Original Article

The Effect of Lavender Oil Aromatherapy on the Shoulder-Tip Pain after Laparoscopic Cholecystectomy: A Randomized Controlled Trial

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Background: Postoperative shoulder pain is one of the complications after laparoscopic cholecystectomy (LC). Medications used to treat shoulder pain have side effects. Objectives: The aim of this study was to examine the effect of lavender oil aromatherapy on shoulder pain after LC. Methods: In this single-blind randomized controlled trial, 64 patients who underwent LC were randomly allocated into two groups to receive lavender oil aromatherapy or routine treatment. The intervention began in the recovery room after the patient responded to stimuli. First, the patient's pain was assessed. Then, aromatherapy was started for the intervention group, and afterward, pain measurement was repeated at 5, 25, and 60 min after the intervention. The pain intensity was assessed using a visual analog scale. Patients in the control group received no intervention other than routine care and treatment, but their pain intensity was measured at the same time as patients in the intervention group. Data analysis was performed using the Chi-square, independent-samples and paired *t*-tests, and repeated-measures analysis. **Results:** The mean baseline pain severity of the control and aromatherapy groups was 6.26 ± 1.44 and 7.20 ± 1.44 , respectively, and changed to 9.06 ± 0.65 and 3.73 ± 0.86 at the end of the study. Repeated-measures analysis showed that over time, the mean pain intensity was decreasing in the intervention group (P < 0.05), while it had an increasing trend in the control group. Conclusion: Lavender oil aromatherapy was effective in reducing the postsurgical shoulder pain after LC.

KEYWORDS: Aromatherapy, Cholecystectomy, Laparoscopic, Lavender, Shoulder pain

Introduction

Postoperative pain management is a major goal for health-care providers. [1] Improper management of postoperative pain can interfere with patients' recovery, delay their return to daily activities, and increase care costs. [2] Pain killers such as opioids and nonsteroidal anti-inflammatory drugs have side effects such as respiratory depression, nausea, itching, and bleeding. [3] Minimally invasive surgery (MIS) has become popular over the last two decades due to its benefits such as smaller incisions, shorter hospital stays, less postoperative pain, and faster return to normal life. As an MIS, laparoscopic cholecystectomy (LC) is commonly used to treat patients with acute or chronic cholecystitis and gallstones. However, some patients complain

of shoulder-tip pain (STP) after this procedure. [4,5] Postlaparoscopic STP may be related to inflammatory damage due to surgical incision, pneumoperitoneum, or phrenic nerve stretching during surgery and subsequent neuropraxia. [4] The incidence of STP varies between 35% and 80%. [6] Some patients suffer from STP for more than

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72 h after the surgery. [7] Researchers have introduced pulmonary recruitment maneuver, intraperitoneal local anesthesia, drainage, intraperitoneal saline instillation, minilaparoscopy, and gasless laparoscopy using the Laprolift to control STP.

Recent studies show that the length of surgery does not affect the severity of STP,^[8] but STP is directly related to the rate at which gas is blown into the abdomen. However, it has been found that patients experience less pain if the gas is blown at a maximum of 2 ml/min. Nevertheless, further studies in this area are still recommended.^[9]

Pain relief is still a challenging issue. Usually, a multidimensional therapeutic approach is needed to reduce postoperative pain. In recent years, researchers have drawn attention to the use of complementary therapies such as aromatherapy. Patients have also shown good acceptance and satisfaction with this method. [2,10] A review study showed that lavender aromatherapy could reduce labor pain.[11] Another study also reported that lavender oil aromatherapy was effective in reducing pain in patients with burn injuries.[12] However, another study showed that inhalation of lavender essential oil did not relieve pain after open-heart surgery.[13] Furthermore, no study has examined the effect of lavender oil aromatherapy on reducing STP after LC. Therefore, the question arises, can lavender oil aromatherapy reduce the STP after LC?

Objectives

This study was conducted to evaluate the effect of lavender oil aromatherapy on STP after LC.

Methods

Study design and participants

This single-blind randomized controlled trial was performed from January to February 2021 on patients who underwent LC in three educational hospitals in Esfahan city, Isfahan, Iran. Inclusion criteria were an age of 20 and over; being a candidate for LC; no history of chronic shoulder pain; no pregnancy; lack of diabetes mellitus; liver, kidney, and smelling disorders; lack of known allergy to the lavender; lack of a known cognitive disorder; no cigarette and drug abuse; receiving no anticoagulant medications; willingness to participate in the study; not using perfume or cologne before the surgery; and the absence of any medical prohibition on the participation in the study.

