Percutaneous Neuromodulation Therapy: Does the Location of Electrical Stimulation Effect the Acute Analgesic Response?

Paul F. White, PhD, MD, FANZCA, William F. Craig, MD, Akshay S. Vakharia, MD, El-sayed A. Ghoname, MD, Hesham E. Ahmed, MD, and Mohammed A. Hamza, MD

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

We studied the effect of the location of electrical stimulation on the acute analgesic response to percutaneous neuromodulation therapy in patients with nonradiating neck pain. Sixty-eight patients received three different nonpharmacologic modalities, namely "needles only" (neck), local (neck) dermatomal stimulation, and remote (lower back) dermatomal stimulation in a random sequence over the course of an 11-wk study period. All treatments were given for 30 min, 3 times per week for 3 wk, with 1 wk "off" between each modality. The assessment tools included the health status survey short form (SF-36) questionnaire, as well as 10-cm visual analog scales for assessing pain, physical activity, and quality of sleep. The pain visual analog scale was repeated 5–10 min after each treatment session. The daily oral nonopioid analgesic requirements were recorded in the patient diary during the entire study period. At the end of each 3-wk treatment block, the SF-36 questionnaire was repeated. Compared with needles only and remote dermatomal stimulation, local dermatomal stimulation produced a significantly greater decrease in pain (38% ± 17% vs 9% ± 16% and 13% ± 18%), increase in physical activity (41% ± 21% vs 11% ± 17% and 16% ± 15%), and improvement in the quality of sleep (34% ± 18% vs 7% ± 17% and 10% ± 18%) compared with baseline values ($P < 0.05$). The need for oral analgesic medications was decreased by an average of 6% ± 15%, 37% ± 18%, and 9% ± 13% during the 3-wk treatment period with the needle only, local dermatomal, and remote dermatomal stimulation, respectively. The posttreatment SF-36 test results revealed that all three modalities produced improvements compared with the prestudy scores for both the physical component summary and mental component summary. However, the magnitude of the changes in the physical component summary and mental component summary with local dermatomal stimulation was significantly greater (+7.9 and +3.6, respectively) than needle only (+3.4 and +1.7, respectively) or remote dermatomal stimulation (+3.7 and +1.9, respectively). No side effects were reported at the needle insertion sites. We conclude that electrical stimulation at the specific dermatomal levels corresponding to the local pathology produces greater short-term improvements in pain control, physical activity, and quality of sleep in patients with chronic neck pain.

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Percutaneous neuromodulation therapy (PNT), a novel pain therapy, has recently been introduced for the treatment of a variety of chronic back pain syndromes (1–4). This therapy has been referred to as percutaneous electrical nerve stimulation in previous publications. However, this description of the therapy may lead to confusion with a neurosurgical procedure (CPT code #64565) involving implantable stimulating electrodes. Our earlier studies have demonstrated that PNT is a safe and effective pain therapy that provides short-term relief of chronic back pain and improvements in physical activity and quality of sleep (1,2,4). These previous studies have evaluated the effect of both the frequency (2) and duration (4) of electrical stimulation on the acute analgesic response to PNT. However, the effect of the location of percutaneous electrical stimulation on the analgesic response has not been studied. If the mechanism for analgesia induced by electrical therapy relates primarily to increases in endogenous analgesic-like substances within the central nervous system (CNS) after peripheral nerve simulation (5), similar analgesic effects

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Address correspondence to Paul F. White, PhD, MD, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., F2.208, Dallas, TX 75235-9068. Address e-mail to paul.white@email.swmed.edu.

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should be obtainable regardless of the level of spinal stimulation. Alternatively, it has been suggested that central neuromodulatory changes are primarily responsible for the analgesic effects produced by peripheral electrical stimulation (6).

