Original Article Comparative study of transcutaneous electrical nerve stimulation, the aromatherapy of Lavandula and physiologic delivery without medication on the neonatal and maternal outcome of patients

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Abstract: Objectives: The complications of normal vaginal delivery (NVD) are one of the issues that researchers have been discussing today and various ways to reduce these outcomes have been presented. In this study, we aimed to compare the effect of Transcutaneous Electrical Nerve Stimulation (TENS), the aromatherapy of Lavandula and physiologic delivery without medication on NVD outcomes. Methods: This randomized clinical trial was conducted on 150 women that were candidates of NVD. The information related had been registered in the Iranian clinical trial registration system with the code IRCT20210501051151N1 (https://www.irct.ir/trial/56014). Patients were divided into three groups of Lavandula, TENS, and physiologic delivery. Postpartum pain, maternal and neonatal outcomes, and labor duration were compared in groups. Results: Labor pain was significantly less in TENS and Lavandula than in the physiologic group, respectively (P<0.001). There was no significant difference between the groups in terms of labor duration and maternal and fetal outcomes. Conclusion: The use of TENS and Lavandula aromatherapy are useful methods for reducing pain in patients undergoing NVD, but using TENS method is better than Lavandula method, and on the other hand, there are no differences between groups as maternal and neonatal complications.

Keywords: Lavandula, transcutaneous electrical nerve stimulation, normal vaginal delivery, outcome, pain

Introduction

Labor pain is very diverse in terms of intensity and has been reported among the most intense pains for humans. A significant relationship is revealed between labor pain and maternal stress, and pain control is essential for modern obstetric care [1-5]. The main objective of obstetric care is to manage labor pain, which is done using both pharmacological and nonpharmacological methods. Pharmacological methods are effective on relieving the physical sensation of pain, while non-pharmacological methods largely prevent pain and suffering [2]. The use of pharmacological methods to reduce labor pain is considered as a risk factor and is usually associated with clinical concerns and complications associated with each method.

On the other hand, the high level of satisfaction of most women with non-pharmacological ways of reducing labor pain shows that these methods probably have other advantages that are unknown [1-6]. Non-Aromatherapy uses extracts obtained from flowers, leaves, and plants of plants to cause a sense of healing. It is believed that aroma odors can activate olfactory nerve cells, which stimulate the limbic system. Depending on the type of aroma, neurons release different neurotransmitters. These neurotransmitters include enkephalin, endorphin, noradrenaline, and serotonin. On the other hand, due to the relationship between smell and the human soul and emotions, aromas can affect the soul and body. Odors can change the feeling in humans [9, 10]. One of the plants used for aromatherapy is Lavandula [11]. Linalool and linalyl acetate in this plant can stimulate the parasympathetic system and linalool acetate has a narcotic effect and linalool acts as a sedative in Lavandula [12].

Transcutaneous electrical nerve stimulation (TENS) is another non-pharmacological method for relieving pain. This method was used in 1974 as an effective method with less complications for relieving pain, which is safe, noninvasive, and non-toxic [13]. One of the mechanisms of action of this method is based on the theory of pain gate control. Electric current activates many afferent fibers, which stimulate the inhibitory nerves of the posterior horn or release endorphins, or both. TENS also prevents pain transmission by activating descending inhibitory systems [14]. On the other hand, electrical stimulation increases blood flow near the electrodes, which indirectly contributes to muscle spasms' healing process or relaxation.

Due to the high prevalence of maternal stress during labor and its undesired complications on the one hand and the advantages of non-pharmacological methods for reducing labor pain and lack of study in this field, on the other hand, the present study was conducted aimed to investigate the effect of non-pharmacological methods for reducing labor pain on perceived stress during and after the labor of mothers referring to Shahid Beheshti Educational and Medical Center in Isfahan.

Materials and methods

Study population

In this clinical trial, 150 patients referred to Shahid Beheshti Hospital in 2018 with gestational age of 38 weeks and above, maternal age 18-35 years, head-down single pregnancy, low-risk pregnancy, no use of special and illegal drugs, alcohol and cigarettes during pregnancy, normal placenta and fetus, no previous history of periods of depression and anxiety and stressful life events in the last 6 to 12 months and willing participated in the study. Also, lack of cooperation and unwillingness of mothers for continuing the intervention or not participating in the study at any stage of the study were considered as exclusion criteria. Prior to this clinical trial, this project was approved by the Ethics Committee of Isfahan University of Medical Sciences and the information related had been registered in the Iranian clinical trial registration system with the code IRCT20210501051-151N1.

