Effect of Transcutaneous Electrical Nerve Stimulation Characteristics on Clinical Pain

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We compared the effects of four treatment variables on the pain reduction produced by transcutaneous electrical nerve stimulation and attempted to establish indications for TENS based on patient history and pain evaluation items. Treatment variables were the therapist and the three TENS stimulus characteristics—pulse width, frequency, and amplitude. We randomly assigned 192 consecutive adult patients suffering from painful conditions to one of four physical therapists and one of 12 stimulus characteristic combinations. We used a standard evaluation form that included a visual analog scale (VAS) to evaluate pain. Patients were given a 30-minute trial using TENS, followed by reevaluation. The VAS line length change after treatment was the criterion score for comparison of stimulus characteristic effectiveness. Although pain was reduced greatly with TENS ($p = .01$), a four-way analysis of variance (pulse width, frequency, amplitude, and therapist) attributed little of the treatment effect to the treatment variables or their interactions ($r^2 = .101$). The amplitude effect, however, was borderline ($p = .056$), and subthreshold stimulation proved more effective than stimulation to tolerance ($p = .05$). Extensive multiple linear regression analyses failed to provide indications for TENS based on patient information and pain evaluation items. Therefore, pain remains the only indication for TENS, and we recommend subthreshold rather than higher amplitude stimulation on the initial TENS trial.

Key Words: *Electric stimulation, Pain, Physical therapy.*

Transcutaneous electrical nerve stimulation is a widely used treatment for a variety of painful conditions. Its treatment effect has been shown to differ significantly from non-treated control groups,[1-3] and several clinical series have documented its effectiveness and usefulness.[4-9] No thorough clinical examination, however, of the effects of the different stimulus characteristics and their combinations has been accomplished.

Since the inception of TENS, the selection of stimulus characteristics has been determined by the clinical experience and judgment of the individual applying the stimulation. The clinician has had to choose between high and low frequency, wide and narrow pulse width, high and low amplitude, and all the possible combinations of the above-mentioned stimulus characteristics. The list of stimulus characteristics is growing, and a thorough clinical evaluation of the effects of each of these on a patient's pain potentially would take days to achieve.

Only a few studies to date have attempted to address the clinical effects associated with a limited combination of stimulus characteristics. Andersson et al compared high and low frequency TENS in 12 patients with low back pain.[10] Only 1 patient responded favorably to low frequency, whereas 7 patients responded favorably to high frequency TENS. Mannheimer and Carlsson evaluated the effects of three different stimulus frequencies on 20 patients with rheumatoid arthritis and found that the higher frequency treatments provided better analgesic effects than the lower frequency treatments.[11] Eriksson et al, in a series of 123 patients with chronic pain, found that almost 70% of the patients who continued to use TENS for a three-month period used high frequency stimulation, and 30% of the patients who did not get relief with high frequency TENS found relief with low frequency bursts of high frequency stimulation.[12] Wolf et al studied the effects of various stimulus characteristics and electrode placement locations on the reduction of pain in 114 patients.[13] They were unable to demonstrate that electrode placement or stimulus characteristics had any effect on the amount of pain reduction. In a crossover-designed study, Mannheimer et al studied the effects of two different stimulus intensities and two different electrode

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placement locations on wrist pain in 19 patients with rheumatoid arthritis.[14] They found high intensity TENS and electrodes placed on the wrist to be more effective than either low intensity TENS and a similar electrode placement or low intensity TENS and distal electrode placement.

The results of three of the above studies suggest that high frequency TENS may be more effective than low frequency or low frequency bursts of high frequency stimulation.[10-12] These results, however, are far from conclusive because of inadequate study design,[12] small numbers of subjects,[10,11] or lack of statistical analyses of treatment results. These clinical studies have not proven that one stimulus characteristic or combination of characteristics is better than another for treating pain in general or pain associated with a particular disease or sign-symptom complex. Additionally, no study has been presented that tests interactions between stimulus characteristics.

