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Effect of massage made with aromatherapy oil after mastectomy on acute arm pain and anxiety: a randomized controlled study protocol

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ABSTRACT

Background: This article summarizes the study protocol currently used to evaluate the efficacy of aromatherapy massage for the relief of post-mastectomy anxiety and acute arm pain.

Methods: It is a prospective interventional type three-group, randomized controlled, drug-free clinical trial. Eligible patients will be randomly assigned to one of three groups. The population of the study will consist of 90 patients who have undergone simple mastectomy (SM) and modified radical mastectomy (MRM) in the general surgery ward of a training and research hospital in Turkey. After the operation, the arm on the operated side will be massaged with sesame oil in the first group (n=30), sesame-lavender oil in the second group (n=30), and paraffin oil in the third group (n=30).

Conclusions: The primary outcome is the level of acute arm pain and the level of state anxiety. The secondary outcome is vital signs and analgesic use status.

Keywords: Acute pain, Anxiety, Mastectomy, Sesame-Lavender oil, Aromatherapy massage

INTRODUCTION

Breast cancer is considered both a local and systemic disease. The stage of the cancer is considered when planning the treatment. If the cancer is stage 1A (T1N0), 1B (T1N1), 2A (TxN1; T1N1, T2N0), stage 2B (T2N1; T3N0), mastectomy, which includes surgery for the primary tumor and partial or complete removal of the breast, is considered. It is the most applied treatment as an intervention for breast tissue.[1,2] Due to the possibility of intercostobrachial nerve injury during axillary lymph node dissection, patients may experience pain, numbness, and weakness in the chest wall, arm, and shoulder in the postoperative period, acute/chronic, neuropathic, and phantom pain, lymphedema may develop aftermastectomy.[3]

In the evidence-based guideline, it is stated that acute pain is an important clinical problem, that more than 80% of patients experience acute pain after surgery, and that approximately 75% of patients describe this pain as moderate, severe, and unbearable.[4] In the study conducted by Andersen et al it was reported that 6% of 475 women who had breast surgery experienced moderate pain in the breast, near the chest, axillary region, and arm in the first three days after surgery.[5]

Most of the patients who are given a mastectomy decision experience anxiety due to the expectation that there will be a change in body image because of the planned surgery and the uncertainty of recovery.[6,7] Surgery is an important treatment step for patients to regain their health. However, patients experience anxiety due to the surgical procedure, which is considered a normal and expected situation about the surgical experience.[8,9] It is stated that the anxiety experienced before the operation begins with the admission of the patients to the hospital, peaks on the day of the operation, and continues in the postoperative period.[8]

In the ERAS (Enhanced recovery after surgery) protocol, which includes multidimensional evidence-based interventions to accelerate recovery after breast surgery, it has been reported that patients should be informed, educated, and counseled before, during, and after surgery to reduce anxiety and complications (Moderate evidence and strong recommendation).[6]

Ineffective and inadequate management of acute pain after breast surgery can cause many clinical conditions such as morbidity, and high hospital costs, affecting the healing process.[4,10] At the same time, acute pain seen in the postoperative period negatively affects recovery and is stated as an important risk factor for the risk of developing more severe and chronic pain.[10]

Current guidelines recommend the use of "multimodal analgesia" in postoperative pain management (high level of evidence and recommendation).[4,11] Multimodal analgesia provides the simultaneous use of different pain control mechanisms and thus effective pain management by taking advantage of the synergistic effect of drugs used together to reduce the opioid dose, increase the analgesic effect, and minimize the risk of side effects in postoperative pain control.[12,13]

There are recommendations on pain management strategies in the ERAS (Enhanced recovery after surgery) protocol, which includes versatile evidence-based interventions to accelerate post-operative recovery. In the ERAS protocol recommendations after breast surgery, it is reported that the use of multimodal analgesia and the use of opioids should be avoided in pain management strategies before, during, and after the surgery (high level of evidence and strong recommendation).[6]

