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Prospective, Randomized, Placebo-controlled Study of the Effect of TENS on Postthoracotomy Pain and Pulmonary Function

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Abstract

We investigated the efficacy of transcutaneous electrical nerve stimulation (TENS) for postthoracotomy pain control in a prospective, randomized, double-blind, placebo-controlled study. We studied two groups of patients undergoing posterolateral thoracotomy. In group 1, TENS was used postoperatively on 60 patients for 5 days. Group 2 contained 56 patients without TENS. In both groups a visual analog scale (VAS) was used to indicate if analgesia was needed. When the VAS was higher than 4, an analgesic was administered. We observed the forced expiratory volume in 1 second (FEV_1), the forced vital capacity (FVC), partial arterial oxygen pressure (PaO_2), partial arterial carbon dioxide pressure ($PaCO_2$), and how many doses of analgesia were given at postoperative 0 (extubation time), 2, 6, 12, 24, 48, 72, and 120 hours. TENS was not employed in patients with cardiac or neurologic disease. In group 1, TENS reduced the need to administer opioids during the 5-day postoperative period. This result is statistically significant ($P = 0.013$). Additionally, following the sixth postoperative hour, TENS increased the spirometric breath function. The FEV_1, FVC, and PaO_2 were high and $PaCO_2$ was low when the first group is compared to the second. All these results are statistically significant ($P = 0.012$, $P = 0.01$, $P = 0.024$, and $P = 0.02$ respectively). We observed that TENS produced no evidence of side effects or intolerance in the patients of group 1. TENS is thus beneficial for pain relief following thoracotomy and has no side effects. Consequently, the routine use of TENS following thoracic surgery is recommended.

Postthoracotomy pain is one of the most severe types of postoperative pain. Insufficient treatment of postthoracotomy pain results in reduced pulmonary compliance and the inability to breathe deeply or cough forcefully, leading to retention of secretions, atelectasis, and pneumonia.[1] Several analgesic techniques, including intercostal, paravertebral, interpleural, and epidural blocks with local anesthetics and opioids have been used to provide pain relief following thoracotomy.[2–4] However, as is known, opioids have been associated with undesirable side effects, such as respiratory depression, sedation, nausea, and vomiting; therefore, adjunctive methods of postthoracotomy pain control that may limit the side effects of opioids are of considerable interest. Transcutaneous electrical nerve stimulation (TENS) has been used to control postoperative pain following various procedures, including cardiac operations[5] and thoracotomy.[6,7] TENS has been used extensively to control postoperative pain, but its effects are controversial[8,9].

The use of electrical stimulators such as TENS for pain control became common after 1965, when Melzack and

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Table 1.
Distribution of ages and genders in the two groups

	Gender		Age group		
Group	Male	Female	20–40 Years	41–60 Years	61–70 Years
Group 1 (TENS), $n = 60$	38	22	14	22	24
Group 2 (controls), $n = 56$	32	24	14	20	22

Wall offered their gate control theory.[10] Treating pain with TENS is based on two fundamental methods. One is presynaptic inhibition, in which thick afferent nerves (A-α, A-β, and A-γ) are stimulated selectively, so stimulation transmission is blocked at the level of the medulla spinalis. The other method, giving a painful impulse, stimulates A-δ and C nerves lacking myelin. In this way endogen opioid (endorphin) is released by inhibitor mechanisms active in the upper levels into the central nervous system.

The time was therefore ripe when Melzack and Wall published anatomic and physiologic evidence for a gate-control theory of pain, which proposed that activation of large myelinated afferent nerve fibers would act in the substantia gelatinosa of the dorsal horn to inhibit onward transmission in small and unmyelinated primary afferent nociceptive fibers. The obvious impetus this theory gave to the development of clinical TENS devices for pain control arose from several considerations.

