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Low and high-frequency TENS in post-episiotomy pain relief: a randomized, double-blind clinical trial

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ABSTRACT | Objective: To evaluate the effectiveness of low-frequency TENS (LFT) and high-frequency TENS (HFT) in post-episiotomy pain relief. **Method:** A randomized, controlled, double-blind clinical trial with placebo composed of 33 puerperae with post-episiotomy pain. TENS was applied for 30 minutes to groups: HFT (100 Hz; 100 μs), LFT (5 Hz; 100 μs), and placebo (PT). Four electrodes were placed in parallel near the episiotomy and four pain evaluations were performed with the numeric rating scale. The first and the second evaluation took place before TENS application and immediately after its removal and were done in the resting position and in the activities of sitting and ambulating. The third and fourth evaluation took place 30 and 60 minutes after TENS removal, only in the resting position. Intragroup differences were verified using the Friedman and Wilcoxon tests, and the intergroup analysis employed the Kruskal-Wallis test. **Results:** In the intragroup analysis, there was no significant difference in the PT during rest, sitting, and ambulation ($P>0.05$). In the HFT and LFT, a significant difference was observed in all activities ($P<0.001$). In the intergroup analysis, there was a significant difference in the resting position in the HFT and LFT ($P<0.001$). In the sitting activity, a significant difference was verified in the second evaluation in the HFT and LFT ($P<0.008$). No significant difference was verified among the groups in ambulation ($P<0.20$). **Conclusions:** LFT and HFT are an effective resource that may be included in the routine of maternity wards.

Keywords: physical therapy; vaginal delivery; postpartum period; transcutaneous electrical nerve stimulation; perineal pain.
Registration Australian New Zealand Clinical Trials Registry: ACTRN12610000529044.

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Introduction

Transcutaneous electrical nerve stimulation (TENS) consists of a non-invasive, easily handled, safe and low-cost resource that sends electrical impulses through the skin[1-3]. It has typically biphasic waves containing positive and negative phases, which may be either symmetric or asymmetric[4], with the main purpose of relieving pain[1-5]. Although its mechanism of electroanalgesia production is still controversial, its effectiveness would be explained by the gate control theory of pain and by the activation of a system of endogenous opioids[1-3,6,7].

Perineal pain is manifested in the postpartum period mostly due to tissue lesions that may occur spontaneously (lacerations) or due to the surgical incision (episiotomy)[8]. Episiotomy is a lesion resulting from a surgical cut to the perineum with scissors or scalpel to help deliver the baby and avoid severe tears that can be difficult to repair. Nevertheless, there is evidence to recommend restricted rather than routine use of episiotomy because the restrictive policy appears to have more benefits[9]. Women submitted to episiotomy have a greater prevalence of pain complaints[10-13] and have difficulty performing functional activities[13,14]. However, despite the recommendations for restrictive use of episiotomy, there is still a high prevalence of this procedure in Brazilian maternities, with rates of up to 60.7%[15], a statistic that supports the development of studies that analyze the techniques that reduce the morbidity caused by this practice.

In the literature, it is possible to verify the use of several pharmacologic and non-pharmacologic resources aimed at reducing pain from perineal trauma[11,14]. The most common resources in obstetric practice include non-hormonal anti-inflammatory drugs applied directly to the perineal trauma site[11],

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oral[8] and rectal[16] analgesics, and non-pharmacologic resources, such as cryoanalgesia[11,17].

Despite the existence of clinical investigations regarding these therapeutic practices in perineal pain[14], there is still a lack of methodological quality and several gaps in the studies regarding their effectiveness. Therefore, new trials are necessary so that decisions can be made regarding the real effectiveness of these modalities. Evaluating the effect of high and low-frequency TENS in post-episiotomy pain relief of puerperae is a great advance for studies in this area and it is justified by the need to broaden the usable resources and behaviors in puerperal care.

Method

This was a randomized, controlled, double-blind clinical trial with placebo carried out with puerperae submitted to post-episiotomy vaginal delivery at a public hospital in Petrolina, Pernambuco, Brazil. Data were collected between August 2009 and July 2010.

The puerperae were included according to the following criteria: (1) low-risk pregnancy; (2) age above 15 years; (3) ability to read, write, and speak in Portuguese; (4) awareness of time and space; (5) between six and 24 hours post-vaginal delivery; (6) midline or mediolateral episiotomy with stitches; (7) post-episiotomy pain; (8) absence of any genitourinary pathology.

