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Original Research Article

Study to Assess the Performance and Safety of Welme Menstrual Pain Relief Device in Women Suffering from Primary Dysmenorrhoea

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Abstract

Background: Many women consider menstrual pain as severe, incapacitating, and inevitable chronic pain during menstruation often accompanied by Primary dysmenorrhea, known for its negative effect on women's quality of life. By saying no more to painkillers, the new TENS device, named Welme come up with instant relief for women who are suffering from this.

Aim: This study is a Randomized, Controlled, Two-arm, Parallel, Sham-controlled, aimed to assess the performance and safety of the Welme menstrual pain relief device in women suffering from PD.

Material and Methods: A total of 60 females aged between 18-35 years with dysmenorrhoeal pain participated in this study and were randomly divided into the intervention group and the sham group, with 30 participants in each group. Participants in the intervention group received TENS, whereas those in the sham group received sham TENS during the menstrual period of 5 days.

Result and Conclusion: The pain intensity reduction measured by a Visual Analog Scale (VAS), the Cox Menstrual Symptom Scale (CMSS), mean data of analgesics usage, mean data of SF-12 patient questionnaire**,** patient global impression of change (PGIC) scale, mean data of diary card pain assessment were evaluated. The participants in both groups received the treatments for 2 menstrual cycles and throughout the study, adverse events were assessed and recorded. The study results show that the active TENS method is much more effective in managing primary dysmenorrhea compared to the sham device and gives immediate pain relief and had no negative impact.

Keywords: Effective, menstrual pain, statistical data, Welme, women

Introduction

Primary dysmenorrhea is defined as suffering during menstruation in the absence of an identifiable pathologic mutilation. This menses pain can have a side effect of nausea, vomiting, diarrhoea, and headache. The cause of dysmenorrhea remains unclear. Dysmenorrhea mainly occurs among adolescent girls and has been identified as a major factor of death in this population, leading to school absence and makes unable

to participate actively. In a larger, representative sample of U.S. adolescents aged 12–17 yr, 14% frequently missed school because of cramps.[6] Those with severe cramps (50%) were more likely to miss school than those with mild cramps (17%), and African-American girls (24%) were more likely than white girls (12%) to miss school due to cramps after adjustment for socioeconomic status. Some authors have estimated that dysmenorrhea is the single greatest cause of lost working hours and school absence in adolescent girls, although no systematic studies have prospectively examined the impact of dysmenorrhea on quality of life or cost. [1]

Transcutaneous electrical nerve stimulation (TENS) is a non-pharmacological and non-invasive pain-relief method that has been proven effective for a variety of conditions. [2]

Treatment with TENS has the advantage of being controlled by the patient and does not involve the use of medication. TENS is inexpensive and virtually without risk, and there are few contraindications. High-frequency, low-intensity current is normally used. [3]

TENS significantly delayed the usage of ibuprofen by an average of 5.9 hours, compared with 0.7 hours when using ibuprofen alone (P less than .05, paired t-test). TENS only provided moderate to high pain relief in 42.4% of subjects, compared with 3.2% with placebo TENS, and significantly reduced diarrhea, menstrual flow, clot formation, and fatigue compared with placebo TENS. [4]

Our present study described A new TENS device named Welme, a menstrual pain relief device (Nerve Stimulator) is a TENS (Transcutaneous Electrical Nerve Stimulator) device, that operates on the principle of electrotherapy. TENS is a technique of electrical stimulation by which the main objective is to provide a level of symptomatic pain relief by exciting sensory nerves and thereby stimulating either the pain gate mechanism or/the opioid system.

