

Original Article

The Effect of Aromatherapy with *Rosa damascena* Essence on Postoperative Pain in Inguinal Hernia Repair: A Randomized Clinical Trial

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ABSTRACT

Background: Despite therapeutic interventions, patients are still dissatisfied with the treatment of postoperative pain. **Objectives:** The aim of this study was to examine the effect of *Rosa damascena* essential oil on postoperative pain in patients undergoing inguinal hernia repair surgery. **Methods:** In a double-blind, randomized trial, 60 patients undergoing inguinal hernia repair surgery were selected consecutively and equally assigned to two groups of experimental and placebo. In both groups, the pain intensity was measured by a visual analog scale in 4, 8, and 12 h after the surgery. Patients in the experimental group received aromatherapy with *R. damascena* essential oil and those in the placebo group treated with almond oil. In both groups, pain intensity was measured before and 20 min after aromatherapy. Data analysis was performed using the repeated-measures analysis, analysis of covariance, independent-samples *t*-test, Chi-square, and Fisher's exact tests. **Results:** The mean pain intensity in the experimental and the placebo groups was 7.10 ± 1.24 versus 7.20 ± 1.10 , 4.56 ± 1.04 versus 4.90 ± 0.84 , and 1.30 ± 0.79 versus 2.46 ± 0.68 after the 4th, 8th, and 12th postsurgical hours, respectively. The repeated-measures analysis showed that the intervention was effective on pain reduction, especially in the 8th and 12th postoperative hours when the pain was at moderate-to-mild levels ($P < 0.001$). **Conclusion:** Aromatherapy with *R. damascena* essential oil was effective in relieving mild to moderated postoperative pain. Yet, further studies are needed to confirm this finding.

KEYWORDS: Aromatherapy, Essential oil, Inguinal hernia, Pain, *Rosa damascena*

INTRODUCTION

A majority of patients experience moderate-to-severe pain during the postoperative period.^[1,2] Uncontrolled postoperative pain can cause acute and chronic consequences such as immune suppression, delayed wound healing, and postoperative hypercoagulability.^[3] Several studies have also shown that poorly controlled postoperative pain is associated with an increase in the frequency of nausea,^[4] delirium,^[5] delayed hospital discharge, and

delayed resuming daily activities.^[6] Inappropriate pain management also reduces the quality of life of patients and imposes a heavy economic burden on the health-care system.^[7]

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Nurses are not only responsible for the management of postoperative pain, but also should train patients and their families on how to prevent and treat pain and pain-related complications.^[8]

Despite the advances in surgical technology, postoperative pain is still a challenge for both patients and nurses.^[9] A study conducted in educational hospitals of Kerman, Iran, also reported that almost all patients were dissatisfied with postoperative pain relief.^[10]

To control postoperative pain, pharmacological and nonpharmacological treatments might be considered. Opioids and nonsteroidal anti-inflammatory drugs are the most common pharmacological treatments for postoperative pain.^[11] However, a long-term use of these analgesics can lead to unwanted side effects such as respiratory depression, gastrointestinal problems, reduced peripheral vascular resistance, and decreased cardiac output, which consequently may delay surgical wound healing.^[12]

Aromatherapy is the science of using aromatic materials, including essential oils, to promote health and well-being.^[13,14] Some studies suggest that olfactory stimulation and changes in brain activity and the limbic system through aromatherapy can result in immediate pain reduction.^[15,16] Aromatherapy also reduces pain sensation by inducing slow and deep breathing. It may also have a placebo effect, as the third mechanism for pain reduction.^[15]

A number of studies are available on the effects of different aromas such as pelargonium,^[17] lavender,^[18] rose and eucalyptus^[16] in reducing postoperative pain. *Rosa damascena* or Mohammadi flower is one of the most famous roses in the world. It contains vitamins, flavonoids, and carotenoids.^[19] It has reported that *R. damascena* exerts hypnotic, sedative, anxiolytic, relaxant, and anticonvulsive effects.^[20] Animal studies indicate that *R. damascena* may induce its analgesic effect due to its flavonoid compounds.^[12,21]

A study in patients with third-degree burn wounds showed that aromatherapy with *R. damascena* can slightly relieve the pain associated with dressing changes.^[19] Another study also reported that *R. damascena* aromatherapy can reduce dysmenorrhea in female medical sciences students.^[22] However, the nature of pain resulted from dysmenorrhea, and dressing change is different from postoperative pain. Moreover, a systematic review of the efficacy and safety of *R. damascena* has reported that many studies on the effects of *R. damascena* have methodological problems, and still high-quality studies on the analgesic effects of this herb are needed.^[23] Considering the availability of

R. damascena essential oil in our country, and the lack of sufficient studies on its effect on postoperative pain, this study was conducted to fill this gap.

