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Protocol

Effect of different positioning before, during and after surgery on pressure injury: a randomized controlled trial protocol

Bedia Güler[1]*, Aysel Gürkan[2]

[1]Marmara University Institute of Health Sciences, Istanbul, Turkey
[2]Department of Nursing, Faculty of Health Sciences, Marmara University, Istanbul, Turkey

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***Correspondence:**
Dr. Bedia Güler,
E-mail: bedia-guler@hotmail.com

ABSTRACT

Background: Patients undergoing surgery are at risk of developing pressure injuries because they remain immobile and in a fixed position on the operating table for a long time under anesthesia. Prevention of surgery-induced pressure injuries is the best strategy and requires risk assessment and timely implementation of preventive interventions. This trial aims to evaluate the effect of positioning in a different position pre-operatively and post-operatively than the position adopted during surgery on pressure injuries.
Methods: This trial was designed as a prospective randomized controlled study. Participants meeting the inclusion criteria will be assigned to the intervention or control groups using a random number generator. The participants in the intervention group will be placed in different positions than their surgical position during the night before surgery, and the first 36 h after surgery. The control group will receive only routine care. The groups will be evaluated in terms of pressure injury development for at least 72 h, until discharge.
Conclusions: Surgery-induced pressure injuries have important effects on patients, healthcare professionals, and healthcare organizations. Current guidelines recommend that patients be positioned in a different position preoperatively and postoperatively than the surgical position to redistribute the pressure generated during surgery. There is a need for well-designed, comprehensive studies to investigate the effectiveness of this weak evidence-level recommendation. This trial will provide valuable evidence to inform clinical practice, guide surgical nurses, and allow evaluation of the effects of this intervention.
Trial registration: Clinical trials registration number NCT05549830

Keywords: Surgery-induced pressure injury, Prevention, Positioning

INTRODUCTION

Surgical interventions are one of the many risk factors that cause the development of pressure injuries.[1] Since patients are immobile and in a fixed position during surgery, with the effect of anesthetic agents, they cannot feel the pain caused by pressure and shear forces and change their positions.[2,3] Therefore, all patients undergoing surgical interventions are at risk of developing pressure injuries.[4-7]

Surgery-induced pressure injury is injuries that occur during surgery, within the first 72 hours, and within the first six days after surgery, and they are an important complication that can lead to undesirable consequences.[4,6,8-11] When it develops, it causes patients to need additional treatment, to experience pain, to be adversely affected physically, mentally, and financially, to be exposed to infection risk and deformities, as well as a decrease in quality of life, an increase in postoperative recovery time, and a longer hospital stay.[3,6,10,12,13] In addition, pressure injuries that develop in the perioperative period are an important indicator of the quality of care for both the patients and the healthcare centers and a serious patient safety issue.[9,11,14]

Despite technological advances, surgery-induced pressure injuries still remain a clinical problem for patients.[4,14] It has been reported in national and international studies that its prevalence varies between 0.3% and 66%, it constitutes 4% to 45% of all hospital-acquired pressure injuries, and its incidence has increased in recent years.[2-4,6,9,10,15-19] Risky surgical interventions have also been shown to be cardiac surgery, general surgery (abdominal and hepatobiliary), orthopedics, neurosurgery, vascular surgery, thoracic surgery, and urology operations.[6,7,10,12,13,15,19-21]

Prevention rather than treatment of pressure injuries is the best strategy.[7] In this regard, it is recommended to assess risk and implement preventive interventions timely.[6,7] Risk assessment, including associated risk factors and a comprehensive skin assessment, is the primary step and enables the identification of patients at risk for the implementation of preventive interventions.[3,5,7,22] Although many risk factors have been defined to contribute to the development of pressure injuries in patients undergoing surgery, the most important evidence-based risk factors have been shown to be preoperative duration of time immobilized, length of surgery, intraoperative hypothermia and hypotension, and reduced mobility on the first postoperative day (level of evidence: weak; strength of recommendation: strong).[2,4,6,10,13,22] Recommendations for prevention include patient positioning in a way to reduce the risk of pressure injury development during surgery (level of evidence: weak; strength of recommendation: strong), use of pressure support surfaces on operating table (level of evidence: strong; strength of recommendation: weak), and redistribution of pressure before and after surgery (level of evidence: weak; strength of recommendation: strong).[2] For redistribution of pressure, it is recommended that patients be placed in different position preoperatively and postoperatively than during surgery.[2,8,18]

There are limited studies in literature investigating the effectiveness of this recommendation, which is based on weak level of evidence but strong recommendation, and it is suggested to conduct studies that focus on post-anesthesia nursing care and standards in practice.[14,20]

Positioning plays a key role in prevention of pressure injuries, and repositioning is recommended for all patients at risk of developing pressure injuries unless contraindicated.[2,23] By repositioning patient, it is aimed at reducing duration and amount of long-term pressure over bony prominences and increasing the duration of the resistance of tissue.[2,14] This is a cost-free, non-invasive, and effective method of redistributing pressure.[14]

Aim

This study to investigate the effect of positioning the patients before and after surgery in a different position than during the surgery on the pressure injury development.

