Efficacy of pulsed electromagnetic wave versus low-level laser therapy in treatment of primary dysmenorrhea: a randomized trial

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Background
Primary dysmenorrhea is defined as pain during menstruation, and it affects participation in daily activities.
Objective
This study was conducted to compare and add evidence between the effect of pulsed electromagnetic wave and low-level laser therapy (LLLT) in the treatment of primary dysmenorrhea.
Participants and methods
A total of 50 female students complained of primary dysmenorrhea, with age ranging from 16 to 22 years and BMI from 18.5 to 25 kg/m^2. They were divided randomly into two equal groups – group A comprised 25 female students who received Pulsed electromagnetic field, and group B comprised 25 female students who received LLLT. Samples of blood were taken before and after treatment to detect the level of prostaglandins in blood. Present pain intensity scale (Ppi) is used for the assessment of pain before and after treatment.
Results
There was a significant reduction ($P<0.05$), in prostaglandin level in both groups post-treatment; when comparing between groups there was no statistical significant difference ($P>0.05$), whereas there was a clinical difference in favor of group A. In addition, there was a statistically significant reduction ($P=0.0001$) post-treatment in Ppi scale in both groups. When comparing between both groups, there was a significant reduction ($P=0.0001$), in Ppi and this significant reduction was in favor of group A.
Conclusion
The results of this study suggested that both pulsed electromagnetic waves and LLLT are effective methods in the treatment of primary dysmenorrhea, with better effects of pulsed electromagnetic waves than LLLT.

Keywords:
dysmenorrhea, low-level laser therapy, prostaglandin, pulsed electromagnetic waves

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Introduction

Dysmenorrhea is a common gynecological complaint among young females with a major effect on work efficiency and quality of life [1]. It is defined as pain during menstruation in females, always starting during adolescence; there are two types: primary and secondary dysmenorrhea [2]. Primary dysmenorrhea occurs without pelvic pathology [1,2]; the most common symptoms are pain in the lower abdomen and back may reach to inner thighs, and other symptoms may occur such as breast tenderness, nausea, vomiting, diarrhea, fatigue, and headache [3]. Primary dysmenorrhea causes are not accurately identified, but most complaints may be because of prostaglandins secretion, particularly (PGF2α). Prostaglandins are important stimulators of uterine contractility [4]. Excessive production of endometrial prostaglandins may be one of the main causes of strong uterine contractions and temporarily ischemia occurs in the uterus; this ischemia decreases uterine oxygen and results in severe abdominal pain [4]. There are alternative methods in physical therapy field such as TENS, Acupuncture, and heat application; low-level laser and aerobic exercise have an analgesic effect that can be used in the treatment of dysmenorrhea without side effects [5].

Pulsed electromagnetic field (PEMF) is an efficient modality used in physical therapy field for treatment of many pathological cases; PEMF has strong analgesic effect, anti-inflammatory effect, and has vasodilatation effect, as well as decreasing edema [6]. PEMF has an electric energy and generates series of magnetic pulses

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through the tissues, and each magnetic pulse induces a tiny electrical signal that stimulates cellular repair, suppressing inflammatory responses, alleviates pain, and increases range of motion [7]. PEMF helps in the reduction of pain perception and resolution of inflammation of musculoskeletal system [8]. It also enhances wound and bone healing, and stimulates neural tissue regeneration [9].

Low-level laser therapy (LLLT) is a noninvasive physical therapy modality that can reduce swelling, decrease pain sensation, treat acute injuries, and improve functional activity; LLLT is considered as a septic, anti-inflammatory, and analgesic modality, and it reduces pain through reducing inflammation. [3,10]. Also, LLLT reduces pain through its effect on serotonin metabolism by increasing 5 hydroxyindoleacetic acid in urine [11]. LLLT has been used as an effective method of treating pain of primary dysmenorrhea [12].

To our knowledge, no study has yet compared magnetic field therapy (which has limited research supporting its use in dysmenorrhea) and LLLT (which is among the most common treatments for dysmenorrhea). Thus, the aim of this study was to investigate which modality gives better results in treating dysmenorrhea.

Participants and methods

Participants

This is a prospective, randomized controlled study, parallel-group study, with a 1 : 1 allocation ratio.

A total of 50 female students complained of primary dysmenorrhea, and they were recruited from Faculty of Physical Therapy, Kafrelsheikh University. The females participated in the study after signing an informed consent form before data collection. The purpose and nature of the study were explained to all participants. Recruitment began after approval of the Faculty of Physical Therapy Ethics Committee (reference number: P.T.REC/012/001409).

