



## Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica

El-sayed A. Ghoname, Paul F. White\*, Hesham E. Ahmed, Mohamed A. Hamza, William F. Craig, Carl E. Noe

McDermott Center for Pain Management, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center at Dallas, Dallas, TX USA

Received 9 November 1998; received in revised form 25 March 1999; accepted 26 April 1999

### Abstract

Sciatica is a common pain problem and current pharmacologic therapies have proven inadequate for many patients. The objective of this sham-controlled investigation was to compare a novel non-pharmacologic technique, percutaneous electrical nerve stimulation (PENS), to transcutaneous electrical nerve stimulation (TENS) in the management of the radicular pain associated with sciatica. Sixty-four consenting patients with sciatica due to lumbar disc herniation were treated with PENS, TENS and sham-PENS according to a randomized, single-blinded, cross-over study. All patients had been maintained on a stable oral non-opioid analgesic regimen for at least 6 weeks prior to entering the study. Each treatment modality was administered for a period of 30 min three times per week for 3 weeks, with 1 week 'off' between each modality. Both PENS and TENS treatments were administered using a stimulation frequency of 4 Hz. The pre-treatment assessment included the health status survey short form (SF-36), as well as visual analog scales (VAS) for radicular pain, physical activity and quality of sleep. The pain VAS was also repeated after each treatment session. At the end of each 3-week treatment block, the SF-36 was repeated. After receiving all three treatment modalities, a global assessment questionnaire was completed. Both PENS (42%) and TENS (23%) were significantly more effective than the sham (8%) treatments in decreasing VAS pain scores. The daily oral analgesic requirements were also significantly reduced compared to the pre-treatment values with PENS ( $P < 0.01$ ) and TENS ( $P < 0.05$ ). However, PENS was significantly more effective than TENS (and sham-PENS) in improving physical activity and quality of sleep. The SF-36 evaluation confirmed the superiority of PENS (versus TENS and sham-PENS) with respect to post-treatment functionality. In the overall assessment, 73% of the patients reported that PENS was the most desirable modality (versus 21% for TENS and 6% for sham-PENS). Finally, 71% of the patients stated that they would be willing to pay extra to receive PENS therapy compared to 22% and 3% for TENS and sham-PENS, respectively. In this sham-controlled study, we concluded that PENS was more effective than TENS when administered at a stimulation frequency of 4 Hz in providing short-term pain relief and improved functionality in patients with sciatica. © 1999 International Association for the Study of Pain. Published by Elsevier Science B.V.

**Keywords:** Percutaneous electrical nerve stimulation; Transcutaneous electrical nerve stimulation; Sciatica; Radicular leg pain

### 1. Introduction

Sciatica due to a herniated nucleus pulposus is a common cause of pain and constitute an important socioeconomic problem in our society (Frymoyer, 1988), with a lifetime prevalence of 40% (Frymoyer et al., 1983; Stevenson and Anderson, 1983). Although epidural steroid injections provide short-term improvement in the leg pain associated with a herniated disc, this treatment offers no significant functional benefit and does not reduce the need for surgery (Carelette et al., 1997). While analgesic medications can

provide temporary pain relief, both opioid and non-opioid analgesics are associated with well-known side effects.

Increasingly, patients are turning to unconventional 'alternative' medical practices [including non-pharmacologic analgesic therapies like transcutaneous electrical nerve stimulation (TENS) and electroacupuncture] (Eisenberg et al., 1993). Percutaneous electrical nerve stimulation (PENS) is a novel analgesic therapy which combines the advantages of both TENS and electroacupuncture by utilizing acupuncture-like needle probes positioned in the soft tissues and/or muscles to stimulate peripheral sensory nerves at the dermatomal levels corresponding to the local pathology. A recent study demonstrated that electrical stimulation at the dermatomal level was equivalent to acupuncture stimulation with

\* Corresponding author. Tel.: +1-214-648-5488; fax: +1-214-648-2920.

E-mail address: pwhite@mednet.swmed.edu (P.F. White)

respect to its analgesic effects (Chen et al., 1998). In a recently published sham-controlled study involving PENS therapy (Ghoname et al., 1999a), it was found to be preferable to TENS and exercise therapy in the management of chronic low back pain.