TENS works by stimulating large diameter, cutaneous, proprioceptive Ab nerve fibres without activating the thinner Ad and C pain fibres. According to the gate control theory of pain, pain signals from the uterus are prohibited from entering the spinal cord, thereby preventing the perception of pain. In addition, TENS can facilitate the release of b-endorphins, which also helps to relieve pain associated with it. The effect is usually evident instantly after applying the TENS Standard devices for TENS are typically too large and heavy for easy use during everyday activities. [1]

The Welme menstrual pain relief device (Nerve Stimulator) device was designed with a specific pulse frequency and pulse length that is suitable for its intended use. Low frequency bursts of mild electrotherapy also help activate the natural pain control response releasing beta-endorphins to ease the pain felt by the patient.

Study Objectives

The main purpose of this study is to examine the Effectiveness and Safety of the Welme menstrual pain relief device on primary dysmenorrhea women and to compare Welme menstrual pain relief device with the Sham device by assessing the pain intensity reduction measured by a Visual Analog Scale (VAS), with other outcome measurements including the Cox Menstrual Symptom Scale (CMSS), mean data of analgesic usage, mean data of SF-12 patient questionnaire, patient global impression of change (PGIC) scale, to check any adverse events that occur related to the treatment, to improve the quality of life of women.

Material and Methods

This study is Randomized, controlled, single-arm, Parallel, and Sham-controlled. A total of 60 females aged between 18-35 years with dysmenorrhoeal pain participated in this study. All cases were diagnosed as primary dysmenorrhea based on their menstrual history, ultrasound, and physical examination done by a gynecologist. Subjects in Group A provide with Welme Wearable Menstrual Pain Relief Device and Sham (TENS) Device. The primary outcome will be pain intensity reduction measured by a Visual Analog Scale (VAS), with other outcome measurements including the Cox Menstrual Symptom Scale (CMSS) Subjects were randomly allocated to Group A and Group B and groups in a 1:1 ratio. All subjects were assessed and treated on the first day of their menstruation.

The procedure was fully explained to the participants they were informed to sign the consent form. All evaluations were performed at the starting point, each menstrual cycle during the treatment period and the follow-up period. Any undesirable effects were recorded throughout the entire study. The study protocol and the patient information sheet(s) were reviewed and approved by the Independent Ethics Committee Pharexcel Consulting Private Limited 11, 10th Cross, AYR layout, Shettyhalli, Jalahalli West, Bangalore - 560015.

Written informed consent was obtained from the subject(s) before the start of the trial and after the approval from IEC. Ethics Committee notifications as per the GCP guidelines issued by the Central Drugs Standard Control Organization and ethical guidelines for biomedical research on human subjects issued by the Indian Council of Medical Research were followed during the conduct of the study.

Using a TENS device at a frequency of 1-120 Hz for 15 minutes. Each device has 2 gel pads attached to a silicon patch. The patch was attached to the painful area. The power was turned on groups. The test device was used when the participants felt the pain associated with PD.

The device should be charged for at least 6 hours before the first use Casing is provided in the box to store the Device Electrode Patches and Electrode Patches Cable.

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 is not relieved, the participants in both groups initially received Analgesic- (Mefenamic acid: 500 mg). 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 2 menstrual cycles. Any adverse events were recorded throughout the study.

Study setting and population

The study was conducted at NRR Hospital Janapriya Apartments 3&3A, Hesarghatta Main Rd, Next to, Geleyara Balaga Layout, Jalahalli West, Bangalore, Karnataka, 560090 from 23/04/2022 till 10/07/2022. A total of 60 participants with PD were randomly divided into the intervention group and the sham group, with 30 participants in each group. Participants in the intervention group received TENS, whereas those in the sham group received sham TENS during the menstrual period of 5 days.

Subjects who had Participated in any other conducted study within the last 30 days had serious health problems, had a history of primary dysmenorrhea with other causes of dysmenorrhea, Pregnant woman, who had

secondary dysmenorrhea related to uterine myomas, endometriosis, adenomyosis, the cardiac problem with an artificial implant, implanted defibrillators, or other implanted metallic or electronic devices were excluded from this study.

