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Effects of Transcutaneous Electrical Nerve Stimulation on Chronic Pelvic Pain in Women: A Systematic Review and Meta-Analysis

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Keywords
Chronic pain · Dysmenorrhea · Pelvic pain · Transcutaneous electric nerve stimulation

Abstract
Introduction: The study aimed to identify the effects of transcutaneous electrical nerve stimulation (TENS) in women with chronic pelvic pain (CPP) by conducting a systematic review and meta-analysis of randomized controlled trials. ***Methods:*** We used five international databases from 2000 to 2020 and selected the clinical trials that reported the effects of TENS on CPP. We excluded the case reports, acute pelvic pain reports, men-related, animal-related, and intravaginal and intrarectal electrical stimulation articles. The level of pain (based on the visual analog scale) was considered for pooling data through the meta-analysis. ***Results:*** Ten studies met the inclusion criteria, and three articles were included in the meta-analysis. The results showed that TENS application mildly reduced pain in women with primary dysmenorrhea (mean difference = −1.29; 95% CI: −2.57 to −0.01; $Z = 1.98$, $p = 0.05$). Also, to reduce pain in patients with CPP, the TENS must be applied at least for 20 min, with a pulse duration of 50–400 μs, at a frequency of 2–120 Hz. The meta-analysis was followed by assessing the risk of bias, including publication bias. Based on the Cochrane risk of bias evaluation, the majority of the included trials were assessed with moderate methodological quality. ***Conclusion:*** TENS application can mildly improve the level of pain in patients with CPP caused by primary dysmenorrhea. Although no distinct agreement was observed among the effective parameters, the high-frequency mode with maximum tolerated intensity was more effective compared to the low-frequency mode.

Auswirkungen der transkutanen elektrischen Nervenstimulation auf chronischen Unterleibsschmerz bei Frauen: eine systematische Übersicht und Metaanalyse

Schlüsselwörter
Chronische Schmerzen · Dysmenorrhoe · Unterleibsschmerz · Transkutane elektrische Nervenstimulation

Zusammenfassung
Einleitung: Das Ziel dieser Studie war es, mittels einer systematischen Literaturübersicht und Metaanalyse randomisierter kontrollierter Studien die Wirkungen der transkutanen elektrischen Nervenstimulation (TENS) bei Frauen mit chronischen Unterleibsschmerzen (CUS) zu betrachten. ***Methoden:*** Aus fünf internationalen Daten-

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banken wählten wir aus dem Zeitraum von 2000 bis 2020 die klinischen Studien aus, in denen über die Wirkungen der TENS bei CUS berichtet wurde. Ausgeschlossen wurden Fallberichte, Berichte über akute Beckenschmerzen sowie Artikel über Männer, Tiere oder intravaginale oder intrarektale elektrische Stimulation. Das Ausmaß des Schmerzes (auf der visuellen Analogskala) wurde beim Pooling der Daten im Rahmen der Metaanalyse betrachtet. ***Ergebnisse:*** Zehn Studien erfüllten die Einschlusskriterien, und drei Artikel wurden in die Metaanalyse eingeschlossen. Den Ergebnissen zufolge führte die Anwendung der TENS zu leichter Schmerzlinderung bei den Frauen mit primärer Dysmenorrhoe (mittlere Differenz: −1.29; 95-%-KI: −2.57 bis −0.01; $Z = 1.98$, $p = 0.05$). Um eine Schmerzlinderung bei den Patientinnen mit CUS zu erreichen, musste die TENS außerdem mindestens 20 Minuten lang angewendet werden, mit einer Pulsdauer von 50–400 μs und einer Frequenz von 2–120 Hz. Auf die Metaanalyse folgte eine Beurteilung des Risikos für verschiedene Formen von Verzerrung einschließlich Publikations-Bias. Die Verzerrungspotenzial-Beurteilung nach Cochrane ergab für den Großteil der eingeschlossenen Studien eine moderate methodische Qualität. ***Schlussfolgerung:*** Die TENS-Anwendung kann das Schmerzlevel von Patientinnen mit CUS infolge primärer Dysmenorrhoe geringfügig verbessern. Während keine klare Übereinstimmung bezüglich der wirksamen Parameter zu erkennen war, war der Hochfrequenzmodus bei maximal tolerierter Intensität wirksamer als der Niedrigfrequenzmodus.

Introduction

Chronic pelvic pain (CPP) syndrome is characterized by a nonmalignant perceived pain in pelvic structures [1, 2]. Pain sensation is continuous or recurrent for at least 6 months in patients with nociceptive pain and becomes chronic [1, 2]. It affected one in seven women in the USA, and about one billion dollars are annually spent to treat the symptoms following CPP [3]. Women with CPP are prone to social isolation, anemia, sleep disorders, fatigue, depression, and anxiety [4, 5]. Women with CPP usually report pain in the perineum, vagina, rectum, bladder, lower abdominal area, and thighs with or without urinary and sexual disorders [1, 3]. The causes are often complicated and include common gynecological and non-gynecological conditions, such as primary dysmenorrhea (PD) and endometriosis, musculoskeletal, urinary, and gastrointestinal disorders [1, 4, 6].

Common pharmacological and surgical treatments were often reported as unsatisfactory in patients with CPP [4, 6]. Moreover, pharmacological treatments may include some side effects such as indigestion, vomiting, reflux, nausea, fatigue, and headaches [7, 8]. The central and peripheral neuromodulation techniques are other treatment methods [5, 9–11]. Transcutaneous electrical nerve stimulation (TENS) is considered to be a common noninvasive peripheral neuromodulation and affordable method to manage pain and guard muscles [11]. Despite all positive clinical reports [12], some experts believe that the method can be ineffective for some types of musculoskeletal disorders [13]. However, TENS is widely applied to improve chronic pain [12]. Although TENS is used as a noninvasive and common intervention to care for the patients with CPP, there is no unanimity on its effectiveness and effective parameters. Therefore, a comprehensive systematic review on the effects of TENS on patients with CPP may help clinicians choose appropriate treatment methods to optimize recovery. The purpose of this study was to conduct a systematic review and meta-analysis of clinical trials that studied the effects of TENS on CPP and its effective treatment parameters.

