consider HRV as a measure of the continuous interplay between sympathetic and parasympathetic influences on heart rate that yield information about autonomic flexibility and thereby represent the capacity for regulated emotional responding (Applehans & Luecken, 2006).

Phase - a measure of the temporal relationship between two signals. Reflects the speed of information sharing between two sites, or between two sites and a third (or more) sites. Two sinewave signals are said to be "in phase" (have zero phase difference) when their peaks and valleys are aligned in time. Phase is generally measured in degrees, ranging from 0 degrees (in phase) to 180 degrees (out of phase).

Protocol - a set of controls, based upon a treatment plan or regimen that determines how neurofeedback training is done. This includes the enhance and inhibit settings, frequency bands, decision criteria, feedback signals, threshold adjustments, and decision points in the training.

Biofeedback: Information provided from some measuring instrument about a specific biologic function.

Thermal: This measures skin temperature.

LITERATURE REVIEW

Migraine and tension-type headache (TTH) are the two most prevalent and disabling headache conditions in adults (Rasmussen, Jensen, Schroll & Olesen, 1991) as well as in children and adolescents (Kroener-Herwig, Heinrich & Morris, 2007). In North America migraine is experienced by 18% of women and 7% of men, with at least one attack per year (Lipton, Stewart, Diamond, Diamond & Reed, 2001). The more common but less disabling episodic tension-type headache (ETTH) is estimated with a one-year prevalence of 38%, while the prevalence of chronic tension-type headache (CTTH), defined as having a frequency of at least 15 days per

month, is estimated at 2%-3% (Schwartz, Steward, Simon & Lipton, 1998). Significant negative social and economic impacts resulting from these headache conditions have been reported (Stovner et al., 2007).

Headache patients frequently experience deteriorated functional levels at home, work and school (Molarius & Tegelberg, 2006). Biofeedback treatments for pain emphasize the patients' active role in managing these conditions, thereby establishing improved coping with the psychological and psychosocial consequences of pain. For the treatment of headache, several different feedback modalities are being used, focussing on multiple psychophysiological parameters more or less directly assumed to underlie the condition. To enhance efficacy, biofeedback is often combined with relaxation and cognitive-behavioral elements such as stress management. The measurement of treatment success, therefore, mostly includes psychophysiological and behavioral variables in addition to the symptom- related ones. Taking this diversity of treatment applications, components, and outcome measures into account is one of the challenges of efficacy reviews today. This comprehensive review will offer an independent evaluation of the efficacy of biofeedback for headache, including moderating effects of feedback modalities, outcome categories, and trial design. Efficacy recommendations, according to the guidelines jointly established by the Association for Applied Psychophysiology and Biofeedback (AAPB) and the International Society for Neurofeedback and Research (ISNR), will be put forward.

In migraine, peripheral skin temperature feedback (TEMP-FB), blood-volume-pulse feedback (BVP-FB) and electromyographic feedback (EMG-FB) are the most prominent applications, while electroencephalographic feedback (EEG-FB) and galvanic skin response training (GSR-FB) are seldom used. The efficacy of biofeedback in treating migraine has been established in earlier reviews with improvement rates for pain from 40% to 65% (Blanchard & Andrasik, 1987; Blanchard, Andrasik, Ahles, Teders & O'Keefe, 1980). Comparable treatment gains resulted for behavioral treatments and pharmacotherapies (Holroyd & Penzien, 1990). In a more recent review medium effect sizes for EMG-FB and TEMP-FB in combination with relaxation have been reported (Goslin et al. 1999). While this was the first review providing standardized measures of treatment effect, the number of integrated studies was very small (n=11) and confidence intervals for the resulting effects were rather broad. Also, analyses were limited to the two aforementioned feedback modalities, only post-treatment data were analysed, and no moderator analyses were performed. BVP-FB was excluded due to the technical difficulty in administering it. Further meta-analytic data integrations are needed to determine the short-term and long-term efficacy of BVP-FB and to establish treatment moderators for migraine.

The most frequently applied behavioral treatment option for TTH is EMG-FB, directed at reducing pericranial muscle activity. Previous quantitative reviews assessing the outcome of various behavioral treatments for TTH, including biofeedback, relaxation, cognitive therapy, and hypnotherapy (Blanchard et al., 1980; Bogaards & ter Kuile, 1994; Haddock et al., 1997; Holroyd & Penzien, 1986; McCrory, Penzien, Hasselblad & Gray, 2001) have shown average improvement rates for pain from 46% (Holroyd & Penzien, 1986) to 61% (Blanchard et al., 1980), exceeding those of no-treatment conditions (Bogaards & ter Kuile, 1994). Two meta-analyses investigating psychological headache treatments have provided standardized measures of treatment success for pain. McCrory and colleagues (2001) have reported medium-to-large average effects for EMG-FB in adults, while Trautmann and colleagues (Trautmann, Lackschewitz & Kröner-Herwig, 2006) documented small-to-medium effect sizes for the efficacy of psychological headache treatments in children and adolescents. Specific comparisons of biofeedback for TTH to other behavioral headache treatments have not yet been meta-analytically integrated. Likewise, the long-term effects of biofeedback for TTH, the efficacy on different outcome measures, and treatment moderators have not yet been systematically analysed. Notably, none of the previous reviews for migraine or TTH have integrated effect sizes for outcome variables other than headache or medication.

In the light of these limitations two recent meta-analyses have established scientifically sound evidence supporting the utility of biofeedback for migraine and TTH (Nestoriuc & Martin, 2007; Nestoriuc, Rief & Martin, 2008). The objective of this comprehensive review is to present an up-to-date evaluation of the efficacy of biofeedback for headache. Drawing upon the two most recent meta-analyses in the field, evidence was incorporated, assessed, and documented according to the guidelines for the evaluation of the clinical efficacy of psychophysiological interventions (LaVaque et al., 2002). Analysed were the short- and long-term efficacy of biofeedback for migraine and TTH, treatment specificity, differential treatment effects in the form of pain measures, psychological, behavioral, and physiological outcome categories, as well as predictors of treatment success, such as patient characteristics and therapy features. Specific meta-analytic techniques were applied to control for possible confounding effects of selective publication, dropout, and study validity.

METHODS

Definitions and operationalization's

Condition of interest: This biofeedback efficacy review covers two conditions of interest (COI), i.e., migraine and TTH. Diagnoses were based on a standardized classification system (i.e., IHS, 2004; IHS, 1988; Ad Hoc Classification System, 1962) or an exact description of the disorder including characteristic features of migraine (i.e., severe pain, throbbing character, nausea,

phono/photophobia or aura) or TTH (i.e., mild to moderate pain intensity, bilateral, nonpulsating quality, pressing or tightening, "band like" feeling, no exacerbation by exercise). Double diagnoses of TTH and migraine (mixed or combination headache) were excluded.

Types of interventions: This review focussed on individually administered biofeedback treatments (TEMP-FB, EMG-FB, BVP-FB, EEG-FB, GSR-FB, or biofeedback in combination with other behavioral therapies).

Outcome variables: Frequency of pain measured with a structured headache diary was considered the primary outcome variable for this review, as recommended by the International Headache Society (IHS, 2000), the AHS Behavioral Clinical Trials Workgroup (Penzien et al., 2005), and Andrasik, Lipchik, McCrory, and Wittrock (2005). Included as secondary outcome variables were intensity and duration of pain as well as headache and medication indices measured with headache diaries or pain scales, anxiety, depression, self-efficacy, and physiological parameters.

Study inclusion criteria: In addition to fulfilling the criteria mentioned before (COI, treatment, outcome) studies included in this review had to be published in English or German and report sufficient statistical data to allow the calculation of effect sizes. Excluded were studies with less than 4 patients per treatment arm and case studies.

Search Procedure

For the purpose of this review, the literature searches conducted in the two meta-analyses by Nestoriuc and Martin (2007) and Nestoriuc et al. (2008) were updated. We used three international and one German databases (Medline, PsycInfo, CENTRAL, and Psyndex from the first available year to March 2008) using the search terms *biofeedback* or *behavioral treatment* or *cognitive therapy* or *nonpharmacological* or *applied psychophysiology*. For the COI "migraine" these terms were paired with *migraine*, *vascular headache* or *mixed headache* and for "TTH" with *tension-type headache, muscle contraction headache, tension headache* or *chronic headache*. In addition to the formerly reviewed studies this search revealed 14 new studies, of which only two were treatment outcome studies. Five studies were reviews or meta-analyses, another five described treatment and assessment of headache conditions without evaluating them directly, and two were experimental investigations. Of the two outcome studies, one was included in the current review (Martin, Forsyth & Reece, 2007), the other one was excluded because no headache outcome variables were reported (Ciancarelli, Tozzi Ciancarelli, Spacca, Di Massimo & Carolei, 2007). Finally, a total of 94 studies met our criteria and were included this review (see Appendix A for a complete reference list of the studies integrated in this white paper).

Study Coding and Validity Assessment

For each study, clinical and methodological aspects were coded with a structured coding scheme, including a 12-item validity scale (see Appendix B for the Study Coding and Validity Assessment Scale). After training in the use of the coding system, all studies were coded by the first author and two independent reviewers (graduate students). A random sample of 20% of the migraine and all of the TTH studies were coded twice to establish reliability of the coding process. The reliability of the coding form as well as the interrater-agreement for the validity scale were proven satisfactory with mean reliability indices ranging from .84 to .91. The evaluation of the randomization procedure (e.g., randomized or quasi-randomized according to pre-existing criteria) or the therapy manual (e.g., provided manual or brief description of procedures) led to more disagreement than the coding of quantitative study aspects. Coding discrepancies were discussed and resolved.

Meta-analytic Procedures

Effect size calculation and integration: Standardized effect sizes using Hedges' g (Hedges & Olkin, 1985) for controlled trials and its pre-post equivalent for uncontrolled studies (Gibbons, Hedecker & Davis, 1993) were calculated for each outcome variable, treatment group and time point. The correction for small samples was applied (Hedges & Olkin, 1985). Multiple effect sizes from a single study were averaged with covariance adjustment prior to effect integration. Independent effect sizes were weighted by their individual sample size. Separate integrations were carried out with respect to different treatment comparisons, feedback modalities, outcome categories, and time points. Contingent with the homogeneity statistic *Q* (Shadish & Haddock, 1994) fixed effect models or random effect models (REM) were applied to compute average effect sizes and confidence intervals. Moderating effects of patient, treatment, and study characteristics were tested with planned contrasts and weighted multiple regression analysis.

Sensitivity analyses: Meta-analytic results can be biased due to the fact that studies with nonsignificant results are less likely to be published than those with significant results. This potential bias is called publication bias and can lead to an overestimation of treatment effects. To control for this bias, we calculated the number of studies with effect sizes of zero (i.e., fail-safe *n* rates) that would be needed to reduce the established average effect to insignificance (Rosenthal, 1979). Intention-to-treat-analyses with a modified last-observation-carried-forward approach were applied to control for potential biases due to treatment dropout. Patients who dropped out of a study after treatment assignment were considered nonresponders and henceforth represented with zero effect sizes (i.e., no change in outcome

variables). The individual completer effect sizes were corrected with those intention-to-treat effects within each study and then reintegrated.

