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Protocol

The effect of lavender oil inhalation on pain, anxiety, and sleep quality after coronary artery bypass graft: a randomized controlled trial protocol

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ABSTRACT

Background: Pain, anxiety, and sleep disorders are common side effects of coronary artery bypass graft (CABG) surgery. Although pharmacological agents are currently used in the treatment of these problems, in addition to their undesirable side effects, they increase healthcare costs, and their inadequate control leads to morbidities, prolonged hospital stay and increased burden of care. Therefore, supportive interventions are needed. The aim of this study is to determine the effect of lavender oil inhalation on the pain intensity, anxiety and sleep quality of patients that underwent CABG surgery.
Methods: This study was planned as a prospective randomized controlled trial. Participants meeting the inclusion criteria will be randomly assigned to the intervention and control groups. During the hospitalization period after CABG surgery, 2% lavender oil (*Lavandula angustifolia*) inhalation will be applied to the intervention group three times a day, while the control group will only receive routine care. The pain intensity of the groups will be evaluated with the numeric rating scale, anxiety levels with the state-trait anxiety inventory, and sleep quality with the Richards-Campbell sleep questionnaire.
Conclusions: There is a need for new approaches to improve the physiological and psychological health of patients after CABG surgery and help them return to their daily life activities and social lives in a shorter time. This trial will allow for the assessment of the effects of this intervention and provide valuable evidence to guide clinical practice.
Trial registration: This trial was registered in May, 2022 (NCT05377983).

Keywords: CABG surgery, Lavender oil, Pain, Anxiety, Sleep

INTRODUCTION

Cardiovascular diseases are the leading cause of mortality in Turkey, as well as across the world.[1] According to the 2018 data of the Turkish Statistical Institute, 38.4% of all deaths were caused by cardiovascular diseases, and 39.7% of these deaths were due to ischemic heart diseases.[2] CABG surgery is one of the frequently preferred open standard heart surgery approaches in the treatment of coronary heart diseases[3,4] and has remained the gold standard method for revascularization in patients with more than two coronary artery stenoses for more than 50 years.[5]

The common side effects of CABG surgery that negatively affect recovery and need to be well managed by nurses are pain, anxiety, and sleep disorders.[3-7] After CABG surgery, pain is experienced by 30-70% of patients, anxiety by 50%, and sleep disorders by 47-68%.[4-10] The intraoperative opening of the sternum, dissection of the intercostal nerves in the chest wall, endotracheal intubation, leg incision for the saphenous vein graft, and invasive procedures can be listed as the causes of acute postoperative pain.[1] Among the causes of anxiety are failure to communicate due to endotracheal intubation, catheters and chest tube inserted for invasive monitoring, pain, feeling of loneliness, and fear.[11,12]

Pain and anxiety also lead to sleep disorders.[7] Studies have shown the relationship between pain and anxiety, with 65% of patients with anxiety being reported to have pain or 85% of patients with pain being reported to have anxiety after cardiac surgery.[8,13,14] There is also an interaction between pain and sleep quality. Insufficient sleep changes the perception of pain and results in an increase in postoperative pain, leading to deterioration in sleep quality.[15] Pain management with opioid-derived analgesics can also impair sleep quality.[16] Furthermore, sleep disorders and anxiety mutually affect each other.[17] In other words, sleep disorders can lead to increased levels of anxiety, or anxiety can lead to sleep deprivation.[17] Pain, anxiety, and sleep disorders, and/or inadequate management of these problems can also elevate blood pressure, respiratory rate, and heart rate through sympathetic stimulation, thus increasing the myocardial oxygen demand and burden on the heart and leading to the development of cardiovascular problems.[3,6,9,17,18,20] These problems may also interfere with immunological recovery, delay wound healing, and adversely affect cognitive functions.[17]