This sham-controlled, cross-over study was designed to test the hypothesis that the short-term analgesic effectiveness of PNT would be similar regardless of whether the stimulus was applied to needles placed in the paraspinous muscle region at the specific (local) spinal dermatomes corresponding to the level of the patient's pain symptoms or at more remote spinal dermatomes. Therefore, the acute analgesic response to electrical stimulation was assessed when patients with chronic neck pain were stimulated in an identical manner at either the cervicothoracic (neck) or lumbosacral (low back) regions. In addition, we determined the effects of the location of the electrical stimulation on the requirement for supplemental oral analgesic medication.

Methods

After we obtained local institutional review board approval and written, informed consent, 68 patients (31 men and 37 women, ages ranging between 27 and 80 yr) with chronic nonradiating neck pain and radiologically confirmed cervical disk disease were treated with dermatomally applied PNT in the "local" neck region, nondermatomally related "remote" PNT in the low back region, and "needles only" in the neck region for 3 wk each during an 11-wk study period according to a randomized, investigator-blinded, cross-over study design. Inclusion criteria included a history of neck pain and cervical disk disease with a stable level of pain for a period of at least 3 mo before enrolling in the study. Exclusion criteria included neck pain with a radicular component, a recent history of drug or alcohol abuse (<1 yr), chronic use of opioid analgesics, previous experience with electroanalgesic therapies, recent change in analgesic medications (<last 3 mo), or an inability to reliably complete the assessment tools used to measure short-term outcomes. All patients were told that they may or may not feel a gentle tapping sensation produced by the electrical current during the treatment sessions.

Treatment Modalities

The local dermatomal stimulation and "needle only" therapies consisted of the placement of 10 32-gauge stainless steel acupuncture needle probes (ITO, Tokyo, Japan) to a depth of 2–4 cm into the soft tissues and/or paraspinous muscles in the cervical region according to the dermatomal distribution of the neck pain as illustrated in Figure 1A. For the electrical therapy treatments, the 10 probes were connected to 5 bipolar leads (with each lead connected to 1 positive and 1 negative probe) from an investigational low-output electrical generator and stimulated for 30 min at an alternating frequency of 15 Hz and 30 Hz (15/30 Hz) (2,4). The intensity of the electrical therapy was adjusted to produce a gentle tapping sensation without muscle contraction. The maximum amplitude of the electrical stimulation produced by the generator was 37 mA with an asymmetric biphasic waveform pattern, a pulse width of 0.7 ms, and a continuous duty cycle.

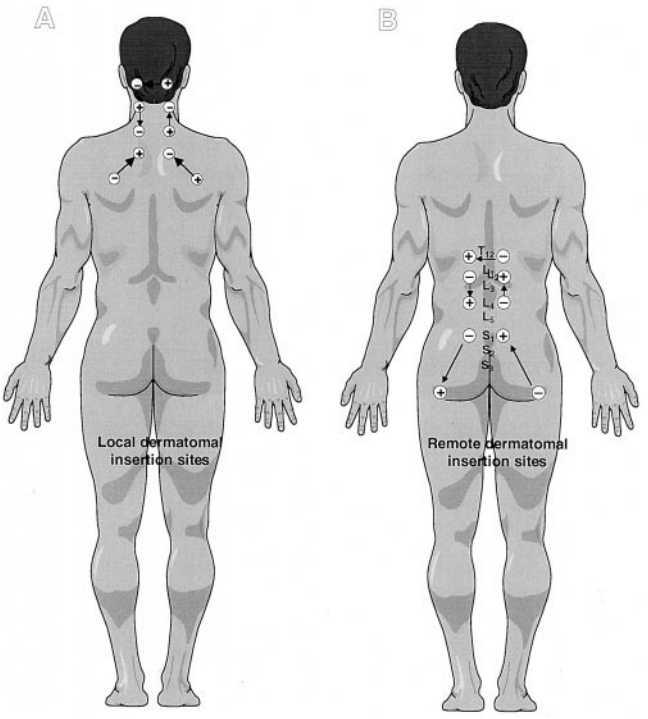

Figure 1. A, The location of the needle electrodes for the "needles only" (control) and the local dermatomal stimulation treatments. With local dermatomal stimulation therapy, each of the five bipolar leads from the stimulating device was connected to a pair of needles, alternating the positive (+) and negative (−) connectors as shown in the illustration. B, The location of the needle electrodes for the remote dermatomal stimulation treatments sessions, with each of the five bipolar leads from the stimulating device connected to a pair of needles, alternating the positive (+) and negative (−) connectors as shown in the illustration.

