

Effect of transcutaneous electrical nerve stimulation therapy for the treatment of primary dysmenorrhea

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Abstract

Background: This study aimed to investigate the effect and safety of transcutaneous electrical nerve stimulation (TENS) therapy for relieving pain in women with primary dysmenorrhea (PD).

Methods: In this study, 134 participants with PD were randomly divided into the intervention group and the sham group, with 67 participants in each group. Participants in the intervention group received TENS, whereas those in the sham group received sham TENS. The primary outcome was measured by the Numeric Rating Scale (NRS). The secondary outcomes were measured by the duration of relief from dysmenorrheal pain, number of ibuprofen tablets taken, and the World Health Organization quality of life (WHOQOL)-BREF score, as well as the adverse events.

Results: A total of 122 participants completed the study. Compared to sham TENS, TENS showed a greater effect in pain relief with regard to the NRS ($P < .01$), duration of relief from dysmenorrheal pain ($P < .01$), and number of ibuprofen tablets taken ($P < .01$). However, no significant differences in the quality of life, measured by the WHOQOL-BREF score, were found between 2 groups. The adverse event profiles were also similar between 2 groups.

Conclusion: TENS was efficacious and safe in relieving pain in participants with PD.

Abbreviations: AEs = adverse events, BMI = body mass index, ITT = intention-to-treat, NRS = Numeric Rating Scale, PD = primary dysmenorrhea, SPSS = Statistical Package for the Social Sciences, TENS = transcutaneous electrical nerve stimulation, WHOQOL = World Health Organization quality of life.

Keywords: clinical trial, effect, primary dysmenorrhea, transcutaneous electrical nerve stimulation

1. Introduction

Primary dysmenorrhea (PD) is defined as cramping pain in the lower abdomen that occurs just before or during menstruation in women, with no identifiable pelvic pathology.^[1] It may be accompanied by nausea, vomiting, fatigue, headache, dizziness, and other symptoms.^[2,3] PD is common among adolescent girls and young women of reproductive age.^[4] The pain often lasts for 8 to 72 hours during the menstrual cycle.^[5] A total prevalence of PD of 88% has been estimated among 1266 female university students.^[6] Of these, 45% students experienced pain during each menstrual period, and 43% experienced some painful menstrual periods.^[6]

The pain can be relieved by nonsteroidal anti-inflammatory drugs and oral contraceptive pills.^[5] Unfortunately, these agents are often associated with adverse events (AEs) such as intermenstrual bleeding and breast tenderness.^[7] Thus, it is necessary to explore an alternative therapy that leads to few or no AEs, for the management of PD.

Alternative medicine has been proposed for relief from a variety of pains,^[8–13] such as knee pain, neck pain, back pain, PD, and many other types.^[14–21] PD is one of the most common conditions treated by alternative medicine, including relaxation therapy, acupuncture, acupressure, heat intervention, and transcutaneous electrical nerve stimulation (TENS) therapy.^[21]

TENS involves stimulation of the skin by using different electrical currents and frequencies, to provide pain relief for patients with PD. In this study, we aimed to explore the effect and safety of TENS for relieving pain in Chinese young women with PD. We hypothesized that for the treatment of PD by TENS therapy would be superior to the effect of sham TENS.

2. Methods and materials

2.1. Study design

This randomized, sham-controlled trial was approved by the ethics committee of The People's Hospital of Yan'an and was conducted at The People's Hospital of Yan'an and Maternal and Child Health Hospital of Yan'an from January 2015 to December 2016. A total of 134 eligible participants were randomly divided into an intervention group or a sham group at a ratio of 1:1. Participants in the intervention group received TENS, whereas those in the sham group received sham TENS.

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Treatments in both groups were administered for no longer than 8 days during each menstrual cycle, for a total of 3 cycles.

2.2. Patients

The participants in this study met the following criteria: (1) diagnosis of PD; (2) age between 18 and 30 years; (3) a history of lower abdominal pain for more than 6 menstrual cycles; (4) moderate or severe pain, with a numeric rating scale (NRS) score ≥ 5 out of 10; (6) no alternative therapy including TENS within 1 month prior to enrollment in the study; and (7) provision of informed consent prior to enrollment in the study. Patients with following criteria were excluded: pregnant or breastfeeding; history of surgery of the lower abdomen; heart disease, skin disease, cancer, or severe mental disorders.

2.3. Randomization and blinding

Stratified randomization was performed by a computerized number generated using SAS package (Version 9.1; SAS Institute Inc., Cary, NC). All participants were randomly assigned to the intervention group or the sham group equally. The patients and investigators were not informed whether a participant was assigned to the intervention or the sham group. The outcome assessors and data analysts were also blinded to the treatment allocation information.