RESULTS

Characteristics of Included Studies

Included in this review were 94 studies, representing data from over 3,500 headache patients, that have been published between 1973 and 2007. Included in the meta-analysis of biofeedback for migraine were 56 studies with a mean of 40 patients per study. The meta-analysis on TTH consisted of 45 studies with a mean of 29 patients per study. In 7 of these studies treatment was provided for both migraine and TTH patients, and results were scored and presented independently. Key features of the integrated studies are presented in Table 1. Age means and gender distributions were similar for the two COI, with 37 and 38 years on average, and 88% and 73% percent women for Migraine and TTH, respectively. The TTH sample additionally included 9 studies investigating the efficacy of biofeedback for children and adolescents.[1] In the studies with adult headache patients, the average number of years since headache diagnosis was 17.1 for migraine and 14.8 for TTH. Diagnoses were made according to a standardized diagnostic system in 80% of the migraine studies and in 50% of the TTH studies. Unstandardized exams and interviews applying characteristic features of the two COI were used for diagnostic purposes in 7% of the migraine and in 34% of the TTH studies. In the remaining 13% of the migraine and 16% of the TTH studies patients' prior medical diagnoses were adopted from their records or interviews. During biofeedback treatment, 14% of the migraine and 8% of the TTH patients discontinued treatment. Information about attrition was provided in 76% of the migraine and 61% of the TTH studies. During follow-up, an additional 6% of migraine patients and 25% of the TTH patients ceased participation. Follow-up evaluations took place 14 months after treatment termination on average. In total, 136 active biofeedback conditions were investigated. For migraine, TEMP-FB in combination with either relaxation or EMG-FB, was the most frequently applied feedback modality, followed by TEMP-FB alone and BVP-FB. Seldom used were EMG-FB alone, EEG-FB and GSR-FB. For TTH, 92% of the biofeedback treatments were EMG-FB. Of these 16% were applied in combination with relaxation training. Other modalities were seldom used. In 80% of the EMG-FB treatments electrodes were placed bifrontal, in 12% multiple placements (i.e., frontal, neck or jaw) were used, and in 8% electrodes were placed on the neck. The number of biofeedback sessions ranged from 3 to 24 with an average of 11 sessions for both migraine and TTH. The duration of a treatment session ranged from 20 to 95 minutes, averaging 43 minutes for the two COI. In 78% of the migraine studies and 80% of the TTH studies treatment manuals were utilized and described in the publications. 78% of the integrated migraine studies and 58% of the TTH studies were conducted with control groups. The remaining 22% of the migraine studies and 42% of the TTH studies were uncontrolled pre-post evaluations. Within the controlled trials waiting list/ no-treatment control groups were applied in 15 of the migraine and 8 of the TTH studies. Placebo control groups were applied in 12 of the migraine and 8 of the TTH studies. The placebo treatments were mostly pseudofeedback conditions, where patients were trained to influence psychophysiological parameter under false or stable feedback or in the opposite direction (e.g., increase of muscle tension). Active control treatments included relaxation training in 18% of the migraine and 11% of the TTH studies. Within the controlled studies, 26% of the migraine and 22% of the TTH studies incorporated single or double-blind designs. Outcome was measured with headache parameters, and at least one other outcome category, in 84% of the migraine and 68% of the TTH studies. Means and standard deviations of the outcome variables that can be directly used for the calculation of effect sizes were presented in 73% of the migraine and 46% of the TTH studies.

Efficacy of Biofeedback in Controlled Trials

For the analysis of general efficacy, the variables headache frequency, duration, and intensity were integrated. These outcome variables were consistently measured with a structured headache diary in 92% of the migraine and 83% of the TTH studies. Mean weighted effect sizes[2] for all controlled comparisons are presented in Table 2. In the migraine studies, biofeedback yielded a significant small-to-medium effect size in comparison to waiting list control groups. An average small-to-medium effect size was found in comparison to placebo groups. However, this effect missed formal significance. A small non-significant effect in comparison to relaxation treatments was established. In the TTH studies, biofeedback yielded a significant medium-to-large effect size as compared to untreated control groups. A significant medium effect size was found in comparison to placebo control groups and a significant small effect size for biofeedback was obtained in comparison to relaxation control groups. For all reported comparisons, effect sizes were homogeneous according to the REM. The comparisons of biofeedback with pharmacotherapy, and physical and cognitive therapies, were insignificant and consisted of too few studies to provide reliable conclusions.

Efficacy in Pre-post and Follow-up Evaluations

Additional pre-post effect sizes were computed for all controlled and uncontrolled comparisons. Weighted mean effect sizes and confidence intervals for all pre-post and follow-up integrations are presented in Table 3. For migraine, 85 independent effect sizes ranging from -0.07 to 1.74 were computed. These effects were homogeneous in the fixed effect model. For all biofeedback modalities, a significant average effect size of medium magnitude resulted. This effect was proven to be robust in intention-to-treat analysis. Over 14 months' follow-up, on average, a significant medium-to-large

average effect size resulted. Reliability of the follow-up effects was established in the intention-to-treat analysis as well.

For TTH, the effect size calculation yielded 49 independent effect measures for headache relief from pre to post-treatment, ranging from 0.06 to 1.99. Effect size integration in the random effects model resulted in a significant large average effect size. In the intention-to-treat analysis, this effect size was shown to be reliable. Over an average 14-month follow-up, this effect was maintained and somewhat enhanced with an average medium-to-large effect size. Evaluation of the follow-up effect sizes in intention-to-treat analysis resulted in a significant medium-to-large average effect size.

Efficacy of Different Feedback Modalities for Migraine

Effect sizes with confidence intervals for the feedback modalities utilized in the biofeedback treatment of migraine are shown in Figure 1. All feedback modalities showed significant effect sizes. The highest treatment gains resulted for BVP-FB, with an average medium-to-large effect size. An overall medium effect size resulted for TEMP-FB in combination with relaxation and EMG-FB, while small-to-medium effect sizes resulted for EMG-FB and TEMP-FB alone. Differences between the modalities were insignificant.

Effects of Biofeedback on Different Types of Outcome Variables

Weighted average effect sizes and confidence intervals for all outcome variables are depicted in Figure 2a for the migraine studies and in Figure 2b for the TTH studies. In migraine, frequency, intensity, duration, and the headache-index were all reduced with significant medium effect sizes. Differences between these outcome categories were insignificant. For medication consumption, a small-to-medium effect size resulted. This effect was significantly smaller than the reduction on headache frequency and duration. Significant stronger improvements were shown for self-efficacy. Here a significant medium-to-large effect size resulted. Depression and anxiety showed medium effects, with confidence intervals ranging from small too large.

In the TTH studies, headache frequency, intensity, and the headache-index were reduced with large average effect sizes. Duration of headache episodes was reduced with a small-to-medium effect size. Physiological outcome (i.e., muscle tension in microvolts) was assessed as changes in muscle tension from baseline to post-treatment, and in some studies, additional within-session changes were reported. Muscle tension was reduced with a significant medium-to-large effect size within treatment sessions and with a significant small effect size (confidence interval including medium effects) across sessions. Over the course of all biofeedback sessions, reductions in headache-index and frequency were significantly larger than the reductions in muscle tension. Self-efficacy, anxiety, and depression all yielded significant medium effect sizes, with corresponding confidence intervals ranging from small to large effect sizes. Medication intake was reduced with a significant small-to-medium effect size. The average effect size for headache-index was significantly higher than the effect size for medication intake. The other symptom categories did not show any significant differences.

Publication Bias

In addition to the graphical method (see funnel plots in Nestoriuc & Martin, 2007), we examined publication bias by calculating fail-safe *ks* for the critical effect sizes 0.01 and 0.20. For migraine and TTH over 4,000 unpublished studies with zero effects would be necessary to reduce the observed average effect to zero. For a reduction to an average effect size of small magnitude (0.20) 148 migraine and 168 TTH studies with zero effects would be required. In sum, publication bias seems rather unlikely.

General Efficacy and Specificity

Overall robust treatment effects of medium magnitude were established for migraine and TTH respectively. Effects are clinically meaningful as they demonstrate symptom improvements of over half a standard deviation for migraine and almost one standard deviation for patients suffering from TTH. The high chronicity of the sample with over 14 years of headache on average further supports the clinical significance of these results. With an overall average of 11 sessions biofeedback treatments were altogether short and economical. Furthermore, the treatment was generally very well accepted, as shown in the low dropout rates.

For migraine, a medium average effect size resulted for biofeedback in comparison to untreated control groups. This effect size corresponds with symptom improvements in headache scores exceeding those of 61% of the patients in the untreated control groups (Rosenthal & Rubin, 1982). As indicated by the confidence interval, migraine patients treated with biofeedback will likely experience symptom improvements of 56-65% over and above those of an average patient in a waiting list control group. Although a small effect size for biofeedback in comparison to placebo was found, biofeedback treatment gains were not reliably higher than improvements in placebo feedback groups (i.e., psychological placebo for biofeedback including TEMP-FB with finger cooling). The average effect size found in comparison to placebo groups corresponds to a 56% success rate in biofeedback compared to 44% (38-50%) improvement in the placebo groups. Likewise, differences between biofeedback and relaxation showed no significance in migraine. Thus, there is strong evidence for the efficacy, but only weak evidence for the treatment specificity of biofeedback in migraine.

In TTH a large average effect size resulted for EMG-FB in comparison to untreated control groups. This effect corresponds with a 69% success rate under biofeedback as opposed to a 31% (25-37%) chance of improvement in the untreated control groups. Superior clinical results also emerged for biofeedback compared to placebo control groups and relaxation therapies. The effect size over placebo was robust and of medium magnitude, corresponding with a 62% success rate versus 38% (34-43%) in the placebo groups. Similar improvement rates for medication placebo were documented by Blanchard, Andrasik et al. (1980). However, the improvements in placebo groups seemed to be higher in migraine than in TTH patients. The effect size over relaxation was small but reliable, corresponding with a 55% success rate versus 45% (42-48%) in the relaxation groups. Strong evidence regarding the efficacy as well as the specificity of biofeedback for TTH can be drawn from these results. Further efficacy comparisons of biofeedback to pharmacotherapy, physical therapy and cognitive therapy included only very few studies and cannot be interpreted reliably at this point.

Results of previous reviews have consistently shown biofeedback to be more effective than headache monitoring (Blanchard et al., 1980; Bogaards & ter Kuile, 1994; Holroyd & Penzien, 1986; McCrory et al., 2001), but were inconclusive about the specificity of biofeedback. Blanchard, Andrasik, and colleagues (1980) pointed out nearly 30 years ago that there were too few studies to draw conclusions about the equivalence of alternative headache treatments. Holroyd and Penzien (1986) reported significant differences between behavioral treatments and placebo conditions, but no differences within the active treatments. Until today, many studies have reported conflicting results with respect to the comparative efficacy of biofeedback and relaxation training, mostly due to underpowered statistical analyses (Houle, Penzien & Houle, 2005). The results of this review point to a comparable efficacy of biofeedback and relaxation therapy in the case of migraine and to a superiority of biofeedback over relaxation in the treatment of TTH.

The efficacy findings from controlled comparisons were subsequently replicated in pre-post treatment comparisons. All available outcome data from the integrated randomized controlled as well as uncontrolled studies were included in the pre-post treatment comparisons. Robust medium average effect sizes resulted for the two COI, with a confidence interval including large effects for TTH. This review is the first to include intention-to-treat analyses for efficacy evaluations in behavioral headache treatments. The inclusion of all patients who dropped out of the active biofeedback groups during treatment resulted in slightly diminished but still significant medium average effect sizes for migraine and TTH. These results point to the robustness and clinical meaningfulness of the established effects, even when dropouts are considered as non-responders.