Our study was undertaken primarily to determine the effects of four TENS treatment variables on the reduction of pain. The treatment variables were the therapist and the three stimulus characteristics—pulse width, frequency, and amplitude. The therapist was included as a treatment variable because the large number of patients required for a three-factorial design on stimulus characteristics with a heterogeneous patient population required more than one therapist. Also, we anticipated that subgroups of the large patient population would share common elements of medical history, sign-symptom complex, or diagnosis. Therefore, we asked the following question: Are certain stimulus characteristics more valuable than others in treating pain associated with particular elements of the medical history, etiology, disease, symptoms, or physical findings? Stated another way: Are any of these elements of patient information, taken either separately or in combination, of value in predicting treatment success with particular combinations of TENS stimulus characteristics?

A secondary purpose of our study, then, was to use patient information and pain evaluation items to establish indications for the use of each of the stimulus characteristics or their combinations. We should emphasize that this was not our primary purpose. Because of the relatively large patient data base, however, we felt obliged to address this prognostic problem.

STUDY DESIGN

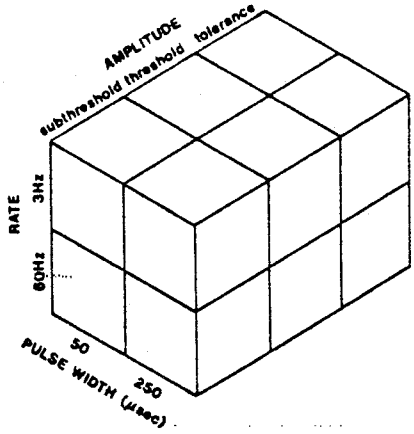

Fig. 1. Study design.

METHOD

We randomly assigned 192 consecutive patients who were referred to the Department of Physical Therapy for reduction of pain using TENS to one of four physical therapists. We also randomly assigned stimulus characteristics as described by one of 12 cells of a 2 × 2 × 3 factorial design (Fig. 1). The stimulus characteristics included in the design were pulse width (50 μsec or 250 μsec), frequency (3 Hz or 60 Hz), and amplitude (subsensory threshold, sensory threshold, or to pain tolerance). The pulse width values were selected because they represented the two ends of the available therapeutic stimulus spectrum. The frequency value of 3 Hz represented a commonly used low frequency and 60 Hz represented a high frequency that has been suggested as effective in reducing clinical pain.[15-17] The three amplitude levels were selected for their clear clinical definitions and common clinical acceptance. Each physical therapist eventually treated 48 patients, 4 patients in each of the 12 cells. Before the patient was assigned to a therapist, a member of the secretarial staff assisted the patient in completing a visual analogue scale (VAS). The scale consisted of a 10-cm line with the words "no pain" on the left side of the scale and the words "intolerable pain" on the right side. The patient marked the line at the point representing his present state of pain. We used the VAS because of its sensitivity, reliability, and ease of use.[18,19] Immediately after the patient completed the VAS, the assigned therapist performed an evaluation that included, but was not limited to, categories listed in the Appendix. After this evaluation, the therapist used his best clinical judgment to place the TENS electrodes, usually interferentially (crisscrossed over the center of pain), on the patient and began a 30-minute trial of stimulation using the assigned stimulus characteristics. After the 30-minute trial, the same member of the secretarial staff readministered the VAS and the patient was reevaluated by the therapist.

Random assignment of treatment variables was essential to the experimental design. Although some clinicians have claimed superior pain relief for a given stimulus characteristic over another for the treatment of specific categories of disease,[10,13] we have not found convincing evidence to support such claims. This issue will be addressed further in the Discussion section.

Data Analysis

A four-way analysis of variance (ANOVA) was conducted to satisfy the primary purpose of our study. Only the percent improvement in the VAS was used in this analysis as follows:

$$\text{percent improvement} = \frac{\text{posttreatment} - \text{pretreatment}}{\text{pretreatment}} \times 100 \quad (1)$$

To achieve our secondary purpose of determining if a relationship existed between treatment outcome and stimulus characteristics in combination with patient information as listed in the Appendix, various multiple linear regression analyses were performed.