Data Analysis

Categorical data, such as gender and medical history, were tabulated with frequencies or percentages; and continuous data, such as age and disease course, were reported as mean ± standard deviation (SD), or median. For the baseline variables, socio-demographic data and other basic indicators were carried out using the t-test and $\chi 2$ test. To compare variables before and after treatment in the same group, a paired t-test was used. Unpaired t-tests were used to compare the inter-group differences between the two groups. P value < 0.05, two-sided indicates a statistically significant difference, with 95% confidence intervals.

Vital signs of the subjects during screening

The mean values of the vital signs at the time of screening were recorded. The mean temperature of the study participants at the time of screening was 36.92±0.38 ºC, the mean blood pressure at the screening visit was 127.2/81.3 mmHg, the mean respiratory rate and mean pulse rate at the screening visit was 81.6±4.55 CPM and 18.2±0.54 BPM respectively.

Results

A total of 60(30 in each Group) Women between the age 18 to 35 years, who have a history of regular menstrual cycles and self-reported history of primary dysmenorrhea were enrolled for the study after fulfilling the criteria

Mean data of vas score

The Average mean of Pain intensity in the welme group and sham group before using the device and after using the device were calculated in two menstrual cycles as shown in (table 1)

Table 1: Mean Data of Vas Score

Parameter	Welme	Sham	p-values
Baseline	7.16±1.82	7.2±1.83	0.471909
Post cycle 1	2.10±0.66	6.83±1.88	< 0.00001
Post cycle 2	1.6±1.07	5.87±2.24	<0 .00001

Mean data of analgesic usage

The Average mean of Analgesic Usage in the Welme group and sham group before using and after using the device was calculated in two menstrual cycles as shown in (table 2)

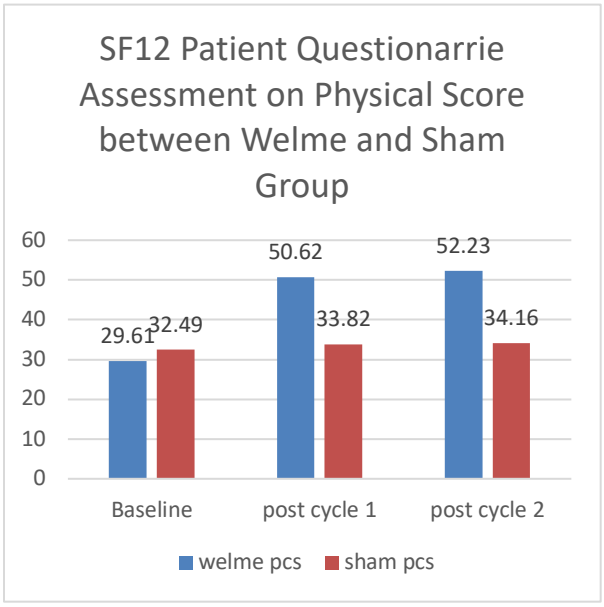
Table 2: Mean Data of Analgesic Usage

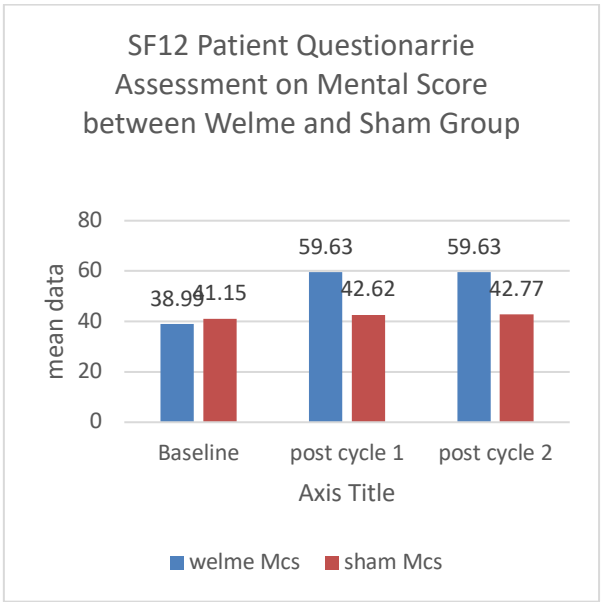
Parameter	Welme group	Sham group	p-values
Baseline	2.53 ± 0.51	2.51±0.51	**0.400142**
Post cycle 1	0.57±0.77	2.27±0.87	**0.000838**
Post cycle 2	0.50±0.73	2.20±1.13	**0.00298**

