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Comparing the Effects of Lavender Aromatherapy and Epidural Analgesia on Fear of Childbirth Experienced during Labor and Postpartum: A Randomized Controlled Trial

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ABSTRACT

Background & aim: While epidural analgesia is regarded as the gold standard for managing labor pain, some studies suggest that it may be linked to increased fear of childbirth (FOC). We aimed to compare the effects of lavender aromatherapy and epidural analgesia on FOC during labor and postpartum.

Methods: This randomized controlled trial was conducted on 56 women with full-term singleton pregnancies, admitted for vaginal delivery at one teaching hospital in Qom, Iran between October 2021 and June 2022. Participants were randomly allocated to either the aromatherapy group (receiving essential oil of lavender) or epidural analgesia with ropivacaine group at the onset of active labor. Outcomes were assessed using the Delivery Fear Scale, the Wijma Delivery Expectancy Questionnaire, and the visual analog scale. Univariate general linear models were employed to compare the groups.

Results: There was no significant difference in mean scores of FOC between the two groups one hour post-intervention (P = 0.629). Postpartum FOC mean scores were significantly lower in the aromatherapy group compared to the epidural group at both two hours (47.0 vs. 63.8, P < 0.001) and five weeks (40.0 vs. 66.1, P < 0.001) postpartum. The mean labor pain intensity was higher and the duration of the active phase was shorter in the aromatherapy group (Ps < 0.001).

Conclusion: Although lavender aromatherapy is not as effective as epidural analgesia in alleviating labor pain intensity, it appears to reduce postpartum childbirth fear and may also shorten the first stage of labor. Larger trials with longer follow-ups are recommended to provide high certainty evidence in this area.

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Introduction

Clinical Fear of childbirth (FOC) is described as a "disabling fear that interferes with occupational and domestic functioning, as well as social activities and relationships". About 7% of women experience very severe FOC during pregnancy and postpartum (1). It can lead to various adverse outcomes, including post-traumatic stress disorder, postpartum depression, disruption of maternal-infant bonding, and an increased preference for cesarean sections. Additionally, it negatively impacts women's interactions with their

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husbands, future sexual desire, and their decisions regarding subsequent pregnancies (2-3). The method used for pain relief during labor may influence levels of fear experienced during labor and in the postpartum period (4-5).

Epidural analgesia is regarded as the gold standard and is a commonly used pharmacological method for pain relief during labor (4, 6-7). However, some observational studies (8-10) and a secondary analysis of a randomized controlled trial (5) have indicated an association between epidural analgesia and increased postpartum FOC. The exact mechanism underlying this association is not fully understood, but it may relate to the more invasive nature of this method (5).

At present, there is growing interest in alternative interventions for labor pain relief. Many women prefer these options because they facilitate a more natural labor experience (11). Such interventions primarily aim to assist mothers in coping with labor pain and reducing their perceptions of pain (5, 12).

In recent decades, aromatherapy using essential oils from medicinal plants has emerged as a popular alternative. Systematic reviews of randomized controlled trials have shown that aromatherapy can safely reduce labor pain, shorten the active phase of labor (13-14), and alleviate anxiety (15, 16). Lavender, one of the most effective aromatic plants, contains compounds such as Linalyl acetate, Linalool, 1,8-cineole, β-ocimene, and terpinen-4- ol. It may act as an anxiolytic by enhancing the response of the $GABA_A$ receptor (17) and/or inhibiting the serotonin transporter (18).

To the best of our knowledge, no trials have directly compared the effects of aromatherapy with those of epidural analgesia during labor. Although some studies have reported the benefits of aromatherapy for reducing anxiety levels, we found no trials specifically assessing its effects on fear of childbirth. Therefore, this trial was designed to compare the effects of lavender inhalation aromatherapy with epidural analgesia during the active phase of labor on the intensity of fear experienced during labor and the postpartum period (primary outcomes) among low-risk women. Additionally, secondary outcomes including pain intensity, labor duration, and satisfaction with the childbirth experience were compared between the two groups.