First, the segmental site of the proposed interaction, the spinal dorsal horn, pointed to the need to activate large fibers from the same area as the pain because they would pass the relevant segment, either synapsing or giving off collaterals there. Second, therapeutic stimulation could be given to peripheral nerve fibers, which could often be done transcutaneously; there was no requirement to access the cord directly. Third, the need to activate the large fibers only indicated what the effective stimulus parameters should be and highlighted the fact that the stimulation itself should be entirely painless. It was well known that large fibers have a low threshold for brief electrical pulses and could be selectively activated in this way. Melzack and Wall were well aware of the clinical implications of their theory, pointing out the widespread use of large-fiber activation in the control of pain (*e.g.*, by rubbing the affected part). TENS offered the prospect of a controllable, nontraumatic way of providing an appropriate pattern of nerve activity without narcotic or other systemic side effects.[11]

Theoretically, high-frequency/low-intensity TENS is assumed to work through segmental pain inhibition processes (gate control theory). In contrast, low-frequency/high-intensity TENS is assumed to be effective by releasing endogenous opioids (suprasegmental effect).[12] Although the frequency of TENS may be the decisive factor in the above-mentioned working mechanism, the results of studies are still inconclusive.[12]

We present a prospective, randomized, placebo-controlled study on the use of TENS with posterolateral thoracotomy over a postoperative period of 5 days.

PATIENTS AND METHODS

This study was supported by Akdeniz University Research Fund, and was completed at Akdeniz University Hospital between August 2003 and August 2004. The patients admitted to the study were both male and female, between the ages of 19 and 70, who were undergoing posterolateral thoracotomy. We did not admit to the study patients who required ventilator support in the intensive care unit or those who required more than 12 hours of nasal O_2 support.

There were no patients who suffered from chronic pain during the preoperative period. TENS was not used on patients with cardiac disease (*e.g.*, an arrhythmia) or those fitted with a pacemaker; nor was it used on patients with neurologic disease such as movement limitation or cerebral confusion. The patients were divided into two study groups (Table 1).

Group 1: Conventional TENS was employed on this group of 60 patients with a mean age of 55.6 ± 11.9 years. Altogether, 38 (63.4%) were male, and 22 (36.6%) were female. TENS was used postoperatively for 48 hours continuously; later we used TENS for 20 minutes at 3-hour intervals for 3 days. The TENS system (System 2000; Biomedical Life Systems, Vista, CA, USA) had two channels and four electrodes; it operated at 100 Hz frequency, voltage intervals of 100 μs, and an amplitude regulated in such a way that it should not disturb the patient and it should be under the motor unit. The TENS' four electrodes were situated 2 cm below and 2 cm above the thoracotomy incision area in the posterior (paraver-

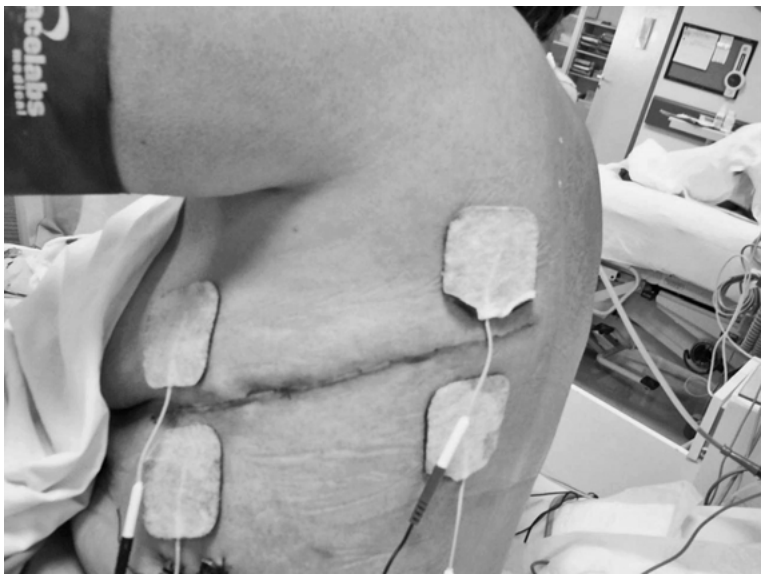

Figure 1. Patient with transcutaneous electrical nerve stimulation (TENS). Electrodes are attached 2 cm above and 2 cm below the thoracotomy incision area.