Maintenance of Biofeedback Effects Over Time

In follow-up evaluations, the established effects were shown to persist up to several years after treatment. One study showed this to be the case whether additional treatment, in the form of booster sessions, was provided or not (Andrasik, Blanchard, Neff, & Rodichok, 1984). The average medium effect sizes remained stable over follow-up intervals of 15 months for migraine and TTH. Supporting prior results (Blanchard et al., 1980) indicating the stability of biofeedback treatment gains, the presented results constitute the most comprehensive meta-analytical confirmation of the long-term efficacy of biofeedback for headache disorders. Intention-to-treat analysis showed that the established follow-up effects persisted even when dropouts were considered as non-responders.

Moderating Effects of Different Feedback Modalities and Outcome Measures

The frequently applied feedback modalities in migraine all showed comparable treatment effects with reasonable confidence. The rarely investigated applications resulted in medium effects as well but produced less stable results. Among these, EEG-FB was applied in three studies only, showing small and medium effect sizes. Due to the small number of integrated studies, it is not possible to draw final conclusions regarding the efficacy of EEG-FB for migraine. It is both interesting and important to note that BVP-FB, a modality that has been excluded from prior efficacy reviews (Goslin et al. 1999), showed the highest improvement rates; effect sizes ranged into large effects. In TTH a differential analysis of feedback modalities is not necessary, as the majority of studies used EMG-Feedback.

With respect to the different outcome variables that have been evaluated, reliable effect sizes occurred for all headache variables. Headache frequency, the primary outcome variable, yielded the highest treatment effects in migraine and TTH. Also, consistently over both COI, the reduction in medication consumption, though robustly present, yielded the lowest effect sizes. In migraine, cognitive aspects, as measured with changes in self-efficacy, yielded higher effect sizes than the other outcomes. In TTH, the reductions in muscle tension as a measure of physiological outcome yielded similarly high effect sizes to the cognitive variables. Anxiety and depression were less often evaluated, resulting in rather imprecise estimated effects. It has to be noted that these results cannot be used to analyze treatment mediators, because the incorporated effect measures are only based on pre-and post-treatment assessment. It is highly recommended to incorporate mediator analyses in future headache trials (Penzien et al., 2005) in order to gain further insight into treatment mechanisms. Promising variables in that respect are self-efficacy and physiological changes, as well as comorbid reductions in

depression and anxiety. There are some additional behavioral and socio-economic outcome categories that have seldom been assessed in the current headache trials (i.e., lost work days, health service use, general activity level, social and role functioning). Thus, in future studies we recommend incorporating direct measures of the functional, social, and socioeconomic burden of headache (Andrasik, 2001; Andrasik et al., 2005).

Influence of Treatment Features, Patient Characteristics, and Study Validity

Analyses of treatment moderators are used to derive recommendations for the clinical utility of treatments. Our moderator analyses in the two recently published meta-analyses on migraine and TTH have established important treatment moderators, which we will briefly describe in the following section.

In the biofeedback treatment of migraine, home training was shown to be an essential component of the efficacy and maintenance of treatment benefits. Treatment manuals incorporating home training led to nearly 20% higher treatment effects for headache reduction. Surprisingly, headache chronicity turned out to be a positive treatment predictor both in adult migraine and TTH patients. This effect accounted for over 20% of the variability in the TTH effect sizes and turned out to be a significant predictor for direct treatment efficacy and follow-up effects in migraine. It might be partly due to particularly high effects in geriatric headache patients (Nicholson & Blanchard, 1993). However, the fact that more years with headache can lead to higher treatment benefits emphasizes the treatment possibilities inherent in biofeedback.

In the treatment of TTH, the combination of biofeedback with relaxation training, and the use of biofeedback alone can be recommended, especially for juvenile headache patients. No moderating effects were found for different training sites within the EMG-FB treatments, for study setting (i.e., outpatient versus including home training), treatment duration, or the diagnostic distinctions between CTTH, ETTH, and TTH with pericranial tenderness. Diagnostic distinctions between ETTH and the clinically more meaningful CTTH were only seldom made. Hence it is not yet possible to draw reliable conclusions regarding the equal effectiveness of EMG-FB for both headache conditions. Further studies directly comparing the efficacy of EMG-FB for episodic and chronic TTH are needed.

The validity levels of the integrated studies were uncorrelated with the treatment effects for both COI at post-treatment. Nevertheless, some validity issues seem present in the field of biofeedback (Yucha, 2002). In some of the studies evaluated in this review, low sample sizes, resulting in power problems, failure to describe basic treatment and patient characteristics, as well as the use of unstructured diagnostic systems had a negative impact on validity levels. A number of excellent suggestions and recommendations concerning behavioral headache research have recently been put forward (Houle, Penzien & Houle, 2005; Penzien et al., 2005; Rains, Penzien, McCrory & Gray, 2005), and future studies would undoubtedly benefit from adopting these standards.

Levels of Evidence of Efficacy

The evidence collected and presented in this comprehensive efficacy review leads to the conclusion that biofeedback for migraine can be supported as an efficacious treatment option. This constitutes *Level 4* evidence according to the AAPB/ ISNR criteria (LaVaque et al., 2002). Efficacy comparisons to no-treatment control groups favoring biofeedback exist in studies from multiple independent research teams, using clearly defined diagnostic criteria and outcome measures as well as appropriate data analysis.

Biofeedback for TTH can be supported as an efficacious and specific treatment option. According to the AAPB/ ISNR criteria this constitutes the highest level of evidence (*Level 5*), reserved for psychophysiological interventions, that have established *Level 4* evidence and have shown additional superior treatment results in comparisons to credible sham therapy or alternative bona fide treatments.

METHODOLOGY

Overview

In this chapter, the research design, survey methods, and data analysis procedures are described.

Statement of the Problem

Headache disorders, characterized by recurrent headache, are among the most common disorders of the nervous system. Headache itself is a painful and disabling feature of a small number of primary headache disorders, namely migraine, tension-type headache, and cluster headache. Headache can also be caused by or occur secondarily to a long list of other conditions, the most common of which is medication-overuse headache. Globally, it has been estimated that prevalence among adults of current headache disorder (symptomatic at least once within the last year) is about 50%. Half to three quarters of adults aged 18–65 years in the world have had headache in the last year and, among those individuals, 30% or more have reported migraine. Headache on 15 or more days every month affects 1.7–4% of the world's adult population. Despite regional variations, headache disorders are a worldwide problem, affecting people of all ages, races, income levels and geographical areas.

Headache disorders impose a recognizable burden on sufferers including sometimes substantial personal suffering, impaired quality of life and financial cost. Repeated headache attacks, and often the constant fear of the next one, damage family life, social life and employment. The long-term effort of coping with a

chronic headache disorder may also predispose the individual to other illnesses. For example, anxiety and depression are significantly more common in people with migraine than in healthy individuals.

Analgesic use, misuse and overuse represent major health problems associated with numerous adverse health consequences. Medication overuse headache is a serious problem that develops from taking headache medications too often, even at the recommended dose. Medication overuse headache is constant-it won't go away until you completely stop taking the drugs that are causing the problem. Any headache medicine can cause medication overuse headache-taking caffeine-containing headache medications doesn't appear to increase the risk.

Purpose of the Study

This study was for teaching purposes that provided skills to participants in the prevention of tension-type and cluster headaches. Very few studies worked with well diagnosed patients and few worked with patients who had clearly failed other therapies which were shown to have been properly applied. This study was aimed at showing that biofeedback works with patients meeting set criteria for Tension-type and Migraine headaches who failed properly provided (adequate medication trials, etc.) standard treatments. Electronic sensors were utilized, attached to various parts of the body (Frontalis: muscle of the forehead, Masseter: muscle of the jaw, Trapezius: muscle of the shoulder) to detect changes in physical responses). These muscles are used in EMG biofeedback because they typically respond to stress and can be easily measured. EMG biofeedback training would start by the placement of the two active sensors in the center of the forehead of the patient. Secondly, we placed the ground or reference sensor in the middle of the two active sensors. Surface EMG is measured in microvolts. SEMG of 2 millivolts or less indicates that the muscles are in relaxed position. If the level remains low even throughout the stress provoking imagery or discussion or after adequate course of forehead EMG biofeedback, little change in headache activity is noted, sensors can be placed in the head and neck region. These active sensors would detect the underlying muscle's action potential that causes the initiation of action potential. The electrical activity traced by the active sensors on the muscles is displayed through a monitor. This feedback helped the patients to regulate their muscle tension by relaxation. The patient was trained by the therapist to read the changes on the monitor and use any of the techniques of his choice to decrease the muscle tension. Thus decreasing the pain related to increase muscle tension.

Rationale

Biofeedback training is a widely used modality with well-established efficacy in the treatment of headaches. The evidence supporting the use of biofeedback comes from numerous research studies and meta-analyses published in peer-reviewed journals. Despite the evidence supporting the use of biofeedback, it continues to be misrepresented and overlooked; many insurance carriers deny or restrict access to biofeedback training. The Association for Applied Psychophysiology and Biofeedback (AAPB) is providing an Ethics Document to help third party carriers make informed decisions concerning biofeedback reimbursement.

Biofeedback is a technique for developing greater awareness of and voluntary control over physiological arousal of the stress nervous system (like muscle tension and shallow breathing) that is often beyond our awareness. Studies show that chronic arousal of the stress nervous system or sympathetic nervous system is strongly linked to headache. In biofeedback treatment, self-monitoring and self-regulation skills are learned using sensitive and non-invasive recording instruments to help the patient actively manage ways their bodies are affected by pain and by other stresses in their lives. The training often leads to surprising insights about ways we carry tension and worries. These are treatment options for headache sufferers who have one or more of the following characteristics:

A. Patient preference for non-pharmacologic interventions
B. Poor tolerance to specific pharmacologic treatments
C. Medical contraindications for specific pharmacologic treatments
D. Insufficient or no response to pharmacologic treatment
E. Pregnancy, planned pregnancy, or nursing
F. History of long-term, frequent, or excessive use of analgesic or acute medications that can aggravate headache problems (or lead to decreased responsiveness to other pharmacotherapies)
G. Significant stress or deficient stress-coping skills

Cognitive and behavioral treatment recommendations include:

A. Relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive-behavioral therapy may be considered as treatment options for prevention of headache.
B. Cognitive-Behavioral Therapy and Stress Management training, which modify overt behavior by altering thoughts, interpretations of events, assumptions, and usual behavioral patterns of responding to events or stressors.

Biofeedback relies on a different model of treatment. Medical treatment emphasizes pharmacotherapy and surgery. The patient has a passive role and is the recipient of an intervention; a drug or surgical procedure. Biofeedback employs a teaching model of enhanced self-regulatory skills. The patient plays an active role, and with the help of the biofeedback therapist, he or she learns to modify physiological activity. Relaxation skills are enhanced and patients are empowered to learn that

they have the capacity to manage their symptoms more effectively.

A relatively brief period of biofeedback training with a skilled provider can make a profound impact on the health and well-being of a patient. It can alter the patients' belief system and empower them to adopt additional health maintenance activities (dietary changes, exercise, smoking cessation, etc.).

