The Effect of Montage on the Analgesic Response to Percutaneous Neuromodulation Therapy

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The analgesic response to percutaneous neuromodulation therapy (PNT) is influenced by the location, frequency, and duration of electrical stimulation. We evaluated the effect of different patterns of stimulation (montages) on the acute analgesic response to PNT when applied at the same dermatomal levels in 72 consenting patients with low back pain. All of the patients received a standardized montage (I) and three alternative montage (II–IV) patterns according to a randomized, single-blinded, crossover study design. All of the PNT treatments were administered at identical alternating stimulation frequencies of 15 and 30 Hz for a period of 30 min, three times per week for two consecutive weeks, with 1 wk "off" between each modality. Pretreatment assessments included the health status survey short form (SF-36) questionnaire, as well as visual analog scale scores for pain, physical activity, and quality of sleep (with 0 = the best to 10 = the worst). The pain visual analog scale was repeated 5–10 min after each treatment session. The daily oral analgesic usage was recorded in a patient diary. All four montages produced significant improvements in pain (42%–64%), physical activity (35%–51%), and quality of sleep (28%–46%), as well as 23% to 47% reductions in the daily oral analgesic usage. However, Montage II was significantly more effective than the standard (Montage I) and the other two montages studied. These data suggest that the pattern of stimulation (i.e., montage) can influence the acute analgesic response to PNT.

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Recent studies involving percutaneous neuromodulation therapy (PNT), formerly referred to as percutaneous electrical nerve stimulation, have demonstrated the analgesic efficacy of this therapy in the short-term management of low back pain (LBP), sciatica, headaches, and diabetic neuropathic pain (1–4). The response to PNT is influenced by the frequency of the electrical stimulus (5), as well as the duration (6) and location (7) of the percutaneously applied electrical stimulation. For example, the use of mixed stimulating frequencies alternating at 15 and 30 Hz (15/30) is more effective than either low- or high-frequency electrical stimulation alone (5), and the optimal duration of the electrical stimulation is determined to be 30–45 min (6). Furthermore, stimulation of the dermatomal levels corresponding to the patients' pain symptoms was more effective than stimulating nonrelated (remote) dermatomes (7). The effect of the specific pattern of electrical stimulation (i.e., montage) when administered at the same dermatomal levels has not been studied.

Therefore, we designed a randomized, single-blinded, cross-over study to test the hypothesis that the pattern of electrical stimulation influences the acute analgesic response to PNT when applied at the same dermatomal levels in patients with LBP. The short-term analgesic efficacy of three different PNT montages was compared with the standard montage used in previous studies (1,5,6). In addition, the comparative effects of the four different montages on the patients' physical activity, quality of sleep, and need for supplemental oral analgesic medication were assessed over the 11-wk study period.

Methods

After obtaining local IRB approval and written informed consent, 72 patients (31 men and 41 women ranging between 21 and 76 yr of age) with LBP of >6-mo duration, were treated with four different PNT montages according to a randomized, single-blinded, crossover study design. Inclusion criteria included age over 18 yr and radiologically confirmed degenerative lumbar spine disease, with a "stable" level of LBP and

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analgesic usage for at least 3 mo before entering the study. Exclusion criteria included LBP with a radicular component (sciatica), history of drug or alcohol abuse, change in the character or severity of the pain within the last 3 mo, recent change in analgesic medications, and inability to reliably complete the health status survey Short-Form (SF-36), or the daily assessment tools.

Each PNT treatment was administered for 30 min, three times per week (on Monday, Wednesday, and Friday afternoons) for 2 consecutive wk, with a 1 wk "washout" period between each treatment modality. All of the patients received the four different montages over the course of the 11-wk study period. Any missed treatment sessions were completed before switching to the next montage. Montage I (Fig. 1A) was used in our preliminary PNT studies, and this standard montage was compared with three other montages (II–IV) when applied at the same dermatomal levels (Fig. 1B–D). The basic PNT procedure consists of the placement of 10 32-gauge stainless steel acupuncture needles into the soft tissue and/or muscle in the low back region to a depth of 2–4 cm. The 10 needles used with all 4 montages were connected to 5 bipolar leads (with each lead connected to one positive and one negative probe) by using a low-output battery-powered generator. The maximal 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. The intensity of the electrical stimulation was adjusted to produce the maximal tolerable "tapping" sensation without eliciting muscle contractions.