Materials and Methods

Search Strategy and Study Selection

This study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (online suppl. File S1; for all online suppl. material, see www.karger.com/doi/10.1159/000528133) [14]. The main question of this systematic review was "Can TENS be effective to control pain in women with CPP?"

The Population, Intervention, Comparison, and Outcome format was used to find relevant articles; while the population was women with CPP, intervention was all types of TENS, comparison would be considered with any other types of electrical modulations or placebo TENS, outcomes were pain relief and improvement in quality of life (QOL). The systematic search was designed to identify the published merited randomized controlled trials, and the protocol for systematic review was registered with Researchregistry.com (number: reviewregistry1312).

Using an identified search strategy, we performed a systematic search of five electronic databases, including PubMed, Science Direct, Embase, Cochrane, and Scopus. A combination of related MeSH terms and free-text words used were matched to the search strategy in each database [15]. The identified MeSH terms used for search strategy were interstitial cystitis, painful bladder syndrome, endometriosis, dysmenorrhea, electric stimulation. The applied text words were chronic pelvic pain, pelvic tenderness, pelvic adhesion, transcutaneous electrical nerve stimulation, TENS, electrical current. Two independent researchers scanned all the titles and abstracts of the identified studies; the potentially eligible abstracts were selected for further investigation. Three reviewers independently retrieved the relevant selected abstracts and then reviewed them in full-text to choose appropriate articles for critical appraisal. Also, a secondhand search was conducted by searching the references of the selected full-texts to identify the possible missing articles. The search string with the search terminology from databases is attached as online supplementary File S2.

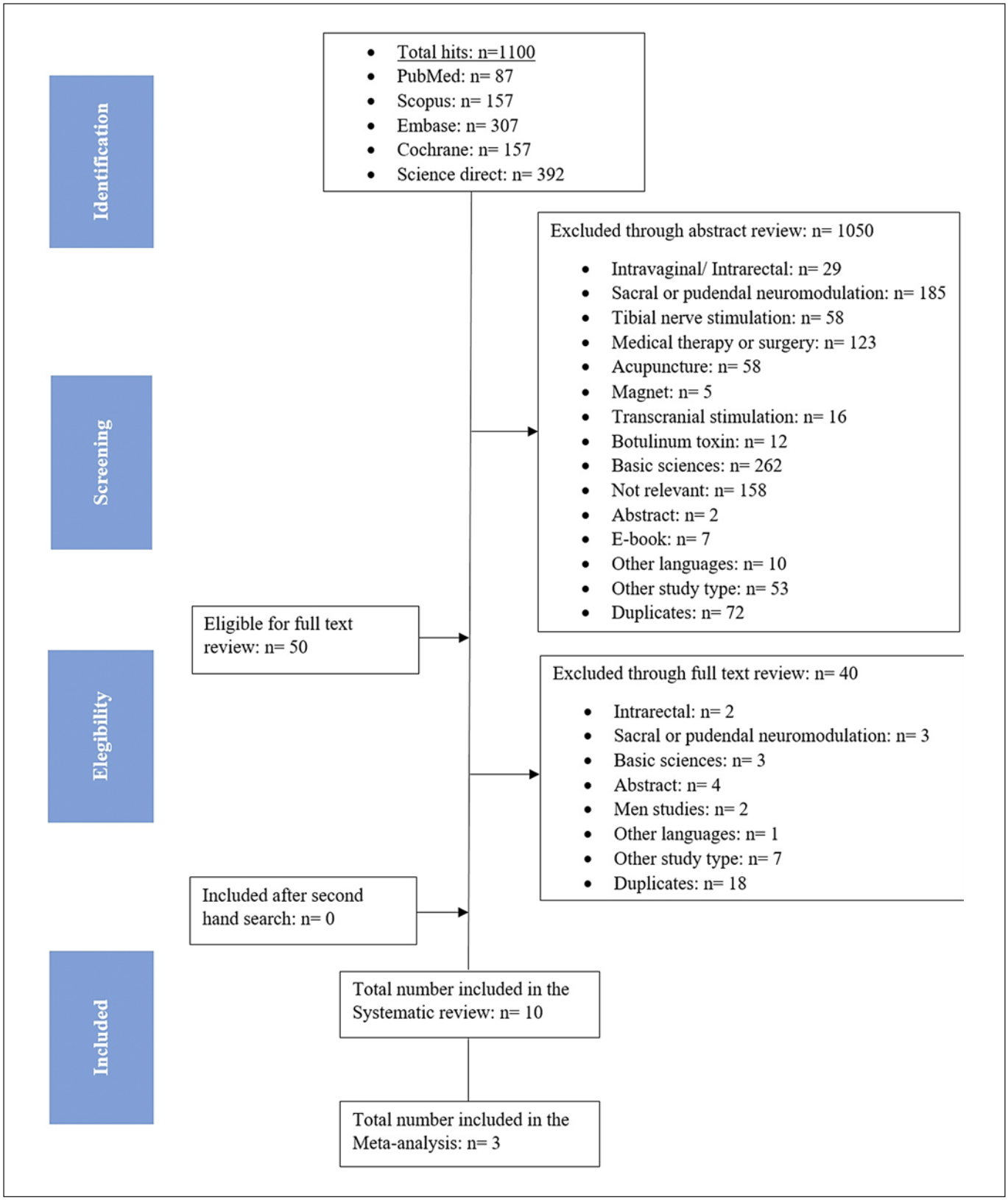

Fig. 1. Flow diagram of the search strategy and summary of reasons for the excluded articles.

