ORIGINAL RESEARCH

Effects of Aromatherapy with Lavender (*Lavandula angustifolia* Mill.) on Post-Dural Puncture Headache: A Randomized Placebo-Controlled Trial

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ABSTRACT

Context • Lavender has been proposed as an analgesic agent for different types of headaches in complementary and alternative medicine. However, no documented trial has been performed to investigate the effects of lavender in managing post-dural puncture headache (PDPH).

Objective • To evaluate the effects of aromatherapy using lavender essential oil in reducing the severity of PDPH.

Design • Randomized, placebo-controlled clinical trial with parallel group design.

Setting • Post-operative wards of Kamkar-Arab-Nia and Nekooei Hedayati Hospitals in Qom, Iran.

Participants • Patients with PDPH caused by spinal anesthesia (n = 50).

Intervention • Patients received 15-minute inhalations of either lavender oil or liquid paraffin as placebo, using the same protocol.

Outcome Measures • The severity of headache was scored before (baseline) and five times after the intervention (immediately, 30, 60, 90, and 120 minutes after) using the visual analog scale. Also, dosage and frequency of the received Diclofenac and adverse effects of the intervention were recorded.

Results • Both groups showed a reduction in headache scores post intervention. However, the headache scores between the groups was significantly different only immediately after the intervention in favor of lavender oil (difference: 1.60 ± 0.63, $P = .015$). Furthermore, it was observed that the mean changes of the headache scores compared to baseline were significant at each time interval in favor of the placebo group ($P < .05$), except immediately after the intervention. No significant difference was observed in diclofenac intake between groups ($P = .440$). Also, no adverse effects were found from the intervention.

Conclusions • Aromatherapy with lavender oil was observed to reduce the severity of PDPH only immediately after the intervention, while only minimal effects were observed at successive time intervals. However, it is noted that the study was likely underpowered and further studies are recommended to better understand the effects of lavender oil on PDPH and compare its effects to other herbal products or pharmacological agents commonly used for managing headaches. (*Altern Ther Health Med.* 2022;28(5):12-19)

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INTRODUCTION

Post-dural puncture headache (PDPH) is an important complication of lumbar puncture (LP) caused by the leakage of cerebrospinal fluid (CSF).[1] PDPH is a post-dural bilateral headache which mostly occurs within 72 hours of a LP and can last for several days.[2,3] This type of headache occurs or exacerbates within 15 minutes of when a patient moves from supine to upright position, and is relieved 15 minutes after

the patient lies down.[4] PDPH incidence and severity varies depending on puncture technique, type of needle, puncture volume, and target population.[5,6] Estimated incidence of this headache after spinal anesthesia is reported to be about 10%.[7] PDPH might be accompanied by lower back pain, vertigo, tinnitus, stiffness, hyperacusis, photophobia, diplopia, nausea, vomiting, and even cortical blindness.[1,2,8] Due to its consequences, prevention and treatment of this disorder is of great importance.

Currently, many types of conservative measures have been suggested for reducing the incidence and severity of PDPH, including use of small-sized needles, systemic hyperhydration (fluid intake), bed rest after LP, and administration of analgesics.[8-10] Among these measures, opioid drugs (such as morphine) are more common.[11] However, since use of such drugs might result in dependency, their effectiveness and usage are limited.[12] Accordingly, considerable attention has been paid to complementary and alternative medicine (CAM) for managing PDPH.

Lavandula angustifolia Mill., known as lavender, is a common herb which has been used in different forms to treat various types of headaches in folk and traditional medicine, especially in Persian traditional medicine (PTM).[11,13-16] Currently, lavender therapy is recommended for alleviating headaches as a method of CAM.[17-19] In an Italian cohort, aromatherapy with lavender oil was reported as a method in CAM for pediatric headaches.[20] Also, lavender essential oil patches are suggested as an alternative therapy with acupuncture for managing pediatric headaches.[21] In addition, recent trials have identified the effects of lavender, administered in different forms, in treating some headaches, including migraine headache,[22,23] hemodialysis-induced headache,[24] primary hypertension-associated headache,[25] nitroglycerine infusion-induced headache,[26] primary dysmenorrhea-associated headache,[27] daily headache,[28] and recurrent headaches.[29] However, to the best of our knowledge, no documented trial has been performed to investigate the effects of lavender in managing PDPH. Consequently, we evaluated the effects of aromatherapy with lavender oil on PDPH.