Therefore, we designed a randomized, sham-controlled, cross-over study to compare PENS to TENS therapy when used in the management of radicular pain associated with sciatica. In addition to assessing the pain response, the patients' physical activity, quality of sleep, sense of 'well-being,' and daily oral analgesic requirements were evaluated.

## 2. Methods

After obtaining institutional review board approval and written informed consent, 64 patients (30 males and 34 females, mean age  $43 \pm 19$  years) with typical radicular pain lasting for 6–28 months (mean duration of  $21 \pm 9$  months) due to radiologically-confirmed lumbar disc herniation were administered three different non-pharmacologic analgesic modalities (namely, sham-PENS, PENS and TENS) according to a randomized, single (investigator)-blinded, cross-over protocol. The mean ( $\pm$ SD) pre-study pain score was  $7.6 \pm 2.1$  cm on a 10 cm visual analog scale (VAS), with 0 = none to 10 = worst pain imaginable. Inclusion criteria included age greater than 18 years, absence of any acute or chronic illnesses involving major organ systems, and a history of sciatica (defined as the presence of constant or intermittent pain in one leg radiating below the knee, a positive straight-leg raising test, evidence of nerve-root compression at the L5-S1 level confirmed by radiologic testing) which had been maintained at a stable level with non-opioid anti-inflammatory analgesics for a period of at least 6 weeks. Exclusion criteria included a history of drug or alcohol abuse, a change in the character or severity of the pain within the last 6 weeks, and an inability to complete the health status survey short form (SF-36), the daily assessment tools, or the global questionnaire.

All patients received the three modalities according to one of three different sequences: (1) Sham – PENS – TENS; (2) PENS – TENS – Sham; or (3) TENS – Sham – PENS. Each treatment was administered for 30 min three times per week (on Monday, Wednesday, and Friday afternoons) for 3 weeks (Ghoname, 1999b). Upon completion of each three-week treatment block, patients were given 1 week 'off' before starting the next modality. All three modalities were administered over an 11 week period.

### 2.1. Treatment modalities

The basic PENS therapy consisted of the placement of 10, 32 gauge stainless steel acupuncture-like needle probes into the soft tissue and/or muscle in the symptomatic leg to a depth of 2–4 cm as illustrated in Fig. 1A. The 10 needle

probes were connected to 5 bipolar leads (with each lead connected to one positive and one negative probe) from a low-output electrical generator and stimulated at 4 Hz (Ghoname et al., 1999c). The intensity of the electrical stimulation was adjusted to produce the highest tolerable electrical 'tapping' sensation without muscle contractions. The maximum amplitude of the electrical stimulation produced by the generator was 250  $\mu$ Amps with a unipolar square-wave pattern and a pulse width of 0.1 s. The electrical current was DC and the duty cycle was continuous.

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

The standard TENS therapy consisted of the placement of four medium-sized (2.5 cm) cutaneous electrode pads (SnapEase<sup>®</sup>, Empi, St. Paul, Minnesota) in a standardized dermatomal pattern (Fig. 1B). These electrodes were also stimulated at a frequency of 4 Hz, with a pulse duration of 0.1 s (Walsh et al., 1995). The intensity of the electrical stimulation was adjusted to the maximum tolerated amplitude without producing muscle contractions.

### 2.2. Assessment procedures

Prior to initiating the non-pharmacologic treatments, patients were required to complete the SF-36 (Ware and Sherbourne, 1992). The physical component summary (PCS) and mental component summary (MCS) scores were utilized to assess the patient's response to each of the therapeutic modalities (Ware et al., 1995). All patients