Materials and Methods

This study was a single-center, two-parallel-arm, randomized controlled trial conducted between October 2021 and June 2022. Due to the nature of the interventions, blinding was not feasible. The trial was conducted at Izadi Teaching Hospital in Qom, Iran, which features eight labor, delivery, and recovery (LDR) rooms. In this hospital, each pregnant woman is assigned to an LDR room upon admission. Typically, a dedicated midwife provides care to each woman during a working shift; only during busy shifts does a midwife attend to more than one woman. Continuous monitoring is provided to all women, but they are free to walk within their rooms. During labor, women are encouraged to engage in relaxing exercises, such as using birth balls. The hospital's routine pain relief options include spinal or epidural analgesia and Entonox gas. However, many women opt not to use these methods and anaesthesia is administered in approximately 15% of vaginal deliveries. Other non-pharmacological pain relief methods are not routinely utilized in this hospital.

Participants in this study were women aged 18 to 45 years with full-term singleton pregnancies who were admitted to the maternity ward for vaginal delivery. Other eligibility criteria included having no more than two prior deliveries, no history of uterine surgery, a healthy sense of smell, regular uterine contractions, cervical dilatation of up to 4-5 cm, and a low-risk pregnancy.

Exclusion criteria included non-cephalic presentation, recent sedation within four hours prior to the intervention, abnormal amniotic fluid volume, non-reactive fetal heart rate, contraindications to epidural analgesia and/or aromatherapy, pregnancies conceived through assisted reproductive technology, major physical or mental illness, severe obesity, or inability to provide informed consent due to distress, as determined by the attending caregiver.

All eligible women admitted to the hospital during the working shifts of the second author (the anesthesiologist) were invited to participate. Eligibility was verified using a checklist. We collected baseline data during the latent phase of labor upon their admission to the

ward. Participants were then individually assigned to either the aromatherapy or epidural analgesia groups at the onset of the active phase of labor.

The allocation sequence was generated using a computer program. We used block randomization with randomly varying block sizes of four and six, and a 1:1 allocation ratio, stratified by parity (nulliparous/parous) and the onset of labor (spontaneous/induced), to allocate recruited participants into intervention or control groups. Allocation concealment was ensured using sequentially numbered opaque sealed envelopes. The sequence generation and the envelope preparation were performed by a person not involved in the recruitment, allocation, or data collection. The envelopes were kept by the person in charge of the delivery ward. At the onset of the active phase of labor, the envelopes were opened sequentially after the woman's name was written on them. The carbon paper inside the envelopes transferred the name onto the assignment paper contained within the envelope. The principal investigator, the first author (ZZ), recruited participants, assigned them to the groups, and collected data.

Interventions were implemented for both groups at the onset of the active labor phase, characterized by regular uterine contractions and cervical dilatation of 4 to 5 cm, and continued until the completion of the second stage of labor (childbirth).

The lavender essential oil used had a 10% concentration, mixed with bitter almond oil, and was produced by Barij Essential Pharmaceutical Company, located in Kashan, Iran. Bitter almond oil was selected for its common use and efficacy as a solvent (19, 20). This concentration of oil is safe (21).

In the aromatherapy group, 0.1 mL of the essential oil was applied to a 15 x 15 cm piece of fabric and placed near the women's nostrils. The principal investigator administered the intervention for this group. This method was selected for its effectiveness in delivering the essential oil to the olfactory system. Linen fabric was utilized to retain the scent, facilitate skin absorption of the oil, and minimize the risk of adverse reactions. Due to the COVID-19 pandemic and the need to prevent disease transmission, certain aromatherapy methods, such as cold fumigation, could not be employed.

In the epidural group, the second author, an anesthesiologist, performed the intermittent injection technique. Depending on the patients' pain levels and individual needs, 5-10 mL of ropivacaine at a concentration of 0.1% was administered every 30-60 minutes.

