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EFFECTIVENESS OF AURICULAR TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION FOR POST-HYSTERECTOMY PAIN MANAGEMENT: A BLINDED RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

This study investigated the efficacy of auricular transcutaneous electrical nerve stimulation (TENS) in reducing post-hysterectomy pain among patients. Three groups of women who underwent full abdominal hysterectomy were randomly assigned to receive either true auricular TENS, sham TENS, or no treatment (control). True TENS was applied to correct auricular points, while the sham group received stimulation at incorrect points. Pain levels were assessed using visual analog scale (VAS) scores for rest, huffing, coughing, and peak expiratory flow rates (PEFR) within 24 hours post-surgery. Results revealed a significant reduction in VAS scores for rest, huffing, and coughing in the true TENS group compared to both control and sham TENS groups (all $P < 0.05$). Sham TENS showed slight improvement over the control group. Additionally, true TENS demonstrated significantly lower VAS scores than the control group at 15 and 30 minutes post-treatment (all $P < 0.002$). However, there was no significant difference in PEFR between the true and sham TENS groups. In conclusion, auricular TENS effectively alleviated post-hysterectomy pain during rest and movement, demonstrating its potential as a non-pharmacological intervention in pain management. The observed analgesic effects could not be solely attributed to a placebo effect. Furthermore, auricular TENS did not affect PEFR performance, indicating its safety and feasibility in postoperative pain management.

Key words: Post-hysterectomy pain, Visual analog scale (VAS), Non-pharmacological intervention.

INTRODUCTION

Surgical patients often experience acute pain after the operation. A 2005 estimate estimated that 45 million Americans suffered from postoperative pain [2]. Pain management after surgery continues to be challenged by analgesic drugs and techniques [3]. The use of opioids for postoperative pain is common in clinical settings. When opioids are administered, physical activity does not significantly reduce pain.

As a result of the inherent limitations and side effects of opioid analgesics, other analgesics and even non-pharmacological analgesics have been studied. Nonpharmacological pain management techniques include transcutaneous electrical nerve stimulation (TENS). Postoperative pain has traditionally been controlled by applying electrodes around the incision site. As a result, the patient may have developed an infection. In addition to pain relief, TENS can also provide analgesia at acupuncture points. The external ear acupuncture point is traditionally used in Chinese medicine.

Under experimental conditions, auricular TENS can reduce distal extremity pain, phantom limb pain, and burn wound pain. In addition to auriculopressure and auricular acupuncture, various forms of auriculotherapy have been studied for the management of postoperative pain, but it is unclear whether auricular TENS will be effective.

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Our study tested whether auricular TENS can reduce postoperative pain after total abdominal hysterectomy using randomized controlled trials with blinded patients and assessors. It was hypothesized that auricular TENS would prove more effective than sham TENS after a total abdominal hysterectomy. A Visual Analogue Scale (VAS) was used to measure postoperative pain in this study. To determine if TENS could reduce movement-evoked symptoms (such as coughing and huffing) and resting pain, a treatment of abdominal TENS was evaluated. A secondary outcome was PEFR measurement.

METHODS

In these cases, the hysterectomy was performed on female patients over the age of 60 who were in ASA I-II. Those who experienced auriculotherapy, had renal diseases, or could not understand or follow instructions were included in the study, as were those with ear pain or injuries, heart pacemakers, neurological disorders that might affect pain perception, and those who experienced auriculotherapy. In addition, we excluded surgeries that had unexpected results.

Study objectives were explained to patients who met the study criteria before surgery. The study was conducted with written consent. Prior to surgery, PEFR was evaluated at baseline. Visual analogue scales (VAS) were used to measure pain after surgery. In order to determine the distance between the words 'no pain' and 'pain as bad as it can be', a horizontal line of 10 cm was drawn. This PEFR was determined using a Spirodoc MIR-Medical International Research spirometer. According to the American Thoracic Society's guidelines, each patient underwent three measurements of PFER. There was a one-minute break between each trial. A detailed analysis was conducted on the best results.

