Use of Percutaneous Electrical Nerve Stimulation (PENS) in the Short-term Management of Headache

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Objective.–To evaluate the short-term effects of percutaneous electrical nerve stimulation (PENS) in the management of three types of chronic headache.

Background.–Traditional electroanalgesic therapies have been reported to be effective in the management of acute headache symptoms. However, no controlled studies have been performed in patients with chronic headache.

Methods.–Thirty patients with either tension headache, migraine, or posttraumatic headache symptoms of at least 6 months' duration were randomized to receive PENS (needles with electricity) or "needles alone" according to a crossover study design. All treatments were administered for 30 minutes, three times a week for 2 consecutive weeks with 1 week off between the two different treatments. For the PENS treatments, an alternating electrical stimulation frequency of 15 and 30 Hz was used. Pain, activity, and sleep scores were assessed using a 10-cm visual analog scale, with 0 corresponding to the best and 10 to the worst, during the 48-hour period prior to the beginning of the two treatments, immediately before and after each treatment session, and 48 hours after completing each treatment modality.

Results.–Compared with the needles alone, PENS therapy was significantly more effective in decreasing the overall VAS pain scores for tension-type headache, migraine and posttraumatic headache (58%, 59%, and 52% versus 20%, 15%, and 20%, respectively). Similarly, PENS therapy produced greater improvement in the patients' physical activity (41% to 58% for PENS versus 11% to 21% for needles only) and quality of sleep (41% to 48% for PENS versus 12% to 20% for needles only). However, there were no differences in the pattern of the response to PENS therapy among the three headache groups.

Conclusions.–Percutaneous electrical nerve stimulation appears to be a useful complementary therapy to analgesic and antimigraine drugs for the short-term management of headache. Interestingly, the analgesic response to PENS therapy appears to be independent of the origin of the headache symptoms.

Key words: tension-type headache, migraine, posttraumatic headache, percutaneous electrical nerve stimulation, PENS, electroanalgesia

Abbreviations: TENS transcutaneous electrical nerve stimulation, PENS percutaneous electrical nerve stimulation, SF-36 short-form health status survey, MCS mental component summary, PCS physical component summary, VAS visual analog scale

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Headache is one of the most common pain problems. Although a wide variety of pharmacological therapies have been used in the management of headache, these drugs are of limited efficacy in relieving headache symptoms and many produce unwanted side effects.[1-3] Nonpharmacological therapies such as biofeedback, relaxation, hypnosis,[4-6] and physical therapy[7] have also been used, but there have been

few well-controlled clinical trials evaluating their efficacy.

Electrical stimulation techniques (so-called electroanalgesia) have become increasingly popular as alternative (or complementary) therapies in the management of acute and chronic pain syndromes. Both transcutaneous electrical nerve stimulation (TENS)[8] and electroacupuncture[9] have been reported to be effective in the management of headache symptoms. Recently, we described the use of percutaneous electrical nerve stimulation (PENS) for the treatment and prevention of migrainelike headaches associated with electroconvulsive therapy (ECT).[10] This therapy involved the insertion of needle probes, akin to those used in acupuncture, in the soft tissues at the dermatomal levels corresponding to the location of the headache symptoms and then applying low levels of electrical current.

Based on the results of our preliminary study,[10] we hypothesized that PENS therapy could also prove beneficial in the management of other more common types of headache. Therefore, we designed a study to evaluate the efficacy of PENS (versus needles alone) for the management of chronic tension headache, migraine, and posttraumatic headache.

