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The effect of transcutaneous electrical nerve stimulation on the severity of labor pain among nulliparous women: A clinical trial

Roonak Shahoei Associate Professor [a], Shole Shahghebi Associate Professor [b, *], Masomeh Rezaei Assistant Professor [b], Shayan Naqshbandi MD Student [c]

[a] Nursing & Midwifery Faculty, Kurdistan University of Medical Sciences, Sanandaj, Iran
[b] Medicine Faculty, Kurdistan University of Medical Sciences, Sanandaj, Iran
[c] Shahid Beheshti University of Medical Sciences, Tehran, Iran

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ABSTRACT

Introduction: This study aimed to investigate the effect of transcutaneous electrical nerve stimulation on labor pain among nulliparous women referred to a hospital in an urban area of Iran.
Materials and methods: Samples were consisted of 90 nulliparous women. They were randomly assigned into three groups with equal number in each groups: experiment group, placebo group and control. Pain was measured using the visual pain severity scale.
Findings: The mean of the severity of labor pain indicated a statistically significant difference after the intervention. The severity of pain indicated a statistically significant difference in the second stage of labor, and 4 h after the labor in the groups. The duration of the first stage of labor was significantly different between the groups.
Conclusion: The application of transcutaneous electrical nerve stimulation affected pain relief in the first and second stages of labor and 4 h after labor.

1. Introduction

Most women experience labor pain during childbirth. Severe labor pain causes long-term emotional disturbances in women and disrupts their mental health. It can negatively affect the mother and child relationship in post-delivery days, disrupt the family relationship and create the fear of future pregnancies [1]. Moreover, labor pain causes fetal asphyxia followed by abnormal heart beat in the fetus and a low Apgar score. Therefore, there is a need to midwifery interventions for reducing complications arising delivery pain [2]. The severity of labor pain depends on personal factors, the number and type of child birth and size and position of the fetus in the uterus. It has been shown that 77% of nulliparous women have described labor pain as severe and unbearable [3].

Various methods are available for labor pain relief such as narcotics, spinal and epidural anesthesia, pudendal nerve block, hypnosis, acupressure and acupuncture [4]. The transcutaneous electrical nerve stimulation (TENS) has attracted great attention in recent years. TENS as a non-pharmacologic method for pain relief has been used for relieving chronic pain such as backaches and rheumatic pain. It has been also approved by the FDA for surgery and traumatic pain. The history of using TENS in relieving labor pain dates back to the late 1970s. The TENS device controls the voltage, frequency and duration of nerve conduction. This method suppresses pain thorough blocking the conduction of the pain signal. TENS exerts its effects through the selected stimulation of thick tactile fibers (Aβ) without the stimulation of thin pain fibers (C) [5].

When Melazack (1962) explained this theory called the pain gate control theory (gate theory), most experts became interested in the application of this method. Nowadays, it has become one of the most common methods for relieving pain in most serious and chronic diseases. One of the common uses of this method is labor pain relief. This method as a non-chemical and non-aggressive method is widely used by healthcare professionals. Some electrodes are placed over the skin related to specific dermatomes i.e. in dermatomes of nerves T10-L1 as well as over lumbosacral nerves S2-S4. Before the application of this method, the individual is

* Corresponding author. Kurdistan University of Medical Sciences, Pasdaran Street, Sanandaj, Iran. Tel.: 00989183712759.
E-mail addresses: rshaho@yahoo.com (R. Shahoei), shahgheibi@yahoo.com (S. Shahghebi), Mrezaie2001@yahoo.com (M. Rezaei), Shayannaqshbandi@yahoo.com (S. Naqshbandi).

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taught about how this device works and switches on the device by pressing a small button to establish the electrical current through electrodes. The voltage and frequency of the electrical current can be changed based on the mother's need and tolerance. With the increase of labor pain, the individual increases the voltage and frequency of the electrical current. This method is more effective and useful if it is used from the early stages of labor [6].

