

Efficacy of Aromatherapy for Night Crying in Infants with Infantile Colic: A Double-Blind Randomized Controlled Trial

Abstract

Background: Too much crying is a self-limiting problem and disappears within a few weeks. However, it can lead to maternal depression and parental stress. This study aimed to evaluate the effect of lavender oil inhalation on the duration of night crying within a week of intervention among infants with infantile colic. **Methods:** In this double-blind randomized clinical trial, the inclusion criteria for infants were being healthy, not taking any medications for colic, having an episode of crying two hours a day, and having a healthy mother. The intervention group received lavender oil inhalation and the control group received sweet almond oil inhalation for seven days. The data pertaining to the duration of crying were collected four times a day (morning, afternoon, evening, and night) via telephone contact. Mothers' mood scores were also assessed at the beginning of the study and on the seventh day of the intervention. **Results:** At first, the two groups were not different in terms of the duration of crying. After the intervention, however, a significant difference was observed in this regard on all seven days of the study ($P < 0.001$). Based on the results of the repeated measures analysis, the difference between the two groups was statistically significant ($P < 0.001$). **Conclusions:** The results showed that inhalation of lavender oil at low concentrations could reduce colic symptoms and improve maternal mood.

Keywords: Aromatherapy, colic, crying, infant, lavender oil, night

Introduction

Infantile colic, or intense crying with unknown causes, is one of the most common reasons for frequent visits to pediatricians in the early stages while the infant looks healthy and well.^[1,2] According to the Wessel criterion, colic can be diagnosed when a healthy infant cries more than three hours a day, more than three days a week, and more than three weeks. Crying and moaning more commonly occur in the evening and at night.^[3] Colic is a common problem, especially in the first three months of life, affecting 10-40% of infants. It has been reported that one out of every five infants suffers from this complication.^[1,2] In a 2008 study, the prevalence of colic was estimated at 20% in Iran.^[4] Night crying in infants may subside for a short time and resume afterwards. Such infants make their parents and others tired and desperate with their long and incessant crying.^[5] One of the most common problems in these infants is that there are usually predictable periods of crying at night, with the infants crying at a specific

time.^[6] This time is usually late evening or early night. Colic episodes usually last from a few minutes to three-four hours. Infants' crying usually starts without any previous symptoms and has no specific causes. At the end of the crying period, the baby may have bowel movements and gas excretion.^[7]

Newborns' cries and moans at night can have a very destructive effect on parents, especially mothers who are in the sensitive period of puerperium and may lead to postpartum depression.^[8,9] While crying too much is a self-limiting problem that goes away within a few weeks, several studies have evaluated the impacts of some drug therapies on the treatment of infantile colic.^[1,2] Some drugs such as dicyclomine are currently contraindicated due to their potentially serious side effects.^[1] Thus, alternative and complementary therapies such as infant shaking, singing, hot towels, massage therapy, kangaroo technique, acupuncture, fennel oil lotion, hypoallergenic formula, and behavioral interventions have been suggested.^[10,11] Nonetheless, no comprehensive treatment is available for colic.

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Phytotherapy is the study of plants for medicinal and aromatherapy purposes. This helps in the usage of essential oils or aromas extracted from aromatic plants for therapeutic purposes.^[12] The properties of essential oils, including their easy penetration into the skin and their effect on the brain by stimulating olfactory receptors, have led to their use in many medical areas.^[13,14] Lavender is an aromatic plant that is widely used in aromatherapy. Previous research indicated that aromatherapy using lavender oil showed antibacterial, antifungal, anti-flatulence, analgesic, anti-inflammatory, anti-depressant, hypnotic, sedative, and antispasmodic properties.^[15,16] In one study, the group that took a bath with added lavender oil had a longer period of deep sleep as well as significantly lower crying, restlessness, and serum cortisol levels compared to the group that took a bath without lavender oil. The results demonstrated that lavender had a sedative and beneficial effects on infants' restlessness, crying, and sleep duration.^[17] In another study, abdominal massage using lavender oil reduced the duration of crying among infants with colic within a week.^[18]

Considering the importance of mother and infant health during puerperium and the fact that colic pain together with infant crying and restlessness lead to maternal stress, anxiety, and depression after childbirth, prevent daily activities, and impose many economic burdens on society. The present study aims to investigate the effect of lavender oil inhalation on the duration of the night crying among infants suffering from infantile colic within one week of intervention. The study also aims at evaluating the correlation between maternal depression and infant crying before and at the end of the intervention.

