

Effectiveness of Transcutaneous Electrical Nerve Stimulation on Postoperative Pain With Movement

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Abstract: This study tested the effectiveness of episodic transcutaneous electrical nerve stimulation (TENS) as a supplement to pharmacologic analgesia on pain with movement and at rest after abdominal surgery and evaluated whether its use during walking and vital capacity maneuvers enhances performance of these activities. TENS, with a modulated frequency, intensity as high as the subject could tolerate, and electrodes placed on either side and parallel to the incision, was compared to placebo TENS and pharmacologic analgesia alone (control) by using a crossover design. Self-report of pain intensity, walking function, and vital capacity were assessed on 33 subjects. TENS resulted in significantly less pain than the control during both walking ($P < .5$) and vital capacity activities ($P < .1$) and significantly less pain than placebo TENS during vital capacity ($P < .01$). TENS also produced significantly better gait speeds than the control ($P < .05$) and greater gait distances ($P < .01$) than the control and placebo TENS. Vital capacity and pain intensity at rest were not significantly different among the 3 treatments. These results suggest TENS reduces pain intensity during walking and deep breathing and increases walking function postoperatively when used as a supplement to pharmacologic analgesia. The lack of effect on pain at rest supports the hypothesis that TENS works through reducing hyperalgesia.

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Key words: Transcutaneous electrical nerve stimulation, postoperative pain, abdominal surgery, movement-evoked pain.

Approximately 23 million surgical procedures are performed in the United States each year.⁵² These procedures cause tissue trauma and release of potent mediators of inflammation and pain. Despite significant progress in understanding the pathophysiology of pain, the development of therapeutic options, and the publication and dissemination of guidelines, patients are often undermedicated^{12,35,38,43} and rarely receive treatment for pain beyond pharmacologic strategies.⁵

Undertreated postoperative pain has been shown to produce a number of adverse effects, including impaired pulmonary function.¹⁴ Perioperative pain is also a potent trigger for the stress response, activating the autonomic nervous system and causing adverse effects on multiple organ systems.^{31,37} Improved management of postoperative pain has been shown to reduce the overall postoperative complication rate, the incidence of cardiovascular failure, and major infectious complications.⁵⁹ The

severity of perioperative pain can also influence the development of postsurgical chronic pain syndromes.^{26,49} Evidence indicates that long-term alterations in neural tissue are initiated within the first few hours after injury.⁵⁸

The complex physiology of the pain pathways suggests that multiple methods of pain control are needed to manage pain adequately, particularly when the pain is severe, such as the pain experienced after major abdominal surgery. Opioids, the most common pharmacologic intervention for postoperative pain control, are primarily C-fiber inhibitors.^{10,40} About 75% of spinal opioid receptors are found at presynaptic sites on C-fiber terminals.¹⁰ It has been suggested, therefore, that sharp, severe, abdominal wall pain due to A-delta fiber stimulation that arises during movement or expectoration is poorly controlled by opioids.⁴⁰ This leaves the patient without adequate pain management during essential postoperative activities.

Transcutaneous electrical nerve stimulation (TENS), a nonpharmacologic strategy with minimal side effects, has been used to treat pain during the postoperative period. Laboratory studies have shown that TENS decreases activity of noxiously evoked dorsal horn cells when applied to somatic receptive fields by activating large, myelinated primary afferent fibers.^{16,23,30,57} An endogenous opioid-dependent mechanism involving the release of endorphins, enkephalins, and dynorphins in the central nervous system has also been identified.²⁰ Studies have shown that the effects of high frequency

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TENS are prevented by blockade of opioid receptors in the central nervous system.^{25,46} Recent evidence suggests that TENS decreases hyperalgesia in the tissues surrounding surgical incisions.¹⁸ Hyperalgesia is characterized by a decrease in pain threshold and an increase in pain to suprathreshold stimuli.⁵⁰ High frequency TENS caused a partial reduction of primary hyperalgesia¹⁸ and a complete reduction of secondary hyperalgesia in laboratory rats.⁴⁵ In addition, high frequency TENS had a longer effect on these outcomes than low frequency TENS, and high frequency TENS was most effective at reducing primary mechanical hyperalgesia when a high intensity was used.¹⁸ In contrast, opioids such as fentanyl and morphine have not been consistently effective in reducing pain associated with hyperalgesia.^{28,55}

Therapies that target hyperalgesia might facilitate recovery by enhancing postoperative respiratory function and mobility. Consequences of poor postoperative pain control, such as ineffective cough and delayed activity progression, are associated with movement-evoked pain. Wilk et al⁵⁶ found that hyperalgesia correlated with movement-evoked pain, indicating that pain during movement might involve sensitization of the nociceptive response. Pain at rest, on the other hand, did not correlate. Control of pain during movement, therefore, might require supplementation of opioids with therapies that impact on hyperalgesia.