According to studies on the effect of TENS on pain relief methods in nulliparous women, greater pain relief was experienced by TENS users compared with other methods [7–10]. Ref. [7] conducted a study on the effect of acupressure and TENS on the severity of labor pain among nulliparous women. A clinical trial with 135 nulliparous women was conducted. Participants were randomly assigned into three groups: acupressure, TENS, and control. Interventions were conducted with 3–4 cm cervix dilation on the point of SP6. Acupressure and TENS were applied to two groups. The severity of pain was evaluated in three groups using a visual numeric severity scale before the intervention in 3–4 cm cervix dilation, right after the intervention, 30 min after the intervention and lastly 60 min after the intervention. The findings of the study indicated that pain was significantly relieved right after the intervention, 30 min and 60 min after the intervention in the acupressure and TENS groups compared with the control group. Moreover, no statistically significant difference was observed concerning the effect of acupressure and TENS on pain relief in 3–4 cm dilation and right after the intervention. However, the severity of pain was significantly lower 30 min and 60 min after the intervention in the TENS group. Therefore, both acupressure and TENS led to relieving labor pains, but TENS was reported more effective [7].

TENS is a side-effect free procedure, cheap, and appropriate for labor pain relief [7,8]. Some studies reported the use of TENS together with other methods for pain relief [11,12]. In a study conducted in Iran, researchers reported that this method had no statistically significant effect on labor pain relief [13]. Moreover, Zonoozy and Hashemijam [8] studied the effect of TENS with the pethidine-promethazine combination on labor pain relief in the active stage of labor. They studied 100 pregnant women referred to a teaching hospital and suggested that the mean of the severity of pain in 3–4 cm dilation was lower in both groups. However, it was not lower in 6–7 cm dilation, full dilation and during labor [8]. In the labor unit of the educational and medical center as this study's research zone, no non-pharmacologic treatment method was common for pain relief. Moreover, since TENS is an inexpensive and safe method that needs no specific knowledge and skill for its application, its efficacy has not been clearly identified. Therefore, the present study aimed to investigate the effect of transcutaneous electrical nerve stimulation on labor pain among nulliparous women referred to a hospital in an urban area of Iran.

2. Methods

2.1. Design

This randomized controlled trial was registered at the Iran's Clinical Trial Database (code: IRCT 2016020914556N3). The population of this study included all nulliparous women referred to a teaching hospital in urban area of Iran. The inclusion criteria were being primiparous, singleton, cephalic, pregnancy age of 38–42 weeks, active phase of labor and intact membranes. Exclusion criteria were fetal growth disorders, Caesarean indication, medical and childbirth diseases, having the experience of TENS use, any skin problems in the areas the electrodes, having chronic underlying diseases and mother's unwillingness to use TENS.

2.2. Sampling

The sample size was determined using the statistical indices from a previous study [12] 0.05 alpha and 20% beta. Therefore, the sample size was estimated 7.2 for the intervention group, and 6.2 for control group. Moreover, the standard deviation was estimated 2.1 for the first group and 1.1 for the second group. Therefore, 30 individuals were selected. The samples were then selected according to a simple randomization method (toss of a coin) and assigned into three groups.

2.3. Data collection

The data collection tool was consisted of the demographic factor form (age, job, education level, planned pregnancy, mother's BMI), labor features (pregnancy age, cervix dilation), pain documentation form (duration of the first stage, duration of the second stage, severity of pre-intervention pain, severity of pain right after the intervention, severity of pain within every hour in the first stage of labor and the second stage of labor, severity of pain 4 h after delivery, type of childbirth, amount of bleeding after delivery, baby's weight, newborn's head circumference, the first and fifth minute Apgar score).

The severity of pain was measured using the visual analogue severity scale (VAS). This was a 10-cm line graded from 1 to 10. Zero stood for a lack of pain and 10 indicated extremely severe pain. Scoring was as follows: minor pain [1–3], moderate pain [4–7] and severe pain [8–10].

