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Research

Transcutaneous electrical nerve stimulation (TENS) reduces pain and postpones the need for pharmacological analgesia during labour: a randomised trial

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KEY WORDS

Transcutaneous electrical nerve stimulation
Labour pain
Analgesia
Randomised controlled trial
Physical therapy modality

ABSTRACT

Questions: In the active phase of the first stage of labour, does transcutaneous electrical nerve stimulation (TENS) relieve pain or change its location? Does TENS delay the request for neuraxial analgesia during labour? Does TENS produce any harmful effects in the mother or the foetus? Are women in labour satisfied with the care provided? **Design:** Randomised trial with concealed allocation, assessor blinding for some outcomes, and intention-to-treat analysis. **Participants:** Forty-six low-risk, primigravida parturients with a gestational age > 37 weeks, cervical dilation of 4 cm, and without the use of any medications from hospital admission until randomisation. **Intervention:** The principal investigator applied TENS to the experimental group for 30 minutes starting at the beginning of the active phase of labour. A second investigator assessed the outcomes in both the control and experimental groups. Both groups received routine perinatal care. **Outcome measures:** The primary outcome was pain severity after the intervention period, which was assessed using the 100-mm visual analogue scale. Secondary outcomes included: pain location, duration of the active phase of labour, time to pharmacological labour analgesia, mode of birth, neonatal outcomes, and the participant's satisfaction with the care provided. **Results:** After the intervention, a significant mean difference in change in pain of 15 mm was observed favouring the experimental group (95% CI 2 to 27). The application of TENS did not alter the location or distribution of the pain. The mean time to pharmacological analgesia after the intervention was 5.0 hours (95% CI 4.1 to 5.9) longer in the experimental group. The intervention did not significantly impact the other maternal and neonatal outcomes. Participants in both groups were satisfied with the care provided during labour. **Conclusion:** TENS produces a significant decrease in pain during labour and postpones the need for pharmacological analgesia for pain relief. **Trial registration:** NCT01600495. **[Santana LS, Gallo RBS, Ferreira CHJ, Duarte G, Quintana SM, Marcolin AC (2016) Transcutaneous electrical nerve stimulation (TENS) reduces pain and postpones the need for pharmacological analgesia during labour: a randomised trial. *Journal of Physiotherapy* 62: 29–34]**

Introduction

Pain during labour is the most intense pain that many women will experience during their lives, and it can be influenced not only by the anatomical and physiological factors of the labouring women, but also by their psychological experiences, as well as cultural, social, and environmental factors.[1–3] Labour pain is associated with adverse physiological consequences for the parturient, the progress of labour, and the well-being of the foetus. The potential effects of labour pain may include: increased oxygen consumption and hyperventilation resulting in hypocarbia and respiratory alkalosis, as well as stimulation of the autonomic nervous system and catecholamine production, which causes increased peripheral vascular resistance, cardiac output and blood pressure; decreased placental perfusion; and unco-ordinated uterine activity.[4,5] During labour, pain should always be relieved in order to reduce its deleterious effects.

Neuraxial analgesia during labour is the most effective method for pain relief, but it appears to be associated with certain side effects, such as maternal hypotension, decreased uteroplacental perfusion, foetal bradycardia, fever, pruritus, an increased oxytocin requirement, a prolonged second stage of labour, a higher rate of operative delivery, and high costs.[5–10] In contrast, many non-pharmacological methods of pain relief appear to be safe, non-invasive, easily applicable and inexpensive.[2,11,12] They have few contraindications and can postpone the use of pharmacological analgesics and their associated adverse results.[2,11,12] Furthermore, many non-pharmacological methods of managing pain increase the satisfaction of women with their childbirth experience. [2,11,12]

Transcutaneous electrical nerve stimulation (TENS) is a non-pharmacological method of labour analgesia that has been used for over 30 years in European countries. Through electrodes applied to the lower back, the parturient can control both the frequency and intensity of the low-voltage electrical impulses emitted from the