Methods

Study setting

This clinical trial was performed on 66 infants referred to two pediatric clinics affiliated to Shiraz University of Medical Sciences. Among the infants, 32 were allocated to the lavender oil group and 34 to the control group using permuted block randomization. Sampling was done from late May to early November 2016.

Sample size

According to the statistical consultation and the data obtained from a similar study^[19] and considering the sample size parameter, $\alpha = 0.05$, $\beta = 0.05$ (power of 95%), and loss rate of 10%, 66-subject sample size was determined using the NCSS software [Figure 1].

Then, the subjects were selected through simple random sampling and divided into different groups, such as supportive care, acupressure, and control using stratified block randomization. Individuals were divided into two groups using the permutation block method and classification was performed as follows: A: represents the person who should receive the intervention, B: represents

the person who is in the control group. Considering the quadruple block, Accordingly, AABB: 0, ABAB: 1, ABBA: 2, BAAB: code 3, BBAA: 4 and BABA code 5 to 9. Then, using a table of random numbers, we randomly select the starting point and then consider 15 numbers as rows or columns. Therefore, by selecting 15 items from the table, the method of allocating a total of 60 people to the two groups will be determined.

Inclusion and exclusion criteria

The inclusion criteria for the infants were having been born at ≤ 37 weeks, term pregnancy, singleton pregnancy regardless of parity, being breastfed, aging four-eight weeks at the beginning of the study, being diagnosed with colic by a pediatrician, and not having any specific medical problems or abnormalities. In addition, the mothers had to be healthy without any specific disease, which could interfere with infant care. In this study, the mothers were asked about their infants' crying and restlessness through phone contact four times a day. Hence, they had to be fully aware about their infants conditions. Other inclusion criteria for the infants were not receiving any medications for colic, not having intolerance or milk allergy, and having had a ≥ 2 -hour episode of crying during 24 hours for three days or more within the past week. It is necessary to explain that infantile colic has been defined by the Wessel criteria as paroxysms of crying episodes lasting for more than 3 hours per day, three or more days per week, and three or more weeks.^[9,20] In the present study, however, continuous crying for more than 2 hours was taken into account, because parents might not be able to tolerate crying for longer periods and might take several measures to calm the infant, which could interfere with the intervention process. Hence, based on the opinions of the neonatologist and project consultant, this criterion was considered to facilitate the collection of samples. The exclusion criteria of the study were using medical and traditional treatments or alternative methods for infantile colic during the study, separation of the mother from her infant, and being diagnosed with medical problems. The infants were selected based on the inclusion criteria through interviews with parents. Then, informed consent forms for participation in the research were obtained from the parents. This was a double-blind study, in which mothers and the research assistant were unaware of the type of aromatherapy.

Tools and procedure

Preparation of lavender oil: Lavender oil was prepared by Bardij Pharmaceutical Company, Kashan, Iran. Then, in the traditional medicine pharmacy, it was prepared by the relevant technician with a concentration of 1% based on sweet almonds.

Placebo preparation: In this study, sweet almond oil was used as the placebo and was prepared by Bardij Essential Pharmaceutical Company, Kashan, Iran.

