The Effects of Two Different Electrical Stimulation Methods on the Pain Intensity of the Patients Who Had Undergone Abdominal Surgery With a Midline Incision: Randomized Controlled Clinical Trial

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This study was conducted as a randomized controlled trial. The primary outcome measures were the effects of TENS and TAES on pain and analgesic drug consumption in patients who had undergone abdominal surgery with a midline incision. Secondary outcome measures were the effects of TENS and TAES use on respiratory functions, vital signs, nausea and vomiting status, dizziness, antiemetic drug consumption, and saturation

Study setting

This study was conducted at the Department of General Surgery of the Gülhane Training and Research Hospital in Ankara, Turkey between May 2015 and November 2016.

Participants

The population consisted of General Surgery patients who underwent planned abdominal surgery with a midline incision between May 2015 and November 2016. The study sample comprised patients who underwent abdominal surgery with a midline incision due to problems related to colorectal cancer and stomach cancer. The principal investigator evaluated patients awaiting abdominal surgery with a midline incision in the hospital room the day before the surgery to ensure that the patients qualified for the study in accordance with the eligibility criteria.

Inclusion criteria

Patients who had an American Society of Anesthesiologists (ASA) score of I-II, were aged over 18 years, who could read and write Turkish, who were scheduled to undergo elective abdominal surgery with a midline incision for a diagnosis of stomach or colorectal cancer, and without any impairment of vision, hearing or speech were included in the study.

Exclusion criteria

Patients who had a pacemaker, whose skin integrity around the incision was degraded, had a cognitive disorder, had a history of chronic pain, or were suffering from neurological, renal, cardiac or pulmonary disorders that could affect the test results, and patients with an opioid addiction, those who had previously undergone electrical stimulation treatment, morbidly obese subjects and patients using

psychoactive drugs were excluded.

Randomization

To determine the groups, randomization was performed with a web-based randomization system with the help of a computer by researchers. A block randomization list was obtained for 3 groups. TENS was implemented to the incision circumference of the patients in the first group and to the acupuncture points of the patients in the second group with no treatment being implemented to the control group.

The interventions

The standard anesthesia protocol was implemented to all patients suitable for the study. All of the patients included in the study were administered 2 mg midazolam IV 5 minutes before the operation as premedication, after the peripheral vein was accessed. Once the ECG, noninvasive blood pressure, and pulse oximeter monitorization was started, preoxygenization was provided and anesthesia induction conducted intravenously with propofol 2-2.5 mg /kg, rocuronium bromide 0.6 mg /kg, and fentanyl 2 mcg /kg. This was followed by oral tracheal intubation 90 seconds after 100% O_2 at 4 l/min was started. After endotracheal intubation, the inhalation agent desflurane was set at 6% concentration. All patients were administered 0.2 mg/kg rocuronium bromide IV at 30-minute intervals and IV remifentanil was adjusted to 0.25 mcg/kg/min. All patients were administered intraoperative ranitidine HCl 20 mg and metoclopramide 10 mg. After the last skin suture was placed, the inhalation agent and remifentanil infusion were terminated. Once spontaneous breathing started, the muscle relaxant agent was antagonized (neostigmin 0.05 mg/kg, atropine 0.015 mg/kg) and the patient was extubated when spontaneous breathing and adequate muscle strength were present.

A standard analgesia protocol for post-operative pain control was used in all patients included in the study. The Patient Controlled Analgesia infusion was administered to the patients for 48 hours. The patients were provided a total of 500 mg Tramadol HCl Patient Controlled Analgesia infusion intravenously (IV) at a concentration of 5 mg/ml, an infusion dose of 5 mg/hr, a bolus dose of 20 mg, and a 150 mg per 4 hour limit with a 30 minute lock-in time. Dexketoprofen Trometamol vial IV and/or 50 mg Pethidine HCl IM were used as rescue analgesic drugs.

A standard antiemetic protocol was used for all patients after surgery. If they had nausea, 4 mg/2 ml ondansetron was administered intravenously.

First Intervention Group: The Patient Controlled Analgesia infusion was started right after the

surgery. 4 electrodes were placed 2-3 cm lateral to the incision of the patients at the 30th minute and 2, 18, 22, 42, and 46th hours after the surgery and electrical stimulation was implemented at varying frequencies of 2-100 Hz for 30 minutes, at a maximum current intensity of 12 milliamperes that would not bother the patient or create muscle contractions, with a pulse duration of 0.25 min. . (Figure 1).

Second Intervention Group: The Patient Controlled Analgesia infusion was started right after the surgery. 4 electrodes were placed at the ST25, P6, ST36, and LI4 acupuncture points of the patients at the 30th minute and 2, 18, 22, 42, and 46th hours after the surgery and electrical stimulation was implemented at varying frequencies of 2-100 Hz for 30 minutes, at a maximum current intensity of 12 milliamperes that would not bother the patient or create muscle contractions, with a pulse duration of 0.25 min. (Figure 2).

