



Lavender Oil Aromatherapy on Infantile Colic and Maternal Mood: A Double Blind Randomized Clinical Trial

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ABSTRACT

Background: Excessive crying is a self-limiting problem and disappears in a few weeks, however, it can be irritating for the parents, leading to maternal depression or exhaustion, and stress in the parents. The study evaluated the effect of lavender oil inhalation on duration of daily crying in the infants who suffered infantile colic.

Methods: In this double blind randomized clinical trial, the main inclusion criteria were: healthy infants, no consumption of any drugs for infantile colic, healthy mothers, having one crying episode ≥ 2 hours per day (prolonged crying). The intervention group received inhalation of lavender oil and the control group received sweet almond oil for seven days. Duration of crying in the four parts of a day (morning, afternoon, evening, and night) was gathered by phone call. Also, maternal mood score was assessed at baseline and 7th day of intervention by the Edinburgh Postnatal Depression scale.

Results: At baseline, the two groups were not different in relation to infant's crying duration. However, they were significantly different after intervention in all seven days of the study ($p < 0.001$). Also, using repeated measures analysis, the difference between the two groups was significant ($p < 0.001$). After intervention, there was fewer prolonged crying in the lavender group compared to the control group. In lavender group, maternal mood score was significantly lower than the control group on the 7th day of intervention ($p < 0.001$).

Conclusion: The results suggest that a 1% concentration of the lavender oil can alleviate the colic symptoms and results in maternal mood improvement.

Introduction

Infant colic, or excessive crying with unknown explanation, is one of the most common causes that can lead to frequent consultation to family physician in early infancy, while the infant appears healthy and well fed. According to Wessel's diagnostic criteria, the crying lasts more than 3 hours a day and more than 3 days a week for more than 3 weeks.¹

The excessive crying baby can be irritating for the parents, leading to maternal depression following delivery or exhaustion, and stress in the parents.^{2,3} Consequently, excessive crying may have a negative effect on family stability.⁴ Recurrent visits to the physician may lead to order numerous laboratory tests to identify changes in baby health and prescription of medication for acid reflux or other intestinal disorders.⁵ However, some medications such as dicyclomine is contraindicated at present because of the potential serious side effects.⁶ Excessive crying frequently results in early ending of breastfeeding, because mothers suppose that crying is a resultant of

inadequate milk.⁵ While, excessive crying is a self-limiting problem and disappears in a few weeks, numerous studies have evaluated some alternative pharmacologic agent for their capacity to manage infantile colic. The effectiveness of breastfeeding,⁷ *Fumaria extract*,⁸ massage,⁹ a mixed extracts of *Matricariae recutita*, *Foeniculum vulgare* and *Melissa officinalis*,¹⁰ Fennel oil emulsion,¹¹ hypoallergenic formulas,¹² and removal of cow's milk protein from the diet of mothers with breastfeeding¹³ have been studied, yet no inclusive treatment method for colic is available. Phytotherapy refers to the study of plants for medical purposes and aromatherapy, the therapeutic use of essential oil from plants, is one of its branches.¹⁴ In aromatherapy, the essential oils of plants are obtained by the hydrodistillation process. The characteristics of essential oils, such as the easy penetration through the skin, the potency on the brain through the sense of smell, and other potent medicinal properties, have led to use them in many areas of medicine.^{15,16}

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Lavender, scientifically known as *Lavendula*, includes different species. The most common species of lavender is *Lavendula officinalis*. It is an aromatic plant that is widely used in aromatherapy practice. Previous researches have indicated that aromatherapy with lavender oil has anti-inflammatory, anti-depressant, hypnotic, sedative, muscle-relaxant, anti-bacterial, and anti-spasmodic effects.¹⁷⁻¹⁹ In a study, the lavender bath oil could decrease cortisol level of the mother – infant pairs compared to the non - aroma bath oil. In addition, after the bath, the infants in the lavender bath oil group cried less and had a longer deep sleep than the non - aroma bath oil group.²⁰ In another study, abdominal massage using lavender oil reduced the duration of weekly crying in the colicky infants.²¹

In the present study, we examined the effects of lavender oil inhalation on the duration of daily crying within the one week intervention in the infants who suffered from infantile colic. Moreover, the maternal mood was evaluated before and at the end of the intervention.