Hypothesis/Research Question

It is my hypothesis that utilizing biofeedback along with analgesics for treating uncontrolled chronic headaches (Tension Type Headaches and Migraines) will reduce the intensity, frequency, and the duration of pain of the headaches as compared to the patients who are using analgesic medication only. A secondary hypothesis is that the need for medication will decrease significantly over treatment. We have selected Tension Type headache/Migraine headache elimination of headache for this study because most of the patients with uncontrolled chronic headache in our clinic have been diagnosed with tension type and migraine headaches. We would be using a combined biofeedback treatment (EMG biofeedback + thermal biofeedback) in each session comprising of 40 minutes' total to all the patients in the study group (Tension headache and migraine headache).

Research Design

Twenty-five patients were randomly selected from the pool of patients in our clinic who failed standard analgesic therapy for Tension-type and Migraine headaches. Each was offered the opportunity to receive biofeedback therapy for their headaches along with their medicinal treatment as part of their regular clinical care. Their information was compared with headache activity of twenty-five similar patients in our clinic who continued to receive standard medicinal care. Each of the people offered biofeedback and those who serve as a comparison were provided with HIPAA and explanation form in which each agreed to the use of their medical data following the participation in the study. Each patient receiving biofeedback was given EMG feedback for 30 minutes and thermal biofeedback for 10 minutes during each of ten weekly sessions. Patients in the comparison (treatment as usual) group received their medication as usual but did not receive any placebo biofeedback as this was simply a comparison group rather than a true "control" group. People treated for headaches in our clinic keep 10 week long logs of headache activity and medication use as part of normal tracking of headache activity so these data were available to use when comparing people receiving biofeedback in addition to standard care with those simply continuing standard care.

The tricyclic antidepressant amitriptyline is the drug of choice for treating chronic tension headaches. Maintenance dose is 30-70 mg/day. Further, the noradrenergic and specific serotonergic antidepressant mirtazapine 30mg/day is known to reduce the headache index by 34%.

Patients in both the study and comparison groups were allowed to use acute headache medication e.g. over the counter medicines like acetaminophen, ibuprofen, aspirin, naproxen. Patients would not be required to change their pattern of use of acute medication during the trial.

We completed 10 sessions of EMG biofeedback, and temperature biofeedback in 3 months. Each biofeedback session lasted for 40 minutes. Out of which 30 minutes were given to EMG biofeedback and 10 minutes to the temperature biofeedback. The initial session was kept short (3-5 minutes). It works as an adaptation period in which the subjects sat quietly with their eyes closed. Later on, in the 2nd or 3rd session the duration of EMG biofeedback increased to 25-30 minutes.

Before starting the first biofeedback sessions the patients were provided complete detail about the biofeedback system being used during the sessions and also how safe the whole process is. It was expected that the patients will be quite anxious since they were not previously aware of this procedure. For example, we let them know when we are placing sensors, or putting the thermistor to their fingers what each one is measuring and that we are learning what stresses and relaxes them. Prior to the initiation of this study subjects used analgesic medication for treating acute headaches. Biofeedback sessions were done along with the use of analgesic medications for part. When the subject does not have any headache at all, biofeedback sessions can still be performed. The SEMG level of less than 2 millivolts indicated that the muscles are relaxed. If the level remains low during the stress provoking imagery or discussion, very little headache activity is seen. In that case sensors were moved to the head and neck region.

During this study the participants were provided with skills for the prevention of Tension-type and Migraine headaches. I utilized EMG electronic sensors attached to various parts of the body (Frontalis: muscle of the forehead, Masseter: muscle of the jaw, Trapezius: muscle of the shoulder) to detect changes in physical responses. These muscles are used in EMG biofeedback because they typically respond to stress and can be easily measured. EMG biofeedback training started by the placement of the two active sensors in the center of the forehead of the patient. Secondly, a ground or reference sensor was placed in the middle of the two active sensors. According to Arena, J. Bruno, G. & Brucks, A. (1997) surface EMG is measured in microvolts. SEMG below 2 microvolts indicates that the muscles are in relaxed position. The electrical activity traced by the active sensors on the muscles was displayed through a monitor. This feedback helped the patients to regulate their muscle tension by relaxation. The patient was trained by the therapist to read the changes on the monitor and use any of the relaxation techniques of his

choice to decrease the muscle tension. Thus decreasing the pain related to increase muscle tension. Throughout stress provoking imagery or discussion or after adequate course of forehead EMG biofeedback a little change in headache activity was noted, sensors were placed in the shoulder and neck region.

Data Collection

Each subject kept a log (Appendix B) of headache activity (frequency, intensity, and duration), medication use, and debilitation for two weeks before and after treatment then again at the six-month follow-up. The patients were also provided with a head pain diagram (Figure 3) to display the shape of every spot on the head that hurts, including a description of pain at each site. Changes from baseline to post treatment and follow-up were compared between and within groups using an analysis of variance. The design is essentially two repeated measures (before and follow-up time was provided to patients) for each group with intergroup independent measures for each time period. Parametric data was compared using a parametric repeated measure ANOVA followed by paired (within groups) or independent "t" tests (between groups). Non-parametric variables such as headache intensity was compared using a non-parametric ANOVA followed by individual Mann-Whitney U tests. A 0.05 level of significance was used as a guide to identify group differences.

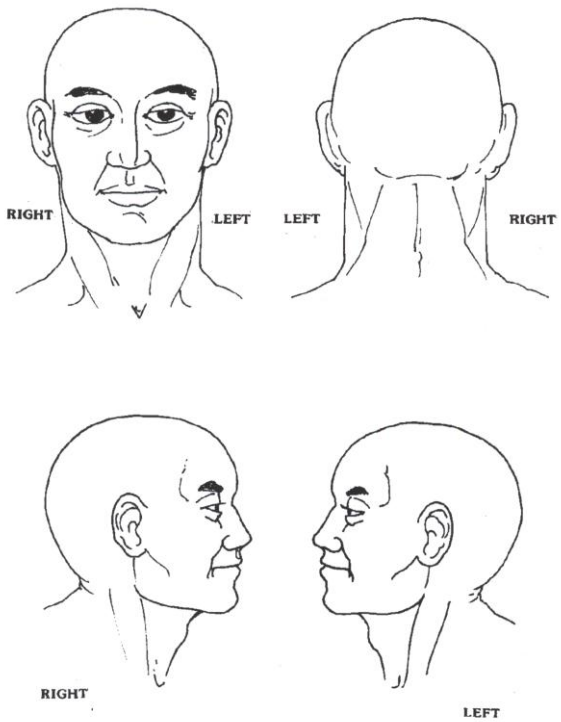


Figure 3: Head Pain Diagram.

Post study collection of data was conducted via interview. We used two methods for the collection of that data. Patients who visited the clinic were asked to complete a questionnaire about the post treatment changes in the frequency, intensity, and duration of headache or the development or relief from any headache related symptoms. In addition, information was collected on the quantity and frequency of using analgesic medication after the completion of study. The rest of the patients in our study cohort that did not present in person were contacted by phone from our Waterford center located at 46 Third St. Waterford, NY 12188 and the caller would conduct a survey (Appendix A) by completing the same questionnaire.

Selection of the Study Participants

Fifty patients were selected from the clinic that have demonstrated clinical issues with chronic headaches in the past 3 years (for example migraine, or tension type headache) that persist for more than a year, from the logbook of our Waterford clinic. These patients were selected between the ages of 18 - 55 yrs., Irrespective of their sex and again randomly assign half of them Group A for biofeedback along with medication therapy. Subjects will be randomized to the comparison or biofeedback treatment group by alternating assignment to groups as the patients are identified in the log book. Participants were asked to sign an informed consent that disclosed the purpose and other details of the study, and guaranteed study disclosure confidentiality.

Power Analysis of Subject Number

Inputs

Estimate of Standard Deviation	o = 2
Discrimination Level	s=0.5
Risk Level	a=0.0.8

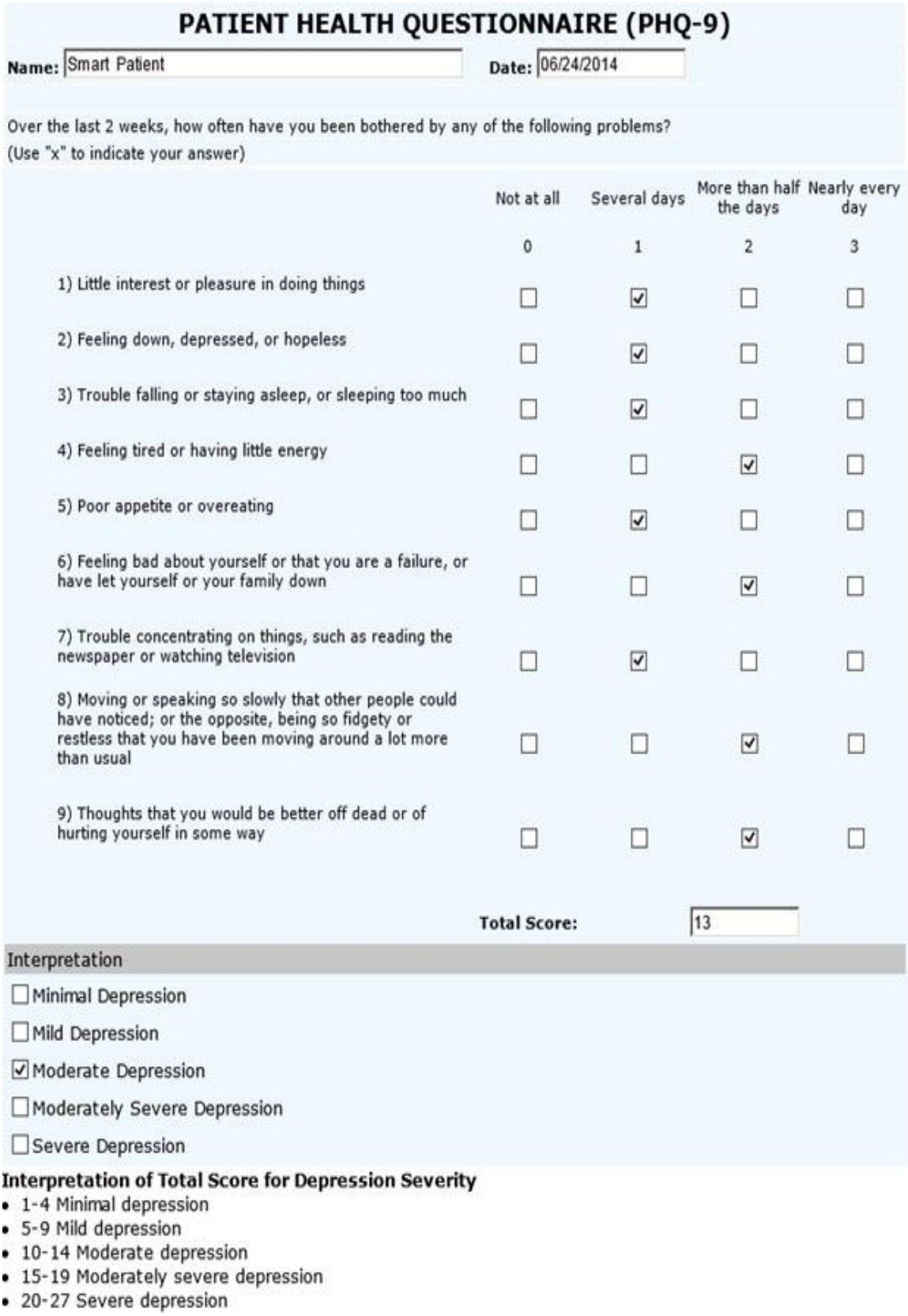
Output

Sample Size n= 50

All subjects kept a log of their headache activity (duration and intensity of the headache, as well as the quantity of medicine intake for one month before biofeedback or the control condition, for one month at the end of therapy and then for a third month six months after therapy is completed. The other half of the subjects or the comparison group would continue using analgesic medication for treating their chronic headache.

