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Impact on Quality of Life of Portable Transcutaneous Electric Nerve Stimulation as an Adjuvant Treatment in Mexican Women with Dysmenorrhea: A Randomized Crossover Trial

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Abstract

Objective: To evaluate the effect on Health-related quality of life (HRQOL), efficacy and safety of a Portable Transcutaneous Electrical Nerve Stimulation (TENS) as an adjuvant treatment to nonsteroidal anti-inflammatory drugs (NSAIDs) for pain relief in Mexican women with primary dysmenorrhea (PDys)

Patients and Methods: A randomized, open crossover clinical trial (Cofepris protocol DIS-SF-2018). A total of 70 Mexican women diagnosed with PDys who required pharmacological treatment to dysmenorrhea and had a Numerical Pain Rating Scale (NPRS) of at least 4 units, were recruited and randomized into two groups, 1:1 (arm A: arm B). In the first cycle, Arm A received NSAIDs and TENS, while Arm B was given only NSAIDs. The treatments were switched for next cycle. TENS treatment consisted of sessions with a portable massage equipment HV-F021/HV-F022 Omron®, up to 3 times a day. Efficacy was defined as a decrease of 2 units between initial vs. final NPRS scores and/or reduction of NSAIDs use. All patients completed a daily symptom diary as well as EuroQoL and safety-related questionnaires before and after treatment in both cycles. Statistical analysis was performed by intention to treat through inferential parametric and non-parametric tests as well as 1-factor ANOVA and correlation tests. Statistical significance was defined as $p < 0.05$.

Results: TENS as adjuvant treatment for PDys aided pain decrease by at least 2 NPRS units in 98% of all patients and lowered NSAIDs intake statistically significant, both with $p \leq 0.000$, with a positive safety profile. There was some impact in terms of recovery of their daily activities, decreasing symptoms, and improving the self-HRQOL, without statistical significance.

Conclusion: TENS use was associated with pain decrease, lower NSAIDs intake, and relieving associated symptoms. Although no statistically significant effect on HRQOL was found. The present study's support the TENS use as an adjuvant treatment to reduce pain in Mexican women with dysmenorrhea.

Keywords: Dysmenorrhea; Pain; Quality of life; Transcutaneous electrical nerve stimulation

Abbreviations

NPRS: Numerical Pain Rating Scale; NSAIDs: Nonsteroidal anti-inflammatory drugs; PDys: Primary dysmenorrhea; TENS: Transcutaneous Electrical Nerve Stimulation

Introduction

Painful menstruation or dysmenorrhea is defined as a cyclic, painful, cramping sensation in the lower abdomen that is often accompanied by other symptoms, such as sweating, headaches, nausea, vomiting, diarrhea, and tremors, that occur the days prior or during the menses. Painful menstruation without any evident pathology to account for them is defined as primary dysmenorrhea [1].

Dysmenorrhea is the most frequent gynecological complaint. A 2014 epidemiological review reported a prevalence of primary dysmenorrhea between 60%–91% of women of reproductive age worldwide [2,3], severe pain was reported in 2%–29% of women, with dysmenorrhea limiting activities in 16% to 29% of women [3]. Often improves after childbirth.

A Mexican high school students survey by Ortiz et al. reported that self-medication was practiced by 64.9% of students, with NSAIDs being used in 34% of reports. 33.5% of them consulted a physician and NSAIDs were prescribed in 34.6% of cases with a 18.4% complete remission of symptoms. 24 percent of dysmenorrheic students reported school absenteeism [4].

Transcutaneous electrical nerve stimulation (TENS) is an established method for pain relief in dysmenorrhea [5,6], which acts by activating a complex neural network to reduce pain [7] first, by blocking the ascending afferent signal of pain in the spinal cord (activating large diameter afferent fibers), followed by a release of endogenous morphine and a local effect of electrostimulation that reduces uterine muscle ischemia through regional vasodilation [8]. Several studies have shown the potential benefit of using TENS as an adjuvant to conventional analgesic treatment for pain control in these patients [6,7].

