

Percutaneous Electrical Nerve Stimulation for Low Back Pain

A Randomized Crossover Study

El-sayed A. Ghoname, MD

William F. Craig, MD

Paul F. White, PhD, MD

Hesham E. Ahmed, MD

Mohamed A. Hamza, MD

Brent N. Henderson, PhD

Noor M. Gajraj, MD

Philip J. Huber, MD

Robert J. Gatchel, PhD

DESPITE THE FACT THAT LOW back pain (LBP) is one of the most common medical problems in our society,¹ current analgesic therapies remain largely unsatisfactory. Conservative treatment with anti-inflammatory drugs and exercise is effective for many patients with acute LBP.² However, when the pain symptoms persist, they can interfere with both physical activity and sleep patterns. While analgesic medications can provide temporary pain relief, these drugs may not improve physical function and are associated with well-known adverse effects. Interest in nonpharmacologic alternatives has led to evaluations of transcutaneous electrical nerve stimulation (TENS),³ acupuncture,^{4,5} electroacupuncture,⁶ spine manipulation,⁷⁻⁹ and exercise therapy⁹⁻¹² in the management of LBP. However, controversy exists regarding the relative efficacy of these nonpharmacologic therapies in the management of LBP because most of the published studies lacked appropriate control (sham) groups or failed to include relevant comparators.

Context Low back pain (LBP) contributes to considerable disability and lost wages in the United States. Commonly used opioid and nonopioid analgesic drugs produce adverse effects and are of limited long-term benefit in the management of this patient population.

Objective To compare the effectiveness of a novel nonpharmacologic pain therapy, percutaneous electrical nerve stimulation (PENS), with transcutaneous electrical nerve stimulation (TENS) and flexion-extension exercise therapies in patients with long-term LBP.

Design A randomized, single-blinded, sham-controlled, crossover study from March 1997 to December 1997.

Setting An ambulatory pain management center at a university medical center.

Patients Twenty-nine men and 31 women with LBP secondary to degenerative disk disease.

Interventions Four therapeutic modalities (sham-PENS, PENS, TENS, and exercise therapies) were each administered for a period of 30 minutes 3 times a week for 3 weeks.

Main Outcome Measures Pretreatment and posttreatment visual analog scale (VAS) scores for pain, physical activity, and quality of sleep; daily analgesic medication usage; a global patient assessment questionnaire; and Health Status Survey Short Form (SF-36).

Results PENS was significantly more effective in decreasing VAS pain scores after each treatment than sham-PENS, TENS, and exercise therapies (after-treatment mean \pm SD VAS for pain, 3.4 \pm 1.4 cm, 5.5 \pm 1.9 cm, 5.6 \pm 1.9 cm, and 6.4 \pm 1.9 cm, respectively). The average \pm SD daily oral intake of nonopioid analgesics (2.6 \pm 1.4 pills per day) was decreased to 1.3 \pm 1.0 pills per day with PENS ($P < .008$) compared with 2.5 \pm 1.1, 2.2 \pm 1.0, and 2.6 \pm 1.2 pills per day with sham-PENS, TENS, and exercise, respectively. Compared with the other 3 modalities, 91% of the patients reported that PENS was the most effective in decreasing their LBP. The PENS therapy was also significantly more effective in improving physical activity, quality of sleep, and sense of well-being ($P < .05$ for each). The SF-36 survey confirmed that PENS improved posttreatment function more than sham-PENS, TENS, and exercise.

Conclusions In this sham-controlled study, PENS was more effective than TENS or exercise therapy in providing short-term pain relief and improved physical function in patients with long-term LBP.

JAMA. 1999;281:818-823

www.jama.com

Author Affiliations: Eugene McDermott Center for Pain Management, Departments of Anesthesiology and Pain Management (Drs Ghoname, Craig, White, Ahmed, Hamza, and Gajraj), Surgery (Dr Huber), and Psychiatry (Drs Henderson and Gatchel), University of Texas Southwestern Medical Center, Dallas.

Corresponding Author and Reprints: Paul F. White, PhD, MD, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, 5161 Harry Hines Blvd, Suite CS 2.202, Dallas, TX 75235-9068 (e-mail: pwhite@mednet.swmed.edu).

Percutaneous electrical nerve stimulation (PENS) is a novel analgesic therapy¹³ that combines the advantages of both TENS and electroacupuncture by using acupuncturelike needle probes positioned in the soft tissues and/or muscles to stimulate peripheral sensory nerves at the dermatomal levels corresponding to the local pathology. In a preliminary study,¹⁴ PENS therapy was found to be preferable to TENS and relaxation therapies in the management of pain secondary to osteoarthritis. Therefore, we designed a prospective, randomized, sham-controlled, crossover trial to compare PENS with TENS and exercise therapy in patients with long-term LBP secondary to degenerative disk disease. In addition to assessing the pain response, the patients' physical activity, quality of sleep, sense of well-being, and oral analgesic requirements were evaluated.

