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Effectiveness of complementary pain treatment for women with deep endometriosis through Transcutaneous Electrical Nerve Stimulation (TENS): randomized controlled trial

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ABSTRACT

Objective: Evaluate TENS effectiveness as a complementary treatment of chronic pelvic pain and deep dyspareunia in women with deep endometriosis.
Study design: This randomized controlled trial was performed in a tertiary health care center, including twenty-two women with deep endometriosis undergoing hormone therapy with persistent pelvic pain and/or deep dyspareunia. This study was registered in the Brazilian Record of Clinical Trials (ReBEC), under n RBR-3rndh6. TENS application for 8 weeks followed a randomized allocation into two groups: Group 1 – acupuncture-like TENS (Frequency: 8 Hz, pulse duration: 250 μs) – VIF ($n = 11$) and Group 2 – self-applied TENS (Frequency: 85 Hz, pulse duration: 75 μs) ($n = 11$). The intensity applied was "strong, but comfortable". We evaluated patients before and after treatment by the use of the Visual Analogue Scale, Deep Dyspareunia Scale and Endometriosis Quality of Life Questionnaire. We used the Wilcoxon and Mann–Whitney tests to compare before and after treatment conditions.
Results: Despite the use of hormone therapy for 1.65 ± 2.08 years, the 22 women with deep endometriosis sustained pelvic pain complaints (VAS = 5.95 ± 2.13 and 2.45 ± 2.42, $p < .001$) and/or deep dyspareunia (DDS = 2.29 ± 0.46 and 1.20 ± 1.01, $p = .001$). We observed significant improvement for chronic pelvic pain, deep dyspareunia and quality of life by the use of TENS. Both application types of TENS were effective for improving the evaluated types of pain.
Conclusions: Both resources (acupuncture-like TENS and self-applied TENS) demonstrated effectiveness as a complementary treatment of pelvic pain and deep dyspareunia, improving quality of life in women with deep endometriosis regardless of the device used for treatment.

Introduction

Endometriosis is a chronic estrogen-dependent inflammatory disease, affecting 5–15% of women in reproductive age, causing infertility and pain. Pain complaints are manifested as chronic pelvic pain, deep dyspareunia, and also dysmenorrhea, dyschezia and dysuria [1–5]. The most used treatment is surgical excision as well the use of drugs that can block the production or action of estrogens [6–8]. Although their use may have positive effects, many women continue suffering from pain. There is scarce literature on the use of complementary therapy for pain management, and acupuncture and exercises are the most commonly proposed alternatives [9–13].

Electrotherapy can treat diverse symptoms produced by diseases that affect the human body. Electrotherapy using Transcutaneous Electrical Nerve Stimulation (TENS) is a low-cost, non-invasive and easily accessible technique to treat pain [14,15]. TENS acts by spinal blocking and endogenous opioids release [16,17]. Its parameters may be adjusted, widening its range of action on pain [18]. Recent technological advances facilitated the use of self-applied TENS devices [19]. In this context, numerous descriptions emerge on the effectiveness of TENS for treating diverse types of pain (e.g. chronic low back pain, knee osteoarthritis, and dysmenorrhea) [20–24]. However, there are no specific studies on pain caused by endometriosis.

The aim of this study was to primarily evaluating the effectiveness of electrotherapy with TENS as a complementary treatment of pelvic pain and/or deep dyspareunia, as well its impact on quality of life of women suffering from deep endometriosis with persistent pain complaints, despite the use of hormone therapy.

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Escore	Description
0	No pain during the intercourse
1	Mild pain, which does not require interruption of the intercourse
2	Moderate pain, which does not require interruption of the intercourse, but difficulted it
3	Intense pain, which requires interruption of the intercourse

Fig. 1. Deep Dyspareunia Scale specifically elaborated for this study and based on the penetration dyspareunia scale created by Marinoff.

Materials and methods

We performed a non-blind, randomized clinical trial, including 22 women with deep endometriosis diagnosed in the cul-de-sac and intestinal loop who sustained pelvic pain and/or deep dyspareunia, despite continuous clinical medication. Participants received intervention and were randomized into two groups: Group 1 – acupuncture-like TENS (Dualpex 961®) ($n = 11$) and Group 2 – self-applied TENS (Tanyx®) ($n = 11$). We applied TENS at the S3–S4 region for both groups. This region is related to the sacral plexus and communicates with the pelvic splanchnic and inferior hypogastric plexus, which are responsible for pelvic structures innervation. The study was conducted in the Women's Hospital of the University of Campinas. This study was approved by the Research Ethics Committee of the institution and recorded in the Brazilian Record of Clinical Trials (ReBEC), RBR-3rndh6. All women signed a consent term before inclusion.

