A CONTROLLED TRIAL OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) AND EXERCISE FOR CHRONIC LOW BACK PAIN

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Abstract A number of treatments are widely prescribed for chronic back pain, but few have been rigorously evaluated. We examined the effectiveness of transcutaneous electrical nerve stimulation (TENS), a program of stretching exercises, or a combination of both for low back pain. Patients with chronic low back pain (median duration, 4.1 years) were randomly assigned to receive daily treatment with TENS (n = 36), sham TENS (n = 36), TENS plus a program of exercises (n = 37), or sham TENS plus exercises (n = 36).

After one month no clinically or statistically significant treatment effect of TENS was found on any of 11 indicators of outcome measuring pain, function, and back flexion; there was no interactive effect of TENS with exercise. Overall improvement in pain indicators was 47 percent with TENS and 42 percent with sham TENS (P not significant). The 95 percent confidence intervals for group differences excluded a major clinical benefit of TENS for most outcomes. By contrast, after one month patients in the exercise groups had significant improvement in self-rated pain scores, reduction in the frequency of pain, and greater levels of activity as compared with patients in the groups that did not exercise. The mean reported improvement in pain scores was 52 percent in the exercise groups and 37 percent in the nonexercise groups (P = 0.02). Two months after the active intervention, however, most patients had discontinued the exercises, and the initial improvements were gone.

We conclude that for patients with chronic low back pain, treatment with TENS is no more effective than treatment with a placebo, and TENS adds no apparent benefit to that of exercise alone. (N Engl J Med 1990; 322: 1627-34.)

IN the United States low back pain, often of a chronic nature, results in expenditures of $13 billion a year for medical care.[1-4] A number of simultaneous treatments are usually advocated for patients with chronic pain, but few of these treatments have ever been subjected to rigorous clinical evaluation.

Transcutaneous electrical nerve stimulation (TENS) is widely used in the management of chronic pain.[5] The use of conventional (high-frequency) TENS was originally based on the gate-control theory of pain,[6] which suggested that counterstimulation of the nervous system could modify the perception of pain. Later studies suggested that with low-frequency, high-amplitude ("acupuncture-like") stimulation, TENS could also raise endorphin levels in the spinal fluid.[7] Nationwide data on the use of TENS are unavailable, but in 1986 the Veterans Administration spent nearly $2 million on TENS units, and the labor costs for personnel to operate the device are high. TENS units are approved for payment by most third-party payers, including Medicare.

Despite its wide use and theoretical rationale, there is meager evidence from controlled clinical trials of the

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efficacy of TENS in treating chronic back pain. Early studies were uncontrolled or nonrandomized.[8-11] Later trials suffered from unreported dropout rates, inadequate blinding, small samples, or crossover designs that precluded patient blinding.[12,13] One randomized trial found "subthreshold" TENS (stimulation at an imperceptible amplitude) to be no more effective than sham TENS for low back pain.[14] A therapeutic trial in patients with arthritis similarly found conventional TENS to be ineffective.[15] The Quebec Task Force on Spinal Disorders concluded that randomized, controlled trials had produced no convincing evidence of the efficacy of TENS.[16]

Various exercise regimens are also advocated for low back pain, but the Quebec task force again concluded that there was no evidence from adequately designed randomized trials to demonstrate the efficacy of either strengthening or stretching exercises.[16] Nonetheless, a program of stretching exercises has been implemented by a popular voluntary organization, and uncontrolled follow-up suggests that the condition of many participants improves.[17-19] Many consider exercise to be a mainstay of chronic pain therapy,[20,21] because it increases muscle tone, flexibility, mechanical efficiency, and the patient's involvement in therapy. The paucity of evidence for the efficacy of TENS or stretching exercises led us to conduct a randomized trial to examine the treatments alone and in combination.

Methods

Selection and Evaluation of the Subjects

Potential subjects were sought by newspaper advertising in San Antonio. Respondents were screened by telephone, and interviews were scheduled for those who appeared to be eligible and interested. Enrollment continued from April 1985 through November 1987. Subjects were treated at the outpatient facilities of the University of Texas Health Science Center at San Antonio.