Materials and Methods

Setting and participants: This double blind clinical trial was performed in 66 infants attending the two pediatric clinics affiliated to Shiraz University of Medical Sciences, Shiraz, Iran. This study included 32 subjects in the lavender oil group and 34 subjects in the control group and lasted from late May to early November 2016. Our study was reviewed by the ethics committee of Shiraz University of Medical Sciences and its code is IR.SUMS.REC.1394.186. Moreover, this study was registered in the Iranian Registry of Clinical Trial under Cod No. IRCT2016072410327N15.

The following inclusion criteria were used: Infants with a birth age of 37-42 weeks and at 4-8 weeks old at onset of the study, healthy and without abnormalities based on a physical examination by a pediatrician, no consumption of any drugs for infantile colic, healthy infant's mother as can take care her baby, having one crying episode 2 hours or more (prolonged crying). The exclusion criteria were: a new onset of drug consumption or starting another alternative method for infantile colic during the study, detection of a medical problem in the infants after entry to the study, a long term separating of the mother and infant during the study.

The researcher selected the infants based on the inclusion criteria through an interview with the parents and the informed consent form was taken from those parents who willingly agreed to participate in the present study.

Lavender oil preparation: the lavender oil was obtained from the Baridge-essence pharmaceutical company, Kashan, Iran. A technician in the traditional medicine pharmacy reduced the concentration based on the sweet almond oil to 1%. In previous studies, different concentrations of lavender oil, up to 10%, were used in the infancy period.^{21,22} Razaghi et al. used ten drops of 0.5% lavender essential oil in Iranian newborns for managing blood sampling pain.²³ We made use of five

drops of 1% concentration approximating to the above mentioned study.

Placebo preparation: In this study, the sweet almond oil was used as placebo and provided by the Baridge-essence pharmaceutical company, Kashan, Iran.

Data collection tools: The maternal diary of infant cry and fuss behavior was recorded in a researcher- prepared questionnaire by phone call. In this questionnaire, a study day (a 24 hour period) was divided into four parts: morning (6-12 o'clock); afternoon (12-6 o'clock); evening (6-12 o'clock); night (12-6 o'clock).²⁴

For each part of the day, six questions were asked of the mother:

- 1- How much time was your baby asleep?
- 2- How much time was your baby awake?
- 3- While your baby was awake, how much time was crying?
- 4- While your baby was awake, how much time was fussy?
- 5- While your baby was awake, how much time was satisfied?
- 6- Did the time was a usual time?

Design and data collection: In the pediatrics clinic, the pediatrician introduced the colicky infants to the researcher. First, the baseline questionnaires were filled out by the researcher and block randomization was done. The mothers were trained to study protocol carefully. The next day, the mothers initiated the use of the lavender or the sweet almond oil for their babies. They used the oils between 8-10 and 16-18 o'clock. During a colicky crying, the mothers could repeat the procedure once again. The study continued for seven days. During aromatherapy, the mothers spilled five drops of the lavender or sweet almond oil on a cotton ball tissue and held close to the infants' face at least for 15 minutes. The research assistant called the mothers two times every day during the study, between 8-9 and 18-19 o'clock, and gathered the data contributed to 4 parts of a day. In addition, maternal depression level was assessed by the Edinburgh Postnatal Depression scale two times, at baseline and 7th day of the study. This questionnaire is comprised of 10 multiple choice questions, the minimum score is 0 and the maximum is 30. Advantage of this questionnaire is that it focuses on psychological signs of depression rather than physical signs.²⁵ It was translated to Persian and was used in the study by Mazhari and Nakhaee, with a validity and reliability of 0.76 and 0.83, respectively.²⁶ At baseline, the questionnaire was filled in by interview. After intervention for the mom's convenience, it was completed by phone.