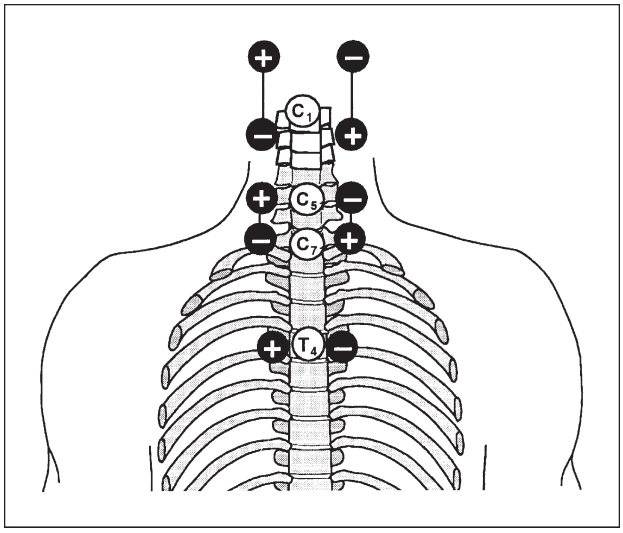
METHODS

After obtaining institutional review board approval and written, informed consent, 30 patients (18 women and 12 men), aged from 24 to 56 years, with long-standing headache symptoms were enrolled in this single-blind, crossover study. The patients received both PENS and "needles-only" treatments in a random sequence for 30 minutes, three times per week for 2 consecutive weeks, with 1 week off between the two modalities. Inclusion criteria included a history of severe headache occurring four or more times per week and managed with oral nonopioid analgesics for a period of at least 6 months. Exclusion criteria included patients younger than 18 years, a history of cluster-type headache, and an inability to understand or perform the daily assessments or the patient preference questionnaire.

Thirteen patients were diagnosed as having chronic tension-type headache according to the criteria of the International Headache Society classification system. The diagnostic criteria included a headache frequency of greater than or equal to 15 days a month and at least two of the following pain characteristics: (1) a pressing or tightening quality, (2) mild or moderate severity, (3) bilateral location and involving the posterior aspect of the head and neck, and (4) no aggravation by routine physical activity. Twelve patients had chronic headache transformed into migraine characterized by a past history of episodic migraine, positive family history of migraine, headache symptoms beginning in the late teens or early twenties, associated symptoms of photophobia and nausea, menstrual aggravation in women, identifiable trigger factors, and unilateral headache occurring every 1 to 2 days (>15 days per month), with an average duration of 4 hours if untreated. Finally, five patients had chronic posttraumatic headaches characterized by a history of head or neck trauma, with headache beginning as a new symptom less than 14 days after the trauma and lasting longer than 6 months.

Treatment Modalities.–Both the PENS and "needles-only" therapies consisted of the placement of ten 32-gauge (0.2 mm), 15-mm-long, stainless steel needle probes (ITO, Tokyo, Japan), like those used in acupuncture, into the soft tissue in the back of the neck (C2, C5, C7, and T4) and scalp in a standardized montage as illustrated in Figure 1. For active PENS treatments, the needle probes were connected to five bipolar leads, with each lead connected to one positive and one negative probe. The leads were connected to an investigational low-output electrical generator and stimulated at an alternating frequency of 15 Hz and 30 Hz (15/30 Hz).[11] The maximum amplitude of the electric stimulation produced by the generator was 25 mA with a unipolar, square pattern and a pulse width of 0.5 milliseconds. The intensity of the electrical stimulation was adjusted to produce the highest tolerable "tapping" sensation without eliciting a muscle contraction. For the needles-only treatments, the probes and leads were connected in an identical manner and the generator was turned on (lights flashing), but the amplitude of each lead was set at zero.

Assessment Procedures.–A detailed headache history was obtained, including the duration and frequency of symptoms, the total number of headaches,



The positions of the acupuncturelike probes used for the treatment of headaches with percutaneous electrical nerve stimulation (PENS) or needles-only (sham) therapies. Ten 32-gauge acupuncture-type needles were positioned in the soft tissue to a depth of 1 to 3 cm and connected to five pairs of positive (+) and negative (−) leads, which were stimulated at an alternating frequency of 15 and 30 Hz for the active PENS treatments.