2.4. Procedure

For conducting this study, nulliparous women referred to the delivery ward were assessed by two midwives with respect to the inclusion criteria. Those women who had the inclusion criteria and were willing to participate in this study were recruited. They were randomly placed in one of the groups i.e. the experiment (switched-on TENS), placebo (switched-off TENS) and control (without using any TENS) groups. In the experiment group, before using the TENS in 4-cm dilation, the mother's pain was measured using the VAS. Next, the electrodes of TENS were placed in an area between the tenth thoracic vertebra to the first lumbar vertebra within 5 cm from the middle vertebral line (two electrodes). Two electrodes were placed symmetrically between the second and fourth lumbosacral vertebra within 5 cm from the vertebral column. The TENS device was then switched on. The voltage of the electrical current was then increased until the mother expressed that she felt minor tingles in the area of the electrodes. The voltage was then fixed on that level. Then, the severity of mother's pain was measured using a numeric severity scale right after connecting the electrodes and within every hour until the end of the first stage of labor and in the second stage of labor. Moreover, the mother's pain was measured 4 h after the delivery and was recorded in the related form. The duration of the first and second stage of labor was also recorded in the form. In the TENS-like group, the TENS electrodes were placed on the same dermatomes of the intervention group, but no electrical current was established. The time for the measurement of pain and the method for measurement and recording were similar to the experiment group. In control group, no device was applied and only routine care was provided to women in the delivery ward. Also, the time for the measurement of pain and the method for measurement and recording were similar to other groups.

2.5. Data analysis

Descriptive and inferential statistics were used for data analysis

vis the SPSS v.18. Descriptive statistics such as mean and percentage were reported. The normal distribution of quantitative variables was assessed using the Kolmogorov-Smirnov test. All variables had a non-normal distribution. Therefore, the Kruskal-Wallis test was used for the comparison of the groups. $P < 0.05$ was considered statistically significant.

2.6. Ethical considerations

This study's research proposal was confirmed by the Research Council and the Ethics Committee affiliated with Kurdistan University of Medical Sciences, Iran. The ethical considerations were corresponded to the Ethics Charter of the Ministry of Health and Medical Education (Iran) and the Declaration of Helsinki, 2001.

2.7. Findings

In this clinical trial, 90 nulliparous women were assigned into three groups as experiment, placebo and control. It was indicated that the groups had no statistically significant differences with respect to age ($p = 0.4$), education level ($p = 0.13$), job ($p = 0.32$), place of residence ($p = 0.27$), planned pregnancy ($p = 0.31$), kind of delivery ($p = 0.27$), age of pregnancy ($p = 0.38$), body mass index ($p = 0.11$) and pre-intervention pain ($p = 0.56$) (Tables 1 and 2).

The mean of the severity of pain 1 h after the intervention was 6.4 (SD = 2.14) 1 h after the intervention in the experiment group. It was 8.4 (SD = 1.38) and 8.2 (SD = 1.6) in the placebo and control groups, respectively. It did not suggest any statistically significant differences between the groups ($P = 0.001$). The mean of the severity of pain showed statistically significant differences between the groups 2, 3 and 4 h after the intervention ($p = 0.000$) (Table 3). It was also indicated that the severity of pain was significantly different in the second stage of labor in the groups ($p = 0.000$). Moreover, 20% of the samples in the experiment group described the severity of pain as severe, while this was 25 and 26% for the placebo and control groups, respectively (Table 4). Moreover, the severity of pain 4 h after delivery showed a statistically significant difference ($p = 0.000$). In addition, 6.67% of the samples in experiment group, 43.33% in the placebo group, and 60% in the control group described their pain severe 4 h after delivery (Table 5).

In this study, the average duration of the first stage of labor was significantly different between the groups ($p = 0.002$). No statistically significant difference was observed in the mean duration of the second and third stages of labor ($p = 0.18$ and $p = 0.29$, respectively) (Table 6). No statistically significant differences was observed concerning the baby's weight, the first and fifth minute Apgar score, post-delivery bleeding between the groups (Table 7).

3. Discussion

According to the findings of the present study, the severity of labor pain was not significantly different in the studied groups before the intervention. However, 1 h after the intervention, the severity of pain was significantly different in the experiment group compared with the placebo and control groups as TENS reduced labor pain. Pain relief was also reported in the experiment group 2 h, 3 h, and 4 h after the intervention. The findings of the present study showed that the severity of pain in the experiment group was lower compared with other groups in the second stage of labor and 4 h after delivery. Other studies reported similar findings [7,14,16]. In the study conducted by Ref. [14], the effect of TENS on labor pain was studied with 64 women in the intervention group and 60 women in the control group. It was indicated that the severity of pain during labor in the intervention group was less than that the control group, because TENS had no negative consequences for the mother and baby [14]. For the comparison of the effects of acupressure and TENS among nulliparous women, Ref. [7] found that both the methods relieved labor pain, but TENS was more effective [7]. However, for the comparison of the effects of Entonox and TENS on the severity of pain in the active phase of labor, Ref. [12] reported that Entonox more effectively reduced pain compared with TENS in the active phase of labor [12].