Studies have shown that pain that is not effectively relieved after cardiac surgery can persist for a long time in the postoperative period, causing physiological and psychological problems and developing into chronic pain.[20-23] It has been reported that patients' anxiety and depression rates increase between six and nine weeks after surgery[24] and can persist even after postoperative six months.[9] Today, pharmacological agents are widely used in the treatment of these problems.[4,8,25] Although opioids (morphine sulfate, tramadol hydrochloride, etc.) or nonsteroidal anti-inflammatory drugs are often used in the treatment of pain, these drugs have certain undesirable side effects, including respiratory depression, nausea-vomiting, itching, reduced blood pressure and heart rate, dizziness, constipation, drowsiness, and drug addiction.[9,26,27] Although various medical treatments are preferred to decrease anxiety and increase sleep quality, there may be problems in their long-term use due to adverse events, such as the development of tolerance to or dependence on drugs, especially sedatives, cognitive impairment, sedation, respiratory depression, and withdrawal.[17,28] In brief, pharmacological methods not only increase healthcare costs but also have undesirable side effects.[18] The inadequate management of these side effects increases the length of hospital stay and burden of care.[13] Therefore, although the effective management of postoperative pain, anxiety, and sleep disorders is the responsibility of all healthcare professionals, they are the primary roles of perioperative nurses and constitute an integral part of nursing care.[27]

Considering the high incidence and serious consequences of pain, anxiety, and sleep disorders after CABG surgery, it is essential to implement applications that can reduce the burden caused by these problems and not only prevent them but also shorten their duration.[26] Therefore, there is a need to investigate low-risk, practical, accessible, and cost-effective non-pharmacological interventions to be adopted in clinical practice.[27] In this context, aromatherapy is one of the non-pharmacological methods preferred in recent years due to its pleasant smell and low cost.[18]

Lavender oil is the most popular and widely used essential oil in aromatherapy, which is accepted as a complementary/supportive treatment method.[6] Lavandula angustifolia is the most commonly used type of lavender in today's medicine.[29] The main components of lavender essential oil obtained by distillation from the flowers of *Lavandula angustifolia* are linalool (35%) and linalool acetate (51%).[27,29] It has been reported that linalool and linalool acetate have an inhibitory effect on the limbic system and autonomic neurotransmission, and this systemic effect increases effect of gamma-aminobutyric acid in the amygdala, thus playing an important role in reducing the level of pain and anxiety.[25,31] In addition, since these 2 components stimulate the parasympathetic nervous system, they have also been found to have analgesic, antiseptic, antidepressant, antispasmodic, antiviral, and diuretic properties.[29] Studies have shown that aromatherapy can be used in addition to existing methods for pain management due to its significant efficacy in reducing anxiety and benefits in mild to moderate sleep disorders.[30,32-34] In studies examining the effect of lavender oil after CABG surgery, this intervention has been reported to reduce pain intensity and anxiety level, and has a positive effect on sleep quality in different patient populations.[3,35-40] It also does not appear to be associated with any significant harm for patients.[3,41] However, there is a need for well-designed studies to evaluate whether the use of lavender oil can be integrated into nursing care practices as supportive/ complementary therapy method to reduce pain intensity and anxiety levels and improve sleep quality in patients that have undergone CABG surgery.

Aim

Aim of the study was to investigate the effect of lavender oil inhalation on patients' pain intensity, anxiety level, and sleep quality after CABG surgery.

Null hypothesis

There is no significant difference in pain intensity, anxiety level, and sleep quality between patients who receive lavender oil inhalation after CABG and those who do not receive this intervention.

METHODS

Trial design

This study designed as a randomized controlled (RCT) trial with two groups including an equal no. of random participants. All stages of RCT "Consolidate standards of reporting trials (CONSORT)" recommendations and

standard protocol items: recommendations for interventional trials (SPIRIT 2013) checklist followed.[42]

Setting

The trial will be conducted at a 32-bed cardiovascular surgery (CVS) ward of a training and research hospital in Istanbul, Turkey. Patients are usually admitted to this ward two days before surgery, and they are postoperatively moved to the CVS intensive care unit (ICU) for close follow-up. After an average of two-or three-day stay in ICU, the patients are moved back to the CVS ward and discharged from the hospital within an average of four to five days.