Before initiating any of the treatment modalities, the patients were required to complete the SF-36 (8). The physical component summary (PCS) and mental component summary (MCS) scores were used to assess the patient's psychological response to each of the different montages (9). All of the patients were asked to assess their level of LBP, physical activity, and quality of sleep during the 24-h interval before the first treatment session by using three separate 10-cm visual analog scales (VAS), with a response of 0 = the best to 10 = the worst. The 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 repeated 5–10 min after completion of each individual treatment to assess the acute analgesic response. The daily oral analgesic requirements were recorded in a patient diary. Finally, the SF-36 was repeated 24 h after completing all six treatment sessions with each of the four montages.

The Number Cruncher Statistical System software package (NCSS 6.0.1 Statistical System for Windows; NCSS Statistical Software, Kaysville, UT) was used for all statistical analyses. An *a priori* power analysis with $\alpha = 0.05$, $\beta = 0.10$ (power = 90%), and standard deviation of 2 cm, suggested that a group size of 72 should be adequate to demonstrate a 17% difference among the pain VAS scores. The changes in the VAS scores over time were analyzed with repeated measures analysis of variance and Student's *t*-test, with a Bonferroni test applied for multiple comparisons. Analysis of discrete data was performed using the χ^2 test. Changes and differences in the SF-36 scores were analyzed by paired *t*-tests. Data were presented as mean values ± SD or SEM and percentages, with *P* values <0.05 considered statistically significant.

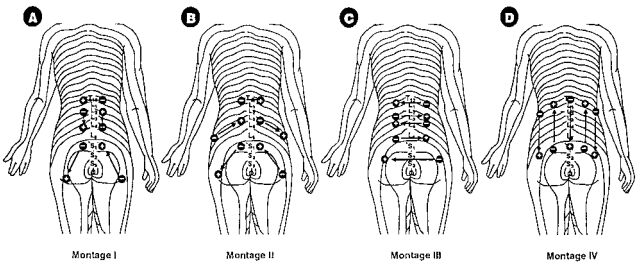

Figure 1. The needle insertion positions and electrode pairing patterns used for the four different PNT montages. Montage I (A) was the standard montage used in all of the earlier PNT studies involving patients with low back pain (1,5,6).

Results

The prestudy SF-36 evaluation suggested that this LBP population reported significantly lower health-related "quality-of-life" scores compared with an age-matched general population without chronic diseases. The prestudy baseline scores were 32.7 and 41.8 for the PCS and MCS, respectively, compared with general population norms of 50 for these two health status survey scores. A comparison of the posttreatment SF-36 test results revealed that all four PNT montages produced significant improvements compared with the baseline scores for both the PCS and the MCS components of the survey ($P < 0.01$). However, the mean magnitude of the changes in the PCS and MCS components with the standard Montage I (+7.1 and +2.9, respectively) and Montage II (+7.6 and +3.2, respectively) were significantly greater than with Montages III (+5.9 and +1.9, respectively) and IV (+5.7 and +1.8, respectively) ($P < 0.05$).

All four montages produced similar 25% to 68% decreases in pain VAS scores immediately after each treatment session (Table 1). However, the cumulative effects over the course of the 2-wk treatment period indicated a better efficacy with Montage II compared with the other three montages (Table 1). Furthermore, the overall percentage changes at the end of the 2-wk treatment period in the VAS pain, physical activity, and quality-of-sleep scores with Montage II (64%,

Table 1. Comparison of the Effects of the Four Montages of Electrical Stimulation on the Pain VAS Scores Before and After Each of the Six Consecutive Treatment Sessions