Aromatherapy, which is one of the non-pharmacological methods, can be applied in different ways. When aromatherapy oils are applied to the skin with massage, both the positive effect of massage on the individual is benefited and the absorption of essential oil is supported.[14] In the current massage therapy guide published by the American massage therapy association, it is reported that massage applied with aromatherapy oils creates a positive mood and is effective on anxiety and

pain.[15]

In studies on sesame oil, one of the oils used in the research, it has been reported that in addition to its antimutagenic and antipyretic effects, it can be used in different forms of use (topical or oral) with its antinociceptive properties and has analgesic effects.[16,17] Thanks to the linalyl acetate and linalool it contains, lavender oil plays a regulatory role in the transport of inhibitory gamma-aminobutyric acid (GAMA) and its binding to the relevant receptor. With the effect of GAMA, the cholinergic system is activated and provides analgesic, anxiolytic, anti-depressive, and anticonvulsant effects.[18,19]

Hypothesis

H1: After SM/MRM, massage with sesame oil reduces the severity of acute arm pain compared to massage with paraffin oil.

H2: After SM/MRM, massage with a sesame-lavender oil mixture reduces the severity of acute arm pain compared to massage with paraffin oil.

H3: After SM/MRM, massage with sesame oil reduces anxiety levels compared to massage with paraffin oil.

H4: After SM/MRM, massage with a sesame-lavender oil mixture reduces anxiety levels compared to massage with paraffin oil.

H5: After SM/MRM, massage with a sesame-lavender oil mixture reduces the severity of acute arm pain compared to massage with sesame oil.

H6: After SM/MRM, massage with a sesame-lavender oil mixture reduces anxiety levels compared to massage with sesame oil.

Aim

This study aims to better understand the effects of these herbal-derived agents in aromatherapy, contribute to nurses' non-pharmacological treatment interventions, and provide quality care in managing anxiety and acute pain in patients. Thus, providing new information to evidencebased nursing practice.

METHODS

Determination of the sample size

In this trial, the difference in medium effect size (f=0.25) in the three independent groups was considered statistically significant and the total sample size was calculated as 66 at 95% power 0.05 alpha significance level. It consists of a total of 66 patients who have the power to represent the universe. However, considering the losses that may occur during the study process, it was decided that it would be appropriate to include 90 patients, 36% more than the sample.

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 activities involving human subjects, and written informed consent will be obtained from all participants throughout the study. This study was approved by the Medipol university non-ınvasive clinical ethics committee [Protocol number: E-10840098-772.02110 Date: 06.01.2022]. Institutional permission was obtained from the Istanbul provincial health directorate (Protocol number: 2022/10, Date: 28.04.2022).

Population and randomization

This study protocol describes the design of a singlecenter, double-blind, and randomized controlled trial. This trial will be carried out in the general surgery service of a training and research hospital located in Istanbul. The study was registered at Clinicaltrials.gov in March 2022 (NCT05658367). The study was planned as three groups. Patients who underwent SM and MRM will be screened for inclusion and exclusion criteria, and those who are eligible will be invited to the study. After obtaining the informed written consent of the participants who agreed to participate in the study, the randomization list created from the computer-based random numbers table will be used with the block randomization method to assign an equal number of people to all three groups. The program "randomizer.org" will be used for the randomization process. Participants will be given a sequence number according to the order of inclusion in the study as well as will be assigned to one of three groups according to the numbers in the randomization list.

Inclusion criteria

18 years and over, literate, agreeing to participate in the study, person-place, and time orientation, visual (except for those with better vision using a visual aid), auditory communication difficulties (except for those with better hearing ability using hearing aid) that will prevent them from understanding the information given and expressing the pain situation correctly, no speech impediment/communication problem, SM and MRM was performed, Not using any complementary alternative therapy method, able to use technology (smartphone, computer, etc.), individuals with technology devices (smartphone, tablet, computer, etc.) will be included in the study.