Table 2.
Distribution of resection types and the number of patients in the two groups

Parameter	Group 1 (n = 60)	Group 2 (n = 56)
Type of thoracotomy		
Posterolateral	60	56
Type of resection		
Wedge resection	12	12
Segmentectomy	8	6
Lobectomy	22	24
Bilobectomy	6	4
Pneumonectomy	4	4
Decortication	8	6
Smoking cigarettes	48	42
Cause of diagnose		
Lung cancer	34	32
Other causes	26	24
Total hospitalization time (days ± SD)	8.95 ± 3.70	8.71 ± 3.60
Duration of chest drain (days ± SD)	7.63 ± 2.10	7.55 ± 2.00

tebral region) and anterior (parasternal region) area of the incision (Fig. 1).

Group 2 (control group): This group consisted of 56 patients with a mean age of 52.93 ± 11.48 years. Among them, 32 (57.1%) were male, and 24 (42.9%) were female. In this group, we used placebo TENS, which was similar to the conventional TENS but inoperative).

Approximately 80% (n = 48) of the patients in group 1 and 75% (n = 42) in group 2 had been smoking at least 20 cigarettes per day for more than 5 years. Additionally 56.7% (n = 34) of patients in group 1 and 57.1% (n = 32) in group 2 had been diagnosed with lung cancer during the preoperative period (Table 2). Table 2 also shows the types of operation and some of the patients' other characteristics.

We used conventional TENS and inoperative TENS in both groups of patients randomly. Neither patients nor physicians knew if the TENS was operative. The results were recorded by blinded observers.

During the operation, we used no other analgesic method or drugs in these two groups. Intraoperatively, we used bupivacaine HCl (0.5% 50 mg) intercostal nerve blockage in both groups. After the operation, we used standard medication, analgesia with diclofenac sodium 75 mg/day (for 3 postoperative days) and pethidine HCl 20 mg/day (postoperative extubation time). Additionally, in both groups, we used pethidine HCl (maximum 1 mg/kg/day) whenever more analgesia was needed. We also supported all patients with oxygen (2 L/min) through a nasal mask for 12 hours in the intensive care unit postoperatively, following which we did not use any additional O_2 support.

The visual analog scale (VAS), divided into 10 units from 0 (no pain) to 10 (worst pain imaginable), was used for both groups. One side was scaled, and the other was blank. The blank side faced the patient. One end of the blank side was marked "worst pain imaginable," and the other end was marked "no pain." When asked, patients would touch a point in between these two ends according to their degree of pain, and this mark indicated the degree of pain on the scale. This question using the scale was asked at 0, 2, 6, 12, 24, 48, 72, and 120 hours while at rest and while coughing by an observer blinded to the treatment groups. The results were recorded.

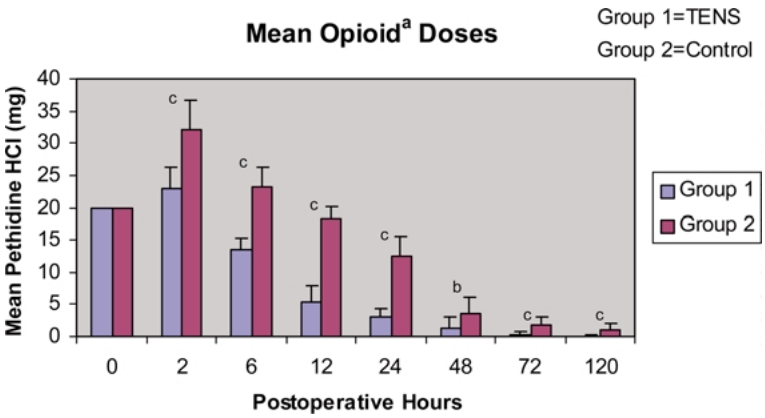

Figure 2. Graph showing the quantity of opioid doses in the two groups. [a]Pethidine HCl. [b]$P < 0.05$. [c]$P < 0.01$).