The majority of clinical studies testing the effectiveness of TENS on postoperative pain have used continuous conventional TENS with varying results. The few studies that used brief, intense or acupuncture-like TENS (ALTENS) reported decreased pain intensity, reduced opioid requirements, and improved pulmonary function when compared to placebo TENS and control groups.^{6,19,22,34,53} A recent meta-analysis investigating the effect of TENS or ALTENS on postoperative analgesic consumption found that TENS, administered with a strong, subnoxious intensity at an adequate frequency in the wound area, can significantly reduce analgesic consumption for postoperative pain.⁷

Most studies administering intermittent TENS have done so at regular intervals while patients rested in bed or sat in a chair. It is unclear what effect episodic TENS would have on postoperative pain during movement and how this would influence walking and pulmonary function.

Purpose of Study

The purpose of this study was to test the effectiveness of episodic TENS on pain with movement after abdominal surgery and to determine whether its use during walking and vital capacity maneuvers improves these activities.

The following hypotheses were tested:

1. Patients will report significantly less pain intensity during movement (walking and vital capacity maneuvers) when receiving episodic TENS than when receiving placebo TENS or pharmacologic analgesia alone.

2. Patients will report no significant difference in pain intensity at rest when receiving episodic TENS than when receiving placebo TENS or pharmacologic analgesia alone.
3. Patients will experience significantly better walking function (faster gait speed, greater gait distance, or reduced level of assistance) when receiving episodic TENS than when receiving placebo TENS or pharmacologic analgesia alone.
4. Patients will achieve significantly higher vital capacity when receiving episodic TENS than when receiving placebo TENS or pharmacologic analgesia alone.

Materials and Methods

Design

A prospective, randomized, repeated measures design was used. Subjects served as their own controls. Three treatments, (1) pharmacologic analgesia and TENS, (2) pharmacologic analgesia and placebo TENS, and (3) pharmacologic analgesia alone, were randomly assigned to each of the first 3 ambulations on a postoperative day in which the subject was experiencing moderate to severe pain.

Sample/Setting

Patients were recruited from an 800-bed Midwestern tertiary health care center that performs approximately 400 abdominal surgeries each year. Those who had recent abdominal surgery and were having pain of 5 or greater on a 0 to 10 numeric rating scale (NRS) or moderate on a verbal descriptive scale were approached to participate in the study. Patients were then evaluated for the following exclusion criteria: (1) non-English speaking; (2) epidural analgesia/anesthesia; (3) preoperative opioid use (regular use of opioid analgesics for more than 2 weeks during the 6-month period before surgery as determined by patient interview); (4) morbid obesity (weight more than 100 pounds of ideal weight); (5) neuroticism (measured by the NEO Personality Inventory-Revised (NEO-PI-R) Neuroticism scale); (6) inability to cognitively follow the required directions (measured by a "directions tool" developed for this study); (7) conditions precluding use of TENS, such as a pacemaker; (8) prior TENS use; and (9) inability to support self or walk safely without use of an assistive device.

An estimation of desired sample size for dependent groups was determined by using pain intensity scores of the first 13 study subjects. On the basis of effect sizes ranging between 0.22 for TENS versus placebo TENS and 0.77 for TENS versus pharmacologic analgesia alone, a moderate effect was assumed. Correlations from this sample were used in the formula for phi prime, and a value of 0.33 was obtained. By using the charts provided by Feldt,¹³ an $a = 3$, $\alpha = .05$, and power = .7 required a sample size of 24 subjects. This sample size also accommodates variability in walking function and vital capacity.

Active TENS

TENS was provided with use of an Epix VT unit (EMPI, St. Paul, MN). The generator emits a balanced, asymmetrical, biphasic waveform and has control buttons for variation of frequency and amplitude. A rate modulation frequency that cycled between 100 pulses per second for 0.5 seconds and then 50 pulses per second for 0.5 seconds was used with a pulse width of 150 microseconds. Evidence suggests that mixing high and low frequencies provides effective pain control postoperatively¹⁶ and is better tolerated than high frequency TENS.⁵¹ The amplitude was set at the highest point the subject could tolerate. The generator used a 9-volt battery, and a voltmeter was used before each use to ensure adequate voltage.

