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Transcutaneous electrical stimulation for pain relief during labor: a systematic review and meta-analysis

Estimulação elétrica transcutânea no alívio da dor do trabalho de parto: revisão sistemática e meta-análise

Larissa F. D. Mello¹, Luciana F. Nóbrega¹, Andrea Lemos²

Abstract

Background: Transcutaneous electrical stimulation (TENS) is a non-pharmacological pain relief method. It is an auxiliary method and not intended to replace other techniques. **Objectives:** To perform a systematic review assessing the effectiveness of TENS compared to no TENS treatment or placebo with the following outcomes: pain relief (primary outcome), analgesic requirements, duration of labor, the mother's satisfaction, type of delivery and fetal repercussions (secondary outcomes). **Methods:** The Pubmed, LILACS and Scielo databases were searched for randomized controlled trials and quasi-randomized trials published between 1966 and 2008 using the keywords 'TENS', 'Labor', 'Labor pain' and 'obstetric labor'. The selection of eligible items and assessment of methodological quality were performed independently by two researchers. Random effects meta-analysis was performed for studies that were sufficiently homogeneous. **Results:** Nine studies involving a total of 1076 pregnant women were included. There was no statistically significant difference between groups in pain relief during labor (pooled RR = 1.09, 95% CI = 0.72 to 1.65) or the need of additional analgesia (pooled RR = 0.89, 95% CI = 0.74 to 1.08). There was no evidence that TENS interfered in any of the outcomes except the mothers' desire to use TENS in future deliveries. **Conclusions:** The use of TENS had no impact on mother or child and no influence on labor. According to the results of this review, there is no evidence that TENS reduces the use of additional analgesia.

Keywords: Transcutaneous Electrical Nerve stimulation; labor pain; obstetric analgesia; labor, obstetric.

Resumo

Contextualização: A estimulação elétrica transcutânea (EET) é um método não farmacológico utilizado no alívio da dor do trabalho de parto. Sua aplicação representa um método adjuvante que não se propõe a substituir outras técnicas. **Objetivos:** Desenvolver uma revisão sistemática para avaliar a eficácia da EET comparada à ausência de EET ou placebo, segundo os desfechos: alívio da dor do trabalho de parto (desfecho primário), uso de analgesia complementar, duração do trabalho de parto, satisfação da parturiente, tipo de parto e repercussões fetais (desfechos secundários). **Métodos:** Realizou-se uma busca sistemática nas bases de dados PubMed, LILACS e SCIELO por ensaios clínicos randomizados e quasi-randomizados, publicados entre 1966 e 2008. As palavras-chave utilizadas foram 'TENS', 'labor', 'labor pain' e 'labor obstetric'. A seleção de artigos elegíveis e a avaliação de sua qualidade metodológica foram feitas independentemente por dois revisores. Meta-análises de efeitos randômicos foram realizadas quando estudos que investigavam um mesmo desfecho eram suficientemente homogêneos. **Resultados:** Nove estudos, incluindo 1076 gestantes, foram selecionados. Não houve diferença significativa entre os grupos no alívio da dor do parto (pooled RR=1,09; 95%IC=0,72-1,65) ou na necessidade de analgesia complementar (pooled RR=0,89; 95%IC=0,74-1,08). Não se observou evidência da interferência da EET em nenhum dos desfechos, exceto no desejo da parturiente em utilizar a EET em futuros partos. **Conclusões:** A utilização da EET não demonstrou nenhum impacto sobre a mãe ou conceito e nenhuma influência no trabalho de parto. De acordo com os resultados desta revisão, não há evidência de que a EET reduz o uso de analgesia complementar.

Palavras-chave: estimulação elétrica transcutânea; dor do parto; analgesia obstétrica; parto obstétrico.

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Introduction ::::

Pain during parturition is a physiological, complex, subjective and multidimensional response to the sensory stimuli principally generated by uterine contraction¹. Pain control plays an important role during labor because it contributes to the physical well-being of both mother and fetus. Drugs, epidural analgesia, local anesthetic blockades, acupuncture, psychoprophylactic methods and transcutaneous electrical nerve stimulation (TENS) are among the alternatives for reducing pain during labor^{2,3}.

TENS is widely used for chronic or postoperative pain control, either replacing or complementing analgesic drugs^{4,5}, and is based on the Gate Theory of Pain proposed by Melzack and Wall⁶ in 1965. According to this theory, the modulation of pain perception induced by TENS is attributed to the recruitment of A β -afferent fibers in the posterior horn of the spinal cord, which would prevent or hamper the activation of the pain-conducting thin fibers⁷. It is postulated that electrical stimulation through the skin would both inhibit the transmission of painful impulses through the spinal cord and stimulate the liberation of endogenous opioids by the brain⁸. The technique consists of applying superficial cutaneous electrodes that emit an electrical current with a typically biphasic symmetric or asymmetric wave form in order to excite nerve fibers, which causes minimal adverse effects to the patient⁸.