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TENS device. The mechanisms by which TENS relieves pain are uncertain, although studies have shown that it has no harmful effects on either the mother or the foetus.[13–16] In current clinical practice, TENS is used to reduce pain during the initial phases of labour and to delay the need for pharmacological interventions. Despite the widespread use of TENS and its potential advantages for the relief of labour pain, evidence from systematic reviews has been inconsistent in demonstrating clear benefits of this method.[10,15,17] In particular, the Cochrane review of trials of TENS used in labour found no information on the use of TENS in very early labour.[15]

Therefore, the research questions for this randomised trial were:

1. In the active phase of the first stage of labour, does TENS relieve pain or change its location?
2. Does TENS delay the request for neuraxial analgesia during labour?
3. Does TENS produce any harmful effects in the mother or the foetus?
4. Are women in labour satisfied with the care provided?

Method

Design

This was a randomised trial with concealed allocation, assessor blinding for some outcomes, and intention-to-treat analysis. The principal investigator (LSS) randomly assigned the eligible women to an experimental group or a control group, according to a computer-generated random assignment list. When 4 cm of cervical dilation and uterine contractions were achieved, the principal investigator applied TENS continuously for 30 minutes to the participants in the experimental group. A second investigator (RBSG) remained blinded to group allocations and was never present while the experimental or control procedures were performed by the principal investigator and obstetricians of the centre at which the study was conducted. The second investigator recorded each participant's responses regarding the pain severity and location immediately before and after the intervention. Blinding was maintained by having the second investigator leave the room after assessing the pain-related outcomes at baseline and returning to reassess the same outcomes after the intervention. All participants were instructed not to make any comments regarding the type of treatment that they received. After labour and before hospital discharge, the second investigator collected the data regarding obstetric and neonatal outcomes and also recorded the opinion of the participants regarding the treatment that they received during the study period.

Participants, therapists and centre

All participants were recruited from a group of women admitted to the Reference Centre of Women's Health of Ribeirão Preto (MATER), state of São Paulo, Brazil, from September 2011 to January 2013. This is a 40-bed unit that serves approximately 3600 low-risk pregnant women per year in Brazil's public health system. The aim and methodology of the study was explained to all recruited women and voluntary participation was requested.

The eligibility criteria included: primigravida parturients with a low-risk pregnancy; a gestational age $>$ 37 weeks; a single foetus in the cephalic position; spontaneous onset of labour; cervical dilation of 4 cm; appropriate uterine contractions; intact ovular membranes; no use of oxytocin or other medications from hospital admission until randomisation; and literacy, including the ability to understand the study. Participants were free to withdraw from the study if they could not tolerate the allocated intervention or if they declined further participation at any stage.

The principal and secondary investigators involved in the intervention and data collection were both physiotherapists and had held specialisations in women's health since early 2008. During the study, to reduce bias, the methods of pain assessment during labour were standardised, and the therapists used the same method for all participants. The principal investigator performed the randomisation and the application of the interventions (TENS or routine obstetric care), while the secondary investigator assessed the outcomes.

Intervention

A portable TENS unit[a] was used by the principal investigator to apply the experimental intervention. Two pairs of electrodes measuring 5 x 9 cm were fixed on the paravertebral regions of the participants of the experimental group using hypoallergenic surgical tape. Two paired electrodes were placed 1 cm laterally on either side of the spine at the T10 to L1 and S2 to S4 levels, because these are the spinal levels that ultimately receive the nociceptive information from the uterus, birth canal, and perineum.[18] This group received TENS continuously for 30 minutes starting at the beginning of the active phase of labour (4 cm of cervical dilation). The TENS unit produces a modified biphasic asymmetric pulse, and was set to a pulse width of 100 μs and a frequency of 100 Hz. The intensity was individually titrated according to the sensitivity of the parturient.

The principal investigator also attended participants in the control group for 30 minutes at the beginning of the active phase of labour, as performed for the experimental group, although the investigator was present merely for observation and to answer questions.