The remote dermatomal (low back region) electrical therapy consisted of the placement of 10 32-gauge stainless steel acupuncture-like needle probes (ITO, Japan) to a depth of 2–4 cm into the soft tissue and/or paraspinous muscle in the lower back region as illustrated in Figure 1B. The 10 probes were connected to 5 bipolar leads (with each lead connected to 1 positive and 1 negative probe) from the same low output electrical generator. The characteristics of the electrical therapy were identical to the dermatomal stimulation therapy as described above.

Each of the three treatment modalities were administered to all patients 3 times per wk for 3 consecutive

wk, with 1 wk "off" between each modality during the 11-wk study period.

Assessment Procedures

Before initiating any of the treatment modalities, patients were required to complete the health status survey short-form (SF-36) (7). The physical component summary (PCS) and mental component summary (MCS) scores of the SF-36 questionnaire were used to assess the patient's response to all three of the treatment modalities. The patients were also asked to assess their level of neck pain, physical activity, and quality of sleep during the 24-h interval before the first treatment and at 24 h after the last treatment with each modality using standard 10-cm visual analog scales (VAS), with 0 = "the best" and 10 = "the worst" scores. Repeat VAS assessments of pain, physical activity and quality of sleep were performed three times per week before each treatment session. In addition, the pain VAS was reassessed 5–10 min after completion of each treatment session to measure the acute analgesic response to individual treatments. All patients were asked to record the number of the oral nonopioid analgesic pills they consumed in their diary at the end of each day. The diary was reviewed by one of the investigators at every treatment visit. The SF-36 were repeated 24 h after completing nine treatment sessions with each of the three modalities.

Data Analysis

The NCSS software package (NCSS 6.0.1™ statistical system for Windows, Kaysville, UT) was used for all statistical analysis. An *a priori* power analysis with $\alpha = 0.05$, $\beta = 0.10$ (power = 90%) and SD of 2.0 and 1.5 determined that a group size of 68 should be adequate to demonstrate a difference of 25% and 14%, respectively, between the VAS scores and daily oral analgesic requirements (pills per day) for the three study modalities (1–4). The changes in the VAS scores and daily oral analgesic medications were analyzed by using repeated measures analysis of variance and Student's *t*-test, with a Bonferroni correction applied for multiple comparisons. Analysis of discrete (noncontinuous) data for the three modalities was performed by using the χ^2 test. Changes and differences in the SF-36 scores were analyzed by using paired *t*-tests. Data were presented as mean values ± SEM in the figures, with P values <0.05 considered statistically significant.

Results

Sixty-eight patients with a mean age of 52 ± 23 yr, weight 76 ± 27 kg, a baseline pain VAS score of 7.8 ± 2.5 cm, and a mean duration of pain of 43 ± 19 mo completed all three phases of the study. Local dermatomal stimulation in the neck region produced significantly greater acute decreases in the pain scores after each of the nine treatment sessions (P <0.01) than either needles only or remote dermatomal stimulation in the low back region (Fig. 2). More importantly, there was evidence of a cumulative effect of the dermatomal stimulation over the course of the nine treatments as evidenced by decreases in the pretreatment pain VAS scores (versus baseline values) at the last seven treatment sessions with the local stimulation. In contrast, there was no evidence of a cumulative hypoalgesic effect with either the needles only or remote dermatomal stimulation. Compared with the needles only and remote (low back) dermatomal stimulation, the percentage improvement in the mean pain, physical activity, and quality of sleep VAS scores from the baseline values (24 h before starting each treatment modality to 24 h after the last treatment session) were also significantly greater with local dermatomal stimulation in the neck region (Fig. 3). There were no significant differences in the outcome assessments between the needles only and remote dermatomal stimulation.