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Table 1. Characteristics of the included trials

Author	Participants	Objectives/aims	Method/ design	Setting	Intention to treat/power calculation	Dropout	Inclusion/exclusion criteria	Funding	Quality score
Tugay et al. [30] 2007	**G1**: TENS *N* = 17 Mean age (SD): 21.29 (1.93) **G2**: interferential current *N* = 15 Mean age (SD): 21.40 (1.59)	To compare effectiveness of TENS and interferential current in women with **PD**	RCT	Hacettepe University School of Physical Therapy and Rehabilitation	NR	2	**Inclusion**: PD according to history, ultrasound findings, and physical examination	NR	6/10
Schiotz et al. [29] 2007	**G1**: TENS *N* = 21 Mean age (SD): 24 (NR) **G2**: no Treatment *N* = 21 Mean age (SD): 24 (NR)	To determine clinical efficacy of TENS (OVA device) in women with P**D**	Single- blinded RCT	NR	NR	0	**Inclusion**: women with PD **Exclusion**: amenorrhea	NR	7/10
Wang et al. [27] 2009	**G1**: TENS *N* = 22 Mean age (SD): 23.2 (3.2) **G2**: placebo *N* = 22 Mean age (SD): 23.2 (3.2)	To evaluate effects of high-Fr TENS in women with **PD**	Double- blinded, cross-over RCT	NR	NR	4	**Inclusion**: women with PD **Exclusion**: presence of structural lesions by ultrasound image	GRANT 300093275 of Industrial Research Institute	5/10
Parsa and Bashirian [26] 2013	**G1**: TENS *N* = 32 Mean age (SD): 16.40 (1.01) **G2**: placebo *N* = 32 Mean age (SD): 15.96 (0.89)	To compare effects of high-Fr TENS and placebo TENS in women with **PD**	RCT	NR	NR	0	**Inclusion**: women were diagnosed as PD on the basis of menstrual history	NR	6/10
Lauretti et al. [24] 2015	**G1**: TENS *N* = 20 Mean age (SD): 20 (4.0) **G2**: placebo *N* = 20 Mean age (SD): 20 (3.0)	To test the effectiveness of TENS (TANYX® device) in women with **PD**	Double- blinded RCT	NR	NR	0	**Inclusion**: past history of painful, debilitating dysmenorrhea and regularly took rescue analgesic such as N-butyl scopolamine combined to the nonsteroidal anti-inflammatory diclofenac for pain control **Exclusion**: cramping pain secondary to the following pathologies: endometriosis, uterine myoma, uterine malformations, other similar uterine diseases, pelvic inflammatory disease, congenital mullerian anomalies, ovarian cysts, inflammatory bowel disease	School of Medicine of Ribeirao Preto – University of Sao Paulo	9/10
Lee et al. [23] 2015	**G1**: TENS and thermotherapy *N* = 57 Mean age (SD): 28.14 (6.17) **G2**: placebo *N* = 58 Mean age (SD): 27.0 (5.94)	To examine efficacy of the combined therapy with high-Fr TENS and thermotherapy in relieving **PD** pain	Single- blinded RCT	Seoul National University Bundang Hospital and Chungbuk National University	Intention to treat reported	0	**Inclusion**: premenopausal women who were over 20 years old, had moderate or severe lower abdominal dysmenorrhea (VAS_ 5/10] that required analgesics to control pain for a minimum of 6 months **Exclusion**: pregnant women, with cancer in the last 5 years, women with history of surgery in the lower abdomen, permanent pacemaker, skin disease, those with contraindications for ibuprofen	Medirune Co., Ltd. and the Industrial Complex Cluster Program of Korea Industrial Complex Corporation	8/10

Table 1 (continued)

Author	Participants	Objectives/aims	Method/ design	Setting	Intention to treat/power calculation	Dropout	Inclusion/exclusion criteria	Funding	Quality score
Mira et al. [31] 2015	**G1**: acupuncture-like TENS *N* = 11 Mean age (SD): 41.0 (5.4) **G2**: self-applied TENS *N* = 11 Mean age (SD): 30.9 (4.5)	To evaluate TENS effectiveness in women with **DE**	RCT	Women'|'s Hospital of the University of Campinas	NR	0	**Inclusion**: women at menace, ranging from 18 to 50 years, diagnosed with DE in the cul-de-sac and/or intestinal loop using imaging tests with ultrasonography, all women were undergoing hormone therapy with continuous progestin alone or combined oral contraceptives for at least 3 months, reporting pelvic pain and/ or deep dyspareunia persistence **Exclusion**: women with decreased skin sensitivity, pacemaker, skin hypersensitivity, epilepsy, heart disease, osteosynthesis in the region of application, full-thickness defects of the skin, malignant tumors, acute inflammatory disease, cognitive deficiency	Research Support Foundation of the State of Sa˜o Paulo (FAPESP)	6/10
Sharma et al. [32] 2017	**G1**: low-Fr TENS *N* = 30 Mean age (SD): 48 (NR) **G2**: medium-Fr TENS *N* = 32 Mean age (SD): 48 (NR) **G3**: high-Fr TENS *N* = 30 Mean age (SD): 48 (NR) **G4**: placebo *N* = 30 Mean age (SD): 48 (NR)	To investigate effect of TENS in idiopathic **CPP**	Single- blinded RCT	Department of Obstetrics and Gynecology, Department of Physiotherapy at Saveetha Medical College, Chennai	NR	0	**Inclusion**: women with CPP not responding to analgesic and anti-inflammatory therapy in the age of 18–60 years **Exclusion**: patients with known abdominal or pelvic pathology, any medication for chronic renal diseases, pregnancy	No funding	7/10
Bai et al. [25] 2017	**G1**: TENS *N* = 67 Mean age (SD): 25.6 (4.3) **G2**: placebo *N* = 67 Mean age (SD): 24.9 (4.5)	To study the effect of TENS on pain intensity in women with **PD**	Double- blinded RCT	PeopleHospital of Yan'an and Maternal and Child Health Hospital of Yan'an	Intent to treat reported	12	**Inclusion**: patients with PD, age 18–30 years, a history of lower abdominal pain for more than 6 menstrual cycles, moderate or severe pain (NRS ≥5 out of 10), no alternative therapy including TENS within 1 month prior to enrollment **Exclusion**: pregnant, history of surgery of the lower abdomen, skin disease, cancer, heart disease, severe mental disorders	No funding	9/10
Fagevik Olsén et al. [28] 2019	**G1**: TENS *N* = 7 Mean age (SD): 26 (NR) **G2**: no Treatment *N* = 9 Mean age (SD): 26 (NR)	To test effects of high-intensity, high-Fr TENS in women with **PD**	Randomized, cross-Over pilot Study	Sweden	NR	6	**Inclusion**: women ≥18 years old, moderate to severe PD. **Exclusion**: secondary dysmenorrhea, newly started hormone treatment, pacemaker, wound or skin disease, planned pregnancy within the next few months	No funding	7/10