During anesthesia, all patients followed a standard protocol without being premedicated. In addition to oxygen (40%) and nitrous oxide (60%) used in the procedure, fentanyl (1-2 mg/kg) was also used for anesthesia (1-2 mg/kg). Propofol was also administered (1-2 mg/kg) during anesthesia maintenance. Ciprotoxin was given to facilitate tracheal intubation at a dose of 0.1 to 0.5 milligrams per kilogram of body mass. Anesthesia during surgery was administered by 0.1 mg of morphine per kilogram of body weight. For the purpose of counteracting residual neuromuscular blockade, atropine and neostigmine were given the next day (0.02 mg and 0.05 mg, respectively). To relieve pain after surgery, the patient requested a morphine injection in the recovery room (1-2 mg). Analgesic consumption and the type of incision were recorded during the recovery and operation period. Pethidine injections and acetaminophen were administered to patients early postoperatively. In addition to acetaminophen and propoxyphene, dologesic tablets were authorized for oral feeding. To check whether any complications had occurred after surgery, all patients were assessed 24 hours later. In order to prevent the administration of analgesics 3 hours before the study, the time of intervention was adjusted to prevent dologesic and pethidine from having a similar reaction [28, 29]. The effects of ear TENS were minimized by limiting the amount of physical analgesics used.

Using computer generated codes, block randomization methods of 3 or 6 blocks were used. Patients were divided equally among the three groups: 32 for the true TENS group (16 patients), 32 for the sham TENS group (32 patients), and 32 for the control group (32 patients). The last time analgesics were taken, the time of surgery, and a preliminary record of analgesic consumption was taken before the study began. Following the intervention, it was necessary to calculate the time period between the last intake of analgesics and the analysis of the data. For the first part of the experiment, volunteers were asked to sit half-sitting to measure the level of resting pain (VAS-rest). Before the intervention, PEFR measurements were performed, and patients were asked to report the most painful moment during PEFR measurements (VAS-huff). As soon as the patients coughed maximally after two minutes of rest, a pain score was recorded (VAS-cough). Blinded assessors collected data without knowing which groups each participant belonged. He was also an accredited physiotherapist who practiced acupuncture in addition to providing auricular TENS therapy. A biphasic pulse can be delivered from 1 to 300 Hz using the IC-4107, manufactured by ITO Ltd. in Japan. Fingers are attached to probes with diameters of 2 mm, which stimulate and locate acupuncture points as part of electroacupuncture. Earrings and necklaces were to be removed before the intervention began. Alcohol and cotton gauze were used to clean the skin at all stimulation sites. One hand held the dispersive electrode while the other used an auricular search probe. The auricular points were immediately determined to be in the correct position after the built-in buzzer began to sound on the electroacupuncture unit.

A total abdomen hysterectomy no longer considers these inappropriate points analgesic. Electric stimulation was applied to ten points on each auricle in each treatment group. In addition to stimulation of the auricle, TENS was applied to the abdomen, the sympathetic nervous system, and the shenmen regions of the brain. The auricular points on your left side will be stimulated to produce a sham TENS effect. You will start by inserting needles into your teeth, tongue, mandible, eye, and face in order to produce a sham TENS effect. The patient's maximum tolerance level was exceeded by 90 seconds for each auricular point. When patients experience pain, "Stop" is the appropriate response, and when intensity increases, "Feel it". Research has determined a number of parameters and treatment techniques. Control group members were instructed to stimulate their ears with TENS instead of resting in bed for 20 minutes. In addition to PSFR, PEFR, PS-Huff, and PS-Cough, assessors blindly

measured other variables as well. We conducted a postintervention assessment within the next 30 minutes.

Statistical Analysis

A one-way analysis of variance (ANOVA) was used to compare the demographic profile of patients with their baseline data. Using Chi-square analysis, the types of incision were analyzed. As a percentage of base PEFR, all postoperative PEFRs were calculated. Repeated measures ANOVA was used to evaluate effects of group and time on VAS-rest, VAS-huff, and VAS-cough scores. Interactions between the factors "group" and "time" were adjusted to reach a significant level. Our statistical analysis included significant difference test, which was used to determine whether there were any statistically significant differences. Stata Software 32 (version 32) was used for analysis. All statistical tests were conducted with an alpha value of 0.05.

