

Protocol

The effect of back massage with mentholated ointment on pain and anxiety after coronary artery bypass graft surgery: a randomized controlled trial protocol

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ABSTRACT

Background: This study summarizes the protocol of a randomized controlled trial designed to evaluate the effectiveness of back massage with a mentholated ointment on postoperative pain and anxiety in patients undergoing coronary artery bypass graft (CABG) surgery.

Methods: This study is a prospective, interventional, three-arm randomized controlled non-pharmacological clinical trial. Eligible patients will be randomly assigned to one of three groups. The study population will consist of 120 patients who have undergone CABG surgery in the cardiovascular surgery ward of a teaching and research hospital in Türkiye. Following surgery, patients in group 1 (n=40) will receive back massage with a mentholated ointment, group 2 (n=40) will receive back massage with paraffin oil, and group 3 (n=40) will receive routine clinical care.

Conclusions: The primary outcomes are postoperative back pain intensity and state anxiety levels. Secondary outcomes include vital signs and analgesic use.

Trial Registration: ClinicalTrials.gov identifier: NCT07508371.

Keywords: Pain, Anxiety, Coronary artery bypass graft, Mentholated ointment, Back massage

INTRODUCTION

Cardiovascular diseases are the leading cause of mortality worldwide. In 2015, approximately 17.7 million people died due to cardiovascular diseases, accounting for 31% of all global deaths. Of these, nearly 7.4 million deaths were attributed to coronary artery disease (CAD).¹ Furthermore, 82% of deaths related to non-communicable diseases occur in low-and middle-income countries, with 37% being caused by cardiovascular diseases. In Türkiye, it has been reported that 42.4% of deaths due to circulatory system diseases are caused by ischemic heart disease and 24.1% by other cardiac conditions.²

CABG surgery is a commonly used treatment for CAD, particularly in patients with advanced ischemic heart disease or when pharmacological and interventional

treatments such as percutaneous coronary angioplasty are insufficient.^{3,4} However, postoperative pain and anxiety are among the most common complications following CABG surgery and significantly affect patients' physical and psychological well-being.⁵ Uncontrolled pain has been associated with an increased risk of postoperative complications, chronic pain, and morbidity.⁶ It has been reported that 30-70% of patients experience pain, and approximately 50% experience anxiety following CABG surgery. Postoperative back pain may result from prolonged sternotomy, intercostal nerve dissection, and the presence of chest tubes.⁵

Enhanced recovery after surgery (ERAS) protocols, which include multidisciplinary and evidence-based interventions aimed at accelerating recovery after cardiac surgery, recommend providing preoperative, intraoperative, and postoperative education, information,

and counseling to reduce anxiety and complications (moderate level of evidence, strong recommendation).⁷⁻⁹

Current pain management guidelines emphasize the use of multimodal analgesia in the postoperative period (high level of evidence, strong recommendation). Multimodal analgesia aims to enhance analgesic effects, reduce opioid consumption, and minimize adverse effects by targeting different pain mechanisms simultaneously.^{10,11} Despite pharmacological approaches, adequate symptom control is not always achieved in the postoperative period.¹² Therefore, integrating pharmacological and non-pharmacological strategies within a perioperative pain management plan is recommended to optimize recovery following CABG surgery.^{9,13,14}

Among non-pharmacological approaches, massage therapy is defined as the manipulation of body tissues with physiological, psychological, biomechanical, and neurological effects.¹⁵ According to American Massage Therapy Association, massage therapy has been shown to improve mood and reduce both anxiety and pain. In addition, recent studies highlight that the use of lubricants is often necessary as part of standard massage techniques to enhance effectiveness and prevent skin irritation.¹⁶

In this study, menthol-one of the active ingredients in the menthol-based topical cream (Vicks VapoRub®, Procter and Gamble, USA) to be applied as a lubricant in the intervention group-is a compound that can produce an analgesic effect by creating a cooling sensation on the skin and can trigger vasodilation.¹⁷ Although menthol and its derivatives have been widely described in the fields of medicine and biotechnology in recent years, it is noted that their use in clinical studies is limited.¹⁸ Paraffin, which was applied as a lubricant in the other intervention group, is a substance composed of melted beeswax and mineral oil and used for therapeutic purposes. The literature reports that paraffin application has pain-relieving effects and improves joint range of motion.¹⁹

Hypothesis

H1

Back massage with mentholated ointment after CABG surgery reduces back pain levels compared to patients receiving routine treatment.

H2

Back massage with paraffin oil after CABG surgery reduces back pain levels compared to patients receiving routine treatment.

