Does transcutaneous electrical nerve stimulation reduces pain free of adverse effects during pregnancy? Systematic review

Estimulação elétrica nervosa transcutânea reduz a dor sem efeitos adversos durante a gestação? Revisão sistemática

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ABSTRACT

BACKGROUND AND OBJECTIVES: Transcutaneous electrical nerve stimulation (TENS) is considered a current that should not be applied in pregnant women to avoid adverse effects. This systematic review aimed to analyze the scientific evidence about the use of TENS during pregnancy.

CONTENTS: This study was conducted on November 2019 by searching the electronic databases: Pubmed, Scielo, LILACS, Science Direct, Cochrane Library and PEDro. The following descriptors were used: "transcutaneous electric nerve stimulation" combined with "pregnancy". Only randomized clinical trials that investigated the use of TENS during pregnancy were selected. Methodological quality was assessed by using the Cochrane Collaboration Tool (RevMan 5.3 software). Studies were classified according to the risk of bias (low, high or unclear). From 691 eligible publications, only two randomized clinical trials were selected according to inclusion criteria. Low risk of bias was detected in most items in one study and high risk for performance, detection and reporting bias were evidenced in the other study. Other bias (TENS intensity control by patient) was considered unclear in both studies.

CONCLUSION: There is not enough support that TENS neither reduces pain intensity nor causes adverse effects in pregnant patients.

Keywords: Analgesia, Pregnancy, Pregnant, Transcutaneous electric nerve stimulation.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Estimulação elétrica nervosa transcutânea (TENS) é considerada uma corrente não recomendada para gestantes a fim de evitar efeitos adversos. O objetivo deste estudo foi analisar as evidências científicas sobre o uso da TENS durante a gestação.

CONTEÚDO: Estudo realizado em novembro de 2019 pela busca nas seguintes bases de dados: Pubmed, Scielo, LILACS, *Science Direct*, *Cochrane Library* e PEDro. Os descritores "transcutaneous electric nerve stimulation" e "pregnancy" foram utilizados. Ensaios clínicos randomizados que investigaram o uso da TENS durante a gestação foram selecionados. A qualidade metodológica dos estudos foi avaliada através da Ferramenta da Colaboração Cochrane (software RevMan 5.3). A partir de 691 estudos encontrados, somente dois estudos clínicos randomizados foram selecionados de acordo com os critérios de inclusão. Baixo risco de viés foi detectado na maioria dos itens em um dos estudos e alto risco de viés de desempenho, detecção e relato foram evidenciados em outro estudo. Outro viés, como controle da intensidade da TENS pelo paciente, foi considerado incerto em ambos os estudos.

CONCLUSÃO: Não há evidências científicas suficientes que suportem a redução da intensidade de dor nem a ocorrência de efeitos adversos promovidas pela TENS em pacientes gestantes.

Descritores: Analgesia, Estimulação elétrica nervosa transcutânea, Gestantes, Gravidez.

INTRODUCTION

During pregnancy, changes caused by hormones such as relaxin, progesterone and estrogen, associated with uterine growth, anterior displacement of the gravity center and increased lumbar lordosis/pelvic anteversion, facilitate the occurrence of musculoskeletal disorders, such as herniated disc, sacroiliitis, symphysitis and, in particular, low back pain[1,2]. These disorders and biomechanical changes, which are physiological and not pathological conditions, cause pain complaints, of either transitory acute or

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chronic characteristic[1,2]. Also, some pregnant women already have previous diseases that worsen during pregnancy, and have pain as the main symptom[3].

Study[4] states that 75% of caregivers who work in the prenatal period usually don't recommend any treatment to control pain symptoms and most of the suggestions offered by the other 25% of caregivers consist of stretching and exercise (10.4%), frequent rest (9.8%) and a combination of other complementary therapies associated with prescription drugs.

Currently, pain management during pregnancy has been conducted with hydrotherapy, manual therapy, cryotherapy, rest, acupuncture, prescription of drugs and postural orientations[5-8]. However, such conservative treatments compared to no treatment (rest, routine pre-natal care, waiting list) have low effectiveness in controlling pain and, since over 70% of pregnant women experience some form of back pain and 20% remain with residual symptoms weeks after childbirth, it becomes necessary to use complementary therapies in order to effectively and safely alleviate pain during pregnancy, mainly for those who do not receive pain treatment recommendations by healthcare professionals[9,10].