The sample size was calculated using G*Power software to detect the difference between two independent means. The calculation determined that a sample size of 23 women was required for each group, based on a mean postpartum fear score of 65.4 with a standard deviation (SD) of 23.0 in one group (21) and aiming to detect a mean difference of 30% (mean score of 45.8) in the other group, assuming SD2 = SD1, with a two-sided significance level of 0.05 and a power of 80%. This sample size was also considered sufficient for comparing the groups in terms of fear during labor, given a mean score of 48.9 and a standard deviation of 15.0 in one group (23) and a mean difference of 30% (mean score of 34.2) in the other group, assuming SD2 = SD1, a two-sided significance level of 0.05, and a power of 90%. To account for a potential attrition rate of 20% (including the possibility of an emergency cesarean section occurring after randomization), the target sample size was adjusted to 28 participants per group.

Primary outcomes included the intensity of FOC during labor and the postpartum period. The Delivery Fear Scale (DFS) (22) was used to assess FOC during labor at baseline and one hour into the intervention. Additionally, the Wijma Delivery Expectancy Questionnaire (W-DEQ-B) (23) was utilized to assess postpartum FOC at two hours and five weeks postpartum. The assessment at two hours post-intervention was omitted, contrary to the original protocol design, for two reasons: first, some women delivered before the assessment could be conducted, and second, many women reported discomfort with the assessment due to increased pain intensity and frequent contractions.

The DFS is a 10-item scale with 10-point Likert options ranging from 10 to 100 (with higher scores indicating greater FOC). This scale was originally developed and validated in Sweden (24). It has been validated in Iran, with the

Persian version demonstrating good internal consistency (Cronbach's alpha = 0.77) (22).

The W-DEQ-B, which is used to assess postpartum FOC, consists of 33 items, each with 6-point Likert options, and includes six subscales. Total and subscale scores are calculated by summing the respective item scores, with higher scores indicating greater FOC. The original version was developed and validated in Sweden (25). The Persian version has been validated in Iran, demonstrating high internal consistency (Cronbach's alpha = 0.93 at two hours and 0.94 at five weeks postpartum) (23).

Secondary outcomes encompassed pain intensity during the active phase of labor, the second stage of delivery, and one hour postpartum; the duration of the first (active phase), second, and third stages of labor and the duration of intervention until delivery, all assessed by the principal investigator through direct observation; satisfaction with the childbirth experience, assessed 12-24 hours postpartum using the Birth Satisfaction Scale-Revised (BSS-R) (26)); and the frequency of emergency cesarean sections.

Pain intensity during labor was assessed using a widely used and validated Visual Analog Scale (VAS) (27) at several time points: baseline, 30 minutes post-intervention, hourly during the active phase, and once during the second stage of labor. The assessments were conducted between contractions by prompting women to report pain intensity experienced during the most recent contraction. The average of the reported pain scores during the active phase of labor (excluding the baseline score) was considered the woman's pain intensity during that phase.

The Birth Satisfaction Scale-Revised (BSS-R) comprises 10 items rated on a 5-point Likert scale, with three subscales. Its original version has been validated in England (28). Its Persian version has been validated in Tabriz, showing high internal consistency (Cronbach's alpha = 0.96 at 12-24 hours after delivery), and a strong correlation (0.91) with scores obtained 40-45 days after delivery (26).

Overall satisfaction with the method of labor pain relief was assessed as an additional secondary outcome using a 5-point Likert scale, ranging from 0 (completely dissatisfied) to 4 (completely satisfied), and was assessed 12 to 24 hours postpartum.

A side-event checklist was utilized to document any side events, including symptoms such as headache, nausea, vomiting, itching, tremors, prolonged low back pain, fever, maternal respiratory distress, an Apgar score of less than seven at five minutes, neonatal admission to the intensive care unit, and an open-ended question to report any other events. The checklist was completed through observation and interviews with the women during childbirth until two hours postpartum, and via follow-up interviews with the women at 12-24 hours and five weeks postpartum.

The face and content validity of the demographic and reproductive, labor duration, and side-event questionnaires, as well as the overall satisfaction question, were confirmed by a panel of 10 experts, including obstetricians, anesthesiologists, and midwives from Tabriz and Qom Universities of Medical Sciences. The internal consistency of the validated scales was evaluated using Cronbach's alpha, yielding values of 0.73 and 0.91 for the DFS at baseline and one hour post-intervention, respectively; 0.89 and 0.95 for the W-DEQ-B, between 0.77 and 0.94 and between 0.80 and 0.90 for the W-DEQ-B subscales at two hours and five weeks postpartum; and between 0.75 and 0.94 for the total and subscales of the BSS-R.