The daily usage of oral nonopioid analgesic medications are summarized in Figure 4. Compared with baseline values 24 h before starting each treatment modality, the need for oral analgesic medications was decreased by an average of 6% ± 15%, 37% ± 18% and 9% ± 13% over the course of the 3-wk treatment period with needles only, local dermatomal, and remote dermatomal stimulation, respectively. Local dermatomal stimulation produced a significantly greater decrease in the daily oral analgesic requirements than either of the other two treatment modalities (p <0.05). There were no observed cutaneous reactions, hematomas, or inflammatory changes at any of the needle insertion sites after the treatment sessions.

Finally, the posttreatment SF-36 test results revealed that all three modalities produced significant improvements compared with prestudy "baseline" values in both the PCS and the MCS components ($P < 0.01$ for needles only and remote dermatomal stimulation, and $P < 0.001$ for local dermatomal stimulation). However, the magnitude of the absolute changes in the PCS and MCS components was significantly greater with local dermatomal stimulation (+7.9 and +3.6, respectively) than the needles only (+3.4 and +1.7, respectively) and remote dermatomal stimulation (+3.7 and +1.9, respectively) ($P < 0.05$).

Discussion

This cross-over study demonstrated that PNT was effective in providing short-term relief of pain and improving

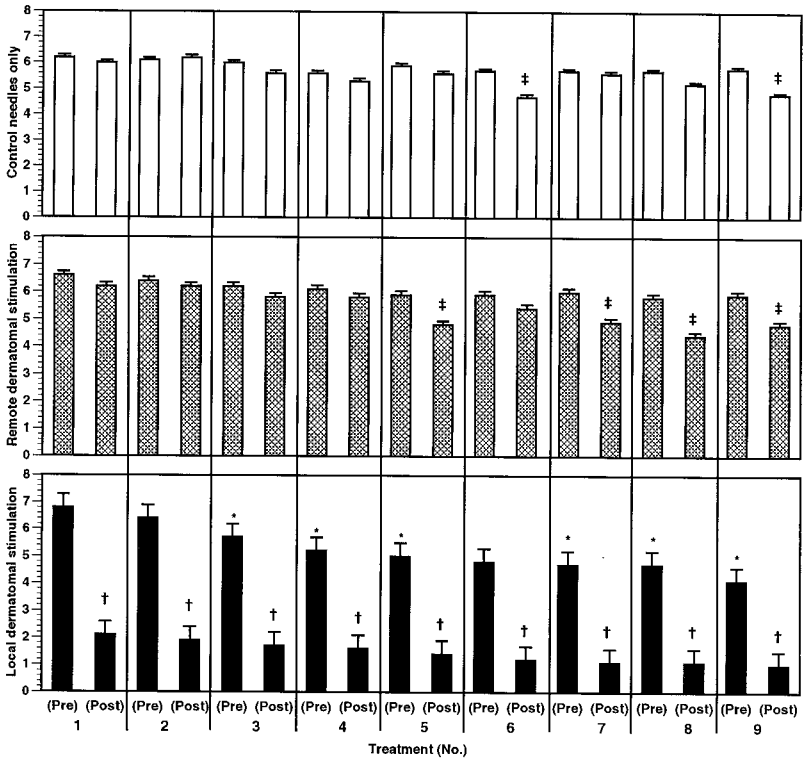

Figure 2. Comparison of the pain visual analog scale (VAS; 0 = "the best" to 10 = "the worst" score) scores before (pre) and 5–10 min after (post) each treatment session with control needles only (□), remote dermatomal stimulation (▨) and local dermatomal stimulation (■). Data are mean values ± SEM. ‡Significantly different from values before (pre) each treatment session, $P < 0.05$. †Significantly different from values before (pre) each treatment session, $P < 0.01$. *Significantly different from values before (pre) treatment Session 1, $P < 0.05$.