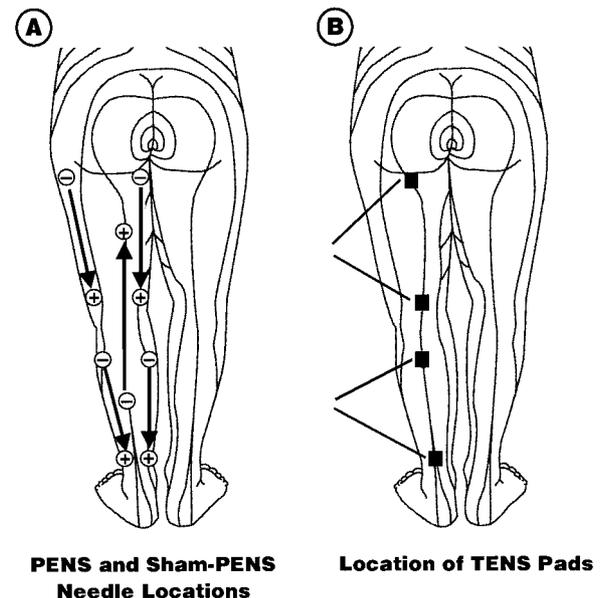


Fig. 1. (A) The peripheral leg montage, with position of needles for sham-PENS and PENS treatments. With PENS therapy, each of the 5 bipolar electrical stimulating leads are connected to a pair of probes, alternating the positive (+) and negative (-) positions as shown in the illustration. (B) The location of the four cutaneous electrode pads used for the TENS treatments.

were also asked to assess their baseline level of leg pain, physical activity and quality of sleep during the 24 h interval prior to each treatment session using standard 10 cm VAS, with 0 = best to 10 = worst. Repeat VAS assessments for the degree of pain, physical activity and quality of sleep were performed three times per week prior to each treatment session. In addition, the pain VAS was repeated immediately after completion of each treatment session. The daily intake of oral non-opioid analgesic medication (i.e. number of pills per day) was recorded in the patient’s diary. The SF-36 was repeated 24 h after completing all nine-treatment sessions with each modality. Finally, each patient completed a global assessment questionnaire to determine the relative effectiveness of the three different modalities 72 h after the last treatment session.

2.3. Data analysis

The NCSS software package (version 6.0.1 statistical system for Windows, NCSS, Kaysville, UT) was utilized for all statistical analyses. An a priori power analysis with  $\alpha = 0.05$ ,  $\beta = 0.10$  (power = 90%), and SD of 2.0, determined that a group size of 60 should be adequate to demonstrate a difference of 25% between the VAS scores for the three treatment modalities. The changes in the VAS scores over time were analyzed with repeated measures analysis of

variance (ANOVA) and Students’ *t*-test, with a Bonferroni correction applied for multiple comparisons. A multivariate ANOVA was used to analyze between (e.g. PENS versus sham-PENS) and within subjects factors (e.g. time). Analysis of discrete (non-continuous) data for the four treatment modalities was performed using the Chi-square test. Pre-versus post-treatment changes and differences between modalities in the SF-36 scores were analyzed using paired *t*-tests. Data are presented as mean values ( $\pm$ SD (Tables),  $\pm$  SEM (Figs. 1–4)), and percentages, with *P*-values < 0.05 considered statistically significant.

3. Results

The pre-study SF-36 evaluation suggested that this study population reported significantly lower health-related ‘quality of life’ scores on the physical component summary (PCS) and mental component summary (MCS) compared to general population norms of 50 for both of the summary scores. The pre-study (baseline) scores for this patient population were  $26.7 \pm 7.6$  and  $39.5 \pm 5.2$  for the PCS and MCS, respectively. Compared to the baseline scores, PENS therapy resulted in the most significant improvements in both the PCS ( $35.3 \pm 8.2$ ) and MCS ( $44.2 \pm 6.4$ ) components ( $P < 0.001$ ). Both TENS ( $29.6 \pm 7.4$  and  $42.1 \pm 6.0$ )