Enrollment required low back pain of at least three months' duration, considered by many to represent the onset of chronic pain.[22] Criteria for exclusion were a history of cancer, the use of corticosteroids or anticoagulant agents, maximal pain above vertebra T-12, age over 70 or under 18 years, the use of a cardiac pacemaker, known heart disease, severe coexisting disease, or a previously unevaluated neurologic deficit. Candidates were also excluded because of factors that would impair follow-up, including the inability to keep twice-weekly appointments, plans to move within three months, inaccessibility by telephone, and inability to speak English. To enhance the blinding of the subjects to their treatment assignment, we excluded candidates who had previously used TENS, and we also excluded those seeking or receiving disability compensation.[23] Eligible subjects provided informed consent, completed baseline questionnaires, and were scheduled for a physical examination at a second visit. The allocation of treatment occurred after the physical examination was complete and full eligibility had been established. The subjects' medical records were requested in order to obtain reports of lumbar spinal imaging studies and laboratory evaluations. Some abnormalities were evaluated further, but no subject was excluded because of imaging or laboratory results. The study protocol was approved by the institutional review board of the University of Texas Health Science Center at San Antonio.

Treatment Assignment

The subjects were randomly assigned to one of four groups: TENS plus exercise; TENS alone; exercise with sham TENS; or sham TENS alone. Other treatments (e.g., heat) were uniform and are described below. Random assignment was performed in blocks of four to ensure approximately equal numbers in the treatment groups. The assignments were drawn from sealed envelopes and were determined by means of a table of random numbers.

Compliance and Cointerventions

Compliance with the TENS treatment and exercise regimen was assessed in several ways. We recorded the number of appointments for treatment that each subject actually kept, and each subject also kept a daily diary indicating whether and for how many minutes the treatments were used. The subjects in the exercise groups were asked to demonstrate the exercises at each visit, and accuracy was rated on a four-point scale (1 being excellent, and 4 poor). At each evaluation, the subjects were asked about the use of new medications, physical therapy, other health care providers, or hospitalization for back pain. Specific treatments were not proscribed, and we expected random allocation to result in similar cotreatments in all the study groups.

Treatment Description

TENS was performed with Epix 982 units (EMPI Corp., St. Paul), each with four round, carbon-impregnated rubber electrodes 5.5 cm in diameter. Identical but nonfunctioning units were provided by the same manufacturer. All the units had "on" lights that flashed at the chosen stimulation frequency and low-battery-indicator lights. All used 9-V, rechargeable nickel–cadmium batteries. The units were given to the subjects with both written[24] and oral instructions for home use, to be undertaken at least three times a day for 45-minute periods. The subjects in the TENS groups received conventional high-frequency TENS for two weeks (80 to 100 pulses per second at an amplitude setting of 30) and were then instructed in acupuncture-like TENS (2 to 4 pulses per second at an amplitude setting of 100). The modulated-pulse-rate mode was used for all stimulation. In this mode, the device automatically and periodically alters the rate of stimulation to reach an average of the specified frequency in each second. After trying acupuncture-like TENS, the subjects selected the mode they preferred for the last two weeks of treatment. The electrodes were initially placed over the area of most severe pain, and they were then moved as necessary to optimize pain relief. For subjects with sciatica, electrodes were placed on the leg as well as the back. The subjects in the sham-TENS groups received identical instructions and similar adjustments in the placement of the electrodes. All the subjects were told that they might or might not perceive stimulation from the units, that stimulation was sometimes below a person's threshold of perception, and that this should not be of concern.

Exercises were adapted from those developed by Kraus and popularized by the Young Men's Christian Association (YMCA),[17,19] and also from the work of Tollison and Kriegel.[25] Rather than individual regimens, we prescribed a uniform set of 12 sequential exercises. Three initial relaxation exercises were followed by nine exercises designed to improve the flexibility of the spine, hip, and lower extremities. These included leg-stretching and "bend-sitting" exercises (exercises 4, 11, and 17 to 20 of Kraus,[19] and the heel-cord stretch, hamstring stretch, and knee–chest stretch of Tollison and Kriegel[25]). The subjects began with the 3 relaxation exercises and were advised to add a new exercise each day until they were performing all 12. Every day each exercise was performed in sequence, with two or three repetitions, and the sequence was then performed in reverse order. Repeated instruction, feedback, and written information were provided to maximize compliance.[26]

The treatments were administered for four weeks, during which the subjects were asked to make twice-weekly visits. At these visits, all the subjects received moist-heat treatment (hot packs), adjustments in the placement of the TENS electrodes, and written and oral advice concerning lifting, standing, and resting positions. We also loaned the subjects electric heating pads for home use and advised them to apply the pads to painful areas for 10 minutes twice a day. For those in the exercise groups, the application of heat was recommended just before exercising. This regimen provided all the

subjects with credible treatment and equal time and attention from the research staff. After the intervention period, the subjects in the exercise groups were encouraged to continue exercising with the help of the written materials. All the subjects were informed of possible sources of continuing TENS therapy, but this could not be provided by the research staff after the first month.