Determination of the sample size

The sample size was determined by power analysis using G*power (v3.1.7) software. Based on the differences between the anxiety level measurements of patients undergoing open heart surgery at the first and last follow-up in a previous study (difference of the means for the control group: 1.11; difference of the means for lavender oil: 2), the effect size was calculated as (d) 0.7320 at a significance level of α=0.05 and statistical test power of 80%.[37] When the type II error was taken as 0.05 and the power of the test as 0.80 (α=0.05, 1-β=0.80), the minimal sample size required according to the standard deviation (SD) value was found to be 62 individuals, 31 for each group. Therefore, a total of 80 patients, 40 in each group, were decided to be included in the study.

Eligibility criteria

The inclusion criteria for the study were determined as follows: 18 years of age or older, undergoing elective CABG surgery, negative lavender oil allergy test, being conscious and oriented to place, person, and time, not having any disability that would make communication difficult, being able to communicate in Turkish, and giving informed written consent to participate in the study. The exclusion criteria were accepted as being diagnosed with a sleep disorder or using any pharmacological and/or herbal medicine for insomnia, being allergic to lavender, cosmetics, or perfume, having a history of dermatitis, sinusitis, upper respiratory tract infection, liver and kidney dysfunction, asthma, and chronic obstructive pulmonary disease, not having regulated blood pressure, having arrhythmia, using patient-controlled analgesia after surgery, and not being able to communicate in Turkish. The remaining exclusion criteria were determined as a positive lavender oil allergy test, development of lavender allergy during the study, voluntarily deciding to leave the study, and not complying with the study process and conditions.

Interventions

Participants will be allocated to either the intervention or control group according to the surgery list in the clinic. After admission to the CVS ward in the postoperative period, the participants assigned to the intervention group will be administered lavender oil inhalation three times a day at the fourth hour of analgesic administration, considering the plasma half-life of the analgesic agent (paracetamol vial).[3] The controls will only be given analgesic treatment three times a day and not receive any intervention.

During the trial, 2% Lavandula angustifolia will be administered to the patients in the intervention group. In order to determine whether the patients in this group have any allergy to lavender oil, the skin prick test (SPT) will be performed by the researcher. SPT is an intradermal test method generally applied to the relatively hairless area of the inner forearm. During the application of SPT, it is essential to use the allergen substance (lavender oil) as well as negative (4% phenol-containing saline) and positive (histamine) control substances.[43] One drop of each substance is applied at a distance of at least 2 cm from each other. The skin is gently punctured and lifted with a separate lancet for each substance at an angle of approximately 60 degrees from the middle of the droplets. The evaluation of the result is made after 15-20 minutes by measuring both the redness and swelling diameter with a millimetric ruler. The validity criteria of the test are as follows: the test will be accepted as negative if the positive control is $\geq$3 mm, the negative control is <3 mm, and the skin reaction to lavender oil is <3 mm, and positive if the skin reaction to lavender oil is $\geq$3 mm.[43] Patients with a positive SPT result will be excluded from the study.

Lavender oil inhalation will be performed by placing two drops of 2% lavender oil on a 5x5 cm sterile gauze cloth and asking the patient to smell it for three to five minutes. Pain intensity and vital signs will be evaluated and recorded before each application and in the first five minutes after the application.