The use of TENS for relief of pain in primary dysmenorrhea has been evaluated in different settings with positive results. Randomized controlled trials on the reduction of primary dysmenorrhea with the application of high-frequency TENS versus placebo [2,9-13] and medication [2,13-15] have reported TENS as effective in primary dysmenorrhea without the potentially adverse effects of analgesics [2,9-15].

Reviews on TENS as an adjuvant treatment have reported that the majority of trials indicate a positive effect of TENS interventions on primary dysmenorrhea [7,16,17] concluding that TENS could help decrease NSAID´s consumption and is a suitable alternative for women who prefer not to use medication. Since an important advantage of the use of TENS in dysmenorrhea may come from a reduction in pain medication intake and the effects on women's daily activities, evidence on the improvement of quality life and treatment safety is required. Bai (2017) evaluated quality of life as a secondary outcome through the World Health Organization quality of life (WHOQOL)-BREF score but no significant differences in the quality of life, measured by the WHOQOL-BREF score, were found [15].

Previous studies have analyzed the effect of TENS with a lack of homogeneity of the participants, including menstrual history and intensity of symptoms. In addition to that, prior studies have established a wide range of intensities of stimulation and number of doses There is no consensus on the duration and number of sessions but recommended intensity of TENS stimulation is to apply TENS at the highest tolerable intensity of each subject [18].

In Mexico, studies on the use of TENS to treat primary dysmenorrhea are scarce, therefore, the objective of the present study was to evaluate the effectiveness and safety of portable electrotherapy massage equipment as an adjuvant to conventional NSAIDs treatment compared to NSAIDs alone for pain relief and its effect on quality of life.

Methods

Study design and sample size

A prospective, randomized, 1:1, two-cycle crossover trial was conducted on a Mexican female population at a private gynecology clinical care. (Cofepris protocol DIS-SF-2018)

Sample size calculation was performed with effect size data based on the results of Schiotz 2007, Lee B 2015, and Bai 2017, who measured changes in NPRS scores after intervention [15,19,20]. The cut-off point was an average decrease of 1.9 points with a bilateral study design and power of 0.80, with statistical significance defined as p <0.05. A total of 35 subjects per group were estimated, considering each group as an independent event, two consecutive menstrual cycles were analyzed for a total of 140 events.

Participants were randomized to either Arm A (TENS plus conventional treatment) or Arm B (conventional treatment) for the first cycle, followed by an arm crossover for the second cycle. Conventional treatment consisted of 400 mg of ibuprofen in accordance with the current national Good Clinical Practice Guidelines (GPC) [21]. Patients were scheduled for a total of 5 visits throughout the study.

Subjects

Mexican women aged 18 - 40 years old with primary dysmenorrhea, regular cycles, no history of childbirth, whose menstrual pain intensity was scored > 4 on the Numerical Pain Rating Scale (NPRS), at least in the previous menstrual cycle, who required intake of non-opioid analgesics or NSAIDs in at least 2 days of the period. All subjects provided written informed consent.

Exclusion criteria

Secondary dysmenorrhea, medical implants, uncontrolled acute or chronic disease, acute intestinal or gastric ulcers, critical or life-threatening medical conditions, any progressive disorder of the central nervous system, any skin affliction, infectious or other, in the placement area of the portable electrotherapy massage equipment pads, or a history of treatment with psychotropic drugs or drug addiction.

Intervention

The intervention consisted of self-administered massage sessions of 15 to 30 (minutes up to 3 times a day with a HV-F021/HV-F022 Omron® massage portable equipment through self-adhering pads applied at the bilateral lumbar level in a pre-configured cycle "Lumbar" mode with a frequency between 1 and 238 Hz. Two repetitions of 15 minutes were allowed if they did not feel any significant improvement, with stimulation intensity set based on the patient´s highest tolerability. Each subject received an instruction pamphlet and recording dairies for each cycle. Pain medication treatment consisted of 400 mg of ibuprofen as needed, and up to 1600 mg/day. For the second menstrual cycle, the patients switched treatment.