Participants in both groups received all other routine obstetric care. In the centre in which the study was conducted, routine obstetric care during the active phase of labour is based on the recommendations of the World Health Organization.[19] After admission to the hospital, a meal was offered to the participants, and resources for pain relief were permitted, if requested by the participant. Such resources included a shower, bath, and neuraxial labour analgesia. In addition, the participants were also instructed to choose the most comfortable position. The presence of an accompanying person was permitted during labour and delivery.

Outcome measures

Primary outcome

The primary outcome was the change in pain severity at the end of the intervention period. The instrument used to measure the severity of pain before and after the intervention was the visual analogue scale (VAS). In the VAS, pain severity is marked by the participant on a scale with a range from 1 to 100 mm, in which 1 represents no pain and 100 represents the most painful situation experienced. A change of 13 mm was nominated as a reduction in acute pain that would be enough to make the simple application of TENS worthwhile.[20,21]

To qualitatively assess the pain experienced by the participants, the classification system described in the study by Jensen and colleagues was used: 100-mm VAS ratings of 0 to 4 mm were considered no pain; 5 to 44 mm, mild pain; 45 to 74 mm, moderate pain; and 75 to 100 mm, severe pain.[22]

Secondary outcomes

The location and distribution of the pain were recorded using a standard body diagram, which consisted of a simple graphical representation of the front and back views of the human body. The areas of pain were noted by the participant and marked on the diagram by the second investigator.

The second investigator also collected obstetric and neonatal outcomes. The obstetric outcomes included the duration of the active phase of labour, time taken for the parturient to request neuraxial labour analgesia after the end of the intervention period, and mode of birth. The neonatal outcomes included the weight, head circumference, chest circumference, and first-minute and

fifth-minute Apgar scores. Twenty-four hours postpartum, the second investigator asked participants to answer questions regarding their satisfaction with the care provided and if they would prefer to receive the same type of care in the future.

The primary researcher recorded the posture adopted by each participant during the intervention. More than one position could be recorded.

Data analysis

After approval of the study by the ethics research committee, a pilot study was conducted with 16 parturients to determine the appropriate sample size. The objective of this test was to determine the standard deviation of the pain severity on the VAS. The goal was to power the study to detect an effect on pain of approximately 13 mm. Using the standard deviation of 15 mm obtained from the pilot data, a significance level of 5% and a test power of 80%, it was calculated that a minimum of 22 participants were required for each group. Few dropouts were anticipated so 46 participants were recruited to allow for loss to follow-up of two participants.

The values for each variable were summarised as mean (SD) or number (%) as appropriate. For pain assessment, a comparative analysis was performed between the experimental and control groups using a linear regression model with mixed effects (random and fixed effects). For dichotomous outcomes, the differences between groups are presented as the relative risk with a 95% CI.

Results

Flow of participants and therapists through the study

The flow of participants through the trial is shown in Figure 1. A total of 283 parturients were assessed, and 237 who did not meet the inclusion criteria were excluded. Forty-six participants were included in the study and were enrolled into the two arms of the study: the experimental group (n = 23) and the control group (n = 23). Each participant received the intervention that was randomly allocated to her. There was no loss to follow-up of participants for any reason. No participant asked to leave the study before completion.

The baseline characteristics of the participants in each group are presented in Table 1. The groups were similar with regard to maternal age, weight, height, body mass index, educational status, marital status, presence of a person during labour, participation in a childbirth preparation course, and uterine dynamics.

Effect of intervention

On the VAS of pain severity, the experimental group improved by a mean of 11 mm (SD 18) from baseline to the end of the intervention. The control group showed a small increase in pain intensity of 4 mm (SD 16). Thus, the effect of TENS can be estimated as −15 mm (95% CI −27 to −2 mm) on the VAS, as shown in Table 2. When pain was qualitatively analysed by the VAS rating, 69% of the control group and 70% of the experimental group