Outcomes

The primary outcomes of this trial are postoperative pain intensity, anxiety level, and sleep quality, and secondary outcomes are blood pressure, heart rate, respiratory rate, oxygen saturation and the need for analgesics in the postoperative period.[3,35,40]

Participant timeline

Patients admitted to the CVS ward for CABG surgery will be evaluated by the researcher in terms of inclusion criteria, and informed written consent will be obtained from those who meet the inclusion criteria and agree to participate in the study. After randomization, SPT will be performed on the patients assigned to the intervention group. During this process, a descriptive characteristics form, the state-trait anxiety inventory (STAI) I-II, and Richards-Campbell sleep questionnaire (RCSQ) will be administered to both groups, and pain intensity will be

evaluated using the numeric rating scale (NRS). During the follow-up, the following measurements will be made: a) pain intensity and vital signs at admission from ICU to the CVS ward, b) pain intensity three times a day before and 20-30 minutes after the administration of analgesics during stay in the ward, and c) pain intensity and vital signs at four hours after analgesic administration before lavender oil inhalation and pain intensity, vital signs, and anxiety levels at five minutes after lavender oil inhalation in the intervention group, and pain intensity, vital signs, and anxiety levels of the controls at the same evaluation times. Sleep quality will also be evaluated every morning during the hospital stay of the patients (Table 1).

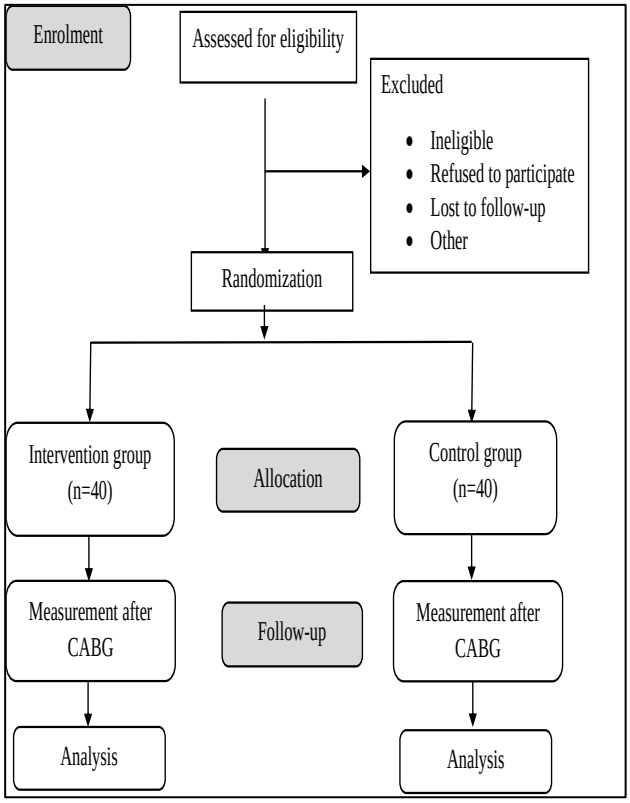

Figure 1: Study flowchart according to CONSORT.

Recruitment and randomization

In the trial, a randomization list created from a table of computer-based random numbers (www.random.org) will be used to determine which group the patients will be included in the study. Before participants are assigned to the groups, patients undergoing CABG surgery will be numbered according to the order of admission to the hospital and assigned to the intervention or control group using the numbers in the randomization list.

Blinding

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

Data collection

The data of this trial started to be collected as of June 17, 2021, and the data collection process is ongoing.

Instruments

Data in the trial will be collected using the descriptive characteristics form, STAI I-II, RCSQ, NRS, and patient follow-up forms.

Descriptive characteristics form

This form was prepared in line with the literature and consists of two parts, each with eight questions.[17,39,40] The first part concerns the patients' age, gender, education level, marital status, occupation, employment status, income status, and health insurance, while the second part questions smoking status, alcohol consumption habits, presence of food/drug allergies, presence of additional systemic diseases, and regular medication and/or plant product(s), previous hospitalization history, previous surgery history, and normal sleep duration.