The generator was connected by lead wires to 2 sterile electrodes with a pregelled contact surface (approximately 1 1/2 × 9 in). These electrodes were placed parallel to and on either side of the subject's abdominal incision, approximately 2 to 3 inches away. This distance was recommended by Mannheimer and Lampe³³ because most pain from the surgical incision is from trauma to tissue and muscle as a result of surgical retraction, not at the incision itself. This area is also associated with secondary hyperalgesia, the aspect of the pain response targeted.

Placebo TENS

Subjects were told that 2 types of TENS therapy were being tested, one in which a strong sensation would be felt and one in which little or no sensation would be felt. During preoperative or prior application of active TENS, the amplitude at which the patient started feeling a sensation was determined, and 1 mA less than this level was recorded as the placebo setting. When the placebo setting could not be determined before the placebo treatment, an arbitrary setting of 2 was used.

A placebo TENS unit was modified by the manufacturer so that it did not emit current. This unit displayed an active indicator light, suggesting to the subject that the unit was active. In addition, the subject was asked whether he/she felt anything each time the placebo level was reached in an effort to reinforce to the subject the idea that an active TENS treatment was being delivered.

Pain Intensity

A vertical, 21-point NRS was used to measure subjects' self-report of pain intensity. The same laminated tool was used with each rating. Subjects were asked to provide a number that represented their pain intensity if 0 was no pain and 20 was the most intense pain imaginable. Instructions were reinforced with each use. This tool has established validity and reliability for assessing acute^{8,11,24,27,36} and postoperative⁴¹ pain and correlates well with the Visual Analogue Scale (VAS) (.62 to .95).^{2,9,11,21,29,39,41} During the postoperative period, reported correlations between the VAS and NRS are .90 to .95.^{9,41}

Walking Function

Walking function was measured by using the Iowa Gait Test involving 3 objective components: gait speed, gait distance, and level of assistance. This test has been shown, along with a slightly different gait speed test, to be responsive, reliable, and valid within 2 to 3 days postoperatively.⁴²

Gait Speed

Gait speed was measured by recording the distance subjects were able to safely walk in 15 seconds while the investigator walked beside the subject with a stopwatch. A piece of tape was placed on the wall at the starting point and at the point the subject reached in 15 seconds. The subject was instructed as follows: "Walk straight forward until I tell you to stop. Do this as fast as you safely can. I will be timing you and will provide any necessary assistance." Subjects were also instructed to avoid talking during the test, to set their own pace, and stay in the middle of the hallway. Those who were not able to walk independently received the assistance needed. Arterial oxygen saturation (SaO₂) was monitored by using a finger oximeter to assure adequate oxygen saturation during testing. If the SaO₂ dropped below 92% or 10% of their baseline reading (whichever was greater), the test was terminated.

Gait Distance

Gait distance was measured by total distance walked during the session. After completing the 15-second gait speed test, subjects were given the following instructions: "I want to see how far you can walk. I would like you to walk as far as you can. I will not be timing you so you can walk at a comfortable pace." Subjects were instructed that they could slow their pace or stop to rest at any time. The total distance the subject walked was recorded from the point the subject started the gait speed test to the point they stopped the gait distance test. A measuring wheel, with reported accuracy within 1 inch every 100 feet, was used to measure the distance subjects walked. Wheel accuracy was validated by remeasuring the gait speed and gait distance for the first 3 subjects. This resulted in 100% agreement between measurements.

Level of Assistance

The maximum number of contact points needed by the subject during walking determined the level of assistance required. Contact points were categorized as independent, no contact; standby, needing standby assistance, no contact but ready to assist; minimum, 1 point of contact by 1 person (eg, holding 1 arm); moderate, 2 points of contact by 1 or 2 people (eg, holding both arms); and maximum, 3 or more points of contact (eg, holding 1 arm and both hands on waist). The maximum assistance required at any one time during the walking session was recorded.

Pulmonary Status

Pulmonary status was assessed by measuring the subject's vital capacity with the Renaissance Spirometry System (Nellcor Puritan Bennett, Hazelwood, MO) and single-patient-use pneumotachometer. This instrument met the criteria set by the American Thoracic Society Spirometry Standards.⁴ With proper use of the criteria for acceptability (satisfactory start-of-test and end-of-test plateau) and reproducibility (maneuvers not varying by more than 0.2 L), it provides valid and reliable measures of vital capacity. The instrument was calibrated daily.