Randomization and grouping

The objective and method of the study were fully explained to these patients. The patients entered the study with full knowledge and authority. Written consent was obtained from all patients admitted to the study. The patients who met the exclusion criteria or were not interested in continuing to cooperate were excluded from the study. The patients were divided into three groups of n=50 by randomization software, which included Lavandula, TENS and control. In a group, normal labor was performed without the use of TENS or Lavandula. In another group, Lavandula extract was used for patients and in the third group, TENS was used.

Interventions

In a group of mothers with the onset of the active phase by establishing a quiet place and observing mother's privacy, Lavandula aromatherapy was used. For aromatherapy, we used essential oil prepared from Kashan Barij Essential Oil Co., which was prepared by the distillation method at the concentration of 1.5%. This essential oil is extracted from Lavandula angustifolia. The effective ingredient in reducing pain is linalool acetate and linalool. One cc of the prepared solution of 20% Lavandula essential oil was impregnated on a cloth measuring $10 \times 10 \text{ cm}^2$ and attached to the mother's breast at the beginning of the active phase. In all three groups, maternal vaginal examinations were performed during labor in the active phase, except when necessary, once every 2 hours and at the second stage of labor every 30 minutes, and fetal heart rate was monitored at the first stage of labor every 30 minutes and at the second stage every 15 minutes. Santocinone and amniotomy were not used for labor progress and it was monitored based on partography. The mothers were encouraged to use oral fluids to prevent dehydration. In TENS group, in the active phase of labor (5 cm dilation of the cervix), two pairs of electrodes were placed in the spinal nerve roots T10-L1 and S2-S4 and at the first and second stages of labor, it was connected to TENS and electrical stimulation was established with an intensity of 10-18 mA and a frequency of 100

Variables		TENS	Lavandula	Control	P-value
Maternal BMI (Kg/m ²)		25.48±3.30	24.41±3.02	25.55±3.12	0.13
Maternal Age (year)		30.10±4.01	29.12±3.72	29.66±4.26	0.47
Pregnancy age (week)		38.82±0.87	39.12±0.71	39.01±0.75	0.16
Gravid numbers	1	27 (54%)	23 (46%)	26 (52%)	0.91
	2	14 (28%)	15 (30%)	15 (30%)	
	≥3	9 (18%)	12 (24%)	9 (18%)	
Neonate Gender	Boy	22 (44%)	23 (46%)	24 (48%)	0.92
	Girl	28 (56%)	27 (54%)	26 (52%)	

Table 1. Demographics information of patients in three groups

(Hz) for 30 minutes. In all three groups, vital signs were measured 4, 8 and 12 hours after labor. No additional intervention was performed in the normal delivery group.

Data gathering

Finally, the pain and vital signs of the patients were compared in the three groups. A visual pain measuring tool was used to measure patients' pain. This tool is graded from zero to 10, which zero shows no pain and 10 is the highest level of pain experienced by the patient and cannot be tolerated. Pain measurement intervals were 5, 10, 15 and 30 minutes after analgesia. Also, the duration of active phase, mean time of the second stage, patient satisfaction (using a Likert scale), neonatal Apgar score and cesarean section percentage of patients were calculated and compared. The patients in the three groups were matched for age, maternal parity, gestational age and maternal BMI.

Sample size calculations and statistical analysis

The sample size was considered n=50 with alpha 0.05 and standard deviation $S_1=2.3$ and $S_2=1.5$ [15] in TENS group, and n=50 with the standard deviation $S_1=2.3$ and $S_2=1.5$ in Lavandula essential oil group. SPSS software version 20 was used to analyze variables. Descriptive data were reported as a frequency (percentage) or mean (± SD). The Kolmogorov-Smirnov test was used to evaluate the normality of variables. The Chi-square test was used to compare qualitative variables between groups, and the one-way ANOVA test was used to compare quantitative variables between groups. The significance level was considered 0.05 for all tests.