The presence of a significant difference between TENS and placebo group indicated that TENS had no placebo effects and labor pain relief was merely depend on the use of TENS. The mechanism

Table 1
Demographics characteristics of subjects according to groups.

Characteristics	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	control group (n = 30) n (%)	Pvalue
Age (year)				
16–20	4 (13.4)	8 (26.7)	6 (20.0)	0.4
21–25	12 (40.0)	17 (56.7)	12 (40.0)	
26–30	12 (40.0)	3 (10.0)	9 (30.0)	
31–35	1 (3.3)	1 (3.3)	2 (6.7)	
≥36	1 (3.3)	1 (3.3)	1 (3.3)	
Education				
Primary	5 (16.7)	8 (26.7)	10 (33.4)	0.13
Diploma	15 (50.0)	19 (63.3)	15 (50.0)	
University	10 (33.3)	3 (10.0)	5 (16.6)	
Occupation				
Home Attendant	26 (86.7)	21 (70.0)	22 (73.3)	0.32
Employed	4 (13.3)	9 (30.0)	8 (26.7)	
Place of Residence				
City	26 (86.7)	28 (93.3)	24 (80.0)	0.27
Rural	4 (13.3)	2 (6.7)	6 (20.0)	
Planned pregnancy				
Yes	26 (86.7)	28 (93.3)	24 (80.0)	0.31
No	4 (13.3)	2 (6.7)	6 (20.0)	
Birth method				
Vaginal	5 (16.7)	3 (10.0)	2 (6.7)	0.27
Vaginal +Episiotomy	25 (83.3)	25 (83.3)	27 (90.0)	
Vaginal + Perineal Tear	0 (0)	2 (6.7)	1 (3.3)	
Tear				
Body Mass Index	26.31 ± 4.62	23.85 ± 3.59	26.09 ± 5.12	0.11

Table 2
Comparison of pain severity in first stage of labor in three groups.

Time	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	control group (n = 30) n (%)	Pvalue
One hour after intervention	6.4 ± 2.14	8.4 ± 1.38	8.2 ± 1.6	0.001
Two hour after intervention	6 ± 2.19	9.1 ± 1.24	8.9 ± 1.1	0.000
Three hour after intervention	5.3 ± 2.15	9.1 ± 1.06	8.8 ± 1.5	0.000
Four hour after intervention	4.9 ± 2.5	9.7 ± 0.59	9.2 ± 1.7	0.000

Table 3
Comparison of pain severity in second stage of labor in three groups.

Pain Severity	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	control group (n = 30) n (%)	Pvalue
Mild [1–3]	12 (40.0)	1 (3.3)	1 (3.3)	0.000
Moderate [4–7]	12 (40.0)	4 (13.3)	3 (10.0)	
Sever [8–10]	6 (20.0)	25 (83.4)	26 (86.7)	

Table 4
Comparison of pain severity four after birth in three groups.

Pain Severity	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	control group (n = 30) n (%)	Pvalue
No pain	13 (43.33)	17 (56.67)	10 (33.34)	0.000
Mild [1–3]	6 (20.0)	0 (0)	1 (3.33)	
Moderate [4–7]	9 (30.0)	0 (0)	1 (3.33)	
Sever [8–10]	2 (6.67)	13 (43.33)	18 (60.0)	

Table 5
Comparision of labor stages duration in three groups.

Group Duration (Min)	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	Control group (n = 30) n (%)	Pvalue
Stage1	158.42 ± 136.64	262.5 ± 125.23	257.16 ± 114.10	0.002
Stage 2	43 ± 29.37	57.5 ± 41.39	44.03 ± 29.17	0.12
Stage 3	11.6 ± 4.2	13.27 ± 8.7	13.00 ± 10.87	0.29

Table 6
Newborn characteristics in three groups.