The participants who were excluded presented: (1) obesity (Body Mass Index [BMI] $\geq$ 30 kg/m^2); (2) puerperal complications; (3) instrumental delivery (use of forceps); (4) perineal lacerations, (5) epidural anesthesia; (6) use of analgesic resources during data collection.

This study was approved by the Research Ethics Committee of Universidade de Pernambuco (CEP/UPE), Petrolina, PE, Brazil, under protocol number 145/09. All participants and legal guardians, in case of participants under 18 years of age, voluntarily signed an informed consent form.

A pilot test with 12 patients was carried out to verify the comprehension and effectiveness of the data collection instruments and to calculate sample size. Reduction in the pain scores post-intervention was applied as a parameter, considering clinically relevant a reduction of 1.39 points in the numeric rating scale (NRS)[18-22]. Sample size was estimated through simple sample equation, with power of 80% and standard deviation of 1.0, which required a sample size of nine volunteers in each group.

The participants were randomized into groups according to a spreadsheet generated in a computer program by a researcher who was not involved in the selection of participants. Randomization occurred in the order in which each patient was enrolled in the study. It was established that the puerperae should be within six to 24 hours post-vaginal delivery. The minimum limit of six hours post-delivery was determined because this is the period recommended for women to leave their bed, whereas the 24 hours is related to the acute phase of the lesion and the peak of the inflammatory process[12]. In the case of medication use and based on the drug dose, the waiting time was counted from the time when the last dose of analgesic/anesthesia was administered, considering the possible interferences that could cause biases in the initial pain assessment.

The main researcher trained two examiners, one responsible for the pain assessments and for filling out evaluation forms and the other responsible for applying TENS. The device KINESIS New Microcontrolled (KW Eletrônica Ltda., Amparo, SP, Brazil) was used with two pairs of silicone-carbon electrodes (5.5cm × 3cm), hypoallergenic conductive gel, and hypoallergenic microporous surgical tapes (25 mm × 10 m). The device was calibrated before data collection.

TENS was applied to the three study groups: high-frequency TENS (HFT), low-frequency TENS (LFT), and placebo TENS (PT). The electrodes were placed in parallel, near the episiotomy, in the region of the pudendal and genitofemoral nerves, both responsible for the perineal area (Figure 1).

The HFT group received frequency of 100 Hz and 100 μs pulse, and the LFT group received frequency of 5 Hz and 100 μs pulse for 30 minutes. The electrical impulse intensity was controlled by the participants and adjusted when necessary. They were instructed that the sensation of strong and tolerable pulses should remain, although it should be sensorially comfortable. At the end of the application, the researcher recorded the intensity employed by each participant.

The participants of the PT group had their electrodes placed similarly to the HFT and LFT groups, and although the device remained on for 30 minutes with the light on to simulate it was working, it did not send any electrical stimulation. At the end of the study, due to ethical reasons, the participants in the PT group were offered HFT to treat the pain. HFT was chosen because it has already been used in a previous study[14] with effective results.

Data collection forms were filled out with the profile of the puerperae, obstetric procedures and

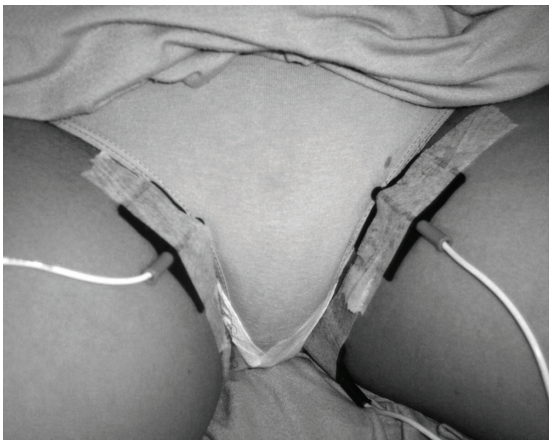

Figure 1. Schematic representation of the positioning of the electrodes.

history, labor and newborn data. Afterwards, four pain assessments were performed. The initial evaluation took place prior to the use of TENS. The participants were questioned regarding the pain from episiotomy and those that mentioned the presence of pain answered the NRS (in the resting position) regarding the movements of sitting and ambulating. At the end of this stage, TENS was applied to the three groups.

The second evaluation began immediately after the removal of TENS. The NRS was applied once again (in the resting position) regarding the sitting and ambulating movements. A questionnaire was applied to the three groups regarding the TENS, with the following questions: (1) is TENS comfortable or uncomfortable?; (2) would you use it again?; (3) were you dissatisfied, slightly satisfied, satisfied or very satisfied?