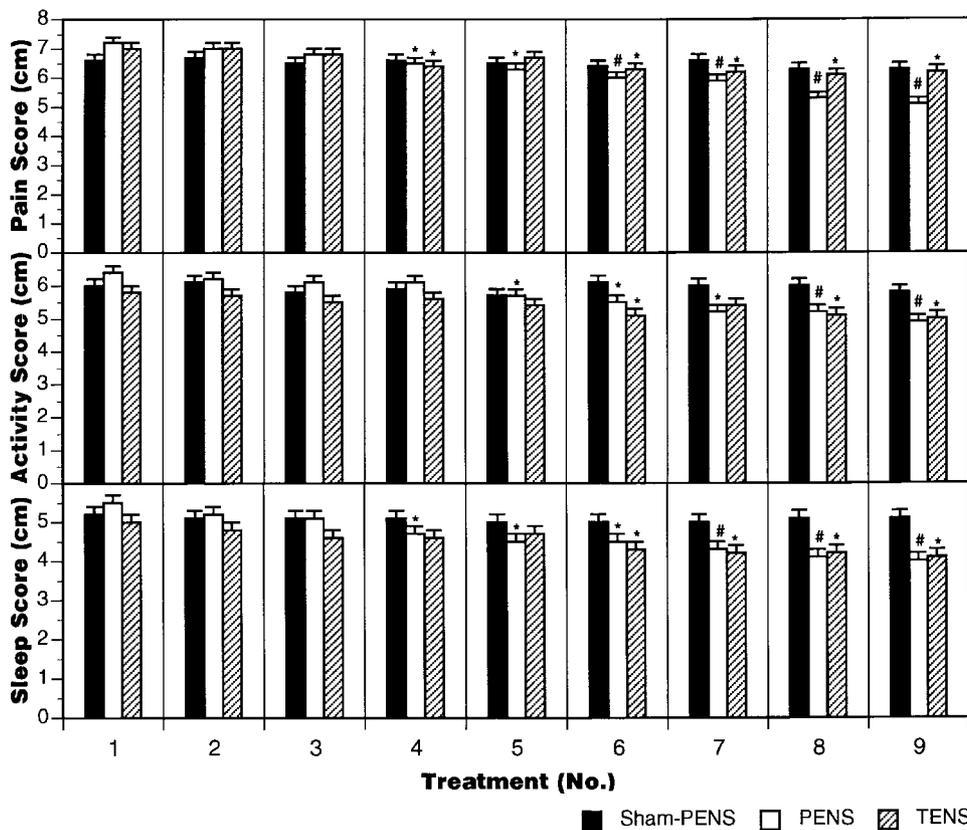


Fig. 2. Visual analog scale scores (cm) for radicular leg pain, physical activity and quality of sleep before each of the nine treatment sessions with the three modalities. Scores of 0 = best to 10 = worst. Data are mean values  $\pm$  SEM. Symbols indicate significant changes from the values prior to the first treatment, \**P*-value < 0.05 and #*P*-value < 0.01.

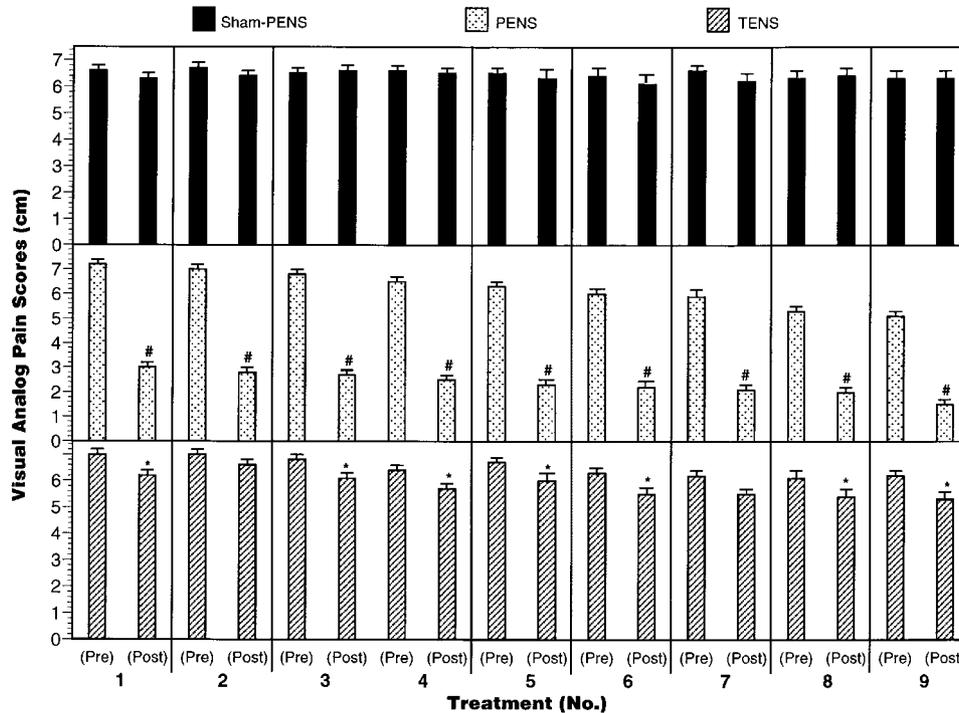


Fig. 3. Visual analog scale (VAS) pain scores with 0 = best to 10 = worst immediately before (pre) and after (post) each of the nine treatment sessions with the three modalities. Data are mean values  $\pm$  SEM. Symbols indicate significant differences from the pre-treatment values, \* $P$ -value < 0.05 and # $P$ -value < 0.01.