MATERIALS AND METHODS

Study Design

This was a randomized, placebo-controlled clinical trial with parallel group design. The trial was registered in the Iranian Registry of Clinical Trials (Approval No. IRCT2017051617468N3) and reported according to the CONSORT 2010 explanation and elaboration for reporting parallel group randomized trials.[30]

Ethical Consideration

The study protocol was reviewed and approved by the Institutional Review Board (Approval No. 96864) and the Regional Research Ethics Committee (Approval No. IR.MUQ.REC.1396.16) of Qom University of Medical Sciences, Qom, Iran. The trial was conducted based on the declaration of Helsinki on research ethics,[31] and all techniques performed in the trial were in accordance with the ethical standards of the Institutional Research Committee. Before the study, the objectives and intervention techniques were explained to all patients using face-to-face method by the principal researcher. Also, all patients were assured that they had the right to withdraw from the trial at any time and would be afforded the opportunity to receive routine treatment. Moreover, written informed consent was obtained from each eligible patient.

Patients

We screened all the hospitalized patients who underwent spinal anesthesia for elective surgeries at Kamkar-Arab-Nia and Nekooei Hedayati Hospitals, Qom, Iran, from June 05, 2017 to August 21, 2018. Inclusion criteria were as follows: (a) both genders aged 18-60; (b) complete consciousness; (c) ability to communicate and speak in Persian; (d) belonging to the American Society of Anesthesiologists grade I or II; (e) PDPH confirmed by an anesthesiologist according to the International Classification of Headache Disorders criteria (second edition);[4] and (f) having permission from their surgeon.

Patients were excluded if they: (a) had a history of seizures, migraine headache, intrathecal disorders, and allergic reactions to herbal oils or paraffin; (b) had experienced severe heart diseases and diabetes (these cases are considered as high risk of anesthesia and it is possible to have an emergency condition in the post-anesthesia care unit); (c) had experienced tension headaches and infectious diseases (i.e., sinusitis and meningitis) within the past 6 months; (d) were pregnant confirmed by negative human chorionic gonadotropin test; (e) were unwilling to continue the trial; (f) had severe complications of spinal anesthesia (i.e., infection); or (g) had experienced allergy to lavender oil (i.e., irritation) or paraffin (i.e., itching and skin rash) during the trial.

Sample Size

The sample size was estimated based on a previous trial indicating a significant difference between mean reduction of migraine headache obtained by a visual analog scale (VAS) ranging from 0 to 10 in patients who received aromatherapy with lavender oil and placebo (3.6 ± 2.8 vs. 1.6 ± 1.6; $P < .0001$).[22] We calculated a sample size of 21 patients per group, using the above mentioned trial and the formula suggested for comparing the two means in clinical trials at a confidence level of 95% and power of 0.08. However, 25 patients were recruited in each group of the study in case of dropouts.

Randomization

All patients were selected by the sequential sampling method and then, spinal needle size, and time of onset of headache after spinal anesthesia, after matching for dural puncture rates, spinal needle size, and onset of headache time

after spinal anesthesia, they were randomly allocated to the lavender oil (n = 25) or placebo (n = 25) groups. Simple randomization (flipping a coin) was used for random allocation. Stratification and random allocation were done by a person who was unaware of the aim of this trial.

Blinding

The trial was performed in a non-blinded design because the patients and the nurse who performed the intervention could not be blinded completely due to the scent of lavender oil. However, the nurse was unaware of the droppers' contents and the patients did not know whether they inhaled lavender oil or placebo during the trial because both were prepared and labeled in completely identical, unnamed droppers (same shape, color, and size). All scorings in both groups were performed under the supervision of a blinded nurse.

Intervention

All the interventions in both groups were performed by a nurse at the post-operative wards during morning and evening shifts to avoid sleep-wake cycle disruptions. In both groups, the same therapeutic procedures were performed. All the patients received the diclofenac suppository (100 mg) as analgesic on demand basis, according to the therapeutic protocol of the hospitals.

The patients in the experimental group received lavender oil while those in the placebo group received liquid paraffin. When the early sign of the PDPH was observed, 3 drops of either lavender oil or liquid paraffin were placed above the upper lip using the prepared droppers.[22] Then, all the patients were asked to inhale the vapor for 15 minutes at their own convenience under the supervision of the assistant nurse. All interventions were performed in a private room and none of the patients saw each other during the intervention times. In addition, all patients were scheduled to rest in bed during the aromatherapy sessions for 15 minutes.

