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Electromagnetic field versus diclofenac drugs on primary dysmenorrhea: A single-blind randomized controlled trial

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Abstract

Aim: Primary dysmenorrhea is one of the most common complaints of women and is also the most common gynecological problem worldwide. The cramps of dysmenorrhea are recurrent and 90% of adolescent girls and about 50% of women suffer from it. This study was aimed to determine which is more effective in alleviating primary dysmenorrhea: pulsed electromagnetic field (PEMF) or diclofenac drugs. Material and Method: Fifty adult females with regular menstrual cycle 21-35 days lasting 3-7 days and having the same ordinary daily living activities participated in this study. They were recruited from the students of the Faculty of Physical Therapy, Cairo University, Egypt, and the study was conducted in the Outpatient Clinic of the Faculty of Physical Therapy. Group A received PEMF applied on the pelvic region, 3 times per cycle for 3 consecutive cycles, 20 minutes per day. Group B received diclofenac tablets, 50 mg, only with onset of menstrual pain for 3 consecutive cycles. All subjects in both groups were assessed through measuring the progesterone level in the blood, pain using the Visual Analogue Scale, and physical as well as psychological symptoms using a menstrual symptom questionnaire. Results: The present study revealed a statistically significant improvement ($P<0.05$) in pain, physical, and psychological symptoms associated with dysmenorrhea and progesterone blood level in Group A compared to Group B. Discussion: PEMF was more effective than diclofenac drugs in relieving pain and associated symptoms with dysmenorrhea.

Keywords

Primary Dysmenorrhea; Pulsed Electromagnetic Field; Diclofenac Drugs

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Introduction

Dysmenorrhea is the most widely recognized gynecological complaint for adolescent and youthful grown-up females [1] with a noteworthy effect on women's personal satisfaction, work efficiency, and healthcare [2]. It is described as unbearable menses in a woman with normal anatomy of the pelvic region, generally starting amid puberty. It can be classified into two types: primary and secondary dysmenorrhea [3]. Primary dysmenorrhea is related to typical ovulatory cycles with no definite pelvic pathology. In primary dysmenorrhea, the discomfort and pain start a few hours before or after the beginning of the menstrual cycle and go on for 24-48 hours. The pain is more prominent in the first days and sometimes continues into the following days. Dysmenorrhea pains are felt mainly in the lower abdominal region and may radiate into the inner aspects of both thighs.

In many cases, the young women may encounter orderly symptoms, for example, generalized fatigue, backache, headache, nausea, vomiting, and diarrhea [4]. The pain and discomfort are due to the impacts of prostaglandins discharged by the disintegrating endometrium during menstruation [5]. The clinical research has recognized a physiological cause behind dysmenorrhea as the incremental product of the uterine prostaglandins. Amid endometrium sloughing, endometrial cells discharge prostaglandins as the period starts. For dysmenorrhea, there is an increased production of uterine prostaglandins [6]. Many approaches have been used for the treatment of dysmenorrhea, including the use of non-steroid anti-inflammatory drugs (NSAIDs), vitamins, and oral contraceptives drugs [7].

Diclofenac is an NSAID that is the most well-known treatment method for both primary and secondary dysmenorrhea. Non-pharmacologic interventions such as acupuncture, herbal preparations, heat therapy, and transcutaneous nerve stimulation [8] have been reported to lessen dysmenorrhea in some studies. Pulsed electromagnetic fields (PEMF) have been recently utilized as one of the most effective modalities in the physical therapy field for treating various pathological conditions. PEMF decreases pain by selective attenuation of neuronal depolarization through modifying the resting potential of the cell membrane. This improves the blood flow, potentially accelerating the healing of tissue and removing any noxious mediators by changing the kinetics of ion binding and in this way modulates the secretion of cytokines and other inflammatory mediators [9]. NSAIDs and PEMF are effective in relieving pain of primary dysmenorrhea by decreasing prostaglandin levels in the blood, resulting in fewer vigorous uterine contractions and less discomfort [10-11]. Unfortunately, the literature review was unable to identify any study comparing the effect of PEMF and diclofenac drugs on alleviating primary dysmenorrhea. Therefore, we sought to determine which is more effective.

Material and Method

The study was designed as a prospective, randomized, pre–post-test, controlled trial. Before beginning the study, ethical approval was obtained from the institutional review board at the Faculty of Physical Therapy, Cairo University, and the trial was registered in Clinicaltrial.gov with identifier number NCT03269591. The study followed the Guidelines of the Declaration of Helsinki on the conduct of human research. The study was conducted between May 2015 and October 2016.