H3

Back massage with mentholated ointment after CABG surgery reduces anxiety levels compared to patients receiving routine treatment.

H4

Back massage with paraffin oil after CABG surgery reduces anxiety levels compared to patients receiving routine treatment.

H5

Back massage with mentholated ointment after CABG surgery reduces back pain levels compared to back massage with paraffin oil.

H6

Back massage with mentholated ointment after CABG surgery reduces anxiety levels compared to back massage with paraffin oil.

Aim

This study aims to evaluate the effects of back massage using mentholated ointment and paraffin oil on postoperative pain and anxiety levels in patients undergoing CABG surgery. It also aims to provide evidence for a low-cost, easily accessible, and feasible non-pharmacological intervention that may be integrated into routine perioperative nursing practice.

METHODS

Determination of the sample size

In this study, a medium effect size ($f=0.40$) was estimated based on findings from a previous study.²⁰ Using G*Power software, the required total sample size was calculated as 102 participants at a significance level of 0.05 and a statistical power of 95% for three independent groups. Considering potential attrition during the study process, the sample size was increased by approximately 18%, and a total of 120 participants (40 per group) will be included in the study.

Ethical considerations

This study will be conducted in accordance with the Declaration of Helsinki (WMA General Assembly, Fortaleza, Brazil, October 2013) and the principles of medical research involving human subjects. Written informed consent will be obtained from all participants before enrollment. Ethical approval has been obtained from the Istanbul Medipol University non-interventional clinical research ethics committee (Protocol No.: E-10840098-202.3.02-1357; Date: 14 February 2025). Institutional permission to conduct the study was obtained from the Istanbul Provincial Health Directorate.

Population and randomization

This study protocol describes the design of a single-center, single-blind, randomized controlled trial. The

study will be conducted in the general surgery department of a teaching and research hospital in Istanbul. The study was registered on Clinicaltrials.gov in April 2026 (NCT07508371). The study is designed with three groups. Patients undergoing CABG surgery will be screened for inclusion and exclusion criteria, and those who meet the criteria will be invited to participate in the study. After obtaining informed written consent from participants who agree to participate, a randomization list generated from a computer-based random number table will be used with the block randomization method to assign an equal number of participants to each of the three groups. The “randomizer.org” program will be used for the randomization process. Participants will be assigned a serial number based on their order of enrollment in the study and will be assigned to one of the three groups according to the numbers in the randomization list.

Inclusion criteria

Participants who meet the following criteria will be included in the study: willingness to participate; age ≥ 18 years; having undergone elective CABG surgery; ASA physical status I-II; being literate; being oriented to person, place, and time; having no visual, hearing, or speech impairments that would interfere with understanding the study procedures or reporting pain (except those corrected with aids); having a sternum exposure time of at least 2 hours during surgery; and not using any complementary or alternative medicine methods.

Exclusion criteria

Participants will be excluded if they have a known allergy to mentholated ointment or paraffin oil; are participating in another clinical study; experience confusion or have cognitive or physical limitations preventing massage application; have a diagnosed mood disorder (e. g., depression, panic disorder, dysthymia, bipolar disorder) or are receiving related treatment; have respiratory problems; are unable to speak, read, or write Turkish; are transferred to the intensive care unit postoperatively; develop severe postoperative complications such as bleeding, hematoma, seroma, or nerve injury; develop an allergic reaction to the intervention during the study; request to withdraw from the study; or fail to comply with the study procedures.

Blinding

Due to the nature of the intervention, participants and the researcher delivering the intervention cannot be blinded. However, outcome assessment and data analysis will be conducted by individuals blinded to group allocation.

Therefore, the study is designed as a single-blind randomized controlled trial.

Interventions

After randomization, participants will be allocated to one of three groups: mentholated ointment massage group, paraffin oil massage group, and control group. Before the intervention, participants in the intervention groups will be assessed for potential allergic reactions to the products used. A patch test will be performed to evaluate sensitivity to the mentholated ointment and paraffin oil.

In the preoperative period, all participants will complete a patient information form, and standardized education will be provided regarding the study procedures. Participants will be informed about the assessment tools, including the Numerical Rating Scale (NRS) for pain and the State Anxiety Scale, and how to complete them. In the postoperative period, routine analgesic treatment will be continued for all groups. The massage intervention will be performed approximately three hours after analgesic administration, taking into account the pharmacokinetic properties of the analgesic agents.

Before the intervention, baseline measurements including pain intensity, anxiety level, and vital signs (heart rate, blood pressure, respiratory rate, and body temperature) will be recorded.