The degree of sedation was measured on a five-point scale (0, alert; 1, mildly drowsy; 2, moderately drowsy, easily rousable; 3, very drowsy, rousable; 4 difficult to rouse; or 5, not rousable) and was recorded by the same observer. Side effects such as nausea, vomiting, respiratory depression, sedation, and pruritus were recorded and were treated with the appropriate medication.

When the value of VAS was above 4 at rest and 6 during effort (coughing for chest physiotherapy), additional analgesic was injected into the patients in both groups. When the pain was persistent, additional pethidine HCl 20 mg (maximum 1 mg/kg/day) via an intravenous bolus was injected. The total amount of additional analgesic dose (opioid dose) used during the 5 days postoperatively was totaled, and the mean amount of analgesic was calculated for both groups.

We totaled the number of analgesic doses and the mean value of spirometric breath functions, including the FEV_1 and the FVC. We also recorded the mean values for blood gases, including the PaO_2 and $PaCO_2$ at postoperative times of 0 hour (extubation time) and at 2, 6, 12, 24, 48, 72, and 120 hours.

Posterolateral thoracotomy was performed in both groups. Other types of incisions were not included in this study. Thoracotomy and the types of pulmonary resection are shown in Table 2.

Blinded observers analyzed the preoperative and postoperative outcomes and the VAS values.

Statistical Analysis

Numerical variables were expressed as the mean ± standard deviation and the categoric variables as percentages. We used Student's *t*-test for a comparisons of the means. Categoric variables were compared with a chi-squared test, and differences were considered to be significant if $P < 0.05$.

RESULTS

There were no statistically significant differences between the two groups with respect to demographic variables ($P = 0.32$), clinical variables, operative resection data ($P = 0.42$), total hospitalization time ($P = 0.81$), or duration of chest drain ($P = 0.89$) (Tables 1, 2).

Importantly, we found that the patients in group 2 needed more analgesic (opioids) than the patients in group 1. We compared the amount of analgesic doses used in groups 1 and 2 and concluded that the amount of pethidine HCl was reduced in group 1 and that this finding became statistically significant after the second postoperative hour ($P = 0.010$) (Fig. 2).

Variations in the VAS at rest and while coughing were recorded periodically in both groups during the postoperative period (Fig. 3). When we compared the VAS levels of the two groups, the VAS in group 1 was less at rest and while coughing. These results were statistically significant after the second postoperative hour ($P = 0.009$ and $P = 0.008$, respectively).

In group 1 patients, FEV_1 and FVC results decreased from 76% and 79% (preoperative results) to 32% and 31% at postoperative hour 0. Similarly, in group 2 patients these results decreased from 79% and 81% to 31% and 33%, respectively. These values indicate that there was a considerable decrease in the FEV_1 and FVC measurements, exceeding 100%. During the following period (for 5 days postoperatively), FEV_1 and FVC results increased progressively, but the increase in the first group was more than that in the second group (Fig. 4). These results at 6 hours postoperatively for FEV_1 and at 48 hours postoperatively for FVC were statistically significant ($P = 0.01$ and $P = 0.012$ respectively).

The PaO_2 and $PaCO_2$ values of the two groups were compared, with the result that the PaO_2 was high and the $PaCO_2$ low in group 1 (Fig. 5). The PaO_2 and $PaCO_2$