H1 hypothesis

There is a significant difference in the development of pressure injuries between patients who were positioned before and after surgery in a different position than the surgical position and those who were not.

METHODS

Trial design

In the trial, a two-group design will be used with an equal number of the random participants assigned to each group.

Setting

The trial will be conducted in the general surgery clinic and intensive care unit (ICU) of a training and research hospital in Istanbul, Turkey.

Participants and sampling

The sample size of the study was determined by power analysis using the G*Power 3 program.[24] In the calculation performed by taking into account the postoperative 1st day pressure injury rates of the groups (17.65% in the control group, 0% in the intervention group) in the study of Guo et al to achieve a statistical testing power of 80% (1-β) at a significance level of 0.05 (α), the effect size was calculated to be (d) 0.31, and according to the standard deviation value (SD), the necessary sample size was found to be 88 (44 for each group).[14] It was decided to include a total of 100 patients (50 in the intervention group and 50 in the control group) to prevent a decrease in test power because of the possibility of data loss during data collection.

Inclusion criteria were defined as being scheduled to undergo elective major abdominal surgery that is expected to take three or more hours, being aged 18 years or older, being able to communicate in Turkish, having no communication problems, being conscious and having location, people, and time orientation, and giving written informed consent to participate in the study.[4-6,14,18]

Exclusion criteria were defined as being undergoing emergency major abdominal surgery and having a preoperative pressure injury. Removal criteria were developing a contraindicated condition during postoperative positioning and being discharged within the first 72 hours postoperatively.

Randomization

The participants will be determined from the scheduled surgery list. The randomization of patients meeting the inclusion criteria will be performed through a random number generator (https://www.randomizer.org).

Instruments

Study data will be collected through the "individual and clinical characteristics form", "Munro pressure ulcer risk assessment scale", "patient mobility and observer mobility scale", "pressure injury diagnosis and staging form" and "patient follow-up form".

Individual and clinical characteristics form

This form, which was prepared based on the literature, includes the individual (age, sex, body mass index [BMI], smoking, chronic disease, medications used continuously, history of surgery and pressure injuries, weight loss within the last six months, any condition that would prevent positioning, loss/change of sensation, presence of incontinence) and clinical (diagnosis, American society of anesthesiologists [ASA] classification grade, preoperative fasting duration, oral carbohydrate loading, laboratory values [hemoglobin, hematocrit, albumin, protein]) characteristics of the patients.[10-12]

Munro pressure ulcer risk assessment scale

The Munro scale, which was developed specifically for surgical patients, allows the evaluation of pressure injury risk development throughout the perioperative period.[7,25,26] The scale consists of three sections: preoperative, intraoperative, and postoperative, in which the risk factors are scored between 1 and 3, and the risk level is determined as low, moderate, or high according to the scores obtained from each section. The risk factors of the preoperative section are mobility, nutritional state, BMI, recent weight loss, age, and co-morbidities, and by summing the risk factors, the score that can be obtained from this section varies between 5 and 21, with a score of 5-6 indicating low risk, 7-14 indicating moderate risk, and ≥15 indicating high risk. The risk factors of the intraoperative section are physical status/ASA score, type of anesthesia, body temperature, hypotension, moisture, surface/motion, and position, and by summing the scores obtained from this section and the preoperative section, a score between 12 and 42 is obtained (≤13 indicates low risk, 14-24 indicates moderate risk, and ≥25 indicates high risk). The risk factors of the postoperative section are the length of the procedure and blood loss. By summing the scores obtained from this section and the intraoperative section, a total score between 14 and 48 is obtained, and ≤15 points indicate low risk, 16-28 points indicate medium risk and ≥29 points indicate the high risk.[25]

The scale has been shown to be a valid and reliable measurement tool in national and international studies.[25-28] In this trial, the scale was preferred because it is specific to the population studied, allows for determining changes in risk during the perioperative period, and is effective in predicting the risk of postoperative pressure injury development.[26]