Objective

This study aimed to examine the effect of *R. damascena* aromatherapy on the intensity of postoperative pain in patients undergoing inguinal hernia repair surgery.

METHODS

Design and participants

As a double-blind, randomized placebo trial, this study was carried out on patients undergoing inguinal hernia repair surgery admitted to the surgical ward of Amir al-Momenin Hospital, Zanjan, Iran. During the 4 months of the study, i.e., from July 29 to November 29, 2018, 60 eligible patients were consecutively recruited. Eligibility criteria were the age of 18 years or over, willing to participate in the study, having an inguinal hernia surgery, lack of olfactory, visual, and mental problems, lack of pregnancy and moderate-to-severe anxiety, ability to understand Persian or Turkish languages, no history of drug abuse, allergy to plants, hypertension, coagulation disorders, diabetes, and respiratory problems, and receiving no analgesic and anxiolytic medications. Exclusion criteria were having postsurgical complications such as bleeding, hematoma of the surgery site, need for oxygen therapy, and a patient's decision to withdraw from the study.

The sample size was estimated based on the findings of a former study^[24] in which the mean and standard deviation of pain reduction score in the intervention group has been changed from 0.23 ± 0.89 to 0.98 ± 0.57 after four hours. Then, with a type I error of 0.05, a type II error of 0.20, a σ_1 of 0.89, a σ_2 of 0.57, a μ_1 of 0.98, and a μ_2 of 0.23, the sample size was estimated to be 28/group. However, considering the possible attrition, 30 people were recruited to each group.

The 60 selected patients were randomly and equally allocated to either a placebo or an experimental group through block randomization in three main steps, namely generation of an allocation sequence, concealment of the allocation, and implementation of the allocation sequence. The allocation ratio was 1:1. Accordingly, fifteen four-patient blocks were generated for the two groups, and the blocks were numbered. Then, for allocation concealment, 60 sealed envelopes numbered from 1 to 60 were used, 30 for Group A (i.e., experimental) and 30 for Group B (i.e., placebo). For each patient, an envelope was selected and the patient was allocated to either of the groups based on the label in the envelope.

Instruments

A three-part instrument was used for data collection. The first part included items on patients' characteristics, including age, gender, marital status, education level, job, place of residence, allergies, and history of serious illnesses. This part was completed through individual interviews. The second part included a visual analog scale (VAS) for the assessment of pain on which 0 stood for no pain and 10 for the worst imaginable pain. The validity and reliability of the VAS have been confirmed by earlier studies.^[25-27] Patients in both groups were asked to mark an X on the place that corresponded with the severity of the pain they experienced.^[28]

Using the Spielberger's State Anxiety Inventory (SAI), all patients were assessed at the beginning of the study. This inventory has 20 items on a 4-choice Likert Scale from "not at all = 4" to "very much = 1". A score between 0 and 20 is considered as no anxiety, and scores from 21 to 40, 41–60, and 61–80 are considered as low, moderate, and severe anxiety, respectively.^[29] The validity and reliability of the SAI were confirmed by former studies.^[29,30]

Rosa damascena essential oil preparation

R. damascena essential oil 40% and the sweet almond oil (as placebo) were supplied from the Tabib Daru pharmaceutical company, Kashan, Iran, with a quality certificate (ISO 9001:2015). The concentration of essential oil was based on literature review and consultation with a herbalist.^[31] The essential oil and the sweet almond were prepared in bottles with similar shape and color, were coded as the drug A or B and were given to the two research assistants who did aromatherapy either for the experimental group or for the placebo group.

Intervention

Before surgery, patients in the experimental and placebo groups were respectively examined for allergy to *R. damascena* essential oil and the sweet almond oil. To do this, a drop of *R. damascena* essential oil and the sweet almond oil were poured into the inner wrists of the patient, and this section was immediately dressed to reduce the amount of inhalation. None of the patients showed allergic reactions. The intervention was done in 4, 8, and 12 h after surgery if the pain score of patients was more than three.^[18] In the experimental group, five drops of *R. damascena* essential oil were poured on a cotton ball and attached to a patient's collar or pillow, and the patients inhaled it for 20 min. The concerned research assistant measured the patient's pain intensity immediately before and 20 min after each aromatherapy.^[31] Patients in the placebo group received

five drops of sweet almond oil (which has no odor) in the same method as the experimental group,^[32] and then, their pain intensity was assessed similarly and at the same intervals.

