

Comparison of Transcutaneous Electrical Nerve Stimulation and Lidocaine on Episiotomy Complication in Primiparous Women: A Randomized Clinical Trial

Abstract

Introduction: Transcutaneous electrical nerve stimulation (TENS) through the skin is a nonpharmacological method of pain relief. The present study aimed to compare TENS and lidocaine on episiotomy complication in primiparous women. **Material and Methods:** In a randomized, controlled clinical trial, 80 participants were included from March to July 2011 at the antenatal clinic and postdelivery ward in the Social Security Organization Hospital, Khorramabad, Lorestan, Iran. Data were collected using a demographic questionnaire, visual analog scale and redness, edema, ecchymosis, discharge, and approximation scales. The participants were randomized into two groups with equal number of participants. All participants received 5 cc of local infiltration of 1% lidocaine before episiotomy, and TENS electrodes were placed on He Gu and Shenmen points during the crowning of fetal head. The TENS group received TENS with 100; 250 μ s, the output range of 15–20 mm amplifier from crowning of first stage of labor to the end of the episiotomy repairing. The lidocaine group received 10 cc of local infiltration of 1% lidocaine before episiotomy repair while did not receive TENS electrodes. The pain intensity during and after episiotomy repair was recorded. **Results:** TENS and lidocaine have similar effects on pain relief at the episiotomy cutting, the start of the episiotomy repair, and at end of the episiotomy repair; however, the pain relief of both the interventions was different during the episiotomy repair. The effect of TENS in reducing edema was statistically significant ($P = 0.001$). **Conclusions:** TENS and lidocaine are effective for the episiotomy complications during and after episiotomy repair.

Keywords: Analgesia, episiotomy pain relief, Iran, transcutaneous electrical nerve stimulation), visual analog scale

Introduction

Episiotomy is the most common incision which is widely used in midwifery.^[1] Although the statistics of episiotomy use are not available, it is estimated that about two-thirds of the parturient in developed countries and a third to half of the parturient in undeveloped countries who are delivered in a hospital setting experience an episiotomy.^[2] Although episiotomy is used to prevent severe damage to the perineum and helps to increase the birth speed in the final stages of labor,^[3] the pain and complications of episiotomy should not be ignored.

There is evidence that the pain following episiotomy induces a stressful experience among primiparous parturient, which has a negative impact on their first motherhood experience and mother–child relationship.^[4] Episiotomy pain is considered to be one

of the most excruciating pain that women experience throughout their lives.^[5] On other the hand, episiotomy cutting and repairing requires anesthesia. Usually, local anesthesia with lidocaine is used as a standard procedure. Lidocaine is associated with systemic side effects, allergies, a quick pass through the placenta, and neonatal toxicity.^[6]

Transcutaneous electrical nerve stimulation through the skin (TENS) is a nonpharmacological method of pain relief. TENS acupuncture is actually a modified method, which provides pain relief with electrical stimulation of the nerves.^[7] The main mechanism of TENS is unclear.

However, TENS induced analgesia has been explained by several theories including the gate control, the endorphin-mediated pain relief, and the diffuse noxious inhibitory

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controls theory, however, the gate control theory of pain is one of the most common mechanisms.^[8] The electric current generated by TENS activates large afferent fibers. Thus, TENS creates a dorsal horn inhibitory nerve stimulation or endorphins releasing or both. In addition, TENS prevents the transmission of pain by activating the descending inhibitory system.^[9] Benefits of using TENS for pain relief include being noninvasive, no undesirable side effects, nontoxic, long-term use, and simplicity of the technique.^[10] Gate control theory of pain, irritation of the skin through a needle, pressure, and massage can stimulate the nerve impulses to the spinal cord fibers to transmit. Consequently, it can immediately inhibit pain transmission gates and decrease pain.^[11] Therefore, the present study aimed to compare TENS and local infiltration of 1% lidocaine on episiotomy complication in primiparous women.

Material and Methods

A randomized, controlled, double-blind clinical trial was conducted from March to July 2011 at the antenatal clinic and post-delivery ward in Social Security Organization Hospital, Khorramabad, Lorestan, Iran.

A pilot study with 10 participants was carried out to calculate the sample size. Sample size was estimated through a simple sample equation, with power of 80% and standard deviation of 1.00. The sample was calculated as 40 participants in each group. The inclusion criteria were age of 18–35 years, prim parity, cephalic presentation, mediolateral episiotomy, and non-use of sedatives over the last 6 hours before labor. The exclusion criteria included labor progress disorders, prolonged second stage of labor of >2 hours, extended episiotomy of >5 cm, conversion of the wound to a 3rd or 4th grade rupture, abnormal vaginal bleeding, shoulder dystocia, placenta retention leading to the manual removal of placenta, hematoma, symptomatic external genital infections, clear neonatal malformation or abnormality in neonates, and no need for episiotomy.

