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Transcutaneous Electrical Stimulation: A Double-Blind Trial of its Efficacy for Pain

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A double-blind trial was done using a stimulator and a placebo device on patients who had chronic pain to determine the effectiveness of transcutaneous electrical stimulation in controlling pain. Ninety-three patients were studied, and 83 of these completed the Minnesota Multiphasic Personality Inventory (MMPI). Thirty-three patients had low-back pain and 24 had neuropathies. The stimulator was more effective than the placebo during treatment when used over the center of pain ($P<.005$) or over an unrelated nerve trunk ($P<.01$) and after treatment over the center of pain ($P<.05$). The stimulator was significantly more effective than the placebo in neuropathies when stimulating over the related nerve trunk ($P<.005$), where the stimulator response was nearly three times better than that of the placebo. The duration of subsequent relief was not significantly different after treatment with the stimulator or with the placebo device. Follow-up showed significant declines in the use and effect of the stimulator with the greatest decline noted by the depressed group.

In 1965, Melzack and Wall[1] introduced a new theory on the neurophysiologic mechanism for pain. They theorized that a therapeutic effect on the gate control could be obtained by using nonpainful tactile stimuli to enhance the input in the large-fiber system. This in turn would modulate the stimuli over the part of the small-fiber system that is related to the pain sensation and would result in analgesia. Since then, several reports have indicated that transcutaneous electrical stimulation is useful in controlling pain.[2-9] None of these studies was double-blind, and none specified the clinical indication for the use of the stimulator. The goal of our study was to determine, by double-blind trial, the effect of the stimulator and the indications for its use.

Methods and Materials

The efficacy of transcutaneous electrical stimulation was studied on outpatients with chronic pain. To be included in the study, the patient must have had chronic pain that lasted more than one month, a complete medical workup, and no relief from other appropriate therapy. Each patient was told that the study was double-blind, consisting of treatment sessions with a genuine stimulator and with a placebo device that gave no electrical output into the electrodes. The expected sensation of stimulation was explained to each patient, and each was asked to record the effectiveness of the device in relieving pain and the duration of relief after treatment. Each patient was to complete the Minnesota Multiphasic Personality Inventory (MMPI).

Each patient was assigned to a randomized treatment schedule that was known only to the supervisors of physical therapy. The sequences of device use and of sites treated were randomized and had a crossover design. In an attempt to decrease the patient's opportunity to learn the placebo, every patient received either all of the stimulator treatment first or all of the placebo treatment first. Each patient had three treatment sessions at different times with the stimulator and three treatments at different times with the placebo device. One type of treatment was completed before the other type was begun. Each treatment session lasted 20 minutes, and the six sessions were usually completed within three days. The following sites were treated with each device: the area over the center of pain, the area over a related nerve trunk, and the area over an unrelated nerve trunk. The selected related nerve trunk was the trunk that innervated the center of pain, and if this was not easily accessible, a nerve trunk from the same spinal segment that supplied the center of pain was selected. The selected unrelated nerve trunk was always one on the side of the body opposite the center of pain, or if the center of pain was in a lower extremity, a nerve trunk in the upper extremity was selected (or vice versa).

The physical therapists applied the device, but they had no knowledge of whether the device was a placebo device or stimulator. They had previously been instructed on the use of the device and were told of the design and goals of the trial. They positioned the patient and applied the electrodes as directed by the physician and the randomized schedule. The range of electrical outputs that the patient could tolerate was used in an effort to find the optimal setting for pain relief. That setting was selected, and the machine was used for 20 minutes for each session. A new setting was selected before each treatment session. This was necessary because prefixed setting would have limited the therapeutic value of the stimulator.

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Table 1: Characteristics of Pain in Group Undergoing Transcutaneous Electrical Stimulation Study

	No. of subjects (N = 93)		
	Aggravation	Relief	No effect
Standing	61	8	24
Walking	63	8	22
Working	81	2	10
Resting	10	42	41
Drugs	0	41	52
Physical therapy	23	23	47

A physician (G.T.) who did not know whether the device was a placebo machine noted the effect on pain relief during and after the treatment as well as the duration of the subsequent relief. The effects were graded as no effect, partial relief, complete relief, or aggravation of pain. A different physician evaluated the results at the end of the six treatment sessions and discussed with the patient whether he wanted to continue to use the stimulator at home. If the patient decided to continue he was given instructions, but he was permitted free selection as to which of the three sites to stimulate and as to the duration of stimulation.