METHODS

After obtaining institutional review board approval and written informed consent, 60 patients (29 men and 31 women; mean \pm SD age, 43 \pm 1.9 years,

and weight, 66 \pm 1.6 kg) with LBP secondary to radiologically confirmed degenerative disk disease were administered 4 different nonpharmacologic treatment modalities according to a randomized, sham-controlled, crossover study design. The 4 modalities consisted of sham-PENS, PENS, TENS, and flexion-extension exercise. Inclusion criteria included age older than 18 years, absence of any acute or long-term illnesses involving major organ systems, and a history of LBP, which had been maintained at a stable level with oral nonopioid analgesics for at least 3 months prior to enrollment in the study. Exclusion criteria included a history of drug or alcohol abuse, long-term use of opioid-containing medication, a change in the character or severity of the pain within the last 3 months, presence of acute nerve root irritation (sciatica), previous use of nontraditional analgesic therapies (eg, acupuncture), pending medicolegal litigation (or worker's compensation claim), or an inability to complete the health status assessment questionnaires. Patients

were told that we were comparing 4 different nonpharmacologic therapies for LBP.

All patients received the 4 treatment modalities according to 1 of 4 different computer-generated sequences: (1) PENS, sham, TENS, and exercise; (2) sham, TENS, exercise, and PENS; (3) TENS, exercise, PENS, and sham; or (4) exercise, PENS, sham, and TENS. Each treatment was administered for 30 minutes 3 times a week (on Monday, Wednesday, and Friday afternoons) for 3 weeks. Upon completion of each 3-week treatment block, the patient was given 1 week off before starting the next modality. The 4 modalities were administered to all patients over the 15-week study period.

Treatment Modalities

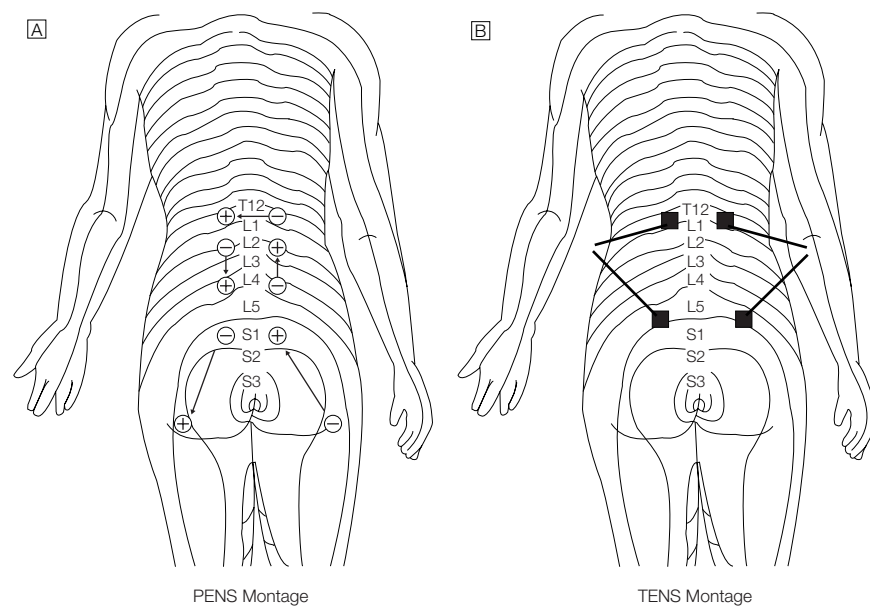
The basic PENS therapy consisted of the placement of ten 32-gauge stainless steel acupuncturelike needle probes into the soft tissue and/or muscle in the lower back region to a 2- to 4-cm depth according to the dermatomal distribution of the pain as illustrated in part A of **FIGURE 1**. The probes were connected to 5 bipolar leads (with each lead connected to 1 positive and 1 negative probe) from an investigational (not approved by the Food and Drug Administration) low-output (<25 mA) electrical generator, which produced a unipolar square-wave pattern of electrical stimulation at a frequency of 4 Hz with a pulse width of 0.5 milliseconds. The intensity of the electrical stimulation was adjusted to produce the maximum tolerable "tapping" sensation without muscle contractions.

The sham-PENS therapy consisted of the placement of 10 acupuncturelike needle probes in an identical montage (**Figure 1, A**); however, no electrical stimulation was applied to the probes.

The TENS therapy consisted of the placement of 4 medium-sized (2.5-cm) cutaneous electrode pads (SnapEase, Empi, St Paul, Minn) in a standard dermatomal pattern (**Figure 1, B**). These electrodes were also stimulated at a frequency of 4 Hz, with a pulse duration of 0.1 milliseconds.

The lower back exercise therapy consisted of spine flexion and extension with

Figure 1. Locations of Needles for PENS and TENS Montage



A, The location of the needles for the sham-percutaneous electrical nerve stimulation (PENS) and PENS treatments. With PENS therapy, each of the 5 bipolar electrical stimulating leads are connected to a pair of needles, alternating the positive and negative positions. B, The location of the 4 cutaneous electrode pads used during the transcutaneous electrical nerve stimulation (TENS) treatments.

the patient seated on a chair with full abduction of both hips.¹⁵ The patient was instructed to slowly touch the floor with both hands while remaining seated, followed by full extension of the back. This maneuver was repeated a minimum of 30 times during each 30-minute treatment session.