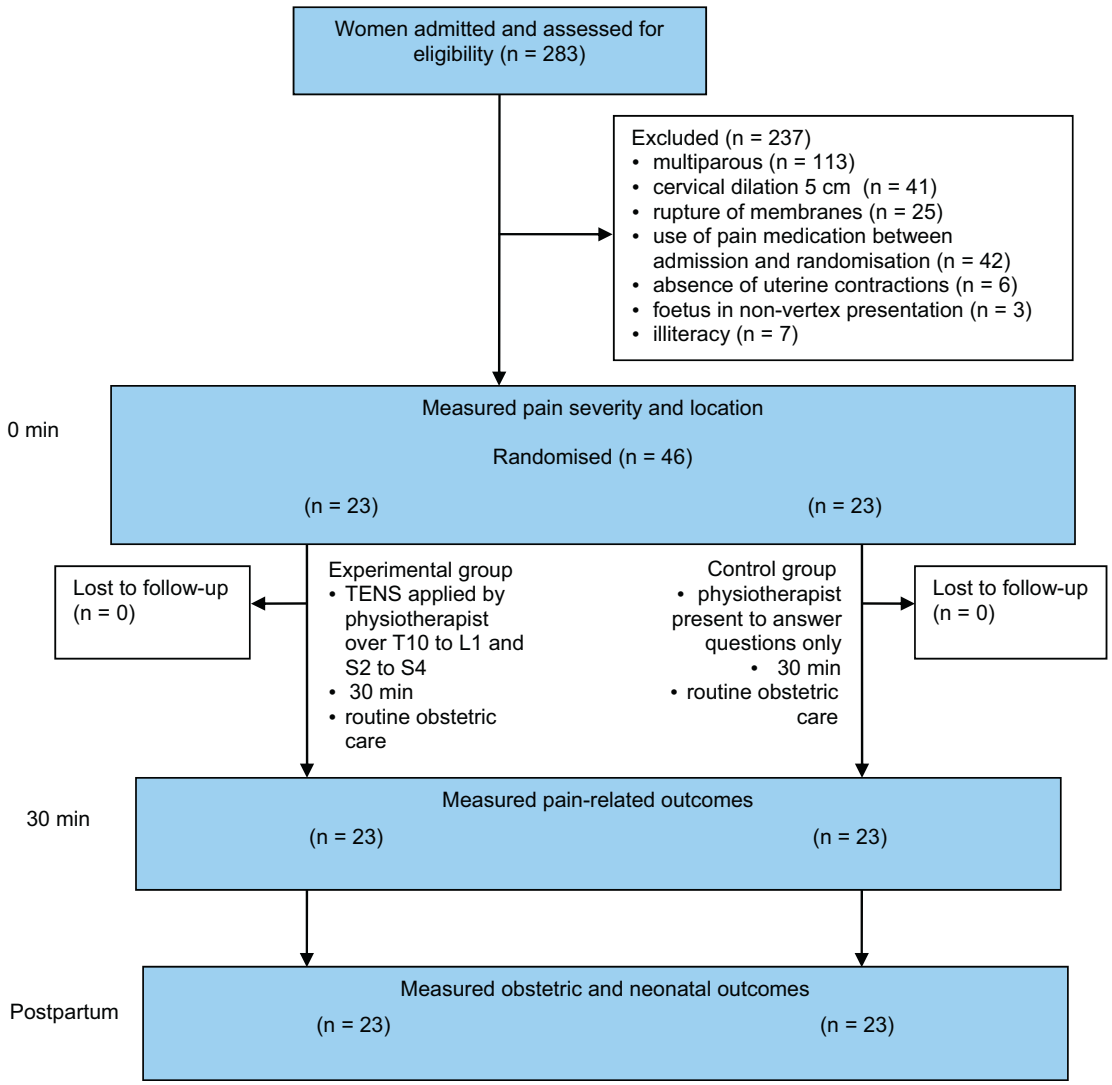

Figure 1. Recruitment and flow of participants through the trial.

Table 1
Baseline characteristics of the participants.