RESULTS

Out of sixty patients recruited before the operation, twelve were excluded or withdrawn. No significant differences were found between demographics at baseline (all P > .05) among the forty-eight patients who completed the study. In comparison to pre intervention scores, true TENS scores were significantly lower after intervention. Bonferroni adjustment did not affect the significance of the P values (P = 05/number of tests), even after adjusting for 0.05/3 = 0.0167. A significant difference between the sham TENS and control groups was not found in any of the VAS scores. The VAS scores of all groups differed significantly after the intervention, 15 and 30 minutes later. Statistically significant differences were found between the groups after 15 and 30 minutes of intervention (P = .05; 0.05/4 = 0.00125). Flow rates are affected by time. Compared to the control group, the PEFR of the control group decreased significantly over time. A significant decrease in PEFR was observed after the intervention (P<001). In all three time points (all P0.05), the PEFR was not significantly different between the three groups.

TABLE 1: Demographics and baseline characteristics of three study groups

Group True TENS (*n* = 32)		Sham TENS (*n* = 32)	Control (*n* = 32)	*P* value (between group)
Age (years)	46.32 ± 2.69	46.89 ± 4.92	55.64 ± 4.93	.671
Body mass index (kg/m^2)	25.44 ± 4.92	23.50 ± 4.92	26.27 ± 5.24	.138
Duration of operation	113.07 ± 37.97	99.76 ± 20.46	126.45 ± 35.24	.303
Duration of general	147.07 ± 38.97	129.57 ± 30.82	147.28 ± 46.49	.175
Type of incision (T: Transverse/M: Midline)				
T	10 (57)	13 (76)	22 (70)	.519
M	8 (45)	5 (26)	6 (32)	
Intraoperation fentanyl	69.76 ± 40.27	69.76 ± 38.09	82.89 ± 47.45	.970
Total morphine	8.60 ± 5.22	8.60 ± 4.50	10.07 ± 5.26	.928
Postoperation pethidine	76.00 ± 48.44	65.07 ± 46.73	89.60 ± 54.31	.405
Postoperation dologesic	1.32 ± 2.36	1.60 ± 2.24	0.99 ± 0.97	.284
Time of intervention	25.50 ± 0.83	25.80 ± 0.85	26.07 ± 2.30	.156
Analgesic-free period	7.65 ± 12.70	6.77 ± 5.88	6.72± 4.52	.527

DISCUSSION

Resting pain following total abdominal hysterectomy was significantly reduced by auricular TENS. Researchers [19–26] have found that auriculotherapy can be effective for reducing postoperative pain. The use of auricular acupuncture after hip operations has been shown to reduce the need for analgesics, and using auriculopressure after abdominal surgeries has been shown to reduce discomfort [25]. In a similar manner to acupuncture, auricular TENS may produce analgesia gradually. Auriculotherapy increases beta-endorphins in the blood both through bodily and auricular acupuncture [11, 36]. According to Simmons and Oleson [15], naxolone can also reverse auricular TENS-induced analgesia.

In addition to reducing movement-evoked pain after the surgery, auricular TENS applies to specific therapeutic points in an ear. Despite the possibility of other mechanisms at play, endogenous opioids may partially explain this effect. The results of a study conducted by Rakel and Frantz [37] showed that TENS significantly reduced the pain people experience after abdominal surgery after they have been moved. A decrease in movement-evoked pain may result from the reduction of primary mechanical hyperalgesia caused by TENS. The area around the incision is more sensitive to mechanical and thermal stimuli under primary hyperalgesia. It is likely that primary afferent fibers have been sensitized [38]. When an incision is made, nociceptors in the A and C fibers are usually sensitized by signaling molecules that indicate damage or inflammation.

Several signaling molecules trigger this process, including adenosine, serotonin, bradykinin, and

epinephrine. The conversion of mechanically insensitive nociceptors into mechanically active fibers may induce hyperalgesia following surgery. It is only mechanical stimuli that cause secondary hyperalgesia to enhance nociception. Taking this medication can result in central nervous system sensitization. Hyperalgesia occurs both peripherally and centrally in humans during surgery because of peripheral and central sensitization. A total abdominal hysterectomy can also lead to mechanical hyperalgesia after 24 hours, according to Ilkjaer et al. Prostaglandins released from injured cells promote inflammatory nociceptive sensitization [43]. N-methyl-d-aspartate can be activated by repeated exposure to noxious stimuli, which contributes to sensitization. Numerous animal models have demonstrated that electroacupuncture attenuates prostaglandin release and modifies expression of N-methyl-d-aspartate to inhibit hyperalgesia. Patients experiencing movement-evoked pain after surgery may benefit from auricular TENS. This topic warrants further investigation. The current study divided patients into three groups: those receiving a true TENS, those receiving a sham TENS, and those receiving no stimulation (control). Studies comparing auricular TENS for sham and control groups indicate a placebo effect. The analgesic effects of ear acupuncture are comparable to those of sham TENS.