A convenient sample of fifty virgin females with regular menstrual cycles (21-35 days and lasting for 3-6 days) and having the same ordinary daily living activities was selected from the students of the Faculty of Physical Therapy, Cairo University. Egypt, and the study was conducted in the Outpatient Clinic of the Faculty of Physical Therapy. Participants were enrolled and assessed for their eligibility to participate in the study. To be included in the study, the participants were clinically diagnosed by a gynecologist as having primary dysmenorrhea and complained of severe cramping pain. Their ages ranged from 18 to 25 years old and their body mass index was BMI<30kg/m [12]. A detailed medical history was obtained to screen for other pathological conditions, and all subjects underwent pelvic ultrasonography to exclude any pelvic pathological problems such as endometriosis, adenomyosis, or pelvic adhesions. Subjects who had irregular or infrequent menstrual cycles, a pacemaker, hyperthyroidism, psychosis, or were using any anti-inflammatory or antispasmodic drugs within two months before the study were excluded. No subjects had participated in any previous treatment program for at least three months prior to the start of our study.

After explaining the aim, nature, and benefits of the study to the participants, we informed them of their right to refuse or withdraw from the study at any time, and they were also informed about the confidentiality of any information obtained. An informed consent was obtained from each participant. Anonymity was assured through coding of all data. The fifty adult females with primary dysmenorrhea were randomly assigned into two groups (Group A and Group B) by a blinded and independent research assistant who opened sealed envelopes that contained a computer generated randomization card. No subjects dropped out of the study after randomization.

Participants randomly assigned into Group A (n =25) received PEMF applied on the pelvic region, three times per cycle for 3 consecutive cycles, twenty minutes per day, starting at the day before beginning of menstrual flow then repeated on the first and second days of the menstrual flow. The PEMF device used was the EASY Qs portable (ASA, Italy) magnetic therapy device. Intensity ranged from 1 to 60 Gauss, with strength 60 Gauss, and frequency of 50 Hz applied in the comfortable modified supine lying position with small pillows under the participants' body curves. Then, PEMF was applied by placing one electrode above the suprapubic region and another electrode on the lumbar region from (T10 – L1), supported by a long strap [13]. Group B (n =25) received only diclofenac tablets, 50 mg, only with few hours at the onset of menstrual pain for 3 consecutive cycles [14].

Progesterone blood level, determined through a blood sample, was the primary outcome measured. The normal progesterone level in the middle of the menstrual cycle is 4 to 20 ng/ml [15]. Blood samples were taken by the physician for each woman in both groups (A and B) before and after the treatment period (12 weeks), and were sent to the laboratory center to measure the progesterone level. The secondary outcomes were pain intensity level and menstrual symptom questionnaire. Visual Analogue Scale (VAS)[16] was used to determine the pain

intensity level. Pain was assessed before and after treatment procedure (3 months) in both groups (A and B). The VAS is a graphic rating scale with numerical values placed equidistantly along the line. The descriptors and numbers help the subject to place her estimate on the line in which (0) means no pain, (1) mild pain, (2) moderate pain, (3) severe pain and (4) unbearable pain. The menstrual symptom questionnaire is a standard method for measuring menstrual symptoms. It is utilized to enable the clinicians and researchers to make efficient, observational assessments of the participant's side effects, and to form etiological hypotheses [17]. It is very accurate and detailed to assess physical symptoms of dysmenorrhea including: severity of physical symptoms, severity of associated symptoms regarding headache, nausea, and vomiting, mood changes, diarrhea, dizziness, water retention, and fatigue. It also assesses severity of psychological symptoms and the effect of primary dysmenorrhea on daily activity including responsibilities at home, academic productivity, and the social activities of life. It was valid and reliable (ICC = 0.82-98). It consisted of 13 of the 22 items of the c-form MSQ (CMSQ) which are used to assess the physical and psychological symptoms associated with dysmenorrhea. The score on each item ranged from 1 (never) to 5 (always) with a higher composite score indicating more symptoms [18].

Statistical analysis

Data analysis was performed using SPSS version 22 for Windows (SPSS, Inc., Chicago, IL, USA). The sample size (50 patients) was calculated to yield an 80% power, effect size = 0.827 calculated from an unpublished pilot study on 12 participants (6 in each group) considering the progesterone level as a primary outcome. The data of this study were analyzed statistically as follows: Results are expressed as mean ± standard deviation, median, minimum, and maximum. Prior to final analysis, data were screened for normality assumption and the presence of extreme scores. This exploration was done as a prerequisite for parametric calculation of the analysis of difference and analysis of relationship measures. Descriptive analysis using histograms with the normal distribution curve showed that the data were not normally distributed and violates the parametric assumption for all measured dependent variables. The Shapiro-Wilk test revealed that the data were not normally distributed for all dependent variables ($p<0.05$). So, non-parametric statistical tests in the form of Mann-Whitney U test were used to compare groups and Wilcoxon Sign Rank test was used to compare pre- and post-treatment within each group. The alpha level was set at 0.05.