Exclusion criteria included any allergic reaction to lavender oil, a patient's decision to withdraw from the study, alterations in consciousness, instability of vital signs, and the occurrence of any complications needing additional medical interventions such as hemorrhage, nausea, and vomiting that interfere with the intervention. The sample size was calculated using the formula for the comparison of two means. Then, considering type one error of 0.05, a power of 80%, and the least difference with the importance of the mean pain score between the two groups about 0.7 standard deviation, [14] the sample size of 32 was determined for each group. Patients meeting the inclusion criteria were recruited conveniently and randomly assigned to an intervention and a control group. We used a block randomization method to allocate the participants into two equal groups. In this way, 64 supposed patients were randomly allocated to 11 blocks of 6, with a 1:1 ratio for the intervention and control groups. To hide the allocation process, the letters A (indicating aromatherapy) and B (indicating the control group) were written on small pieces of paper and put in serially numbered, opaque, envelopes. The envelopes were then opened in the order in which the participants entered the study to determine their group.

Data collection instruments

We used a two-part instrument to collect the study data. The first part consisted of five questions on patients' demographic and clinical characteristics including age, sex, weight, and the use of narcotics and muscle relaxants during and after the surgery. The second part included an open question that asked the patient about the severity of his/her pain (i.e. How severe is your pain?) and a visual analog scale (VAS) for measuring pain. The VAS used was in the form of a ruler scored from 0 to 10 to represent the least and the most severe pain patient has ever experienced. Then, the scores 0-3, 4-7, and 8-10 were regarded as no pain, moderate, and severe pain, respectively.[15] The researcher asked each patient to show her a point on the VAS that represented the severity of their pain, and then marked that point on the VAS. Earlier studies confirmed the validity and reliability of VAS for pain assessment.[16]

Intervention

First, the data related to anesthesia method and medications received by each patient (i.e., propofol, atracurium, fentanyl, isoflurane, and N2O) were extracted from the patients' files and documented in the questionnaire. Next, to assess the sensitivity of patients in the intervention group to lavender, we soaked the skin of the inner wrist of the patients with a small amount of lavender essential oil and covered it with a gauze. After 2 min, we examined the area for allergic symptoms such as redness, itching, and swelling. Two percent lavender essential oil was steam distilled from fresh flowers by Barij Essence Pharmaceutical Co., in Kashan, Iran. Before the study

began, the first researcher was trained in aromatherapy techniques by an expert. The intervention began after the patient regained consciousness in the postanesthesia room and responded to stimuli. First, the patient's pain was assessed using the VAS. In addition to the routine care and treatment, each patient in the intervention group was then asked to inhale the aroma for 2 min with five deep breaths. Afterward, a nonabsorbent tissue impregnated with 2% lavender essential oil was attached to the patient's clothing at a distance of 10–15 cm from the nose. Pain measurements were then repeated 5 min after the intervention, 25 min later (immediately before the patient was discharged from the recovery room), and 1 h later (when the patient was in the surgical ward).

Patients in the control group received no intervention other than routine care and treatment, but their pain intensity was measured at the same time as patients in the intervention group. The type and amount of analgesics received were recorded in both groups of patients.

Ethical considerations

The study protocol was reviewed and approved by the Ethics Committee of Isfahan University of Medical Sciences, Isfahan, Iran (approval code: IR.MUI. NUREMA.REC.1400.071) and registered in the Iranian Registry of Clinical Trials (registration code: IRCT20150715023216N9). The subjects were informed about the research objectives and procedures. Written informed consents were obtained from all of them. They were assured of the confidentiality of their information and also were informed about their right to withdraw from the study at any time. All patients were assured that they would receive pain medications as routine. The research was conducted in accordance with the Helsinki Declaration about the ethical standards of medical research on human subjects.^[17]

Data analysis

Data analysis was done using SPSS software version 16 (SPSS Inc., Chicago, IL, USA). The normality of data was checked using the Kolmogorov–Smirnov and Shapiro–Wilk tests. The personal and clinical characteristics of the study groups were compared using the Chi-square test. The paired t-test was used to compare the pre- and postintervention pain scores. In addition, repeated-measures analysis of variance was used to compare the mean pain intensity between the two groups at the four measurement time points. The level of significance was set at < 0.05 in all tests.

RESULTS

In total, 64 people participated in this study [Figure 1], of whom 55.2% were women. No significant difference

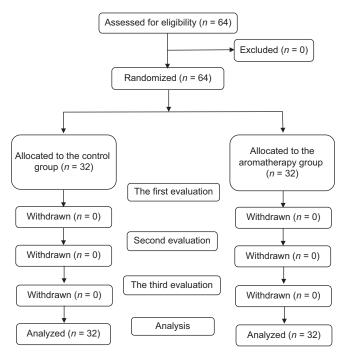


Figure 1: The study flow diagram

found between the two groups respecting was their demographic characteristics as well as the medications used for them [P > 0.05, Table 1]. In the repeated-measures analysis, the Mauchly test showed that the sphericity is not established (P < 0.001). Therefore, the Greenhouse-Geisser test was used and showed that over time, the mean pain intensity was decreasing in the intervention group [P < 0.001, Table 2]. An interaction was also found between the time and the intervention (P < 0.001); therefore, the t-test was used to conduct pair-wise comparisons between the two groups at the four measurements. The results showed that the mean pain scores were not significantly different at the first measurement (P = 0.012). However, the mean pain was significantly different between the two groups at all three postintervention measurements [Table 2 and Figure 2].