CPP, chronic pelvic pain; DE, deep endometriosis; G, group; high-Fr, high-frequency; NR, not reported; PD, primary dysmenorrhea; RCT, randomized controlled trial; SD, standard deviation; TENS, transcutaneous electrical nerve stimulation.

Table 2. Interventions, outcomes, and results of the trials on patients with other causes of CPP

Author	Tx time Tx session Period of Tx	Tx zone (electrode placement)	Treatment parameters				Clinical outcomes	Results	Follow-up
			intensity, mA	pulse duration, μs	Fr, Hz	current type			
Mira et al. [31] 2015	Group 1						VAS DDS QOL	↓Pain in both groups ($p = 0.002$ and $p = 0.01$) ↓DDS in both groups ($p = 0.03$ and $p = 0.03$) ↑QOL in both groups ($p < 0.001$)	No
	30 min 1/week 8 weeks	S3–S4 Region	Strong and comfortable	250	8	NR			
	Group 2								
	20 min 2/day 8 weeks	S3–S4 region	Strong and comfortable	75	85	NR			
Sharma et al. [32] 2017	30 min 5/week 2 weeks	Suprapubic dermatome	0–80 (maximum tolerated)	50–400	Group 1: <25 Group 2: 25–75 Group 3: 75–100	Square biphasic	VAS	↓Pain in group 1, 2, and 3 ($p < 0.001$) No pain reduction for placebo group ($p > 0.05$)	4 weeks

CPP, chronic pelvic pain; DDS, deep dyspareunia scale; QOL, quality of life; Fr, frequency; NR, not report; Tx, treatment; VAS, visual analog scale.

Inclusion and Exclusion Criteria

The search strategies were applied to all identified databases from 2000 to December 2020. The inclusion criteria were clinical trials that reported the effects of TENS on patients with CPP. All published articles in English that reported any types of CPP (including interstitial cystitis, painful bladder syndrome, endometriosis, dysmenorrhea, pelvic adhesion) under the application of any types of superficial TENS (including conventional TENS, high- and low-frequency TENS, acupuncture-like TENS, burst TENS, intense TENS) were selected for this study. Besides, the articles were excluded if they were animal and experimental studies, case reports, former systematic reviews or meta-analyses, acute pelvic pain reports, animal and men-related studies, and intravaginal or intrarectal electrical stimulations. Figure 1 shows the flow diagram of the search strategy.

Placebo

The placebo groups in all selected trials were sham TENS application. The placebo TENS had exactly the same appearance as the active TENS, but the placebo TENS had no current output.

Data Extraction

Two reviewers independently extracted the data of each article and imported them into a specific chart. The extracted data included the participants' information, objectives, method/setting, dropout, intention to treat/power calculation, inclusion/exclusion criteria, funding (Table 1), outcome measures, the characteristics of interventions, and the trials' results (Table 2 and online suppl. Table). All primary outcomes of the included trials were identified through searching the selected articles' Materials and Methods. They were including a visual analog scale (VAS), number of analgesic intake, and QOL scores.

Assessment of the Quality and Risk of Bias in the Selected Articles

Using the PEDro quality scores [16], two independent raters critically appraised the articles. The selected trials were classified into three levels of quality as high (PEDro scores >8), medium (PEDro scores from 5–8), and low (PEDro scores <5) [16].

The risk of biases was also scrutinized through the selected trials by two independent researchers, based on the Cochrane Risk of Bias tool [17]. We evaluated the methods of all selected trials to identify the risk of bias among them. Besides, we prepared a table for the risk of bias assessment for all selected trials and considered the signs of negative, positive, and question marks to show low risk, high risk, and unclear risk, respectively, for each study [18]. The risk of bias evaluation is a common method of assessment for the biases among the included trials. The common assessable biases include random sequence generation for selection bias, allocation concealment for selection bias, the blinding of participants and personnel for performance bias, the blinding of outcome assessment for detection bias, incomplete outcome data for attrition bias, and selective reporting for reporting bias [18].

Data Synthesis and Meta-Analyses

The statistical calculations were performed, and descriptive statistics were retrieved for all eligible trials. The mean ± SD scores of common outcome measures among the selected trials (pain level measured by VAS) were used to perform a meta-analysis, pool the data, and have better clarification on the effects of TENS on the CPP symptoms.

We calculated *Q* statistics to test the homogeneity of the selected trials for meta-analyses. A significant *Q* statistic identifies that the variance between the trials is inconsistent with study sampling error [19]. Also, a significant *p* value in the homogene-

ity test indicates heterogeneity in the selected trials, which are not measuring an effect of the same size [20]. Contrarily, if the trials are not heterogeneous, they can be considered similar; therefore, they can be combined [21]. Furthermore, the *F* value for equality of variance (Levene's test), the *t* value, the degree of freedom, mean difference, and 95% CI were reported through each eligible study.