and sham-PENS ( $28.4 \pm 6.7$  and  $41.7 \pm 6.2$ ) therapies produced smaller, but statistically significant improvements in the PCS and MCS scores, respectively ( $P < 0.05$ ). Moreover, when PENS therapy was compared to each of the other therapeutic modalities, significantly greater improvement in post-treatment functionality was found (+5.7 and +2.1 versus TENS and +6.9 and +2.5 versus sham-PENS with respect to PCS and MCS scores, respectively).

The VAS scores for pain, physical activity and quality of sleep 24 h prior to the first treatment session and 24 h after the last treatment session with each of the three modalities are summarized in Table 1. The average decrease in the VAS pain scores 24 h after the last treatment session was

significantly greater with PENS therapy ( $42 \pm 18$  versus  $23 \pm 16\%$  for TENS and  $8 \pm 11\%$  for sham-PENS). After three to four treatments, patients receiving PENS also reported significant improvement in their pre-treatment VAS scores for both activity and sleep (Fig. 2). Although TENS was also associated with improvement in the VAS scores for the degree of pain, physical activity and sleep quality, the magnitude of the changes were less than with PENS ( $P < 0.05$ ). In addition, PENS therapy produced the greatest decrease in VAS pain scores immediately after each treatment ( $P < 0.01$ ) (Fig. 3). However, TENS also produced a significant decrease in VAS pain scores immediately after eight of the nine treatment sessions ( $P < 0.05$ ).

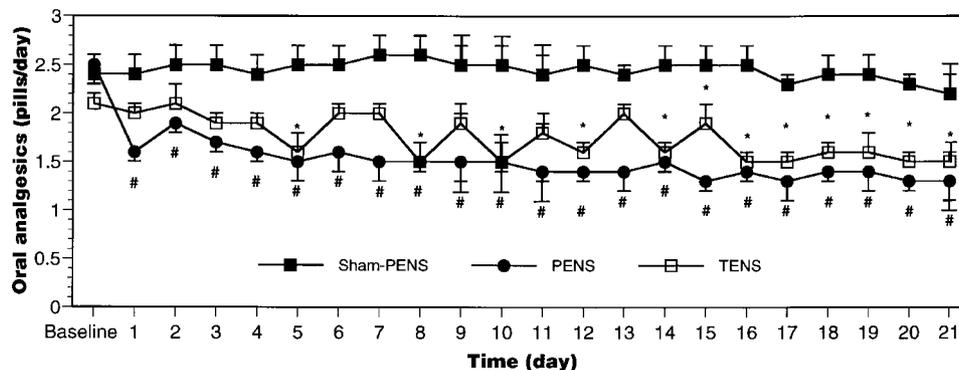


Fig. 4. Daily oral intake (pills/day) of non-opioid analgesic medications during the 3-week treatment period with each of the three modalities. Data are mean values  $\pm$  SEM. Symbols indicate significant differences from baseline values 24 h prior to the first treatment with each modality, \* $P$ -value < 0.05 and # $P$ -value < 0.01.

Table 1

Comparison of visual analog scale (VAS) scores for sciatic pain, level of activity and quality of sleep 24 h prior to receiving the first treatment (before) and 24 h after the last treatment (after) with each modality, with 0 = best to 10 = worst<sup>a</sup>

	Sham-PENS	PENS	TENS
<i>Degree of pain</i>			
Before (cm)	6.6 ± 1.9	7.2 ± 1.8	7.0 ± 1.9
After (cm)	6.1 ± 1.9	4.1 ± 1.4 <sup>b,c</sup>	5.4 ± 1.9*
<i>Level of activity</i>			
Before (cm)	6.0 ± 1.9	6.4 ± 2.1	5.8 ± 1.7
After (cm)	5.5 ± 2.1	4.0 ± 1.7 <sup>b,c</sup>	4.5 ± 1.7 <sup>b</sup>
<i>Quality of sleep</i>			
Before (cm)	5.2 ± 2.1	5.5 ± 1.9	5.0 ± 2.0
After (cm)	4.9 ± 1.9	3.1 ± 1.9 <sup>b,c</sup>	4.0 ± 2.0 <sup>b</sup>

<sup>a</sup> Values are means ± SD, PENS, Percutaneous electrical nerve stimulation; TENS, Transcutaneous electrical nerve stimulation.