Follow-up, Assessments of Outcome, and Blinding

Physical examinations and questionnaires were repeated after two and four weeks of therapy, and again two months after the intervention period had ended. Because the four-week evaluation came after the subjects had selected the mode of TENS stimulation they preferred and after four weeks of intensive exercise, we assumed that it would reflect the maximal benefit of treatment. Its results were therefore taken as the primary outcome. The subjects were reminded of assessment visits by postcard or telephone, and if they did not keep an appointment, we made a number of attempts to reschedule, interview by telephone, or obtain a mailed-in questionnaire.

Measures of outcome were grouped in four categories: functional status, which included a modified Sickness Impact Profile (a comprehensive health-status questionnaire previously validated for use in low back pain)[27,28] and a self-assessment of whether the subject's level of activity increased, decreased, or was unchanged; pain ratings, which included a self-assessed overall-improvement rating on a six-point ordinal scale (1 = pain entirely gone, and 6 = much worse), a 10-cm visual-analogue pain scale, a 10-cm visual-analogue scale of improvement (from 0 to 100 percent), and an ordinal scale of pain frequency (1 = never, and 5 = all the time); physical measures, including the extent of straight-leg raising on the more limited side (using a gravity goniometer), spinal and hip flexion as assessed by the distance from the fingertips to the floor on maximal forward flexion, and spinal flexion as measured by the Schober test[29]; and the use of medical services, including visits to other health care providers for back pain and hospitalization. The Sickness Impact Profile was modified by deleting the categories of eating and communication, previously shown to be largely irrelevant to patients with back pain.[27] Response formats for part of the category of work were slightly modified to improve clarity. All measures of outcome were obtained either by the subjects themselves or by evaluators (physicians or nurse practitioners) blinded to the TENS or exercise assignments.

At the four-week assessment, the success of blinding to TENS therapy was examined by asking the evaluator and the subject to guess whether the subject had received true or sham TENS. Patients were asked to rank their certainty about therapy on a five-point scale (1 = "I am certain my TENS unit was working properly," and 5 = "I am certain my TENS unit was not working properly"). Only the research assistant who supervised both TENS and exercise was aware of the treatment assignments, and she performed no evaluations of outcome.

The reproducibility of scores on the Sickness Impact Profile has been well established in previous studies.[27,30] We assessed the reliability of the other indexes by measuring each index twice in 10 to 15 subjects at the same visit. Visual-analogue scales and ordinal scales of pain and activity had test–retest intraclass correlations ranging from 0.88 to 1.00. Intraclass correlations between observers for physical examinations (straight-leg raising and flexion) ranged from 0.49 to 0.99.

Statistical Analysis

A multivariate analysis of variance was used as a single overall test of the effects of treatment. The analysis employed all four-week measures of outcome as dependent variables and treatment assignment as the independent variable. Because there were no hospitalizations for back pain during the study and few visits to other health care providers, these were not included in the multivariate analysis.

Individual analyses of variance were then performed for each of the outcome measures. For measures with base-line scores, the base-line values were entered as covariates. The results presented in the tables are adjusted means with tests for significance from these analyses. Confidence intervals for group differences were calculated with use of a linear model.[31] Finally, the analyses of variance were repeated, with all base-line characteristics that showed appreciable differences among study groups entered as covariates to determine whether the results would change. All the analyses were performed with the Statistical Package for the Social Sciences, version 10.[32]

Results

Study Sample

There were 543 telephone responses to our recruitment publicity. Ninety-six people declined to participate, and 302 were excluded. The most common reasons for exclusion were the inability to attend twice-weekly appointments (97 people), pain of less than three months' duration (43), the previous use of TENS (41), and disability compensation (31). Thirty-seven people were excluded because of coexisting conditions or previously unevaluated neurologic deficits.

Thus, 145 subjects were enrolled and randomly assigned to study treatments: 36 to TENS alone (group 1), 37 to TENS plus exercise (group 2), 36 to no exercise and sham TENS (group 3), and 36 to exercise and sham TENS (group 4). By the four-week assessment, 20 subjects had dropped out (14 percent): 5 from group 1, 3 from group 2, 5 from group 3, and 7 from group 4 ($P = 0.6$). The most common reasons for dropping out were inconvenience and difficulties with transportation (11 subjects); only 1 dropout (who was receiving both active treatments) reported that the treatments were of no help. The dropouts and the remaining subjects were similar with regard to most base-line demographic, historical, physical, and functional traits, although the dropouts had a shorter median duration of pain (24 vs. 60 months) but greater severity. At the three-month follow-up, data were obtained for 122 subjects (84 percent).