COX Menstrual Symptom Scale

The Assessment of the Cox menstrual symptom scale before and after the usage of both devices demonstrated that there is a decrement in the frequency and severity ratings of the Cox menstrual symptom scale in the Welme group compared to the Sham group.

SF-12 Patient Questionnaire

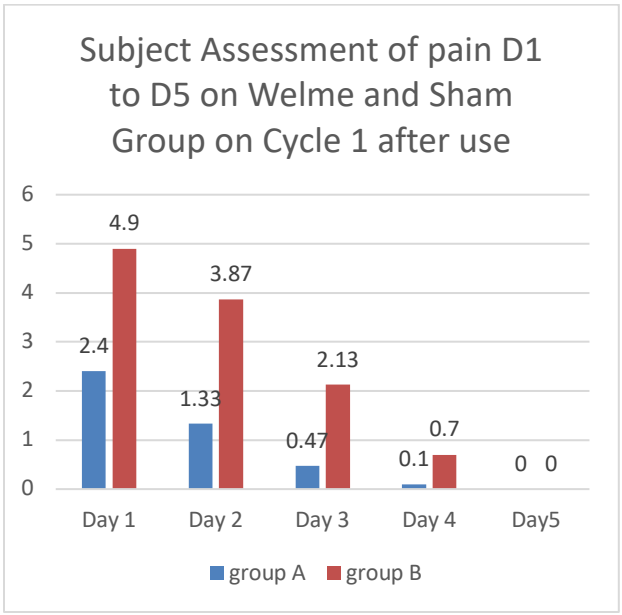




A) Physical Score (PCS) **B) Mental Score(MCS)**

Figure 1: The mean average of the physical score of both groups before using and after using the device was determined and represented in fig 1a & b

Subject Assessment – Diary Card



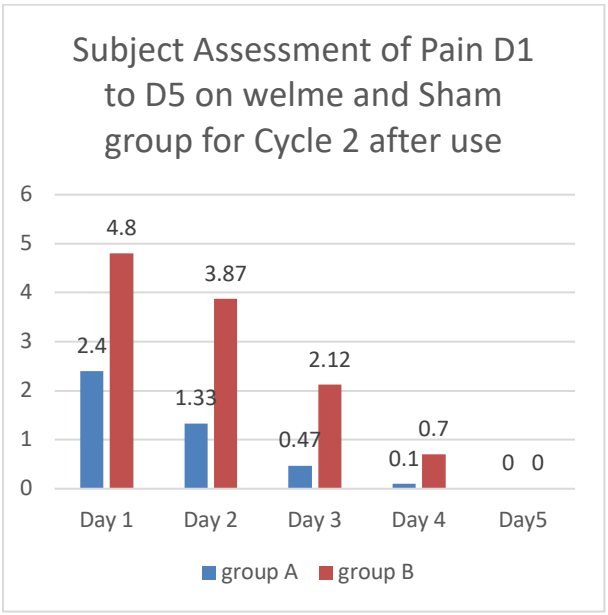


Figure 2: The mean average of pain assessment for Day 1 to Day 5 after the use

Patient global impression of change (pgic) scale

The Patient Global Impression of Change scale was assessed for the subject's health after using the device for Welme and sham group which is represented in (table 3)