The first report on the use of TENS in obstetrics came from Scandinavia in the 1970s, where it was introduced as a non-pharmacological resource for pain relief during labor. Since then it has been used broadly worldwide^{9,10}. It is an auxiliary method and not intended to substitute existing techniques or to be used as the sole treatment¹¹.

In current clinical practice, TENS is used to reduce pain during the initial phases of labor and to delay the need for pharmacological methods¹¹. Consequently, the benefit would be reduced exposure to drugs, which would decrease the incidence of adverse effects, such as interrupting the birth process and fetal depression, to both mother and fetus¹¹⁻¹³.

Therefore, the present review aims to evaluate the effectiveness of the use of TENS during labor versus no TENS treatment or a placebo, including analysis of possible maternal and fetal repercussions.

Methods ::::

The PubMed, LILACS and SCIELO databases were searched for articles published from 1966 and 2008 including the MeSH keywords: "TENS", "Transcutaneous Electrical Nerve

Stimulation", "Stimulation Transcutaneous", "labor", "labor", "labor pain", "labour pain", "labor, obstetric", "labour, obstetric", "analgesia, obstetric", "childbirth" and "parturition". A search with the same keywords was also carried out in Portuguese. The keywords were combined using the Boolean operators AND, OR, and NOT AND, without language restriction.

To be included in the present systematic review, the studies identified in the search strategy had to consist of randomized or quasi-randomized clinical trials using TENS as a form of analgesia during labor that included a control group without TENS or a placebo group. Studies comparing TENS to pharmacological methods of analgesia that used brain and/or rectal stimulation and those that studied high-risk pregnancies were excluded. Moreover, studies in which the electrodes were not placed on the thoracolumbar and/or sacral spine and those with a sample of ten or fewer participants in each group were also excluded.

Abstracts of the studies identified in the search were evaluated according to the above-mentioned eligibility criteria, and those that raised questions were retained for a subsequent evaluation of the full text. The methodological quality of the studies selected for the review was evaluated by two independent reviewers (LF and LN) according to the following individual components: randomization, allocation concealment, blinding and intention-to-treat analysis. The assessment criteria were: adequate, inadequate, unrealized and not described. Any differences in opinion were discussed with a third reviewer (AL).

Pain relief during labor was considered as a primary outcome and analgesic requirements, duration of labor, the mother's satisfaction, type of delivery and fetal repercussions were considered as secondary outcomes.

After data extraction, the possibility of performing a meta-analysis with sufficiently homogeneous studies that used the same outcome was explored. A meta-analysis of fixed effects was carried out and the random effects model was used when a significance level of 0.05 was detected in the heterogeneity test. Statistical analysis was carried out with RevMan version 5.0.0.

Results ::::

Of the 1913 articles initially identified in the database search, 46 were selected for a careful evaluation and 22 of these were excluded after analyzing the abstracts. Twenty-four full texts were evaluated for eligibility, of which 15 were excluded for not meeting the inclusion criteria (Figure 1). A total of nine studies from different countries were included. Two of

them were randomized controlled trials^{4,14}, four were quasi-randomized controlled trials¹⁵⁻¹⁸ and three studies^{3,5,19} did not report the method of randomization.

The studies investigated 1076 women, 529 who received TENS and 547 who either did not receive TENS or received a placebo treatment. The five studies^{4,14,16,18,19} involving placebo TENS used an inoperative unit otherwise identical to that of the experimental group whose power light came on. The studies by Erkkola, Pikkola and Kanto¹⁵, Miller Jones⁵ and Van der Spank et al.¹⁷ used a control group without TENS. Lee et al.³ used two groups (placebo and control without TENS), although information on the inoperative unit was not provided.

Only two studies^{4,18} reported the information given to placebo group patients. In the study by Nesheim⁴, the mother was informed that she would not feel any sensation in the area of the electrodes, except perhaps some local heating. In the study by Knobel, Radunz and Carraro¹⁸, a limited interaction strategy was used (researchers avoided questions or comments that allowed patients to notice whether the treatment was real or not). Other studies^{3,5,14-17,19} did not specify what information was given to the mothers in the group without TENS and/or the placebo group.