<sup>b</sup> Significantly different from 'baseline' prior to receiving treatment No. 1, *P*-value < 0.05.

<sup>c</sup> Significantly different from sham-PENS and TENS, *P*-value < 0.01.

The daily intake of oral non-opioid anti-inflammatory analgesic medication (pills per day) is displayed in Fig. 4. Compared to the pre-treatment values (24 h before starting each treatment modality), PENS therapy was associated with a 50 ± 19 percent reduction in the daily oral analgesic requirements over the 3-week interval. In contrast, TENS and sham-PENS therapies decreased the oral analgesic intake by 29 ± 17 and 8 ± 13%, respectively.

Finally, the overall evaluation of the three modalities indicated that PENS was the preferred therapy by 73% of the study patients compared to 21 and 6% for TENS (*P* < 0.05) and sham-PENS (*P* < 0.01), respectively (Table 2). In addition, PENS was significantly more effective than sham-PENS (*P* < 0.01) and TENS (*P* < 0.05) therapies in improving the patients' sense of 'well-being.' Compared to TENS (22%) and sham-PENS (3%) therapies, 71% of the patients indicated that they would be willing to pay extra money ('out of pocket') to receive PENS therapy in the future.

Table 2

Overall patient evaluation of the relative effectiveness of sham-PENS, PENS and TENS therapies after receiving all three modalities

	Sham-PENS	PENS	TENS
Most desirable modality (%)	6	73 <sup>a,b</sup>	21 <sup>a</sup>
Improved sense of 'well-being' (%)	8	66 <sup>a,b</sup>	26 <sup>a</sup>
Preferred pain therapy (%)	6	73 <sup>a,b</sup>	21 <sup>a</sup>
Willing to pay extra for therapy (%)	3	71 <sup>a,b</sup>	22 <sup>a</sup>

<sup>a</sup> Significantly different from the Sham-PENS group, *P*-value < 0.05.

<sup>b</sup> Significantly different from the TENS group, *P*-value < 0.05.

#### 4. Discussion

Many patients with sciatica have been successfully treated with conservative medical management consisting of bed rest, anti-inflammatory analgesic drugs and epidural steroids (Frymoyer, 1988). Although this approach can effectively decrease the radicular pain, improvement in functionality has been more difficult to demonstrate. If the pain associated with sciatica can be adequately controlled, spontaneous regression of the herniated nucleus pulposus has been reported to occur in the vast majority of patients (Bush et al., 1992).

The use of peripheral electrical stimulation with TENS units has previously been reported to be beneficial in treating the pain associated with radiculopathies, including sciatica (Woolf and Thompson, 1994). Blockade of the sciatic nerve distal to the site of the lesion with local anesthetics has also been reported to produce long-lasting relief of radicular leg pain (Xavier et al., 1988). Although the current study confirmed the efficacy of TENS, it was significantly less effective than PENS therapy in providing short-term relief of pain and improvement in functionality in patients with sciatica due to herniation of a lumbar disc. These findings indicating the superior efficacy of PENS (versus TENS) are consistent with the preliminary studies by Sun et al. (1997); Ghoname et al. (1999a) in patients with low back pain due to osteoarthritis and degenerative disc disease, respectively. The more limited efficacy of TENS is related in part to the cutaneous pain associated with the higher amplitudes of electrical stimulation required with TENS because of the skin resistance to the transmission of the electrical impulses. Although the tapping sensation produced by PENS was not considered uncomfortable by the patients, some preferred TENS because it was less invasive (i.e. did not require placement of needle probes).