Exclusion criteria

Not speaking Turkish and illiterate in Turkish, those who are allergic to the oils to be used in the massage during the application, involved in a different study conducted in the clinic, breast prostheses placed during surgery, having physical and cognitive problems at a level that cannot apply massage, individuals diagnosed with mood disorders (using any medication for depression, panic attack, dysthymia, bipolar disorder) will not be included in the study, transferred to the intensive care unit in the postoperative period, severe bleeding, hematoma, seroma, nerve injury or lymphedema developing in the postoperative period, developing an allergy to the oils to be used in the massage during the application.

Blinding

Although there is information in the literature that it is not possible to blind the participants due to the characteristic smell of aromatherapy oils, patients are shown blind because the oils are formulated in aromatherapy massage and the oil content is not known by the patients.[16,20] Due to the feasibility and nature of the trial, the principal investigator cannot be blinded during grouping, while blinding will be provided to the patient and analyst. The direction of this work will have a

"double-blind" design.

Interventions

After randomization, group 1 will apply aromatherapy arm massage using sesame oil; group 2 will apply aromatherapy arm massage using a sesame-lavender oil mixture; group 3 will apply arm massage with paraffin oil. In the literature, it is seen that whether patients are allergic to the oils to be used in aromatherapy massage is evaluated with the "patch test".[9,21-24] For this reason, a "patch test" will be applied to evaluate allergic sensitivity in the study. An allergic sensitivity test will be done for the 1st and 2nd groups.

In the pre-operative period, all groups will be filled with a patient diagnosis Form, training and information will be given to the patients about the arm massage they will apply, and a massage training brochure and massage application video will be given.[6,25] They will be informed about filling out the state anxiety scale and numerical ratio scale forms before and

after the massage. Patients will be asked to fill out the state anxiety scale and the numerical ratio scale and their vital signs (body temperature, pulse, respiration, and blood pressure) will be measured.[8]

Routine analgesic administration will continue in the clinic in all groups in the postoperative period. The massage application was planned to be performed three hours after the start of the application of the drug, based on the half-life of the analgesic substance.

In all groups, vital signs will be taken before and 30 minutes after the analgesic intervention, given after the patient comes to the service after the surgery, and they will be asked to fill in a numeric ratio scale for pain assessment.

Before the arm massage application in all groups, the patient's vital signs will be measured, and they will be asked to fill in a numerical ratio scale for pain assessment. Vital signs will be measured 15 minutes after the massage, and they will be asked to fill in the numerical ratio scale and anxiety scale.

A postoperative analgesic follow-up form will be obtained from the patient's file until the patient's discharge.