Regarding other aspects of methodological quality, there was no blinding in only three studies^{5,15,17} and no study

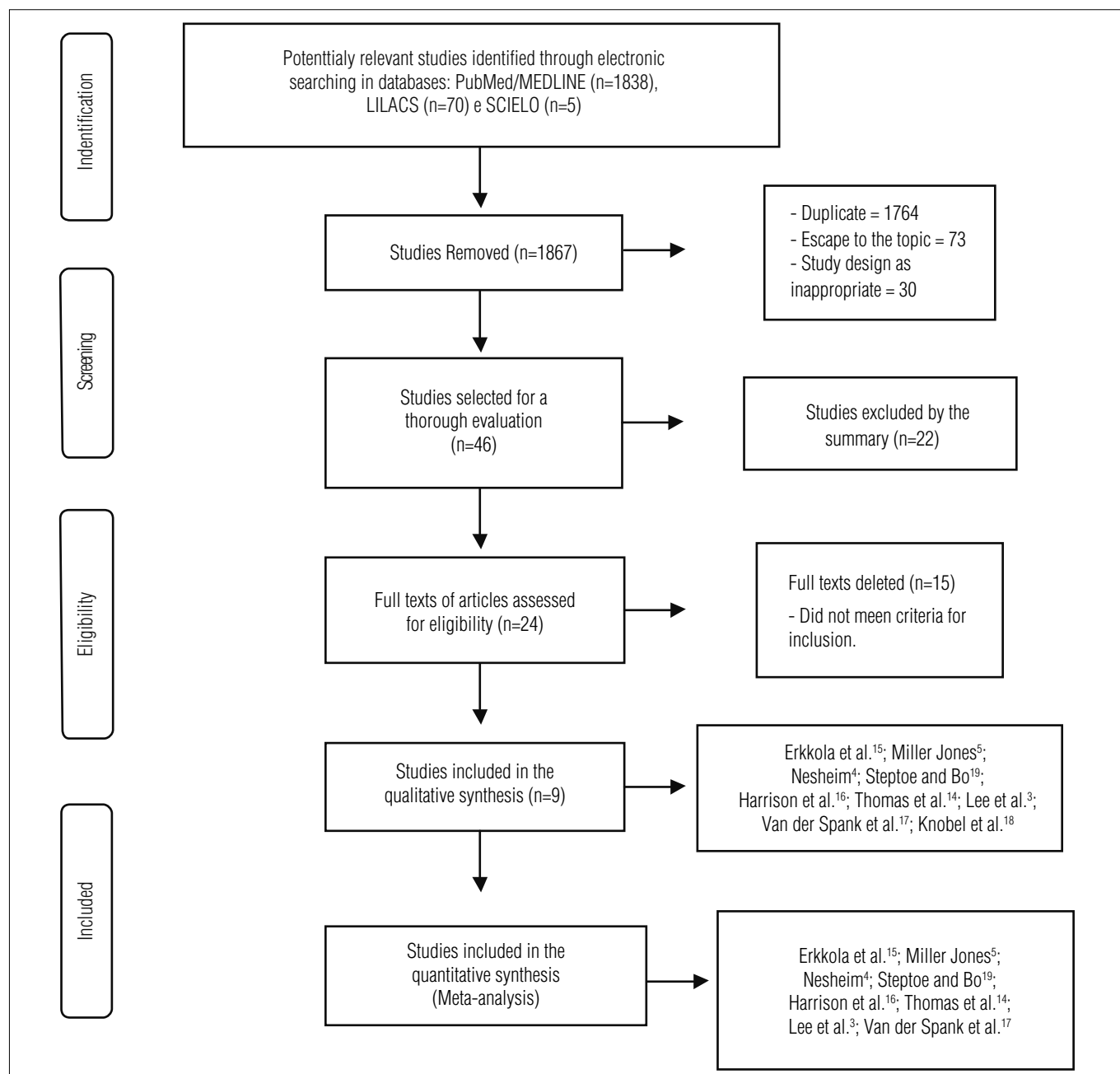


Figure 1. Search and selection of studies for systematic review according PRISMA.

performed an intention-to-treat analysis. Allocation was adequately concealed in four studies^{4,14,16,18} (Table 1).

The included studies were similar regarding basal characteristics of the patients, methodological details, electrode location and duration of labor (Table 1). However, the studies used different TENS parameters (Table 1). The methods for measuring pain relief, the beginning of stimulation and the results of intervention are shown in Table 2. Only five studies^{3,14,15,17,18} reported the point in time when TENS application began (Table 2). The mother herself controlled the apparatus in most of the studies, but Steptoe and Bo¹⁹ and Knobel, Radunz e Carraro¹⁸ were unclear about the procedure.