Outcome measurement

Quality of life was assessed by EuroQoL scores and changes in the number of analgesics used in both cycles. Treatment efficacy was defined as a pain reduction of at least 2 units in the NPRS of initial pain, and/or a decrease in the use of NSAIDs in relation to usual consumption. Treatment safety was analyzed through adverse event reports.

The EuroQoL questionnaire analysis was descriptive of the effect in all 5 dimensions of the quality of life of daily activities, pain, depression or anxiety, according to the patient's assessment of her health status by levels of severity and on the visual analog scale of general evaluation performed on the same day in which the questionnaire was answered.

Patients recorded daily pain perception within the NPRS 10 points scale and amount of pain medication. This simple instrument has been well tested and is easily understood by patients used in dysmenorrhea[15,19,20], as well as quick and easy to use. Additionally, an inventory of accompanying symptoms of dysmenorrhea was documented in the patient's diary.

Statistical analysis

Descriptive statistics were used to describe continuous variables, frequencies, and proportions for categorical variables. Means were compared using a paired two-sample t-test. The chi-squared test and Fisher's exact test were used to compare categorical variables between groups. Statistical significance for all tests was set at $p < 0.05$.

An ANOVA test was performed on the pain variable, global health perception for each day of cycle, symptom inventory, and QoL evolution on diaries as well as NSAIDs record intake. Each subject served as their own control for comparing TENS plus conventional therapy to conventional treatment only. Any participant who received protocol-treatments and completed at least 80% of clinical assessments and diaries, were considered protocol compliant in the defined population for efficacy subset analyses. The magnitude of association was identified by simple correlation analysis between pain intensity and affected domains in EuroQoL [22]. All study data were recorded in MS Excel and processed with Stata 13.0 software.

Results

A total of 73 female patients were included (one selection and two inclusion failures), and seventy patients were randomized. Thirty-five patients in arm A were first treated with conventional treatment plus TENS (ibuprofen 400 mg + TENS), and thirty-five in arm B received conventional treatment first (Figure 1). A total of 140 events were analyzed.

The general characteristics are shown in Table 1. Age average was 23.7 years (SD± 3.8 years), 28.5% (20) had a history of contraceptive use, 57.1% (40) perceived themselves as anxious, 63.5% commented

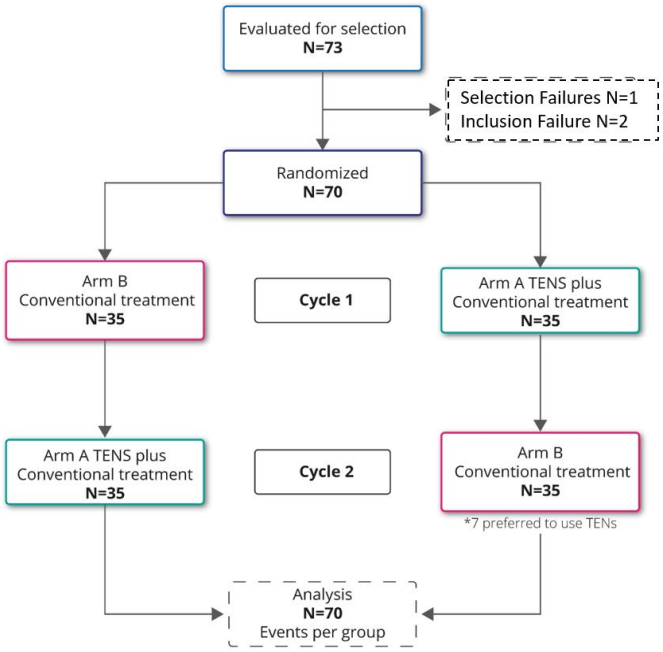


Figure 1: Patient flow diagram of the study.

Table 1: Characteristics of patients with primary dysmenorrhea by starting treatment arm in intention to treat population.