(2) Age range of subjects: between the ages of 18 -55 yrs. Psychological assessment was done by the physician to analyze the patient's psychological status and make sure that they are capable to learn and benefit from the biofeedback techniques and interact actively to the investigators during the clinical study. We would use the following assessment tools for interviewing and screening.

- Patient Health Questionnaire PHQ 9 would be used to assess depressive disorders. PHQ 9 score should be more than or equal to 11 to detect depressive disorder and these patients are excluded. (Figure 4)



PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

Name: Smart Patient **Date:** 06/24/2014

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use "x" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
1) Little interest or pleasure in doing things	☐	☑	☐	☐
2) Feeling down, depressed, or hopeless	☐	☑	☐	☐
3) Trouble falling or staying asleep, or sleeping too much	☐	☑	☐	☐
4) Feeling tired or having little energy	☐	☐	☑	☐
5) Poor appetite or overeating	☐	☑	☐	☐
6) Feeling bad about yourself or that you are a failure, or have let yourself or your family down	☐	☐	☑	☐
7) Trouble concentrating on things, such as reading the newspaper or watching television	☐	☑	☐	☐
8) Moving or speaking so slowly that other people could have noticed; or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	☐	☐	☑	☐
9) Thoughts that you would be better off dead or of hurting yourself in some way	☐	☐	☑	☐

Total Score: 13

Interpretation

- ☐ Minimal Depression
- ☐ Mild Depression
- ☑ Moderate Depression
- ☐ Moderately Severe Depression
- ☐ Severe Depression

Interpretation of Total Score for Depression Severity

- 1-4 Minimal depression
- 5-9 Mild depression
- 10-14 Moderate depression
- 15-19 Moderately severe depression
- 20-27 Severe depression

Figure 4: PHQ9 Patient Health Questionnaire.

- Headache Impact Test HIT 6 measures the impact of headache on the quality of life.

Sex and racial composition of subjects: All ethnic groups and gender groups will be accepted in this research study. (Figure 5)

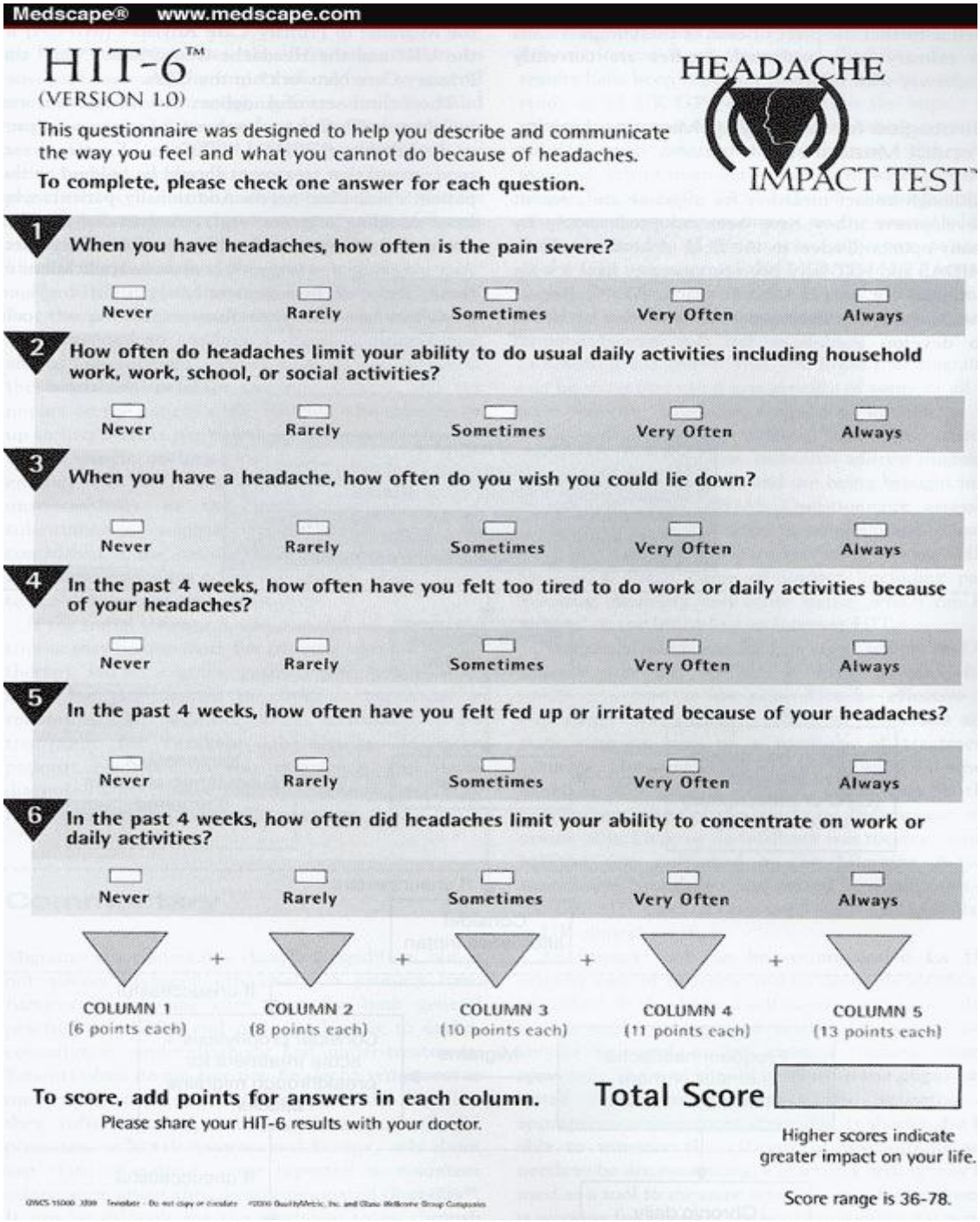


Figure 5: Hit 6- Headache Impact Test.

(4) Source and availability of subjects: Would be determined by the records on the clinic log, where patient's medical histories have been evaluated to meet the research criteria.

(5) Inclusion, exclusion, and diagnostic criteria:
Patients with chronic headache selected from the logbook of Waterford clinic are between the ages of 18 - 55 yrs. We only selected those patients who have the capacity to learn and apply the biofeedback techniques. We used "Rey Auditory-Verbal learning test" to measure the memory span and learning ability of the subject. Participants are given a list of 15 unrelated words repeated over five different trials and are asked to repeat. Another list of 15 unrelated words are given and the client must again repeat the original list of 15 words and then again after 30 minutes. Approximately 10 to 15 minutes is required for the procedure (not including 30 min. interval) (Result Filters, 2015).

The "Rey Auditory-Verbal learning test was done at the time of screening to discern learning capacity, memory, concentration and perception of the subject (Result Filters). A survey was done by using HIT-6 (Headache

impact Test) questionnaires (Assessing the impact of Migraine). HIT-6 was completed during their regular clinic visits. HIT-6 measures the impact headaches have on the subject's abilities to work on their job, school, home, or other social situations.

A. Inclusion Criteria

1. Patients must be 18-55 yrs.
2. Patients must have been diagnosed as having either non-traumatic onset migraine (with or without aura) or tension headaches. Rule out trigger point, jaw joint (TMJ), sinus, cluster, withdrawal, and medication side effect headaches as biofeedback has not been shown to be effective for these headaches. Medication overuse headaches e.g opiate containing medicines and triptans or medicines that contain hormones e.g estrogen replacement therapy drugs
3. Patients must be able to understand the concepts being taught and have the capacity to learn and apply them.
4. Patients with at least 2 episodes of chronic headache (Tension/Migraine Headache) per month are preferred. So the changes in headache activity are readily noted by both the patient and the provider.

B. Exclusion Criteria

1. Psychiatric problems potentially liable to result in an adverse reaction to the equipment e.g Paranoia, Suicide ideation, ADHD, Depression. Patients with Axis I (substance use disorders, mood, and anxiety disorders) and Axis II (Personality disorder) of DSM IV are also excluded.
2. Patients with history of stroke.
3. Headache initiated by trauma:

a. History of previous hospital admission for head injury. Subjects developing Chronic post traumatic headache in relation to whiplash injury will also be excluded. Chronic post traumatic headaches usually present as tension type or migraine headaches, but they are also commonly associated with symptoms like dizziness, memory loss, insomnia, poor concentration, mood changes and depression.

b. Predominance of other types of headaches (e.g sinus, cluster, or medication side effects jaw joint TMJ trigger point) obscuring migraine or tension headache. Medicine rebound headaches are permitted only if the headaches are initiated by headache medicines, or hormones like estrogen replacement therapy.

4. Unexplained changes in headache frequency or character during the last four months – especially constant, unremitting pain which requires an immediate referral to a physician.
5. Patients below 18 yrs and above 55 yrs of age.
6. Reynaud's or muscle damage.

Study Components

Setting

This study was conducted in the private office of Dr. Mohammed Ismail located at 46 Third St. Waterford, NY 12188. Dr. Mohammed Ismail has agreed to the use of his office space, time and resources necessary including but not limited to funding for the educational/research purpose of Dr. Ghazala Nathu. (Appendix A)

Investigative Process

Tension and migraine headaches have been treated by behavioral interventions for the last 50 years. The interventions involve teaching patients with Tension headaches to release the inappropriate tension in their muscles to get relief from their headache, and teaching patients with migraine headache to learn the technique of keeping their hands warm to prevent the onset of migraine headaches. Muscle tension is recorded by placing the sensors over forehead, face, and shoulder muscles. Increased muscle tension is shown to the patient through a computer monitor. By observing tension levels, patients gradually learn to relate them with their body changes, such as change in posture, or stress responses and learn to control them. Exercises done at home can also help them to control their muscle tension. Biofeedback is generally a technique which helps us to control our body functions e.g., heart rate, muscle tension etc. EMG Biofeedback is typically used to treat Tension Type headache; this machine usually monitors the muscle tension. Three most common muscles that are monitored are:

Frontalis: muscle of the forehead
Masseter: muscle of the jaw
Trapezius: muscle of the shoulder

These muscles are used in EMG biofeedback because they typically respond to stress and can be easily measured (Biofeedback and Relaxation Training for Headaches.

Before actually starting the biofeedback sessions the patients were given a complete detail about the EMG machines being used during the sessions and also how safe the whole process was. It is obvious that the subjects would have been quite anxious if they were not aware of this therapy. For example, we elimination of use to let them know ahead of time before we were placing sensors, or putting the thermistor to their fingers. Our therapist was trained in performing surface EMG, thermal biofeedback therapy and progressive muscle relaxation exercises as well. "Biofeedback is performed and taught by many healthcare professionals, including doctors, nurses, psychologists, and physical therapists. Biofeedback therapists may be certified by organizations such as the Biofeedback Certification Institution of America (BCIA)" (Biofeedback Therapy). EMG biofeedback training would start by the placement of the two active sensors in the center of the forehead of the patient. Secondly, we would place the ground or reference sensor in the middle of the two active sensors (Figure 6). To ensure against infections we will use disposable sensors. Surface EMG is measured in microvolts. SEMG of 2 millivolts indicates that the

muscles are in relaxed position. If the level remains low throughout the stress provoking imagery or discussion or after adequate course of forehead EMG biofeedback, little change in headache activity is noted, sensors can be placed in the frontalis and trapezius region (Figure 7).