State-trait anxiety inventory (STAI)

This instrument was developed by Spielberger et al in 1970, and its validity and reliability study for the Turkish population was carried out by Öner and Le Compte in 1975.[44] It consists of two subscales for the measurement of state anxiety (STAI-I) and trait anxiety (STAI-II). Each subscale includes 20 items scored based on a four-point Likert scale. For each subscale, the minimum score is 0 and the maximum is 80, and a score of 0-19 indicates no anxiety, 20-39 low anxiety, 40-59 moderate anxiety, and 60-80 high anxiety.[44] In this trial, permission for the use of the scale was obtained from the community development and education foundation-YÖRET (Innovative, Pioneer, Guiding, Effective, Social) and the authors that adopted the scale into Turkish.

Richard's-Campbell sleep scale (RCSQ)

This scale was developed by Richards in 1987, and the validity and reliability analyses of the Turkish version were undertaken by Özlü and Özer in 2015.[45] RCSQ consists of six items that assess the depth of night-time sleep, time it takes to fall asleep, frequency of waking up, time to return to sleep when awakened, sleep quality, and noise level in the environment. The total score of the scale is evaluated over five items, with the sixth item evaluating the noise level in the environment being excluded from the total score evaluation. Each item is rated on a chart from 0 to 100 with the Visual Analog Scale. A score of 0-25 in the scale indicates very poor sleep quality, 26-75 moderate sleep quality, and 76-100 very good sleep quality. A higher score indicates better sleep quality.[45] To use this scale in this trial, we obtained permission from authors who adapted the scale into Turkish.

Table 1: Participant timeline.

Study period post-operative																		
Time of evolution	**Intervention group**									**Control group**								
	Pre-op	**At admission**	**Before analgesic**	**20-30 min after analgesic**	**Before lavender oil inhalation**	**5 min after lavender oil inhalation**	**Every morning**			**Pre-op**	**At admission**	**Before analgesic**	**20-30 min after analgesic**	**4th hour after analgesic**	**Every morning**			
Informed consent	X									X								
Descriptive characteristics form	X									X								
STAI-I	X					X				X				X				
STAI-II	X									X								
RCSQ	X						X			X					X			
NRS	X	X	X	X	X	X				X	X	X	X	X				
Vital signs*		X			X	X					X			X				

Pre-op: Pre-operative period, NRS: Numerical rating scale, STAI I-II: State-trait anxiety inventory, RCSQ: Richards-Campbell sleep questionnaire, *Vital signs: heart rate, blood pressure, respiratory rate, and oxygen saturation.

Numeric rating scale (NRS)

This is a single-dimension self-assessment scale used to evaluate pain intensity over numerical values from 0 to 10 at equal intervals.[46,47] In this scale, 0 indicates no pain, 1-3 mild pain, 4-6 moderate pain, and 7-10 unbearable pain. The reason for choosing this scale to be used in the trial is that it is valid, reliable and widely preferred in national and international studies.[46-49] In addition, it has been shown to be the most appropriate tool for the evaluation of postoperative pain for the elderly, as well as young adults, and it is also suitable for use in elderly patients with mild to moderate cognitive impairment.

Patient follow-up form

This is the form on which the NRS pain intensity scores and vital signs (blood pressure, pulse rate, respiratory rate, and oxygen saturation) of the patients in both groups will be recorded starting from admission to the CVS ward. These evaluations will be repeated three times a day every eight hours throughout all the patients' hospital stay. Furthermore, they will be undertaken before and 20-30 minutes after the administration of analgesics in the control group, and before and 20-30 minutes after analgesic administration and before as well as five minutes after the lavender oil inhalation in the intervention group.

Data management

The researchers will ensure the accurate and complete coding of all data and their entry into the statistical analysis software. All original documents, including medical records, questionnaires, informed consent forms, and other relevant records obtained during the trial period will be retained and kept confidential by the researchers. Data will be stored for ten years after the completion of the study.