Therefore, the use of transcutaneous electrical nerve stimulation (TENS) for pain management during pregnancy is suggested, as a non-pharmacological analgesic technique that acts through both central and peripheral nervous mechanisms[11,12]. Centrally, TENS promotes hypoalgesia through activation of regions in the spinal cord and medulla mediated by opioid, serotoninergic and muscarinic receptors[13,14]. Peripherally at the site of application, opioids and α-2 noradrenergic receptors are involved in analgesia induced by TENS[11]. These mechanisms of action of TENS provide the capacity to reduce pain in a variety of clinical conditions, such as fibromyalgia, osteoarthritis, low back pain, postoperative pain, obstetric, and gynecological pain[15-23].

Although clinical studies show the effectiveness of TENS for pain relief, there is no consensus on which medical conditions should be treated with TENS and the appropriate parameters of use[18,24,25]. Among the clinical conditions, the application of TENS during pregnancy for pain relief is very important, since prescription drugs, especially in the first trimester, are restricted and must be taken with caution due to the risk of generating intercurrences in fetal development when it crosses the placental barrier[26-29]. The proper fetal development depends on optimal conditions for the maintenance of high levels of cell proliferation, growth and differentiation that are characteristic of this process[30]. Study[30] suggest that TENS may be harmful to intrauterine development since it is a complex and dynamic process characterized by the interaction of maternal and fetal factors.

Clinically, contraindications for TENS use are few and mostly hypothetical, such as undiagnosed pain, cardiac pacemaker, pregnancy and epilepsy, with few or no reports of associated adverse events, such as dermatitis at the site of electrode, and electric shock that can be avoided if TENS application is in accordance with the security parameters. However, there is a theoretical contraindication for the use of TENS on the uterus during pregnancy, in order to avoid premature labor, even though it's routinely administered to alleviate spinal pain during labor, and practical and reliable information are necessary in order to indicate or make absolute/relative contraindication to the use of TENS in pregnant women[22,31].

Therefore, TENS could be indicated during pregnancy, because it's a non-pharmacological resource used for relieving pain. However, the absence of reports in the literature from controlled and randomized clinical trials showing or justifying the contraindication due to deleterious biological effects of the application of TENS during pregnancy make this technique not widely used for pain control in such cases. Thus, the aim of this study was to systematically review and analyze the scientific clinical literature on the use of TENS during pregnancy for pain relief and possible adverse effects.

CONTENTS

Search strategy and protocol register

The study was conducted in November 2019 by searching the electronic databases: Pubmed, Scielo, Lilacs, Science Direct, Cochrane Library and PEDro. Descriptors were used as follow: "Transcutaneous electric nerve stimulation" and "TENS", combined with "pregnancy". The search strategy used the descriptor and the synonyms extracted from MeSH Terms. Systematic review protocol was registered on PROSPERO (CRD 42016048725).

Data selection and extraction

In the search strategy, all studies published up to November 2019 were identified, regardless of language. After reading the studies, only randomized clinical trials that investigated the use of TENS during pregnancy were included. Initially, the titles and abstracts of all articles identified by the descriptors presented were investigated, seeking to determine the texts relevant to the research question. Next, the complete manuscripts of all articles judged to be relevant were obtained, at which time the inclusion criteria were applied. Studies were selected by two independent investigators and they were involved in both preliminary analysis and review of full texts. The list of articles was decided by consensus in a common agreement. Review authors were not blinded to the names of authors and institutions or study results.

For each study included, data was recorded as: authors, sample size, study groups, protocol of electrical stimulation (frequency, intensity, pulse duration, electrode application site), intervention characteristics such as number and duration of application, variables analyzed and gestational trimester. Authors performed data extraction independently and disagreements were then resolved by consensus and, when necessary, with a third investigator, the senior one.

Risk of bias assessment

Studies were assessed for the risk of bias based on the Cochrane Collaboration's tool. This tool is composed of seven domains: sequence generation, allocation concealment, blinding of study participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and

"other bias", such as TENS intensity control by the patient or by the investigator, considered for this item judgment. Each domain is judged as 'Low risk', 'High risk', or 'Unclear risk' of bias. Each study was assessed by two independent investigators and their results were compared till having a final consensus about the risk of bias.