Patient mobility and observer mobility scale

This scale, which was developed to measure patient perceptions and objective observations regarding postoperative mobility, comprises two scales: patient mobility and observer mobility.[29,30] The patient mobility scale will be used to evaluate the levels of pain and difficulty experienced by the patient when performing four activities (turning from one side to the other in bed, sitting by the bed, standing by the bed, and walking in the patient room) before and after surgery. Each activity has two sub-dimensions: pain and difficulty levels. The numerical value for the degree of pain and difficulty experienced is obtained by measuring the distance between the starting point and the point marked by the patient on a 15 cm horizontal line (0= no pain/very easy, 15=worst pain ever imagined/very difficult). The obtained scores constitute the patient's mobility score for each activity, and total score that can be obtained varies between 0 and 120, with an increased score indicating an increase in pain/difficulty related to activity. Observer mobility scale will be used to evaluate the patient's degree of dependence/independence (1=independently without verbal stimulation or physical assistance, 5=unable to perform despite verbal stimulation or physical assistance) in performing same four activities in preoperative and postoperative periods. By summing the score of each activity, a total of 4-20 points are obtained, with increase in the score indicating the insufficiency in mobility skills of patients after surgery, and the decrease indicating that mobility is good/sufficient.[30] Reason for choosing this scale in this study is that it has been tested for validity and reliability in our country and has been used in many other studies.[31,32]

Pressure injury diagnosis and staging form

This form, which was prepared according to the international classification system included in the "prevention and treatment of pressure ulcers: clinical practice guideline" published by the national pressure ulcer advisory panel, European pressure ulcer advisory panel, and pan pacific pressure injury alliance (NPUAP/EPUAP/PPPIA), will be used to diagnose and stage the patients' surgery-induced pressure injuries. The injuries will be assessed in six categories: stage I, non-blanchable erythema; stage II, partial-thickness skin loss; stage III, full-thickness skin loss; stage IV, full-thickness tissue loss; unstageable, depth unknown; and suspected deep tissue injury, depth unknown.[2]

Patient follow-up form

This form, which is prepared based on the literature, consists of three parts in which the surgical positions, pre- and postoperative positions/positioning techniques, pressure injury development status, and other risk factors of the groups will be recorded.[6,11,12] In the first part of the form preoperative (vital signs, mobility score, pressure injury risk score, skin condition, nutritional status,

positions the night before surgery), in the second part intraoperative (type of surgical intervention, duration of surgery, type of anesthesia, anesthetic drugs, vital signs, surgical position/s, positioning devices, use of pressure support surface, development of hypotensive attack, presence of bleeding and blood transfusion, body temperature, use of warming method, exposure of the skin to moisture, pressure injury risk score), and in third part postoperative (pressure injury risk score, time of transfer to surgical clinic/ICU, positioning/repositioning techniques applied in the intervention group, routine positions of the control group, mobility scores, mobilization and oral nutrition status, skin condition, and the pressure injury development status) data will be recorded.

Intervention

The participants will be assigned to one of the two groups according to the randomization list. The participants assigned to the intervention group will be placed in different positions than their surgical position during the night before surgery and the first 36 hours after surgery, and the participants assigned to the control group will only receive routine care.

Both groups will be evaluated for the development of surgery-induced pressure injuries for at least 72 hours postoperatively, until discharge.

Patient positioning technique

Major abdominal surgery is usually performed in supine position.[21] Additionally, Trendelenburg, reverse-Trendelenburg, and lithotomy, which are modifications of supine position and rarely lateral positions, can also be applied.[33] Pressure points of the supine (occiput, back, elbows, sacrum, coccyx, and heels) and lateral (face/ear on bottom, shoulder/ axilla on bottom, arms, hip/knee on bottom, legs, ankles, and feet) positions are different from each other.[1] Therefore, right/ left lateral positions will be applied before and after surgery as different positions from supine position used during surgery since they reduce/ redistribute pressure at pressure points of supine position during surgery and prevent re-pressurization of these areas. In addition, as result of continuous exposure of capillary end-arterial pressure to twice its own pressure for 2 hours, skin hyperemia (redness) may develop from the 30th minute and may take 1 hour to resolve.[1] As result of exposure of capillary end-arterial pressure to pressure between 2-4 hours, ischemia may develop and may take up to 36 hours to resolve.[1] Therefore, patients will be positioned and repositioned at 2-hour intervals and up to 36 hours after surgery. Positions that can be applied before and after surgery, which differ according to the surgical positions, are shown in Table 1. Lateral positions will be applied at an angle of 30° by supporting with pillows. In addition, preoperatively, the prone position could also be used.