Because our experience dictated that many patients would not exhibit satisfactory relief from the first TENS trial, the therapist, at his own discretion, was allowed to change any of the stimulus characteristics and begin a second 30-minute trial. The decision of whether to offer a second trial was left entirely to the discretion of the therapist, based on the success of the first treatment. Seventy-five percent of the second treatments were administered because the patients received less than 50% pain relief from the first treatment. After the second trial, the VAS was administered again by the secretarial staff member and the patient was reevaluated by the

TABLE 1
Patient Information (n = 192)

	%
Duration of painful condition	
Greater than one year	44
Six to 12 months	13
One to 6 months	32
Less than 1 month	10
Primary source of pain	
Orthopedic	50
Neurologic	9
Other	37
Multiple sources	4
Limitations because of pain	
Strength	60
Range of motion	63
Activities of daily living	77
Treatment history of pain	
Surgical	2
Pharmacological	23
Electrical	1
Rest	4
Other	10
Multiple treatments	49
Medication for pain	
Analgesics	30
Anti-inflammatory	23
Relaxation	2
No medication	22
Multiple medication	23

therapist. The purposes of the second trial were the same as for the first trial. In addition, we were able to compare first and second trial conditions and outcomes. Because, however, this subgroup of our larger patient group was unique—that which, in general, responded unfavorably to the first treatment—and because the second trial did not follow a prospective design, we were less optimistic that useful findings could be derived from the second trial data base as from the first trial data.

RESULTS

Table 1 provides descriptions of the patients' history and their painful conditions. The average pain improvement produced in all 192 patients by the first randomized treatment session was 47% ($p < .01$). This includes results for some patients whose pain increased with treatment. Fifty-one percent of the patients attained greater than 50% pain relief. The four-way ANOVA demonstrated no significant difference in the treatment effect among stimulus characteristics or therapists. This analysis included stimulus characteristic interactions but did not include therapist–stimulus characteristic interactions, a meaningless relationship. Little of the total variance in pain change could be explained by the model ($r = .101$). None of the main or interactive effects had F values that were statistically significant at the .05 level. The intensity effect was borderline, however, with a p value of .056. Because the average pain improvement for subthreshold stimulation was 18% greater than for stimulation to pain tolerance (Fig. 2), we believed further analysis of the intensity effect was warranted. Comparison of means by Tukey's Studentized range test demonstrated that subthreshold intensity provided better pain reduction than stimulation to tolerance; this finding was statistically significant at the .05 level. We found no significant differences between subthreshold intensity and sensory threshold or between sensory threshold intensity and stimulation to tolerance.

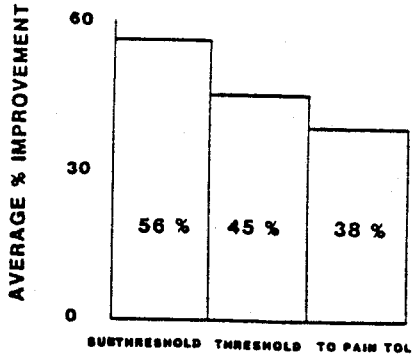

Fig. 2. Percent average improvement associated with amplitude.

To achieve the second purpose of our investigation, a multiple linear regression analysis was used to determine which variables, separately or in combination, were the best predictors of treatment success. The analysis showed that no variables or groups of variables listed in Table 1 could predict accurately treatment outcome when considered in combination with the stimulus characteristics. Therefore, none of our demographic or evaluation data were useful for selecting stimulus characteristics based on the likelihood of success.