Measurements were made with subjects positioned in a wheelchair with a pillow behind their back or on the edge of their bed sitting up as straight as possible. The same position was used during all sessions. Dentures were left in place, and a nose clip was applied. The subject was coached through the maneuver and asked to perform it twice. If both maneuvers met acceptability criteria, reproducibility was determined. If reproducibility criteria were met, the highest value was used. If reproducibility criteria were not met, the subject was asked to perform a third maneuver, and the average of the 3 results was used. If acceptability criteria were not met, the subject was asked to repeat the maneuver up to 4 times (or less depending on the subject's ability/condition). If acceptability criteria could not be met on any of the maneuvers, vital capacity was not recorded during that session. Subjects who could not meet acceptability criteria during any of the 3 sessions were only included in the analyses for walking ability and pain intensity.

Data Collection Procedure

After approval by the Institutional Review Board, informed consent was obtained and, if exclusion criteria were not met, the subject was asked to fill out a demographic questionnaire. The order of the treatments was then randomly assigned. The subject's sessions were spaced 2 to 4 hours apart. To control for the influence of extraneous variables (fatigue, practice effect with spirometry) on walking function and vital capacity, the subject was asked to use the incentive spirometer once and not walk outside the room between study sessions.

Before each intervention, the investigator assessed the subject's activity and analgesia use before the session and, if the session was one in which the subject was to receive TENS or placebo TENS, the skin was washed with soap and water and the TENS electrodes were applied. The TENS unit was then activated, and subjects made adjustments in the amplitude, as needed, to achieve and maintain a tolerable but intense sensation. When the subject was receiving placebo TENS, the settings were applied by using the placebo TENS unit, and no adjustments were made.

The unit was left in place for 15 minutes to allow for peak effect to be reached and then continued for the duration of the session. The subject was asked to rate his/her pain intensity while lying in bed and during the movement of transferring from a lying to sitting posi-

tion. Gait speed testing was performed by walking in the hallway according to the above procedure. The subject was then asked to rate his/her maximum pain intensity during the gait speed test. Next, the subject was asked to walk as far as possible with the least amount of assistance and to rate the worst pain intensity during the walk. Last, the subject was given instructions on performing the vital capacity maneuvers and, at the end of each maneuver, asked to rate his/her pain intensity during the maneuver. The highest pain intensity value for all the maneuvers during that session was used.

Data Analysis

The amplitude of TENS self-selected by subjects ranged from 3 to 57 mA. Because the TENS amplitude varied widely, to address its potential interaction with the 3 treatments, repeated measures analysis of variance (ANOVA) procedures were used with TENS amplitude as an independent variable. The sample was split into 2 groups; high amplitude (9 to 57 mA, $n = 20$) and low amplitude (3 to 8 mA, $n = 13$). These grouping were determined on the basis of what other clinical researchers identify as high intensity (9 to 15 mA).^{19,53} Tukey procedures were used to follow up on significant results. Means, standard deviations, and effect sizes were used to explain treatment effects further. Homogeneity of variances was retained for all dependent measures by using the F_{max} test. Missing values were filled in for subjects who completed 2 of the 3 treatments by using the SAS "proc-mixed" program (SAS Institute Inc, Cary, NC) that estimates the covariance for 2 of the 3 treatments and, on the basis of the covariance of non-missing values, estimates the missing values. This method is based on the assumption that the covariance between different treatments is the same for all subjects. The percentages of missing values for each variable averaged 15% and ranged from 9% for level of assistance to 26% for pain during transfer.

Results

During the 10 months of data collection, a total of 44 patients who met the inclusion criteria consented to participate. Of these, 33 patients were tested with at least 2 treatments, and 30 performed all 3. The major reason subjects failed to complete all testing sessions was the development of postoperative complications. The 33 subjects ranged in age from 20 to 77 years with a mean of 40 ± 15 years. There were a similar number of women (52%) and men (48%). Most were white (88%), married (61%), had end-stage renal disease or diabetes, and underwent a renal and/or pancreas transplant (40%) or had a donor nephrectomy with no primary diagnosis (21%).