Composition of Lavender Oil and Placebo Used

We used commercial lavender oil with 2% concentration produced by Eadeh Darou Teb Co., Tehran, Iran. The ingredients of this oil were reported as linalool (33.25%), linalyl acetate (35.35%), camphor (17.77%), borneol (4.26%), γ-terpinene (0.16%), 1,8-cineol (8.1%), α-pinen (0.13%), β-pinen (0.14%), and limonene (0.26%). The commercial liquid paraffin used as placebo was produced by Farabi Pharmaceutical & Cosmetic Co., Isfahan, Iran. To evaluate the adverse effects of the lavender oil and liquid paraffin, we conducted a pilot study on 10 patients. Based on the findings, inhalation of both products was found to have no adverse effect.

Outcome measures

Diagnosis of PDPH. PDPH was diagnosed according to the International Classification of Headache Disorders criteria (second edition), developed by the Headache Classification Subcommittee of the International Headache Society. Based on this guideline, patients with the following criteria were diagnosed having PDPH: (a) headache that worsens within 15 minutes after sitting or standing and improves 15 minutes after lying down, accompanied by stiffness, tinnitus, hypacusia, photophobia, and nausea; (b) undergoing dural puncture; (c) headache develops within 5 days of dural puncture; and (d) headache resolves either spontaneously within one week or within 48 hours after effective treatment of the leakage of CSF.[4] The diagnostic criteria were assessed by the principal researcher under the supervision of the assistant anesthesiologist, and patients who had all 4 criteria were diagnosed with PDPH.

Demographic and Clinical Data

Following the diagnosis of PDPH, the patients were assessed based on the inclusion criteria. Then, their demographic and clinical data were obtained from interviews and clinical records using data capture forms which included fields for gender, age, marital status, occupation, place of residence, dural puncture rates, spinal needle size, time of headache onset (after the spinal anesthesia), and dosage and frequency of the received diclofenac. In addition, body mass index (BMI) was recorded as it affects the spinal needle size.

Severity of PDPH

The severity of headache was evaluated as the primary outcome by visual analog scale (VAS). The patients were asked to measure their level of headache on a scale of 0 (lack of headache) to 10 (very severe headache). This scale has been used to measure PDPH of patients in different trials and is considered as a reliable and valid scale in the assessment of this disorder.[32,33] Headache was scored before random allocation on the first day as the baseline and 2 hours after the intervention with 30 minute intervals (immediately, 30, 60, 90, and 120 minutes after the intervention).

Adverse Effects of the Intervention

All unintended effects and significant harms during the trial were assessed and documented by observation and follow-up of all the patients.

Statistical Methods

All the data were analyzed using Statistical Package for Social Sciences (SPSS) software version 22 (SPSS, Inc. Chicago, IL, USA). Independent samples *t* test and Chi-square test (or Fisher's exact test) were used to test the homogeneity of groups for demographic and clinical data. The normal distribution of variables was confirmed using Kolmogorov–Smirnov test. Independent samples *t* test was employed to compare the groups in relation to VAS scores at different times. In addition, analysis of covariance (ANCOVA) was used to compare the mean changes of VAS scores at the 5 time intervals (immediately, 30, 60, 90, and 120 minutes after the intervention) compared to the baseline, since there was a discrepancy of VAS scores between groups at baseline ($P = .051$). Repeated-measures analysis of variance (rANOVA)