Sample size and statistical analysis: Based on the data obtained from a similar study²⁰ with $\alpha = 0.05$, $\beta = 0.2$ and power =80% the sample size was concluded 30 participants for each group, totally 60 participants.

The data was analyzed via the SPSS software, v.18. $P < 0.05$ was considered statistically significant. The normal distribution of the data was determined using Kolmogorov- Smirnov test. After that, the independent t-

test or the Mann–Whitney U test as a nonparametric test was used for comparing the means between the groups. Moreover, the qualitative data was analyzed using Chi-square test or Fisher's exact test. Also, the repeated measures test was used to assess the changes over time. This study was double-blinded. The mothers were uninformed on the type of aromatherapy. Also, the research assistant who gathered the data was blind to group allocation.

Results

Totally, 70 infants participated in this study. Four infants

could not complete the study and we had to dismember them (Figure 1), therefore, data from 56 infants were analyzed. The mean age of the mothers was 27.55 ± 5.11 years. The most of them were housewives and their education level was high school diploma. At birth, the mean gestational age of the infants was 39.72 ± 1.36 . Of total, 39 infants (52.1%) were males and 27 infants (40.9%) were females. The mode of delivery was normal vaginal delivery in 31 mothers (47%) and caesarean section in 35 mothers (53%). The two groups were not different in relation to demographic data (Table 1).

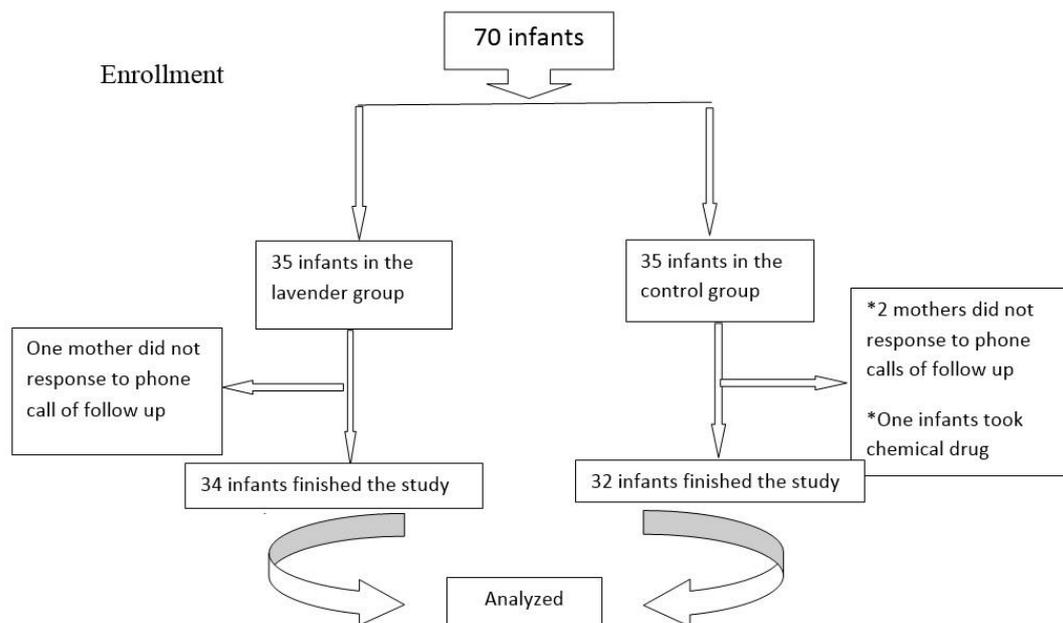


Figure 1. Flow chart of sampling.

Table 1. Comparison of demographic data between the lavender and control groups.