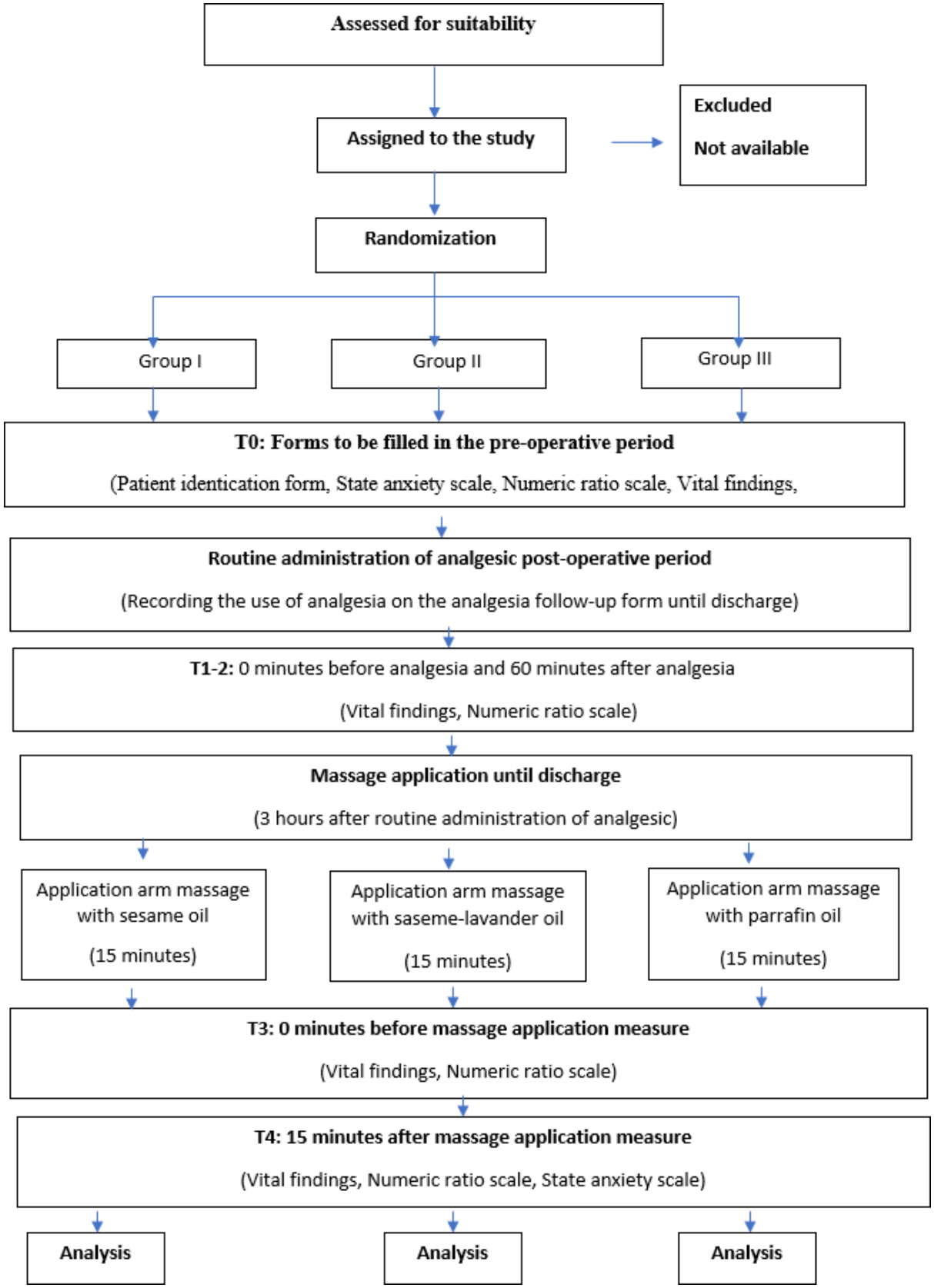

Figure 1: Data collection procedure.

Outcome measures

The patient identification form, which is a data collection tool, was designed by the literature.1,5,10,21,26,27 In the form, there are characteristics related to the individual, characteristics related to health and disease, and characteristics related to surgery. It will be collected after the approval of the participants. Primary outcomes

Post-operative acute pain

Postoperative pain of the patients will be evaluated with the numerical ratio scale based on the report by the patient. The score obtained will be 0: no pain, 1-3: mild pain, 4-6: moderate, and 7-10: severe pain. Current evidence-based guidelines state that the patient's pain severity should be determined in the preoperative period in terms of pain management planning and goals in the postoperative period. 4 Diagnosing acute pain requires using a measurement tool that can be easily understood, applied, and preferred by patients.28,12 The study on pain forms determined that no errors were observed in the numerical ratio scale among the scales used for pain assessment. It is stated that NPC should be preferred as the first choice in the evaluation of acute pain after surgery in clinical and research areas because it is easy to understand and apply.28

Level of state anxiety

Anxiety levels of the patients will be evaluated with the state anxiety scale. Due to its proven prevalence, ease of use, validity, and reliability, it is recommended to use the state anxiety form to evaluate anxiety levels in patients scheduled for surgery.8

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 the considered severe anxiety.29

Secondary outcomes

Vital findings

Anxiety is an uncomfortable situation that causes behavioural and physiological changes in the patient, and the stress response that develops due to the patient's feeling of pain negatively affects the physiological systems.8,30 The patient's body temperature, pulse, respiratory rate, and blood pressure will be recorded at 0 minutes before analgesic, 30 minutes after analgesic, 0 minutes before the massage, and 15 minutes after the massage.