Table 1: Patient positions to be applied before and after surgery.

Before surgery	During surgery	After surgery	
		First 36 hours	**After 36 hours**
Right lateral left lateral prone	Supine, Lithotomy, Trendelenburg, Reverse-Trendelenburg	Right lateral, Left lateral at 2-hour intervals	If a pressure injury is not present, Supine for 30 minutes Right and left lateral at 2-hour intervals If a pressure injury is present, Right lateral Left lateral at 2-hour intervals
Left lateral supine prone	Right lateral	Left lateral Supine at 2-hour intervals	If a pressure injury is not present, Right lateral for 30 minutes Left lateral and supine at 2-hour intervals If a pressure injury is present, Left lateral Supine at 2-hour intervals
Right lateral supine prone	Left lateral	Right lateral Supine at 2-hour intervals	If a pressure injury is not present, Left lateral for 30 minutes Right lateral and supine at 2-hour intervals If a pressure injury is present, Right lateral Supine at 2-hour intervals

Intervention group

The first interview with the patients in this group will be held in the afternoon on the day before surgery. In this interview, the individual and clinical characteristics form, the preoperative section of the Munro scale, and the patient and observer mobility scale will be completed, and their scores will be recorded on the preoperative part of the patient follow-up form. During this process, the patients/relative will be informed of their anticipated surgical position to be applied, to lie in positions other than their surgical position tonight and after the surgery, and the importance of this application. Before the patient

is transferred to the operating room, the previous night's position(s) will be recorded on patient follow-up form.

After the patient is transferred to the operating room, the intraoperative sections of the patient follow-up form and the Munro scale will be completed. At the end of the operation, the postoperative section of the Munro scale will be completed, and the total score and risk level of each patient will be calculated and recorded on the postoperative part of the patient follow-up form.

After the patient is transferred to the surgical clinic or ICU, first of all, the pressure injury development status will be evaluated (T_0) using the pressure injury diagnosis and staging form and recorded on the postoperative part of the patient follow-up form. Then, the patient will be placed in a different position than used during the surgery, and the position will be changed every 2 hours using the different positions than the position during surgery until the 36th postoperative hour, and the development of pressure injury will be evaluated again at the 36th hour (T_1). If no pressure injury has developed in this period, the patient will alternately be placed in the position used during surgery for a duration that will not exceed 30 minutes, and then the different positions will be applied at 2-hour intervals. If a pressure injury has developed, repositioning will be continued using the different positions at 2-hour intervals. The mobility levels of the patients will be evaluated using the patient and observer mobility scale beginning on the first postoperative day and recorded on the postoperative section of the patient follow-up form. In addition to this intervention, the patients will be evaluated daily for the development of pressure injuries for at least 72 hours after surgery and until discharge (T_2, T…).

Control group

The first interview with the patients in this group will be held in the afternoon on the day before surgery. In this interview, the individual and clinical characteristics form, the preoperative section of the Munro scale, and the patient and observer mobility scale will be completed, and their scores will be recorded on the preoperative part of the patient follow-up form. Before the patient is transferred to the operating room, the previous night's position(s) will be recorded on the patient follow-up form.

After the patient is transferred to the operating room, the intraoperative sections of the patient follow-up form and the Munro scale will be completed. At the end of the operation, the postoperative section of the Munro scale will be completed, and the total score and risk level of each patient will be calculated and recorded on the postoperative part of the patient follow-up form.

After the patient is transferred to the surgical clinic or ICU, the pressure injury development status will be evaluated (T_0) using the pressure injury diagnosis and staging form and recorded on the postoperative part of the patient follow-up form. The positions of the patients in this group will be monitored and recorded at 2-hour intervals, and the development of pressure injuries will be evaluated again at the 36th hour (T_1). Their mobility levels will be evaluated using the patient and observer mobility scale beginning on the first postoperative day and recorded on the postoperative section of the patient follow-up form. The patients will be evaluated daily for the development of pressure injuries for at least 72 hours after surgery and until discharge (T_2, T…) (Figure 1).