Eighty-three patients received a second treatment in which the stimulus characteristics and electrode placements were selected by the therapist. Despite the fact that 21 (25%) of these patients received greater than 50% additional pain relief, an ANOVA failed to demonstrate any significant difference between the stimulus characteristics or their combinations. Table 2 shows the percent of additional pain reduction associated with each of the stimulus characteristics. Little difference exists between the percentages when comparing the levels of each factor individually or when comparing one factor to another. The only exception was for the intensity levels. The percentage of patients receiving greater than 50% additional pain reduction from a subthreshold stimulus was zero, as compared with 26% and 25% for threshold and tolerance groups, respectively. This finding, however, is of no consequence, because only 1 of the 83 patients received subthreshold stimulation on the second trial. Table 3 shows the numbers and percentages of patients who received greater than 50% and patients who received less than 50% additional pain relief for each stimulus characteristic change from the first to the second treatment. These data were subjected to chi-square tests for equality of proportions and failed to demonstrate any pain-relief superiority associated with the changes in the stimulus characteristics between the first and second treatments.

Multiple linear regression analyses similar to those described for the first treatment data also were performed using the results of the second treatment. None of the patient information items or categories in the Appendix, either separately or combined with the stimulus characteristics, demonstrated prognostic significance.

DISCUSSION

In this investigation, we were able to identify the pain-relief superiority of subthreshold amplitude over stimulation to tolerance. The intermediate amplitude, sensory threshold, did not differ significantly from the extreme levels, although the pain-reducing properties were midrange between those of the two extremes. Despite this relationship between stimulus intensity and treatment effect (Fig. 2), none of our therapists changed to subthreshold intensity stimulation for second trials (Tab. 3). As a result of this study, however, many of our therapists now use subthreshold stimulation during their first trial.

The finding that subthreshold amplitude stimulation is more effective in relieving pain than higher amplitude stimulation is contrary to the opinion of some clinicians who prefer stimulation to tolerance.[8,10] Andersson and associ-

ates, who used an amplitude limited by patient tolerance, showed that, in healthy subjects subjected to tooth pain, high amplitude stimulation was necessary to increase the pain threshold.[10] Based on their experience and that of a Peking study, they further claimed that failure of TENS to produce the desired pain relief occurs because patients may not tolerate local stimulation of adequate amplitude to increase the pain threshold at the site of pain. Unfortunately, these investigators neither presented nor cited a controlled study with patients to support this claim.

Some clinicians and TENS manufacturers have claimed that the total current delivered, rather than the amplitude, is the essential pain-reducing characteristic of TENS treatment.[15] If this were true, we would have expected to see an interaction between stimulus duration and intensity. We failed to find such an interaction effect. We are, however, currently testing related hypotheses.

Our findings that stimulus characteristics other than amplitude do not relate to pain relief concur with similar results of Wolf et al who found no clear correlation between stimulus characteristics, electrode placement, and pain relief.[13] In certain instances, however, they found a positive correlation between higher amplitude stimulation and amelioration of pain in cases of radiculopathy or peripheral nerve injury. In both our study and that of Wolf et al,[13] the patient populations were highly variable. Our 192 consecutive patients had different pain complaints, emotional and psychological statuses, and histories. This variability, combined with the inherent difficulty of pain measurement, may have masked treatment effect differences. Bates et al summarized this concept after their analyses of a seven-year series of over 200 patients with chronic pain: "In view of all the variability occurring in patients with chronic pain, the authors think it would be impossible to establish that any of these apparatuses or electrodes are superior to others."[20]

Most studies attempt to restrict the patient population variability to avoid masking a possible treatment effect. Often, attention centers on one or more treatments to patients having a particular disease of interest. For instance, TENS effects have been studied in populations restricted on diagnostic or anatomical bases.[10-14] Although we acknowledge the desirability of reducing population variability, we were unable to find a rationale for restricting the population in our study. Numerous diseases contribute noxious stimuli at varied tissue sites. No evidence, however, suggests that the pain experiences associated with such stimuli are mediated via differing neurological mechanisms as a function of disease or any other subject variable. No evidence proves that the subject's pain response to TENS treatment differs as a function of disease. Adams and Victor emphasized our very limited understanding of pain production and the central mechanisms that mediate the perception of pain when they cited clinical observations that do not support the gate theory.[21] They stated that in certain kinds of peripheral neuropathies characterized by a selective loss of large myelinated fibers (resulting in a pathological predominance of small C fibers that presumably carry painful stimuli), pain is not a feature; in fact, some neuropathies characterized by a predominant loss of small fibers may be quite painful.[21]