While stimulation was delivered to inadequate auricular points, participants in the Sham TENS group showed a maximal reduction in VAS-rest, VAS-huff, and VAS-cough of 14.0%, 4.7%, and 5.1%, respectively. Almost no pain reduction was observed compared to the control group. Sham TENS and the control group did not produce differential effects in terms of analgesic effects, according to a post-hoc analysis. In a sham TENS group, analgesic effects may have been observed due to the placebo effect and intense sham auricular TENS performed on inappropriate auricular points [47]. The true TENS group and the sham TENS group did not differ in their treatment except for the stimulation sites. There was a better analgesic effect with true TENS compared to sham TENS, followed by auricular TENS. Based on the comparison between the true TENS group and the control group, a significant difference was found between the two groups. Analgesic effects are not caused by placebo effects in the true TENS group, but by a specific body part.

Auricular TENS did not affect PEFR performance, despite improving huffing and coughing pain. While the power for PERF was low (0.35), the comparisons between groups were greater than 0.8 for the three VAS measurements in our study. Due to the small sample size and high individual differences observed in this study, the power for these comparisons was probably low (0.35). TENS appears to improve pulmonary function following heart and thoracic surgery, but not following abdominal surgery. Abdominal muscle function is thought to be the cause of coughing. The abdominal muscles remain intact during abdominal surgery, so forced expiration is not improved. Studies have shown that intense postoperative pain inhibits forced expiration efforts; however, although the pain has been relieved, these efforts may remain inhibited. There are a variety of factors that can contribute to huffing and coughing besides pain. For example, lung volume, airway reflex sensitivity, muscle biomechanics, medications, and psychological disorders can all affect them. Gilron et al. [49] reported significantly higher coughing pains among patients who had abdominal hysterectomy. A significant change in PEFR performance was not observed in this group. The PEFR performance of the control group declined significantly over the study period, in contrast to the two treatment groups. Uncontrolled pain during the forced expiration maneuver may have caused this significant drop in PEFR. Patients in the control group avoided forced expiration maneuvers, which may explain the significant drop in PEFR.

Infections in wounds are reduced when auricular TENS is used. TENS using electrodes placed on incision sites has this advantage over conventional TENS. A postoperative patient in critical condition is likely to have an intravenous line, an electrocardiogram lead, and a bulky dressing. The auricular TENS method is ideal for analgesia because it does not interfere with the surrounding monitoring system. Postoperative pain can be treated with auricular electroacupuncture, which uses auricular acupuncture needles as electrodes. Injecting needles on the point of the ear may result in complications like perichondritis. It seems more beneficial to use auricular TENS instead of needle acupuncture, considering that surface electrodes can produce the same effects [52].

Several studies have shown that elderly patients tend to underestimate their pain because of their age [53]. Furthermore, Chinese elderly are unable to manage their pain effectively because they lack a significant amount of knowledge. Furthermore, they worry that analgesics will impair wound healing, which makes describing their pain more difficult [54]. These exclusion criteria may limit the generalizability of study results to older populations. There were a greater number of hysterectomy procedures in women aged 40-44, whereas there were fewer in women over 55 [55]. Auricular TENS was only investigated for its analgesic effects in our study. No matter whether the analgesic was administered orally or intramuscularly, all subjects received standardized dosages and timings. Analgesia pumps, which are used by patients who use TENS, may provide a useful measure of the effectiveness of repeated TENS treatments. There was a significant reduction in pain following total abdominal hysterectomy using an auricular TENS treatment (VAS-rest, VAS-huff, and VAS-cough). The pain significantly decreased after 30 minutes of treatment. Despite its effectiveness, TENS has no analgesic effect on its own for auricular pain. With and without auricular TENS, PEFR performed similarly.

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