Treatment no.	Montage I	Montage II	Montage III	Montage IV
1				
Pretreatment	6.0 ± 1.6	6.1 ± 1.7	5.5 ± 1.9	5.5 ± 1.9
Posttreatment	3.8 ± 1.7*	3.2 ± 1.5†	3.9 ± 1.8*	4.1 ± 1.8*
2				
Pretreatment	5.9 ± 1.7	5.3 ± 1.7‡	5.8 ± 1.8	5.9 ± 1.8
Posttreatment	3.2 ± 1.9†	2.9 ± 1.8†	3.7 ± 1.7*	3.9 ± 1.7*
3				
Pretreatment	5.3 ± 1.8‡	5.1 ± 2.0‡	5.4 ± 1.9	5.4 ± 1.7
Posttreatment	2.8 ± 1.9†	2.5 ± 1.8†	2.9 ± 1.7†	3.6 ± 2.0*
4				
Pretreatment	5.1 ± 1.5‡	4.9 ± 1.6‡	5.2 ± 1.7	5.3 ± 1.6
Posttreatment	2.8 ± 1.9†	1.9 ± 1.6†	2.2 ± 1.8†	2.5 ± 1.9†
5				
Pretreatment	4.7 ± 1.8‡	4.3 ± 1.9‡	4.8 ± 1.8‡	5.0 ± 1.8
Posttreatment	1.9 ± 1.5†	1.6 ± 1.5†	2.0 ± 1.7†	1.9 ± 1.6†
6				
Pretreatment	4.4 ± 1.6‡	3.8 ± 1.4‡	4.5 ± 1.5‡	4.6 ± 1.5‡
Posttreatment	1.4 ± 1.3†	1.2 ± 1.7†	1.6 ± 1.5†	1.5 ± 1.4†

Pretreatment = VAS score 5–10 min before the start of each treatment session.
Posttreatment = VAS score 5–10 min after the end of each treatment session.
VAS = visual analog scale. Mean (±SD) VAS scores, with 0 = the best to 10 = the worst.
* Significantly different from the pretreatment score, $P < 0.05$.
† Significantly different from the pretreatment score, $P < 0.01$.
‡ Significantly different from values before treatment session 1, $P < 0.05$.

51%, and 46%, respectively) were significantly greater compared with the standard (Montage I) (47%, 42%, and 30%, respectively), as well as Montages III (43%, 37%, and 28%, respectively) and IV (42%, 35%, and 29%, respectively) (Table 2). Although the need for oral analgesic medications was decreased over the course of the 2-wk treatment period with all four PNT montages (Fig. 2), the percentage of decrease over the course of the 2-wk treatment period with Montages I (43% ± 23%) and II (47% ± 21%) were significantly greater than with Montages III (27% ± 23%) and IV (23% ± 23%) ($P < 0.05$).

Discussion

Consistent with the previous PNT studies in patients with chronic LBP (1,5,6), Montage I produced both acute and cumulative analgesic effects over the course of the two-week treatment period. This "standard" montage also produced comparable improvements in physical activity and quality of sleep, as well as a reduction in the need for supplemental oral (nonopioid) analgesic medication, as reported in the previous studies involving a similar patient population. These data also support the hypothesis that electrical stimulation of myotomes and sclerotomes at dermatomal levels corresponding to the local pathology is an important factor in the analgesic response to PNT.

In contrast to the previous study (7), in which we evaluated the effect of local-versus-remote dermatomal stimulation, we evaluated the acute analgesic response to PNT when it was administered using different patterns of electrical stimulation at the *same* dermatomal levels. These data suggest that the pattern of stimulation or montage (as determined by electrode placement) influences the acute analgesic response even when the same electrical current is applied at identical dermatomal levels.

Of interest, stimulating along the involved nerve roots at the dermatomal levels corresponding to the patients' pain symptoms (Montage II) was found to be more effective for the acute and short-term pain-reducing effects of PNT, as well as in improving the patients' perceived levels of physical activity and quality of sleep. Although the precise mechanism of PNT-induced analgesia is not known, we speculate that the stimulation pattern used with Montage II produces more effective electrical stimulation of the involved myotomes and/or sclerotomes. On the basis of the PNT studies performed to date, it is recommended to start the therapy using Montage II. If this montage fails to achieve the expected benefits, the patient should be switched to Montage I or one of the other two montages studied.