Following the collection of all data, the analysis was performed using SPSS version 25 software, employing intention-to-treat analysis to include all randomized women in the analyses. The normal distribution of quantitative outcomes by study groups was confirmed using the Kolmogorov-Smirnov test. Although a few secondary outcomes were not normally distributed, the log transformation normalized their distribution. Univariate general linear models were employed to compare quantitative outcome scores between study groups, with adjustments made for the baseline values (when available), stratification factors (parity and labor induction), and occupation, which displayed differing distributions between the groups.

Results

Participant recruitment occurred between October 2021 and June 2022. All 28 individuals assigned to each study group were followed up and included in the analyses (Figure 1).

The two groups were almost comparable regarding baseline characteristics, except for the women's occupations (Table 1). All participants delivered via vaginal birth.

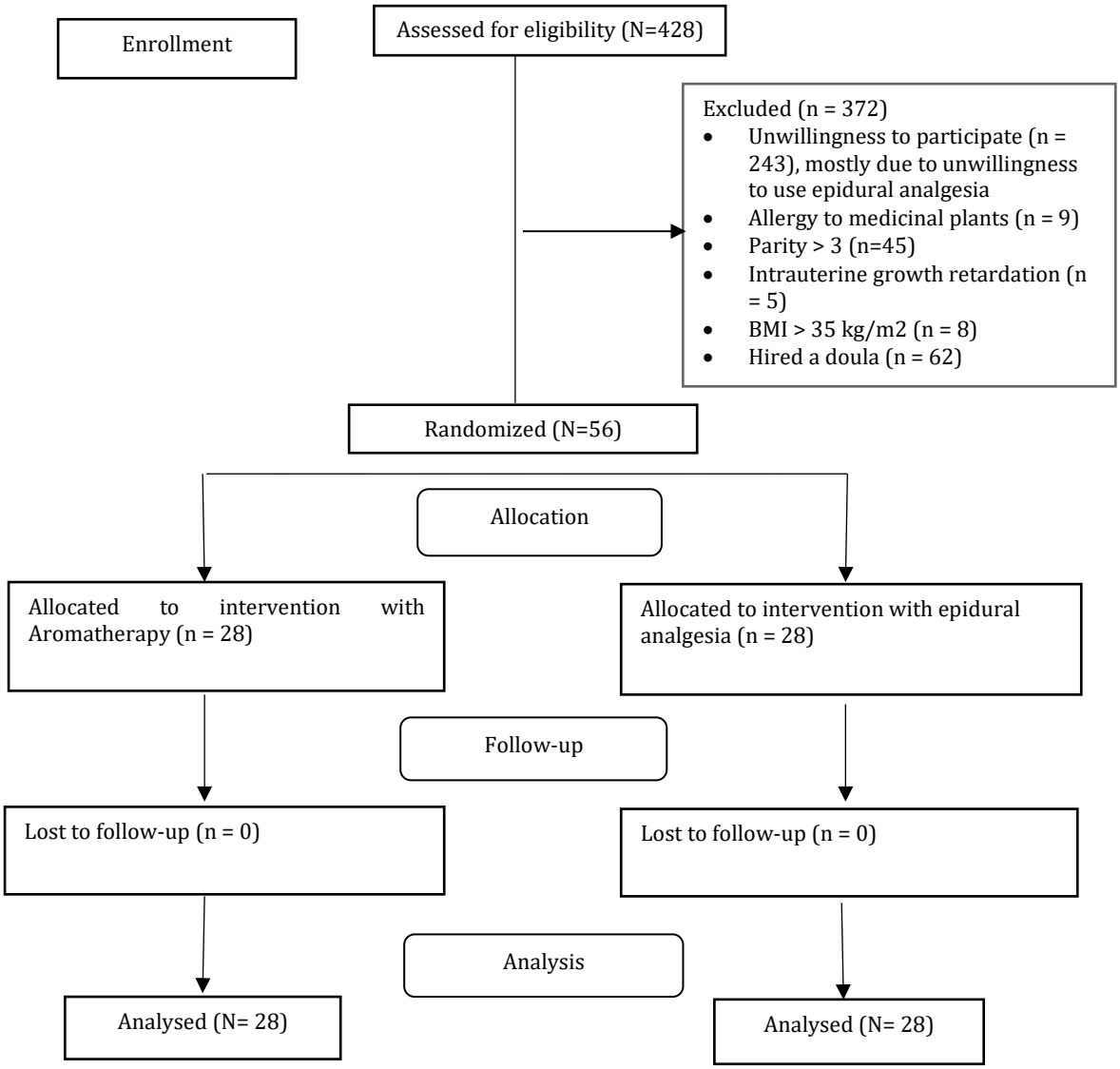

Figure 1. CONSORT Flowchart of the study

There was no significant difference in the mean fear score one hour post-intervention between the aromatherapy and epidural groups (46.0 vs. 46.7; adjusted mean difference [AMD] -1.6, 95% CI -8.2 to 5.0). However, the mean total childbirth fear score in the aromatherapy group was significantly lower than that in the epidural group at both 2 hours (47.0 vs. 63.8; AMD -17.2, 95% CI -26.5 to -8.0) and five weeks (40.0 vs 66.1; AMD -26.4, 95% CI -36.1 to -16.7) post-delivery (Table 2).

Table 1. Baseline characteristics of the study participants by the groups

Characteristics	Aromatherapy (N=28)	Epidural (N=28)	P-Value
Age (years), Mean (SD)	26.8 (4.4)	25.8 (3.2)	0.343[a]