Variable	Lavender (n=34)	Control (n=32)	p- value
Maternal 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
Maternal education, n (%)			
High school	7 (20.6)	8 (25)	0.237
High school diploma	13 (38.2)	17 (53.1)	
University	14 (41.2)	7 (21.9)	
Maternal job, n (%)			
Housewife	28 (82.14)	28 (87.5)	0.734
Employed	6 (17.6)	4 (12.5)	
Mode of delivery, n (%)			
C/S	19 (55.9)	16 (50)	0.632
NVD	15 (44.1)	16 (50)	
Sex of infants			
Female	13 (38.2)	14 (43.8)	0.649
Male	21 (61.8)	18 (56.3)	
Birth order			
Firstborn	22 (64.7)	20 (62.5)	0.537
Secondborn	12 (35.3)	10 (31.3)	
Thirdborn	0 (0)	2 (6.3)	
Nutrition			
Breastfed	27 (79.4)	20 (62.5)	0.176
Formula	7 (20.6)	12 (37.5)	

Table 2. Comparisons of daily crying duration of the infants between the lavender and control groups and the results of repeated measures analysis.

Study days	Lavender group Mean (SD) (Minute)	Control group Mean (SD) (Minute)	p-value ^a	p-value Time ^{bc}	p-value group ^{bd}	p-value time* group ^{be}
Day 0 (Baseline)	361.02(32.51)	365.15(34.20)	0.576			
Intervention	Day 1	94.70(54.50)	380.46(97.53)	<0.001		
	Day 2	58.23(51.53)	420.93(72.26)	<0.001		
	Day 3	48.23(46.33)	437.65(96.47)	<0.001	<0.001	<0.001
	Day 4	27.79(36.60)	492.50(104.95)	<0.001		
	Day 5	22.50(35.85)	514.53(132.52)	<0.001		
	Day 6	5.44(15.97)	516.87(96.19)	<0.001		
	Day 7	2.64(8.63)	592.18(78.78)	<0.001		

^a Student's t test

^b Repeated measures analysis

^{bc} Within subject result

^{bd} Between subject result

^{be} Interaction between group and time

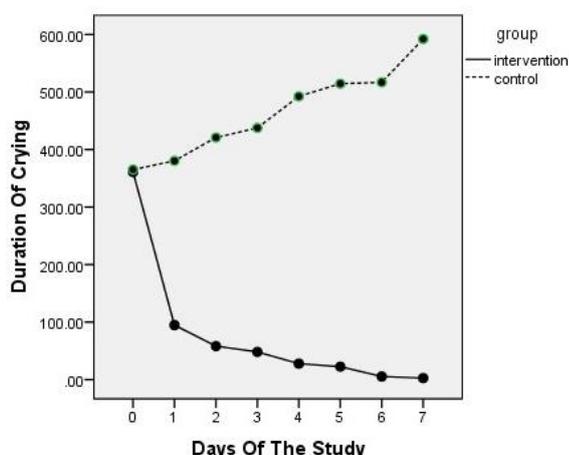


Figure 2. The lavender and control groups changed over time in relation to daily crying duration (P<0.001).

At baseline, the two groups were similar in relation to the crying duration per day (p= 0.576). However, after intervention, the two groups were different in the all days of the study (p< 0.001). Based on the repeated measures analysis, the crying duration per day changed over time absolutely (p<0.001). Moreover, the interaction of time and group was different between the two groups and they

were significantly different in relation to the crying duration per day (Table 2). The repeated measures analysis showed the crying duration per day decreased over time in the lavender group (p<0.001). However, it ascended in the control group (p<0.001) (Figure 2).

When we analyzed the data of the four parts of the days (morning, afternoon, evening and night) separately, the two groups were different after intervention in relation to the crying duration (p<0.001).