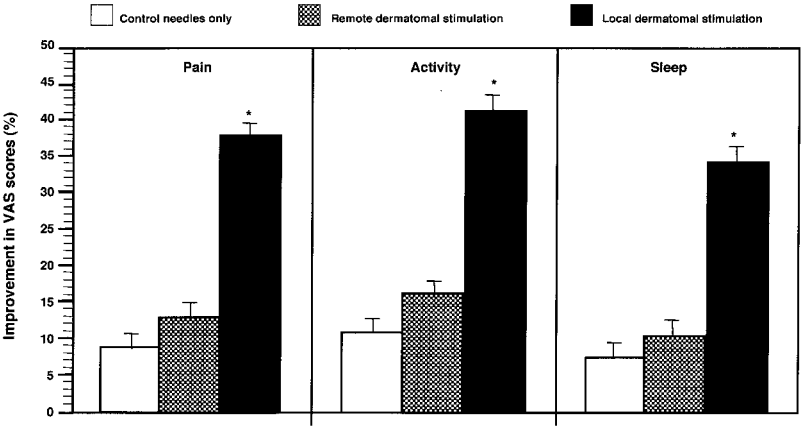

Figure 3. Comparison of the percentage improvements in pain, activity and sleep visual analog score (VAS) scores between the baseline values 24 h before the first treatment session with each modality and the values 24 h after completion of each 3-wk treatment period. Data are mean values ± SEM. Symbols indicate significant differences compared with the control needles only and remote dermatomal stimulation values, *$P < 0.05$.

physical function in patients with chronic neck pain only when applied at the symptomatic (local) dermatomal levels. These findings support and extend our earlier studies involving the use of percutaneously administered electrical therapy in the management of low back pain (1,2,4) and sciatica (3). In one study involving the use of transcutaneous electrical nerve stimulation (TENS) after surgery (8), we similarly found that the opioid-sparing effect was greater with dermatomal compared with remote (nonrelated) dermatomal stimulation. Analogous to our findings with TENS in patients with acute postoperative pain, these results suggest that there is minimal "placebo effect" with PNT when it is applied to remote dermatomes in this chronic pain population. This finding may relate, in part, to our inability to conduct this study in a double-blinded manner because the tapping sensation produced by the electrical stimulation "unblinded" the location (level) of the stimulation and was totally lacking in the control ("needles only") group.

Although this study was not designed to examine the long-term benefits of PNT therapy, patients began to report more sustained beneficial effects of PNT therapy on their level of pain after only 2–3 treatment sessions with local, dermatomally applied stimulation in the paraspinous region corresponding to their symptoms. In addition to providing enhanced pain control, PNT applied at the involved dermatomes resulted in increased physical activity and the improved

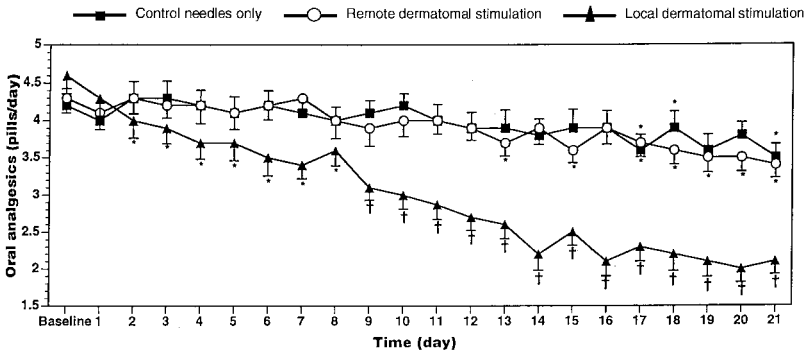

Figure 4. Changes in the daily oral intake of nonopioid analgesic medications (pills per day) during the 3-wk treatment period with each of the three modalities. Data are mean values ± SEM. Symbols indicate significant changes from the values 24 h before the first treatment (baseline), $*P < 0.05$ and $\dagger P < 0.01$.

quality of sleep compared with the needles only and remote dermatomal stimulation. These findings are important because enhanced physical activity and improved quality of sleep are considered important outcome variables in the management of chronic neck pain (9).