Assessment Procedures

Prior to initiating the first of the 4 treatments, patients were required to complete the Health Status Survey Short Form (SF-36).¹⁶ The physical component summary (PCS) and mental component summary (MCS) scores were used to assess the patient's response to each of the therapeutic modalities.¹⁷ All patients were also asked to assess their baseline level of LBP, physical activity, and quality of sleep during the 48-hour interval prior to each treatment session using standard 10-cm visual analog scales (VASs), with a score of zero equalling the best to a score of 10 equalling the worst (TABLE 1). Repeated VAS assessments of pain, activity, and sleep were performed 3 times a week prior to each treatment session by the patient. In addition, the pain VAS was repeated immediately after completion of each treatment. The SF-36 was repeated 24 hours after completing all 9 treatment sessions with each of the 4 modalities. Patients were instructed not to change the type of nonopioid analgesic medications used during the course of the study. They were also asked to maintain a di-

ary in which they recorded their daily usage of all analgesic medications (eg, pills per day) and any unusual reactions to the investigational therapies. Finally, each patient completed an overall assessment of the relative effectiveness of the 4 different modalities 72 hours after the last treatment session.

Data Analysis

The Number Cruncher Statistical System software program (version 6.0.1 for Windows, Kaysville, Utah) was used for all statistical analyses. An a priori power analysis (α , .05; β , .10; power, 90%; and SD, 2.0) determined that a group size of 60 should be adequate to demonstrate a difference of 25% between the VAS scores for the 4 modalities. The changes in the VAS scores over time were analyzed with repeated measures analysis of variance and *t* test, with a Bonferroni comparison test (vs control values and pairwise data), applied for multiple comparisons. Analysis of discrete (noncontinuous) data for the 4 treatment modalities was performed using the χ^2 test. The pretreatment and posttreatment changes and the differences between the modalities in the SF-36 scores were analyzed by paired *t* tests.

RESULTS

The pretreatment SF-36 evaluation suggested that this LBP population reported significantly lower health-related quality-of-life scores compared

with the general population. The prestudy scores for this LBP population were 28.4 ± 8.4 and 40.2 ± 5.0 for the PCS and MCS, respectively, compared with general population norms of 50 for these 2 summary scores.¹⁸ The post-PENS treatment SF-36 scores were significantly improved over the prestudy scores for both the PCS (34.2 ± 7.4 ; $P = .003$) and MCS (42.8 ± 5.2 ; $P = .007$) components. Both TENS and sham-PENS produced small but statistically significant improvements in the PCS (29.6 ± 8.4 and 29.4 ± 8.6 , respectively) and MCS (41.1 ± 5.5 and 41.0 ± 5.4 , respectively) scores ($P < .02$). When the changes in the SF-36 scores with the PENS therapy were compared with the other 3 modalities, PENS was found to produce significantly greater improvement in posttherapy function (eg, PENS vs sham-PENS differences were $+4.97 \pm 2.99$ and $+1.84 \pm 3.56$ for PCS and MCS, respectively; PENS vs TENS differences were $+4.66 \pm 2.85$ and $+1.7 \pm 4.19$ for PCS and MCS, respectively; and PENS vs exercise differences were $+5.82 \pm 2.93$ and $+1.84 \pm 3.56$ for PCS and MCS, respectively).

The VAS scores for pain, physical activity, and quality of sleep prior to the first treatment session (baseline) and 24 hours after the last treatment session with each of the 4 modalities are summarized in Table 1. Compared with the baseline values, posttreatment VAS scores for pain, physical activity, and quality of sleep were improved by $46\% \pm 18\%$, $42\% \pm 19\%$, and $44\% \pm 20\%$, respectively, with PENS therapy ($P < .007$). TENS also produced significant decreases in the degree of pain and improvement in physical activity after 6 of 9 treatment sessions ($P < .03$) with an average overall improvement in the degree of pain and physical activity (from the baseline values) of $11\% \pm 14\%$ and $15\% \pm 16\%$, respectively. No significant pain-relieving effects were demonstrated with either the sham-PENS or exercise therapies. Comparing the effects of the 4 treatment modalities on VAS scores for pain, physical activity, and sleep quality revealed that PENS produced significantly greater improve-

Table 1. Comparison of the Average Visual Analog Scale Scores for Low Back Pain, Level of Activity, and Quality of Sleep Prior to Receiving the First Treatment and at 24 Hours After the Ninth Treatment With Each of the 4 Modalities*

Treatment	Sham-PENS	PENS	TENS	Exercise
Degree of pain				
Before	5.7 (1.8)	6.3 (1.5)	6.2 (1.7)	6.5 (1.4)
After	5.5 (1.9)	3.4 (1.4)†	5.6 (1.9)‡	6.4 (1.9)
Level of activity				
Before	5.1 (2.1)	5.5 (2.0)	5.5 (2.1)	5.7 (1.8)
After	4.9 (2.1)	3.2 (1.7)†	4.7 (1.9)‡	5.7 (1.8)
Quality of sleep				
Before	5.0 (2.3)	5.5 (1.9)	5.6 (2.1)	5.8 (1.9)
After	5.0 (2.1)	3.1 (1.6)†	5.3 (2.2)	5.5 (1.9)

*Values are mean (SD) centimeters. PENS indicates percutaneous electrical nerve stimulation; TENS, transcutaneous electrical nerve stimulation.