Results

Study population

The study included one hundred fifty mothers with a mean age and gestational age of $29.62\pm$ 4.01 years and 38.98 ± 0.78 weeks and divided into three groups of TENS, Lavandula, and control. No significant difference was identified between the three groups based on maternal BMI, maternal age, gestational age, gravida and neonatal gender (P>0.05) (Table 1).

Patient's outcomes

A significant difference was between the three groups based on pain intensity so that pain intensity was lower in TENS, Lavandula and control groups, respectively (P<0.001). There was no significant difference between the three groups based on the duration of the active phase and the second stage, Apgar score of 5 minutes, NICU hospitalization, postpartum and cesarean section atony (P>0.05).

Postpartum satisfaction

A significant difference was between the three groups based on postpartum satisfaction so that satisfaction level of the control group was significantly lower than TENS and Lavandula groups (P<0.001) but no significant difference was found between TENS and control groups (P=0.07) (**Table 2**).

Discussion

According to the study results, the use of TENS caused less pain than aromatherapy using Lavandula, which had relatively less pain than physiological delivery. On the other hand, the level of satisfaction with TENS and natural labor was relatively higher than normal labor.

Variables		TENS	Lavandula	Control	P-value
Severity of pain		4.76±2.20	6.18±2.12	7.94±1.28	<0.001
Duration	Active phase	257.60±125.23	297.60±124.48	289.20±140.02	0.27
	Second stage	33.92±31.44	33.20±23.64	33.10±21.23	0.98
Apgar scoring of 5 minutes		9.30±0.99	9.24±1.02	9.24±1.04	0.94
NICU admission		2 (4%)	2 (4%)	3 (6%)	0.86
Postpartum uterine Atony		3 (6%)	4 (8%)	3 (6%)	0.89
Caesarian		4 (8%)	6 (12%)	3 (6%)	0.55
Satisfaction		4.04±0.90	3.66±1.09	2.92±1.10	<0.001

 Table 2. Variables of study between three groups

In a study, Yazdkhasti et al. investigated the effect of aromatherapy using Lavandula, and concluded that the use of Lavandula for aromatherapy was an effective method that reduced labor pain and on the other hand did not reduce the duration of the active phase and the second stage [16]. In our study, the use of Lavandula significantly reduced pain compared to the control. On the other hand, no difference was between Lavandula and control groups in terms of the duration of the active phase and the second stage.

In a study by Shahoei et al., which investigated the use of TENS, it was concluded that the use of this method reduced labor pain at the first and second stages and 4 hours after delivery, and the duration of the first stage [17]. In our study, the use of TENS reduced pain in patients compared to control and Lavandula, and on the other hand, TENS did not reduce the duration of labor at the first and second stages.

In a study which was conducted on 74 kidney donor patients, TENS was used in a group and placebo was used in the control group. In both groups, respiratory muscle strength (maximal inspiratory and expiratory pressure), vital signs, pain, and time out of bed were investigated, and it was concluded that the use of TENS significantly reduced patients' pain and increased respiratory muscle strength and patients got out of bed faster [18].

Another study assessed the effect of aromatherapy on labor process, pain and stress and showed that aromatherapy during labor with a reduction in labor time significantly reduced the duration of labor, but its effect on reducing maternal stress was not confirmed [19].

A review study conducted in 2019 concluded that the use of TENS reduced pain intensity

slightly compared to control, but there are few studies in this field. On the other hand, this study stated that this method did not affect maternal and fetal complications [20]. Other studies have also shown similar results [21-25]. In our study, no difference was between groups in terms of complications such as Apgar score, NICU hospitalization, uterine atony, and risk of cesarean section.

Limitations of our study included: • Small sample size. • Not investigating other maternal and fetal complications. • Few studies in this field.

To the best of our knowledge, our study was the first to compare the above three methods in this regard.

Conclusion

According to the results of our study and other studies in this field, using TENS and Lavandula are two practical methods to reduce pain in patients undergoing normal delivery, but using TENS is relatively better than Lavandula. On the other hand, no difference is identified among the three methods in terms of maternal or fetal complications. Therefore, we suggest that further studies will be conducted in this field.

We observed that Lavandula, Transcutaneous Electrical Nerve Stimulation, normal vaginal delivery, Outcome, Pain. We suggest that further research should be conducted in this regard.

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