The selected articles were heterogeneous regarding the instruments used for pain evaluation (Table 2), although a meta-analysis of three of these studies^{3,4,14} involving 417 mothers was performed with data they supplied about the degree of pain relief (Figure 2). Because the methods of analgesic evaluation used in these clinical trials were divergent, the data were homogenized by considering any degree of pain relief in the authors' classifications (some relief, moderate relief, good relief, free from pain, no relief and worsening) as clinically relevant.

Since the need for analgesia after TENS is another way to measure pain relief during labor, a second meta-analysis was carried out (Figure 3) of six studies^{3,5,15-17,19} that included 667 mothers. The three excluded studies^{4,14,18} presented

Table 1. Characteristics of included studies.

Author	Randomization	Blinding	Allocation concealment	Sample	TENS control setting / Parameter	Duration of labor
Erkkola, Pikkola e Kanto ¹⁵ (Finland)	Inadequate Quasi-randomized (in alphabetical order – the first parturient with the cervix dilated to less than 4cm was placed in the TENS group and the alphabetically next parturient was taken in control group)	Unrealized	Inadequate	***TG: 100 participants: 65 para 0; 29 para 1 and 6 para > 1 *CG without tens: 100 participants: 52 para 0; 33 para 1; e 15 para > 1 (parity)	T10-L1 and S2-S4; Intensity: High during contractions and a second lowest among them (20 - 25 V); Frequency: Not described; Pulse width: Not described; Length: Not described.	***TG: ‘1st stage: 185±103 min ‘2nd stage: 16±3 min Total: 403±188 min *CG: ‘1st stage: 178±95 min ‘2nd stage: 13±10 min Total: 408±185 min
Miller Jones ⁵ (England)	Not described	Unrealized	Inadequate	***TG: 51 participants *CG without TENS: 56 participants	T10-L1 50 cm apart from the other pair of electrodes located at the level of S3; Intensity: Not described; Frequency: Not described; Pulse width: Not described; Length: Not described.	***TG: ‘1st stage: primíparous (9.6±4.2h) and multiparous (7.1±3.3h). ‘2nd stage: primíparous (0.72±0.53h) and multiparous (0.3±0.2h). Total: primíparous (10.4±4.5h) and multiparous (7.5±3.4h). *CG without TENS: ‘1st stage: primíparous (9.0±4.4h) and multiparous (5.4±3.1h). ‘2nd stage: primíparous (0.77±0.37h) and multiparous (0.3±0.3h). Total: primíparous (9.8±4.5h) and multiparous (5.8±2.9h).
Nesheim ⁴ (Norway)	Adequate Tossing of a Coin	Adequate Single Blind (parturient)	Adequate	***TG: 35 participants: 25 para 0; 6 para 1; and 4 para > 1 *PG: 35 participants: 21 para 0; 10 para 1; and 4 para > 1	T10-L1 and S2-S4; Intensity: 0 to 40 mA; Frequency: 100 Hz (40 -150 Hz); Pulse width: 0.25ms; Length: Not described.	‘1st stage: Not described. ‘2nd stage: Not described. Average Duration: ***TG: 8 ¾ h (6-11h) *PG: 9 ½ h (8-12h)

Table 1. Continued.