Results

A total of 56 adult females with regular menstrual cycle 21-35 days lasting 3-6 days were eligible for inclusion, and 50 were randomized for study intervention (Figure 1). Group A (n=25) received PEMF applied on the pelvic region, 3 times per cycle for 3 consecutive cycles, 20 minutes per day. Group B (n=25) received diclofenac tablets, 50 mg, only with onset of menstrual pain for 3 consecutive cycles. All randomized participants completed the trial. There were no statistical significant differences between groups in their ages, weight, height, or body mass index (Table 1). Table 2 presents descriptive statistics (median and (minimum-maximum)) and comparison tests for the menstrual symptoms questionnaire, pain level, and progesterone level between both groups. A Wilcoxon signed rank tests revealed that there was a significant increase in progesterone level ($p<0.05$) in Group A but no significant difference ($p>0.05$) in Group B. In addition, in both groups there was a statistically significant reduction ($p<0.05$) in adverse effects measured by the menstrual symptoms questionnaire and in pain level, comparing post-treatment to pre-treatment. Considering the effect of the tested group (first independent variable) on menstrual symptoms questionnaire, pain level, and progesterone level, the Mann-Whitney U test revealed a significant increase in progesterone level at post-treatment in favor of Group A compared to Group B ($p<0.05$). As well, there was a significant reduction in the menstrual symptoms questionnaire scores and the pain level at post-treatment in favor of Group A compared to Group B ($p<0.05$).

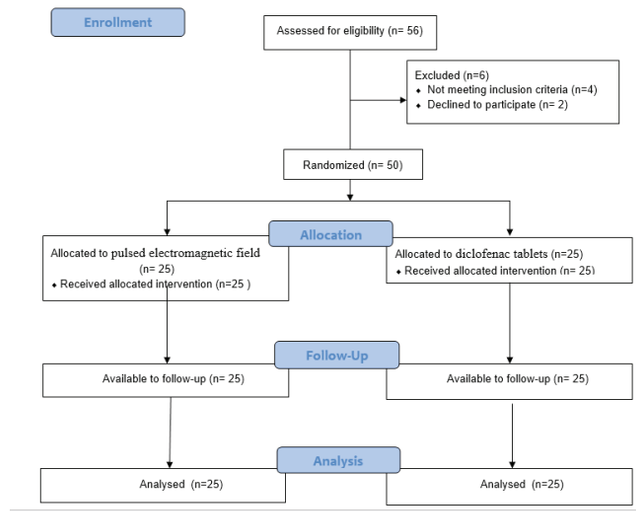

Figure 1. Flow chart of the study.

Table 1. Physical (general) characteristics of the two studied groups.

Variables	Group A (n= 25)	Group B (n= 25)	T value	P value
Age (yrs.)	22.72 ± 2.03	21.04 ± 2.20	0.526	0.601
Weight (Kg.)	59.61 ± 5.85	60.35 ± 3.01	-0.860	0.394
Height (cm.)	158.60 ± 5.27	160.28 ± 4.56	-1.665	0.102
BMI (kg/m^2)	23.47 ± 1.57	23.66 ± 1.40	0.482	0.632

*significant ($p<0.05$).

Table 2. Descriptive statistics (median and (minimum-maximum) and comparison tests between participants with primary dysmenorrhea in pre and post treatment for both groups.

	Group A (N=25)		Group B (N=25)	
	Pre treatment	Post treatment	Pre treatment	Post treatment
Progesterone level	3.13 (0.4-12.1)	8.86(4.07-17.83)	5.7 (0.10-16.05)	5.42 (0.20-15.75)
Pain level	3.0 (2.0-4.0)	1.0 (0.0-2.0)	4.0 (2.0-4.0)	2.0 (1.0-3.0)
Menstrual symptoms questionnaire	29.0 (20.0-36.0)	17.0 (12.0-28.0)	30.0 (21.0-35.0)	22.0 (12.0-31.0)

Table 3.

Within groups (Pre Vs. Post)			
p-value	Progesterone level	Pain level	Menstrual symptoms questionnaire
Group A	0.0001*	0.0001*	0.0001*
Group B	0.98	0.0001*	0.0001*
Between groups (Group A vs. Group B)			
p-value	Progesterone level	Pain level	Menstrual symptoms questionnaire
Pre treatment	0.277	0.319	0.425
Post treatment	0.008*	0.001*	0.001*

*significant difference ($p<0.05$)

Discussion

Dysmenorrhea is the most common problem in women of reproductive age. Primary dysmenorrhea is characterized as recurrent, cramping pain occurring with the menses in the absence of any identifiable pelvic pathology [19]. Evidence shows that most of the women who complain of primary dysmenorrhea have an increased or abnormal release and production of the uterine prostanoid, which leads to pain due to the abnormal uterine activity [20].