The patients and the research assistants who did the intervention or assessed the outcome were blind to the intervention. To avoid being identified, patients in the experimental and the placebo groups were respectively admitted to separate rooms namely the room A or B at the beginning or at the end of the ward. The *R. essential* oil and the sweet almond oil were also prepared in similar bottles, were coded as the drug A or B, and administered by two independent research assistants either for the experimental group or for the placebo group. Patients in the experimental and placebo groups had no contact with each other. Different research assistants assessed the pain intensity before and after every intervention, for the experimental and the placebo groups. Patients in both groups received routine pain medication (paracetamol ampoule) after surgery.

Ethics considerations

The study was approved by the Ethics Committee of Zanjan University of Medical Sciences, Zanjan, Iran (approval code: IR. ZUMS. REC.1397.021) and registered by the Iranian Registry of Clinical Trials (registration code: IRCT20140304016843N12). At the beginning of the study, we provided the patients with explanations about study aims. Although the study participants were aware that something might be applied to their collar, they did not know the exact material. All patients were assured that they will receive pain medications as routine. They were also informed about their right to either participate in or withdraw from the study at any time, were asked to sign a written consent form at the start of the study, and were assured of the confidentiality of their personal information.

Data analysis

Data analysis was done using SPSS software version 16 (SPSS Inc., Chicago, IL, USA). The data were described through the measures of descriptive statistics such as frequency, percent, mean, and standard deviation. The normality of quantitative data was assessed by the Kolmogorov–Simonov test. Chi-square and independent samples *t*-test were used to test the homogeneity of the characteristics of the two groups. The repeated-measures analysis was performed four times respectively, to compare the variations in the mean pain scores in all six consecutive times, in the three prearomatherapy times, in the three postaromatherapy times, and in the mean difference of pain scores at the three aromatherapies (postaromatherapy pain score– prearomatherapy pain score). Greenhouse–

Geisser estimation was used for epsilon correction if needed, and independent-samples *t*-test for pairwise comparisons. The marital status was included as a covariate in the repeated measures test. Also, one-way analysis of covariance (ANCOVA) was conducted for three times to determine the statistically significant differences between *R. damascena* essence and sweet almond oil on the postsurgical pain intensity when adjusted for prearomatherapy pain scores. The level of significance was set at <0.05.

RESULTS

In total, 60 patients participated in the study [Figure 1]. Most patients in the placebo and the experimental groups were male (90% vs. 86.7%) and married (73.3% vs. 96.7%). There were no significant between-group differences respecting patients' demographic characteristics ($P > 0.05$) other than marital status [$P < 0.029$; Table 1].

In a repeated-measures analysis for all the six measurements, the Mauchly's test illustrated that sphericity was not assumed ($\chi^2 [14] = 208.59$; $P < 0.001$), then the Greenhouse–Geisser test was used and showed that the mean pain intensity significantly decreased over time [$F = 37.082$, $df = 2.298$, $P = 0.001$, Table 2 and Figure 2]. No interaction was observed between marriage and pain scores ($P > 0.05$). However, due to the significant interaction between time and the mean pain scores ($F = 8.446$, $df = 2.260$, and $P = 0.001$), the *t*-test was used for pairwise comparisons between the two groups at different times. The results revealed that the mean pain in the two groups was only different before and after the 12th postoperative hour ($P < 0.05$). As shown in Table 2, although the mean pain score in the placebo group was lower than that of the experimental group immediately before the 12th postoperative hour; 20 min later, it was significantly lower in the experimental group.

In repeated-measures analysis for the three pre-aromatherapies, although the trend of pain scores was decreasing, no significant difference was observed between the mean pain scores in the two groups at the three measurement time points ($P = 0.368$).