Treatment Comparisons

The amount of time subjects waited between sessions averaged 179 minutes (approximately 3 hours) and did not differ between treatments ($P = .36$) with repeated measures ANOVA. Subject activity before each treatment also did not differ. This included going to the bathroom ($P = .06$), sitting in a chair ($P = .58$), walking ($P =$

Table 1. Descriptive Statistics for Pain Intensity During Transfer, Gait Speed, Gait Distance, and Vital Capacity

TREATMENT		TENS INTENSITY							
		MEAN		SD		MEAN		SD	
		HIGH (≥ 9 MA)		LOW (≤ 8 MA)		TOTAL SAMPLE			
Transfer		(n = 19)		(n = 13)		(N = 32)			
	TENS	9.5	5.898	10.5	4.539	9.9	5.330		
	Placebo	11.1	5.641	11.2	5.031	11.1	5.318		
	Control	10.7	4.711	10.8	4.560	10.7	4.576		
Gait speed		(n = 16)		(n = 12)		(N = 28)			
	TENS	6.9	3.714	9.8	4.808	8.1*	4.369		
	Placebo	9.1	4.299	11.1	4.641	9.9	4.483		
	Control	10.2	4.175	9.8	3.129	10.1*	3.702		
Gait distance		(n = 20)		(n = 13)		(N = 33)			
	TENS	9.3	3.932	9.6	4.930	9.4	4.280		
	Placebo	9.5	4.691	10.2	4.902	9.8	4.712		
	Control	11.1	3.967	10.8	3.018	11.0	3.576		
Vital capacity		(n = 18)		(n = 12)		(N = 30)			
	TENS	7.8	4.579	7.9	4.448	7.8*†	4.450		
	Placebo	9.7	5.594	9.9	4.776	9.8*	5.197		
	Control	11.0	3.629	9.1	4.101	10.2†	3.876		

Abbreviation: SD, standard deviation.

*Significantly different at $P < .05$.

†Significantly different at $P < .05$.

.17), frequency of spirometer use ($P = .09$), number of breaths with each use ($P = .40$), or the highest spirometer level reached ($P = .33$). The length of the active TENS treatment (including the 15-minute premeasurement period) ranged from 30 to 60 minutes, depending on the rate at which the subjects could complete the required activities, and averaged 42 minutes.

Twenty-two subjects received patient-controlled analgesia at some point during their testing. These subjects used an average of 7.0 morphine equivalent mg before the sessions and an average of 0.57 morphine equivalent mg during the sessions. There was not a significant difference in the percentage of maximum available medication used by these subjects between ($P = .27$) or during ($P = .30$) the 3 sessions. Ten subjects received analgesia as required (by mouth or intravenously) at some point during testing. The majority received hydromorphone (Dilaudid) (6) or Dilaudid with acetaminophen (Tylenol) (3). Others received Tylenol (2), oxycodone hydrochloride and acetaminophen (Percocet) (1), intravenous meperidine (Demerol) (1), intravenous morphine (1), or acetylsalicylic acid (1). These subjects also received a similar amount of medication between ($P = .50$) and during ($P = .14$) sessions. No subjects reported using nonpharmacologic pain relief measures between or during treatments.

Hypothesis One: Pain During Movement

Average pain intensity scores for TENS ranged from 7.8 during vital capacity maneuvers to 9.9 during transfer. Mean pain intensity scores with placebo TENS ranged from 9.8 during gait distance to 11.1 during transfer, and

average pain intensity scores for pharmacologic analgesia alone (control) ranged from 10.1 during gait speed to 11.0 during gait distance (Table 1). Scores were lower with TENS than with the other 2 treatments during all 4 activities, with a difference ranging from 0.8 to 2.4 between TENS and pharmacologic analgesia alone and from 0.4 to 2.0 between TENS and placebo TENS.

Effect sizes were small, ranging from -0.17 to -0.58 for TENS versus pharmacologic analgesia and 0.07 to -0.40 for TENS versus placebo TENS. The highest effect was between TENS and pharmacologic analgesia for pain during vital capacity (-0.58), followed by pain during gait speed (-0.47). The lowest effect sizes were between placebo TENS and pharmacologic analgesia alone for pain during gait speed (-0.03) and pain during transfer (0.08).

Repeated measures ANOVA with high versus low TENS amplitude as an independent variable showed significant differences in pain intensity scores during gait speed ($P < .05$) and vital capacity ($P < .01$) but no significant differences during transfer or gait distance. Tukey follow-up tests found significance between TENS and control treatments for pain intensity during both gait speed and vital capacity and between TENS and placebo TENS for pain intensity during vital capacity.