The failure to conduct the study in a double-blinded manner is a valid criticism of the study. However, all of the evaluations were performed by an independent observer who was unaware of the montage. Another concern relates to the potential residual ("carryover")

Table 2. Comparison of the Average VAS Scores, as Well as the Percentage Changes, for the Degree of Pain, Level of Activity, and Quality of Sleep During the 24-Hr Period Before Receiving the First Treatment (Before) and 24 Hr After the Last Treatment (After) With Each of the Four Montages

	Montage I	Montage II	Montage III	Montage IV
Degree of pain				
Before (cm)	6.0 ± 1.6	6.1 ± 1.7	6.1 ± 1.6	6.2 ± 1.7
After (cm)	3.2 ± 1.2*	2.2 ± 1.3*	3.5 ± 1.5*	3.6 ± 1.5*
Change (%)	47 ± 2	64 ± 2†	43 ± 2	42 ± 2
Level of activity				
Before	6.2 ± 1.6	6.1 ± 1.7	6.3 ± 1.8	6.3 ± 1.7
After (cm)	3.6 ± 1.4*	3.0 ± 1.3*	4.0 ± 1.3*	4.1 ± 1.5*
Change (%)	42 ± 2	51 ± 2‡	37 ± 2	35 ± 2
Quality of sleep				
Before (cm)	5.4 ± 1.8	5.2 ± 1.7	5.3 ± 1.9	5.5 ± 1.7
After (cm)	3.8 ± 1.2*	2.8 ± 1.4*	3.8 ± 1.5*	3.9 ± 1.5*
Change (cm)	30 ± 2	46 ± 2§	28 ± 2	29 ± 2

Mean (± SD) VAS scores, with 0 = the best to 10 = the worst.
VAS = visual analog scale.
* Significantly different from the 24-h period before the first treatment, $P < 0.05$.
† Significantly different from the 24-hr period before the first treatment, $P < 0.01$.
‡ Significantly different from Montages III and IV, $P < 0.05$.
§ Significantly different from Montages I, III, and IV, $P < 0.05$.

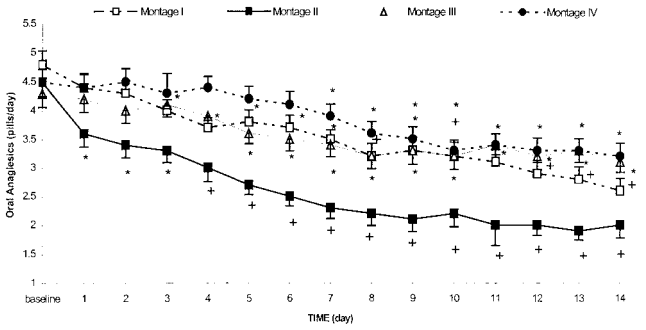

Figure 2. The daily nonopioid analgesic usage (pills per day) during the 2-wk treatment period with each of the four different montages. Baseline refers to the average number of pills consumed per day before entering the study. Values are means ± SEM *Significantly different from the baseline, $P < 0.05$. +Significantly different from Montages III and IV, $P < 0.05$.

effect of the previous montages. To minimize this effect, the montages were evaluated in random order, and a one-week washout period was allowed between the different montages. Finally, the failure to distinguish between the different types of nonopioid analgesic drugs used by the patients may have confounded the interpretation of the effects of the montages on the patient's oral analgesic requirement.

In future studies involving this chronic pain population, the long-term effects of PNT should be evaluated by using the treatment variables that have been established in the preliminary studies (1,5,6). These studies should not only assess pain, physical activity, sleep, and oral analgesic requirements, but also more important outcome measures such as resumption of normal activities and patient satisfaction. Another important area for future investigation relates to the beneficial effects of using PNT as a complementary therapy in a multimodal rehabilitation program (10). Finally, the availability of a simple, inexpensive, disposable electrode system would facilitate the use of PNT in the management of both acute and chronic pain disorders.

We conclude that the pattern of electrical stimulation can influence the effects of PNT even when applied at the same dermatomal levels. Peripheral stimulation along the involved nerve roots appears to be the most effective approach in patients with LBP.

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