2.4. Intervention

The participants in the intervention group received TENS, whereas those in the sham group received sham TENS at the painful lower abdominal area, using the TENS device (HANS-100, Nanjing Jisheng Medical Technology Co., Ltd) at a frequency of 2 to 100Hz for 30 minutes. Each device had 2 gel pads attached to a silicon patch. The patch was attached to the painful area. The power was turned on in the intervention group, whereas it was kept off in the sham group. The TENS device was used when the participants felt the pain associated with PD. The starting time of TENS and the pain intensity were recorded immediately after its application. If the pain was sufficiently relieved after the treatment, the degree of pain was recorded. If

the pain was not relieved, the participants in both groups initially received a 200-mg tablet of ibuprofen. If ibuprofen failed to relieve the pain, an additional ibuprofen tablet was given at least 4 hours after the first tablet. The maximum daily dose of ibuprofen was 1200mg. All participants started receiving treatment on the first day of menstruation and the treatment ended on the last day of menstruation, as determined by the disappearance of bleeding; however, no participant received the treatment for more than 8 days in a month. The participants in both groups received treatments for 3 menstrual cycles.

2.5. Outcome measurements

The primary outcome of the intensity of lower abdominal pain was measured by NRS. The secondary outcomes included pain and the quality of life. The pain was also measured by the duration of relief from dysmenorrheal pain and the number of ibuprofen tablets taken. The quality of life was measured by the World Health Organization quality of life (WHOQOL)-BREF score.^[22] In addition, any AEs were recorded to evaluate the safety of TENS.

2.6. Statistical analysis

All data in the present study was analyzed by the Statistical Package for the Social Sciences (SPSS) software v.15.0. The sample size was calculated based on the difference in the mean rate change of the dysmenorrheal pain score with $\alpha = 0.5$, $\beta = 0.8$, and assuming a 15% drop-out rate.^[23] Therefore, the required sample size of this study was estimated to be 134 patients, with 67 assigned to each group. The *t*-test or Mann-Whitney rank sum test was used to analyze the continuous data. Pearson's chi-square test or Fisher's exact test was used to analyze the categorical data. All data were analyzed by intention-to-treat (ITT). The statistical significance level was set at $P < .05$.

3. Results

In total 195 participants were initially recruited and screened in this study (Fig. 1). Of these 195 subjects, 51 did not meet the inclusion criteria, and 10 declined to participate in this study.

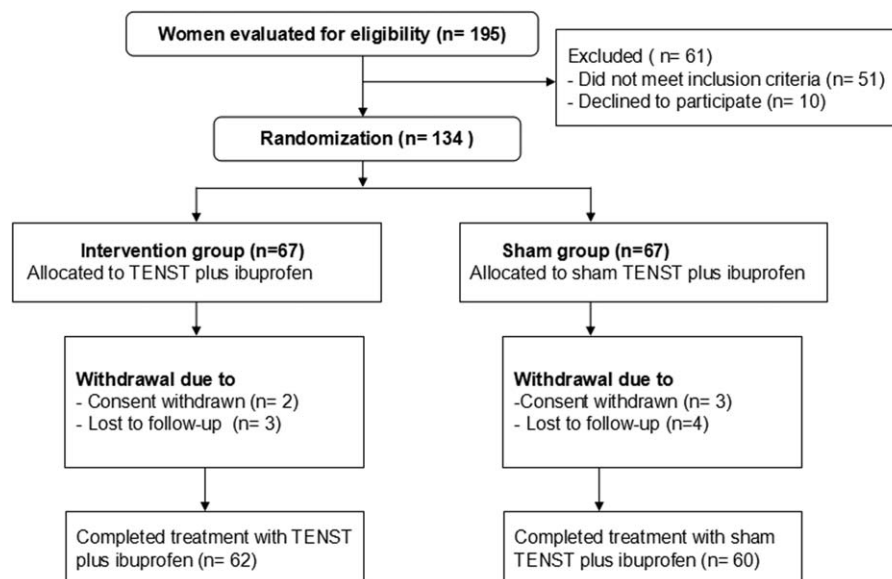


Figure 1. Flow diagram of participants through the study.

Table 1
Characteristics of study population at baseline.

Characteristics	Intervention group (n=67)	Sham group (n=67)	P
Mean age, y	25.6 (4.3)	24.9 (4.5)	.36
Race, Asian-Chinese	67 (100.0)	67 (100.0)	1.00
Ethnicity, Han	67 (100.0)	67 (100.0)	1.00
BMI, kg/m ²	20.2 (3.1)	20.5 (3.2)	.58
NRS	7.3 (1.4)	7.2 (1.4)	.68
Duration of PD, y	4.1 (1.0)	4.4 (1.2)	.12
Occupation			
Workers	41 (61.2)	44 (65.7)	.59
Students	26 (38.8)	23 (34.3)	.59
Marital status			
Married	45 (67.2)	48 (71.6)	.57
Single	22 (32.8)	19 (28.4)	.57
ASA			
I	51 (76.1)	49 (73.1)	.69
II	16 (23.9)	18 (26.9)	.69

Data are present as mean ± standard deviation or number (%).