Two types of statistical models are applicable for effect size calculation in meta-analysis; they include fixed- and random-effects models [19]. Both fixed- and random-effects models can be used to determine substantial differences among the combined results [19]. The fixed-effects model would be applicable if we had homogeneity on effect sizes [19], while the random-effects model is suggested at the time of the heterogeneity of variance [19]. So, the results of the random-effects calculation are more conservative compared with the results of the fixed-effects model [20]. We pooled the data based on similarity for selected trials and used both random and fixed-effects models since we would like to estimate both conservative and nonconservative models of calculation for analyses. The random-effects model is also advised for the authors who want to generalize their findings [19].

All data were entered into the RevMan software version 5.3 [18]. The RevMan can be applied for meta-analysis to provide a *Z* value and construct forest and funnel plots to show overall effect size, related 95% CI, and risk of biases. The forest plot is a graphical design of estimated results for several trials that focus on similar questions and give the overall results [22]. Also, the funnel plot is a graphical design to represent the chance of publication bias, especially in systematic reviews and meta-analyses [22].

The publication bias was evaluated by the computation of the fail-safe N. The fail-safe N can be derived from the equation $K_0 = K(\text{Mean d} - d_{\text{trivial}})/d_{\text{trivial}}$, where K_0 is the number of needed trials to produce trivial effect size, K is the number of trials in meta-analysis, Mean d is the mean effect size from all trials, and d_{trivial} is the estimate of trivial effect size [19]. The reviewers were in full agreement in all steps of the procedure, and any discrepancies were resolved through meet-up sessions if necessary.

Different researchers had used different indicators to evaluate effects of the TENS application on patients with CPP [23–32]; however, the majority of them used the VAS to assess level of pain [23, 24, 26–32]. In total, eight studies (out of 10) were conducted on the patients with PD [23–30], and two remaining studies were about the other causes of CPP [31, 32]. Seven articles (out of eight) evaluated the pain level based on the VAS [23, 24, 26–30], while the other used the NRS [25]. Beyond, some researchers also used the other outcome measure methods to evaluate severity of pain including number of analgesic intake [23–26, 28] and QOL scores [23–25, 27, 31]. Level of pain based on the VAS was considered as the major dependent variable in all seven trials (out of eight), and the VAS scores before and after interventions were reported usually based on mean ± SD. One trial (out of seven) involved no control group and compared the TENS with another type of intervention (IFC) [30]. Parsa and Bashirian [26] used TENS only for 1 day of menstruation, and Lee et al. [23] applied both thermotherapy and TENS for the patients. Olsen et al. [28] applied just 1 min of TENS and reported that the intervention was ineffective. They also reported the results based on a 100 score level [28]. So, we could not consider data from these four trials for pooling because of the differences in their research frameworks [23, 26, 28, 30]. Therefore, three relevant trials could be considered for pooling data and included in a meta-analysis [24, 27, 29].

The authors of two trials (out of ten) focused on and reported the other causes of CPP [31, 32], and they applied VAS as the major outcome measure to evaluate pain. The data from these two trials could not be suitable for meta-analysis because of different research frameworks. One of these two trials did not have control group as well [31].

Four trials reported QOL scores in patients with PD [23–25, 27]. The methods of their measurements were different, so it was not possible to perform a meta-analysis to represent pooling data for QOL. Besides, there were not enough data for another common outcome measure, analgesic intake, to perform another meta-analysis among the eligible trials, since there were just two studies reported mean and standard deviation of analgesic intakes before and after treatment [23, 29]. Among these two studies, the researchers in one study had another type of intervention simultaneously that might have affected final results, and it was not possible to pool the data of the studies [23–26, 28, 29].

Results

Outcome of Literature Searches

The initial search generated a total of 1,100 hits. In total, there were 87 hits that were recognized in PubMed, 157 in Scopus, 307 in Embase, 157 in Cochrane, and 392 in Science direct. After the identification process, 1,050 studies were excluded through abstract review, and 50 studies were eligible for full-text review. Among fifty eligible studies that were fully retrieved, 40 studies were excluded, and 10 trials met the inclusion criteria for the systematic review. There were no additional articles to be selected after secondhand search of the selected articles' references. Among all retrieved studies, three trials had a common outcome measure, and their data could be pooled through a meta-analysis (Fig. 1).

Five authors compared effects of TENS with sham TENS [23–27], while Fagevik Olsén et al. [28] and Schiotz et al. [29] compared effects of this modality with control groups that received no treatment. Besides, Tugay et al. [30] compared TENS with another type of electrical stimulation (interferential current), and Mira et al. [31] and Sharma et al. [32] compared the different parameters of TENS.

Quality of the Evidence

Two raters independently evaluated the qualities of the selected trials through the PEDro scale. In total, eight trials had medium quality [23, 26–32], and two trials were classified as high quality based on the PEDro scale [24, 25] (Table 1).

Outcome Measures

Eight studies (out of 10) were conducted on the patients with PD [23–30], and two remaining studies were about the other causes of CPP [31, 32] including Mira et al. [31] that reported patients with deep endometriosis and Sharma et al. [32] that did not report any causes for CPP [31]. In most of the trials, the researchers used the VAS (0–10 cm, where "zero" meant "no pain" and 10 meant "extreme amount of pain") to examine the level of