Author	Randomization	Blinding	Allocation concealment	Sample	TENS control setting / Parameter	Duration of labor
Stephoe and Bo ¹⁹ (Denmark)	Not described	Adequate Single Blind (parturient)	Inadequate	***TG: 13 primiparous *PG: 12 primiparous	T10-T12 and S2-S4; Intensity: 0 – 60 mA; Frequency: 1-4Hz, 100 Hz; Pulse width: 0.2ms; Length: 30 min.	'1st stage: Not described. "2nd stage: Not described Total: ***TG: 4h e 1 min *PG: 4h e 28 min
Harrison et al. ¹⁶ (Ireland)	Inadequate Quasi-randomized (patients were allocated to one of six numbered machines. Numbering was changed at regular intervals by a third party)	Adequate Double Blind (parturient and midwife)	Adequate	***TG: 76 participants: 49 primiparous and 27 multiparous *PG: 74 participants: 51 primiparous and 23 multiparous	T10-L1 and S2-S4; Intensity: Not described; Frequency: Not described; Pulse width: 60 – 80µs; Length: Not described.	The duration of labor was lower in primiparous who used TENS and Placebo alone (p=0.0005)
Thomas et al. ¹⁴ (Australia)	Adequate List of random numbers	Adequate Double Blind (parturient and staff member)	Adequado	***TG: 132 participants (57% primiparous) *PG: 148 participants (45% primiparous)	T10-L1 and S2-S4; Intensity: Not described; Frequency: High during contractions and Low between them; Pulse width: Not described; Length: Not described.	No significant difference was found
Lee et al. ³ (Hong Kong)	Not described	Adequate Double blind (parturient and obstetric staff)	Inadequate	***TG: 58 participants: 42 primiparous and 16 multiparous. **PG: 33 participants: 24 primiparous and 9 multiparous *GC: 34 participants: 27 primiparous and 7 multiparous	T10-L1 and S2-S4; Intensity: 0-50mA; Frequency: High during contractions and low between them (1 st stage); High during all 2 nd stage; Pulse width: Not described; Length: Not described.	***TG: primiparous (7.66±2.34h) and multiparous (3.45±1.90h). **PG: primiparous (6.25±2.54h) and multiparous (3.53±1.52h) *CG: primiparous (7.54±3.26h) and multiparous (3.34±2.50h) No significant difference was found. (p>0.01)
Vand der Spank et al. ¹⁷ (Belgium)	Inadequate Quasi-randomized (chosen when they were admitted to hospital).	Unrealized	Inadequate	***TG: 24 participants: 19 nuliparous and 5 multiparous *CG without TENS: 36 participants: 26 nuliparous and 9 multiparous	T10-L1 and S2-S4; Intensity: Not described; Frequency: 80Hz (fixed) and Burst 2Hz; Pulse width: 275µs; Length: Not described.	'1st stage: Not described "2nd stage: Not described Total: ***TG: 10.5h *CG without TENS: 9.7h
Knobel, Radunz and Carraro ¹⁸ (Brazil)	Adequate (through the numbering of wires – stickers numbering each wire bonded at 60 equal closed, opaques, shuffled and numbered envelopes).	Adequate Triple blind (parturient, health staff and researches)	Adequate	***TG: 40 participants – Primiparous: Plate electrodes (13) and #SSP Electrodes (9) – Multiparous: Plate electrodes (7), # SSP electrodes (11) *PG: 20 participants: primiparous (11) and multiparous (9)	1st and 2nd sacral foramen, bilaterally; Intensity: Not described; Frequency Alternate 2-15Hz; Pulse width: Not described; Length: Not described.	Not described

*CG without TENS: control group; **PG: Placebo group (sham); ***TG: treatment group; '1st stage: first stage of labor; "2nd stage: second stage of labor; #SSP: Model of electrode (Silver Spike Point). The intention to treat analysis was not performed in included studies..

Table 2. Analgesic measures and results.

Author	Beginning of stimulation	Pain outcomes	Interventions outcomes
Erkkola, Pikkola and Kanto ¹⁵ (Finland)	When the cervix was one to seven cm dilated and the contractions were becoming unpleasant.	Questionnaire 1-2h after delivery on the pain experienced during labor and on the effects of TENS (the midwifery also filled out a questionnaire, giving her impression of the pain experienced by the mother).	TG***: 31 parturients related good relief and 55 parturients related moderated relief; CG without TENS*: Not described.
Miller Jones ⁵ (England)	Not described	The patients were asked for their comments regarding the pain relief in different stages of labor.	TG***: 72 % of womens had satisfactory pain relief in the first stage of labor and 17% at second stage; CG without TENS*: Not described.
Nesheim ⁴ (Norway)	Not described	Questionnaire after childbirth (pain free, good relief, some relief, no relief and worsening); Other analgesic interventions.	TG***: 25 parturients related some relief (some relief, good relief, pain free) PG*: 19 parturients related some relief (some relief, good relief, pain free) There wasn't significant difference between groups. The author doesn't describe p value.
Step toe and Bo ¹⁹ (Denmarck)	Not described	Visual analogue scale (does not refer the time of application)	There wasn't significant difference between TG*** and PG*. The author doesn't describe p value.
Harrison et al. ¹⁶ (Ireland)	Not described	Questionnaire of the pain relief and favorable or unfavorable comments; Other analgesic interventions. Assessment of pain threshold as measured by Montsanto Gun (0 - 4) for parturient and midwifery	There wasn't significant difference between TG*** and PG*. The author doesn't describe p value.
Thomas et al. ¹⁴ (Australia)	When the patient reported discomfort.	Visual analogue scale (each hour); Questionnaire (one day following delivery).	TG***: 89 parturients related some relief (excellent, good, moderate and sligth); PG*: 99 parturients related some relief (excellent, good, moderate and sligth);
Lee et al. ³ (Hong Kong)	When the patient was admitted to the service.	Questionnaire one day following delivery; only for TG e PG. (effectiveness of TENS and IF would use again in other delivery) Visual analogue scale (every 30 min);	TG***: 32/41 parturients realated that TENS was benneficial at first stage; 19 /40 parturients related improvement at second stage; CG*: Not described; GP*: 16/26 parturients realated that TENS was benneficial at first stage; 13/23 parturients related improvement at second stage; There wasn't significant difference between the groups. The author doesn't describe p value.
Vand der Spank et al. ¹⁷ (Belgium)	When women mentioned painful contractions inflicting on a regular base.	Visual analogue scale (pain intensity during the last contraction) before, during and after TENS.	TG***: 23 parturients considered satisfactory intervention CG without TENS*: Not described.
Knobel et al. ¹⁸ (Brazil)	When the patient reported discomfort.	Visual analogue scale, before the aplication and after 10, 30, 60 minutes and again every 60 minutes	Obtained a significant difference of #SSP group in relation to Placebo group at 10 minutes (p=0.005) and 30 minutes (p=0.001). Also obtained a significant difference of Plate electrode group to the Placebo group at 10 minutes of treatment (p=0.04)