Characteristics of the Subjects

Demographic and clinical characteristics of the subjects for whom follow-up data were available are shown in Table 1. Only the proportions of those with a neurologic deficit or previous hospitalization for back pain differed significantly among groups. When all the TENS subjects were compared with all the sham-TENS subjects, only mean educational level was significantly different (13.7 vs. 14.9 years, respectively). There were no significant differences between all the exercise subjects and all the nonexercise subjects. Sixty-six percent of the subjects were white, 31 percent Mexican American, 2 percent black, and 1 percent belonged to other ethnic or racial groups. Fifty-six percent of the subjects had coexisting conditions, the most common being arthritis, hypertension, and diabetes. At entry, 70 subjects were employed outside the home, 20 were homemakers, 28 were retired, and 7 were unemployed. The most common occupations were teaching, nursing, accounting, and sales.

We agree with expert panels that have concluded that a definitive diagnosis cannot be made for most subjects with low back pain.[16,33] Thus, study physi-

cians usually gave nonspecific diagnoses, such as chronic lumbar strain or myofascial pain, with or without signs of nerve-root irritation (93 percent). Another 3 percent of the subjects were thought to have pain due to degenerative disk disease, and the remainder were given a variety of diagnoses. Radiographic diagnoses (not necessarily considered the causes of pain) are shown in Table 1.

The study subjects had more favorable psychological profiles and employment status and used narcotic drugs less than the patients attending our outpatient pain clinic.[34] Most subjects described their pain as moderate or mild. Thus, they resembled patients with chronic pain managed by personal physicians more than those treated at chronic-pain centers. Nonetheless, previous medical care for low back pain was common, as Table 1 shows in part. Eighty percent of the subjects had used pain medications, 42 percent had received physical therapy, and 47 percent had undergone spinal manipulation. For all 145 subjects the median duration of pain was 4.1 years.

Table 1. Demographic and Clinical Characteristics of the Study Subjects Who Were Available for Follow-up, Determined at the Time of Random Assignment.

Characteristic	Group 1 (TENS Alone)	Group 2 (TENS and Exercise)	Group 3 (Sham TENS Alone)	Group 4 (Exercise and Sham TENS)	All Subjects
No. of subjects	31	34	31	29	125
Mean age (yr)	53.7	53.0	48.1	50.6	51.4
Sex (% female)	58	59	58	59	58
Mean education (yr)	13.7	12.7	15.3	14.5	14.3
Married (%)	84	76	74	90	81
Employed at entry (%)	58	53	61	52	56
Median duration of current episode of pain (mo)	84	66	60	36	60
Previous back surgery or chymopapain therapy (%)	19	3	10	10	10
Neurologic deficit (%)*	16	6	3	24	12
Nerve-root irritation (%)	21†	18	6	17	16
Radiographic findings (%)					
Normal	10	12	19	17	14
Degenerative changes	52	53	32	41	45
Other‡	10	12	10	14	11
Unavailable	29	24	39	28	30
Any coexisting condition (%)	64	47	52	62	56
Self-reported history of "arthritis" (%)	32	29	26	34	30
Mean initial modified SIP score§	7.7	11.0	10.3	11.3	10.1
Mean physical-dimension score¶	6.5	6.1	5.7	6.8	6.2
Mean psychosocial-dimension score¶	5.6	12.3	10.8	12.9	10.4
Mean depression score‖	32.4	34.6	35.2	36.2	34.6
Mean visual-analogue pain score	39.9	43.1	37.9	44.2	41.3
Mean ordinal pain score**	2.4	2.5	2.4	2.5	2.4
Previous hospitalization for back pain (%)*	39	12	13	21	21
Previous spinal CT or myelography (%)	42	21	26	34	30
Finger-to-floor distance with maximal flexion (cm)	10.6	5.3	10.9	12.5	9.7
Schober test (cm)††	4.6	4.4	4.5	4.1	4.4
Straight-leg raising on more limited side (degrees)	80	81	79	78	80

*Significant difference ($P<0.05$) between groups.

†Data were not available for three subjects.

‡Other radiographic diagnoses included spondylolysis (2 subjects), spondylolisthesis (7), compression fracture (3), and scoliosis (7).

§SIP denotes Sickness Impact Profile. Scores range from 0 to 100, with higher scores indicating worse function. The mean score in a general population is 3.6.