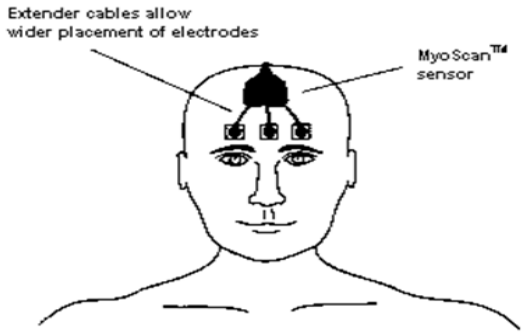


Figure 6: Forehead Placement of EMG Sensors.

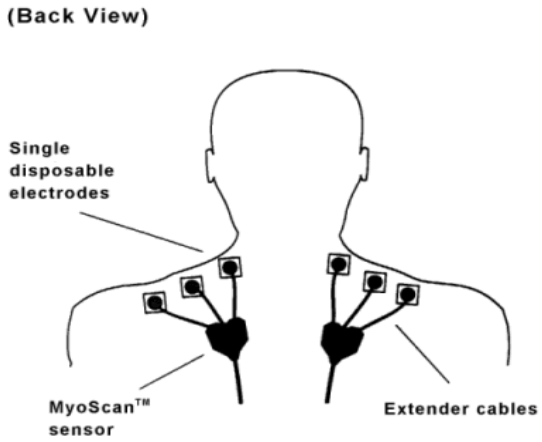


Figure 7: Trapezius Placement of EMG Sensors.

These active sensors would detect the underlying muscle's action potential that causes the initiation of action potential. The electrical activity traced by the active sensors on the muscles is displayed through a monitor.

A shaping procedure was used to train patients through a process of successive approximations to the eventual goal of muscle relaxation. Learning can be accelerated through positive reinforcement. In humans, simply meeting a goal of lowering the tone of a biofeedback instrument or dropping the signal representing muscle activity below a threshold line displayed on a computer screen can be an effective source of positive reinforcement. Muscle tension and temperature are among the easiest parameters to shape. There are several methods for shaping responses which are covered in biofeedback and pain courses. The easiest is to establish a baseline for the integrated signal you are recording and then move the threshold line so it is just above or below the integrated signal line (depending on which way you want the subject to change the signal). When the subject moves the signal to the threshold line, move it slightly again so that the patient has to continue moving the signal to get it to the threshold line (Figure 8).

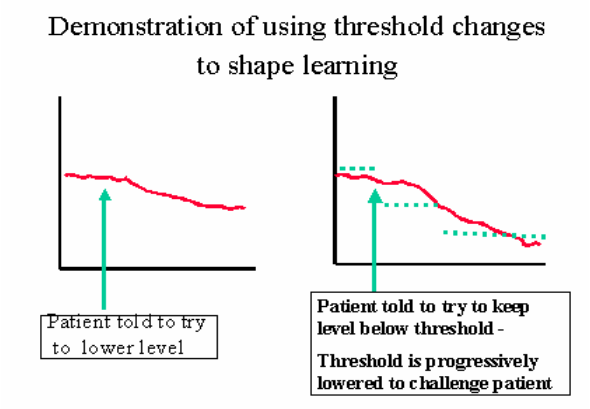


Figure 8: Threshold Line.

This feedback would help the patients to regulate elimination of their muscle tension by relaxation. The patient would be trained by the therapist to read the changes on the monitor and use any of the technique of his choice to decrease the muscle tension. Thus decreasing the muscle tension lowers the level of pain related to increase muscle tension increased the stress/pain level.

Tension headaches are caused by an increase in muscle tension in the areas of head, neck, and shoulder region. To relieve the muscle tension in these areas, patients are taught how to become aware of it and then learn to decrease the muscle tension; this is achieved by applying different techniques. For example, relaxing imagery, repeating relaxing autogenic phrases, deep breathing technique, awareness of muscle tension and muscle relaxation by keeping their minds empty or distracting their minds by focusing on different games or colors. (Biofeedback for the treatment of Headaches, 2015).

Our EMG biofeedback sessions would start with six possible strategies shown in Relaxation Strategies (Figure 9). The relaxation strategies mentioned in Figure 9 will be used in EMG biofeedback Training. These measures are used to change the psychological state of the subjects during the EMG sessions. We will keep the first session very short at 3-5 minutes due to the individual differences. The relaxation strategy that helps the subjects achieve their baseline EMG levels more quickly will be chosen. By applying these relaxation techniques, one can change their blood flow, and muscle tension (basic causes of migraine and tension headaches). Relaxing imagery or guided imagery would help the patients to create calm and pleasant images in their minds. The participant would be asked to think or imagine a pleasant experience or soothing environment. This would require full concentration of the patient to the extent that their mind would be focused and absorbed that he/ she would not feel the stress or pain anymore. This helps in reducing the stress, anger, pain and

depression etc. (Diseases and Conditions, 2015). Progressive muscle relaxation: by focusing on their breathing, participants would take deep breaths and exhale slowly. They would let go as much tension as they could and let all muscles completely relax. After recalling pleasant thoughts and holding their breath for a few seconds, they would take another deep breath and exhale slowly. Deep breathing: The participant would inhale by focusing into an imaginary spot below their navus. They would fill them with air from their abdomen up and they would let it go. Just like a balloon is deflated. With every long slow exhalation, they would feel more relaxed (Relaxation Techniques for Migraines and Headaches, 2015). First a 3-5 min of adaptation period for just sitting quietly with their eyes closed and then after that a maximum of 12-15 min of biofeedback. Length of biofeedback sessions would be gradually increased to 40 minutes in later sessions. It has always been emphasized that the ability to voluntarily relax our muscles is a difficult response to learn and the patients would need sometime before they could reliably lower their muscle tension of forehead muscles. Patients were always guided to be passive while trying to relax their muscles, because pushing too hard to make the relaxation happen would not help. We let them choose whichever auditory or visual feedback they like for their session. At the end of the session when the sensors were removed and the session data was saved we inquired about the strategy they used and whether they found it to be effective or not. We also obtained self-report recording the relaxation, muscle tension and pain levels on a 1-10 scale before and after the completion of session. The use of computers helps us review the minute by minute printout of the data with the patient (The Use of EMG Biofeedback for the Treatment of Chronic Tension Headache, 2015).

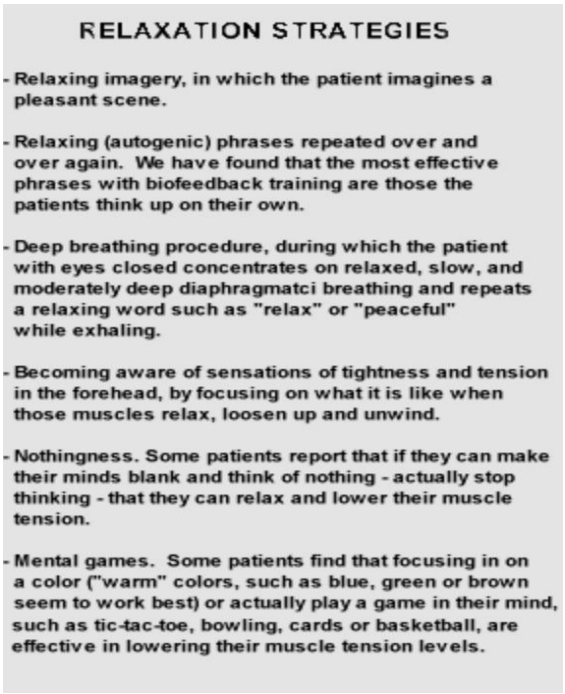


Figure 9: Relaxation Strategies.

The biofeedback technique generally used for chronic headaches is EMG biofeedback and thermal biofeedback. In thermal biofeedback skin temperature is recorded a thermistor placed on the middle finger. It is a thermometer that detects the skin temperature when it is attached to the finger or toe of the patient. It is a thermally sensitive resistor which shows a precise change in the resistance with the change in the body temperature. Its resistance decreases with an increase in body temperature.

Thermal biofeedback was also used along with the EMG biofeedback during each clinical session. All patients in Group A are provided with thermal units and are taught how to warm their hands and could use them outside the clinic as long as they kept their diary updated. Subjects of group A are given every detail about how and when to use the hand warming technique. The patients would learn to reduce their level of arousal by applying hand warming techniques. Then, whenever they would experience stress, they would use their hand warming skills and become relaxed. They are also required to keep their diary updated, which could be an app on their android, or a hand written diary. The purpose is to write down the details of all the headache episodes and any relaxation exercise or hand warming exercises they have been doing.

During stress the blood vessels typically respond by narrowing (vasoconstriction) and our fingers and hands become cold. When we are relaxed our hands are warmer because our blood vessels are expanded (vasodilation). So, the level of stress can be determined by checking the temperature of fingers by a thermistor.

After the completion of each session, patients would be given audio tapes and scripts and would be guided to practice those breathing exercises and relaxation techniques at home. Patients were also asked to complete a checklist after every EMG/ thermal biofeedback session indicating the appearance of any symptom such as depression, behavioral problems, or pain in other parts of the body etc.

Assign Homework

Homework assignments would help the subjects gain awareness and control of the different activities of their life by applying the relaxation techniques at home. More practice at home would help them apply the skills they learn at the clinic during the biofeedback sessions to their daily life. This way they would add the total time of practice to the 40 minutes of biofeedback session at the clinic. Headache diary or journal gives the best insight of the pain and the management of the headache. It answers all the questions regarding the type of pain, triggers, remedies, medication, relaxation exercises, sleep, emotions, depression etc. (Headache Journal: A necessary evil, 2015).