Characteristic	Participants	
	Exp (n = 23)	Con (n = 23)
Maternal age *(y)*, mean (SD) range	20 (4) 18 to 21	20 (4) 18 to 21
Weight *(kg)*, mean (SD)	71 (12)	71 (9)
Height *(m)*, mean (SD)	1.59 (0.10)	1.61 (0.10)
BMI, mean (SD)	28.0 (3.9)	27.6 (3.3)
Skin colour, n (%)		
Caucasian	14 (61)	13 (56)
other	9 (39)	10 (44)
Marital status, n (%)		
single	10 (43)	7 (30)
with partner	13 (57)	16 (70)
Educational level *(y)*, n (%)		
≤ 8	8 (35)	6 (26)
> 8	15 (65)	17 (74)
Accompanying person during the active phase of labour, n (%)	23 (100)	23 (100)
Childbirth preparation course	3 (13)	6 (26)
Uterine contractions at the moment of enrolment *(n in 10 min)*, n (%)		
2	7 (30)	6 (26)
3	13 (57)	15 (65)
4	3 (13)	2 (9)

BMI = body mass index, Exp = experimental group, Con = control group.

classified the pain as ≥ 7 before the intervention. After the intervention, 34% of the experimental group rated the pain as ≥ 7, as opposed to 83% of the control group, demonstrating a statistically significant reduction of pain during labour (RR 0.42, 95% CI 0.23 to 0.76). This result equates to a 'number needed to treat' statistic (NNT) of 2 (95% CI 1 to 5), which means that for every two women treated with TENS, one will report pain as < 7 who would otherwise have reported pain as ≥ 7.

An analysis of the pain location and distribution according to the body diagram demonstrated that before the intervention, 18 (78%) parturients in the experimental group and 16 (70%) in the control group reported pain both in the suprapubic and lumbar regions. After the intervention period, 10 (43%) participants in the experimental group and 15 (65%) in the control group reported suprapubic and lumbar pain. Despite the apparent decrease in the percentage of participants in the experimental group who reported pain in those areas, no significant between-group difference was observed (RR 0.49, 95% CI 0.2 to 1.1).

The mean duration of labour was 6.5 hours (SD 2.3) in the experimental group and 5.7 hours (SD 1.5) in the control group. The mean difference was 0.8 hours, with no significant difference between groups (95% CI −0.3 to 2.0). The mean time to neuraxial analgesia after the end of the intervention was 7.0 hours (SD 1.7) in the experimental group and 1.9 hours (SD 1.2) in the control group. The mean between-group difference was 5.1 hours, which statistically significant (95% CI 4.1 to 5.9). Therefore, TENS postponed the need for pharmacological analgesia for pain relief during the active phase of labour. The parturients in the experimental group were more likely to have adopted a left lateral decubitus position during the intervention period than those in the control group (RR 10.0, 95% CI 1.4 to 72.0). These results are shown in Tables 3 and 4. For individual participant data, see Table 5 on the eAddenda. The mode of birth was similar between the groups. The high rates of vaginal births in both the experimental and the control groups are noteworthy, but the groups did not differ significantly (RR 1.1, 95% CI 0.8 to 1.4).

All anthropometric measures of the newborns are presented in Tables 3 and 4. The mean newborn weight and head and chest circumference were not significantly different between groups. The mean newborn weight was greater in the experimental group, as opposed to the chest circumference, which was smaller than that of the control group. In both groups, approximately 90% of the newborns had Apgar scores > 7 by the first minute after birth, and all had normal scores by the fifth minute after birth.

No significant between-group differences were observed regarding the labour experience and satisfaction with the care provided during labour. Regarding the experience of the participants during labour, 78% of the parturients in the experimental group and 74% of the control group described it as terrible. However, all participants stated that the quality of care provided by a physiotherapist during labour was very important. The intervention was classified as excellent by 74% of the participants in the experimental group and 70% in the control group. Those women reported relief of pain, stress, and anxiety during labour. All parturients in the experimental group and 94% of the control group stated that they would prefer to receive the same type of care during future childbirths.

Discussion

The results of this study have demonstrated that the use of TENS at the beginning of the active phase of labour produces a significant

Table 2
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for pain assessed by the Visual Analogue Scale.