Women were recruited through their medical records and also during routine consultation at the Endometriosis Outpatient Facility from November 2013 to June 2014. Inclusion criteria: women at menacme, ranging from 18 to 50 years-old, diagnosed with deep endometriosis in the cul-de-sac and/or intestinal loop using imaging tests with ultrasonography after bowel preparation. The exam was performed by a single specialized ultrasonographist. All women were undergoing hormone therapy with continuous progestin alone or combined oral contraceptives for at least three months, reporting pelvic pain and/or deep dyspareunia persistence, associated or not with other pain complaints (dysmenorrhea, dyschezia and dysuria). Exclusion criteria: women with decreased skin sensitivity, implanted with a pacemaker, skin hypersensitivity (allergic reactions to gel or electrodes), epilepsy, heart disease (cardiac arrhythmia), osteosynthesis in the region of application, full-thickness defects of the skin, malignant tumors, acute inflammatory disease, and cognitive deficiency that precluded comprehension of the instruments in this study.

Randomization was generated by a computer program. Opaque sealed envelopes were used for participant randomized allocation into the two groups. Both processes were performed by a person who did not participated in the study.

All study participants responded to the Visual Analogue Scale [26,27] for quantification of pain complaints (chronic pelvic pain, dyschezia, dysuria and dysmenorrhea). We evaluated pain characteristics according to sexual intercourse pain (deep dyspareunia) in response to the Deep Dyspareunia Scale, specifically elaborated for this study and based on the penetration dyspareunia scale created by Marinoff. Fig. 1 shows our scale grading.

A quantitative measurement on quality of life impact was performed by using the Endometriosis Health Profile (EHP-30) [28], which was validated for the Portuguese language [29]. The instrument has 53 questions, divided into two parts: general information (pain, control/powerlessness, emotional well-being, social support and self-image) and specific information (work, intercourse, relationship with children, medical profession, treatment and infertility). The better the quality of life the lower the total score. All instruments were applied before and after treatment. Table 1 describes a summary of all application methods and interventions applied.

Since there were no previous studies using TENS to treat endometriosis and pain in women, the sample size was calculated based on a study by Wang, Lee and Hwa (2009). Those authors evaluated TENS by administering the Visual Analogue Scale in women with primary dysmenorrhea [30]. TENS treatment obtained a sample size of 16 patients, with a 90% test power and 5% significance level. Considering a 20% loss during follow-up, the total sample size achieved was 20 women, equally distributed between the two groups.

The Fisher's exact test measured group differences. The paired Wilcoxon test compared quantitative variables before and after treatment. Mann–Whitney test compared variables between groups. We assumed p-values <0.05 as statistically significant.

Results

Table 2 shows demographic and clinical characteristics. Fig. 2 shows an eligibility summary for our clinical trial at a Flow Chart for Randomized Controlled Trials [25].

The main sites of pain pointed by women were suprapubic (22%), sacral (9%) and in both regions in association in 69% of them.

Table 1
Summary of the applied application methods and interventions (acupuncture and self-applied TENS).

	Acupuncture-like TENS	Self-applied TENS
Protocol	*Frequency*: 8 Hz *Pulse duration*: ~250 μs and VIF (variation in intensity and frequency of 1 ms) *Intensity*: adjusted according to the woman (“strong, but comfortable”) without any motor stimulation. *Application site*: sacral region (S3–S4). *Method*: A dual-channel TENS unit was used, equipped with four rubber electrodes (~5 cm × 3 cm) and neutral aqueous gel lubricant, attached to the skin with adhesive tape crossed in an “X” pattern. *Time*: 30 min and sessions were performed once a week, for a period of 8 weeks.	*Frequency*: 85 Hz *Pulse duration*: ~75 μs *Intensity*: adjustable in three options: 10, 20 or 30 mA. Women were instructed to choose the intensity that was “strong, but comfortable” *Application site*: sacral region (S3–S4). *Method*: The correct placement of the device was initially explained and demonstrated on the patient during evaluation, and doubts were dispelled by the researcher. TENS application was performed at home by the patient herself. She could follow instructions from a didactic illustration showing the exposed sacral region of a supine woman next to another illustration of the same woman with the equipment in place. *Time*: Twice a day, 20 min per application, setting an interval of 12 h between applications. A return visit was scheduled after four weeks of treatment for follow-up of the use of the device. A final reassessment was carried out after 8 weeks.