†Significantly different from value prior to receiving the first treatment (before), $P < .03$, and from sham-PENS, TENS, and exercise therapies, $P < .02$.

‡Significantly different from value prior to receiving the first treatment (before), $P < .04$.

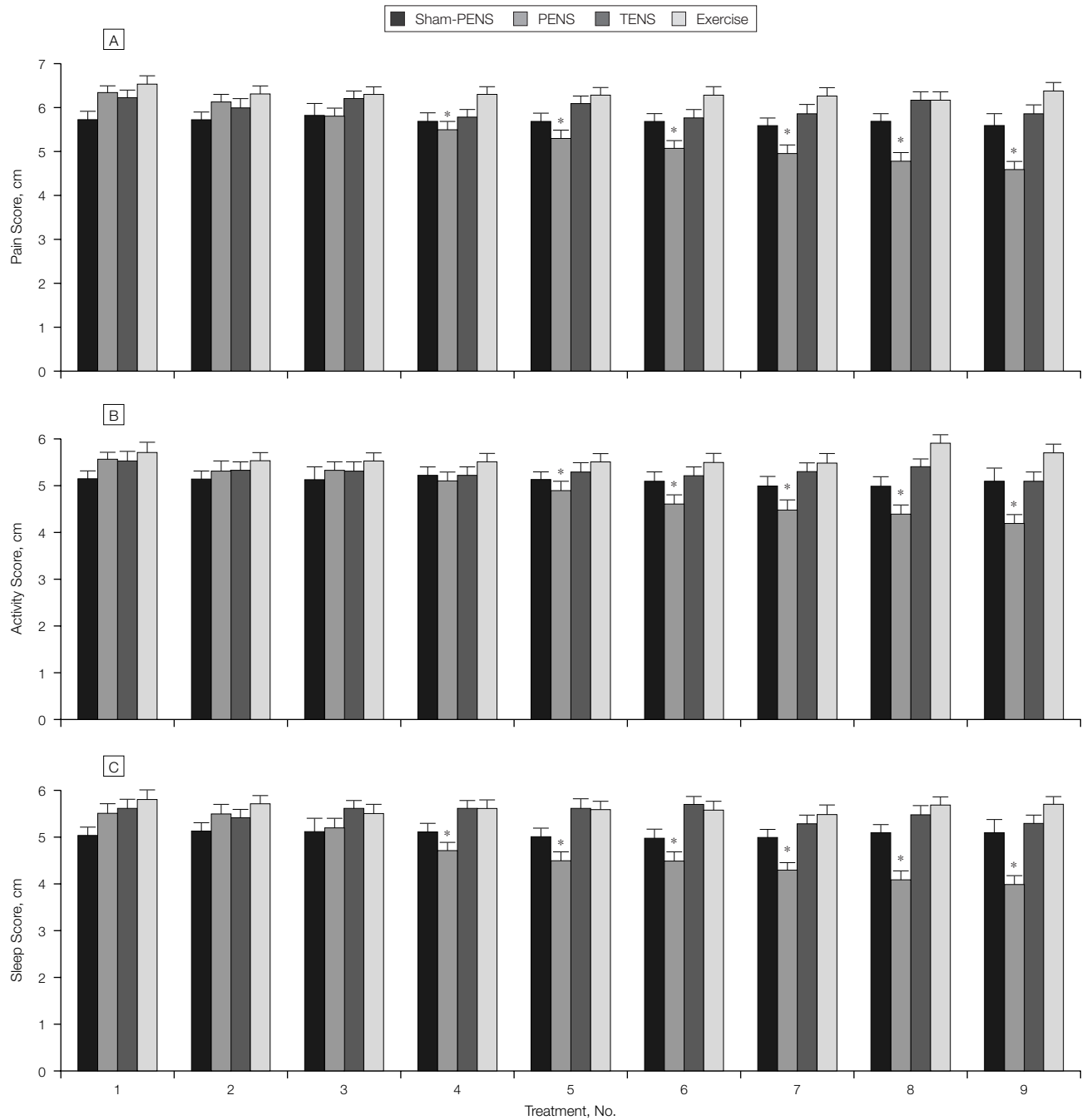
ments than sham-PENS, TENS, or exercise therapies ($P < .02$).