¶A subscale of the Sickness Impact Profile.

‖According to the Zung Depression Scale, on which raw scores range from 20 to 80, with higher scores indicating more severe depression. Normal subjects have an average raw score of 26, and patients hospitalized for depression have an average raw score of 59.

**Ordinal pain ratings were (1) extremely severe, (2) somewhat severe, (3) minimal, and (4) almost none.

††Scores of less than 5.0 cm are considered to indicate reduced lumbar flexion.

Blinding and Compliance with Treatment

On the basis of the questions answered at the end of the intervention period, patient blinding with regard to TENS therapy was partially successful. Among the subjects receiving true TENS, 100 percent guessed that their TENS units were functioning properly. In the sham-TENS group, 84 percent guessed that they had functioning units, but their degree of certainty was less than that of the true-TENS group.[35] As reported in the daily diaries, compliance with both true and sham treatment with TENS was good. For the subjects who completed four weeks of treatment, the TENS units were used a mean of 25.5 and 24.9 days in the true-TENS and sham-TENS groups, respectively. The units were used for a daily average of 122 and 150 minutes in the two groups. In both the sham-TENS and the true-TENS groups, 23 percent chose conventional TENS for their final therapy, and the remainder chose acupuncture-like TENS. In the exercise groups, the exercises were performed on a mean of 24 days for 25 minutes a day. At the end of the intervention period, mean accuracy in performing the exercises was 2.1, indicating good adherence to the techniques as taught. However, at the three-month follow-up, only 46 percent of the subjects reported that they were still performing regular back exercises. Attendance at the 8 study visits was good; the subjects made a mean of 7.2 visits, and there were no significant differences among treatment groups. The use of heating pads was reported for a mean of 23 days, 45 minutes per day.

Cointerventions

At the four-week visit there were no significant or substantial differences among study groups with regard to nonstudy treatments. No subjects were hospi-

talized for back pain, only two began taking new medications, and six received physical therapy outside the study.

Therapeutic Outcomes

Significant improvement in nearly every outcome was observed in all four study groups. Improvement was progressive from week 2 to week 4, but outcomes had returned toward base line at the three-month follow-up.

Four-week group comparisons were first tested by multivariate analysis of variance, with the nine measures of function, pain, and physiologic outcome. This analysis revealed no significant treatment effect of TENS for all outcomes together ($P = 0.7$) or for any individual outcome ($P>0.2$ in each case). However, the main effect of exercise was significant ($P = 0.03$) overall and for four individual measures of outcome. There was no significant interaction of TENS with exercise. Individual measures of outcome were then examined in separate analyses of variance. Since no treatment interaction was observed, the results for TENS and exercise are shown separately in Tables 2 and 3.

There were no clinically important or statistically significant differences in any outcome between the subjects receiving true TENS and those receiving sham TENS (Table 2). For several outcomes, the mean scores were virtually identical. The upper 95 percent confidence limit for an advantage of TENS was 0.38 point on the ordinal scale of improvement, 9.6 mm on the visual-analogue pain scale, and 2.2 points on the Sickness Impact Profile. These are below the levels generally regarded as clinically important.[36-38] It is thus unlikely that major clinical benefit was overlooked because of the size of the sample.

By contrast, the analysis of the effects of exercise (Table 3) showed an advantage of exercise in several outcomes. The subjects assigned to the exercise program had significantly higher activity levels, greater improvement on the visual-analogue scale of pain, and significant reduction in the reported frequency of pain. Among the physical measures, only finger-to-floor distance showed an advantage for exercise that approached statistical significance. Unfortunately, there appeared to be no difference in overall function as judged by scores on the modified Sickness Impact Profile. The clinical importance of the differences observed is difficult to gauge, but intuitively, a 52 percent improvement in the pain scale seems substantially better than a 37 percent improvement. The scores of frequency of pain indicate that on average the nonexercise groups continued to have pain somewhat more than half the time, whereas the exercise groups had pain less than half the time. Thus, there was a slight advantage for the exercise groups in symptoms, but little evidence of an advantage in daily functioning.

We examined outcomes at the two-week and three-month follow-ups in a similar manner. There were substantial improvements in most measures at the two-week visit, but no significant differences among treatment groups. Two months after active intervention had ended there was a slight trend toward worsening (a return toward base line) for most physical measures and measures of pain, and there were no longer any significant treatment effects. Table 4 shows results at the three-month visit for the exercise and the nonexercise groups.