Figure 1. CONSORT flow diagram of the patients

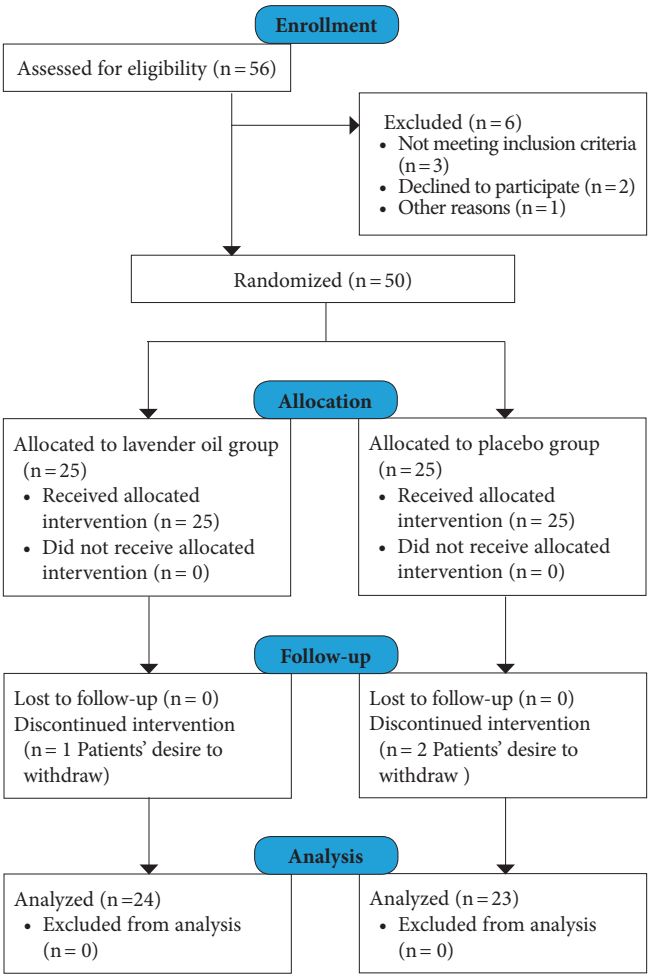
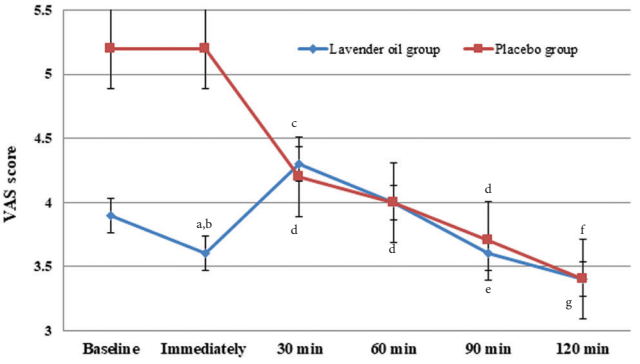


Figure 2. Post-dural puncture headache in patients who received 15-minute inhalation of lavender oil or placebo (liquid paraffin)



[a]between group difference ($P = .015$)
[b]In the lavender oil group: significant difference in comparison with baseline ($P = .015$)
[c]In the lavender oil group: significant difference in comparison with immediately after the intervention ($P = .008$)
[d]In the placebo group: significant difference in comparison with baseline and immediately after the intervention ($P < .05$)
[e]In the lavender oil group: significant difference in comparison with 30 min after the intervention ($P = .021$)
[f]In the placebo group: significant difference in comparison with baseline and also all other times ($P < .05$)
[g]In the lavender oil group: significant difference in comparison with 30 min ($P < .001$) and 60 min ($P = .007$) after the intervention

Note: All two by two comparisons of times were obtained by Bonferroni adjustment

was applied to assess changes in VAS scores over time within groups. Since the results of rANOVA were statistically significant, Bonferroni adjustment as *post hoc* test was used for two-by-two comparisons of times within groups. Moreover, two-way analysis of variance was utilized to evaluate the effect of receiving diclofenac as analgesic on VAS score and for this, $P < .05$ was considered to be statistically significant.

RESULTS

Follow-up

Of the 50 randomized patients, 3 were excluded during the course of the follow-up. Hence, statistical analysis was conducted on 47 patients (Figure 1).

Patients' characteristics

The mean age of patients was 36.3 ± 13.5 years. Thirty-three of the patients (70.2%) underwent cesarean section, and the remaining 14 patients (29.8%) had general or urological surgeries. As shown in Table 1, no significant difference was found between the two groups in terms of demographic and clinical characteristics.

PDPH Scores

The PDPH scores of both lavender oil and placebo groups are presented in Table 2 and Figure 2. Independent samples *t*-test indicated no significant difference in the VAS scores between the two groups at baseline as well as 30, 60, 90, and 120 minutes after the intervention although the mean difference was significant immediately after the intervention in favor of the lavender oil group (1.6 ± 0.6, $P = .015$). However, considering the baseline as covariate using ANCOVA, mean changes of the VAS score compared to the baseline were significant at each five-time interval after the intervention in favor of the placebo group ($P < .05$), except at immediately after the intervention ($P = .107$).