Control Group: The Patient Controlled Analgesia infusion was started right after the surgery. No intervention was performed to the patients in the control group. The data of the patients were recorded at the post-operative 30th minute and 2, 18, 22, 42, and 46th hours. The flow chart of the study is shown in Figure 3.

The TENS device used in this study was a dual channel nerve stimulator. This device had 7 preset pain programs and 3 special programs. The program and the amplitude could be set individually for each channel. The electrodes of the device were 4x4 cm in size with 4 pieces in total. The electrodes were placed 2-3 cm lateral to the incision area and at the relevant acupuncture points. The current intensity was manually set according to the patient's tolerance.

Measurements

Baseline measurements

Preoperative measurements: The patients' age, gender, height, weight, diagnosis, history of a chronic sleep disorder and ASA class data were recorded. Pulmonary functions (PEF, FVC), vital signs, respiratory rate, saturation and pain level data were also recorded.

Outcome measurements

Intraoperative measurement: All patients received general anesthesia with the same protocol. The patients were observed during the surgical procedure and data such as incision length, duration of anesthesia, duration of surgery and number of drains were recorded.

Postoperative measurements: The medical findings of all patients after the surgical procedure were recorded.

Pain: VAS with a range of 1-10 points was used while the pain levels of all patients were evaluated. Pain levels of all patients were evaluated at rest.

Analgesic drug consumption: All patients were administered IV Contramal infusion with PCA for the first 48 hours. Dexketoprofen Trametamol vial IV and/or 50 mg. Pethidine HCl IM was used as the rescue analgesic.

Nausea severity: VAS with a range of 1-10 points was used while evaluating the nausea severity of all patients .

Vomiting: The number of times the patients vomited was recorded.

Antiemetic drug consumption: The antiemetic drug amount administered to the patients was recorded in mg.

Pulmonary function tests: The pulmonary functions of the patients were evaluated with a portable spirometer. PEF and FVC values were recorded. The measurement of respiratory functions was performed with the patient wrapping the disposable mouthpiece well with the lips during the measurement. The patient was asked to breathe deeply and exhale suddenly and quickly. This process was repeated three times and the best performance was taken as the base value.

Sample size: The software package G-power 3.1.3. was used to conduct a prior power analysis to calculate the number of participants required. Sixteen participants were required to detect an effect size of 1.4 at 80% power. The alpha level used to define significance was 0.05.

Blinding: Because the patients and data collector were aware they were implementation electrical stimulation or not, there was no blinding to the study.

Data collection: Data collection was started on the day before the patients underwent surgery and finished on the 2nd day after surgery.

Preoperative data collection: The characteristics of the patients and ASA classifications, vital signs and respiratory functions were evaluated one day prior to the surgery.

Postoperative data collection: The medical information of the patients was recorded within the initial 48 hours after the surgery. Vital signs, respiratory functions, pain levels, nausea severity, vomiting status, dizziness status, analgesic and antiemetic drug consumption of all patients included in the study were recorded. Vital signs and pain levels of the patients in the control group were evaluated at the post-operative 30th min. and 2,18,22,42, and 46th hours. Vital findings and pain levels of the patients who were included in the intervention groups before and 30 minutes after the implementation were evaluated. All evaluations of the patients were performed during bed rest. Nausea levels, vomiting status and dizziness status of the patients were evaluated at the periods of 0-6, 6-24, and 24-48 hours. Analgesic and antiemetic drug consumption of the patients was

evaluated at the periods of 0-24 and 24-48 hours. Respiratory function evaluations of the patients were performed at the 24th and 48th hours.

Data analysis:

The data obtained from this study were evaluated by using the Statistical Package for the Social Sciences (SPSS,Inc.,Chicago,IL,USA) 22.0 software program.

After the data were transferred to the SPSS database, error controls were performed. Their compliance with a normal distribution was evaluated with Kolmogorov Smirnov test. The data determined were mean ± standard deviation (X ± SS), median and minimum-maximum (min-max) for the variables determined by the measurement and number (n) and percent (%) for the variables determined by counting. Since the variables determined by counting did not comply with a normal distribution, the difference between the three groups was evaluated by the Chi square test. The one-way ANOVA test was used to investigate the difference between the three groups regarding the measured values for values complying with normal distribution and the Kruskal-Wallis test was used for the values that did not comply with a normal distribution. The Bonferroni correction was implemented to determine the source of the difference in group comparisons. The Mann-Whitney U test was used to investigate the difference between two groups of variables. A p value <0.05 was accepted as statistically significant. The Paired Sample T Test was used for values complying with a normal distribution and the Wilcoxon Test was used for values not complying with a normal distribution when comparing the values of patients in the same group before and after the implementation.

Ethical consideration: Written permission and approval was obtained from the Gülhane Military Medical Academy's Head of Clinical Studies Ethics Committee before the study started. Physicians and nurses working at the Gülhane Military Medical Academy, General Surgery Clinic, Post-Operative Care Unit and Post-Anesthesia Care Unit within the Anesthesiology and Reanimation Clinic were informed of the study and verbal approval was obtained.