RESULTS

Two hundred and twenty-seven (n=227) studies were identified after duplicates were removed, whereas 225 were excluded. Only two (n=2) studies were selected in the complete manuscript analysis stage (Figure 1), being the only two considered relevant for the purpose of this review. None of the other studies met the eligibility criteria, as it involved research related to topics such as: acupuncture, electroacupuncture, acupoints, ear acupuncture (n=68) and TENS administration in labor (n=90), postpartum (n=9), abortion (n=1), episiotomy (n=2), dysmenorrhea (n=1), infertility (n=1), placental insufficiency (n=8), non-clinical studies and case reports (n=1), or TENS used to treat other health condition than pregnancy (n=43).

Another full text study about TENS during pregnancy (n = 1) was inaccessible after many attempts (corresponding author was contacted through email three times 10 days apart and a last attempt with co-author was done with no success). (Figure 1) The only two eligible articles were randomized clinical trials[32,33]. Characteristics of included studies, as sample, TENS protocol, control group protocol, outcome measured, assessment instrument and main results are described on Table 1. Both studies included pregnant women with low back or pelvic pain which were randomly assigned in different treatment protocol groups. In one study[32], women were allocated into four study groups (n=22, each): control, exercise (such as stretching, postural exercises and isometric abdominal contraction), acetaminophen and TENS (Table 1). On the other study[33], pregnant women were

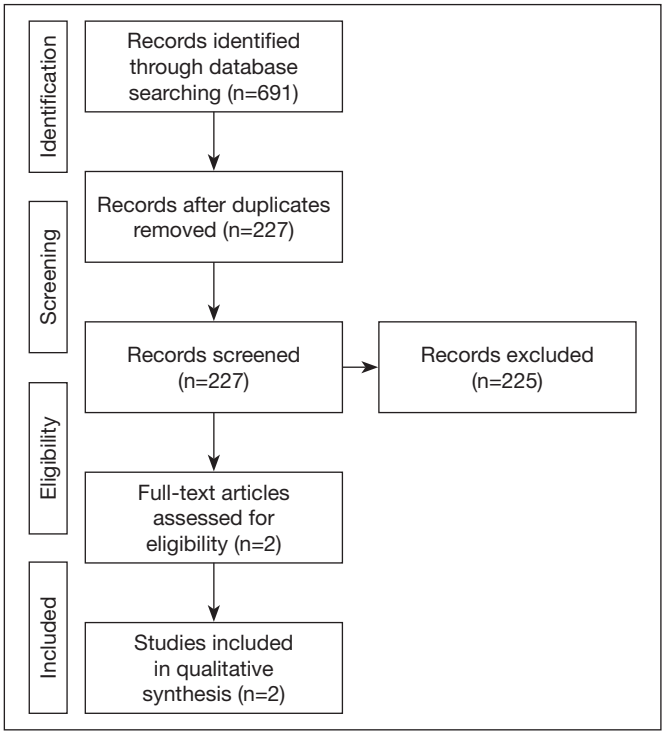

Figure 1. Flowchart of the literature search in the databases

Table 1. Characteristics of the included studies

Authors	Sample	TENS Protocol	Control Group	Outcome measured	Assessment instrument	Results
Keskin et al.[32]	88 pregnant women with low back pain were randomly assigned to four study groups (n = 22, each): control, exercise, acetaminophen, and TENS	Type: Continuous electrical stimulation Frequency: 120 Hz Pulse duration: 100 µs Intensity: adjusted according to a paresthesia sensation 2-3 times the subject's sensory threshold Duration: six sessions of TENS therapy (twice a week for three weeks) Electrodes: superficially placed over the painful lumbar region	Exercise: home exercise program supervised by a physical therapist, twice a day for three weeks Analgesic drug: acetaminophen (500 mg, tablet) was administered twice a day for three weeks Control: no-treatment	Pain Intensity Disability Before and after the third week of treatment	Visual Analog Scale (VAS) Roland-Morris Disability Questionnaire (RMDQ)	After treatment, control group presented an increase in both pain intensity and functional disability. In contrast, all active treatment groups (exercise, acetaminophen and TENS) showed a reduction of both pain intensity and functional disability after treatment.
Vaidya[33]	32 pregnant females with posterior unilateral or bilateral pelvic pain (VAS > 50 mm and positive FABER'S Patrick's test) randomized in two groups (A and B)	Type: high frequency low intensity TENS from a single channel Frequency: 150Hz Pulse duration: 80-100 µs Intensity: minimal sensory perception Duration: 30 minutes/ twice a week Electrodes: two electrodes placed over the painful area	Sacroiliac joint (SIJ) mobilization based on Maitland concept (Grade 1 and 2 mobilization – 30 seconds oscillation – twice a week) Both groups received lumbo-pelvic stabilization exercises	Pain intensity Disability Prior to first session and after completion of five sessions.	VAS RMDQ	Intragroup analysis revealed pain and disability improvement in both groups. Intergroup analysis showed that SIJ mobilization was superior in both outcomes compared to TENS at the end of five sessions

allocated into only two groups (TENS and sacroiliac joint mobilization - SJM).