Hypothesis Two: Pain at Rest

The mean pain intensity score at rest was 4.2 for TENS, 5.5 for placebo TENS, and 5.4 for pharmacologic analgesia (Table 2). Although average pain intensity scores were lower with TENS than with the other 2 treatments,

Table 2. Descriptive Statistics for Subjects' Pain Intensity at Rest

TREATMENT	TENS INTENSITY					
	HIGH (≥ 9 MA) (N = 20)		LOW (≤ 8 MA) (N = 13)		TOTAL SAMPLE (N = 33)	
	MEAN	SD	MEAN	SD	MEAN	SD
TENS	3.9	3.083	4.9	3.760	4.2	3.345
Placebo	5.0	3.536	6.2	4.059	5.5	3.731
Control	4.9	2.984	6.1	4.323	5.4	3.559

Abbreviation: SD, standard deviation.

effect sizes were small, ranging from -0.02 for placebo TENS versus pharmacologic analgesia to -0.34 for TENS versus placebo TENS. Repeated measures ANOVA procedures with TENS amplitude as an independent variable showed no significant differences in pain intensity scores.

Hypothesis Three: Walking Function

Only 3 subjects used a different level of assistance between the 3 treatments. As a result, the means were similar for all 3 treatments (1.8 for TENS, 1.6 for placebo TENS, and 1.7 for control) and the effect sizes were small (-0.03 to 0.11). Average gait speeds and gait distances, however, were higher with TENS than with the other 2 treatments with differences between TENS and control treatments of 76.54 inches for gait speed and 850.95 inches for gait distance (Table 3).

Effect sizes were small for all 3 measures, ranging from 0.09 to 0.35 for TENS versus control and 0.06 to 0.19 for TENS versus placebo TENS. Repeated measures ANOVA procedures with TENS intensity as an independent vari-

able showed no difference in level of assistance but showed significant differences for both gait speed ($P < .05$) and gait distance ($P < .01$). Tukey follow-up tests showed that TENS resulted in significantly better gait speeds and greater gait distances when compared to pharmacologic analgesia and significantly greater gait distances when compared to placebo TENS.

Hypothesis Four: Vital Capacity

Mean vital capacity liters were similar for all 3 treatments, ranging from 2.68 for placebo TENS to 2.73 for both TENS and pharmacologic analgesia (Table 4). Effect sizes were extremely small, ranging from -0.005 for TENS versus control to -0.06 for TENS versus placebo TENS. Repeated measures ANOVA procedures with TENS amplitude as an independent variable showed no significant differences in vital capacity measurements.

TENS Amplitude

Average pain intensity scores were lower and average walking function and vital capacity scores were higher

Table 3. Descriptive Statistics for Subjects' Walking Function

TREATMENT	TENS INTENSITY					
	HIGH (≥ 9 MA)		LOW (≤ 8 MA)		TOTAL SAMPLE	
	MEAN	SD	MEAN	SD	MEAN	SD
Level of assist	(n = 20)		(n = 13)		(N = 33)	
TENS	1.8	0.894	1.7	1.251	1.8	1.032
Placebo	1.7	0.979	1.5	1.330	1.6	1.113
Control	1.8	0.851	1.5	1.330	1.7	1.051
Gait speed	(n = 16)		(n = 12)		(N = 28)	
TENS	474.31	278.101	357.00	206.075	424.04*	252.514
Placebo	440.89	249.536	365.25	201.254	408.47	229.233
Control	381.13	180.056	302.67	187.901	347.50*	184.280
Gait distance	(n = 20)		(n = 13)		(N = 33)	
TENS	3759.50	4171.86	3128.93	1555.53	3511.09*†	3367.36
Placebo	3163.71	4146.40	2433.92	1319.63	2876.22†	3315.46
Control	3098.36	4097.83	1985.95	1256.83	2660.14*	3296.58

Abbreviation: SD, standard deviation.

*Significant difference, $P < .05$.

†Significant difference, $P < .05$.

Table 4. Descriptive Statistics for Subjects' Vital Capacity

TREATMENT	TENS INTENSITY							
	HIGH (≥ 9 mA) (N = 18)		LOW (≤ 8 mA) (N = 11)		TOTAL SAMPLE (N = 29)			
	MEAN	SD	MEAN	SD	MEAN	SD	MINIMUM	MAXIMUM
TENS	2.76	0.942	2.70	1.042	2.73	0.963	1.49	4.83
Placebo	2.74	0.929	2.59	0.797	2.68	0.870	1.40	5.05
Control	2.67	1.125	2.83	1.197	2.73	1.134	1.27	5.56

Abbreviation: SD, standard deviation.

during the active TENS treatment when high amplitude TENS was used versus low amplitude TENS (Tables 1 to 4). However, differences also favored high amplitude TENS during placebo TENS and control treatments, and no significant differences were found between subjects by using high and low TENS amplitudes for any of the measures.