Because base-line differences among groups (even if not statistically significant) could confound the results, we also analyzed the four-week outcomes while controlling for the previous duration of pain and for the presence of neurologic deficits, sciatica, previous back surgery, previous spinal-imaging studies (myelography or computed tomography), previous hospitalization for back pain, and any coexisting condition. Entering these as covariates in the analyses of variance in Tables 2 and 3 produced no substantial change in the results. No advantage for TENS became statistically significant ($P>0.2$ in all cases). The advantages of exercise in the measures of frequency of pain and activity level remained significant, and those for improvement in the scale of pain nearly so ($P\leq0.07$).

Although dropouts were similar in most respects to the subjects who remained in the study, we conducted

Table 2. Outcomes of Therapy with TENS or Sham TENS at Four-Week Follow-up.*

Measure	Sham TENS (N = 60)	True TENS (N = 65)	Difference†
Functional status‡			
Overall modified SIP score	6.2	5.7	−0.5 (−2.2, 1.3)
Physical-dimension score	3.2	3.2	0.02 (−1.1, 1.1)
Psychosocial-dimension score	5.7	5.9	0.2 (−2.3, 2.6)
Self-rated activity level	1.7	1.7	0.01 (−0.19, 0.21)
Pain			
Self-rated improvement§	2.9	2.9	−0.01 (0.38, 0.35)
Visual-analogue pain scale (mm)	24.0	21.7	−2.3 (−9.6, 4.9)
Visual-analogue improvement scale (mm)	41.8	47.0	5.2 (−6.6, 16.9)
Frequency of pain¶	3.0	2.9	−0.1 (−0.5, 0.3)
Physical measures			
Finger-to-floor distance (cm)	8.7	8.7	0.04 (−2.5, 2.6)
Schober test (cm)	4.1	4.2	0.13 (−0.24, 0.50)
Straight-leg raising (degrees)	84	84	0.5 (−2.2, 3.2)
Use of services			
Days in hospital	0	0	0
Visits to other providers (mean no.)	0.30	0.22	−0.08 (−0.033, 0.25)
Wish to continue TENS therapy (%)	56	68	12 (−4.9, 28.9)

*Values shown are adjusted means after control for base-line values and for the main effect of exercise. None of the differences were statistically significant ($P>0.3$ by analysis of covariance in all cases).

†Difference is the score with true TENS minus the score with sham TENS. Values in parentheses are 95 percent confidence limits.

‡SIP denotes Sickness Impact Profile. Scores range from 0 to 100, with higher scores indicating worse function. The physical-dimension and psychosocial-dimension scales are major subscales of the modified SIP, scored similarly. The self-rated activity level is scored 1 (more active than base line), 2 (equally active), or 3 (less active).

§Scored on a six-point scale: 1 = pain entirely gone, 4 = no change, and 6 = much worse.

¶Scored on a five-point scale: 1 = none, 2 = occasionally, 3 = about half the time, 4 = more than half the time, and 5 = all the time.

a best-case analysis with assumptions that heavily favored TENS therapy over sham-TENS therapy. We assumed that every dropout from true TENS had a 25 percent improvement in each outcome at the four-week follow-up and that every dropout from sham TENS had scores unchanged from base line. Even in this analysis, the effect of TENS remained nonsignificant for every outcome variable except straight-leg raising (84 degrees vs. 87 degrees; $P = 0.045$). Similarly, we conducted a worst-case analysis for the effects of exercise, assuming that the dropouts had no improvement in any variable, regardless of study group. The effects of exercise on the visual-analogue improvement scale and the frequency of pain remained significant, and the effects on the ordinal scale of improvement and the self-rated activity level remained nearly so (both $P<0.06$).

Although we believe our analysis of the intact randomized groups to be the most valid, we also compared four-week outcomes for several clinically important subgroups. Among the 107 subjects with good TENS compliance (≥20 days of use), outcomes were similar to those in the entire group, with no significant effects of TENS. The outcomes among subjects with good exercise compliance (exercise on ≥20 days; $n = 50$) were slightly better than those in the overall exercise groups. For subgroups with visual-analogue pain scores above or below the median, the results were similar to the overall results. The benefits of exercise were more apparent among subjects with a shorter duration of pain (≤49 months; $n = 59$) than among those with longstanding pain. Even in the group with shorter duration, there was little effect of TENS.

