STUDY PROTOCOL

STATİSTİCAL ANALYSİS PLAN (SAP)

INFORMED CONSENT FORM (ICF)

Human Subjects Review Approved Dated: 10.09.2018

10.10.2018

STUDY PROTOCOL

1.1. Study Design and Patient Selection

This study was designed as a randomised, 3-way blinded, placebo-controlled study to determine the effect on GIS functions, pain and anxiety of acupressure applied for a total of 12 mins, as 3 mins at each of the ST25, CV12, TH6, and HT7 acupuncture points, at 0, 4 and 8 hours after laparoscopic cholecystectomy operation.

Patients were randomly assigned to the intervention and placebo groups in this clinical study. The study group was formed of patients who underwent laparoscopic cholecystectomy in a state hospital in Turkey.

1.2. Anaesthesia protocol

All patients received 2 mg of midazolam intravenously in the premedication unit 5 minutes before surgery. For anesthesia induction, tracheal intubation was performed with the simultaneous use of rocuronium bromide 0.6 mg / kg, intravenous propofol 2-2.5 mg / kg and fentanyl 2 mcg / kg, at 4 l / min 100% O2. IV remifentanil was set at 0.25 mcg / kg / min and 0.2 mg / kg rocuronium bromide was given intravenously every 30 minutes. After tracheal intubation, the inhalation gas desflurane was adjusted to 6% concentration. All patients were intraoperatively administered metoclopramide 10 mg and ranitidine HCl 20 mg. Remifentanil infusion and inhalation agent were discontinued after the last skin suture was made. When spontaneous breathing started, muscle relaxant was administered (neostigmine 0.05 mg / kg and atropine 0.015 mg / kg), and patients were extubated when sufficient muscle strength and spontaneous breathing were available. After surgery, 4 milligrams of ondansetron was administered intravenously to patients who had nausea and vomiting.

1.3. Process and Intervention

Intestinal sounds were listened to with the same stethoscope, by dividing the abdomen into 4 quadrants and evaluating each quadrant. A time of one minute was set on a chronometer for each evaluation, and the number of the intestinal sounds in one minute were counted and recorded. To prevent errors in the evaluations, the accuracy of the measurements was confirmed by a doctor at the same time. Patients who had been discharged before gas output and defecation were telephoned and questioned about the times of these outputs. The applications made to the intervention and the placebo group are shown in Table 1.1.

Table 1.1. Applications made to the Intervention Group and the Placebo Group

	Preop	Periop	Postop	Before acupressure	After acupressure		
					0 hour	4 hours	8 hours
Informed consent	X						
Sosyodemographic characteristics	X						
Clinical characteristics	X	X	X				
TAI	X						
Blood pressure-pulse				X	X	X	X
Intestinal sounds				X	X	X	X
First flatus				X	X	X	X
First defecation				X	X	X	X
Pain				X	X	X	X
Nausea				X	X	X	X
Vomiting				X	X	X	X
SAI				X			X

1.4. Safety Evaluation

Stimulation of the acupuncture points due to the prolongation of the fasting period before the surgery may decrease the blood glucose level of the patient. Therefore, the patient was observed in terms of symptoms such as pallor and apathy during acupressure. In addition, patients were observed in terms of side effects such as bruising, bleeding and increased pain during the application. No complications developed in patients.

Acupressure steps

Informed consent for the procedure was obtained from each patient then acupressure was applied using the following steps.

1. The hands of the practitioner were washed with warm water.

2. The patient was positioned supine or half- sitting in a comfortable position with the knees slightly bent and the support of a small pillow under the knees.
3. The ST 25, CV 12 and TH 6 acupuncture points to be used were determined using measurements of the patient's fingers.
4. Acupressure was applied for 3 minutes at each point starting from HT 7, then moving to TH6, ST 25, and CV 12.
5. Using the tips of the thumbs of both hands, pressure was applied for 10 seconds continuously then rested for 2 seconds, and this cycle was repeated for 3 mins.
6. The level of pressure applied was adjusted according to the tolerance level of the patient. VAS was used to evaluate positive pain, and the feeling of fullness or heat (Deqi). Evaluation of the intensity was controlled at 5.
7. The acupressure procedure was performed 3 times at 0, 4 and 8 hours postoperatively.

1.5. Sapmle size

The population of the study consisted of adult patients who underwent laparoscopic cholecystectomy. Between July 2018 and July 2019, 132 patients underwent surgery. Tan et al. (2016), the sample of the study was determined by power analysis using the difference (4 hours) between the first flatus time of the patients after laparoscopic cholecystectomy in the experimental and placebo group. A total of 60 patients were planned to be included in the study, 30 of which were experiments and 30 were placebo. According to the results obtained for the State Anxiety Inventory with post-power analysis applied to the data obtained in the study, it was deemed necessary to include a total of 53 patients in the study, as 26 in the intervention group and 27 in the placebo group for power size of 0.006 and statistical powere of 0.087 with 5% type 1 error for two-way variance analysis of repeated measurements.