The results of the SF-36 assessments further support the clinical findings that dermatomal (versus remote dermatome) electrical therapy is more beneficial in improving the physical (e.g., fewer limitations in self-care, less severe body pain) and mental (e.g., less psychological distress, less disability caused by emotional problems) health and well-being of this patient population. These findings are also important because they suggest that PNT may enhance the patient's ability to participate in other therapeutic modalities that can also lead to functional improvement (e.g., physical therapy, massage). An improvement in psychological well-being can contribute to increased physical activity, thereby allowing patients with chronic pain to achieve greater benefit from a multimodal rehabilitation program (10).

There is little scientific information available from well controlled clinical studies to support the current treatments for mechanical neck pain (11). Acupuncture, electroacupuncture, and TENS have all been used with varying degrees of success in the management of chronic neck pain (12–14). PNT combines the advantages of both electroacupuncture (e.g., application of low-level electrical current to fine needles placed through the skin at specific accupoints) and TENS (e.g., dermatomally applied peripheral electrical stimulation) therapies. In addition to relieving upper and lower back pain, recently published studies suggest that PNT is effective in providing short-term relief for patients with a wide variety of other acute and chronic pain syndromes [e.g., hepatic neuralgia (15), diabetic peripheral neuropathy (16), headaches (17)]. To date, this novel nonpharmacologic analgesic therapy has proven remarkably safe with no clinically significant side effects or complications reported in any of the clinical trials (1–4,15–17).

It has been suggested that electroanalgesic therapies stimulate the release of endogenous analgesic-like substances within the CNS (5). However, an alternative explanation for the pain relieving effects of PNT relates to a direct effect of the electrical stimulus on spinal neural modulation pathways (6). The proposed neuromodulatory mechanism for electroanalgesia relates to stimulation of A-β fibers that inhibit small C fibers, thereby interrupting (or gating) pain input into the CNS (18). Finally, the positive response to local dermatomal electrical therapy may simply represent a placebo-like reaction that reflects patient beliefs and expectations, the beneficial effect of the patient-provider relationship, or other nonspecific treatment effects. Neck pain symptoms reflect complex interactions between anatomical and neurophysiological progress, as well as cognitive-behavioral and environmental factors (19).

The major deficiency in the study design relates to the fact that the electrical (tapping) sensation precluded our ability to perform the treatments in a blinded fashion (because the patients were easily able to ascertain the area being electrically stimulated). Another concern relates to the patients inherent beliefs and expectations. In Western society, patients expect treatments for neck pain to focus on the local area where the pain originates. Therefore, remote (i.e., remote dermatomal) stimulation may not be "expected" to provide the perceived benefits of local dermatomal stimulation. The final deficiency is a result of our failure to assess patient beliefs and expectations regarding the proposed treatments. For example, the failure to perceive a stimulus with the "needles only" treatments may have contributed to the negative findings.

It is difficult to apply a rigorous biomedical study design to a qualitative process because it ignores the fact that chronic neck pain is a highly complex, multidimensional experience. A biopsychosocial model (20) that also considers the social, psychological, and behavioral dimensions of the illness might be a more useful approach to studying the mechanism of action of PNT in this patient population. However, 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 PNT therapy, the needles only treatment was described as an "acupuncture-like" therapy, and they were told that they may or may not detect a tapping sensation during the treatments.

In conclusion, this study demonstrates that electrical stimulation at the dermatomal levels corresponding to the local pathology produces a greater hypoalgesic effect than stimulation at remote dermatomes in patients with chronic neck pain. These data suggest that PNT-induced analgesia represents a safe and effective form of electroanalgesic therapy in this chronic pain population.

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