The transcutaneous stimulator used was the Stimtech EPC Personal Stimulator (Stimulation Technology Co., Minneapolis). The pulse generated is a modified rectangular pulse, and the output has a constant current characteristic, which is adjustable from 0 to 50 mA (personal communication from N. Hagfors). The duration of the pulse is adjustable from 50 to 500 μs, and the frequency is adjustable from 15 to 180 pulses/sec. Surface electrodes made of medical grade stainless steel in a cellulose sponge were used for contact with the skin, and tap water was used as electrolyte solution. Follow-up at three months and at six months was done by questionnaire on the 93 patients who completed the trial to determine whether the patient continued to use the stimulator and received benefit from it.

Table 2: Diagnostic Groups in Transcutaneous Electrical Stimulation Study

	No. of patients	
	Primary	Secondary (associated)
Malignant disease	0	1
Tauma (posttraumatic)	5	20
Neuropathy	24	6
Arthritis	3	7
Amputation	0	1
Pelvic floor pain	1	1
Other neurologic problems	6	4
Surgery (postsurgical)	5	50
Low-back pain	33	14
Neck pain	5	13
Psychiatric	0	7
Neuroma	3	1
Fracture	1	1
Other orthopedic problems	7	3

Various statistical tests were used, depending on the problem to be solved. The tests most used were the following: Student's t test, test on percentages (modified t test), delta t test, chi-square goodness of fit (χ^2-goodness of fit), one-way analysis of variance test (one-way AOV). Wilcoxan signed-rank test, test of least significant difference (LSD). Kruskel-Wallis one-way analysis of variance by rank, and a few other less used tests.

Results

A total of 107 patients entered the study, and 93 (53 women and 40 men) completed the trial. The age distribution for the women and men had the same mean (48.7 years) and standard deviation (11.8 years). The duration of the pain syndrome varied from 1 month to 30 years: 17% less than 1 year and 50% 1 to 5 years. The average duration of the pain syndrome was 4 years 10 months. The characteristics of the pain also varied (table 1). Of the 93 patients, 82 reported constant pain and 30 had more than one center of pain. The primary diagnosis and the secondary associated conditions are listed in table 2. Thirty-three patients (22 women and 11 men) had low-back pain. Thirty of these patients had previous surgery: 18 had laminectomy and 12 had laminectomy plus fusion. Fifteen patients with low-back pain had histories of trauma. Other conditions associated with the low-back pain were arthritis of the spine, psychiatric problems and neurologic problems (other than

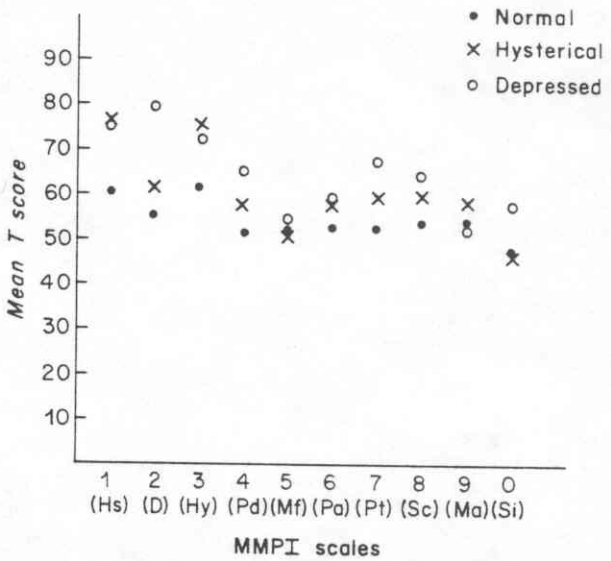

Fig 1—Mean T scores on MMPI scales for three groups of patients with chronic pain syndromes. Scales: 1 = Hs = hypochondriasis, 2 = D = depressed, 3 = Hy = conversion hysteria, 4 = Pd = psychopathic deviate, 5 = Mf = masculinity-feminity, 6 = Pa = paranoia, 7 = Pt = psychasthenia, 8 = Sc = schizophrenia, 9 = Ma = mania, 0 = Si = social introversion.