PENS produced an acute analgesic effect immediately after each treatment session (with an average $82\% \pm 23\%$ de-

crease in the pain VAS scores vs $26\% \pm 19\%$, $9\% \pm 15\%$, and $4\% \pm 11\%$ decreases with TENS, sham-PENS, and exercise, respectively). After 3 to 4 treatments with PENS, patients began report-

ing significant improvement in their pre-treatment VAS scores for pain, activity, and sleep compared with their baseline values (FIGURE 2). PENS also significantly decreased the consumption of oral

Figure 2. Visual Analog Scale Scores



Visual analog scale scores for low back pain (A), physical activity (B), and quality of sleep (C) before each of the 9 treatment sessions with the 4 study modalities. Values are mean (SEM). Asterisk indicates value is significantly different from baseline value ($P < .03$). PENS indicates percutaneous electrical nerve stimulation; TENS, transcutaneous electrical nerve stimulation.

nonopioid analgesic medication ($P < .009$) (FIGURE 3). Compared with the prestudy values, PENS therapy was associated with a 50% reduction in the daily oral analgesic requirement. In contrast, TENS therapy decreased the need for analgesic medication on only 6 days during the 3-week study period ($P < .04$). Neither sham-PENS nor exercise therapies altered the patients' usage of their oral analgesic medication.

Finally, the overall evaluation of the 4 treatment modalities indicated that PENS was the preferred therapy in 91% of the study patients (TABLE 2). In addition, PENS was reportedly more effective than TENS and exercise therapies in improving the patients' physical activity and sense of well-being. More than 80% of the patients indicated that they

would be willing to pay extra money (out-of-pocket) to receive PENS therapy in the future.

COMMENT

This crossover, sham-controlled study demonstrated that PENS was more effective than TENS and exercise therapies in providing short-term relief of pain and in improving function in patients with stable LBP of at least 3 months' duration. PENS was also significantly more effective than TENS and exercise therapies in reducing the need for oral analgesic medications. These findings are consistent with earlier studies by Deyo et al¹⁹ and Marchand et al,²⁰ suggesting that TENS therapy is only marginally more effective than a placebo treatment (eg, sham-PENS) in this patient popu-

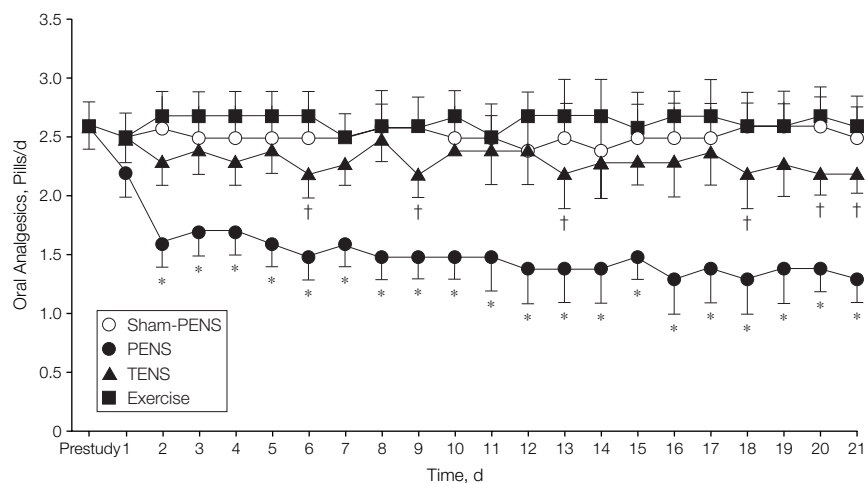
lation. Of interest, Moore and Shurman²¹ reported that combined neuromuscular electrical stimulation with TENS was significantly more effective than TENS alone in the management of long-term back pain.

PENS therapy was also highly effective in producing acute analgesia in this LBP population. More importantly, the patients began to report more sustained beneficial effects on their level of pain and physical activity, as well as their quality of sleep, after 3 to 4 PENS treatments. Due to the apparent cumulative effects of PENS over the course of the 3-week treatment period, these data would suggest that the use of this treatment modality over a longer period of time has the potential to produce prolonged beneficial effects in patients with long-term LBP. However, a more prolonged period of PENS therapy with careful follow-up at 3-, 6-, and 12-month intervals would be required to assess the long-term effects of this novel therapeutic modality in improving patient outcome.

Enhanced physical activity may be the most important outcome variable in the treatment of LBP.^{19,22,23} To achieve the maximal benefit from nonpharmacologic (so-called complementary) analgesic therapies such as PENS, it is recommended that PENS be used as part of a multimodality rehabilitation program, which also includes an ongoing exercise program. Although the simple spine flexion-extension exercise used in this investigation failed to produce a significant improvement in patient well-being when administered alone, this may be a reflection of the lack of effectiveness of this particular exercise maneuver or an inadequate period of exercising. In contrast to our findings, other investigators have found a more extensive exercise program to be as effective as TENS in reducing pain scores and disability in workers with acute LBP.²⁴ Future studies need to evaluate the effectiveness of PENS therapy in combination with a comprehensive exercise program.