The result of the current study revealed that there was a statistically significant improvement in pain, and physical and psychological symptoms associated with dysmenorrhea and progesterone blood level in Group A compared to Group B. Correlated general symptoms, like lumbago, nausea, vomiting, headache, and diarrhea, are the sequelae of the influx of prostaglandin and its derivatives into the systemic circulation [21]. It has been reported that progesterone inhibits prostaglandin synthesis and therefore decreases myometrium contractility by blocking the action of prostaglandin, decreasing the synthesis of prostaglandin and increasing its inactivation rate [22]. Nowadays, magneto-therapy is considered a very safe, non-invasive, and easy modality to directly treat an injured site, an inflammation and pain area, and many pathologies and diseases [23]. Magnetic stimulation provides a new treatment technique for treatment of chronic pelvic pain in patients who do not respond to pharmacotherapy [24]. NSAIDs have been approved specifically by the US Food and Drug Administration (FDA) for the treatment of dysmenorrhea [25].

The results of the current study are in line with those of Scisciolo et al. [26], who studied the impact of using repetitive magnetic stimulation in the treatment of both pelvic floor dysfunction and chronic pelvic pain syndrome. They studied 48 patients with chronic pelvic pain. After five weeks of PEMF exposure (two days per week), pain remission was reported in 67% of patients who were stimulated with repetitive magnetic stimulation both of the sacral spinal cord and the pain site and then placebo controlled patients. The results of this study agreed with Moffett et al. [27], who stated that PEMF treatment was followed by the gene expression profiles' alteration of various variables related to alleviation of pain and inflammation, including enhancing the outflow of cytokines and metabolic pathways associated with resolving and dampening the inflammatory reaction, and increasing the endogenously expressed opioid precursors, both of the peptides and of the messenger (m) RNA levels.

The results of the current study agree with those of Jahromy et al. [28], who examined the impact of using the low frequency of the magnetic field (LF-MF) on the formalin that produced chronic pain in mice. In this trial, 32 adult male mice were divided into four groups (n = 8). Three groups of the animals were exposed every day to an electromagnetic field for thirty minutes with a frequency of 25, 50, or 75 HZ (intense 250 **μT**) for one week. The fourth group was a control group with no exposure. By the end of the week, the formalin test was performed. They reported that PEMF is viable to lessen the formalin that caused the chronic pain in the mice in both the acute and chronic phases, and the best responses were recorded at frequency of 50 HZ.

Concerning the effect of PEMF on the progesterone level in the blood, the results of the current study are in line with those of Katalin, et al. [29], who studied the effect of using a sinusoidal 50-HZ magnetic field on cultured human ovarian granulosa cells. In this study, the granulosa cells were separated from the follicular aspirates of 25 in- vitro fertilization treated females. The cells were cultured and exposed to a sinusoidal 50-Hz AC of the magnetic field during the time of a 48-h incubation with the flux density of B (AC) = 100 **μT**. Progesterone production by granulosa cells was determined by radioimmunoassay. By the end of the study, there were significant increases in progesterone production by granulosa cells. In the present study, the PEMF has a positive effect on progesterone and is effective in decreasing the menstrual pain by increasing opioid precursors and increasing progesterone, leading to production of fewer prostaglandin and fewer leukotriene and cytokines. This process accounts for the reduction in menstrual pain and symptoms in 32% of patients who are exposed to the magnetic field. On the other hand, results of this study were not in agreement with the results of Huuskonen et al. [30], who examined the effects of using sinusoidal magnetic fields (MFs) with a frequency of 50-Hz on the implantation of embryo and progesterone during the pre-implantation and implantation periods in rats. At the end of the study, magnetic fields had not affected the mean of the total number of implantations, and serum progesterone levels did not significantly change. In this study, pregnant rats were exposed to very low intensity magnetic (0.13 or 1.3 Gauss) and duration (from day 0 of the pregnancy for 24 hours /day and killed during dark and light periods between 70 hours and 176 hours after the ovulation). But in the current study, PEMF was used with intensity 60 Gauss for three months. The findings of the study may be limited by psychological physiological factors. In conclusion, this study shows that PEMF was more effective than diclofenac drugs in reducing pain and associated symptoms in dysmenorrhea by increasing progesterone blood level, thereby decreasing myometrium contractility.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research

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Conflict of interest

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