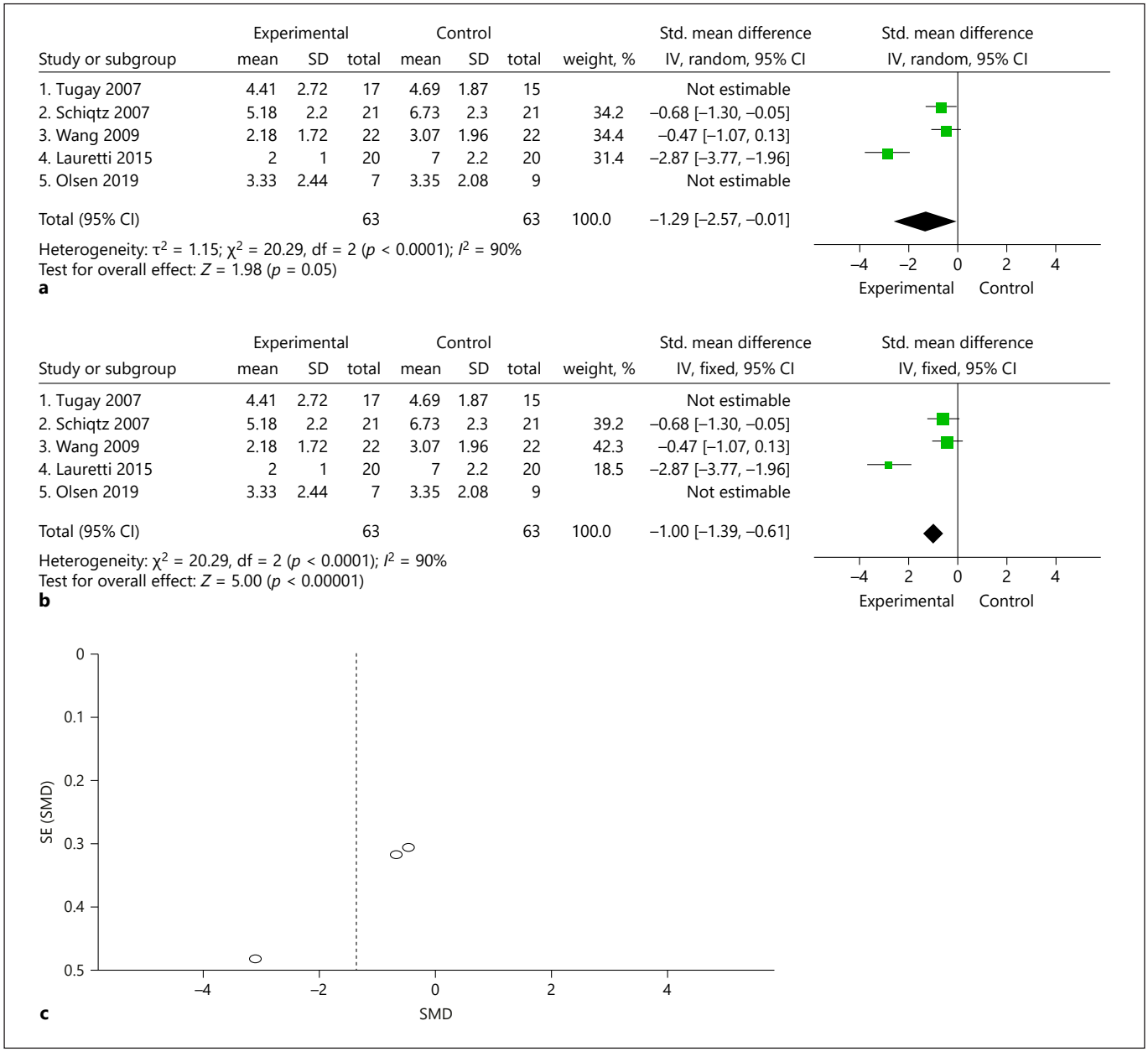

Fig. 2. a Sample size, weight, and forest plot of the random-effects model based on the VAS score changes after TENS application in patients with CPP caused by PD. **b** Sample size, weight, and forest plot of the fixed-effects model based on the VAS score changes after TENS application in patients with CPP caused by PD. **c** Funnel plot following random-effects model analysis after TENS application in patients with CPP caused by PD.

pain [23, 24, 26–32], and just Bai et al. [25] applied the numeric rating scale (NRS).

The QOL is an important factor for patients with CPP [33]. Five researchers reported the QOL scores [23–25, 27, 31]. Although women's sexual function is an important variable [33], Mira et al. [31] were the only authors who reported it in their trial. There were six trials (out of 10) that reported number of analgesic intakes [23–26, 28, 29] in their research. Wang et al. [27] included pre-post intervention measurement and autonomic symptoms questionnaire as outcome measures. Fagevik Olsén et al. [28] reported physical function.

Safety of the Intervention

There were seven trials that considered adverse effects [23–27, 29, 30]. Only one author among seven, Wang et al. [27], reported positive adverse effects following the treatment including increased menstrual bleeding during TENS and increased heart rate during sleep.

Effects of Interventions

The TENS parameters were reported to identify many effective approaches. The parameters were time of treatment, number of sessions, treatment zone (electrode placement), intensity, pulse duration, frequency, and type of current.

We divided the trials into two main categories. In the first category, we discussed CPP as a result of PD, and in the second category, the other causes of CPP were considered. We found eight trials that included PD and two trials with other causes of CPP. Most of the patients in the first category were young participants (15–28 years), and the researchers investigated the application of TENS on PD signs and symptoms [23–30]. As it was clarified in the selected trials that included PD, at least 20 min of electrical stimulation, once a day, with a pulse duration of 50–200 μs, must be applied to effectively reduce the pain level in PD patients. The frequencies of application varied in the range of 2–120 Hz. However, there was no consensus over the shape of the waves among the authors. Also, the current intensities differed between the trials, and the location of the application of TENS was mostly on the lower back region [23–30]. The mean pain reduction in active TENS groups based on the VAS/NRS was 2.82, while it was 1.09 in the placebo/control group. Also, in most trials that evaluated the number of analgesic intake, application of TENS reduced the intake of the medical drugs [23–26, 29].

The second category only included two trials that applied the frequencies of 8–100 Hz [31, 32], pulse duration of 50–400 μs [32], and intensity at the maximum tolerable level on suprapubic or S3–S4 regions for at least 20 min [31, 32]. In the study by Sharma et al. [32], the mean pain reduction based on the VAS was 4.76 in active TENS and 0.7 for the placebo groups. In the study by Mira et al. [31], mean pain reductions in acupuncture-like TENS and self-applied TENS were 3.18 and 3.82, respectively.