The results of the SF-36 psychological assessments further support and strengthen the clinical findings by providing additional outcome measures, which demonstrates the superiority of PENS over the other

Figure 3. Effect of Sham-PENS, TENS, and Exercise Therapies on the Daily Oral Analgesic Requirements



Change in the daily oral intake of nonopioid analgesic medications during the 3-week treatment period with each of the 4 study modalities. Values are mean (SEM). Asterisk indicates value is significantly different from prestudy value ($P < .008$) and from sham-percutaneous electrical nerve stimulation (PENS), transcutaneous electrical nerve stimulation (TENS), and exercise therapy values ($P < .03$). Dagger indicates value is significantly different from prestudy value ($P < .04$).

Table 2. Overall Patient Evaluation of the Relative Effectiveness of Sham-PENS, PENS, TENS, and Exercise Therapies After Receiving all 4 Treatment Modalities*

Result	Sham-PENS	PENS	TENS	Exercise
Most desirable modality	1 (2)	55 (91)†	4 (7)	0 (0)
Improved physical activity	2 (4)	31 (51)†	5 (8)	0 (0)
Improved sense of well-being	7 (12)	46 (76)†	10 (16)	6 (10)
Preferred pain therapy	1 (2)	55 (91)†	4 (7)	0 (0)
Willing to pay extra for therapy	4 (6)	49 (81)†	5 (9)	2 (4)

*PENS indicates percutaneous electrical nerve stimulation; TENS, transcutaneous electrical nerve stimulation. Values are expressed as number (percentage) of patients.
 †Significantly different from sham-PENS, TENS, and exercise therapies, $P < .02$.

nonpharmacologic treatments used in this study. These data suggest that PENS therapy was the most beneficial modality in improving the physical (eg, fewer limitations in self-care, less severe body pain) and mental (eg, less psychological distress, less disability due to emotional problems) health and well-being of these patients with long-term LBP.

The nature of the electrical (tapping) sensations precluded our ability to perform the treatments in a double-blind fashion. In an attempt to minimize investigator bias, all patient assessments were performed by individuals not involved in administering the therapies. To avoid prejudicing patients in favor of PENS therapy, the sham treatment was described to the patients as an acupuncturelike therapy. Since the needles for the sham-PENS treatments were placed in a dermatomal montage rather than at specific acupoints, it would be inappropriate to conclude that classic Chinese acupuncture is of no benefit in this patient population.

Another potential criticism of the study design relates to the selection of a low-stimulus frequency (4 Hz) for 30-minute intervals for both the PENS and TENS treatments. However, Walsh et al²⁵ reported that the hypoalgesic effect of TENS

was more effective at 4 Hz than 110 Hz. Other investigators have found that more prolonged periods of stimulation (>40 minutes) may be associated with the development of tolerance to the analgesic effect of the electrical stimulus.²⁶

Future studies are clearly needed to determine the relative effectiveness of different frequencies and durations of electrical stimulation with PENS therapy. Preliminary experience with PENS in other patient populations suggests that an improved analgesic response may be achieved by using higher (50-100 Hz) or mixed (15 Hz and 30 Hz) stimulating frequencies at subsequent treatment sessions.^{13,14} Similarly, this dermatomal montage was selected as a starting point for PENS therapy because it was found to be highly effective in this patient population during our pilot studies. However, depending on the associated manifestations of the pain (eg, radiation down the leg), other needle locations may prove to be more effective for subsequent PENS treatments.

Since long-term LBP is extremely costly to society and can have debilitating effects on both patients and their families, this patient population is increasingly turning to unconventional al-

ternative medical practices (including various forms of nonpharmacologic analgesic therapies).²⁷ In determining the cost benefit of any new analgesic therapy, it is important to carefully consider both the pertinent costs (eg, equipment, disposables, personnel requirements) and the consequences or outcome of the treatment (eg, patient satisfaction, quality of life, resumption of normal activities) in monetary terms.²⁸ Future studies should be designed to examine the cost benefit of using PENS therapy as part of a multimodal approach, which would also include anti-inflammatory analgesic drugs and a low back exercise program.

In conclusion, this sham-controlled study demonstrated that PENS is more effective in improving short-term outcomes than TENS and exercise therapies in patients with long-term LBP. The use of PENS therapy significantly decreased the need for oral nonopioid analgesic medications in this patient population.

Funding/Support: The Ambulatory Anesthesia Research Foundation of Dallas, Dallas, Tex (Dr White, President), and the Egyptian Cultural and Educational Bureau, Washington, DC, provided fellowship training of Drs Ghoname, Ahmed, and Hamza at the University of Texas Southwestern Medical Center, Dallas. The pilot study was funded by the Forest Park Institute for Pain Management, Fort Worth, Tex.