In contrast to the observations of Ad-

TABLE 2
Comparison of Percent Additional Pain Reduction for Various Stimulus Characteristics After Second Treatment (n = 83)

Stimulus Characteristics	Additional Pain Reduction			
	>50%		≤50%	
	n	%	n	%
Frequency (Hz)				
3	7	26	20	74
60	14	30	42	70
TOTAL	21		62	
Pulse width (μsec)				
50	13	26	37	74
250	8	24	25	76
TOTAL	21		62	
Intensity				
Subthreshold	0	0	1	100
Threshold	14	26	39	74
Tolerance	7	25	21	75
TOTAL	21		61[a]	

[a] Amplitude data missing for one patient.

TABLE 3
Additional Pain Relief Versus Stimulus Characteristic Change (n = 83)

Stimulus Characteristics		Patients			
		>50% Relief		≤50% Relief	
First Treatment	Second Treatment	n	%	n	%
Frequency (Hz)					
3	60	10	23	34	77
60	3	6	25	18	75
	Constant	5	33	10	67
	TOTAL	21		62	
Width (μsec)					
250	50	6	26	17	74
50	250	6	27	16	73
	Constant	9	24	29	76
	TOTAL	21		62	
Amplitude					
Subthreshold	Tolerance	3	30	7	70
Subthreshold	Threshold	7	35	13	65
Tolerance	Threshold	2	13	13	87
Threshold	Tolerance	1	13	7	87
	Constant	8	27	21	73
	TOTAL	21		61[a]	

[a] Amplitude data missing for one patient.

ams and Victor, our finding that lower amplitude stimulation produces better results than stimulation of higher amplitude is best explained by the basic premise of the gate theory. This premise states that peripheral nerve activity that is dominated by large myelinated fiber firing can block transmission of pain carried by small unmyelinated fibers. Myelinated fibers have lower electrical thresholds than do smaller fibers, thus, explaining why our smallest amplitude was the most effective in reducing pain. Our subthreshold stimulation was the most effective in creating an imbalance between large and small fiber firing and, therefore, was most effective in blocking pain.

One possible explanation for the basic lack of difference in clinical effectiveness between most of the stimulus characteristics is that the stimulus characteristics we tested are equal in producing the treatment effect. The results of our study indicate that stimulus differences may not be very important. The effect of TENS possibly is due to a generalized electrical phenomenon, of which all of the stimulus characteristics we tested are an equal subset. This reasoning can be likened to that associated with the theory of counterirritation. This theory states that a broad class of peripherally applied counterirritants somehow can suppress cortical response to noxious inputs through a mechanism that is not yet fully understood.[17] In our study, the "counterirritant," or its equal, was supplied by the electrical current whose characteristics were varied systematically without altering the effectiveness of the general class of electrical stimulation. Also, it appears that the stimulation need not be perceptible to produce its effect on the nervous system.

A generally accepted notion is that trying a variety of stimulus characteristics will increase the chance of being clinically effective. Mannheimer and Lampe suggested a treatment protocol that included altering stimulus characteristics in a systematic way to improve TENS effectiveness.[15] Indeed, in our second trial, we found that 21 of 83 patients (25%) reported additional relief after changing from one set of stimulus characteristics to another (Tab. 2). This is about one half the response of 51% seen for the first treatment and may reflect a diminished placebo effect associated with another treatment having changed stimulus characteristics. Thorsteinsson et al[1] and Melzack[2] found the placebo effect to be 32% and 38% effective, respectively. We assume for our study that the placebo effect occurred, in the magnitude of 30% to 40%, during the first treatment. Because no statistical significance existed in the treatment effect among stimulus characteristics in the second treatment, we may assume that at least part, if not the majority, of the 25% treatment effect could have been a result of a present but diminished placebo effect.