Body mass index (kg/m^2), Mean (SD)	26.9 (2.0)	26.0 (2.0)	0.118[a]
Gestational age, (weeks), Mean (SD)	38.7 (0.7)	39.2 (1.3)	0.061[a]
Education, n (%), College	19 (67)	15 (53)	0.274[b]
Occupation, n (%), Employed	13 (46)	4 (14)	0.009[b]
Primipara, n (%)	18 (64)	19 (67)	0.778[b]
Induced Labor, n (%)	12 (42)	11 (39)	0.786[b]
Attendance at birth classes, n (%)			
8 sessions	4 (14)	8 (28)	0.317[c]
< 8 sessions	8 (28)	3 (10)	
None	16 (57)	17 (60)	
Prenatal care visits (at least 4) (yes), n (%)	28 (100)	28 (100)	
Neonatal birth weight, Median [25th, 75th]	3000 [2900, 3200]	3150 [3000, 3400]	0.053[d]

[a] Independent T-test, [b] Chi-square test, [c] Linear-by-Linear association, [d] Mann-Whitney U

Table 2. Comparison of the study groups in terms of primary outcomes

Outcomes	Aromatherapy (N = 28) Mean (SD)	Epidural (N = 28) Mean (SD)	Comparison between groups AMD[a] (95% CI)	P-Value
Antepartum fear assessed by Delivery Fear Scale (DFS) (10-100)[b]				
Baseline	60.6 (10.0)	59.0 (11.8)	2.14 (-4.2 to 8.5)	0.504
1 h of intervention	46.0 (11.7)	46.7 (10.7)	-1.6 (-8.2 to 5.0)	0.629
Postpartum fear assessed by Wijma Delivery Expectancy/Experience- B (W-DEQ-B) (0-165)[b, c]				
2 h post-delivery	47.0 (13.2)	63.8 (18.9)	-17.2 (-26.5 to -8.0)	0.001 <
5 weeks post-delivery	40.0 (12.2)	66.1 (20.1)	-26.4 (-36.1 to -16.7)	0.001 <

[a]Adjusted mean difference using Univariate General Linear Model adjusted for the stratification factors (parity, labor onset), and occupation for the baseline comparison and adjusted for the above variables and baseline antepartum fear for the other comparisons
[b]The higher the score, the greater fear
[c]Greenhouse-Geisser test in repeated measures ANOVA showed a significant interaction effect of time and group ($p < 0.001$). Therefore, the comparisons were done at each time point separately.