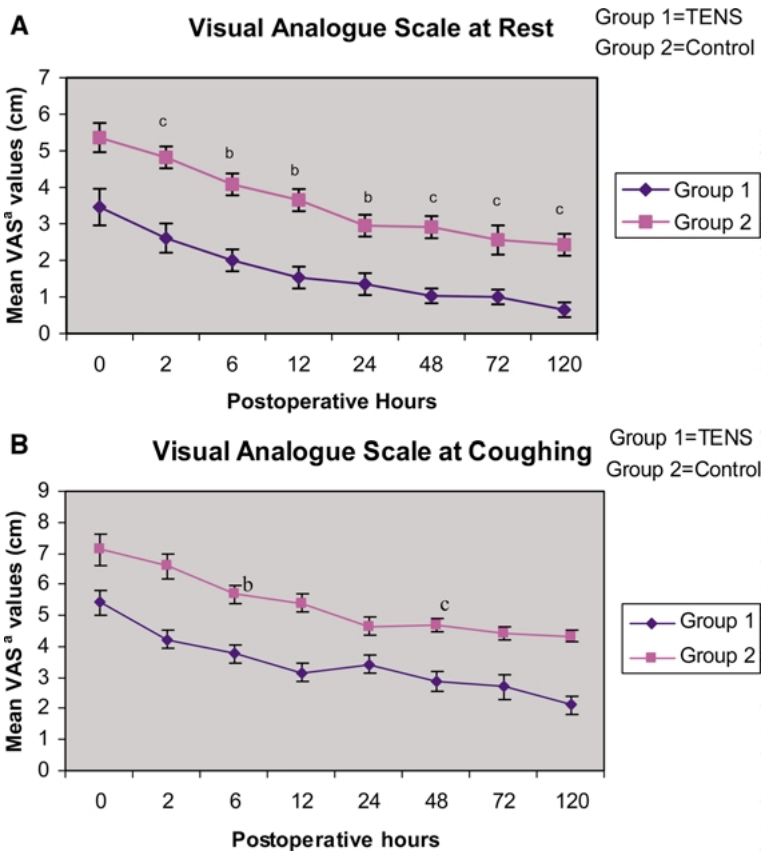

Figure 3. A. Graph showing a resting visual analog scale ([a]VAS) variation of the two groups. [b]$P < 0.05$. [c]$P < 0.01$. **B**. Graph showing cough VAS variation of the two groups. [b]$P < 0.05$. [c]$P < 0.01$.

results obtained 6 hours postoperatively were statistically important ($P = 0.024$ and $P = 0.020$, respectively).

In group 1, we observed neither side effects nor intolerance related to using TENS. In group 2 (controls), however, there were some side effects, including vomiting (11 patients), nausea (7 patients), and pruritus (4 patients) attributable to the use of opioids. We did not detect respiratory depression in any of the patients in either group.

DISCUSSION

Pain associated with many surgical procedures is often inadequately treated. Acute postoperative pain can cause detrimental effects in multiple organ systems, including cardiovascular stress, autonomic hyperactivity, tissue breakdown (production of a catabolic state with suppression of anabolic hormones), increased metabolic rate, pulmonary dysfunction (most commonly after upper abdominal and thoracic surgery), increased blood clotting (hypercoagulability), fluid retention, dysfunction of the immune system, delayed return of bowel function (ileus), and the development of chronic pain syndromes after certain surgeries (phantom limb pain after amputation, postthoracotomy syndrome).[13] Postthoracotomy pain is one of the most severe operative pains, and it often requires opioid treatment. We know that opioids have some severe side effects, including nausea, vomiting, breathing depression, and sedation. This problem requires the use of additional analgesic methods such as TENS.

TENS has long been used to reduce postoperative pain, and it was found that TENS helps reduce some acute postoperative pain. In one study Rakel and Frantz concluded that TENS reduces pain intensity during walking and deep breathing and increases walking function postoperatively when it is used as a supplement to pharmacologic analgesia. They also reported that the lack of effect on pain at rest supports the hypothesis that TENS works through reducing hyperalgesia.[14] However, these results applied only to laparotomy. There are few reports about thoracotomy pain control with TENS, and the results are controversial; furthermore, many other studies were not randomized, one that included a placebo-control study.[7,8,15]