General characteristics	Total group	ARM A	ARM B	
		Conventional treatment + Massage equipment	Conventional treatment	p value
	n=70	n=35	n=35	
Age (± SD)	23.7±3.8	24.2±4.43	23.1±3.85	0.229
Marital status				
Single	94.2% (66)	97.0% (34)	91.6% (32)	0.331
Other	5.8% (4)	3.0% (1)	8.4% (3)	
Body mass index BMI ($\bar{x}$ ± SD)	24.7±3.93	23.7±2.8	25.8±4.5	0.025
Age at menarche (± SD)	12±1.6	11.8±1.6	12±1.6	0.478
History of hormonal contraceptives use*	28.6% (20)	26.5% (9)	30.6% (11)	0.705
Menstrual characteristics				
Cycle duration	28.6±2.4	28.7±1.4	28.5±3.0	0.727
Period duration	5.1±1.7	4.8±1.2	5.4±2.1	0.804
Dysmenorrhea onset (years)	5.7± 4.2	6.1±4.6	5.3±3.79	0.84
Heavy menstrual loss**	80% (56)	80.5% (27)	79.4% (29)	0.905
Initial NPRS score	7.9 ±1.5	8.1 ±1.5	7.7±1.3	0.167
Symptoms				
Average number of symptoms	3.8±1.1	3.85±1.0	3.58±1.5	0.307
Weakness %	92.8% (65)	91.4% (32)	94.2% (33)	0.816
Irritability %	91.4% (64)	94.2% (33)	88.5% (31)	0.214
Headache %	78.5% (55)	80.0 % (28)	77.1% (27)	0.386
Nausea %	61.4% (43)	62.8% (22)	60% (21)	0.307
Affectation of daily activities %	58.5% (41)	60% (21)	57.1% (20)	0.808
Anxiousness%	57.1% (40)	57.1% (20)	57.1% (20)	0.060

*Use of hormonal contraceptives the month prior to study start

**Defined as the use of 4 or more fully soaked menstrual pads a day for any duration during the menstrual cycle

Regarding menstruation characteristics, the mean age at menarche was 12.0 years (SD ± 1.6 years), the mean duration of menstruation was 5.1 days (SD± 1.7 days) and the average menstrual cycle duration was 28.6 days (SD ±2.4 days).

Table 2: Improvement of accompanying symptoms between the treatment arms.

Symptoms	Total events n (%) N:140	Patients improve Arm A n (%) N:70	Patients improve Arm B n (%) N 70	Statistical significance
Weakness	122 (87.1%)	33 (47.1%)	30 (42.8%)	0.734
Irritability	129 (92.1%)	40 (57.1%)	34 (48.5%)	0.3973
Nausea	42 (30%)	23 (32.8%)	19 (27.1%)	0.58
Headache	96 (68.5%)	29 (41.4%)	21 (30%)	0.035 (<0.05)
Lumbar pain	123 (87.5%)	41 (58.5%)	20 (28.5%)	0.0003 (<0.05)
Lower NPRS score*	113 (80.7%)	50 (71.4%)	63 (65.7%)	0.009 (<0.05)

*Patients whose NPRS scores improved by at least 2 points

that dysmenorrhea had a negative effect on their daily activities, and 52.8% reported use of NSAIDs as a treatment for dysmenorrhea during their last cycle.

The average NPRS scores for pain perception at baseline was 7.3 points (SD +2.0); with no difference between treatment arms, there were a progressive decrease in patient's diaries reports of more than 2 units between initial and final NPRS scores, with statistically significant differences between arm A (71.4%, n=50) and arm B (65.7%, n=63) respectively p-value 0.009. Table 2 The evolution of NPRS scores during the days of the cycle is shown in Figure 2.

The NSAIDs consumption was 2.2 capsules (SD ± 2 capsules) in average. At baseline, 42 patients (30%) in Arm A and, 9 (6.6%) in Arm B did not require NSAIDS, this difference was statistically significant (p =0.000).