Statistical analyses

The number Cruncher statistical system 2007 statistical software (NCSS LLC, Kaysville, Utah, USA) will be used for the statistical analysis. In addition to descriptive statistical analyses (mean and standard deviation), Student's t-test will be used in the comparison of normally distributed variables in the comparison of quantitative data, and the Mann-Whitney U test for the variables that do not show a normal distribution. The repeated-measures analysis of variance will be conducted for the intra-group comparisons of normally distributed parameters, and the paired-samples t-test for the evaluation of changes in morning, afternoon and evening follow-up. The Friedman test will be used for the intra-group comparisons of non-normally distributed variables, and the Wilcoxon signed-rank test for paired follow-up evaluations. The Pearson chi-square and Fisher's exact tests will be conducted to compare qualitative data. Statistical significance will be evaluated at $p<0.05$ level.

Data monitoring

All data to be obtained will be tracked. In order to test the feasibility of the study, a pilot study has been undertaken with eight patients in lavender oil inhalation group, and these patients will not be included in intervention group.

Harms

In the trial, all the unexpected and undesirable reactions among the participants will be recorded and closely monitored by the researcher and categorized as related or unrelated to the intervention.

Auditing

Adaptation to every stage of the research process will be provided by the researchers. Since lavender oil used in

the study is not available in the institution where the study will be conducted, it will be supplied by the researcher from Florame organic essential oils and organic cosmetics. The non-invasive automatic repeating electronic device (WelchAllyn® Connex vital signs monitor, USA) will be used for the measurement and monitoring of the patients' vital signs. The device is available in the clinic where the study is carried out and no additional purchase is required.

Ethical considerations

This study was approved by the clinical research ethics committee of Marmara university faculty of medicine (decision number: 09.2020.666, date: 23.06.2020). In addition, permission was obtained from the medical specialization and education board of Istanbul Bakirkoy Dr. Sadi Konuk training and research hospital operating under the provincial health directorate of Istanbul (decision number: 9, date: 19.03.2021). Written consent will be obtained from all the participants to be included in the study. The study will be conducted in accordance with the principles of the declaration of Helsinki (64th World medical association general assembly, Fortaleza, Brazil, October 2013) and the Turkish law on medical research involving human subjects.

Access to data

Both the researchers will have access to all data during the study period. At the end of the study, the data will be retained for future research.

Ancillary

Participants will not be charged for lavender oil or SPT, and the cost will be covered by the researcher. No additional provisions are required for participants.

Dissemination policy

The results of the study will be shared through a publication in an international peer-reviewed scientific journal and/or presentation at a national congress. The authors will adhere to the ethical standards of authorship.

DISCUSSION

Pain, anxiety, and sleep disorders are common problems after CABG surgery, which is a major intervention.[7,32] Failure to manage these problems appropriately after surgery may adversely affect the recovery process of individuals and prolong their hospital stay.[8,13] This not only has negative effects on individual due to financial losses and being away from social environment but also causes an increase in the cost of care and workload of care providers.[18] Lavender oil inhalation, which is the intervention to be applied in this trial, can reduce the pain and anxiety level of patients after CABG surgery, shorten hospital stay due to increased sleep quality, decrease the loss of work force, and facilitate adaptation to social life in a shorter time. At the same time, determining the effect of lavender oil inhalation on pain, anxiety, and sleep quality after CABG surgery can contribute to clinical practice and future scientific studies in this patient population. It is also considered that this will have positive effects on the efficient use of workforce among healthcare professionals.

CONCLUSION

This is a trial that will meticulously evaluate the effects of lavender oil inhalation after CABG surgery on outcomes that concern perioperative nursing practices; i.e., patients' postoperative pain, anxiety, and sleep quality. The results of this trial will allow for the evaluation of effects of using this intervention alongside pharmacological methods to address these problems and will provide valuable evidence to guide clinical practice.

Marmara university faculty of medicine (decision no: 09.2020.666). Medical specialization and education board of Istanbul Bakirkoy Dr. Sadi Konuk training and research hospital operating under the provincial health directorate of Istanbul (decision number: 9, date: 19.03.2021).

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Ethical approval: The study was approved by the Institutional Ethics Committee

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