REFERENCES

- Hadler NM. Workers with disabling back pain. *N Engl J Med.* 1997;337:341-343.
- Frymoyer JW. Back pain and sciatica. *N Engl J Med.* 1988;318:291-300.
- Melzack R, Vetere P, Finch L. Transcutaneous electrical nerve stimulation for low back pain. *Phys Ther.* 1983;63:489-493.
- Laitinen J. Acupuncture and transcutaneous electric stimulation in the treatment of chronic sacrolumbalgia and ischialgia. *Am J Chin Med.* 1976;4:169-175.
- Liao SJ. Acupuncture for low back pain in huang di nei jing su wen (Yellow Emperor's Classic of Internal Medicine Book of Common Questions). *Acupunct Electrother Res.* 1992;17:249-258.
- Lehmann TR, Russell DW, Spratt KF, et al. Efficacy of electroacupuncture and TENS in the rehabilitation of chronic back pain patients. *Pain.* 1986;26:277-290.
- Hadler NM, Curtis P, Gillings DB, Stinnett S. A benefit of spinal manipulation as adjunctive therapy for acute low-back pain. *Spine.* 1987;12:703-706.
- Shekelle PG, Adams AH, Chassin MR, Hurwitz EL. Spinal manipulation for low back pain. *Ann Intern Med.* 1992;117:590-598.
- Twomey L, Taylor J. Exercise and spinal manipulation in the treatment of low back pain. *Spine.* 1995;20:615-619.
- Faas A. Exercises: which ones are worth trying, for which patients, and when? *Spine.* 1996;21:2874-2878.
- Manniche C. Assessment and exercise in low back pain with special reference to the management of pain and disability following first time disc surgery [review]. *Dan Med Bull.* 1995;42:301-313.
- Manniche C, Lundberg E, Christensen I, Hesselsoe G. Intensive dynamic back exercises for chronic low back pain: a clinical trial. *Pain.* 1991;47:53-63.
- Ahmed HE, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation: an alternative to antiviral drugs for acute herpes zoster. *Anesth Analg.* 1998;87:911-914.
- Sun R, Kim DW, White PF, Craig WF, Taylor S, Handel D. A randomized comparison of non-pharmacologic therapies for the relief of chronic back pain [abstract]. *Anesth Analg.* 1997;84:S339.
- Thompson A. *Thompson's Maneuver: A New Way for You to Cure Your Aching Back.* Stearn J, ed. New York, NY: Doubleday & Co Inc; 1973.
- Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36), I: conceptual framework and item selection. *Med Care.* 1992;30:473-483.
- Ware JE, Kosinski M, Bayliss MS, McHorney CA, Rogers WH, Raczek A. Comparison of methods for the scoring and statistical analysis of SF-36 health profile and summary measures: summary of results from the Medical Outcomes Study. *Med Care.* 1995;33(suppl):AS264-AS279.
- Ware JE, Kosinski M, Keller SD. *The SF-36 Physical and Mental Health Summary Scales: A User's Manual.* Boston, Mass: Health Assessment Lab, New England Medical Center; 1994.
- Deyo RA, Welsh NE, Martin DC, Schoenfeld LS, Ramamurthy S. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med.* 1990;328:246-252.
- Marchand S, Charest J, Li J, Chenard J-R, Lavigne B, Laurencelle L. Is TENS purely a placebo effect: a controlled study on chronic low back pain. *Pain.* 1993;54:99-106.
- Moore SR, Shurman J. Combined neuromuscular electrical stimulation for treatment of chronic back pain: a double-blind, repeated measures comparison. *Arch Phys Med Rehabil.* 1997;78:55-60.
- Kraus H, Nagler W, Melley A. Evaluation of an exercise program for back pain. *Am Fam Physician.* 1983;28:153-158.
- Waddell G. A new clinical model for the treatment of low-back pain. *Spine.* 1987;12:632-644.
- Herman E, Williams R, Stratford P, Fargas-Babjak A, Trott MA. A randomized controlled trial of transcutaneous electrical nerve stimulation to determine its benefits in a rehabilitation program for acute occupational low back pain. *Spine.* 1994;19:561-568.
- Walsh DM, Liggett C, Baxter D, Allen JM. A double-blind investigation of the hypoalgesic effects of transcutaneous electrical nerve stimulation upon experimentally induced ischaemic pain. *Pain.* 1998;61:39-45.
- Romita VV, Suk A, Henry JL. Parametric studies on electroacupuncture-like stimulation in a rat model: effects of intensity, frequency, and duration of stimulation on evoked antinociception. *Brain Res Bull.* 1997;42:289-296.
- Eisenberg DM, Kessler RC, Foster C, Norlock FE, Norlock DR, Delbanco TL. Unconventional medicine in the United States: prevalence, costs, and patterns of use. *N Engl J Med.* 1993;328:246-252.
- Watcha MF, White PF. Economics in anesthesia. *Anesthesiology.* 1997;86:1170-1196.

In contrast, no signs and symptoms of the hemispheric disconnection syndrome are reported, either because they were absent or because no neuropsychological examinations were done. Thus, the MRI findings reported by Hackett et al do not explain the neurological signs and symptoms found in their patients with HACE, and it is not clear whether the MRI findings were symptomatic. Consequently, the intense T₂ signals in the corpus callosum and the splenium reported by Hackett et al do not prove that HACE is related to cerebral edema.