The study was blinded to women and the data analyzing team, however, it was not blinded to investigators. Regarding anesthesia during episiotomy cutting, all participants received 5 cc of local infiltration of 1% lidocaine at the time of fetal crowning. In addition, TENS electrodes (Med 400, Novin Company, Iran) were placed on acupuncture points; He Gu is the 4th point on the Large Intestine meridian and shenmen. Previous studies have confirmed the effect of He Gu acupressure on labor^[12] and episiotomy pain.^[13] In addition, the effect of acupuncture in shenmen point has been confirmed in a previous study.^[13]

The TENS group received TENS with 100 Hz; 250 μ s, the output range was 15–20 mm amplifier from crowning to the end of the episiotomy repairing.^[14] However, they did not receive additional doses of 1% lidocaine.

In the 1% lidocaine group, even though TENS electrodes were placed on both He Gu and shenmen acupuncture

points, the patients did not receive any waves from the TENS electrodes. The participants in this group received 10 cc of local infiltration of 1% lidocaine before episiotomy repair.

The participants were blinded and randomly assigned to the groups. In addition, participants in both the groups received an equal of 1% lidocaine before episiotomy cutting. TENS electrodes could be installed at the same time and same location for participants in both the groups, therefore, the only difference between interventions was the waves in the TENS group while there were no waves in the 1% lidocaine group. Further, 1% lidocaine group received 10 cc of 1% lidocaine whereas a double dose was not injected in the TENS group. Hence, it can be claimed that the differences between the results in the two groups is due to the differences in the type of interventions.

Data were collected using a demographic questionnaire, REEDA scale, and VAS by a trained ward midwife.

REEDA scale includes 5 variables of redness, edema, ecchymosis, discharge, and approximation of wound edges. Each variable was scored between 0 and 3. The total score was calculated by summing the scores of 5 variables, ranging between 0 and 15; higher scores indicated less wound healing.^[15] A study has confirmed the reliability of the REEDA scale ($r = 0.89$) in Iranian population.^[16]

Perineal pain intensity was measured in participants using VAS. Women were asked to score their pain from 0 (no pain) to 10 (worst possible pain) in the VAS.^[17] A study has confirmed the reliability of VAS ($r = 0.676$) in Iranian population.^[18]

After completing the demographic questionnaire and pregnancy-related forms, the participants were transferred to the delivery ward. All participants lay in the lithotomy position as soon as the active phase of the labor started. The participants were randomized into two equal groups (TENS and 1% lidocaine) of 40 participants in each group. Randomization was carried out at the obstetric triage unit using a random-number chart and opaque, sealed, consecutively numbered envelopes as they did in a previously conducted randomized study.^[19]

The primary outcomes were pain intensity while episiotomy cutting, start of the episiotomy repairs, during the episiotomy repair, end of the episiotomy repairs, and 1, 6, and 12 h after the end of the episiotomy repair. The secondary outcomes included the REEDA scale variables as redness, edema, ecchymosis, discharge, and approximation of wound edges.

Permission was obtained for this study from the deputy of research as well as the ethics board of the Tehran University of Medical Sciences (Grant No: 347; 2007).

Data were analyzed in the program SPSS version 16.0 (IBM Cor., Armonk, NY, USA). Independent *t*-test was used for

the following continuous variables: Age, stages of labor, gestational age, weight, height, and newborn's Apgar score. The Chi-square test was used for the analysis of the categorical variables. The level of significance adopted was $P \leq 0.05$.

Ethical considerations

The participation in the study was voluntary and the participants were free to withdraw from the study whenever they wished. After explaining the study objectives to participants, an informed consent was obtained from participants who were eligible and agreed with the study procedures during active phase of labor.

Results

None of the 80 enrolled women withdrew for any reason. Participants' characteristics were not different between the groups ($P > 0.05$). Baseline characteristics of the participants are presented in Table 1.

Study outcome data were available for 100% of the women while episiotomy cutting, start of the episiotomy repairs, during of the episiotomy repair, end of the episiotomy repairs, and 1, 6, and 12 h after end of the episiotomy repair. Comparison of the Mean (SD) intensity of pain in the two groups is presented in Table 2.

The episiotomy incision edema was compared between the two groups using the REEDA scale. The effect of TENS in reducing edema was higher compared with lidocaine. This difference was statistically significant ($P = 0.001$). Results are presented in Table 3.

Discussion

Some side effects of lidocaine as the method of choice for pain reduction in episiotomy led to increase in the tendency to use nonpharmacological methods for pain reduction episiotomy.