The third evaluation was performed 30 minutes after removing TENS, and the fourth evaluation was performed 60 minutes after removing TENS. These evaluations measured pain through the NRS only in the resting position.

Data were analyzed in the program SPSS version 16.0. The Kruskal-Wallis test and Dunn's post-test were used for the following continuous variables: age, number of pregnancies, deliveries, abortions, number of prenatal appointments, gestational age, weight, height, and newborn's Apgar score. The chi-square test was used for the analysis of the categorical variables: marital status, ethnicity, education, occupation, prenatal care, pudendal block, episiotomy, gender, use of pain relief resources, type of pain relief resource. Intragroup differences in the pain assessments were verified through Friedman's test for the resting position, and Wilcoxon's test for the sitting and ambulating activities. In the intergroup analyses, Kruskal-Wallis's test was employed. The level of significance adopted was $p \leq 0.05$.

Results

Out of the 50 patients evaluated for eligibility in this study, 16 were excluded because they did not meet the inclusion criteria, and one was excluded from randomization, totaling 33 evaluated puerperae (Figure 2). The three groups were homogenous as to sociodemographic variables: age (P=0.10), marital status (P=0.41), ethnicity (P=0.37), education (P=0.10) and occupation (P=0.20); obstetric and labor variables: prenatal care (P=1.00), number of appointments attended (P=0.47), number of pregnancies (P=0.51), deliveries (P=0.62), miscarriages (P=0.89), gestational age (P=0.56), type of episiotomy (P=0.34); and neonatal variables: gender (P=0.31), weight (P=0.09), height (P=0.20) and Apgar score in the first minute (P=0.21) and the fifth minute (P=0.08). Among the pain relief resources used by the participants, non-pharmacological therapeutic methods were not observed, but oral dipyrone was taken by 65.6% (n=21) of the participants (P=0.64).

The initial mean of pain intensity was similar in the three groups. In the intragroup analysis, there was no significant difference in the PT group regarding pain intensity in the resting position and in the activities of sitting and ambulating in any evaluation (P>0.05). In the HFT and LFT groups, in the resting position, a significant difference was observed between the first and all following evaluations, and between the second and the third and fourth evaluations (P<0.001). There was also a significant difference in the sitting and ambulating activities (P<0.001).

In the results of the intergroup analysis, there was a significant difference in the resting position in the comparison among the groups in the second (P<0.046), third (P<0.001), and fourth (P<0.001) evaluations, evidencing the reduction in pain scores in the HFT and LFT groups. In the sitting activity, a significant difference was verified in the second evaluation, indicating reduction in the pain scores of the HFT and LFT groups when compared to the PT group (P<0.008). No significant difference was verified among the three groups while ambulating (P<0.20; Table 1). The amplitude in the HFT group was 21.77±2.11 mA with variation between 19 and 26 mA, whereas in the LFT group it was 24.08±2.55 mA with variation between 21 and 30 mA.

In the HFT and LFT groups, 100% of the puerperae referred to TENS as comfortable and