In this study, we were mainly concerned with the effectiveness of TENS therapy during the first 5 days following thoracic surgery. We wanted to determine if TENS is a useful tool for controlling acute postthoracotomy pain, improving pulmonary function, and reducing

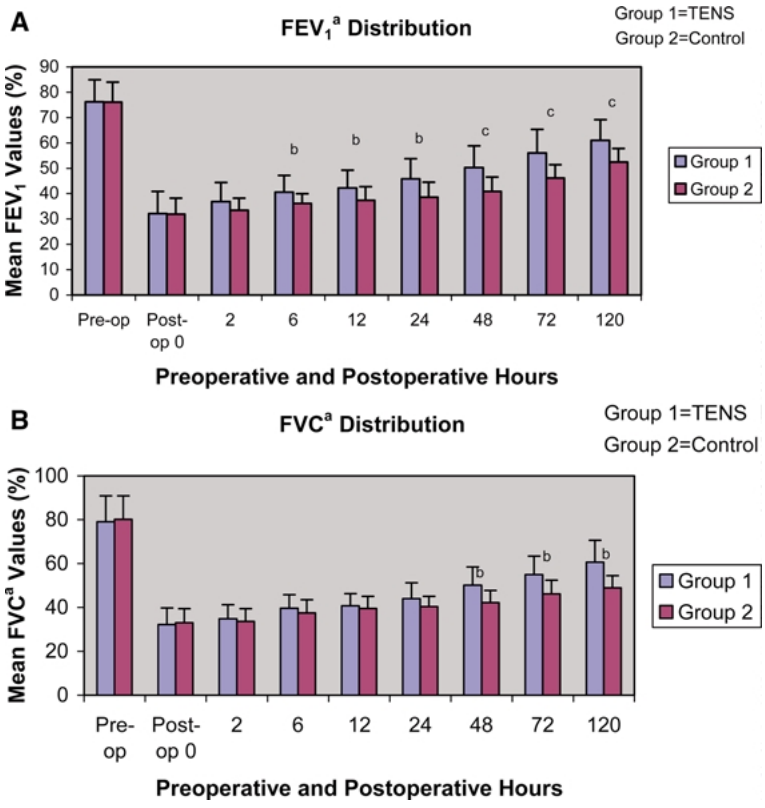

Figure 4. A. Preoperative and postoperative FEV_1 and the statistical results of these two groups. [a]Forced expiratory volume in 1 second. [b]$P < 0.05$. [c]$P < 0.01$). **B**. Preoperative and postoperative FVC and the statistical results of these two groups. [a]Forced vital capacity. [b]$P < 0.05$.