*CG without TENS: control group; **PG: Placebo group (sham); ***TG: treatment group; #SSP: Model of electrode (Silver Spike Point).

insufficient data for inclusion in this statistical analysis. In Nesheim's⁴ study, the group without TENS received more regional blockade (63%) than the intervention group (26%), although the number of patients who received pethidine and diazepam was similar in both groups. In Thomas et al.¹⁴ there was a similar need for nitric oxide and pethidine in both the treatment and control groups, but the epidural rate was higher, although not significantly, in the experimental group.

In Knobel, Radunz e Carraro¹⁸, less medication was used in the intervention groups (p=0.02).

In six studies^{3,5,14,15,17,19} there was no significant difference in the duration of labor between experimental and control groups. In Harrison et al.¹⁶, the primiparous who did not need additional analgesia had significantly shorter births (p<0.005), although there was no significant difference between TENS and placebo groups in the multiparous or when patients used

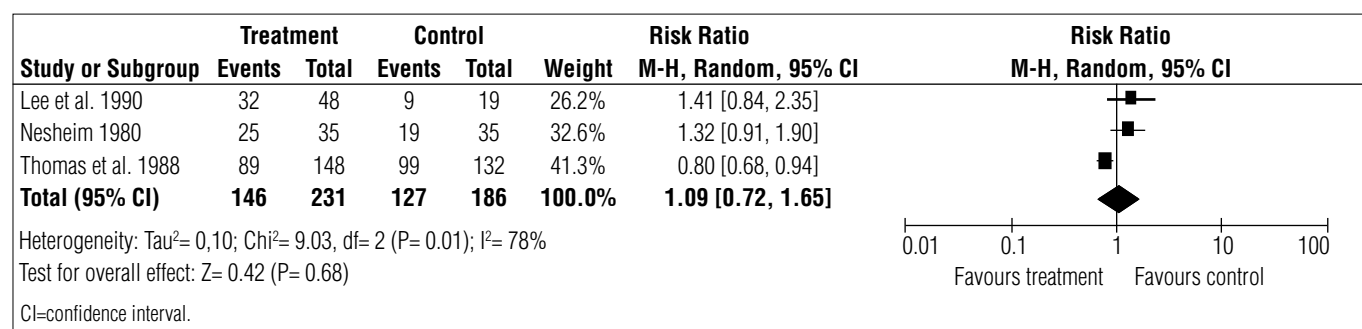


Figure 2. Effect of TENS on pain relief during labor in randomized and quasi-randomized studies and resultant meta-analysis using random effect model. Review Manager (RevMan). Version 5.5 The Cochrane Collaboration, 2007.