We conducted extensive analyses in this study to determine the relationship between patient evaluation information (Appendix) in conjunction with stimulus characteristics and TENS treatment effect. We had hoped to discover indications for specific TENS treatment based on information readily available to the physical therapist. Ten percent (r^2 = .101) of the treatment effect was explained by stimulus characteristics alone. Two-way frequency tables were studied and many linear models were tested using multiple linear regression analyses. When all patient evaluation information was included in the model, 26% of the pain improvement was explained by the model. When only those variables with higher partial correlations to improvement were retained in the model, all stimulus characteristics had been excluded systematically, and only 16% of the pain improvement was explained. Therefore, the model was of no value for matching patients and selected combinations of stimulation characteristics to improve the probability of treatment success. We were disappointed, but not surprised, that our model accounted for only 26% of the treatment effect. Although this study addressed many factors in a comprehensive manner, a number of treatment variables and patient factors remain that were not studied. Since the completion of this study, we have begun a number of parallel studies that systematically address various additional treatment factors with more limited patient populations than were used in this study. In addition, we are currently involved in a cooperative pain control study that is emphasizing the psychological aspects of pain as previously investigated by Turk et al.[22,23]

Despite our population variability, 51% of our subjects had greater than 50% pain relief after their first treatment. This compares very favorably to other reports on TENS effectiveness. From these findings, we believe that TENS, applied interferentially around the anatomical site of pain, can be used effectively to help manage a variety of painful conditions and that pain is the only indication for a TENS trial.

In view of the emphasis that clinicians and educators have placed on patient history and physical examination before treatment, we were disappointed that none of our evaluation items were of value in matching patient conditions to effective stimulus characteristics. This finding underscores the significant need

APPENDIX
Items Used in Evaluation

1. Source of pain
   a. Neurological origin
      1. Peripheral neuropathy
      2. Peripheral nerve injury
      3. Radiculopathy
      4. Herpes Zoster
      5. Sympathetic system
      6. Central pain syndrome
      7. Headache
   b. Orthopedic origin
      1. Arthritis
      2. Fracture
      3. Bursitis
      4. Bony metastasis
      5. Back pain with radiculopathy
      6. Neck pain with radiculopathy
      7. Back pain without radiculopathy
      8. Neck pain without radiculopathy
   c. Other
2. Is strength limited by pain?
3. Is range of motion limited by pain?
4. Is patient tender to palpation?
5. Previous treatment for this painful condition?
   a. Surgical
   b. Pharmacological
   c. Electrical
   d. Rest
   e. Other
6. Length of time painful condition has been present?
   a. Less than one month
   b. Between one month and six months
   c. Between six months and one year
   d. Greater than one year
7. Medications now taking?
   a. Anti-inflammatory
   b. Analgesic
   c. Relaxation or mood altering
   d. None
8. Activities that are significantly limited by pain?
   a. Employment
   b. Homemaking
   c. Leisure time
   d. Social activities
   e. None
   f. Other

for further investigation into mechanisms through which TENS produces its effects.

SUMMARY

We evaluated the effects of rate, pulse width, amplitude, and therapist on TENS treatment outcome and observed substantial reduction in pain. Subthreshold amplitude proved superior to high amplitude in reducing pain. A second TENS trial with changed stimulus characteristics produced additional relief for many patients who did not respond satisfactorily to the first trial. Extensive multiple linear regression analyses failed to explain treatment response differences among patients on the basis of demographic and pain evaluation information. Therefore, pain remains the only indication for TENS; we recommend subthreshold over high amplitude stimulation on the first trial and at least one additional TENS trial of different stimulus characteristics if the first trial is unsuccessful.

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