TENS protocol was similar in both studies using high frequency, sensory intensity, twice a week with electrodes placed on the painful area[32,33] (Table 1). In a study[32], nine cases were excluded from the analysis, considering that one left the TENS treatment because of the uncomfortable sensation, one suspended the use of acetaminophen due to anxiety and another due to gastric intolerance. On the other hand, only two (n=2) subjects lost follow-up in study[33] due to inconvenience in travel (n=1, SJM group) and inconvenience in time (n=1, TENS group).

In both included studies, visual analog scale (VAS) and Roland-Morris Disability Questionnaire (RMDQ) were used to assess pain intensity and disability, respectively, before and after the third week of treatment[32] and prior to first session and after completion of five sessions[33]. Results[32] evidenced that pre-treatment pain intensity was higher in TENS group than in both control groups (p<0.001) and acetaminophen, while physical impairment was similar between groups. After the treatment period, control group showed an increase in both pain intensity and functional disability (pain intensity: 6 to 7 using VAS, and disability: 14 to 15 using RMDQ). In contrast, all active treatment groups (exercise, acetaminophen and TENS) showed a reduction of both pain intensity and functional disability after treatment[32].

As for results of one study[33], intragroup analysis revealed significant improvement in terms of VAS and RMDQ score (p-value <0.0001) at the end of five sessions in TENS and SJM group, respectively[33]. Intergroup analysis proved that SJM is superior in terms of pain and disability measures as compared to TENS, at the end of five sessions (p<0.0001)[33].

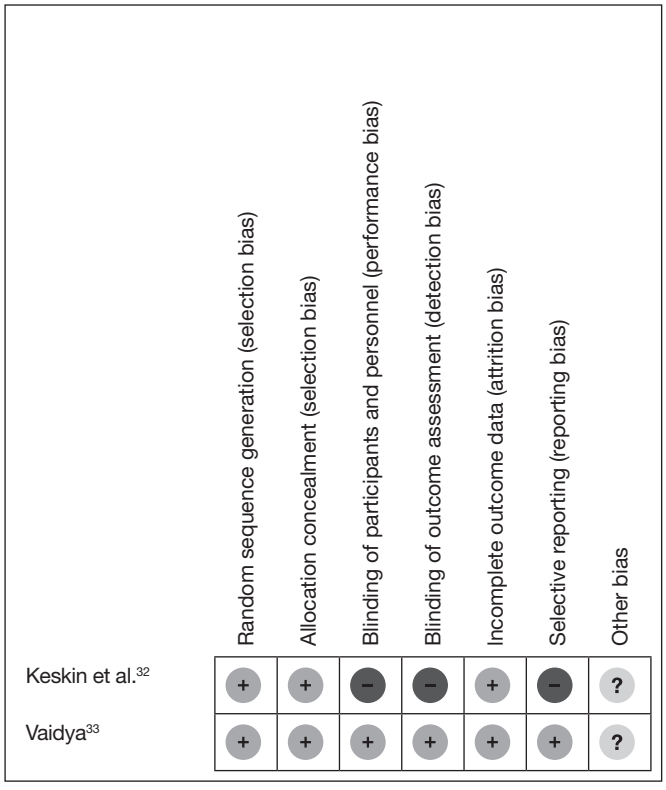

Figure 2. Risk of bias summary: review of authors' judgments about each risk of bias item for the included study

The selected studies presented different levels of biases in all items analyzed. On the first study[32] it was evidenced high risk of bias related to 1) the lack of participant and personnel blinding (performance bias), 2) the lack of blinding of outcome assessment (detection bias), 3) subjects were excluded for analysis with no explanation reported on manuscript (reporting bias). On the other hand, low risk of bias was evidenced for selection and attrition bias in this same study[34]. Low risk was also evidenced for selection, performance, detection, attrition and reporting bias in the second study analyzed[33].