Patients were given homework of doing muscle

relaxation, breathing techniques, and hand warming exercises at home The patients were guided to keep a complete record of headache, sign and symptoms, duration, intensity, medication used etc. before and during the whole treatment. These records would help us evaluate the difference in the effect of two types of treatments. (Figure 10)

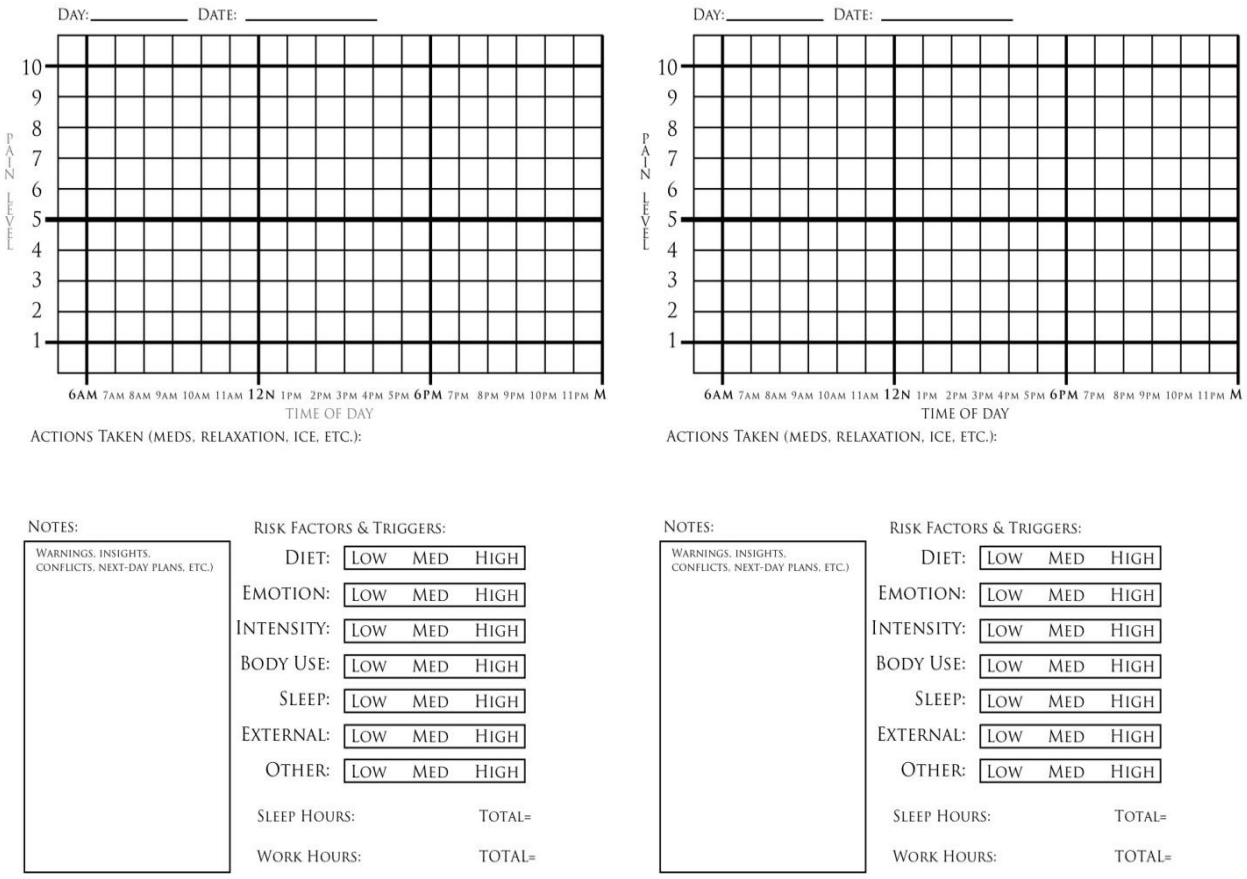


Figure 10: Homework Journal.

Ethics and Data Security

The study has been approved by the Dissertation Committee for Saybrook University. All data will be anonymized. An informed consent was taken from the patients to participate in the research as well as undergoing biofeedback procedures. All of the signed copies of the informed consent would be at the Waterford clinic, and the author would have the access on that data. She would also take full responsibility on the accuracy, and privacy of that data (by taking reasonable precautions to save the patient's confidential information stored in any medium). Only Dr. Ghazala Nathu would have access to the patient's confidential information.

Summary

Migraine and Tension-type headache (TTH) are two of the most common form of headache, and chronic tension-type headache (CTTH) is one of the most neglected and difficult types of headache to treat. The first step in caring for a tension-type headache involves treating the cause. Its name indicates the role of stress and mental or emotional conflict in triggering the pain and contracting muscles in the neck, face, scalp, and jaw. The pathogenesis of TTH is multifactorial and varies between forms and individuals. Muscle tension and tightness (temporal/facial/neck) and central mechanisms (tension, anxiety or endogenous triggers) are intermingled: Drug therapy can be ineffective for some episodes and at times becomes hard to treat. Preventive treatment or EMG and thermal biofeedback can help frequently and have an impact of the patient's lives. For most patients with Migraine and Tension-type headache the combination of drug therapies and non-drug therapies such as EMG and thermal biofeedback can be recommended. There is clearly an urgent need to improve the management of patients who are disabled by these headaches. This Review summarizes the present knowledge on migraine and tension-type headache and opens the discussion some of its more problematic features.

RESULTS

Data Analysis

All the 25 patients in the biofeedback treatment group completed the study protocol. All patients in the ongoing

traditional treatment comparison group also completed the study. The mean age was 29.6 years in study group and 31.2 years in the ongoing treatment group. All the cases were fresh, and the duration lasted one year between pre/during/post studies. Social demographics such as marital status, rural/ urban domicile and educational status were comparable between the groups. All patients suffered from headaches with at least 2 episodes of chronic headaches per month. In both the groups, there was almost similar representation for both the sexes. Tension and sinus headaches were the most common diagnosis in both genders, but migraine headaches were overrepresented among females.

In the study group, at the beginning of the study, 19 patients in the study group showed a rating of 50 or higher on the Headache Impact Test indicating headaches had a heavy impact on their ability to function at job, at school, and in social situations (Table 6). This number came down to 5 by the end of 6 sessions (middle assessment) of biofeedback treatment; and to 3, by the end of 10 sessions. The efficacy of interventions for headache is often based on patient estimates of the headache parameters of frequency, intensity and duration, which was ascertained from interview and headache diary. The findings suggest that when compared with the use of a headache diary, patient estimations of headache frequency and duration by diary are reasonably accurate. Headache intensity appears to be more difficult to remember and report, possibly because of the multidimensional nature of pain, as opposed to the temporal characteristics of frequency and duration (Appendix O).

The aim of the present study was to test the accuracy of retrospective patient reports of headache frequency, intensity and duration, with respect to measures derived from a daily headache diary. In comparison, patients without receiving biofeedback treatment still had to rely on analgesics in order to reduce pain from headache.

This is a retrospective, single blind, single centered controlled trial, which composes the analysis of a study group and ongoing treatment group. In group A (the biofeedback treatment group), positive outcome was obtained by statistically analyzing the difference in pain scores (Table 9), between pre-treatment and post-treatment using non-parametric ANOVA followed by Mann-Whitney "u" tests. A P value of 0.004 ($P<0.05$) was calculated, indicating the presence of significant difference between pre-treatment and post-treatment in terms of patient pain level. Most (96%) of the subjects from both study groups experienced reduced pain. Elimination of patients in Group A (biofeedback treatment) experienced much less pain after the biofeedback treatment. Similar situation applies to group B (ongoing treatment), where patient pain score after treatment is lower than pre-treatment. This was concluded by obtaining a P value of less than 0.0001, showing that the difference between pre and post treatment is true and significant. For Intensity, Frequency, Duration the following calculation was used: Intensity x duration x log (frequency) on the right of the table is the result of these calculations (Appendix O). Table 5,6,7,8, 9 outlines the variables produced from patient outcomes.

The significance of the study can be further verified by utilizing the ANOVA calculation. For both the biofeedback treatment group and the ongoing treatment group, the calculated F values are greater than the F values found in the table, concluding that the pain score after the biofeedback treatment is significantly lowered from the pain score prior to treatment, which indicates the effectiveness of the biofeedback treatment method (Table 11). The literature clearly shows that pain ratings on the universal pain scale above 50 indicate significant interference with everyday life. At the start of the study, 19 of the 25 patients receiving biofeedback had scores above 50 while 20 of the 25 patients in the ongoing treatment group had scores above 50. By the end of the study, only 3 of the 25 patients receiving biofeedback showed scores above 50 while 15 of those in the ongoing treatment group continued to show scores above 50. This difference was significant with Chi Square showing p less than 0.0001. An overall statistical difference in universal pain scores with p less than 0.05 between pre, post, and follow-up pain ratings for the two groups was identified using a non-parametric ANOVA so individual Mann-Whitney "U" tests could be run to identify the source of change. Sixteen of 25 patients in the biofeedback group experienced much less headache pain after the biofeedback treatment with a change in ratings from pre to post (Mann-Whitney "U" = 105, p less than 0.05). Twenty-four of 25 patients in the ongoing treatment group also showed a decrease in headache with a change in ratings from pre to post (Mann-Whitney "U" = 74, p less than 0.05). There was a clinically important as well as a statistically significant change in analgesic use with the biofeedback group showing a change from pre to post while the treatment as usual group showed no change. Chi Square indicated p less than 0.05 Indenting The results of this study show that the addition of biofeedback to standard analgesic therapy helps to treat uncontrolled chronic headache patients.

Table 5: Pre/Post Treatment Differences of Pain Scale Results- Biofeedback Treatment and Ongoing Treatment.

Group	Mean Change
Biofeedback	3.88 Gain
raditional	1.76 Gain

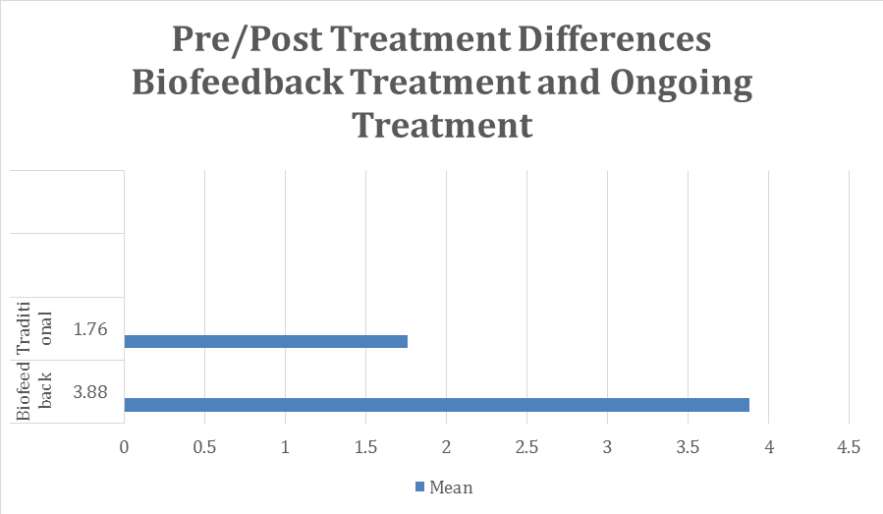


Table 6: HIT-6 Headache Impact Test Group A (Biofeedback Treatment Group).

Patient	Initial Hit Score Result (19)	6 Week Hit Score Result (5)	10 Week Hit Score Result (3)
1	66	48	46
2	78	60	50
3	46	44	40
4	68	56	44
5	66	38	38
6	72	46	40
7	70	48	48
8	48	46	34
9	76	48	48
10	68	46	38
11	66	60	50
12	70	62	44
13	54	46	38
14	62	44	40
15	48	44	38
16	66	46	38
17	72	46	40
18	40	32	38
19	48	38	38
20	50	44	42
21	74	66	52
22	72	48	38
23	68	46	40
24	44	40	40
25	62	42	40

Table 7: Hit 6 Headache Impact Test Group B (Ongoing Treatment Group.

	Initial Hit Score Result (20)	10 Week Hit Score Result (15)
1	48	44
2	68	60
3	66	61
4	48	44
5	72	61
6	68	56
7	72	60
8	46	44
9	74	61
10	72	56

11	62	54
12	50	38
13	68	54
14	48	44
15	66	46
16	78	54
17	66	42
18	76	71
19	44	42
20	54	44
21	62	42
22	68	54
23	72	60
24	50	42
25	66	38

Table: 8 Temperature Values of Study Group A (Biofeedback Treatment Group).

Patient	Temperature Reading
1	98.5
2	98.4
3	98.0
4	97.8
5	97.6
6	97.6
7	97.4
8	97.4
9	97.4
10	97.4
11	97.4
12	97.4
13	97.4
14	97.4
15	97.4
16	97.4
17	97.4
18	97.4
19	97.4
20	97.4
21	97.4
22	97.4
23	97.4
24	97.4
25	97.4

Table 9: Universal Pain Scale Pre/Post Scores, Group A (Biofeedback Group).