Group Characteristic	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	Control group (n = 30) n (%)	Pvalue
Newborn weight (Kg) Mean & SD	2.9 ± 0.49	2.8 ± 0.46	2.9 ± 0.80	0.61
Apgar 1 Min Mean& SD	9 ± 0.5	9 ± 0.3	9 ± 0.2	0.25
Apgar 5 Min Mean & SD	9 ± 0.5	9.1 ± 0.4	9.1 ± 0.4	0.71
Head circumference (Cm) Mean & SD	34.7 ± 1.3	34.7 ± 1.3	34.5 ± 1.5	0.78

Table 7
Post Partum hemorrhage in three groups.

Group Hemorrhage (CC)	TENS group (n = 30) n (%)	TENS-like (n = 30) n (%)	Control group (n = 30) n (%)	Pvalue
≤500	27 (90.00)	27 (90.00)	25 (83.30)	0.66
500–1000	3 (10.00)	3 (10.00)	5 (16.70)	

of pain relief by TENS is explained through the pain gate control and increase of endorphin and enkephalin in the central nervous system [9].

The findings of the present study showed that the mean duration of the first stage of labor Tin the experiment group was less than other groups. While the mean duration of the second and thirds stages of labor was not significantly different between the groups. In a quasi-experimental study, Asnaashari et al. (2000)

randomly divided 120 primiparous women referred to Mashhad maternity hospitals into three groups as experiment, placebo and control. The severity of pain was measured using the visual analogue severity for pain from the beginning of the active phase until the end of the second stage of labor. The findings indicated that no statistically significant difference in the severity of pain in the first stage of labor and duration of the first and second stages of labor between the groups. The severity of pain in the first stage of labor was less than the other groups. Also, the duration of active phase in the first and second stages of labor in the TENS group was shorter than that of the other groups [17].

Ref. [15] studied the application of TENS on four pressure points for labor pain relief. They used 2-cm dilation of TENS for 160 nulliparous women on four the points of B121, BL19, PC6 and L14. Also, 145 nulliparous women were selected for the control group. This study indicated that the duration of the first, second and third stage of labor were not significantly different [15]. Moreover, a study conducted by Ref. [16] indicated that the duration of the first and second stage of labor was not significantly different between TENS and placebo groups [16].

The findings of the present study showed that the use of TENS had no effect on the consequences of childbirth and also did not affect the first and fifth minute Apgar score. Other studies did not confirm the findings of this study as no childbirth complications were reported so far [9,11,12,15,16]. A systematic meta-analysis study (2011) reported that the use of TENS had no consequences on mothers and their children [4]. The findings of this study suggested no significant differences with respect to post-delivery bleeding between the groups, which was consistent with the findings of studies by Ref. [11,15,18].

In the delivery units of Iranian hospitals no specific methods for relieving labor pain were available. This is owing to the lack of specialist healthcare staff, treatment costs, and the fear for the consequences of analgesics. Therefore, the application of non-pharmacologic drugs without any negative consequences on the mother, fetus and the child are of utmost importance.

According to the findings of the present study, the severity of pain in the experiment group in the first and second stage of labor and the duration of the first stage of labor was less compared with the placebo and control groups. TENS helps with the delivery progress through relieving pain in the first stage of labor and makes the first stage of labor shorter. Since it has no negative consequences for mothers and their fetus, it is considered a safe pain relief method.

4. Conclusion

The education of midwifery students and healthcare staff regarding TENS as a safe method for pain relief during childbirth encourage women to choose normal delivery as the method for childbirth. Therefore, delivery becomes a favorite experience in mother-friendly hospitals and reduced requests for Caesarean delivery due to the fear of delivery pain. Policy makers need to work on the development of damage-free and inexpensive methods for relieving pain. Familiarizing women with labor pain and education about the pre-delivery period are needed for promoting non-drug pain relief methods and alleviating their fear of labor pain.

As the limitations of this study, the sample size was low. Also, this study was conducted only with nulliparous women. Therefore, other studies should be done with larger sample sizes and the comparison of nulliparous and multiparous women. Also, other studies should compare TENS with other non-pharmacologic pain relief methods.

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