In both studies[32,33], an unclear risk on "Other bias" was detected, once it was not possible to access on manuscripts how TENS intensity was controlled (if it was done by patient or investigator or both). These studies only describe that intensity was set according to sensory threshold of the subject, with no description of more details about this parameter (Figure 2).

DISCUSSION

In this systematic review, which aimed to analyze the effect of TENS on pregnant women, authors concluded that this modality reduced pain intensity and functional disability on their sample. However, it was also showed that TENS effect was not better than other modalities on control groups using exercise, acetaminophen or SJM, which presented also pain and disability improvements as results.

Methodological quality of the included studies in this review was considered appropriate to suggest TENS effect on pregnancy once most items were considered as low risk of bias. In exception, unclear risk in both studies and high risk in some items in the study[32] can contribute to a weakness in methodological accuracy, so its results should be interpreted with caution.

Since maternal and fetal complications were not identified during development of studies[32,33], TENS is defended and preferred for being the most effective, easy to apply and safe modality for this disorder. On the other hand, the claim that this modality has no adverse effects on mothers and newborns is insufficient, considering that no indicative measures of maternal-fetal development, such as placental activity, fetal heart rate, Apgar score, blood pH, presence or absence of malformations and fetal distress were investigated in these studies, only suggesting that there were no significant changes in relation to fetal birth weight[30,34].

Clinical trials suggest that TENS at a frequency of 60-80 Hz and pulse duration of 250 μs, when applied in humans with decreased placental flow, produces an increase in placental perfusion assessed by the method of radioisotopes, and can thus be used for therapeutic purpose in the case of placental dysfunction[35]. Other studies show that TENS excite nerve fibers, with minimal adverse effects for patients acting to promote activation of central opioid receptors and muscarinic receptors[12,13,36] and release of catecholamine, specifically by activation of pe-

ripheral adrenergic receptors[11,36,37]. However, these adrenergic receptors suffer degeneration with loss of potentiation during pregnancy, thus leading to increased uterine contractility, resulting in premature labor and impaired fetal growth[38].

Furthermore, there are evidences in the literature for the use of drugs for treating pain during pregnancy[39,40]. However, pharmacological treatment must be prescribed cautiously in this population, since it can present adverse effects, such as malformation, respiratory complications and congenital cryptorchidism in the fetus, and the onset of preeclampsia and maternal thromboembolic disease[27-29]. Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most common drugs prescribed to pregnant women, despite the fact that its adverse effects on the fetus are known. Use of NSAIDs during pregnancy can cause dysfunction of several organ systems of the newborn, including the brain, cardiovascular system, lung, skeleton, gastrointestinal tracts, and especially the renal system[41].

Recently, acetaminophen was considered the analgesic drug of choice for pregnant women when non-pharmacological treatments are ineffective; however, it presents a risk for the development of asthma in newborns[29]. It was also shown that the use of acetaminophen during pregnancy may influence fetal brain development, resulting in behavioral problems and hyperkinetic disorders in the infant[42]. Acetaminophen appears to freely cross the placenta and can induce liver toxicity in both the mother and the fetus[43]. Thus, TENS appears as a non-pharmacological therapeutic tool for pain relief associated to no adverse effects neither on the fetus nor pregnant women, resulting in a treatment within easy reach and applicability with satisfactory outcomes for pain relief, as well as a complementary resource in the treatment of musculoskeletal dysfunctions caused by pregnancy[18,24,25].

In an experimental animal study, application of TENS was carried out in mice divided into three groups: placebo, low frequency TENS (10Hz, intensity of 2mA) and high frequency TENS (150Hz, current of 2mA)[44]. In this study, sensory intensity was increased by 1mA in every 5 minutes, electrodes were applied on the abdominal region, and mice were placed in a retainer to not move. The mother's weight was evaluated according to gestational period, and some gestational variables such as implantations, resorptions, fetuses, placenta and malformations were recorded. Finally, authors concluded that TENS caused no adverse effects neither on the mother nor on the infant in an animal model.

Studies that have created conditions of stress in pregnant rats by prenatal restraint have reported that the fetus subjected to the stressor placental environment is more likely to have intrauterine growth restriction[43,44]. These findings point to the need for substantial data to secure the indication or absolute contraindication for the use of TENS in pregnant women because electrotherapy can also promote stress when applied close to the uterine region.

