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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
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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