The mean pain intensity was significantly higher in the aromatherapy group across all assessments compared to that of the epidural group (Ps < 0.01). However, the overall satisfaction level with the pain relief method, assessed 12-24 hours post-delivery was significantly higher in the aromatherapy group than in the epidural group (P = 0.022).

The active phase of labor was significantly shorter in the aromatherapy group than in the epidural group (P < 0.001), whereas no significant differences were observed between the groups concerning the durations of the second and third stages of labor.

Compared to the epidural group, the aromatherapy group achieved significantly higher mean scores for total birth satisfaction and the quality of care subscale. However, no significant differences were observed between the groups in the stress and women's attributes subscales.

At 2 hours postpartum, the mean scores for three out of six WDEQ-B subscales (concerns about labor pain, loneliness, and concern about baby) were significantly lower in the aromatherapy group than in the epidural group. Additionally, at the five-week post-delivery assessment, the mean scores for all subscales were significantly lower in the aromatherapy group (Table 3).

No neonatal complications were reported in either group. A few maternal side events were reported only in the epidural group, including headaches (9 cases) and prolonged low back pain and numbness in the legs (1 case). None of the participants in either group requested

alternative pain relief methods during labor up to one hour post-delivery.

Table 3. Comparison of the study groups in terms of secondary outcomes

Outcomes	Aromatherapy (n = 28) Mean (SD)	Epidural (n = 28) Mean (SD)	Comparison between groups	
			AMD[a] (95% CI)	*P*-value
Pain intensity (0-10)[b,c]				
Baseline	6.7 (1.5)	7.5 (1.4)	-0.9 (-1.8 to -0.1)	0.028
mean pain of the active phase	7.1 (1.1)	6.1 (1.6)	1.5 (0.8 to 2.2)	< 0.001
Second stage	8.6 (1.0)	6.8 (2.9)	2.3 (1.0 to 3.5)	< 0.001
1 h after delivery	2.1 (0.6)	1.8 (0.8)	0.5 (0.1 to 1.0)	0.009
Overall satisfaction with labor pain relief (0-4)[d]	3.7 (0.5)	3.1 (0.9)	0.7 (0.3 to 1.2)	0.001
Length of labor				
Active phase (h)	3.2 (1.0)	4.8 (1.5)	-1.5 (-2.2 to -0.7)	<0.001
Second stage (min)	29.2 (19.1)	26.8 (11.0)	3.0 (-6.1 to 12.2)	0.506
Third stage (min)	4.8 [4.8, 5.4)	4.8 [4.8, 5.4)	-0.03 (-0.13 to 0.05)	0.439[c]
Birth satisfaction scale-revised (BSS-R)[e]				
Total score (0-40)	29.2 (3.0)	24.8 (4.7)	3.9 (1.7 to 6.2)	0.001
Stress (0-16)	7.7 (1.1)	7.2 (1.2)	0.4 (-0.1 to 1.1)	0.146
Quality of care (0-16)	13.8 (1.2)	11.3 (1.6)	2.2 (1.4 to 3.1)	< 0.001
Women's attributes (0-8)	2.9 (0.8)	3.2 (1.8)	-0.2 (-1.0 to 0.6)	0.586
W-DEQ-B subscales[b,c]				
2 h after delivery				
Concerns about labor pain (0-45)	17.0 (4.7)	23.4 (6.5)	-7.0 (-10.2 to -3.8)	< 0.001
Lack of positive behaviors (0-20)	5.8 (2.7)	6.4 (3.6)	-0.5 (-2.3 to 1.2)	0.540
Loneliness (0-35)	7.6 (4.1)	12.1 (6.8)	-4.2 (-7.5 to -0.9)	0.012
Lack of positive feelings (0-45)	11.8 (2.5)	13.6 (4.8)	-1.9 (-4.1 to 0.2)	0.780
Concerns about childbirth (0-15)	2.2 (1.2)	2.6 (1.7)	-0.3 (-1.1 to 0.4)	0.405
Concerns about baby (0-10)	0.0 [0.0, 1.0)	0.0 [0.0, 4.0)	-0.3 (-0.6 to -0.01)	0.044[c]
5 weeks after delivery				
Concerns about labor pain (0-45)	15.3 (3.6)	24.0 (6.1)	-8.9 (-11.9 to -5.9)	< 0.001
Lack of positive behaviors (0-20)	4.4 (2.3)	7.2 (3.5)	-2.7 (-4.5 to -1.0)	0.002
Loneliness (0-35)	6.2 (4.3)	12.5 (6.9)	-6.1 (-9.5 to -2.7)	< 0.001
Lack of positive feelings (0-45)	10.4 (3.3)	13.6 (5.0)	-3.2 (-5.8 to -0.7)	0.013
Concerns about childbirth (0-15)	1.7 (1.2)	3.0 (1.8)	-1.2 (-2.2 to -0.3)	0.009
Concerns about baby (0-10)	0.0 [0.0, 0.0)	1.5 [0.0, 5.7)	-0.4 (-0.7 to -0.12)	0.010[c]