Randomisation: Patients were randomly assigned to the intervention and placebo groups in this clinical study. 65 patients who met the inclusion criteria were included in the study.

53 patients included in the study were randomly assigned to 2 groups. For randomization, the randomization list produced in a computer program that produces random numbers as numbers 1 and 2 was used. Patients were randomized into intervention and placebo groups in order of hospitalization using the randomization list (http://www.randomizer.org/form.htm).

1.6. Ethical Approval

Approval for the study was granted by the Ethics Committee of Kahramanmaraş Sütçü Imam University Medical Faculty, and the Academic Committe of Erciyes University health Sciences Faculty (Decision no: 2018/10). Written permission was obtained from the Medical Director of Kahramanmaraş Sütçü Imam University Medical Faculty Hospital. Verbal and written informed consent was obtained from all the patients in the study.

Author contributions

Dilek Soylu: Conceptualisation, methodology, formal analysis, data collection, evaluation, manuscript writing, original design, checking and corrections.

Pınar Tekinsoy Kartın: Conceptualisation, methodology, formal analysis, manuscript writing, checking and corrections.

Conflict of Interests

The authors have no conflict of interests to declare

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Financial Disclosure

No funds have been received in respect of this study from any public or private institution.

STATİSTİCAL ANALYSİS PLAN (SAP)

Data obtained in the study were analysed statistically using IBM SPSS software (IBM Corporation, Armonk, NY, USA). Conformity of the data to normal distribution was assessed with the Shapiro Wilk test. In the comparison of the two groups, the Independent Samples t-test was applied to age, BMI, and TAI points showing normal distribution and the Mann Whitney U-test to clinical variables not showing normal distribution. For internal consistency of the scales, the Cronbach alpha coefficients were calculated. The systolic and diastolic blood pressure, pulse and VAS values before and after acupressure at 0, 4 and 8 hours showed normal distribution so intergroup comparisons were made with Two-Way Variance analysis on the repeated measurements from the general linear models. Bonferroni correction was applied when comparing the main effects. In the inter-group comparisons of intestinal sound, gas output, defecation, distension and nausea, which did not show normal distribution, the Mann Whitney U-test was used and in the intra-group comparsions, Friedman analysis. When differences were found in the intra-group values, multiple comparison tests with Bonferroni correction were used. Correlations between the scales were evaluated with Pearson correlation analysis. The relationships between categorical variables in the groups were examined with the Pearson Chi-square Exact test in 2 x2 and r x c tables. When a correlation was determined in the Chi-square test, the difference in the categories between the groups was determined with the Bonferroni corrected two ratio z-test. A value of $p<0.05$ was accepted as statistically significant.

INFORMED CONSENT FORM (ICF) (INTERVENTION GROUP)

In this research, after laparoscopic cholecystectomy surgery, acupressure will be applied to ST 25, CV 12 and TH 6 acupuncture points for 3 minutes and 15 minutes in total at 0, 4 and 8 hours. It will be performed to determine the effect of acupressure on postoperative gastrointestinal system functions (bowel movements, gas-stool output, nausea-vomiting), pain and anxiety. During this study, acupressure will be applied and compared with the other group. We think that this application may have a positive effect on your gastrointestinal system functions and anxiety problems that you experience due to your treatment.

Acupressure application and evaluation will be done by the researcher at 0, 4 and 8 hours postoperatively. You are free to participate in this work. You can accept it at the beginning, then change your mind and leave the study without any reason. In this case, there will be no change in medical care about you.

Acupressure application and evaluation will be done by the researcher at 0, 4 and 8 hours postoperatively. You are free to participate in this work. You can accept it at the beginning, then change your mind and leave the study without any reason. In this case, there will be no change in medical care about you.

Thank you.

The researcher;

Name-Surname: Dilek SOYLU Tel: *** *** ****

Consent to Participate in the Study:

Participant's statement: “I have read all the explanations on the Informed Consent Form. Written and verbal explanation about the research whose subject and purpose was mentioned above was given to me by the research director. I know that I can leave this study without any justification. I agree to participate in the aforementioned research of my own free will, without any pressure or coercion. "

Participant

Name Surname: Date: ..... /… ../ ……

Tel: Signature

INFORMED CONSENT FORM (ICF) (PLESABO GROUP)

In this research, after laparoscopic cholecystectomy surgery, acupressure will be applied to ST 25, CV 12 and TH 6 acupuncture points for 3 minutes and 15 minutes in total at 0, 4 and 8 hours. It will be performed to determine the effect of acupressure on postoperative gastrointestinal system functions (bowel movements, gas-stool output, nausea-vomiting), pain and anxiety. Acupressure application and evaluation will be done by the researcher at 0, 4 and 8 hours postoperatively. You are free to participate in this work. You can accept it at the beginning, then change your mind and leave the study without any reason. In this case, there will be no change in medical care about you.

Acupressure application and evaluation will be done by the researcher at 0, 4 and 8 hours postoperatively. You are free to participate in this work. You can accept it at the beginning, then change your mind and leave the study without any reason. In this case, there will be no change in medical care about you.

Thank you.

The researcher;

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