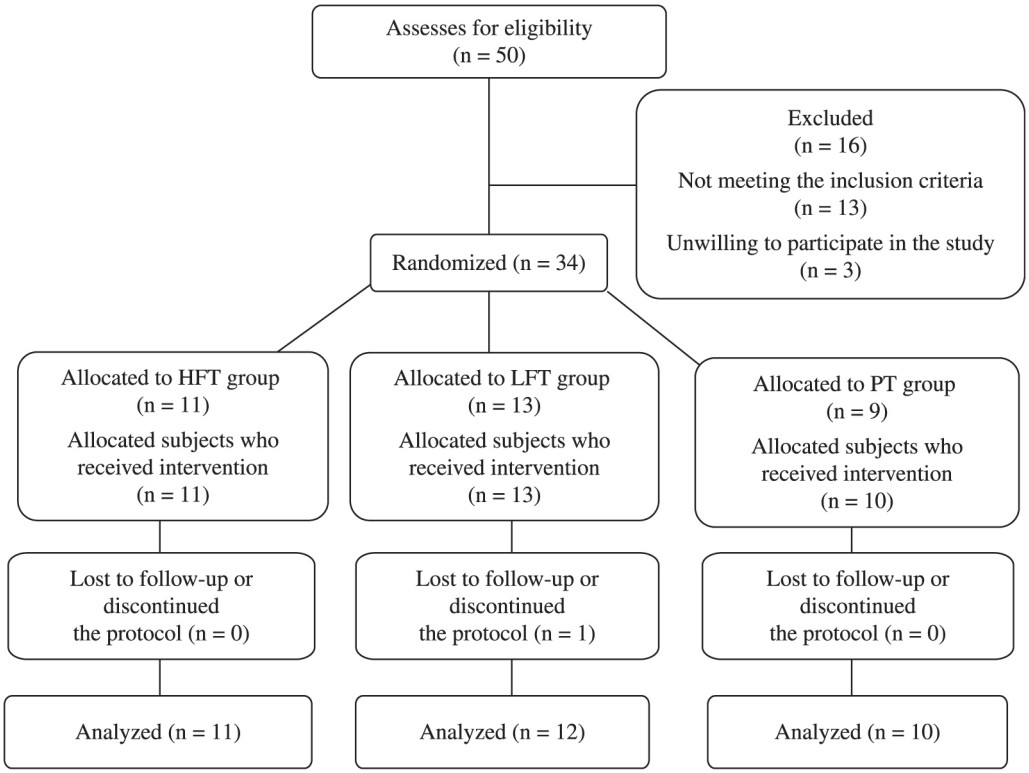

Figure 2. Flow diagram of the included patients.

Table 1. Post-episiotomy pain intensity.

	Mean (SD)			
	Group HFT (n = 11)	**Group LFT (n = 12)**	**Group PT (n = 10)**	**P-value**
First evaluation				
Rest	4.54±2.38[a,b,c]	4.50±2.02[a,b,c]	4.11±1.69	.940
Sitting	6.81±1.60[a]	6.08±1.88[a]	6.77±1.78	.504
Ambulating	6.18±2.31[a]	5.66±2.57[a]	5.44±1.87	.695
Second evaluation				
Rest	1.72±2.19[d,e,f]	2.25±1.60[d,e,f]	3.88±2.08	.046
Sitting	3.18±2.04[f]	3.75±1.65[f]	6.44±2.18	.008
Ambulating	3.36±2.33	3.83±2.16	5.22±2.16	.208
Third evaluation				
Rest	0.81±1.66[f]	1.66±1.43[f]	4.44±2.18	.001
Fourth evaluation				
Rest	0. 27±0.64[f]	1.16±1.46[f]	4.11±2.20	.001

P<0.05. Data are reported as mean (SD). [a]Intragroup difference between the first and second evaluation. [b]Intragroup difference between the first and third evaluation. [c]Intragroup difference between first and fourth evaluation. [d]Intragroup difference between second and third evaluation. [e]Intragroup difference between second and fourth evaluation. [f]Intergroup difference HFT and LFT vs. PT. Columns: intragroup analysis. Rows: intergroup analysis. Intragroup analysis - P values: HFT and LFT<0.001. PT>0.05. Intragroup analysis - Rest: Friedman test. Sitting and Ambulating: Wilcoxon test. Intergroup analysis: Kruskal-Wallis. HFT, high frequency TENS. LTF, low frequency TENS. PT, placebo TENS.

stated they would use it again, whereas in the PT group, the answers were 89% (n=8) and 56% (n=5), respectively. Regarding the satisfaction with the use of TENS, 45% (n=5) of the participants in the HFT group stated they were satisfied and 45% (n=5) very satisfied, whereas in the LFT group 75% (n=9) were satisfied and 17% (n=2) very satisfied. As for the PT group, 45% (n=3) mentioned they were satisfied and 11% (n=1) were very satisfied.

Discussion

These findings suggest that both HFT and LFT cause clinically relevant reduction in pain intensity immediately after its application, with a residual effect lasting for one hour after use. TENS in the HFT and LFT groups reduced the intensity of initial pain scores, measured as moderate in both groups, and later as weak.

In the four evaluations performed in the resting position, in the HFT group, there was pain reduction measured by the NRS (4.54/10; to 1.72/10; to 0.81/10; to 0.27/10), and this pattern was also observed in the LFT group (4.50/10; to 2.25/10; to 1.66/10; to 1.16/10). In the sitting activity, the pain intensity scores decreased from the first to the second evaluation in the HFT group (6.81/10 to 3.18/10) and in the LFT group (6.08/10 to 3.75/10).

Similar data were observed in the ambulating activity, evidencing the reduction in pain scores in both groups, HFT (6.18/10 to 3.36/10) and LFT (5.66/10 to 3.83/10). No significant difference was verified in the pain score of the PT group in any evaluation.

Therefore, it is clear that both HFT and LFT reduced the levels of pain in the resting position. In both groups that employed TENS, there was a clinically relevant difference in the intragroup analysis in all situations evaluated, i.e. TENS reduced pain in the puerperae by more than 1.39 units in the NRS, which is considered a relevant value for moderate pain intensity[18,19,21,22].