Analgesic use status

It will be taken with the analgesic follow-up form. There is information about the name, type, number/dose, route of administration, and frequency of analgesic administered in the postoperative period, and the data will be obtained from the patient file.

Data collection procedure

This is a trial conducted as an RCT in the surgical ward after mastectomy surgery. To assign an equal number of subjects to all three groups, patients who underwent SM and MRM, met eligibility criteria, and gave written informed consent, will be assigned to the group using block randomization.

Patient identification form, which contains patient demographic and clinical information, state anxiety scale, numerical ratio scale, and vital signs will be collected in the preoperative period (T0). Follow-up measurements will be made immediately before (T1) and 60 minutes after (T2) analgesia. It is applied just before the massage (T3) and 15 minutes after the massage (T4). After each massage, the state anxiety scale will be applied in addition to the vital signs and numerical ratio scale. The patients included in the study will continue their routine analgesic treatments and will perform arm massages with an analgesic half-life after 3 hours. After mastectomy, patients perform 6 massage treatments for 2 days until discharge (Figure 1).

Statistical analysis

Data analysis on the final dataset will use SPSS statistical software (SPSS, Inc., version 21.0). Descriptive statistics: numbers and percentages for categorical variables, mean, standard deviation, minimum and maximum for numerical variables. When the differences of numerical variables in the dependent groups satisfy the condition of normal distribution, the changes, and the differences of the changes in the groups will be compared with the Wilcoxon analysis in the groups when the condition is not met with repeated measurement analysis of variance. Comparisons of numerical variables in more than two independent groups will be made using the One-Way ANOVA test when the normal distribution condition is met, and the Kruskal-Wallis Test when the normal distribution condition is not met. Subgroup comparisons will be made with the Tukey nonparametric test in the parametric test and the Mann Whitney U test in the nonparametric test and interpreted with Bonferroni correction. The ratios of the categorical variable between the groups will be tested with Chi-square analysis. The statistical alpha significance level will be accepted as $p<0.05$.

DISCUSSION

Breast cancer is the most frequently diagnosed type of cancer among women worldwide. About the stage of cancer, the most commonly used treatment is mastectomy, which involves partial or complete removal of the breast tissue as an intervention.1,2

Patients experience acute pain after surgery and acute pain severity is affected by both surgery-related and preoperative anxiety.7,10

In current evidence-based guidelines, the importance of "multimodal analgesia" in postoperative pain management has been emphasized and its use has been recommended. It is mentioned that non-pharmacological methods can be used in addition to pharmacological treatment to assist treatment in pain management.4,12,13

Today, it is known that aromatherapy has an important place among complementary and holistic therapy methods.31 However, it is stated that studies on aromatherapy massage are weak in terms of evidence level and more studies should be done on this subject.32 It is stated that aromatherapy oils are applied by inhalation alone rather than massage, and there are few studies on the effectiveness of massage with aromatic oils, so more studies on aromatherapy massage should be done in the treatment of pain, anxiety, and depression.33,34

CONCLUSION

This article summarizes the protocol of a randomized controlled trial conducted to demonstrate the effectiveness of aromatherapy massage on the arm on acute arm pain and anxiety after mastectomy. It is seen that studies conducted after breast surgery are mostly focused on the development of chronic pain rather than acute pain intensity after surgery. This is the first study on the effectiveness of aromatherapy massage applied to the arm after mastectomy on acute pain and anxiety.

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