Results of Meta-Analysis

There were 126 patients available to perform this meta-analysis. The Q statistic result showed a statistically significant value ($Q = 20.29$, $p < 0.0001$) for the samples in this study ($N = 3$). Therefore, the distribution of the effect sizes was heterogeneous for the calculation. Accordingly, we combined the results of the trials using the random-effects model. The results of pooled data from the eligible three trials, calculation of standard means differences, and pooled standard deviations clarified that TENS application could mildly decrease level of pain in the patients with PD (mean difference = −1.29; 95% CI: −2.57 to −0.01; $Z = 1.98$, $p = 0.05$) (Fig. 2a). The results of the meta-analysis of the eligible trials showed mild-quality evidence for TENS effectiveness in pain reduction for patients with PD. Figures 2a and b represent the forest plot,

Table 3. Risk of biases among the selected trials

Study or subgroup	Tugay et al. [30] 2007	Schiotz et al. [29] 2007	Wang et al. [27] 2009	Lauretti et al. [24] 2015	Fagevik Olsen et al. [28] 2019	Parsa and Bashirian [26] 2013	Lee et al. [23] 2015	Mira et al. [31] 2015	Sharma et al. [32] 2017	Bai et al. [25] 2017
Risk of bias										
Rsg	−	−	−	−	−	−	−	−	+	−
Acs	?	?	?	−	−	?	−	−	+	−
Bpp	+	+	+	+	+	+	+	+	+	+
Boa	+	−	−	−	+	+	−	+	−	+
Iod	−	−	+	−	+	−	−	−	−	−
Srr	−	−	−	−	−	−	−	−	−	−

Acs, allocation concealment (selection bias); Boa, blinding of outcome assessment (detection bias); Bpp, blinding of participants and personnel (performance bias); Iod, incomplete outcome data (attrition bias); Rsg, random sequence generation (selection bias); Srr, selective reporting (reporting bias).

sample sizes, means, the difference in means, standard deviations, and relative weights of the selected trials. We applied the random-effects model to consider the heterogeneity of the trials (Fig. 2a). However, if we applied a fixed-effects model for the calculation, the results would show more effectiveness for TENS application on pain levels in patients with PD (mean difference = −1.00; 95% CI: −1.39 to −0.61; $Z = 5.00$, $p = 10^{-5}$) (Fig. 2b).

The asymmetrical situation of the funnel plot for identified trials (Fig. 2c) clarified the existence of the risk of publication bias through the results. However, considering that just three trials met the inclusion criteria, a higher number of eligible trials might help decrease the risk of this bias. The fail-safe N calculation showed that 37.14 (= 38) more unpublished articles are needed to nullify our results (online suppl. Table; Fig. 2a). Table 3 also reports the risk of bias assessment for all selected trials. The high risk of biases in most of the selected articles was referred to lack of therapist blinding in research frameworks.

Discussion

In general, different types of TENS have been used to decrease the level of pain in patients with CPP. Most of the researchers in this systematic review have reported that TENS could effectively decrease the level of pain in patients with CPP [23–27, 29–32], and many trials supported the efficiency of high-frequency TENS [23, 24, 26, 27, 29, 30, 32]. According to our results, TENS application mildly decreases pain in patients with PD. However, no identified protocol (TENS parameters) could be considered to have the most effective treatment characteristics.

Overall, most of the researchers found that TENS was more effective in pain relief compared with the placebo and/or control groups in patients with PD [23–25, 29, 30]. However, Parsa and Bashirian [26], Wang et al. [27], and Fagevik Olsén et al. [28], that had moderate quality, reported similar pain reduction for both groups of TENS and placebo/control, based on the VAS. It was shown that the expectation of pain relief could significantly modulate pain, which was expressed as placebo analgesia [34]. Some of the researchers have compared the effects of TENS and sham TENS on different types of chronic pain and reported no difference between the groups [35]. Contrarily, the other researchers indicated that TENS-related improvements longer than 3 months could not be associated with placebo effects [36, 37]. So, the utilization of a blind placebo group seems important and necessary for the relevant studies. This approach will help us have the placebo analgesic effects in patients with CPP in the placebo groups and clarify real effectiveness for identified TENS parameters [38].

Based on the results of this review, the effective parameters were restricted owing to the lack of appropriate TENS characteristics and detailed data of the studies. Most of the reviewed trials that studied the effects of TENS on the CPP patients selected the high TENS characteristics (above 50 Hz) for their studies and reported effective results for treatment [23, 24, 26, 27, 29, 30, 32]. However, there were just two studies that compared the effects of high- versus low-frequency TENS (Sharma and Mira) in which one of them reported much effectiveness on high-frequency application [32] and the other reported no difference between high- and low-frequency TENS [31]. The reported mechanism of pain reduction following the high-frequency TENS application differs from those of the placebo and low-frequency TENS. The mechanism of high-frequency TENS relies on the gate control theory and acts through blocking sensory inputs or axonal reflexes [27]. Conversely, the mechanism of low-frequency TENS was reported as similar to that of the placebo effect, which was referred to as triggering endorphin circuits in the spinal cord and inhibiting detrusor muscles [39]. High-frequency TENS can stimulate peripheral nerves, leading to angiogenesis around the region, while the placebo TENS mechanism is similar to endorphin release, where the reactions in the cortex and brainstem may lead to pain reduction [40, 41]. The application of high-frequency TENS (above 50 Hz) activates the δ-opioid receptors, while the low-frequency TENS (10 Hz or less) may activate μ-opioid receptors in the rostral ventral medulla [42]. High-frequency TENS for pain relief in patients with CPP may pose anti-ischemic effects instead of the inhibition of pain afferents [43]. In this regard, Sharma et al. [32] reported much effectiveness for high-frequency TENS in pain reduction for patients with CPP. The results of this trial showed a dose-response relationship, leading to decreased pain levels after TENS application [32]. High-frequency TENS might transmit stronger afferent inputs to the central nervous system and lead to stronger segmental inhibition in nociceptive transmitters from second-order neurons [44]. Nevertheless, there were some controversies between the researchers about effective parameters to decrease pain in patients with CPP. For instance, some researchers reported a decrease in pain level in patients with dyschezia when the patients were under acupuncture-like TENS (below 10 Hz) [31]. But some others believed that most pain reduction might happen for the patients with CPP following the application of high-frequency TENS (above 50 Hz) [23, 24, 27, 29, 30, 32].