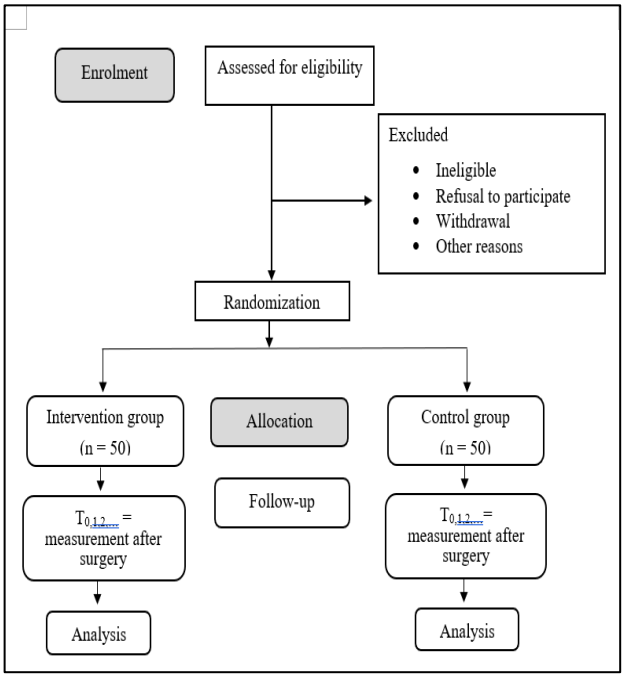

Figure 1: Study flowchart according to CONSORT.

Outcomes

The outcomes of this trial are surgery-induced pressure injuries evaluated using repeated measurements in adults.

Blinding

Due to the feasibility and nature of the study, the principal researcher and patients cannot be blinded to patient grouping, but the evaluator will be blinded to the groups of the participants.

Data collection

The collection of the data of this trial began on June, 2023, and the data collection process is ongoing.

Data management

The accurate and complete coding of all data and their entry into the statistics software will be undertaken by the researchers. All original documents, including medical records, scale forms, informed consent forms, and other

relevant records obtained during the trial period, will be kept confidential by the researchers. Data will be retained for 10 years after the completion of the study.

Statistical analysis

Trial data will be statistically analyzed using SPSS ver. 23.0 (IBM Corp., Inc., Armonk, NY, USA). The conformity of continuous data to the normal distribution will be examined with the Shapiro-Wilk test, and normally distributed variables will be presented as mean and standard deviation; non-normally distributed variables as median, 25th, and 75th percentile values; and categorical variables as numbers and percentages. The comparisons of continuous variables between groups will be performed using the t-test or the Mann-Whitney U test for independent samples in the case of two groups and the ANOVA or Kruskal-Wallis tests in the case of three or more groups. The intergroup comparisons of categorical variables will be analyzed using the chi-square, Fisher's exact chi-square, or Fisher-Freeman-Halton test. The results will be evaluated at the 95% confidence interval and $p<0.05$ significance level.

Ethical considerations

For the collection of trial data, ethical approval was obtained from the clinical research ethics committee of Marmara university faculty of medicine (protocol code: 09.2023.370, date: 10.04.2023) and written permission from the institution (date: 14.03.2023) where the study will be conducted. Before data collection, informed, voluntary verbal and written consent will be obtained from all the participants after explaining the purpose of the study, the application process, and their rights in this process. The Helsinki declaration 2008 principles will be upheld throughout the study. For the scales to be used in the study, written permission was received from the authors, who performed their validity and reliability analyses in Turkey.

DISCUSSION

Interventions to prevent pressure injuries should begin during the preoperative period and continue during the postoperative recovery period.[18,34] Studies on the prevention of surgery-induced pressure injuries have mostly focused on risk identification and interventions that can be applied during surgery, such as the use of pressure support surfaces and appropriate patient positioning.[4,6,14,20,22,35-39] Preventive interventions that can be applied before and after surgery are limited to skin care/moisture protection, the use of pressure support surfaces and prophylactic dressings, and patient positioning/transfer by avoiding friction and shear.[2,5,18,40] Although the current guidelines recommend patient positioning in a different position preoperatively and postoperatively than the surgical position as a weak level of evidence and a strong recommendation, the effectiveness of this method has not been adequately investigated. This trial will be the first to evaluate only this method for preventing the development of surgery-induced pressure injuries.

The prevention of pressure injuries is among the primary roles of nurses.[13] Nurses play a key role in the assessment of risks associated with surgery-induced pressure injuries and the implementation of preventive interventions.[7] Moreover, they are responsible for determining the best intervention for the prevention of pressure injuries as a quality indicator sensitive to patient-centered care.

CONCLUSION

Patients undergoing surgery are at risk of developing pressure injuries because they remain immobile during surgery and under anesthesia for long periods of time. Prolonged immobility before and after surgery further increases this risk. This trial will provide valuable evidence to inform perioperative clinical practice by meticulously evaluating the effect of positioning the patient before and after surgery in a different position than during the surgery on the development of pressure injuries.

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