Perception of TENS Sensation

Three patients (9%) reported that TENS sensation was irritating and felt like "pinpricks," whereas others stated it was soothing and felt like "fingers massaging the area." Those who stated the sensation felt like pinpricks tended to dislike the stimulation and felt it either did not help or increased their pain. Those who thought the TENS sensation felt like fingers massaging the area tended to like the TENS and stated it reduced their pain. Those subjects were often able to tolerate higher TENS amplitudes.

Discussion

Pain With Movement

Episodic TENS used as a supplement to pharmacologic analgesia was found to lower pain intensity significantly during 2 of 4 postoperative activities (gait speed and vital capacity) when compared to pharmacologic analgesia alone and placebo TENS. This finding is consistent with meta-analyses of past research showing TENS reduces pain intensity beyond that of pharmacologic analgesia.¹ It is also supportive of past research suggesting that high frequency TENS, used in combination with a high intensity, reduces primary mechanical hyperalgesia¹⁸ and that a reduction in hyperalgesia corresponds to a reduction in movement-evoked pain.⁵⁶ Although this relationship was not specifically tested in this study, the results suggest that such a relationship might exist. If hyperalgesia contributes to movement-evoked pain, then a decrease in pain intensity during movement is likely mediated by a decrease in the hyperalgesia present around surgical incisions. Further research is needed to validate these relationships.

The large placebo component to TENS' effectiveness that was identified in previous meta-analyses¹ was not supported by these data. Average pain intensity scores were often higher during placebo TENS than during ac-

tive TENS, and they were significantly higher during vital capacity maneuvers. One reason for this difference might be the unique strategy used for placebo TENS in this study. The repeated measures design made it impossible to administer a true placebo treatment for high intensity TENS, because participants who were randomized to receive the TENS treatment before the placebo would recognize a difference in this sensation (or lack thereof). Instead, patients were told that 2 different types of TENS therapy were being tested. It is possible that subjects did not equate the low sensation TENS with the same pain-relieving benefits of the high sensation therapy.

Small sample size might have contributed to the lack of significance in pain intensity during transfer and gait distance. Effect sizes comparing TENS to pharmacologic analgesia and placebo TENS for pain intensity during transfer were -0.17 and -0.23 , respectively, and -0.40 and -0.10 , respectively, during gait distance. This suggests a smaller effect than was originally assumed with data from the first 13 subjects. Calculations with a small effect rather than a moderate effect were performed by using correlations from the study data for these variables. A phi prime of $.20$ was obtained for pain during gait distance, requiring a sample size of 66 for each treatment if $a = 3$, $\alpha = .05$, and power = $.7$. The sample in this study was much smaller than what was needed to determine significance in this variable. Pain during transfer resulted in a phi prime of $.37$, requiring a sample of only 20 subjects in each treatment to achieve significance. The sample of 32 subjects used to assess pain intensity during transfer in this study is well above this required number. Therefore, although lack of power might explain why pain during gait distance was not significant, it does not clarify the non-significance of pain intensity during transfer. Other factors might have diminished the differences in pain intensity during transfer including variability in the amount of assistance subjects accepted while performing the maneuver of transferring from a lying to sitting position.

Pain at Rest

TENS did not significantly decrease pain intensity scores at rest. This finding supports the hypothesis that pain at rest is influenced by different mechanisms than

pain with movement. Past research suggests that a decrease in movement-evoked pain correlates with reductions in hyperalgesia but that a reduction in hyperalgesia does not correspond to a decrease in pain at rest.^{18,56}

Walking Function

Both gait speed and gait distance were significantly improved with TENS used as a supplement to pharmacologic analgesia compared with pharmacologic analgesia alone. Gait distance was also greater with TENS when compared to placebo TENS. The improvement in gait speed was associated with a significant decrease in pain intensity during this activity, suggesting that the impact of TENS on pain intensity influenced subjects' ability to walk quickly. This is consistent with past research showing that significant differences in painful movements correspond with significant differences in pain intensity.^{24,32,48}

The significant increase in gait distance was not associated with a significant decrease in pain intensity scores during this activity. This finding suggests that variables other than the control of pain might have influenced subjects' walking distance. Whereas gait speed was a controlled activity that depended largely on the subject's ability to walk with a painful incision, gait distance was less dependent on this relationship and often varied according to the subject's personal motivations to achieve a predetermined destination.