Ralf W. Baumgartner, MD
University Hospital
Zurich, Switzerland

1. Hackett PH, Yarnell PR, Hill R, Reynard K, Heit J, McCormick J. High-altitude cerebral edema evaluated with magnetic resonance imaging: clinical correlation and pathophysiology. *JAMA*. 1998;280:1920-1925.
2. Geschwind N, Kaplan E. A human cerebral disconnection syndrome. *Neurology*. 1962;12:675-685.

In Reply: We entirely agree with Dr Basnyat that HACE is a clinical diagnosis generally not requiring MRI, which is expensive and often unavailable. Magnetic resonance imaging may be helpful, however, when the diagnosis is unclear. The purpose of our study was to use MRI to understand the pathophysiology, not to advocate MRI as essential for diagnosis.

The findings published by Dr Surks 33 years ago have been confirmed in many subsequent studies. The mechanism of this shift of fluid from the vascular space on ascent to high altitude and the exact division of the fluid between the intracellular and interstitial spaces are not as clear. Nor is it known whether the brain participates in this fluid translocation to the same extent as other tissues. The studies done by Surks et al were in persons without altitude illness. In those who are ill with acute mountain sickness, a net fluid retention or antidiuresis also takes place, which would aggravate any fluid shift into the brain that might be taking place and contribute to cerebral edema. However, the fluid shift from the vascular space does not, in itself, provide a clue as to whether and to what extent the brain is involved, and as to whether the brain edema is cytotoxic (intracellular) or vasogenic (blood-brain barrier leak of proteins and water).

We disagree with Dr Baumgartner that the absence of a hemispheric disconnection syndrome is evidence against a vasogenic edema. The 2 are unrelated. We are well aware of the disconnection syndrome and since discovering the finding of splenial edema, we have been looking for it. However, our patients are in no condition for such testing while acutely ill; many are unconscious. Recently, our colleague Dr Ron Kramer of Denver, Colo, examined a patient with HACE (and high-altitude pulmonary edema) 10 days after the acute illness, when the brain MRI showed splenial edema, and found no evidence of a disconnection syndrome. Sophisticated testing earlier in the course of the illness is necessary before concluding the disconnection syndrome is not present to some degree. It should not be surprising, however, that involvement of a small portion of the corpus callosum with reversible edema (as opposed to stroke, for example) may not be reflected in a disconnection syndrome. We think that the symptoms of HACE are

due to intracranial pressure increase, for which there is much clinical and autopsy evidence. The cause of death is brain herniation. We did not mean to imply that HACE is due to corpus callosum dysfunction. The reversible high T₂ signal in the white matter is indicative of vasogenic edema in HACE.

Peter Hackett, MD
St Mary's Hospital
Grand Junction, Colo
Phil Yarnell, MD
University of Colorado School of Medicine
Denver

Informing Patients About Urinary Incontinence

To the Editor: In the December 16, 1998, issue, *JAMA* published an excellent Patient Page on urinary incontinence.¹ Almost simultaneously, the American Urological Association (AUA) was launching a comprehensive long-term public awareness campaign on female incontinence.

One of the biggest problems about female incontinence is that so many women fail to seek treatment—either because of embarrassment or because they mistakenly believe that effective treatment modalities do not exist. To address this situation, the AUA developed and initiated its public awareness effort.

As part of the campaign, the AUA has developed 2 information sources for the general public: a toll-free telephone number (1-800-DRYLIFE) and an incontinence Web site (www.drylife.org). We invite physicians to refer female patients with incontinence problems to these resources.

Roy J. Correa, Jr, MD
American Urological Association, Inc
Baltimore, Md

1. Urinary incontinence (Patient Page). *JAMA*. 1998;280:2054.

In Reply: We are pleased to learn about the new public awareness campaign on urinary incontinence sponsored by the AUA and the American Foundation for Urologic Disease. We hope that these new information sources, along with the *JAMA* Patient Page on this topic, will help increase public awareness of potential treatments for this common problem.

Richard M. Glass, MD
Mi Young Hwang, MSJ
JAMA

CORRECTION

Incomplete Financial Disclosure and Incorrect Numbers: In the Preliminary Communication entitled "Percutaneous Electrical Nerve Stimulation for Low Back Pain: A Randomized Crossover Study," published in the March 3, 1999, issue of *THE JOURNAL* (1999;281:818-823), a potential financial conflict was not revealed. One month after submission of their manuscript to *JAMA*, Drs White and Craig incorporated a company named PENS Inc to produce a Food and Drug Administration–approvable stimulating unit to provide percutaneous electrical nerve stimulation (PENS) therapy. Drs White and Craig completed their financial disclosure statements at the time of submission but these disclosure statements were not updated after the company was incorporated.

Also, on page 819, under the heading "Methods," "mean ± SD age, 43 ± 1.9 years, and weight, 66 ± 1.6 kg" should have read 43 ± 1.9 years and 66 ± 16 kg.