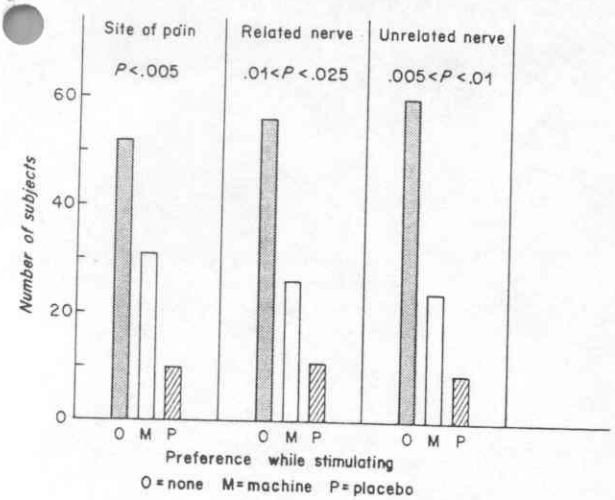

Fig 2—Number of patients and preference for device, while stimulating, according to site treated. Probability of effect difference between stimulator and placebo is shown.

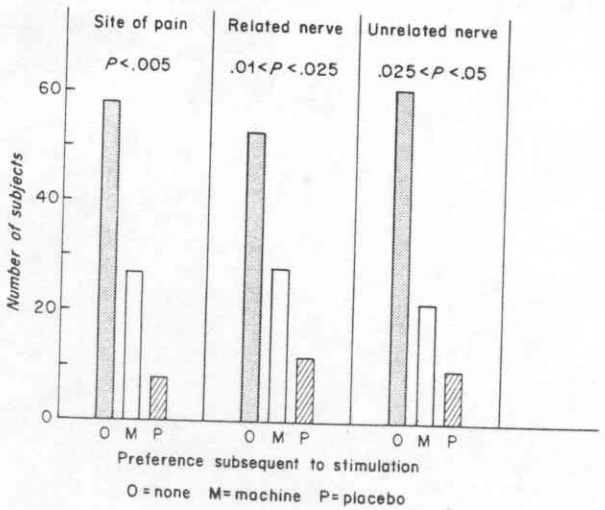

Fig 3—Number of patients and preference for device, subsequent to stimulation, according to site treated. Probability of effect difference between stimulator and placebo is shown.

radiculopathy). Twenty-four patients (16 men and 8 women) had neuropathy (proved in 15 by nerve conduction studies and electromyography): 10 had radiculopathy, 6 had postherpetic neuropathy, 2 had diabetic neuropathy, and 6 had other neuropathies. The other diagnostic groups were too small for valid statistical analysis.

Eighty-three patients completed the MMPI. These 83 patients were divided into three personality groups, according to the T scores on the first three clinical MMPI scales: hypochondriasis, depression and hysteria (fig 1). There were 30 patients in the group with normal MMPI (19 women and 11 men) who had T scores lower than 70 on the first three clinical scales. The hysterical group consisted of 30 patients (19 women and 11 men) who had elevated scores on scales 1 and 3 (hypochondriasis and hysteria) but lower scores on scale 2 (significantly lower by 8 or 10 score points).[10] The depressed group consisted of 23 patients (12 men and 11 women) who had elevation on scale 2 but did not have an hysterical profile.

The effectiveness of the stimulator was compared with the effectiveness of the placebo for each patient in the series. This was done by matching the effect of the stimulator to that of the placebo for the same site treated in each patient. A better effect from one device was called "preference" for that device (fig 2 and 3), and equal effect gave no preference. Comparison of effectiveness was done separately on the effect during application (fig 2) and subsequent to application (fig 3). The effectiveness was then also evaluated according to diagnosis, sex, and personality characteristics. The stimulator was significantly more effective (higher preference) than the placebo in the following situations: first, in the overall series, (1) during application over the center of pain ($P<.005$); (2) subsequent to application over the center of pain ($P<.005$); and (3) during application over unrelated nerve trunk ($P<.01$); second, in the group of patients with normal MMPI during application over unrelated nerve trunk ($P<.005$); and third, in the group of patients with neuropathies both during application over related nerve trunk ($P<.01$) and subsequent to treatment over related nerve trunk ($P<.005$).

Forty-one patients received the stimulator first, and 53 received the placebo first (unequal numbers because some of the patients did not complete the trial). No significant order effect was detected.