The data indicate mean (SD) or median [Percentile 25, 75), unless otherwise indicated

[a]Adjusted mean difference using ANCOVA adjusted for the baseline values, stratification factors (parity, labor onset), and occupation, bGreenhouse-Geisser test in repeated measures ANOVA showed a significant interaction effect of time and group ($p < 0.001$). Therefore, the comparisons were done at each time point separately. cThe higher score, the greater the pain/fear, dAfter log10 transformation, the distribution became normal, eThe higher the score, the greater the satisfaction

Discussion

To the best of our knowledge, this study is the first trial to compare the fear of childbirth between women receiving aromatherapy and those receiving epidural analgesia during the active phase of labor. The results indicated that while the FOC during labor was slightly lower in the aromatherapy group compared with the epidural group, this difference was not statistically significant. However, the postpartum FOC was significantly lower in the aromatherapy group.

The results of this study regarding higher postpartum FOC among those receiving epidural analgesia are consistent with a secondary analysis of a trial conducted in the Netherlands, which showed a higher prevalence of severe postpartum FOC in the group receiving epidural analgesia (26%) compared with the group

receiving no pain relief (7.5%) and those receiving remifentanil-PCA (12.5%) (5). Additionally, in a prospective observational study, women who received epidural analgesia reported elevated levels of postpartum FOC compared with those who did not receive this form of pain relief, both at two hours (67 vs. 40) and five weeks (55 vs. 29) postpartum, while there was no statistically significant difference in median FOC score between the groups at 37-39 weeks of gestation (8). Furthermore, a nationwide retrospective cohort study conducted in Finland, which compared pregnancies with and without diagnosed maternal FOC, indicated a higher rate of epidural analgesia among multiparous (47% vs. 29%) and nulliparous (70% vs. 67%) women experiencing FOC (10). Similarly, an observational study showed that women with severe FOC in their second pregnancies were more likely to have received epidural analgesia in their first pregnancies compared with controls without severe FOC (78% vs. 64%, $P = 0.011$) (9). The lack of a significant difference between the groups concerning fear of labor at one hour post-intervention in our study may be attributed to the short interval between intervention and assessment.

No studies investigating the effect of aromatherapy on FOC were identified in our review. Given the strong correlation between FOC and anxiety (26), we present the effect of aromatherapy on anxiety levels. A meta-analysis involving four trials with 372 participants demonstrated the positive effect of aromatherapy in reducing anxiety during the latent phase of labor (12). Our previous trial also supported the effectiveness of lavender essential oil aromatherapy in alleviating postpartum anxiety (29). The effect may be related to the constituents of lavender, including Linalyl acetate, Linalool, 1,8-cineole, β-ocimene, and terpinen-4- ol which have anxiolytic properties by enhancing GABAA receptor responses (17) and/or inhibiting the serotonin transporter (18).