The rANOVA revealed a significant decrease in the VAS score at the 120-minute interval both in the lavender oil and placebo groups (Sphericity Assumed, $F = 19.47$, $P_{time} < .001$). The mean difference between the baseline and immediately after the end of the intervention was significant in the lavender oil group (−0.36 ± 0.10, $P = .026$), whereas no significant difference was observed in these times in the control group (−0.04 ± 0.22, $P > .97$) (Table 3).

Table 1. Demographic and clinical variables between the lavender oil and placebo groups

Variables		Groups		*P* Value
		Lavender oil[a] (n= 24)	Placebo[b] (n= 23)	
Gender	Male	6 (25.0%)	7 (30.4%)	.677[c]
	Female	18 (75.0%)	16 (69.6%)	
Marital status	Single	1 (4.2%)	1 (4.3%)	>.97[d]
	Married	23 (95.8)	22 (95.7%)	
Occupation	Housewife	16 (66.7%)	16 (69.6%)	.913[d]
	Employee	4 (16.7%)	2 (8.7%)	
	Farmer	2 (8.3%)	2 (8.7%)	
	Others	2 (8.3%)	3 (13.0%)	
Place of residence	City	22 (91.7%)	21 (91.3%)	.679 [2]
	Village	2 (8.3%)	2 (8.7%)	
Surgery type	Cesarean section	15 (62.5%)	18 (78.3%)	.238[c]
	General or urological	9 (37.5%)	5 (21.7%)	
Dural puncture rates	Once	11 (45.8%)	9 (39.1%)	.971[d]
	Twice	5 (20.8%)	6 (26.1%)	
	Thrice	6 (25.0%)	6 (26.1%)	
	Four times	2 (8.3%)	2 (8.7%)	
Spinal needle size (inch)	25	4 (16.8%)	1 (4.3%)	.348[d]
	26	20 (84.2%)	22 (95.7%)	
Diclofenac intake (times)	One	7 (46.7%)	8 (47.1%)	.460
	Two	6 (40.0%)	3 (17.6%)	
	Three	2 (13.3%)	5 (29.4%)	
	Four	0 (0.0%)	1(5.9%)	
Onset of headache time after spinal anesthesia (hours)		18.62 ± 9.83	20.65 ± 10.99	.508[e]
Age		37.00 ± 14.66	35.47 ± 12.51	.704[e]
Body mass index (kg/m²)		28.01 ± 4.46	26.77 ± 4.22	.334[e]

[a]Received 15-minute inhalation of lavender oil.
[b]Received 15-minute inhalation of placebo (liquid paraffin).
[c]Chi-square test.
[d]Fisher's exact test.
[e]Independent samples *t* test.

Note: All data are presented as number (percent) or mean ± standard deviation.

Table 2. Post-dural puncture headache between the lavender oil and placebo groups at different times[a]

	Groups		*P* Value[d]	Changes compared with the baseline		
				Groups		
	Lavender oil[b] (n= 24)	Placebo[c] (n= 23)		Lavender oil[b] (n= 24)	Placebo[c] (n= 23)	*P* Value[e]
	M±SD	M±SD		M±SE	M±SE	
Baseline	3.92 ± 2.34	5.20 ± 2.01	0.051	-	-	-
Immediately after intervention	3.55 ± 2.25	5.15 ± 2.08	0.015	-0.41± 0.17	-0.006 ± 0.17	0.107
30 min after intervention	4.25 ± 2.35	4.18 ± 1.93	0.910	0.24 ± 0.22	-0.93 ± 0.22	0.001
60 min after intervention	4.04 ± 2.35	4.06 ± 1.99	0.976	0.04 ± 0.22	-1.06 ± 0.22	0.002
90 min after intervention	3.61 ± 2.39	3.73 ± 1.76	0.849	-0.43 ± 0.25	-1.33 ± 0.25	0.019
120 min after intervention	3.35 ± 2.37	3.39 ± 1.70	0.946	-0.71± 0.25	-1.65 ± 0.26	0.016
P Value (time)[f]	$F = 19.47$, $P < .001$					

[a]Headache was scored before (baseline) and five times after the intervention (immediately, 30, 60, 90, and 120 minutes) using the visual analog scale (VAS) ranging from 0 (lack of headache) to 10 (very severe headache).
[b]Received 15-minute inhalation of lavender oil.
[c]Received 15-minute inhalation of placebo (liquid paraffin).
[d]Independent samples *t*-test.
[e]Analysis of covariance (baseline values as covariates).
[f]Repeated-measures analysis of variance.

Note: All data are presented as mean ± standard deviation or mean ± standard error.