The existence of prolonged crying (a crying episode ≥ 2 hours a day) was compared between the two groups. At baseline, all members of the two groups had a prolonged crying. After the intervention, there was fewer prolonged crying in the lavender group compared to the control group (Table 3). The mean score of depression was similar in the lavender group (11.11± 0.76) and the control group (11.06± 0.77) at baseline (p= 0.90). After intervention (7th day), the difference between the groups was significant (2.08± 1.11 vs 17.18± 2.32, p< 0.001).

Discussion

In the present study, we examined the effectiveness of the lavender oil inhalation on the crying duration per day in 56 colicky infants.

Table 3. Prolonged crying at baseline and seven days intervention.

Times	Group	Prolonged crying		p- value	
		Yes	No		
Day 0(Baseline)	Lavender	34 (100)	0	-	
	Control	32 (100)	0		
Intervention	Day 1	Lavender	0	34 (100)	<0.001
		Control	29 (90.6)	3 (9.4)	
	Day 2	Lavender	1(2/9)	33 (97.1)	<0.001
		Control	32 (100)	0	
	Day 3	Lavender	0	34 (100)	<0.001
		Control	30 (93.8)	2 (6.3)	
	Day4	Lavender	0	34 (100)	<0.001
		Control	31 (96.9)	1 (3.1)	
	Day 5	Lavender	0	34 (100)	<0.001
		Control	32 (100)	0	
	Day 6	Lavender	0	34 (100)	<0.001
		Control	32 (100)	0	
	Day 7	Lavender	0	(100) 34	<0.001
		Control	32 (100)	0	

The result showed the total duration of crying was less in the lavender group compared to the control group. The results of the repeated measures analysis confirmed the efficacy of the lavender oil on the duration of crying. Excessive crying usually occurs during the evening and crying in the night leads to some displeasure in parents.² The results showed the lavender oil was effective in relieving colic symptom in the evenings and nights. In addition, prolonged crying occurred less often in the lavender group than the control group. We found only one study that evaluated the effects of the lavender oil on crying and sleeping length and cortisol level in infants. In this study, the aroma bath could produce a shorter crying time and a longer sleep, and lower level of cortisol compared to a non-aroma bath.²⁰ In another study, aromatherapy massages by lavender oil reduced weekly crying time of colicky infants.²¹ On the other hand, massage therapy without aromatic oil had beneficial effects in management of colic.^{27,28} The present study showed that inhalation of lavender oil can be useful for infantile colic as well. The accessible records suggests that short-term treatment with lavender is not dangerous.²⁹ In line with previous studies, our participants did not experience any side effect during the study period.²¹⁻²³ Furthermore, we observed high level of the parents' satisfaction regarding lavender aromatherapy. Unfortunately, the parents' satisfaction did not assay systematically by a questionnaire.

The other result of our study was an improvement in maternal mood after one week intervention for their colicky infants. It is not clear that, maternal mood improvement was due to maternal inhalation of lavender oil when they applied the aromatic oil for their infants or reduction in excessive crying resulted in an improvement in maternal mood. There are some studies that showed lavender oil aromatherapy, by inhalation or massage, can be useful for maternal mood improvement in the postnatal period.³⁰⁻³² Also, antianxiety and antidepressant effects of lavender were shown in several human studies.²⁹

Strengths and limitations: One of the strengths of the present study is its double-blind design, though it has some limitation. We could not observe the infants by video to gather the data and trusted to the reports of their mothers. Also, a lab test such as cortisol level that might provide more consistency for our results was not made available. The participants were selected from two pediatrics clinics in Shiraz. This group of participants may not be representative of the target population. No treatment-related effects were observed in the present study.

Conclusion

The results suggest that a low concentration (1%) of the lavender oil can alleviate the colic symptoms and results in maternal mood improvement. Further studies should be conducted in order to support the results of the present study.

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The present study was approved by the Ethics Committee of Shiraz University of Medical Sciences with the ethics code 94-01-08-10216. A written informed consent was obtained from all parents who were willing to participate in the present study.

Conflict of interests

The authors claim that there is no conflict of interest.

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