Table 3. Outcomes of Exercise or No Exercise at Four-Week Follow-up.*

Measure	No Exercise (N = 62)	Exercise (N = 63)	Difference†
Functional status‡			
Overall modified SIP score	6.3	5.6	−0.07 (−2.2, 0.9)
Physical-dimension score	3.2	3.2	−0.02 (−1.1, 1.1)
Psychosocial-dimension score	6.2	5.5	−0.7 (−3.2, 1.7)
Self-rated activity level	1.8	1.6	−0.2 (−0.4, −0.01)§
Pain			
Self-rated improvement¶	3.1	2.7	−0.4 (−0.8, −0.02)§
Visual-analogue pain scale (mm)	25.9	19.8	−6.1 (−13.3, 1.3)
Visual-analogue improvement scale (mm)	37.3	51.6	14.3 (2.7, 26.2)§
Frequency of pain‖	3.2	2.7	−0.5 (−0.9, −0.2)§
Physical measures			
Finger-to-floor distance (cm)	9.8	7.6	−2.2 (−4.8, 0.4)
Schober test (cm)	4.1	4.2	0.1 (−0.3, 0.4)
Straight-leg raising (degrees)	84	84	0.8 (−1.8, 3.5)
Use of services			
Days in hospital	0	0	0
Visits to other providers (mean no.)	0.3	0.2	−0.1 (−0.3, 0.2)

*Values shown are adjusted means after control for base-line values and for the main effect of TENS.

†Difference is the score with exercise minus the score with no exercise. Values in parentheses are 95 percent confidence limits.

‡SIP denotes Sickness Impact Profile. Scores range from 0 to 100, with higher scores indicating worse function. The physical-dimension and psychosocial-dimension scales are major subscales of the modified SIP, scored similarly. The self-rated activity level is scored 1 (more active than base line), 2 (equally active), or 3 (less active).

§$P<0.05$ by analysis of covariance.

¶Scored on a six-point scale: 1 = pain entirely gone, 4 = no change, and 6 = much worse.

‖Scored on a five-point scale: 1 = none, 2 = occasionally, 3 = about half the time, 4 = more than half the time, and 5 = all the time.

Table 4. Outcomes of Exercise or No Exercise Two Months after the End of Active Intervention.*

Measure	No Exercise (N = 60)	Exercise (N = 62)	Difference†
Functional status‡			
Overall modified SIP score	5.2	5.2	−0.07 (−1.9, 1.7)
Physical-dimension score	2.5	3.5	−1.0 (−0.5, 2.4)
Psychosocial-dimension score	5.1	4.7	−0.4 (−3.1, 2.1)
Self-rated activity level	1.8	1.7	−0.1 (−0.3, 0.1)
Pain			
Self-rated improvement§	3.2	3.0	−0.2 (−0.6, 0.3)
Visual-analogue pain scale (mm)	25.6	26.5	0.9 (−8.0, 9.7)
Visual-analogue improvement scale (mm)	40.9	47.9	7.0 (−6.4, 20.1)
Frequency of pain¶	3.0	2.9	−0.1 (−0.6, 0.3)
Physical measures			
Finger-to-floor distance (cm)	9.9	7.6	−2.3 (−5.3, 0.8)
Schober test (cm)	4.1	7.2	0.1 (−0.2, 0.5)
Straight-leg raising (degrees)	84	86	2.0 (−3.1, 4.9)
Use of services			
Days in hospital	0	0	0
Visits to other providers (mean no.)	0.6	0.9	0.3 (−0.6, 1.0)

*Values shown are adjusted means after control for base-line values and for the main effect of TENS. Numbers vary because of missing values, and there were only 107 subjects for the physical measures.

†Difference is the score with exercise minus the score with no exercise. Values in parentheses are 95 percent confidence limits. None of the differences were statistically significant ($P>0.1$ by analysis of covariance in all cases).

‡SIP denotes Sickness Impact Profile. Scores range from 0 to 100, with higher scores indicating worse function. The physical-dimension and psychosocial-dimension scales are major subscales of the modified SIP, scored similarly. The self-rated activity level is scored 1 (more active than base line), 2 (equally active), or 3 (less active).

§Scored on a six-point scale: 1 = pain entirely gone, 4 = no change, and 6 = much worse.

¶Scored on a five-point scale: 1 = none, 2 = occasionally, 3 = about half the time, 4 = more than half the time, and 5 = all the time.