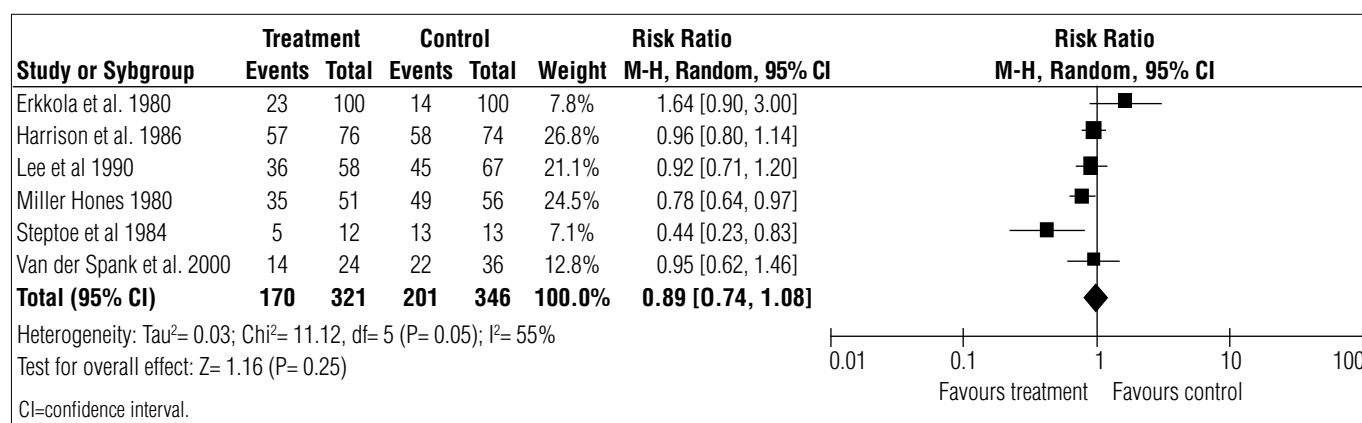


Figure 3. Effect of TENS on the need for additional analgesia in randomized and quasi-randomized controlled studies and resultant meta-analysis using random effects models. Review Manager (RevMan). Version 5.5 The Cochrane Collaboration, 2007.

entonox. Only Knobel, Radunz and Carraro¹⁸ did not report the duration of labor.

In five studies^{3,14,15,17,19}, the pregnant women were questioned about the use of TENS in the future. Steptoe and Bo¹⁹ reported that 91.7% of the treatment group wanted to use TENS in future births compared to 38.5% of the group that did not receive TENS treatment ($p < 0.05$). In Harrison et al.¹⁶, 68.4% of the treatment group reported wanting to use TENS in the future, while only 40.5% of the control group reported the same. Thomas et al.¹⁴ reported a number of undecided participants (25.7% in the control group and 14.4% in the treatment group) besides more treatment group participants who were interested in using TENS in a future birth. In Lee et al.³, 39.4% of the control group expressed interest in using TENS in a subsequent birth but only 27.6% of the treatment group did. Van der Spank et al.¹⁷ did not question their control group about the use of TENS in future births but 87.5% of the treatment group wanted to use it in another gestation. The remaining studies^{4,5,15,18} did not mention this topic.

Regarding the type of delivery, 22.9% of the births in the control group were operative (seven vacuum extractions and

one cesarean section) and 8.6% in the experimental group were operative (two vacuum extractions and one forceps delivery⁴). Harrison et al.¹⁶, reported 55 normal births, 15 with forceps, three vacuum extractions and three cesarean sections in the treatment group ($n = 76$). On the other hand, the placebo group included 50 normal births, 19 with forceps, one vacuum extraction and four cesarean sections ($n = 74$). Thomas et al.¹⁴ reported that 83.8% of their control group deliveries were spontaneous vaginal births, 8.8% involved forceps/vacuum and 7.4% were cesarean sections. Their intervention group deliveries, however, were 80.3% vaginal births, 8.3% forceps/vacuum and 11.4% cesarean sections. In Lee et al.³, there was no significant difference between groups. The reported data in the five remaining studies^{5,15,17-19} was insufficient.

Regarding fetal repercussions, five studies^{5,14-16,19} reported no significant differences in Apgar scores at the first and fifth minute. Two other studies^{2,17} did not report on this. Umbilical cord blood gas analysis was carried out only in Harrison et al.¹⁶, and no difference was observed in the means between groups.

Discussion ...

In the present systematic review, a meta-analysis of three studies demonstrated no statically significant difference in pain between mothers using TENS and those submitted to a placebo treatment. The studies not included in this meta-analysis also indicated that TENS was not effective for pain relief during labor.

Moreover, a meta-analysis of six studies regarding analgesic requirements demonstrated no evidence that TENS was effective. Like the meta-analysis on labor pain, this analysis could not include all of the articles in the review due to their heterogeneity. Comparison between studies was difficult because the types of available analgesic differed depending on the country and the institution in which the research was carried out¹⁸. There was no evidence that TENS affected the duration of labor or had fetal repercussions.

The results of the present systematic review are similar to those of three other systematic reviews published in 1997²⁰, 2009²¹ and 2010²² about TENS and pain relief during labor. Carroll et al.²⁰ analyzed eight studies with a total of 712 women. It was not possible to determine the effectiveness of TENS during labor as a form of analgesia due to the conflicting results observed. Dowswell et al.²¹ analyzed 19 studies, totaling 1961 women. They observed limited evidence on the effectiveness of TENS as pain relief during labor. In the most recent systematic review, Bedwell et al.²² analyzed 14 studies, totaling 1256 women. Their conclusions were similar to those of the two above-mentioned studies. These three systematic reviews differed from the present review in that their conclusions were based on studies involving other analgesia methods (i.e., drug types) as well as placebo-controlled studies.