The most frequent symptoms at baseline were irritability (92.1%), weakness and lumbar pain (87.1%), headache (68.5%), and nausea (30%), with no statistically significant differences between arms. Table 2 summarizes the improvement in accompanying symptoms, there is a statistical significance in headache, lumbar pain, and patients with at least 2 points of pain decrease.

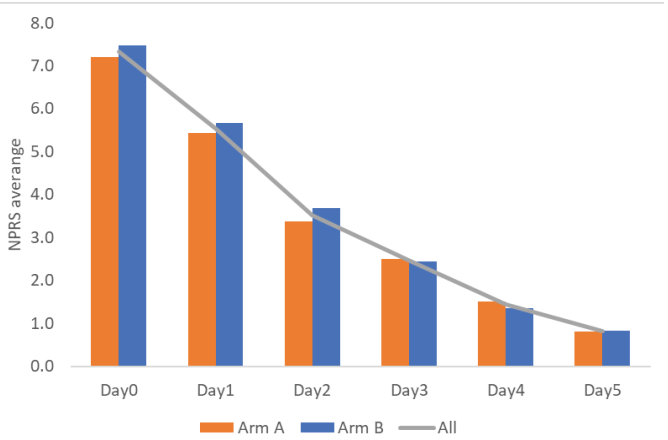
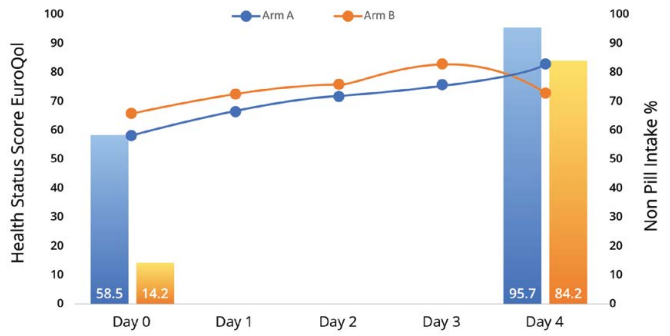


Figure 2: Pain perception, NPRS scores during the cycle.

Concerning the quality of life. The average health status score was 58.5 points (SD ±23.5) with no statistical differences between arms. The most affected domains in Euroqol at the beginning of each cycle were pain (80% n=112), difficulty to performing their daily activities



Lines: Health status score. Bars: No pill intake % Chi test p 0.0003

Figure 3: Relation between NSAIDs intake and health status score improvement.

(56.4%, n=79), anxiety (40.7%, n=57), and mobility (46.4%, n= 65). A higher proportion of improvement was observed in arm A (81.4%, n=57) vs. arm B (78.5%, n=55) for the pain and daily activities domain, in arm A (52.7%, n=39) vs. arm B (51.4%, 36), respectively, without a statistically significant difference. When comparing the health status score during the worst pain day with lowest pain day, the average score was 58.0 points (SD ±22) in arm A and 65.4 points (SD+21) in arm B with a $p = \leq 0.05$.

The ANOVA analysis confirmed statistically significant differences between arms A and B in the initial vs. final NPRS ($p = 0.000$) and the perception of the visual analog scale of the health state perception baseline vs. final ($p = 0.007$). Additionally, figure 3 shows the relationship between the need to take NSAIDs with an improvement in health status; the intake difference had statistical significance (p 0.0003)

As high as 75% (105) of patients had a thirty-minute session, with an average intensity of 6 in a predetermined function. Ninety-eight percent (138) reported being "comfortable without interference to their daily activities" and would prefer to use it in the following cycles. Only 1 patient reported that use is difficult because their work requires great mobility and physical effort. There were no reported adverse incidents or events during the treatment or follow-up period.

Discussion

Evidence shown in previous articles and systematic reviews support the usefulness of associating TENS with conventional treatment for dysmenorrhea [2,9-15,23]. The association of TENS with conventional therapy presents an opportunity for multimodal intervention in pain through minimally invasive, non-pharmacological interventions that offer improved control with electro-stimulation for pain [24].