The results of the present study showed that, although the TENS and local infiltration of 1% lidocaine have similar effects on pain relief at the episiotomy cutting, the start of the episiotomy repair, and end of the episiotomy repair, the pain relief of both the interventions was different at during of the episiotomy repair.

"Lidocaine alters signal conduction in neurons by blocking the fast voltage-gated Na^+ channels in the neuronal cell membrane responsible for signal propagation."^[20] Several different hypotheses have been proposed regarding TENS mechanism including the gate control, the endorphin-mediated pain relief, and the diffuse noxious inhibitory controls theory.^[8] On the other hand, the half-life of lidocaine is 90–120 minutes in most patients,^[21] however, findings of a recent clinical trial showed that TENS can reduce the pain intensity immediately after its application, and its effect persists an hour after the end of the intervention.^[22] Therefore, several studies

Table 1: Comparison of participants' characteristics in the two groups

Characteristic	Group (n=40)		P
	TENC, Mean (SD)	lidocaine, Mean (SD)	
Maternal age (years)	23.2 (1.5)	24 (1.1)	0.238
Gestational age (days)	39.7 (1)	39.8 (0.9)	0.470
BMI (kg/m ²)	22.3 (1.5)	21.9 (1.8)	0.910
Birth weight (g)	3150.3(410)	3280.3 (300)	0.084
Apgar score <7 at 1 min*	0 (0)	0 (0)	0.249

*N (%); SD:Standard deviation; BMI: Body mass index

Table 2: Comparison of the Mean±standard deviation of intensity of pain between groups

Variables	Group (n=40)		P
	TENS, Mean (SD)	lidocaine, Mean (SD)	
Episiotomy cutting	1.62 (1.14)	2.1 (1.15)	0.129
Start of the episiotomy repair	1.47 (0.93)	1.55 (0.88)	0.623
During of the episiotomy repair	2.7 (0.68)	2.25 (0.83)	0.014
End of the episiotomy repair	2.25 (0.8)	2.5 (0.95)	0.268
1 hour after end of the episiotomy repair	2.05 (0.78)	2.45 (0.78)	0.042
6 hours after end of the episiotomy repair	1.92 (0.58)	2.7 (0.79)	0.000
12 hours after end of the episiotomy repair	1.62 (0.58)	2.8 (0.56)	0.000

Table 3: Comparison of the episiotomy incision edema intensity using the REEDA scale between groups

Variables	Edema intensity	Group (n=40)		P
		TENS*	lidocaine*	
End of the episiotomy repair	Zero	29 (72.5)	3 (7.5)	0.001
	<1 cm	11 (27.5)	30 (75)	
	1-2 cm	0 (0)	7 (17.5)	
1 hour after end of the episiotomy repair	Zero	36 (90)	9 (22.5)	0.001
	<1 cm	4 (10)	28 (70)	
	1-2 cm	0 (0)	3 (7.5)	
12 hours after end of the episiotomy repair	Zero	38 (95)	22 (55)	0.002
	<1 cm	2 (5)	15 (37.5)	
	1-2 cm	0 (0)	3 (7.5)	

*N (%)

have recommended TENS to be a safe and viable nonpharmacological analgesic resource for episiotomy pain relief^[22,23] as well as other pains.^[24-26]

We found a study regarding the effect of He Gu and Shenmen points to relief of episiotomy pain.^[13] However, other studies have evaluated the effect of He Gu point stimulation for pain relief during and after childbirth.^[27,28]

The results of the present study showed that the TENS induced the higher pain relief than local infiltration of 1%

lidocaine at the 1, 6, and 12 h after end of the episiotomy repair. The main point is that the safety of TENS has been confirmed in previous studies.^[21,28]

We find that both TENS and 1% lidocaine has been reduced the episiotomy incision edema intensity in study participants. In addition, the effect of TENS in reducing edema was higher compared with 1% lidocaine. This difference was statistically significant ($P = 0.001$). In line with our results, a randomized controlled trial reported that any participants treated with TENS experience the swelling and edema in their perineum period.^[29]

Several studies showed that massage in the acupuncture points, especially the He Gu and Shenmen stimulate endorphins and relieve pain. On the other hand, massage in acupuncture points induces the cortisol secretion, which has anti-inflammatory properties. Therefore, it can be stated that the secretion of cortisol, is one of the influencing factors for further reduction of edema in the TENS group compared to the lidocaine group.

Conclusion

The TENS and local infiltration of 1% lidocaine have similar effects on pain relief at the episiotomy cutting, the start of the episiotomy repair, and end of the episiotomy repair; however, the pain relief of both interventions was different during the episiotomy repair. In addition, the effect of TENS in reducing edema was higher compared with lidocaine.

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Conflicts of interest

There are no conflicts of interest.

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