Side Effects of TENS

Approximately one third of the subjects reported minor skin irritation at the sites of electrode placement, with equal proportions in the true-TENS and sham-TENS groups. Standardized skin care was prescribed in this circumstance,[39] but topical corticosteroids were sometimes necessary. One subject (receiving sham TENS) had a severe dermatitis four days after therapy began, requiring the discontinuation of treatment. Allergic dermatitis and skin irritation have been previously described with TENS.[40]

Discussion

The most striking result of this randomized, controlled trial was the absence of an apparent benefit of TENS. Although contrary to conventional wisdom, this finding is in accord with the results of some smaller, well-blinded trials of TENS for painful chronic conditions.[14,15] It may also explain why TENS appears to have little long-term benefit, even in trials suggesting short-term efficacy.[8,10] Advocates have long recog-

nized a placebo effect of TENS,[12] but our results suggest that for chronic back pain, this may be its only effect.

Our negative results may be a consequence of successful blinding that included a credible placebo and strong suggestion. Langley and his colleagues reached a similar conclusion, noting that placebos mimic the pharmacologic effects of active drugs and implying that placebo effects explain many of the actions attributed to TENS.[15] Petrie and Hazleman showed that sham TENS with visual and verbal suggestion was a highly credible placebo,[41] and follow-up questions suggested that this technique was successful in our trial. We also excluded persons with previous TENS therapy from our study and avoided the crossover design employed by others.[11,12] Our results challenge the wide use of TENS for chronic low back pain and suggest a need for further controlled trials with rigorous blinding.

There are several possible reasons for negative results other than ineffective therapy.[42] There may be inadequate statistical power to detect important differences, but confidence intervals around our group differences were small and excluded a major clinical benefit of TENS. Dropouts can unfavorably bias results, but in our study the numbers of dropouts were similar among groups, the dropouts closely resembled the subjects who remained, and a best-case analysis still showed no significant effect.

Negative findings may also occur if a trial includes patients unlikely to respond to therapy. Our subjects had some characteristics believed favorable for a response to TENS (limited previous surgery, no work disability, and minimal use of narcotics, for example)[43] but that may simply indicate a better underlying prognosis. Subgroup analyses did not uncover benefits related to the duration of pain, the severity of pain, or compliance. We had too few subjects with sciatica to assess outcome confidently in this subgroup.

Negative results may occur if the dose or the manner of intervention is inadequate. In our trial, 100 percent of the subjects receiving TENS believed they had true TENS, suggesting that all perceived the stimulation. We sought the best possible placement of the electrodes and used differing frequencies and amplitudes of stimulation (although acupuncture-like stimulation was offered for only half the treatment period), and we still observed no benefit.

Finally, measures of outcome may be too unresponsive to detect clinically important differences. We used a broad range of measures, however, and they were sufficiently responsive to detect the treatment effects of exercise. Furthermore, in most measures of outcome (including the modified Sickness Impact Profile), significant improvements were demonstrated over time (perhaps as a nonspecific result of attention, placebo effects, and regression to the mean).

Our negative results do not invalidate the gate theory of pain modification.[6] For some persons with chronic pain, there may be little or no nociceptive stimulation, and learned pain behavior may be the chief problem. Counterstimulation would not be expected to help in this situation. This form of counterstimulation may simply be inadequate for some persons with low back pain, and perhaps TENS is efficacious for other pain syndromes.

The regimen of stretching exercises that we also evaluated was designed to improve mobility and reduce pain by limbering muscles and ligaments that had become restricted in response to pain. The results of our study suggest mild improvement in combined spinal and hip flexion (finger-to-floor distance) and moderate improvement in subjective reports of pain. There was little evidence, however, of change in behavior or daily functioning. Unlike TENS, which is thought to have an immediate effect that wanes with time, exercise requires sustained performance for beneficial effects. One month of intervention may be insufficient to observe the full effect,[44] but our program was more intensive than that provided in most physicians' offices. The YMCA program involves six weeks of exercises.[18] In our trial, most subjects were no longer exercising two months after the intervention period, reducing the apparent benefits of therapy. Thus, methods of improving long-term compliance with exercise regimens are needed. Furthermore, trials are needed to compare our exercises with other effective exercises,[44] in order to establish the most successful regimen.

We had no placebo counterpart to exercise, so our results may be due to the nonspecific effects of instruction and attention. We attempted to minimize such effects by ensuring that visits were equally frequent and long and by providing credible therapy to every subject. Nonetheless, the subjects randomly assigned to no exercise may have believed that they had less intensive therapy, thus influencing their results.

Our data support a trend favoring active over passive therapy for both acute and chronic back pain.[21] They suggest that TENS may be no better than placebo for these patients with back pain, and they indicate that TENS and exercise are no better than exercise alone. There appear to be modest subjective benefits from the regimen of stretching exercises, but few short-term effects on actual behavior. A longer period of exercise therapy may provide more substantial benefits, but it will require ongoing efforts to maintain compliance.

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