Table 3. The mean change of post-dural puncture headache in the lavender oil and placebo groups at different times[a]

Groups	Times		Mean difference	Standard error	*P* Value[c]
Lavender oil[a] (n= 24)	Baseline	Immediately	-0.36	0.10	.026
	Baseline	30 min	0.33	0.22	>.97
	Baseline	60 min	0.12	0.22	>.97
	Baseline	90 min	-0.30	0.26	>.97
	Baseline	120 min	-0.56	0.28	.861
	Immediately	30 min	0.69	0.17	.008
	Immediately	60 min	0.48	0.18	.206
	Immediately	90 min	0.05	0.24	>.97
	Immediately	120 min	-0.20	0.25	>.97
	30 min	60 min	-0.21	0.06	.069
	30 min	90 min	-0.63	0.17	.021
	30 min	120 min	-0.90	0.15	<.001
	60 min	90 min	-0.42	0.18	.489
	60 min	120 min	-0.68	0.17	.007
	90 min	120 min	-0.26	0.08	.061
Placebo[b] (n= 23)	Baseline	Immediately	-0.04	0.22	>.97
	Baseline	30 min	-1.02	0.22	.002
	Baseline	60 min	-1.14	0.22	.002
	Baseline	90 min	-1.47	0.26	<.001
	Baseline	120 min	-1.80	0.26	<.001
	Immediately	30 min	-0.97	0.16	<.001
	Immediately	60 min	-1.09	0.16	<.001
	Immediately	90 min	-1.42	0.23	<.001
	Immediately	120 min	-1.76	0.23	<.001
	30 min	60 min	-0.12	0.07	>.97
	30 min	90 min	-0.44	0.19	.509
	30 min	120 min	-0.78	0.21	.019
	60 min	90 min	-0.32	0.18	>.97
	60 min	120 min	-0.33	0.08	.012
	90 min	120 min	-0.33	0.08	.012

[a]Headache was scored before (baseline) and five times after the intervention (immediately, 30, 60, 90, and 120 minutes after intervention) using the visual analog scale (VAS), ranging from 0 (lack of headache) to 10 (very severe headache).
[a]Received 15-minute inhalation of lavender oil.
[b]Received 15-minute inhalation of placebo (liquid paraffin).
[c]Obtained from *post hoc* analysis, using the Bonferroni adjustment.

Diclofenac Intake

At baseline, no significant difference was observed between the groups in relation to time of diclofenac intake (Table 1). Also, mean intake of diclofenac was 120.36 ± 32.1 mg and 131.06 ± 16.5 mg in the lavender oil and placebo groups (t = 1.428, P = .160). In addition, no significant group difference was found during the trial in mean intake of diclofenac (166.66 ± 72.37 mg vs 191.17 ± 100.36 mg; t= -0.78, P = .440). Two-way ANOVA test indicated no significant difference in percentage change of the VAS score between the placebo group (−17.01%) and lavender oil group (−20.26%) in terms of receiving diclofenac at the baseline and the end of the intervention (F = 0.58, P = .564). Also, group type (F = 1.10, P = .301) and receiving diclofenac (F = 0.008, P = .928) did not have a significant effect on change of VAS score. Moreover, there was no significant interaction between change of VAS score, group, and receiving diclofenac (F = 4.01, P = .054).

Adverse Effects

At the end of the trial, no adverse effects related to the intervention were reported.

DISCUSSION

This is the first attempt to assess the effects of aromatherapy with lavender oil on managing acute PDPH in patients who underwent spinal anesthesia. Findings showed that the mean score of VAS decreased more in the lavender oil group than the placebo group only at immediately after the intervention. Considering baseline values as covariates, mean changes of the VAS score compared to the baseline were significant at each time interval (except immediately after the intervention) in favor of the placebo group. In addition, as the intervention progressed and the time passed, more significant reduction in the VAS score was noted in the placebo group. Indeed, noticeable and significant reduction was found in the placebo group at 30, 60, 90, and 120

minutes after the intervention, whereas a significant increase of VAS scores in the lavender oil group was observed between the time immediately after the intervention and 30 minutes after. This suggests that the efficacy of lavender oil on acute PDPH might be limited within several minutes. However, further evaluation is needed to better understand this unexpected increase due to some confounding factors.