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

Characteristics ^a	Experimental	Placebo	<i>P</i>
Age	42.86 ± 10.74	43.90 ± 13.41	0.743 ^b
Gender			
Male	26 (86.7)	27 (90)	0.99 ^c
Female	4 (13.3)	3 (10)	
Marital status			
Single	1 (3.3)	8 (26.7)	0.026 ^c
Married	29 (96.7)	22 (73.3)	
Job			
Unemployed or housekeeper	3 (10)	4 (13.3)	0.570 ^c
Manual worker	17 (56.7)	19 (63.4)	
Employee	3 (10)	4 (13.3)	
Self-employed or retired	7 (23.3)	3 (10)	
Educational level			
Illiterate	5 (16.7)	10 (33.3)	0.430 ^c
Primary	9 (30)	6 (20)	
Under diploma	10 (33.3)	8 (26.7)	
High school diploma	5 (16.7)	3 (10)	
Academic	1 (3.3)	3 (10)	
Place of residence			
Urban	11 (36.7)	8 (26.7)	0.405 ^d
Rural	19 (63.3)	22 (73.3)	
Having a health insurance			
Yes	27 (90)	28 (93)	0.99 ^c
No	3 (10)	2 (6.7)	
Income			
Relatively adequate	18 (60)	21 (70)	0.312 ^c
Sufficient	9 (30)	4 (13.3)	
Inadequate	3 (10)	5 (16.7)	

^aData presented as *n* (%) or mean±SD, ^b*t*-test, ^cFisher's exact test, ^dChi-square test. SD: Standard deviation

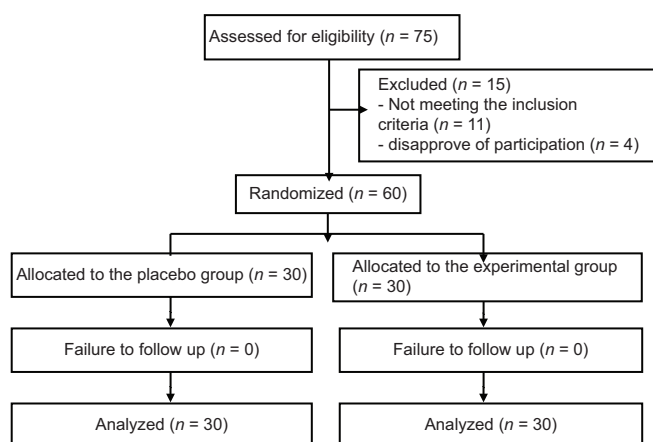


Figure 1: The study flow diagram

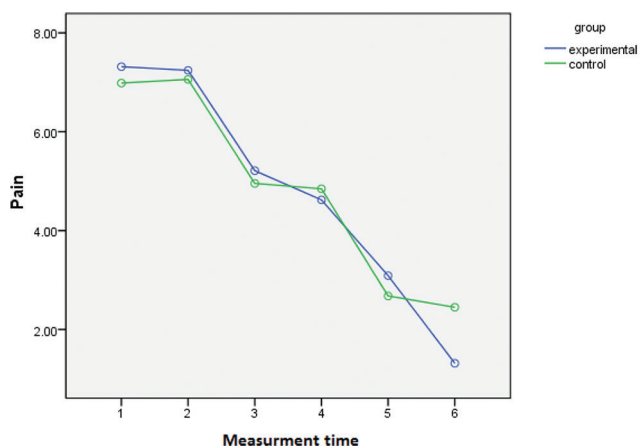


Figure 2: Trend of pain scores over the six measurement time points

Repeated-measures analysis of the three postaromatherapies also showed a decreasing trend in pain scores and a significant difference between the two groups at the three measurement time points [$P = 0.001$; Table 2].

In repeated-measures analysis for the mean differences in pain scores at the three aromatherapies, the sphericity was assumed ($\chi^2[2] = 5.156$; $P < 0.076$). Then, the Wilks' Lambda test was used and showed that the difference in scores was significant at the three subsequent times. Furthermore, considering the significant interaction between time and pain intensity ($F = 53.399$, error $df = 57.0$, and $P < 0.001$), t -test was used for pairwise comparisons between the two groups at different times and showed that the difference between the scores of the two groups was significant in all the three times, and as shown in Figure 3, the experimental group experienced a greater reduction in postoperative pain scores on all three occasions [Table 3].

Results of ANCOVA showed a significant difference in mean pain reduction between the two groups at the first ($F [1,57] = 4.072$, $P = 0.048$), second ($F [1,57] = 8.398$, $P = 0.005$), and third time ($F [1,57] = 56.776$, $P < 0.001$). However, according to the partial eta squared, the difference between the two groups was small in the first (0.067) and the second time (0.128) and was moderate in the third time (0.5).