Table 3: Patient Global Impression of Change (PGIC) Scale

How would you describe the change in Activity Limitations symptoms, emotions, and overall quality of life, related to the painful conditions?				
	Post Cycle 1		**Post Cycle 2**	
Parameters	**WELME**	**SHAM**	**WELME**	**SHAM**
No change	0/30 (0%)	20/30 (66.6%)	0/30 (0%)	20/30
Almost the same	0/30 (0%)	0/30 (0%)	0/30 (0%)	0/30
A Little Better	0/30 (0%)	10/30(33.3%)	0/30 (0%)	5/30
Somewhat better	0/30 (0%)	0/30 (0%)	0/30 (0%)	5/30
Moderately better	5/30 (16.6%)	0/30 (0%)	5/30 (16.6%)	0/30
Better	10/30 (33.3%)	0/30(0%)	5/30 (16,6%)	0/30
A great deal%	20/30 (66.6%)	0/30(0%)	25/30 (83.3%)	0/30

Discussion

Primary dysmenorrhoea is defined as repeatedly occurring, a painful involuntary spasmodic contraction of muscle happening during menstruation excluding diagnosed pelvic-related disease. It usually starts in adolescence among females in their reproductive stage. PD occurs due to the activity of the muscular layer of the wall of the uterus that leads to uterine ischemia which is painful. This myometrial activity is regulated and augmented by the production of prostaglandins. The tightening and shortening of Uterine muscle contractions can last many minutes and may produce the pressure within the uterus which is more than 60 mm Hg. Multiple other factors may play a role in the perception and the degree of severity of the pain. [5]

The study was conducted to assess the performance and safety of the Welme menstrual pain relief device in women suffering from primary dysmenorrhoea. The Welme is a period pain relief device that principally works on scientifically-proven TENS, a therapy that releases an impulse that reduces pain with the help of sticky electrode patches. This electrical current impulse which is characterized by low voltage inhibits the transmission of pain signals, thus altering the perception of pain. It also triggers the release of endorphins, the chemical known to get rid of pain in the body. It is entirely not affected by a chemical substance and is appropriate for women of all age groups. It claims to help with PCOS and PCOD pain relief when used at a comfortable frequency but is not recommended for use during pregnancy. [5]

The study was conducted among 18-35 years of the age group of females associated with primary dysmenorrhoea. Our results demonstrated that the Welme device was highly efficacious in the treatment of PD symptoms and it is also well-tolerated and safe in study subjects (n=60) having complaints of PD. The study was conducted over 2 months during the menstrual period of 5 days.

In this study, 60 participants with PD were randomly divided into the intervention group (Welme group) and the sham group, with 30 participants in each group. Participants in the intervention group received TENS, whereas those in the sham group received sham TENS during the menstrual period of 5 days.

A significant decline was seen in the mean Pain intensity in each evaluation cycle of study subjects in active Welme TENS than in the Sham group. Our result indicated that The Analgesic usage in active TENS Welme group was significantly decreased than in the

Sham group. Also, there is a decrement in the frequency and severity ratings of the Cox menstrual symptom scale in the Welme group compared to the Sham group after usage of the device.

The study on SF 12 patient questionnaire demonstrated that there is an improvement in the subject's physical score and mental score after using the Welme Tens device than the Sham Tens device. The Patient Global Impression of Change scale Assessments also indicated that the improvement in quality of life after the usage of the device is higher in Welme than compared to the Sham group.

Many women prefer taking small doses of painkillers to ease their menstrual cramps. Well, anti-inflammatory painkillers like diclofenac, ibuprofen, and naproxen can help relieve severe period pain but these medications sometimes have side effects such as stomach problems. [7] taking related adverse effects into consideration the present study showed superior results as compared to the previous studies as it provides the best available data on the pathophysiology and mechanism of action of TENS in dysmenorrhoea, and well-supported statistical analysis of given parameter by using sham TENS device as a comparison,

The Welme Device does not cause any adverse events on the subjects hence the welme device can be used as an effective and safer option of treatment for patients with primary dysmenorrhoea.

Conclusion

This study led us to conclude that Welme's TENS method seems to be effective in treating primary dysmenorrhoea. It is free from the adverse effects of medications, gives instant pain relief, and had no undesirable effects.

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