The effect of stimulator treatment in relieving pain was recorded as complete or partial (both successful responses) or none or aggravation of pain (both failures). Successful responses with the stimulator and with the placebo device were more frequent when treating over the center of pain than when treating over the related nerve trunk, which in turn was more frequent than when treating over an unrelated nerve trunk (table 3). Aggravation of pain was reported 11 times when using the stimulator (5 times while stimulating and 6 times subsequent to stimulation) and 8 times while using the placebo machine. This difference was not significant.

A successful response with the stimulator occurred in 48.7% during treatment and in 47.3% subsequent to treatment. For the placebo machine, a successful response occurred in 33% while using the machine and in 31.5% subsequent to its use.

Patients noted subsequent (lasting) relief more frequently after using the stimulator than after using the placebo machine, but this difference was not significant (table 4). There was no difference in frequency

Table 3: Type of Responses (in Percentages) to the Stimulator and Placebo While and Subsequent to Treatment Over the Three Different Sites of Application

Site of treatment		Stimulator*				Placebo*			
		+2	+1	0	-1	+2	+1	0	-1
Over center of pain	W†	10.8	48.4	37.6	3.2	6.5	34.4	58.1	1.1
	S†	12.9	40.9	40.9	5.4	6.5	30.1	61.3	2.2
Over related nerve trunk	W	8.6	41.9	49.5	0.0	3.2	33.3	61.3	2.2
	S	6.5	43.0	50.5	0.0	5.4	28.0	65.6	1.1
Over unrelated nerve trunk	W	4.3	32.3	61.3	2.2	4.3	17.2	77.4	1.1
	S	8.6	30.1	60.2	1.1	5.4	19.4	74.2	1.1

*+2, complete relief; +1, partial relief; 0, no relief; and -1, aggravation of pain.
†W, while treating; S, subsequent to treatment.

distribution of the duration of subsequent relief between the stimulator and the placebo for any site treated. There were no differences in duration of subsequent relief after using the stimulator or the placebo among personality groups and between diagnostic groups.

Follow-Up

At the end of the trial, the stimulator was prescribed for 48 patients (table 5). Of these, 42 (87.5%) were followed up for three months and 33 (68.8%) for six months. Of the 45 patients for whom the stimulator was not prescribed, 39 (86.7%) had three-month follow-up and 30 (66.7%) had six-month follow-up.

Of the 48 patients who had used the stimulator at the structured trial, at three-month follow-up 27 were still using it; at six months, only 21 were still using it, which was a significant decline ($P<.005$). Comparison of the declines experienced by the two diagnostic groups revealed no differences in decline in use. Comparison of the decline in use among the personality groups revealed that the decline was greatest in the depressed group (table 5). Lack of significant pain relief was the main reason given for decline in stimulator use after the trial.

Most of the patients stimulated the area over the center of pain, but at six-month follow-up, there was some evidence of a shift toward using the stimulator over a related nerve trunk. There was also evidence of increased stimulation time at six-month follow-up ($P<.01$). Most frequently, the stimulator was used once or twice a day. Only three patients reported complete relief at three months and only one reported complete relief at six months. When this follow-up report by the patients was compared with their report on the relief for the same site treated during the trial, there was a significant decline in report on complete relief ($P<.005$). The duration of subsequent relief did not change significantly during the follow-up period. There was evidence of decreasing use of tranquilizers during the first three months, both by the group that still used the stimulator ($P<.025$) and by the group that did not ($P<.05$), but the use of tranquilizers increased again during the next three months. No significant change was observed with continuing use of the stimulator in the ability of the patients to work or to perform daily activities at six-month follow-up, as compared with the abilities at the time of the trial (fig. 4).

Table 4: Duration of Subsequent Relief According to Site Treated and Device Used

Site and model	N*	Duration, hour		
		Mean	SD	SE
Center of pain				
Placebo	33	3.84	2.29	0.40
Stimulator	48	3.90	2.17	0.31
Related nerve				
Placebo	30	6.77	3.21	0.59
Stimulator	44	5.26	3.37	0.51
Unrelated nerve				
Placebo	22	4.21	2.06	0.44
Stimulator	33	5.17	2.83	0.49

*Number of subjects reporting subsequent relief.