The level of assistance required by subjects was very consistent throughout the testing period and did not appear to be a sensitive indicator of the impact of pain on walking function. On the basis of these findings, level of assistance is not recommended as a useful indicator for measuring the influence of pain on walking function.

Vital Capacity

TENS had no effect on vital capacity measurements beyond placebo TENS or pharmacologic analgesia alone despite significant differences in pain intensity during these maneuvers. This finding, while inconsistent with the total body of research testing the effectiveness of TENS on pulmonary function, is consistent with research specific to abdominal surgery. Studies showing TENS to improve pulmonary function significantly have been conducted predominantly on cardiac and thoracic surgery populations.^{3,54} Studies testing abdominal surgery patients (eg, cholecystectomy and hernia repairs) tend to show no difference both with and without significant differences in pain intensity scores during these activities.^{15,17,47}

Effect Size of TENS

Even though statistical significance was reached showing TENS to decrease pain intensity during walking and deep breathing and increase walking function postoperatively, effect sizes were small, ranging from 0.07 to 0.58 and averaging 0.29. This finding is not unique to this study. Sim⁴⁴ found a significant difference between TENS and a control group on pain during deep breathing

exercises ($P < .05$) while reporting differences of 17 mm between pain intensity scores by using a 10-cm VAS. The degree of difference between TENS and the other treatments might not be large enough to be clinically significant or to justify the added expense of using this treatment in a routine fashion. TENS, however, might provide significant benefit to certain patients. Further research is needed to determine the specific patient characteristics that are associated with greater benefits from the use of TENS therapy to assist clinicians in appropriately selecting patients who might achieve clinically significant results.

TENS Amplitude

Subjects in this study used a broad range of TENS amplitudes, ranging from 3 to 57 mA with a mean of 9 mA. Despite this large difference and the use of very high amplitudes in some subjects, no significant differences in pain intensity during the 4 activities were found between subjects using high and low TENS sensations. Although this might be a reflection of a lack of statistical power arising from the small sample size, it might also be a function of the electrode placement. Wang et al⁵³ found intermittent, high intensity transcutaneous acupoint electrical stimulation (TAES) was more effective than low intensity TAES when used in conjunction with patient-controlled analgesia (PCA) and with electrodes placed at the Hegu acupoint of the nondominant hand in addition to both sides of the surgical incision. This approach might have been more sensitive to the differences in TENS amplitude than placing the electrodes exclusively around the incision.

Limitations

A limitation of this study was the lack of control subjects felt over their ability to adjust the intensity of the TENS. The EMPI Epix VT unit used in this study required the subject to push a button to increase the amplitude by 1 mA. Many were startled by the initial increase in sensation each time they adjusted the amplitude, and that appeared to influence the degree of TENS intensity subjects were willing to tolerate. Although this increase was not large, subjects frequently reported that the sensation was stronger when the button was initially pushed than afterwards. It was also difficult to push and release the button without increasing the intensity more than 1 mA. The lack of control subjects felt over the intensity of the sensation they received each time they pushed the button might have influenced their decision to stop at a lower intensity and, therefore, influenced the pain they experienced.

Another limitation is the lack of blinding. Unfortunately, blinding was not possible given the study design. Investigator bias was minimized, however, by using only objective measures and consistently recording the highest number when the subject gave a range of pain intensities.

Finally, the average interval between sessions was approximately 3 hours. It is possible there were carryover

effects from the active TENS therapy that might have influenced the results of the placebo TENS or control treatments. Sluka et al⁴⁵ found the effect of high frequency TENS on secondary hyperalgesia to be as long as 24 hours. This carryover effect might have contributed to the lack of significant differences in some measures and lower effect sizes. However, those measures that demonstrated significant differences would persist and potentially be even larger in the absence of carryover effects.

Conclusion

The results of this investigation showed that TENS significantly decreases pain intensity during walking and deep breathing maneuvers and significantly improves

the distance and speed subjects are able to walk postoperatively when used as a supplement to pharmacologic analgesia. Effect sizes suggest that selective use is most appropriate in the practice setting. The lack of effect TENS had on pain at rest supports the hypothesis that TENS works through reducing hyperalgesia. Further research is needed to investigate the influence of TENS on hyperalgesia around human surgical incisions.

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