the location, quality, and intensity of pain, impact on physical activity and quality of sleep, occurrence of associated symptoms (eg, nausea, vomiting, photophobia), and history of head or neck trauma. Prior to initiating any of the treatment modalities, patients were asked to complete the short-form health status survey (SF-36) questionnaire. The physical component summary (PCS) and the mental component summary (MCS) scores were used to assess the patient's response to each treatment modality. All the patients were asked to assess their baseline level of pain, physical activity, and quality of sleep 48 hours prior to starting treatment using standard 10-cm visual analog scales (VAS), where 0 corresponds to best and 10 to worst and repeat VAS assessments were performed three times a week prior to each treatment session. The pain VAS was also repeated 5 to 10 minutes after each treatment session. The average number of pills taken for headaches during the 2-week interval prior to entering the study (baseline) and daily oral analgesic requirements were recorded in the patient's diary. After receiving both treatment modalities, patients completed a preference questionnaire comparing the relative effectiveness of the active PENS and the needles-only treatments.

Data Analysis.–The NCSS software package (NCSS 6.0.1 statistical system for Windows, Kaysville, UT) was used for all statistical analyses. An a priori power analysis determined that a group size of 18 should be adequate to demonstrate a difference of 25% in pain VAS scores between the active PENS and needles-only treatments ($\alpha = 0.05$ and $\beta = 0.10$). The changes in the VAS scores were analyzed with repeated measures of analysis of variance (ANOVA) and Student *t* test, with the Bonferroni correction for multiple comparisons. Analysis of discrete (noncontinuous) data for the two treatment modalities was performed using the chi-square test. Data are presented as mean values (±SD), and percentages, with $P<.05$ considered statistically significant.

RESULTS

The demographic characteristics of the patients are summarized in Table 1. Percutaneous electrical nerve stimulation therapy was found to reduce significantly pain scores and improve activity and sleep scores compared with the needles-only treatments (Table 2). Compared with the pretreatment pain scores, the pain assessments 48 hours after completing each treatment modality demonstrated overall

Table 1.–Demographic Characteristics of the Study Patients and the Frequency and Duration of Chronic Headache Symptoms

	Tension Headache	Migraine	Posttraumatic Headache
No. of patients	13	12	5
Sex (F/M)	7/6	8/4	3/2
Mean age, y (±SD)	38 ± 11	38 ± 13	41 ± 12
Mean duration of symptoms, y (±SD)	4 ± 1	11 ± 3	4 ± 1
No. of headaches per week (±SD)			
Baseline	6 ± 2	6 ± 1	6 ± 3
Post-PENS*	3 ± 1†	3 ± 2†	4 ± 2
Post–needles only	6 ± 2	6 ± 2	6 ± 3

*PENS indicates percutaneous electrical nerve stimulation.
†Significantly different from baseline value, $P<.05$.

Table 2.–Visual Analog Scale Scores for Pain, Physical Activity, and Quality of Sleep

	Baseline	Needles Only	PENS
Tension headache			
Pain	7.1 ± 1.0*	6.3 ± 0.9	3.1 ± 0.7†‡
Activity	6.4 ± 0.9	5.8 ± 0.9	3.0 ± 0.7†‡
Sleep	5.2 ± 1.1	4.3 ± 0.8	2.9 ± 0.6†‡
Migraine headache			
Pain	7.6 ± 1.1	6.5 ± 0.9	3.0 ± 0.7†‡
Activity	5.8 ± 1.0	5.1 ± 0.9	2.8 ± 0.7†‡
Sleep	5.2 ± 0.8	4.2 ± 0.9	2.9 ± 0.6†‡
Posttraumatic headache			
Pain	7.3 ± 1.0	5.7 ± 0.9	3.1 ± 0.6†‡
Activity	6.0 ± 0.8	5.3 ± 1.0	3.0 ± 0.6†‡
Sleep	4.5 ± 1.0	4.1 ± 0.8	2.7 ± 0.6†‡

Scores calculated 48 hours before the first treatment session (baseline) and 48 hours after completing the last treatment session.
*Values are means ± SD.
†Value is significantly different from needles-only treatment ($P<.05$).
‡Value is significantly different from pretreatment baseline value ($P<.05$).

decreases of 58%, 59%, and 52% for PENS therapy and 20%, 15%, and 20% for the needles-only treatments in the tension headache, migraine, and posttraumatic headache groups, respectively. Similarly, there were significant improvements in physical activity (41% to 58% for PENS versus 11% to 21% for the needles only) and quality of sleep (41% to 48% for PENS versus 12% to 20% for the needles only) compared with baseline scores with PENS (versus needles only) treatments in all three headache groups.