Discussion

The study revealed that transcutaneous electrical stimulation was indicated in painful neuropathies and that the best effect was obtained when stimulation was directed over the nerve trunk related to the painful area. This is in agreement with the results that Wall and Sweet[7] had in their small series of patients with neuropathies whom they stimulated over the related nerve. Meyer and Fields[8] had similar results with stimulating the related nerve in patients who had causalgia. The most likely explanation for this pain relief is that the electrical stimulation provides tactile stimulus for central inhibition.[11] Another alternative to explain this pain relief was indicated by Taub,[12] who emphasized the blocking mechanism of electrical current on nerves. This blocking mechanism does not apply to the many patients who had radiculopathies and had the stimulation distal to the lesion. It may be that the same mechanism was at work when the stimulation was successful in relieving pain during use over the center of pain (especially in low-back pain syndromes). How much the pain relief was related to relief of muscle spasms, which accompany the low-back pain, has to be left unanswered at this stage. The

Table 5: Results of Follow-Up of 49 Patients*

		3-month follow-up			6-month follow-up		
	N	Using	Not using	No follow-up	Using	Not using	No follow-up
MMPI							
Normal	18	11	7	0	9	8	1
Hysterical	18	13	4	1	9	2	7
Depressed	9	2	4	3	2	2	5
None	4	2	1	1	1	1	2
Females	30	18	11	1	13	9	8
Males	19	10	5	4	8	4	7
Diagnosis							
Neuropathy	12	6	4	2	5	4	3
Low-back pain	21	13	7	1	10	4	7
Other	16	9	5	2	6	5	5
Total	49	28	16	5	21	13	15

*Stimulator prescribed for 48 patients, and 1 man obtained it on prescription from outside source.

finding that the stimulator was more effective than the placebo during stimulation over an unrelated nerve (in patients with normal MMPI) does indicate that modulation of pain does take place over other parts of the nervous system rather than over only the segment of the spinal cord that supplies the painful area.[13] There were 13 patients (14%) who had no benefit from the stimulator or the placebo for any of the sites used. Six of these patients were in the depressed group. Patients with abnormal MMPI profiles tended to rate their pain relief higher than did patients with normal MMPI profiles. This was true for their relief from the stimulator as well as from the placebo.

The placebo effect was similar to the effect described in other double-blind trials[14] in which placebo medications were used. This was evident by the placebo effect being highest when the apparent effect of the stimulator was highest (over the center of pain) and lowest when the apparent effect of the stimulator was lowest (over the unrelated nerve). Also the time effect (duration of relief) was similar for the placebo and the stimulator; that is, no significant differences were found between the means in duration of subsequent relief for the two devices.

The number of patients using the stimulator declined with continuing use, as did the incidence of complete pain relief. It may be that the stimulator can effectively relieve pain partially, the report of complete relief during the trial period being rather a part of the "placebo complex."

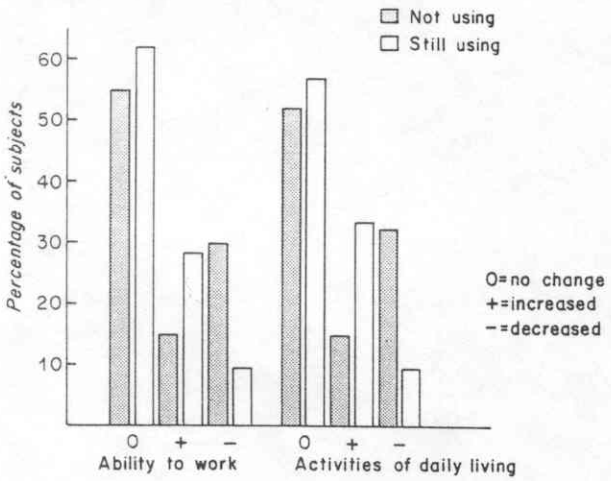

Fig. 4—Comparison between group that used stimulator and group that did not in ability to work and carry out daily activities at 6-month follow-up.

Conclusions

1. Transcutaneous electrical stimulation was successful (relieved pain) in only 48% of the instances in which it was used in patients with chronic pain syndrome. The placebo device was successful in 32%. This difference is not enough to allow the indiscriminant use of the stimulator in these patients.

2. Transcutaneous electrical stimulation is indicated in patients with painful neuropathies in whom medical or surgical (or both) treatment is not successful in controlling the pain.

3. There was no difference in duration of subsequent relief after the structured treatment trial between the stimulator and the placebo device.

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