The main objective of a systematic review transcends the mere formal presentation of whether or not there is a difference between treatments. Its essence is also to evaluate the methodological rigor of the studies involved in order to ascertain the veracity of the observed results. Thus, in the present review, after a transparent and meticulous search for studies with the best evidence levels, methodological rigor was still inadequate in most of the included studies.

Randomization and allocation concealment represent the best way to minimize selection bias and certify the treatment effect. When these criteria are inappropriate, the overestimated size of this effect can be as much as 40%²³⁻²⁵. In the present review, most of the included studies did not report concealment allocation or randomization in an appropriate way, which may have interfered in the results. Thus, it is possible that the effectiveness of TENS is even lower in studies with proper randomization and concealment allocation.

Moreover, blinding is as important as randomization because it reduces the probability that investigator, therapist or examiner expectations about the benefit of the treatment will be transferred to the participants^{23,25}. The inclusion of a TENS placebo group is controversial since, according to Orange et al.¹¹, no placebo could mimic the sensorial stimulation produced by TENS. Erkkola, Pikkola and Kanto¹⁵ demonstrated that patients who participated in the placebo group were not convinced that the TENS treatment functioned and judged it inefficient. However, contrary to these two studies, Thomas et al.¹⁴ verified the existence of a placebo effect because 40% of those in the placebo group felt more pain when the apparatus was turned off.

No study included in this review carried out intention-to-treat analysis, a strategy that compares patients in the group in which they were originally randomized, independent of whether they abandon the study. This type of analysis maintains the similarity between allocated groups, and its absence may lead to overestimation of the treatment's clinical effect²⁶. The appropriate application of intention-to-treat requires either complete results for all randomized participants²⁶ or indication in the text that intention-to-treat was carried out, which was not the case in any of the studies involved in this review.

Regarding the placement of TENS electrodes, the procedure in this review was to homogenize the studies by choosing those with the same electrode placement areas, i.e., in the thoracolumbar and sacral regions over the nerves that conduct painful stimuli to the uterus, cervix and perineum during labor. Through the stimulation of these nerves, the mechanism is activated before reaching the brain, blocking or altering nociceptive impulses originating from the spinal cord^{27,28}. Although there are reports in the literature that TENS may be applied at any moment during labor, including some studies indicating that its effectiveness would be better in the initial phases of the first stage^{12,27,29}, this could not be evaluated directly due to a lack of standardization at the beginning of the procedure.

The results show that there was no uniformity in the frequency or intensity of electrical stimulus, although studies suggest that the combination of frequency and intensity is of fundamental importance for preventing accommodation to repeated stimuli³⁰. Corroborating this, Van der Spank et al.¹⁷ used low frequency and high intensity stimulation between contractions, which, according to the authors, would activate the opioid system. Alternatively, the use of high frequency and low intensity during contractions would inhibit pain by neural blockade, although this was not discussed by other authors.

The reliability of pain assessment in some studies might have been compromised by relying on a third party. Erkkola, Pikkola and Kanto¹⁵ described how the pain level was

underestimated when a nurse evaluated the degree of pain relief. Because pain is a personal experience, it is difficult to define and there is no objective method for measuring it³¹. Pain intensity and analgesic effects can only be judged by the person who is suffering. The mother's perception of pain during labor depends on the intensity and duration of contractions, the speed with which the cervix dilates, woman's physical and emotional condition, previous experience, present expectations and cultural factors^{29,32}. Therefore, the best way of assessing the perception of pain should be the parturient's report.

In two studies^{14,16} the patients had previous contact with TENS, although this data was not well explored. The exclusion of mothers who had received information about TENS during prenatal care would have minimized bias¹⁴ because they would have been able to distinguish the genuine sensation.

The current concept of evidence-based practice requires conscientious and judicious use of the best evidence from clinical studies to guide the choice of treatment as well as practical experience and patient choice³³. Thus, even before referring to the best level of available evidence,

i.e., systematic reviews, the use of prudence, professional experience and patient involvement in the decision process cannot be excluded^{33,34}. The fact that the mothers' level of satisfaction was higher when TENS was applied, which was reflected in the desire to use it in subsequent births, would justify the use of TENS, complementary analgesia and other outcomes, even if it does not effectively reduce pain. However, this was not confirmed in this review and should be investigated in future studies.

Conclusion ...

This systematic review was inconclusive regarding the effect of TENS on pain control during labor compared to a placebo group since low methodological quality was found in most of the included studies. Therefore, adequate randomized controlled trials that use intention-to-treat analysis and that clearly demonstrate the study parameters should be developed.

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