Although all patients in both groups were asked to stay in bed and rest during the intervention, we could not uniformly limit patients' mobility and position during treatment times due to the different types of surgeries they had undergone. Hence, patients' position during bed rest and also their levels of immobilization may have had an effect on PDPH as this type of headache exacerbates within 15 minutes of when a patient moves from supine to upright position, and is relieved within 15 minutes of when the patient returns to a supine position.[4] In addition, to control differences in pain reporting and aromatherapy technique, the intervention and scoring were done under the supervision of two independent assistant nurses and all patients received sufficient training on how to report pain and do aromatherapy using simple and understandable sentences.

However, errors in technique and pain reporting might be a factor in the unexpected findings of this research. Systemic hyperhydration, as a conservative measure for reducing the incidence and severity of PDPH, could be another important factor because we were unable to control the rate and type of fluid intake during the treatment. Moreover, since the trial was scheduled to be conducted in the post-operative wards, we were unable to control some confounding factors in the operating room setting such as puncture technique, surgery duration, anesthesia duration, recovery time, and patients' anxiety.

Although we showed that lavender oil was not more effective than the placebo in treating PDPH, the findings at immediately after the intervention support previous trials showing the effectiveness of lavender therapy on different type of headaches. In a single-blind trial on patients experiencing migraine headache, it was indicated that a 15-minute inhalation of two or three drops of Iranian lavender oil significantly reduced the VAS score at all four measurement times (30 minute intervals for a total of two hours) in comparison with the placebo (paraffin).[22] In another trial involving patients with headache induced by nitroglycerine infusion, it was found that 30 minutes of aromatherapy with Iranian lavender oil (using a cotton cloth soaked in three drops) resulted in a significant reduction in patients' VAS score in comparison with a placebo of liquid paraffin applied similarly and acetaminophen (one 325 mg tablet).[26] The discrepancies between findings could be attributed to differences in type of headaches, treatments, follow-up periods and lavender oil administered (brands, concentrations, and percentages).

In this trial, we administered lavender inhalation to treat PDPH and did not find any adverse effect during the trial. Surprisingly, headache was reported as a side effect of lavender therapy in two recent trials.[34,35] In adults with mild to moderate depression, headache was observed more as a side effect in patients who received a lavender tincture in comparison with those who received an imipramine tablet.[34] In another trial on postmenopausal women, headache was reported as a side effect following the intake of lavender capsules.[35] Differences in administration techniques, species of lavender and also participants could be the reasons for these unexpected findings.

Currently, no exact mechanism of action has been identified for the effects of lavender oil on headache. It was proposed that lavender oil, a nutraceutical, could prevent pediatric headache with anti-anxiety, analgesic, sedative, and spasmolytic mechanisms of action.[36] Also, it was reported that lavender acts as a mild neuronal depressant due to its relaxing properties, thereby alleviating headache.[18] In animal models, it was indicated that lavender (*Nepeta menthoides*) prevented morphine dependence and tolerance, partly through inhibition of nitric oxide overproduction, and could be used in addition to opioid drugs, such as morphine, for managing different types of pain (specifically headache and bone pain).[11] In another experimental study on mice, it was shown that lavender oil suppressed both phases of formalin test and reduced the number of abdominal constrictions in the acetic acid-induced writhing test. Hence, the authors confirmed the traditional use of lavender for treating different painful conditions, especially migraine headaches.[37]

In most previous trials, the intervention and scoring were done by the patients due to the nature of their headache. The main strength of this study however, is that all interventions were conducted by a nurse and all assessments were performed under the supervision of a blinded nurse. That said, one critical limitation of this study was our inability to perform long-term follow-ups on patients due to the limited duration of hospitalization. Furthermore, we could not completely blind the patients and the nurse who performed the intervention due to the scent of lavender oil.

CONCLUSION

Aromatherapy with lavender oil was found to reduce the severity of PDPH only immediately after the intervention. Since the effects of the intervention were found to be minimal at subsequent time intervals, we recommend future trials to focus more on the effect of liquid paraffin as placebo on PDPH, by comparing it with different types of lavender oil (brands, concentrations, and percentages), considering long-term follow-up and confounding factors. Also, we encourage future studies to better understand the effects of lavender oil on PDPH and compare its effects to other herbal products or pharmacological agents that are commonly used for managing headaches.

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TRIAL REGISTRY INFORMATION

The trial was registered in the Iranian Registry of Clinical Trials (Approval No. IRCT2017051617468N3).

CONFLICT OF INTEREST

The authors declared no conflict of interest.

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