ASA = American Society of Anesthesiology, BMI = body mass index, NRS = numeric rating scale, PD = primary dysmenorrheal.

Thus, 134 women were randomly divided into the intervention group and the sham group in a ratio of 1:1. All the primary and secondary outcome data were analyzed using the ITT approach. Of all 134 included women, 12 withdrew from the study, because of the consent withdrawal and lost to follow-up (Fig. 1).

The characteristics of all included participants were listed in Table 1. No significant differences in age, race, ethnicity, body mass index (BMI), NRS, duration of PD, occupation, marital status, and ASA stage were found between 2 groups at baseline (Table 1).

All outcome measurements were examined by the mean change from baseline (95% CI), and by the difference (95% CI) between the 2 groups, to assess the effect of TENS (Table 2). The results of all outcome measurements are summarized in Table 2. Compared to sham TENS, TENS immediately decreased the intensity of the pain associated with PD, as measured by NRS ($P < .01$); the overall pain, as measured by the duration of dysmenorrheal pain relief ($P < .01$); and the number of ibuprofen tablets taken ($P < .01$). However, the quality of life, as measured by the WHOQOL-BREF scores, did not differ between participants in the 2 groups. Additionally, no AEs occurred in any of the groups during the study period.

Table 2
Primary and secondary outcome measurements (change from baseline).

Outcomes	Intervention group (n=67)	Sham group (n=67)	Difference	P
NRS	-1.9 (-3.1, -0.5)	-0.5 (-1.2, 0.1)	-1.5 (-1.8, -1.2)	<.01
WHOQOL-BREF				
General	3.7 (2.9, 4.5)	3.5 (2.7, 4.4)	0.2 (0.1, 0.3)	.67
Health	3.6 (2.8, 4.4)	3.5 (2.6, 4.3)	0.1 (0.0, 0.3)	.84
Physical	92.4 (80.3, 99.7)	88.6 (75.3, 95.8)	4.5 (5.9, 3.6)	.23
Psychological	81.2 (69.5, 90.1)	78.7 (67.9, 86.6)	-2.5 (3.1, 1.7)	.45
Social	40.9 (34.8, 45.5)	41.3 (35.3, 45.8)	-0.4 (-0.6, -0.1)	.71
Environmental	93.7 (80.4, 99.8)	91.9 (77.6, 95.5)	1.8 (1.1, 3.4)	.38
Duration of PD pain relief, h	4.1 (0.5, 8.3)	0.8 (0.1, 2.5)	3.3 (0.4, 5.6)	<.01
Number of ibuprofen taken	0.9 (0.4, 2.0)	1.7 (0.8, 3.3)	-0.8 (-1.3, -0.5)	<.01

Data are present as mean change ± standard error.

NRS = numeric rating scale, PD = primary dysmenorrheal, WHOQOL-BREF = World Health Organization quality of life.

4. Discussion

The results of the present study confirmed the hypothesis that compared to sham TENS, TENS showed promising treatment outcomes after 3 menstrual cycles in women with PD. To the best of our knowledge, the present study is the first blind, randomized sham-controlled trial of using TENS as an adjunctive therapy for treating women with PD in China. The findings demonstrated the encouraging effect of TENS for treatment of women with PD.

Previous studies conducted in other countries also reported encouraging effects of TENS for treating women with PD.^[23,24] One study evaluated the effect of high-frequency TENS (hf-TENS) and thermotherapy for treating patients with PD.^[23] The results found that hf-TENS can significantly reduce pain in patients with PD, and no AEs were observed related to the hf-TENS.^[23] Another double-blind, prospective, randomized study conducted in Brazil included 40 women with PD.^[24] The participants were divided into the active group, where participants received TENS, and the sham group, where the participants received sham TENS.^[24] This study reported that TENS could not only induce prompt pain relief, but also could improve the quality of life of women with PD.^[24] This study also reported no AEs.

In the current study, the pain associated with PD, as measured by the NRS, the duration of relief from dysmenorrheal pain, and the number of ibuprofen tablets taken were significantly greater for participants in the TENS group than for those in the sham TENS group. These results indicate the promising effect of TENS for pain relief in participants with PD, although no encouraging improvement was found in the quality of life, as measured by the WHOQOL-BREF scores. Furthermore, no AEs were reported in any of the groups in this study.

This study had several limitations. First, the observed effect in the present study is the synergistic effect of TENS and painkillers, and not TENS alone, because it was impossible for all participants to interrupt their pain medicine regimens. Second, the patients were not followed up after the treatment because of the short duration of the study. Third, this study was only conducted at the The People's Hospital of Yan'an, and Maternal and Child Health Hospital of Yan'an, including only Chinese Han ethnicity. Thus, the results may not be generalized to other hospitals and ethnicities in China.

5. Conclusion

The results of the present study demonstrate that TENS can reduce the intensity of the pain associated with PD without any

AEs. However, further studies with follow-up assessments are warranted to confirm our results.

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