Consistent with a review in 2020 [45], the results of our study show that the maximum tolerable intensity will lead to greater pain relief in patients with CPP. Chen et al. [46] reported that the current intensity must be strong enough to achieve pain relief. Moran et al. [47] measured pain

threshold in healthy people and reported that electrical stimulation with the highest tolerable intensity for any patient led to the highest level of pain reduction. These results may clarify why dose-response effects will decrease pain levels following the application of TENS [47]. The dose-response effects explain the relationship between the intensity of TENS and its analgesic effects on tissues and organs [47]. Based on this relationship between pain reduction and pain threshold increase, the patients with CPP might have central sensitization that might be considered a reason for resistance against treatment in some patients [48].

Among the five trials that examined the QOL, only two trials reported the improvement of QOL scores following the TENS application [24, 31]. In the study by Lauretti et al. [24], the mean reduction in pain for the TENS group was about 6/10 points. In the study by Mira et al. [31], the mean pain reduction in both groups of TENS (acupuncture-like TENS and self-applied TENS) was about 3.5/10 points. In all three trials in which TENS was not reported to be effective for QOL improvement, levels of pain reduction were about 2/10 points. The results showed that average pain reduction was an important factor for QOL improvement.

TENS has been shown to be free from intense adverse effects [49]. It has been reported that the most common adverse effect of TENS is skin irritation and burning sensation under the electrode place [50]. As it was explained, most of the selected trials reported no adverse effects following the TENS application [23–26, 29, 30]. Wang et al. [27] were the only authors who reported side effects in 2 patients including increased menstrual bleeding during TENS application and increased heart rate during sleep time.

According to the results of this systematic review, the parameters of applied stimulation currents (such as frequency, pulse duration, and stimulation time) were constant and similar throughout each trial, and it was just the intensities that were increased based on the patients' threshold level [23, 24, 27, 28, 30]. It was the individualized adjustments for the current intensities that led to increased effectiveness through the treatment periods [29, 51]. Although adjusting other parameters, such as frequency and pulse duration, might have helped increase the effectiveness, there were no clarified adjustments for the other parameters through the selected trials. Further investigations with well-designed studies and placebo groups are necessary to suggest more effective TENS parameters that would help reach better improvement in patients with CPP.

The TENS is an appropriate alternative modality for women who prefer not to use medication or wish to minimize the NSAID intake to reduce pain during menstruation. This systematic review clarified that TENS with different parameters has mild beneficial effects on pain in patients with CPP caused by PD. Since most of the identified studies reported high-frequency TENS as an effective mode with appropriate results [23, 24, 26, 27, 29, 30, 32], the high-frequency TENS can be considered more effective in pain reduction for patients with CPP. Besides, the maximum tolerable intensity will lead to longer relief for these patients. There was no unanimity on other TENS parameters to reduce pain levels in CPP patients. Thus, robust randomized controlled trials with a higher number of participants and groups of controls are necessary to identify more effective parameters.

Implication for Clinical Practice and Future Research

The TENS application could mildly decrease pain in patients with CPP due to PD. Although there is no agreement on effective parameters, high-frequency TENS and maximum tolerated intensity could be much beneficial. The applied TENS frequencies were reported widely from 2 to 120 Hz, but most of the effective studies selected high-frequency TENS for their research (above 50 Hz) [23, 24, 26, 27, 29, 30, 32]. The TENS must be applied at least for 20 min per day, with a pulse duration of 50–200 μs and frequencies of 2–120 Hz to reduce pain in patients with CPP due to PD. Besides, TENS application with the pulse duration of 50–400 μs, frequencies of 8–100 Hz for at least 20 min were reported much effective to reduce pain levels in patients with CPP that arise because of causes other than PD.

Future studies must concentrate on more effective TENS parameters to control pain levels in patients with CPP. The effects of TENS should also be compared with the effects of percutaneous tibial nerve stimulation, sacral neuromodulation, and invasive interventions, such as pudendal, caudal, and epidural neuromodulation, on the patients with CPP. The results will help clinicians establish effective protocols, especially if researchers follow up on these patients.

Strength and Limitations of the Study

We pooled the data among the trials that reported the effects of TENS intervention on pain level in patients with CPP. Considering the available evidence, we recommend relevant clinicians to use high-frequency TENS at a well-tolerated intensity to decrease pain in patients with CPP.

This study also included some limitations.

1. The authors could not review relevant non-English studies for this systematic review.
2. Just a few trials compared the TENS parameters and their effects on the patients with the CPP [31, 32]. Accordingly, it was impossible to suggest highly effective TENS parameters.

3. Several trials had considerable limitations on methods [26, 30, 31]. So, they cannot be affordable for the systematic review conclusion.
4. We could not perform a sensitivity analysis since the data were not complete among the selected trials.

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Statement of Ethics

An ethics statement is not applicable because this study is based exclusively on published literature.

Conflict of Interest Statement

The authors declared no conflict of interest.

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Author Contributions

Seyedeh Saeideh Babazadeh-Zavieh and Seyed Mohammad Jafar Haeri: data collection, project development, manuscript writing, and critical appraisal. Siamak Bashardoust Tajali: project development, data analysis management, manuscript writing and revising, and critical appraisal. Amirhossein Shamsi: project development and manuscript writing and revising.

Data Availability Statement

The main contribution expressed in the study is given in the paper.

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