In all evaluations the reduction in pain scores was higher than 1.8 units in the NRS, which is considered a significant value for severe pain. In the HFT group, all scores were higher than 2.4, indicating great improvement in the pain treatment[20].

In the intergroup analysis, there was a significant difference in the pain scores in the resting position between the HFT and LFT groups *versus* the PT group in the second, third, and fourth evaluation. There was also a significant difference in the second evaluation in the sitting activity, however, there was no difference among the three groups in the ambulating activity.

Similarly to this study, other authors observed a reduction in the post-operative pain score after the application of TENS through the NRS[14,23,24]. Nevertheless, the exact mechanism of action of TENS in different conditions of pain is still uncertain[1,25,26].

Studies suggest that the analgesic effect obtained by LFT and HFT may be produced by the interference of the therapeutics in the blocking of the transmission of the nociceptive input at the level of the spinal cord through the activation of δ-opioids and $GABA_A$ receptors, subsequently reducing input through the spinothalamic tract[3,27-29]. LFT would induce the antihyperalgesia mediated by the release of serotonin and δ-opioid receptors in the spinal cord dorsal horn, whereas HFT would release δ-opioid receptors[27-29].

Furthermore, it is important to make the right adjustment to the position of the electrodes and the intensity of the electric stimulation to ensure ideal pain relief. Normally, there may be differences in the intensity of the stimulation between HFT and LFT. HFT is applied at the level of sensorial stimulation and LFT at the motor level[1,3]. In HFT, the stimulation must be increased until the point that the patient feels a comfortable tingling sensation, being increased until the maximum level tolerated by the patient without being harmful, whereas in LFT, the patient will report the sensation of "tapping", but with no muscle contraction[1,30].

In the present study, the electrodes were placed in parallel near the episiotomy site, thus, the current generated paresthesia in the entire perineal area, relieving the pain. In general, HFT is applied at low intensities and LFT at high intensities[1], and some authors suggest that the amplitude of the current must be over 15 mA[31]. Agreeing with the literature, in this study the puerperae of the LFT group was submitted to higher intensities than those of the HFT group and, the amplitude of the stimulation in the groups varied between 19-30 mA.

Except for some reports of uncomfortable stimulation, TENS has no acute side effects. In the long term, an adverse effect that may be observed in some patients is skin irritation[32]. However, no side effect was verified in this study, and the authors believe this fact may be explained by the short time of application (30 minutes). Similar results were found by other studies also with no side effects resulting from the use of TENS[14,23,31].

Several authors state that TENS is more effective when applied at lower intensities of pain than in severe pain[23], and its application is indicated when the pain intensity varies from weak to moderate[33], a

situation analyzed in this study. Despite the fact that the results have showed the effectiveness of TENS, it is important to highlight that the evaluation of its effect lasted one hour after its application, and the authors suggest that future studies verify the residual effect of TENS for longer periods.

Regarding the effect of TENS during movement and in functional activities, authors confirm the improvement of pain scores in ambulation[6,14], respiratory function, and movement[6]. In the intragroup analysis of this study, pain decreased significantly in all activities, i.e. resting, sitting, and ambulating. However, when comparing HFT and LFT groups to the PT group, there was no difference observed in the ambulating activity, which may have resulted from the influence of other variables of the pain complaint.

Regarding patient satisfaction, in the HFT and LFT groups, 100% of the puerperae reported that they found TENS comfortable and they would use it again, and in the PT group most of the patients confirmed these findings as well. Hence, it is possible to observe that even though there was a confirmed reduction in pain scores only in the groups that used active TENS and a higher percentage of puerperae claimed to be satisfied with the treatment in these groups, good satisfaction levels were also observed in the PT group, a fact that was also verified in other studies[24].

Unfortunately, it is not possible to know the influence of the placebo effect on the satisfaction of these patients, since the referred satisfaction could be associated with the attention offered by the professionals to these women during collection. However, it is possible to guarantee that in this study an appropriate methodology was used with placebo and the blinding of the patients.

Some limitations may be found in this study. Due to the routine of the service, ethical aspects and practical reasons of the collection, it was not possible to verify the use of drugs by the puerperae after the application of TENS. Other limitations are related to the sample size and the duration of follow-up in the effect of TENS (one hour after its application), thus the authors suggest the development of future studies with larger samples aimed at verifying the benefits of this treatment for longer periods.

Conclusion

HFT and LFT are safe and effective resources without side effects and presenting good acceptance, which may be included in the routine of maternity wards, thus contributing to the improvement of the care provided to puerperae.

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