Outcome	Groups				Difference within groups		Difference between groups
	0 min		30 min		30 min minus 0 min		30 min minus 0 min
	Exp (n = 23)	Con (n = 23)	Exp (n = 23)	Con (n = 23)	Exp	Con	Exp minus Con
Pain *(mm)*	68 (15)	69 (17)	57 (24)	73 (15)	−11 (18)	4 (16)	−15 (−27 to −2)

Exp = experimental group, Con = control group.
Shaded row = primary outcome.

Table 3
Mean (SD) for each outcome in each group and mean difference (95% CI) between groups for continuous obstetric and neonatal outcomes.

Outcome	Groups		Mean difference between groups Exp minus Con
	Exp (n = 23)	Con (n = 23)	
Duration of labour *(hr)*, mean (SD)	6.5 (2.3)	5.7 (1.5)	0.8 (−0.3 to 2.0)
Time from the end of the intervention until neuraxial analgesia was requested *(hr)*, mean (SD)	7.0 (1.7)	1.9 (1.2)	5.1 (4.1 to 5.9)
Newborn weight *(kg)*, mean (SD)	3.2 (0.3)	3.2 (0.3)	0.1 (−0.1 to 0.3)
Newborn length *(cm)*, mean (SD)	49.0 (1.5)	49.3 (1.7)	−0.2 (−1.2 to 0.7)
Newborn head circumference *(cm)*, mean (SD)	34.4 (1.6)	34.6 (1.7)	−0.2 (−1.2 to 0.8)
Newborn chest circumference *(cm)*, mean (SD)	33.0 (1.3)	33.1 (1.6)	−0.1 (−0.9 to 0.8)

Exp = experimental group, Con = control group.

Table 4
Number of participants (%) for each outcome in each group and relative risk (95% CI) between groups for dichotomous obstetric and neonatal outcomes..

Outcome	Groups		Relative risk (95% CI)
	Exp (n = 23)	Con (n = 23)	Exp relative to Con
Position adopted during intervention, n (%)			
sitting	8 (35)	10 (45)	0.8 (0.4 to 1.6)
lateral decubitus	10 (44)	1 (4)	10.0 (1.4 to 72.0)
dorsal decubitus	4 (17)	9 (39)	0.44 (0.2 to 1.2)
sitting and dorsal decubitus	0 (0)	1 (4)	NC
sitting and lateral decubitus	0 (0)	1 (4)	NC
lateral and dorsal decubitus	1 (4)	1 (4)	1.0 (0.1 to 15.0)
Path of delivery, n (%)			
Caesarean delivery	2 (9)	4 (17)	0.5 (0.1 to 2.5)
vaginal delivery	21 (91)	19 (83)	1.1 (0.8 to 1.4)
Apgar Score of newborn *(0 to 10)*, n (%)			
> 7 at first minute	20 (87)	20 (87)	1.0 (0.8 to 1.2)
> 7 at fifth minute	23 (100)	23 (100)	NC

Exp = experimental group, Con = control group, NC = not calculable.

decrease in pain. However, the application of TENS does not alter the location or distribution of the pain. Beyond pain relief, this study showed that the mean time until the participants requested neuraxial labour analgesia after the end of the intervention was greater in the experimental group, and no impact of the intervention on maternal or neonatal outcomes was observed.

The findings of the present study are similar to those of previous studies. Bundsen et al,[23] Van der Spank et al,[13] and Chao et al[14] reported a significant reduction in pain intensity in the TENS group. However, the methods of those studies are very different from those of the present study. The Bundsen study included patients undergoing induction of labour and receiving TENS at two different locations simultaneously during labour. Van der Spank et al adopted different TENS parameters. Chao et al investigated the efficacy of TENS in relieving pain during labour at specific acupuncture points.