In this trial, we compared aromatherapy—an alternative approach aimed at helping to cope with pain—with the gold standard pharmacological pain management method, epidural analgesia (5). Therefore, we anticipated significantly lower levels of labor pain in the epidural group compared with the aromatherapy group. A Cochrane systematic review also indicated lower pain scores in the epidural group compared to those receiving opioids (4) and a meta-analysis indicated a modest effect of lavender inhalation aromatherapy on pain relief (12). The higher overall satisfaction with labor pain relief reported by the aromatherapy group 12-24 hours post-delivery may be attributed to the pain coping mechanism it utilized, as observed in previous studies utilizing alternative interventions (5, 12).

The shortened active phase experienced by the aromatherapy group compared with the epidural group may be linked to aromatherapy's labor duration reduction effects, as indicated in a recent systematic review (13). It could also be influenced by the effect of epidural analgesia in prolonging labor duration, as demonstrated in the Cochrane systematic review (4).

Women in the epidural group reported lower satisfaction with childbirth experience, compared with those in the aromatherapy group, which aligns with an observational study that indicated a negative association between birth satisfaction and the use of epidural analgesia (30). This may be attributed to the longer active labor phase experienced by those receiving epidural analgesia, a factor that has negatively affected childbirth satisfaction and experiences in prior studies (30-31).

Our study adhered to a rigorous randomization processwhich minimized the risk of selection bias. We achieved complete follow-up of all randomized participants and assessed and reported all primary and secondary outcomes without missing values, thus maintaining a low risk of attrition and reporting biases.

Blinding participants, health providers, and outcome assessors was not feasible in this study, potentially introducing performance and detection biases. However, we believe that the performance bias was minimal since care was mainly provided by staff unaware of the study's objectives. Additionally, we think the detection bias was also low, as primary and most secondary outcomes were reported by participants who were unaware of the study hypotheses. Other secondary outcomes, assessed by the investigator who was aware of the study

objectives (such as the duration of labor in different stages), were objective measures that were less likely to be influenced by unblinding.

Due to ethical considerations, we were unable to include a comparison group with no intervention. Consequently, we could not make judgments about the effects of each of these interventions compared with no intervention.

The rate of women declining to participate in the study was relatively high. However, since most reluctance was due to unwillingness to receive epidural analgesia, we believe that it would not lead to an overestimation of the effects of aromatherapy.

Due to the small sample size and short follow-up period, we were unable to compare the effects of the interventions on some important outcomes such as low neonatal Apgar score, neonatal admission to the intensive care unit, and future pregnancy decisions. Therefore, multicenter trials conducted in diverse settings with larger samples and longer follow up are recommended to enhance generalizability and assess neonatal and longer-term outcomes.

If the beneficial effects of aromatherapy are confirmed in future trials, this will have important implications for practice due to its low cost, suitability for midwife administration, minimal training requirements, and lack of need for specialist personnel. Consequently, its regular use could be advocated in various settings, including those with limited resources.

Conclusion

Based on the results of this study, lavender aromatherapy, when compared with epidural analgesia, reduces postpartum fear of childbirth and may shorten the duration of labor. Additionally, it may enhance satisfaction with the childbirth experience and with labor pain relief. Although aromatherapy is not as effective as epidural analgesia in reducing pain during labor, if its beneficial effects are confirmed in future trials involving larger sample sizes and extended follow up periods across diverse settings, its regular application could be suggested in various contexts, including low-resource settings.

Declarations

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Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

We designed and executed this study in accordance with the Helsinki Declaration. The trial was prospectively registered at Iranian Registry of Clinical Trials [IRCT20100414003706N39] on 23 September 2021. Written informed consent was obtained from all individuals participating in this study before baseline data collection.

Code of Ethics

This study received approval from the Ethics Committee of Tabriz University of Medical Sciences, Tabriz, Iran on 23 Aug 2021, under approval number IR.TBZMED.REC.1400.414.

Use of Artificial Intelligence (AI)

We have not used any AI tools or technologies to prepare this manuscript.

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Authors' contribution

ZZ, SMAC, and MM contributed substantially in the conception and design of the study. ZZ and MP implemented the interventions. ZZ carried out the data collection. ZZ and SMAC analysed, interpreted the data, and drafted the manuscript. MM and MP reviewed the manuscript critically for important intellectual content. All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work in ensuring that questions related to the

accuracy or integrity of any part of the work are appropriately investigated and resolved.

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