DISCUSSION

The present study showed that aromatherapy with *R. damascena* essence was effective in reducing postoperative pain. However, its effect was significantly

greater in the 8th and 12th postoperative hours. Limited studies are available on the effect of *R. damascena* aromatherapy on postoperative pain. However, consistent with our results, two studies have reported that *R. damascena* aromatherapy can significantly reduce the lumbar pain in pregnant women^[33] and pain of patients with renal colic.^[34] A study also reported that aromatherapy with *R. damascena* was effective in reducing postoperative pain in children undergoing surgery.^[32] As we observed the greatest effect of aromatherapy at the 12th postoperative hour, it might be concluded that aromatherapy with *R. damascena* essential oil has the greatest effect in relieving mild-to-moderate pain after herniorrhaphy. This is also consistent with what reported by a previous study on the

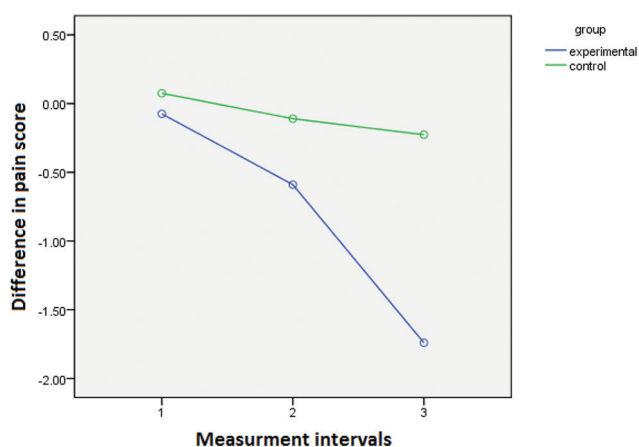


Figure 3: Trend of changes in pain scores differences over three aromatherapy sessions

Table 2: The mean and standard deviation of pain scores in experimental and placebo groups in terms of time measurement (repeated measure)

Time	Group		P (t-test)	P
	Experimental	Placebo		
4 h after surgery				
Before	7.16 ± 1.17	7.13 ± 1.10	0.910	Time-group interaction before aromatherapy 0.409
After	7.10 ± 1.24	7.20 ± 1.10	0.742	Time-group interaction after aromatherapy 0.001
8 h after surgery				Effects of groups over time, before aromatherapy 0.368
Before	5.13 ± 1.04	5.03 ± 1.03	0.710	Effects of groups over time, after aromatherapy 0.006
After	4.56 ± 1.04	4.90 ± 0.84	0.178	
12 h after surgery				
Before	3.06 ± 0.25	2.70 ± 0.53	<0.001	
After	1.30 ± 0.79	2.46 ± 0.68	<0.001	

Table 3: Differences in mean reduction of pain scores in study groups (after intervention pain - before intervention pain) (repeated measure)

Difference of pain	Group		P (t-test)	P
	Experimental	Placebo		
Pain difference at 4 th h	-0.06 ± 0.25	0.06 ± 0.25	0.046	Time-group interaction <0.001
Pain difference at 8 th h	-0.57 ± 0.73	-0.13 ± 0.43	0.007	Effects of time <0.001
Pain difference at 12 th h	-1.76 ± 0.87	-0.23 ± 0.5	<0.0001	Effects of groups over time <0.001

effect of aromatherapy with *R. damascena* essence on the pain intensity after dressing change in patients with burns.^[31]

The exact mechanism of the analgesic effects of *R. damascena* is not clear. It has no side effects^[23] and induces analgesic effect due to its constituents and flavonoid compounds.^[19] It is also believed that *R. damascena* reduces pain by stimulating the olfactory system, reducing the activity of the sympathetic system, increasing parasympathetic activity, and releasing endorphins.^[35] Like other aromatherapies, it also stimulates deep and slow breathing, which can reduce pain.^[15]

This study was a double-blind placebo trial. However, replication of the study with a control group receiving no placebo is suggested. The results of this study might not be generalized to other patients or patients from other cultures. Examining the effects of aromatherapy with *R. damascena* essential oil in other acute postsurgical pains are recommended.

CONCLUSION

The present study provided evidence regarding the effect of aromatherapy with the essence of *R. damascene* on pain after inguinal hernia surgery. Based on the results of this study, nurses can use this noninvasive method to relieve mild to moderate pain after inguinal herniorrhaphy.

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Conflicts of interest

There are no conflicts of interest.

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