Group A Analgesic/EMF BFD	Pre Treatment Mean	Post Treatment Mean	Difference
1	8	3	+5
2	7	8	-1
3	9	8	+1
4	8	3	+5
5	6	5	+1
6	7	4	+3
7	5	5	0
8	8	3	+5
9	8	6	+2
10	6	6	0
11	9	5	+4

12	6	6	0
13	9	5	+4
14	7	3	+4
15	8	8	0
16	7	7	0
17	8	6	+2
18	9	4	+5
19	7	5	+2
20	8	5	+3
21	5	6	-1
22	7	7	0
23	8	8	0
24	9	5	+4
25	7	3	+4

Difference Mean: 51/25 = 2.04
S_d= 2.837, therefore *SE()* = 2.84, Standard error of mean = 0.63443

	N	Mean	Std. Deviation	Std. Error Mean	P
Difference	25	2.04	2.84	0.634	.0004

Plot Graph of Pre/Post Universal Pain Score, Group A (Biofeedback Group)

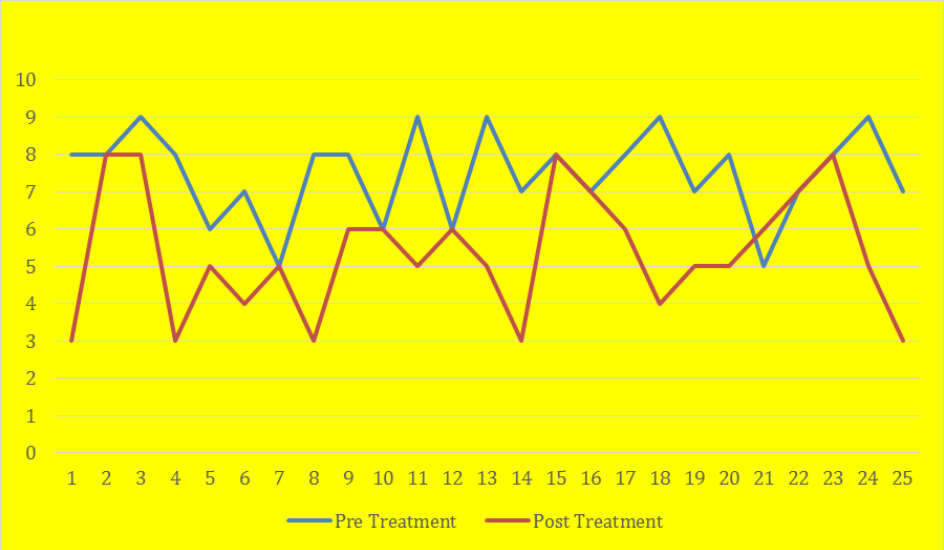


Table 10: Universal Pain Scale Pre/Post Scores, Group B (Ongoing Treatment Group).

Group B Analgesic	Pre Treatment Mean	Post Treatment Mean	Difference
1	8	6	+2
2	8	5	+3
3	7	6	+1
4	9	7	+2
5	8	6	+2
6	8	6	+2
7	7	5	+2
8	6	4	+2
9	6	4	+2
10	7	5	+2
11	7	6	+1
12	6	4	+2
13	6	4	+2
14	8	6	+2
15	7	5	+2

16	6	6	0
17	6	5	+1
18	8	7	+1
19	8	7	+1
20	9	7	+2
21	7	4	+3
22	7	4	+3
23	8	7	+1
24	7	5	+2
25	8	6	+2

Difference Mean: 31/25 = 1.24

S_d=0.7071 therefore *SE()* = 0.71 , Standard error of mean = 0.63443

	N	Mean	Std. Deviation	Std. Error Mean	P
Difference	25	1.8	0.71	0.1414	.0004

Plot Graph of Pre/Post Universal Pain Score, Group B (Ongoing Treatment Group)

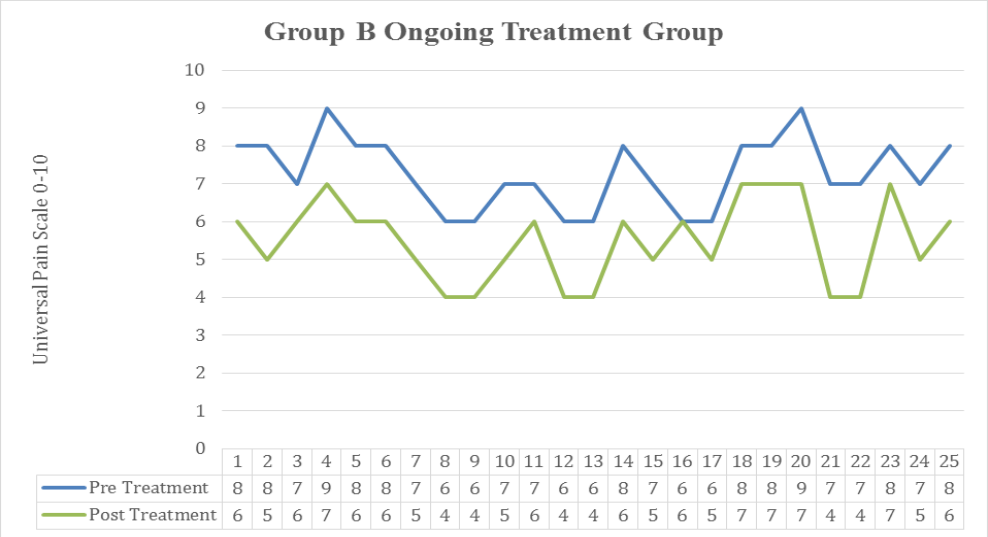


Table 11: ANOVA Calculations Pre/Post Pain Scale.

Group A		
	pre	**post**
1	8	3
2	7	8
3	9	8
4	8	3
5	6	5
6	7	4
7	5	5
8	8	3
9	8	6
10	6	6
11	9	5
12	6	6
13	9	5
14	7	3
15	8	8
16	7	7
17	7	3
18	9	4
19	7	5
20	8	5
21	5	6

22	7	7
23	8	8
24	9	5
25	7	3
N	25	25
X	7.400	5.240
S	1.190	1.739
$\mathbf{X}_{ave}$	6.320	

source	**df**	**SS**	**MS**	**F**
treatments	1	58.320	58.320	26.2703
error	48	106.560	2.220	
total	49	164.880		

Group B		
	pre	**post**
1	8	6
2	8	5
3	7	6
4	9	7
5	8	6
6	8	6
7	7	5
8	6	4
9	6	4
10	7	5
11	7	6
12	6	4
13	6	4
14	8	6
15	7	5
16	6	6
17	6	5
18	8	7
19	8	7
20	9	7
21	7	4
22	7	4
23	8	7
24	7	5
25	8	6
N	25	25
X	7.280	5.480
S	0.936	1.085
$\mathbf{X}_{ave}$	6.380	

source	**df**	**SS**	**MS**	**F**	
treatments	1	40.500	40.500	39.4481	
error	48	49.280	1.027		
total	49	89.780			

Table 12: Group Pre/Post Differences.

Group/ Pre/Post Differences	**Pre Rx**	**Post Rx**
Biofeedback Treatment	Mean (2.04 /sig change from pre to post (P=0.004)	Mean (1.68) / sig diff between the two post groups (P=0.0001)
Ongoing Treatment	Mean (1.8) / sig change from pre to post (P=0.009)	Mean (1.32)

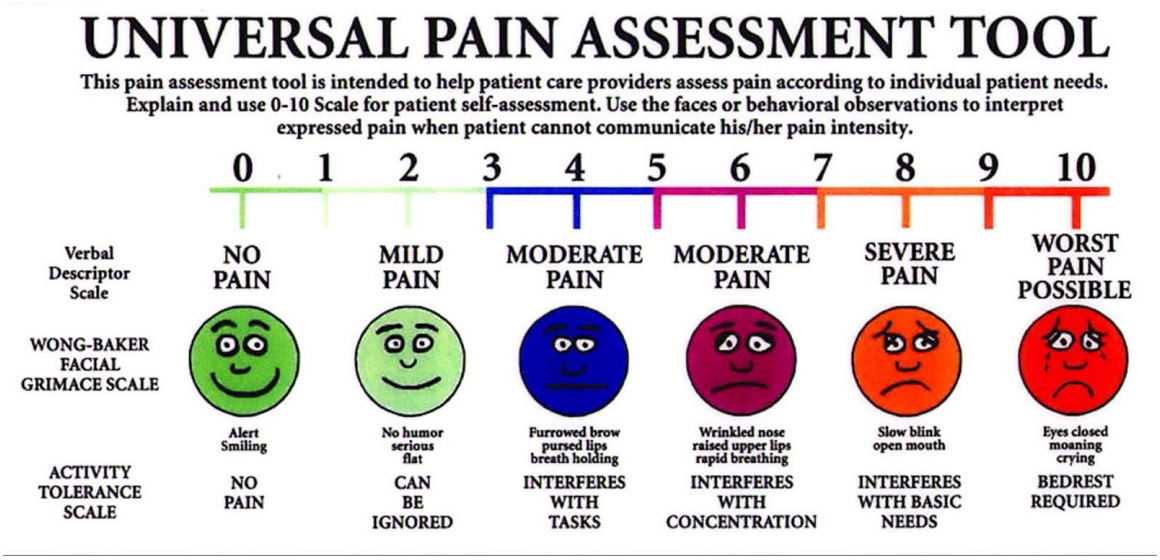


Figure 11: Universal Pain Assessment Tool.

DISCUSSION

This white paper review provides an up-to date evaluation of the efficacy of biofeedback as a behavioral treatment option for headache. The integration of 102 studies with over 140 active biofeedback treatment conditions allows us to draw generalizable conclusions regarding the efficacy of biofeedback. Depicted are data from over 3,500 headache patients with an average chronicity of migraine and TTH of over 14 years. The results apply for adult and geriatric headache patients.

CONCLUSION

Biofeedback is effective treatment modality that in our study provided additional benefit when compared to taking only analgesics medication for migraine and tension-type headache in adults. EMG and thermal biofeedback not only helped dependency on analgesics but significantly helps patient manage their pain better. Patients may have to make lifestyle changes, are often required to make self-management choices in the treatment of individual headaches, and should maintain a diary to clarify the frequency, severity, triggers, and treatment responses. This may was difficult for some patients making their overall treatment not as successful as it may have been without the complete change of lifestyle.

ACKNOWLEDGMENTS

I am truly grateful because I was able to complete the study on Electromyography and Temperature Biofeedback Among People Who Failed Standard Treatment within the time given by our Committee and Saybrook University. This study and dissertation would not have been able to be completed without the cooperation from the following involved: Dr. Mohammed Ismail, Jessica Porter and Fang Zhao. We also sincerely thank our mentor Dr. Richard Sherman for the guidance and encouragement in finishing this study and for the background knowledge and learning's of Biofeedback obtained. Last but not least, I would like to express our gratitude to our friends and respondents for the support and willingness to take part in this study as participants.

Dedication

I dedicate this to my nephew Aziz Khan whose determination gives me the resolve to keep going, his believe in serving humanity, his courage, determination, dedication, competitive drive after his diagnosis of bone cancer and his journey of survival. Never give up attitude, high spirit and his will to do well, excel in field of medicine and serve our community has always been inspiring.

Author contributions

Adila Nathu, MD co-wrote the manuscript. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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