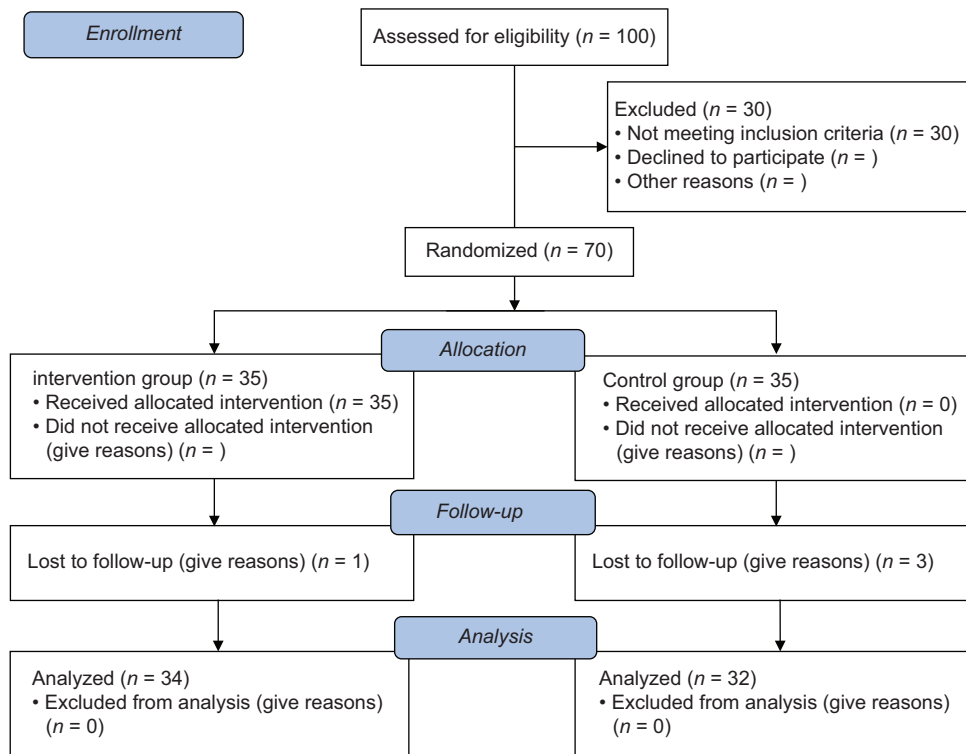


Figure 1: CONSORT flow diagram of sampling

The study data were collected using a demographic information questionnaire, the parental diary of infant crying questionnaire, and the Edinburgh Depression Scale. The demographic information questionnaire consisted of 16 questions.

To determine the duration of crying and sleeping, use was made of the parental diary of infant crying form, which is an international standard tool. The validity of this questionnaire was measured by Barr *et al.*^[21] through recording infants' voices. In Iran, the content validity of this questionnaire has been confirmed.^[22] In this way, after translating into Persian and ensuring that the translation version corresponds to the original version, 10 professors and faculty members of Tehran University of Medical Sciences were appointed and according to their suggestions, necessary corrections were made. And the final modified form was prepared. In order to determine the reliability of the form of recording parents' memories of infant crying test re-test was used and was recognized as reliable with a kappa score of 0.80.^[21]

The Edinburgh Postpartum Depression Inventory was introduced by Cox as a valid tool in 1987. One of the advantages of this questionnaire is that it only takes psychological symptoms into account and does not consider the somatic symptoms that are common in pregnancy and may interfere with other diseases. This tool consists of 10 questions. In a study performed by Mazhari & Nakhaee the reliability of this instrument was approved by Cronbach's $\alpha = 0.77$. In another study, this questionnaire was

confirmed to be a reliable and valid tool with a sensitivity of 95.3% and a specificity of 87.9%.^[23]

The parental diary of infant crying questionnaire was completed via telephone contact. In this questionnaire, a study day (a 24-hour period) was divided into four parts as follows: 6-12 in the morning, 12-6 in the afternoon, 6-12 at night, and 12 at night until 6 in the morning.^[21] For each part of the day, the mother was asked six questions:

1. How many hours has your infant been sleeping?
2. How many hours has your infant been awake?
3. How many hours has your infant been crying while you have been awake?
4. How many hours has your infant been crying and nodding while you have been awake?
5. How many hours was your infant calm while he/she was awake?
6. Was it a normal day?

Method of intervention

At the pediatric clinic, with the permission of the parents, the infants with colic who met the inclusion criteria were selected with the approval of a specialist. First, the basic questionnaires were completed by the researcher and block randomization was performed. The mothers were instructed to read the protocol carefully. On the next day, the mothers started using lavender oil or sweet almond oil for their infants. They used the oils from 8:00-10:00 AM to 4:00-6:00 PM. They could also repeat the process once more during intense crying periods. During aromatherapy, the mothers used three

layers of linen napkins and dripped five drops of lavender or sweet almond oil on top of their infants' clothes for at least 15 minutes with the help of a researcher. A phone call was made to mothers every 12 hours. Thus, the data related to the four parts of the day were collected from 8:00-9:00 AM to 6:00-7:00 PM. In addition, maternal depression was recorded using Edinburgh Postpartum Depression Scale at the beginning of the study and on the seventh day.

Statistical analysis

The collected information was coded on the data collection forms. Then, the Statistical Product and Service Solutions (SPSS software; version 20, Developed by IBM Data Science Community". An IBM Company, USA, on July 28, 2009, Retrieved 2021-06-30) was used to analyze the data. The normal distribution of the data was determined using a one-sample Kolmogorov-Smirnov test. The Chi-square test was used to examine the homogeneity in the variables of mother's job, mother's education, sex of the baby, and type of delivery, and according to the level of significance, the variables are homogeneous in the two groups.

Then, an independent t-test or Mann-Whitney test was used to compare the means between the study groups. Descriptive statistics were estimated using mean and standard deviation. In addition, qualitative data were analyzed using the Chi-square test or Fisher's exact test. Repeated measurement tests were also used to assess the changes over time.

Ethical considerations

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.REC.1394.186) and was registered in the Iranian Registry of Clinical Trials (2016072410327N15).