Thus, it follows that there is insufficient evidence from randomized clinical trials on the effects of TENS in the placenta, the uterus or the evolution of fetal development, as well as the development of cerebral circuits of the offspring, as those involved in the regulation of nociceptive perception and motor control. Therefore, studies with animal experimentation would allow assessing whether the application of electrical current during pregnancy may or may not cause changes in pregnancy and/or offspring development.

Studies involving the application of TENS during pregnancy are inconsistent regarding safety, mostly because there is no assessment of maternal-fetal measures appropriately and difference in performance between TENS, acupuncture and electroacupuncture has not been considered[45,46]. Clinical trials report that the use of electroacupuncture during pregnancy (12-31 weeks) or during labor does not cause side effects, however, when used on specific points of acupuncture, induces uterine contraction and hence labor ends with the interruption of the electric stimulation[43,47]. Other studies reported no changes in fetal development when the mother uses TENS for the treatment of musculoskeletal pain during labor or placental insufficiency[48,49]. Therefore, the claim that TENS is safe for pregnant women should be interpreted with caution, since what is widely described in the literature as a safe analgesic electrotherapeutic modality is concerning to the effect of acupuncture and electroacupuncture and not of TENS.

In order to clarify the current situation regarding the application of TENS during pregnancy, the Association of Chartered Physiotherapists in the Women's Health (ACPWH) gathered several experts who were based on the relevant literature related to clinical experience. The scientific foundation of this study consists of studies on electroacupuncture, acupuncture points and TENS during labor to affirm that TENS has been safely used by pregnant women without causing side effects, therefore not considering the difference between different techniques and gestational periods. However, the study shows important considerations in relation to uterine contraction, which is intensified by the application of electrical stimulation and therefore should be widely monitored. Another important consideration relates to the balance between the potential risks of choosing between TENS and the use of drugs that may cross the placental barrier, being the application of TENS preferable[43].

Currently, there are no studies to elucidate biological therapeutic effects of TENS application in the gravid uterus or its adverse effects as well. Such information is extremely necessary for clinical trials to be conducted in a safe manner for both the mother and the fetus. Taking into consideration that pain may start and remain during and after pregnancy, it becomes necessary to conduct studies that assess the applicability of TENS in initial, intermediate and final stages of pregnancy in a single or long-term repeated administration and in different points of application[3,9,10].

Thus, one suggestion is that preclinical research may be useful for investigating the potential effects of TENS during different gestational periods and the effect of different parameters of TENS on possible changes during pregnancy, childbirth or fetal development, making it relevant to conduct clinical trials or multicenter studies to examine the safety of this modality of electrotherapy in pregnant women. As another

suggestion, these randomized clinical trials should be performed with well-designed control groups as placebo TENS, with no comparison to other treatments, and different TENS parameters could be tested, such as high and low frequency with different electrodes placement and adverse effects.

Based on this criterion for control groups in RCTs, a limitation of this systematic review was the impossibility to perform a meta-analysis with data extracted from the included studies. Despite both of them assessed pain intensity and functional disability using the same instruments, VAS and RMDQ, one study has 3 control groups (acetaminophen, exercise and no treatment) and the other one has a control group using joint mobilization as treatment. Due to this heterogeneity between groups, it was not possible to compare data in a meta-analysis. Scientific evidence about the effects of non-pharmacological therapies for pain management during pregnancy is important to elucidate new methods of rehabilitation in this population and improve quality of life and functionality during this period. Thus, it is questionable if a modality for producing analgesia such as TENS could not be used in pregnant women due to the lack of scientific evidence about this topic, the uncertainty by professionals and theoretical contraindications. Thus, it's important to emphasize the need for studies that focus on specific effects of TENS during pregnancy not associated with other techniques such as acupuncture and electroacupuncture, which are already known to produce deleterious biological effects in pregnant uterus and fetus, inducing labor when applied at specific acupuncture points, in order to know the electrical stimulation applicability safely and with well-defined parameters. In addition to that, pre-clinical studies are suggested to explain the mechanisms involved on the development of adverse effects during TENS application in different pregnancy stages.

CONCLUSION

This study showed that there is no evidence for supporting or refusing the use of TENS for either relieving pain or promoting adverse effects during pregnancy. Therefore, future studies, both pre-clinical experiments and clinical trials, should to be conducted to clearly present the application form, localization (lumbosacral, uterus/placental, extrasegmentar) and parameters of TENS that are safe or not for the pregnant population in different gestational quarters.

AUTHORS' CONTRIBUTIONS

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