In the mentholated ointment group, a standardized 15-minute back massage using mentholated ointment will be applied once daily for five consecutive days. In the paraffin oil group, the same massage protocol will be applied using paraffin oil. In the control group, no massage intervention will be performed, and only routine care will be provided.

Following each intervention session, pain intensity, anxiety level, and vital signs will be reassessed 15 minutes after the massage. Additionally, routine postoperative analgesic follow-up data will be collected from patient records until discharge. All interventions and assessments will be conducted according to a standardized protocol by the same trained researcher.

Outcome measures

A patient identification form developed by the researcher based on the relevant literature will be used as a data collection tool. The form includes sociodemographic characteristics, clinical information, and variables related to the surgical procedure and the cardiovascular surgery unit. The data will be collected after obtaining informed consent from the participants.

Primary outcomes

Post-operative back pain

Pain intensity will be assessed using the NRS, where 0 indicates no pain, 1-3 mild pain, 4-6 moderate pain, and 7-10 severe pain.²¹ The NRS is widely used due to its

ease of understanding, practicality, and high reliability in assessing acute postoperative pain in adults.²² In this study, pain intensity will be evaluated based on patient self-report at the following time points: before analgesic administration (0 minutes), 30 minutes after analgesic administration, immediately before massage (0 minutes), and 15 minutes after massage.

Level of state anxiety

Anxiety levels will be assessed using the State Anxiety Scale, which is part of the state-trait anxiety inventory developed by Spielberger et al.²³ The Turkish validity and reliability of the scale were established by Öner and LeCompte. There are 20 items on the state anxiety scale. According to the score obtained, the individual does not have anxiety about getting a score of 20 or less on the scale, a score between 21-39 will be considered mild anxiety, a score between 40-59 will be considered moderate, and a score between 60-80 will be considered severe anxiety.²⁴ In this study, anxiety levels will be assessed before and 15 minutes after each massage session.

Secondary outcomes

Vital findings

Anxiety is a complex and distressing condition that leads to behavioral and physiological changes, and the stress response triggered by the patient's experience of pain exerts negative effects on physiological systems.^{25,26} Vital signs, including heart rate, blood pressure, respiratory rate, and body temperature, will be recorded using a structured follow-up form. Measurements will be performed at predefined time points: before analgesic administration (0 minutes), 30 minutes after analgesic administration, immediately before massage (0 minutes), and 15 minutes after massage.

Analgesic use status

Analgesic use will be recorded using a researcher-developed follow-up form. This form includes information on the name, type, dose, route of administration, and frequency of analgesics administered in the postoperative period. These data will be obtained from patient records.

Data collection procedure

This study is designed as a randomized controlled trial (RCT) conducted in the surgical ward following CABG surgery. To ensure equal allocation across the three groups, eligible patients who meet the inclusion criteria and provide written informed consent will be assigned using block randomization.

Baseline data, including demographic and clinical characteristics, State Anxiety Scale scores, NRS scores,

and vital signs, will be collected at T0 (preoperatively). Follow-up measurements will be obtained immediately before analgesic administration (T1) and 60 minutes after analgesic administration (T2). Additional assessments will be performed immediately before the massage intervention (T3) and 15 minutes after the massage (T4).

At each measurement point, pain intensity, anxiety levels, and vital signs will be recorded. Following each massage session, the State Anxiety Scale will be administered alongside the NRS and vital signs assessments.

All participants will continue to receive routine postoperative analgesic treatment. Patients in the intervention groups will receive one massage session per day for five consecutive days following CABG surgery until discharge (Figure 1).