A significant reduction in the frequency of headaches was noted after the PENS therapy in two of the three groups (Table 1). The average daily requirement for oral analgesic (headache) medication was reduced by over 50% during PENS therapy compared with only a 13% to 23% reduction with the needles-only treatments. Assessment of PCS and MCS scores revealed significant lower baseline scores (35.4 ± 5.2 and 33.7 ± 4.3 for PCS and MCS, respectively) than the norms for the general population ($P<.05$). Compared with needles-only treatments, the posttreatment assessments revealed significantly greater improvements after PENS treatments (43.2 ± 4.6 and 43.1 ± 3.7 versus 38.9 ± 5.1 and 39.3 ± 3.9, $P<.01$). There were no significant differences among the three headache groups after PENS treatment with respect to pain, activity, sleep, and posttreatment SF-36 scores.

COMMENTS

Similar to our preliminary findings in patients with ECT-evoked headache, this study demonstrated that PENS therapy decreases pain scores, improves physical activity and quality of sleep, and decreases analgesic drug requirements in a population of patients with chronic tension headache, migraine, and posttraumatic headache. These results are consistent with the findings of Costantini et al[12] in a study involving the use of electroacupuncture for the management of craniofacial pain. Using TENS therapy, Farina et al[13] reported an improvement of greater than 60% in headache symptoms in up to 80% of the cases. Similarly, Solomon et al[8] reported that 55% of patients with tension headaches or migraines reported improvement after TENS therapy compared with only 18% of those receiving placebo (sham) treatments.

Although the precise mechanism of PENS-induced analgesia is not known, it has been speculated that both alterations in neural modulation produced by electrical stimulation,[14] as well as an increase in endogenous morphinelike substances within the central nervous system (CNS),[15,16] contribute to PENS-induced analgesia. Previous studies have reported that electroacupuncture-induced analgesia can be blocked by an opioid receptor antagonist.[17,18] Using experimental pain models, investigators have suggested that three types of CNS opioid receptors (ie, mu, sigma, and kappa) are important mediators of analgesia produced by electroacupuncture and TENS.[15,16]

The psychological (SF-36) assessment further supports and strengthens the clinical findings by providing additional outcome measurements. The superiority of active PENS therapy over the nonelectrical ("sham") needle therapy was demonstrated with respect to improvement in the physical (eg, fewer limitations to self care, less severe body pain) and mental (eg, less psychological distress, less disability due to emotional problems) health and well-being of this pa-

tient population with long-term headaches. It is clear that additional studies will be required to evaluate the long-term effects of PENS therapy in the management of chronic headaches.

One deficiency of our study design related to the fact that the so-called sham (needles-only) treatments were necessarily administered without any form of electrical stimulus. Since the patients were not blinded, the possibility exists that they could be biased in favor of active PENS therapy. To minimize this bias, the needles-only treatments were described to the patients as "acupuncturelike" therapy. Although the needles-only treatments decreased the pain scores compared with the prestudy (baseline) values, the changes were significantly less than with PENS therapy and may represent the residual ("carry-over") effect of PENS therapy in those patients who received the active treatments first. Given the small group sizes, it was not possible to compare the responses to active PENS versus needles-only treatments in the initial phase of the study (ie, prior to the crossover). Since the needles were placed in a dermatomal pattern rather than at specific acupoints, the placebo effect of the needles-only treatments should not be considered equivalent to classic Chinese acupuncture therapy.

In conclusion, PENS therapy would appear to be a useful complementary therapy for the short-term management of patients with debilitating recurrent headache symptoms.

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