Results

Study flow chart and demographic features

In this study, 70 eligible infants were initially included to compensate for the possible sample loss. Four infants were excluded from the study due to the mothers' non-responsiveness to the relevant follow-up. Therefore, the data obtained from 66 infants were analyzed [Figure 2]. The mean age of the mothers was 27.66 ± 5.11 years. Most of the mothers were homemakers and had diplomas. In addition, the mean age of the infants at birth was 39.72 ± 1.36 weeks. Among the infants, 59.1% ($n = 39$) were male and 40.9% ($n = 27$) were female. The method of delivery was natural vaginal delivery in 31 mothers (47%) and cesarean section in 35 ones (53%). The two groups were identical in terms of demographic information [Table 1].

Assessment of night crying in infants with colic before and after the intervention

Before the intervention, the two groups were similar in terms of the duration of crying at night ($P = 0.583$). After

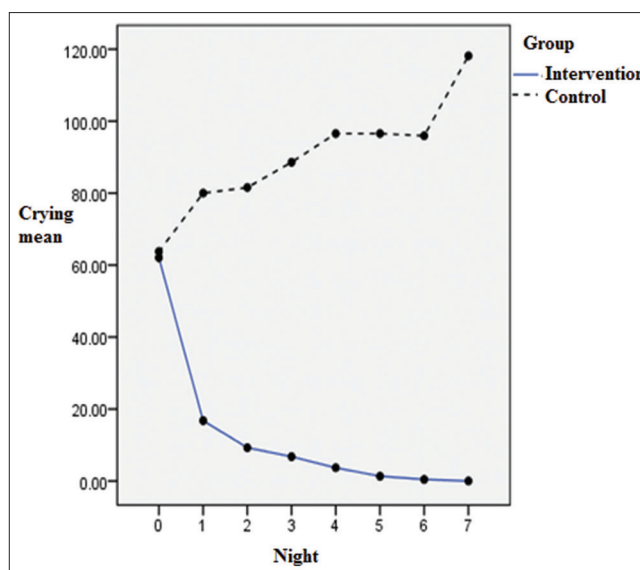


Figure 2: The trend of changes in the mean of night crying in the two groups

the intervention, however, the two groups were different on all days of the study ($P < 0.001$). Based on the results of the repeated measures test, the duration of crying at night changed completely over time ($P < 0.001$). In addition, the results revealed a difference between the two groups regarding the time/group interaction as well as the duration of crying at night [Table 2]. According to [Table 2], the interaction of time and group with night crying in infants with colic was significant. This means that in the present study, time has a significant effect on Reduced the duration of night crying and the use of aromatherapy significantly reduced the duration of crying.[Table3].

Assessment of maternal depression before and after the intervention

The mean score of depression was similar in the lavender oil and control groups (11.1 ± 0.76 vs. 11.06 ± 0.77) at the beginning of the study ($P = 0.9$). After the intervention (day 7), however, a significant difference was observed between the two groups in this regard (2.08 ± 1.11 vs. 17.18 ± 2.32 , $P < 0.001$) [Table 4].

Discussion

In the present study, the effect of lavender oil inhalation on crying duration was investigated amongst 66 infants with colic. The results indicated that the duration of the night crying was shorter in the lavender group compared to the control group. The results of repeated measures analysis also confirmed the effect of lavender oil on the duration of crying. Excessive crying usually occurs during the night, eventually leading to parental dissatisfaction.^[8] The current study results showed that lavender oil was effective in relieving colic symptoms in the evening and at night. In addition, prolonged crying occurred less frequently in the lavender group than in the control group. Till now, only one study has assessed the effect of lavender oil on

Table 1: Comparison of the two groups regarding the demographic data

Variable	Lavender (n=34)	Control (n=32)	P*
Mother's age (years), mean (SD)	27.82 (5.36)	27.50 (4.91)	0.837
Gestational age at birth (week), mean (SD)	39.58 (1.35)	39.87 (1.38)	0.389
Birth weight (gram), mean (SD)	3144.41 (370.02)	3000.93 (244.41)	0.096
Mother's education level, n (%)			0.237
High school diploma	7 (20.6)	8 (25)	
Academic	13 (38.2)	17 (53.1)	
Mother's job, n (%)			0.734
Homemaker	14 (41.2)	7 (21.9)	
Employed	28 (82.14)	28 (87.5)	
Mode of delivery, n (%)			0.632
Cesarean section	6 (17.6)	4 (12.5)	
Natural vaginal delivery	19 (55.9)	16 (50)	
Infant's sex			0.649
Female	15 (44.1)	16 (50)	
Male	21 (61.8)	18 (56.3)	