Sciatic neuralgia has also been successfully treated with acupuncture stimulation (Leung, 1973; Jiang et al., 1984). Although many of the reports describing the effectiveness of acupuncture (or electroacupuncture) have failed to include a placebo (sham) treatment arm, Duplan et al. (1983) performed a double blind, placebo-controlled study of acupuncture in patients with acute sciatica. These investigators reported that acupuncture stimulation produced statistically significant improvement in the Lasegue sign and a reduction in oral analgesic usage. Analogous to the earlier findings of Duplan and colleagues, PENS therapy proved to be highly effective in this patient population.

In order to determine the role of PENS in the long-term management of sciatica, longitudinal studies are required. However, this sham-controlled study indicates that PENS produced profound acute analgesic effects and the pain relieving effects appeared to accumulate over the course of the three-week treatment period. These data suggest that the use of this non-pharmacologic analgesic modality over a longer period of time has the potential to produce long-term beneficial effects in patients with sciatica. To test

this hypothesis, a more prolonged period of PENS therapy with careful follow-up at 3, 6 and 12 month intervals would be required.

While this was a sham-controlled study, the unique tapping sensation associated with PENS therapy precluded our ability to perform the study in a double-blind fashion. In order to minimize investigator bias, all patient assessments were performed by an individual not involved in administering the therapies. In addition, to avoid prejudicing patients in favor of PENS therapy, the sham treatment was described to the patients as an 'acupuncture-like' therapy. However, since the sham-PENS needles were placed in a dermatomal montage rather than at specific acupoints, it would be incorrect to conclude that classical Chinese acupuncture (or electroacupuncture) would be of no benefit in patients with sciatica.

Another potential criticism of the study design relates to the selection of a low stimulus frequency (4 Hz) for 30 min intervals for both PENS and TENS treatments. These variables were chosen because it was previously reported that low frequency (4 Hz) is more effective than high frequency (>100 Hz) stimulation in producing hypoalgesic effects with TENS using an experimental pain model (Walsh et al., 1995). Moreover, recent studies in humans using TENS (Hamza et al., 1999) and PENS (Ghoname et al., 1999a) have found no significant differences in the analgesic responses to high and low frequency stimulation. A 30 min period of stimulation was selected because more prolonged periods of stimulation (>30 min) may be associated with the development of tolerance to the electrical stimulation (Romita et al., 1997). When using PENS therapy, we also found no additional benefit when the stimulation intervals were increased from 30 to 45 min (Ghoname et al., 1999b). However, additional studies with PENS are needed to determine the relative analgesic effectiveness of different frequencies and durations of electrical stimulation in this patient population.

Experience with PENS in other patient populations [e.g. chronic osteoarthritis (Sun et al., 1997), acute herpes zoster (Ahmed et al., 1998) and low back pain (Ghoname et al., 1999c)] has suggested that improved analgesic responses may be achieved by using higher (50–100 Hz) or mixed (15/30 Hz) frequencies of electrical stimulation at subsequent treatment sessions. Similarly, the standardized montage used in this study was based on anecdotal clinical experience (W.F. Craig, unpublished data). However, depending on the associated manifestations of the pain symptoms (e.g. bilateral radicular leg pain, low back pain), other needle montages may prove to be more effective for subsequent treatment sessions.

The results of the psychological (SF-36) assessment further support and strengthen the clinical findings by providing an additional outcome measure which demonstrates the superiority of PENS over TENS and sham therapies. These data suggest that PENS was the most beneficial modality in improving the physical (e.g. fewer limitations in

self-care, less severe body pain) and mental (e.g. less psychological stress, less disability due to emotional problems) health and well-being of patients with sciatica.

In order to determine the cost-benefit of any new analgesic therapy, long-term outcome studies are needed which carefully consider the pertinent costs (e.g. stimulating device, disposables, personnel requirements), as well as the consequences or outcomes of the treatment (e.g. patient satisfaction, quality of life, resumption of normal activities) in monetary terms (Watcha and White, 1997). Long-term outcome studies should be designed to examine the cost-benefit of using PENS therapy as part of a multi-modal rehabilitation program which also includes anti-inflammatory drugs and specific low back exercises.

In conclusion, this sham-controlled study demonstrates that PENS is more effective than TENS in improving short-term outcome in patients with sciatica. The use of PENS therapy improves physical activity and the quality of sleep while decreasing the need for oral non-opioid analgesic medications.

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