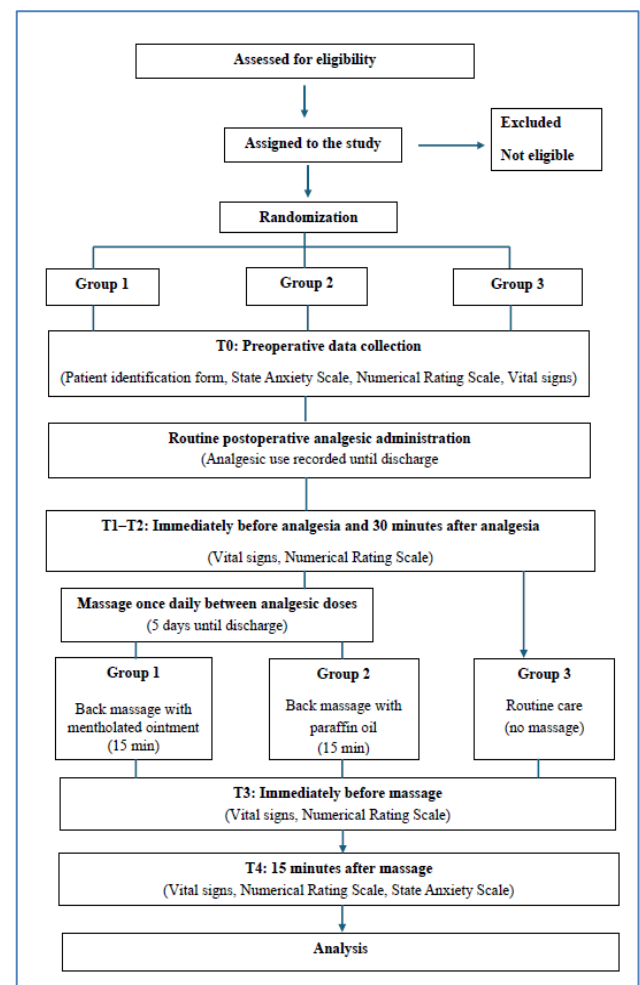


Figure 1: Data collection procedure.

Statistical analysis

Statistical analyses will be performed using SPSS (IBM SPSS Statistics for Windows, version 22.0). A $p < 0.05$ will be considered statistically significant. Descriptive statistics will be presented as numbers and percentages for categorical variables, and as mean $\pm$ standard deviation

or median (min-max) for continuous variables. The normality of data will be assessed using the Shapiro-Wilk test. For comparisons among more than two independent groups, one-way ANOVA will be used for normally distributed data and the Kruskal-Wallis test for non-normally distributed data. Post hoc analyses will be conducted using the Tukey test for parametric data and the Mann-Whitney U test with Bonferroni correction for non-parametric data. For within-group comparisons, a paired t-test will be used for normally distributed data and a Wilcoxon signed-rank test for non-normally distributed data. Categorical variables will be analyzed using the chi-square test.

DISCUSSION

CABG surgery is a widely performed cardiac surgical procedure worldwide, and patients often experience moderate to severe pain and increased anxiety levels during the postoperative period.^{13,21} Postoperative pain is a complex, multifactorial experience influenced not only by surgical factors such as sternotomy and surgical positioning but also by psychological variables such as anxiety, and this can negatively impact recovery and overall patient outcomes.¹¹ Inadequate pain control during the postoperative period has been associated with impaired respiratory function, limited mobility, and prolonged recovery.^{27,28}

Current evidence-based guidelines emphasize the use of multimodal analgesia in postoperative pain management and recommend combining pharmacological and non-pharmacological interventions to enhance patient comfort and reduce opioid consumption.^{10,13} Among non-pharmacological approaches, massage therapy is recognized as a safe and supportive method for alleviating pain and anxiety, primarily by increasing blood circulation and stimulating the release of endorphins.^{16,29} Previous studies have demonstrated the effectiveness of various massage techniques, including foot, hand, and aromatherapy massage, in reducing postoperative pain and anxiety.^{30,31}

Topical agents used during massage, such as menthol-containing ointments and paraffin-based products, can further enhance the therapeutic effects of massage by providing additional physiological benefits. Menthol is widely used as a non-opioid analgesic due to its cooling, antispasmodic, and sensory-modulating effects.^{17,18}

Similarly, paraffin oil may promote vasodilation, increase local circulation, reduce muscle stiffness, and facilitate relaxation.¹⁹ Despite these potential advantages, the use of menthol-containing ointments in back massage to manage postoperative pain and anxiety following CABG surgery has not been sufficiently investigated. Current evidence on topical agents remains limited and heterogeneous, and high-quality clinical trials in specific surgical populations are still lacking.^{18,32}

Furthermore, although topical agents containing menthol are widely available, low-cost, and commonly used in daily life, their clinical efficacy in managing postoperative pain and anxiety has not been clearly established.

CONCLUSION

This article presents the protocol of a randomized controlled trial evaluating the effects of back massage using a menthol-containing ointment and paraffin oil on postoperative pain and anxiety in patients undergoing CABG surgery. This study is expected to provide evidence on the clinical effectiveness of menthol-containing ointments-widely available, low-cost, and easily applicable topical agents-and to support their integration as non-pharmacological nursing interventions in perioperative care. Despite their widespread use in daily practice, the clinical efficacy of menthol-containing topical agents in managing postoperative pain and anxiety has not been clearly established. Given the limited number of studies examining the effects of massage with menthol-containing topical agents in cardiac surgery patients, this trial is anticipated to contribute to filling an important gap in the literature.

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