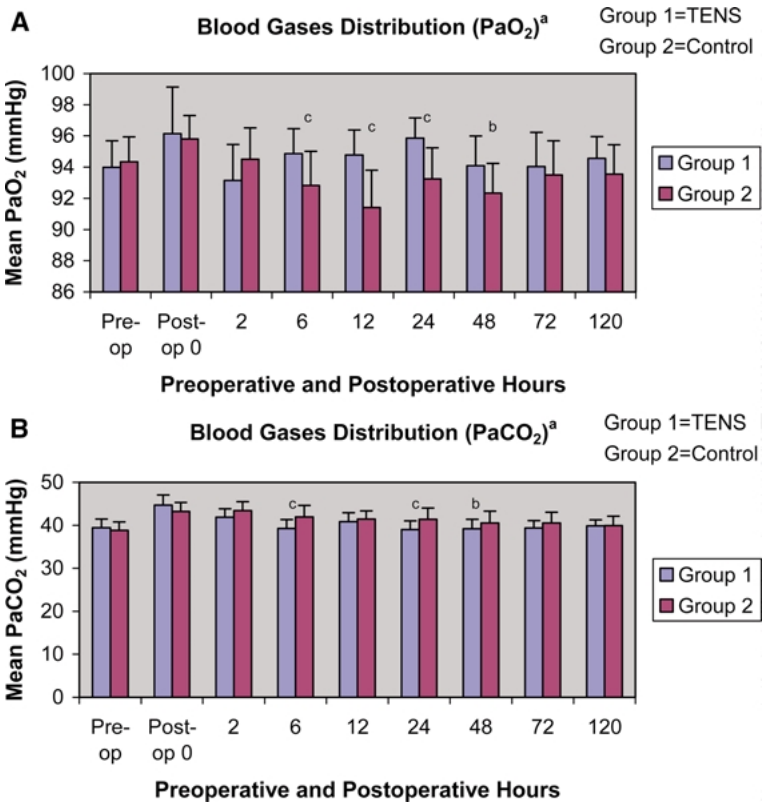

Figure 5. A. Preoperative and postoperative PaO_2 and the statistical results of these two groups. [a]Partial oxygen pressure) [b]$P < 0.05$. [c]$P < 0.01$. **B**. Preoperative and postoperative $PaCO_2$ and the statistical results of these two groups. [a]Partial carbon dioxide pressure. [b]$P < 0.05$. [c]$P < 0.01$.

the need for opioids; we also wanted to determine if TENS produced fewer side effects than other methods. We found that TENS did indeed reduce postthoracotomy pain, improve pulmonary function, and reduce opioid (additional analgesics) requirements. Additionally, we concluded that TENS has no side effects. Consequently, TENS helps control acute postthoracotomy pain; when used alone, however, TENS is not effective against severe postthoracotomy pain, such as can occur with posterolateral thoracotomy. For these patients, additional analgesic medication is strongly recommended instead of using TENS as the primary and only pain control solution. However, TENS helps reduce the need for opioid intake during the postoperative period; moreover, it is quite effective in reducing acute post-thoracotomy pain after posterolateral thoracotomy. Similarly, Benedetti and colleagues reported that TENS is effective in controlling mild or moderately acute postthoracotomy pain caused by muscle-sparing thoracotomy, median sternotomy, and video-assisted thoracoscopic surgery.[15]

Our study confirms previous reports of the efficacy of TENS in the control of postoperative pain and supports the use of this therapy in patients undergoing thoracotomy. Our study showed that using TENS caused the spirometric respiratory function test values (FEV_1 and FVC) to increase, and these patients needed less opioid. Furthermore, we did not observe any side effects, such as nausea, vomiting, sedation, or pruritus, which are related to taking opioids.

Although there are no conclusive data suggesting that TENS inhibits the output of some cardiac pacemakers, this potential side effect should be kept in mind.[16,17] Also, some patients may experience irritation at the electrode site owing to the adhesive or gel employed.[18] Despite these side effects, TENS is a safe, inexpensive, easy-to-use analgesic method. Additionally; if we consider the risk/benefit ratio, the risk can be extremely low for selected patients. We did not observe any side effects using TENS, although we did not use TENS in patients who had cardiac disease.

It has not been reported that TENS is associated with side effects or intolerance except for minimal, unimportant discomfort.[19,20] Similarly, we did not observe any side effects or intolerance related to TENS in our (TENS) study group. In contrast, in the other (placebo TENS) study group, there were some side effects, including vomiting, nausea, and pruritus due to the use of opioids. These results suggest that TENS neither has side effects nor is there intolerance to it.

We used only one frequency for stimulation with TENS, so we are unable to report whether other frequencies could be beneficial in posterolateral thoracotomy patients. However, benefit from using other frequencies is unlikely, as it has been widely demonstrated that a frequency of around 100 Hz is most effective for a variety of painful conditions.[21,22]

CONCLUSIONS

Based on our results—the absence of complications and side effects with the use of TENS compared with conventional opioids and nonopioids analgesics—we concluded that electrical stimulation is a safe and effective adjunctive therapy for acute postthoracotomy pain control. When used together with opioids, TENS significantly decreases subjective pain levels and reduces the duration of the recovery period during intensive care. It also increases the coughing attempts during chest therapy. We therefore advocate routine use of TENS after thoracotomy for pain control and to reduce opioid intake.

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