*Chi-square test for homogeneity

Table 2: The results of repeated measures test related to night crying

Group	Lavender group	Control group	P-value time	P-value group	P-value time* group
Time	M (SD) (minutes)	M (SD) (minutes)			
Night 0	62.05±14.09	63.75±12.63	0.001>	0.001>	0.001>
Night 1	16.76±16.82	80.00±38.18			
Night 2	9.26±13.82	81.56±23.15			
Night 3	6.76±12.48	88.59±33.72			
Night 4	3.67±8.98	96.56±42.92			
Night 5	1.32±5.68	96.56±41.55			
Night 6	0.44±2.57	95.93±28.60			
Night 7	0.00±0.00	118.12±32.27			

*Significant: Less than 0.001

Table 3: Statistical value, P value, Machley tests, time effect, group effect and time and group interaction for night crying in analysis of variance with repeated measures

	Value of test statistics	P
Machley sphericity test	0.135	0.001
Time effect	6215	0.001
Group effect	505.261	0.001
Interaction of time and group	44.73	0.001

crying and sleep durations and cortisol levels amongst infants. In that study, lavender baths resulted in shorter crying periods, longer sleep durations, and lower cortisol levels compared to non-lavender baths.^[19] In another study, massage with lavender oil reduced weekly crying in infants with colic.^[18] Massage therapy without aromatic oils also exerted beneficial effects on the improvement of colic.^[24,25] In another study, the effect of breastfeeding as a sedative method was investigated among infants with colic. The results demonstrated a significant relationship between exclusive breastfeeding for six months and the improvement

of colic and the reduction of infant crying.^[26] If an infant is breastfed, colic may be due to the baby's sensitivity to cow milk protein. In such cases, mothers are recommended not to consume cow products including meat and milk for ten days. If the symptoms go away, mothers should take calcium supplements instead of cow milk until the infant receives complementary feeding.^[1] According to Harvard studies, breastfeeding has a protective effect on calming infants. Therefore, parents need to be educated about the correct breastfeeding pattern by attaching the infant to the breast and proper nutrition to prevent air ingestion.^[26,27]

A previous study assessed the effect of kangaroo care on crying among infants with colic. The results revealed a significant decline in the duration of crying and restlessness among the infants after kangaroo care.^[28] Another study evaluated the antispasmodic effects of herbs such as chamomile, dracocephalum, and fennel on infantile colic. The results showed a significant reduction in infants' crying compared to the control group.^[29] In one study on inhalation aromatherapy, lavender was given within the first 24 hours after birth. Based on the findings, mothers' mood scores were significantly better

Table 4: Comparison of the two groups regarding the mean score of depression

Group	Before the intervention M (SD)	After the intervention M (SD)	Differences before and after the intervention M (SD)
Lavender	11.11±0.76	2.08±1.11	9.02±1.31
Control	11.09±0.77	17.18±2.32	6.09±2.11
<i>P</i>	0.9	0.001>	0.001>

The above table was analyzed using Mann-Whitney nonparametric test

in the intervention group in comparison to the control group.^[30] In another study, the impact of massage with lavender oil was evaluated during the morning of the second day after delivery. According to the results, the anxiety questionnaire score was significantly lower among the massage group participants and none of them had maternal grief.^[31] Studies in other medical fields also showed that lavender essential oil reduced anxiety and increased mood scores.^[32]

The present study findings indicated that inhalation of lavender oil was beneficial for infantile colic. The results also revealed an improvement in maternal mood after one week of intervention. However, it could not be determined whether the improvement in maternal mood was due to the inhalation of lavender oil when using aromatic oils for infants or the reduction of excessive crying. Up to now, several studies have demonstrated that lavender oil aromatherapy through inhalation or massage could be useful for improving mothers' mood in the postpartum period.^[32,33] The anti-anxiety and anti-depressant effects of lavender were also emphasized in another human study.^[34]

One of the strengths of the present study was its double-blind design. However, it had some limitations. Firstly, the researchers were not able to watch the babies and had to collect the data by trusting the mothers. Secondly, such laboratory data as cortisol levels were not available.

Conclusions

The results indicated that inhalation of low concentrations of lavender oil could reduce the symptoms of colic at night and improve maternal mood.

Declaration of patient consent

The authors declare that they have obtained all appropriate consent forms. In these forms, the participants gave their consent for their clinical information to be reported in the journal. They were also informed that their names and initials would not be published and due efforts would be made to conceal their identity, but anonymity could not be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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