DISCUSSION

The present study showed that lavender oil aromatherapy could effectively decrease the postsurgical STP in patients undergoing LC. This is while the pain intensity in the control group had an increasing trend in consecutive measurements. The pain-relieving effect of lavender oil began shortly after aromatherapy and peaked 25 min later. However, this analgesic effect lasted up to an hour (although to a lesser extent). Consistent with our results, two studies have reported that lavender aromatherapy can remarkably reduce the intensity of lumbar and perineal pain in pregnant women^[18] and postpartum mothers with normal labor.^[11] In another

Table 1: Demographic characteristics of participants in the intervention and control groups

| Characteristics ^a | Experimental 1 | Control | P b | |
|-------------------------------------|-----------------|-------------------|------------|--|
| | (aromatherapy) | | | |
| Age | 46.03±13.8 | 48.38±11.43 | 0.688 | |
| Weight | 76.10 ± 16.70 | 76.93 ± 14.74 | 0.155 | |
| Gender | | | | |
| Male | 13 (40.60) | 16 (50.00) | 0.745 | |
| Female | 19 (59.40) | 16 (50.00) | | |
| Muscle relaxer | | | | |
| Atra | 25 (78.10) | 25 (78.10) | 0.202 | |
| Cia-atra | 7 (21.90) | 7 (21.90) | | |
| Pain killer | | | | |
| Morphine | 24 (75.00) | 27 (84.40) | 0.540 | |
| Pethidine | 8 (25.00) | 5 (15.60) | | |
| Narcotic | | | | |
| Fentanyl | 27 (84.40) | 25 (78.10) | 0.365 | |
| Sufentanyl | 5 (15.60) | 7 (21.90) | | |

^aData presented as *n* (%) or mean±SD, ^b*t*-test or chi-squared test. SD: Standard deviation

Table 2: The mean and standard deviation of pain scores in aromatherapy and control groups at the four measurement times

| Time | Groups | | P(t-test) | P | |
|---------------------------|---------------|-----------|-----------|--|--|
| | Aromatherapy | Control | | | |
| Before | 7.20 ± 1.44 | 6.26±1.45 | -2.59 | 0.012 | |
| intervention | | | | | |
| After first intervention | 5.59±1.59 | 7.31±1.14 | 4.97 | Time-group interaction before aromatherapy and after first intervention: <0.001 | |
| After second intervention | 4.00±1.02 | 8.39±0.96 | 17.65 | Time-group interaction before aromatherapy and after 25 min: <0.001 | |
| After third intervention | 3.73±0.86 | 9.06±0.65 | 28.82 | Time-group interaction before aromatherapy and after 60 min: <0.001 | |

study of postarthroscopic pain, lavender showed a mild analgesic effect 72 h after surgery but no immediate analgesic effect. [19] Contrarily, a study has reported that lavender oil aromatherapy could not reduce pain after open-heart surgery. [13] Such a contradictory finding might be attributable to the fact that open-heart surgery is a highly invasive surgery with an extensive incision and causes severe pain that might not be easily relieved by lavender oil aromatherapy. A study has also reported

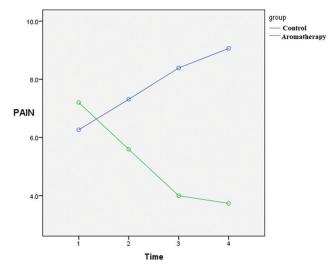


Figure 2: Trend of pain scores over the four measurement time points

that lavender oil aromatherapy was not effective on pain caused by intrauterine device insertion. [20] One of the reasons why lavender oil aromatherapy was ineffective in the latter study is that the participants were anxious. This may have reduced the pain-relieving effect of lavender.

The analgesic effect of lavender might be attributable to its active ingredients such as linalool and linalool acetate, which have local anesthetic effects. Linalool also inhibits some chemical pathways in the brain and therefore exerts anticonvulsant activity.[13] Furthermore, the aromatic nature of linalool stimulates the olfactory nerve and sends messages to the limbic system in the brain. The limbic system then evokes pleasant memories which may contribute to the amplification of sedative effects of lavender oil. Moreover, inhalation of lavender oil and subsequent entry of its active ingredients into the bloodstream and then toward the brain and limbic system may intensify this process.^[21] Although aromatherapy is not widely used in hospitals right now, some of the benefits of this method, such as limited side effects, cheapness, ease of use, and availability, can make it a valuable way for reducing STP. This study was single-blinded and was conducted on a small sample of patients. Furthermore, differences in pain tolerance between patients may have affected the results of the study. We also assessed the pain intensity only up to 1 h after the intervention. Further research with a larger sample size and longer follow-up is recommended to more accurately determine the pain-relieving effect of lavender aromatherapy and the longevity of its effect.

CONCLUSION

The present study provided evidence regarding the effectiveness of lavender oil aromatherapy on STP

after LC. Therefore, physicians and nurses can use this technique to reduce the patients' pain after laparoscopic surgeries and decrease the need for analgesics.

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Conflicts of interest

There are no conflicts of interest.

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