TENS as an adjuvant in the treatment of dysmenorrhea in Mexican women that favored the reduction of pain by at least 2 units of NPRS ($p \leq 0.000$) and improvement in pain relief was statistically significant ($p=0.05$), where the initial score average was 8.90 (SD ±0.8) and it decreased to 4.5 points (SD±3.2) in their final score in two consecutive cycles [20].

The reduction in NSAIDs consumption was significant, and 57% of all evaluated cycles did not require the use of NSAIDs. There was an improvement in nausea, that even though it had no statistical significance, one might consider that the reduction of NSAIDs related to the use of TENS may have contributed to this effect.

The improvement of accompanying symptoms in the literature [2] reports an improvement of fatigue in up to 27%, and weakness improvement up to 92.8% of all patients evaluated. Our study found no statistically significant changes in those symptoms, but a headaches and lumbar pain presented a significant reduction in 41.4% and 58.5% of patients, respectively.

These results confirm previous reports on pain reduction outcomes [16,23], and similar to Bai's 2007 study on quality of life, no significant differences between arms were found [15].

A previous study in a Mexican population indicated that 60.9% of students with dysmenorrhea reported that menstrual pain had a negative impact on their activities in at least one menstrual cycle; as well as anxiety / depression in similar proportion 47% vs. 48.4% [4].

This study showed that 98% of the patients, in addition to the positive effects on pain and symptoms, mentioned that they would continue to use TENS as adjuvant treatment in future menstrual cycles because they found it comfortable and perceived that it did not affect their daily activities.

Some limitations in the design must be considered: The present study focused on patient selection considering that childbirth, hormonal contraceptives, and age over 40 related to a reduction in dysmenorrhea severity [25], selecting young nulliparous women with no history of hormonal contraceptives might have proven a bias towards more severe cases of dysmenorrhea.

Each patient was evaluated subjectively twice, in the absence of an untreated group. Our study found no statistically significant effect on QoL variables, although patients reported a significant improvement in pain and during the second cycle, NSAIDs use was lower and associated with the use of TENS.

The present study focused on short-term usage, which may prove a bias towards the novelty effect of a new treatment and longer testing periods of study are required to discard this possibility. The only long-term study on TENS and dysmenorrhea by Lauretti et al. reported a period of use of TENS for 3 months, but they did not evaluate the effectiveness of the treatment over time [9]. However, the evidence on the use of TENS in other types of chronic pain for long periods of time has proved significant reduction in the consumption of pain medication, physical therapy, and an increase in physical activity [26-28]. A longer-term study on the use of TENS in dysmenorrhea might provide evidence of its effect on quality of life by a sustained improvement in pain levels and reducing the need for NSAID intake.

Conclusions

The use of TENS as adjuvant treatment for dysmenorrhea reduced pain by decreasing the perception of pain by at least 2 NPRS units, reducing the need to take NSAIDs for pain, improving headaches and lumbar pain. No adverse events/incidents were observed until the end of the study.

The equipment's used was reported as comfortable, easy to use and did not prevent continuation of activities at work, school, or even at home. Although we found no statistically significant effect on patient's quality of life, the present study contributes to the evidence that TENS can improve pain relief and reduce NSAID intake. It is important to continue with a follow-up to assess the long-term efficacy of TENS, the long-term effects on quality of life and the use of TENS as exclusive treatment in those patients whose use of anti-inflammatory drugs and/or hormonal therapy is contraindicated.

The present evidence supports the recommendations of use of TENS as an adjuvant treatment to reduce pain and lower NSAIDs intake in Mexican women with dysmenorrhea.

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Declaration of Conflicts of Interest

This article was made with the full autonomy of the authors and

GVS, who is responsible for the article content, declare have received honoraria from OMRON. GVS is an employee of HS Estudios Farmacoeconómicos S.A. de C.V., is an ISPOR member and declare have received honoraria also from Roche, Novartis, Sanofi, Pfizer, and Biogen as well as have served in a consulting or advisory role for Roche, Celgene, and AstraZeneca. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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