Unique Protocol ID: 2025/284

Brief Title: Effect of Foot Bath on Pain, Sleep, and Comfort Levels After Abdominal Surgery

Official Title: Effect of Foot Bath on Pain, Sleep, and Comfort Levels After Abdominal Surgery: A Randomized Controlled Trial

25.08.2025

EFFECT OF FOOT BATH ON PAIN, SLEEP, AND COMFORT LEVELS AFTER ABDOMINAL SURGERY: A RANDOMISED CONTROLLED STUDY

MATERIALS AND METHODS

Study Design

This study was a prospective, two-arm randomised controlled trial. The study will conduct on who underwent abdominal operation between December 2025 and December 2026 in the General Surgery Service of the Hospital of a University.

Population/Sample of the Study

The sample calculation was made by predicting an effect size of 0.8, 95% confidence level and 95% power. The power analysis of the study was performed with the G*POWER 3.1.9.4 (Power analysis statistical software) programme. The sample was found to be 88 (44:44). To avoid the risk of sample loss, it was decided to include 48 patients in each group. A total of 96 women with abdominal surgery (Foot bath group (EG): 48 patients, Control group (CG): 48 patients) constituted the sample.

Randomisation

Before starting the study, two groups were randomly formed among patients. As a randomisation method, women who met the inclusion criteria for the study were identified and listed. The individuals to be included in the 2 groups were determined by randomisation method from the random numbers table (https://randomizer.org/).

Consort Diagram

A total of 96 patients were determined to be eligible in the Consort Diagram.

Blinding

The researchers implementing the foot bath and the participants were all blinded to group allocation.

Experimental Group

Patients will be informed about the study on the morning of the surgery. Written and verbal consent to participate will be obtained. Before the procedure, the patient will be informed that the procedure will take place in the patient's room. Their feet will be physically examined for any wounds or lesions. If there are no problems, the patient will be seated on the edge of the bed and their feet will be placed in a disinfected, warm water bath for 20 minutes. After the procedure, the patient will be instructed to wipe their feet with a towel and wear appropriate socks. The patient will be asked the questions listed on the "Patient Information Form". The RCSQ will be administered to assess preoperative sleep quality.

On the day of surgery, patients will receive a foot bath between 9:00 pm and 10:00 pm. Any socks or clothing on both feet will be removed. The feet will be visually and manually examined to determine if

they show any signs of illness (pressure ulcers, discoloration, wounds, etc.). The patient will be informed that the foot bath device is disinfected before each use and that water-tight bags will be placed around the device to prevent contact between the foot and the water to facilitate repeated use. The water temperature will be adjusted to 41-42°C using an infrared thermometer (non-contact digital thermometer). Both feet will be placed inside the foot bath device. The patient's feet will remain in the foot bath device for 20 minutes. After the foot bath, the patient's feet will be thoroughly dried with a towel, and the patient will be re-dressed in their existing socks or anti-embolic stockings. Any side effects/ adverse reactions, etc., related to the foot bath will be questioned. Adverse effects (through observation and feedback from the patient) will be assessed during application and approximately 12 hours after the application.

On the morning of the first postoperative day, the patient will be asked the questions in the RCSQ and VAS and the pain score will be learned. Then, the data collection process of the study will be terminated. The application will be done only once on the planned day. It will not happen again another day.

Control Group

Patients will be informed about the study on the morning of the surgery. Written and verbal consent to participate will be obtained. Patients will be asked the questions listed on the "Patient Information Form". The RCSQ will be administered to assess preoperative sleep quality.

On the day of surgery, patients will receive routine care.

On the morning of the first postoperative day, patients will be asked questions from the RCSQ and VKS, and their pain score will be obtained. Data collection will then be concluded.

Data Collection Tools

"Patient Information Form" and "*The Richards-Campbell Sleep Questionnaire (RCSQ)"* were used in the study.

"Patient Information Form"

The form consists of questions that inquire about individual variables and characteristics related to the medical condition. Patients' pain levels will be assessed using a numerical rating scale (0-10). The questions in the form were prepared in accordance with the literature.

"The Richards-Campbell Sleep Questionnaire (RCSQ)"

Developed by Richards in 1987 and adapted into Turkish by Özlü and Özer in 2015 for surgical intensive care patients, the RCSQ is a six-item scale that assesses nighttime sleep depth, time to fall asleep, frequency of awakenings, time awake upon awakening, sleep quality, and ambient noise levels. Each item is scored using a visual analog scale on a scale ranging from 0 to 100. Scores between 0 and 25 indicate very poor sleep, while scores between 76 and 100 indicate very good sleep. The total scale score is scored out of five items, and the sixth item, which assesses ambient noise levels, is excluded from the total score. As the scale score increases, patients' sleep quality also improves. The Cronbach's α value for the scale developed by Richards was found to be 0.82.

"General Comfort Scale"

The scale, developed by Kolcaba (2003), was adapted into Turkish by Kuğuoğlu and Karabacak in 2008. The scale has 48 items, 3 sub-dimensions, and a 4-point Likert-type scale. Possible scores range from 48 to 192. A score of 0-48 indicates poor comfort, 49-96 indicates moderate comfort, 50-144 indicates good comfort, and 145-192 indicates very good comfort. Cronbach's alpha value for the scale was reported as 0.85.

Data Evaluation

Descriptive statistics (mean ± standard deviation, median, first and third quartiles, number (n) and percentage (%) for categorical results), non-parametric (Mann Whitney U test, Kruskal Wallis test) and or parametric (ANNOVA, t test, etc.) analysis methods will use to evaluate the data. The normal distribution of the data was analysed by Kolmogorov-Smirnov test. SPSS 22.0 package programme will use for statistical analyses. The statistical significance limit value will accept as $p < .05$.

Ethical Aspects of the Study

For the ethical compliance of the study, ethical approval numbered 2022/428 (12.12.2022) was obtained from the Non-Interventional Scientific Research Ethics Committee of the Faculty of Medicine of a Trakya University and written permission was obtained from the Tekirdağ Namık Kemal University Hospital for data collection. In addition, written informed consent will obtain from patients who agreed to participate in the study. The study will conduct in accordance with the rules of the Declaration of Helsinki.