In contrast, controlled clinical trials have questioned the effectiveness of TENS for pain relief during labour. Thomas et al[24] and Labrecque et al[25] evaluated the impact of TENS applied to the lower back and compared their results with those achieved with a TENS placebo or no intervention. No significant difference in pain relief was found in any of the studies. A meta-analysis published by Carroll et al[17] showed conflicting results related to pain relief when eight controlled clinical trials involving 712 women were analysed. No significant difference in pain relief was found, although three studies noted improvements in secondary outcomes, such as a reduction of additional analgesic interventions. We propose that the discrepancies between the findings of those studies and the present study could be explained by methodological differences between the studies and by differences in obstetric care. Many studies had small sample sizes, unbalanced groups, or various outcomes and measurement scales for the assessment of pain.

Although several studies have not provided any evidence of significant differences in pain relief, many of their participants have stated that they would prefer to use TENS for future labour. A systematic review by Bedwell et al[16] included 14 randomised, controlled trials comparing women receiving TENS during labour versus routine care or placebo devices. The authors demonstrated little difference in satisfaction with pain relief or in pain ratings between the TENS and control groups. However, approximately two-thirds of women who received TENS reported that they would prefer to use it again for future labour. In the present study, 74% of the parturients in the experimental group reported being satisfied with TENS, and 100% of them would prefer to use this method again for future childbirths.

Few of the trials of TENS in labour have been conducted with full regard to the use of pharmacological analgesia, and most of them have suggested no significant differences in the ratio of women who receive neuraxial analgesia in the control and experimental groups.[23,25–27] These data are similar to those obtained in the present study. However, the present results also show that the mean time until pain medication was requested after the end of the intervention was greater in the experimental group. Therefore, TENS postponed the need for pharmacological analgesia for pain relief during labour, as also observed by de Orange et al.[28] However, readers should be aware that de Orange et al defined the time of pharmacological pain relief as the time at which women reported a pain level of 6 on the VAS.

In the present study, the mode of birth was similar between groups. Unfortunately, most previous studies did not report information on maternal and neonatal outcomes.[15,16] Few studies have found a lack of significant differences between groups regarding the mode of delivery, as demonstrated by the present results.[23,25,28,29] A meta-analysis published by Bedwell et al[16] included two studies that reported information on foetal distress.[23,28] No statistically significant between-group differences were observed. Ratna and Rekha[29] did not report any significant differences between the Apgar scores of neonates in their two experimental groups. Our results are consistent with those that confirm that TENS has no deleterious effects on the foetus. These findings are also similar to those of the Cochrane review performed by Dowswell et al.[15]

Although the present study was a randomised trial in which the random allocation of participants allowed for control of confounding factors, some methodological limitations were still present. The findings may have been more conclusive if TENS had been applied for more than 30 minutes in the experimental group. Furthermore, it was not possible to use a sham intervention in the control group due to the difficulty of mimicking the sensory stimulation promoted by TENS. However, providing words of support may also generate placebo responses. Colloca and Benedetti[30] reported that the expectations associated with some procedures could influence the responses to interventions, in both positive and negative terms. Another limitation was the size of the sample, which may have been insufficient to determine the relative risk of maternal and perinatal outcomes.

In conclusion, TENS administered at the beginning of the active phase of labour produces a significant decrease in pain and postpones the need for pharmacological analgesia with no deleterious maternal and perinatal effects. Therefore, it can be considered an alternative and useful method for labour analgesia.

What is already known on this topic: Pharmacological analgesia during labour is effective, but it can have adverse side effects. Transcutaneous electrical nerve stimulation (TENS) is widely used for pain relief during labour, but a systematic review indicates that the available trials of TENS during labour do not clearly determine its effects.
What this study adds: TENS administered at the beginning of the active phase of labour reduces pain and postpones the need for pharmacological analgesia, with no harmful effects on mother or neonate.

***Footnotes*:** [a]KW National Industrial Electronic Technology Ltd, Amparo, São Paulo.

***eAddenda*:** Table 5 can be found online at doi:10.1016/j.jphys.2015.11.002

***Ethics approval*:** The Ethics Committee of the University Hospital of the Ribeirão Preto Medical School approved this study under the protocol HCRP 4262/2009. All participants gave written informed consent before data collection began.

***Competing interests*:** The authors have no conflicts of interest to declare.

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