The inclusion criteria were as follows: age ranging from 16 to 22 years old, and their BMI ranging from 18.5 to 25 kg/m^2. The exclusion criteria were any medical problems such as diabetes, cardiac disease, pelvic abnormalities, polycystic ovary, any hormonal abnormalities, irregular menses, and any psychological problems.

Randomization

Females were divided randomly into two groups A or B by simple randomization, by using the envelope method. After female students agreed to participate in the study, cards with either 'PEMF' or 'LLLT' written on them were sealed in envelopes; these envelopes were given to a staff physical therapist who was blinded to this study, and she/he picked one envelope. Depending on which card was selected, participants were allocated to their respective group. Group A comprised 25 female students who received PEMF and group B comprised 25 female students who received LLLT. Personal data of all participants were recorded in a data sheet; these data included age, weight, height, and BMI.

Instrumentation

The following instruments were used:

PEMF: Fisiofield Mini (Italy) (dir. 93/42/CEE) frequency 1–100 Hz and intensity of 1–100 G, Italy.
LLLT: model number: RG-300IB (Shenzhen ray com Health Technology, China), GaAlAs – wavelength 904 nm, power 5 mW.

Treatment procedure

Group A

Each female lay in a comfortable modified side position with small pillows under her body curves. Then, one of the PEMF electrodes was applied on the suprapubic region and the other electrode on the lower lumbar region from L4 to S3, and they were fixed by long strap for 1 h. The application of PEMF was administered during the first and second day of menstruation. The used parameters of PEMF were 50 Hz in frequency and 60 G in intensity.

Group B

Each female lay in a comfortable crock lying position, and LLLT was applied on the suprapubic region with a wavelength of 904 nm and maximum peak power of 5 mW. The head of the laser device was held in direct contact on the most painful area in the suprapubic region (three shots); each shot was for 90 s and then the patient was asked to lie in prone position and apply LLLT on paravertebral region from L4 to S3, which was treated by three shots for each side, and each shot was irradiated for 90 s in the first and second day of menstruation [12].

Outcome measures

The first outcome was the change of prostaglandin level measured before and after the treatment by sample of blood was taken for analysis, and the second outcome was the change of pain level before and after treatment was measured by present pain intensity scale (Ppi); it is a graphic rating scale with numerical values placed equidistantly along the line, on which pain intensity was scored as follows: 0, no pain;

1, mild pain; 2, moderate pain; 3, severe pain; and 4, unbearable pain [13].

Sample size determination

Power analysis was performed using a general power analysis program (G_Power 3.0.10; Kiel, Germany). Determination of minimum sample size was calculated by power calculation, assuming an α of 0.05 at 80% power, based on an effect size of 0.55. A sample size of 25 patients per group would be required.Statistical analysis

Statistical analysis was conducted using SPSS for Windows, version 18 (SPSS Inc., Chicago, Illinois, USA). Normality test of data using Shapiro–Wilk test was used, which reflected that the prostaglandin in level in blood was normally distributed for prostaglandin level in blood, and thus parametric statistical tests in the form of (paired *t*-test) were used to compare between 'pretreatment' and 'post-treatment' for each group and 'unpaired *t*-test' was conducted to compare prostaglandin in level in blood between both groups in the 'pretreatment' and 'post-treatment'. The dependent variable (present pain intensity) is an ordinal variable. Normality test of data using Shapiro–Wilk test was used, which reflects that the data were not normally distributed for present pain intensity, and thus nonparametric statistical tests in the form of Wilcoxon's signed-rank tests was used to compare between 'pretreatment' and 'post-treatment' for each group and 'Mann–Whitney tests' were conducted to compare present pain intensity between both groups in the 'pretreatment' and 'post-treatment'. The α level was set at 0.05.

Results

A diagram of the participant's randomization in the study is shown in Fig. 1. A total of 60 participants were initially screened. After the screening process, 50 participants were found to be eligible to participate in the study. In total, 50 (100%) participants completed the treatment program.

Demographic characteristics of the participants in both groups A and B

There were no statistically significant differences ($P>0.05$) between participants enrolled in the study in both groups A and B concerning age, height, weight, and BMI, as shown in Table 1.

Prostaglandin level in blood

'Paired *t*-test' revealed that there was a significant reduction of prostaglandin level in blood after treatment compared with before treatment in both groups ($P<0.05$). However, between groups, 'unpaired *t*-test' revealed that the mean values of the 'pretreatment' test between both groups showed there were no significant differences ($P>0.05$). In addition, the mean values of the 'post-treatment' test between both groups showed that there were no significant differences ($P>0.05$). In addition, there was no statistical significant difference between both groups, whereas there was clinical difference and high percent of improvement in favor of group A, as shown in Table 2.

Present pain intensity

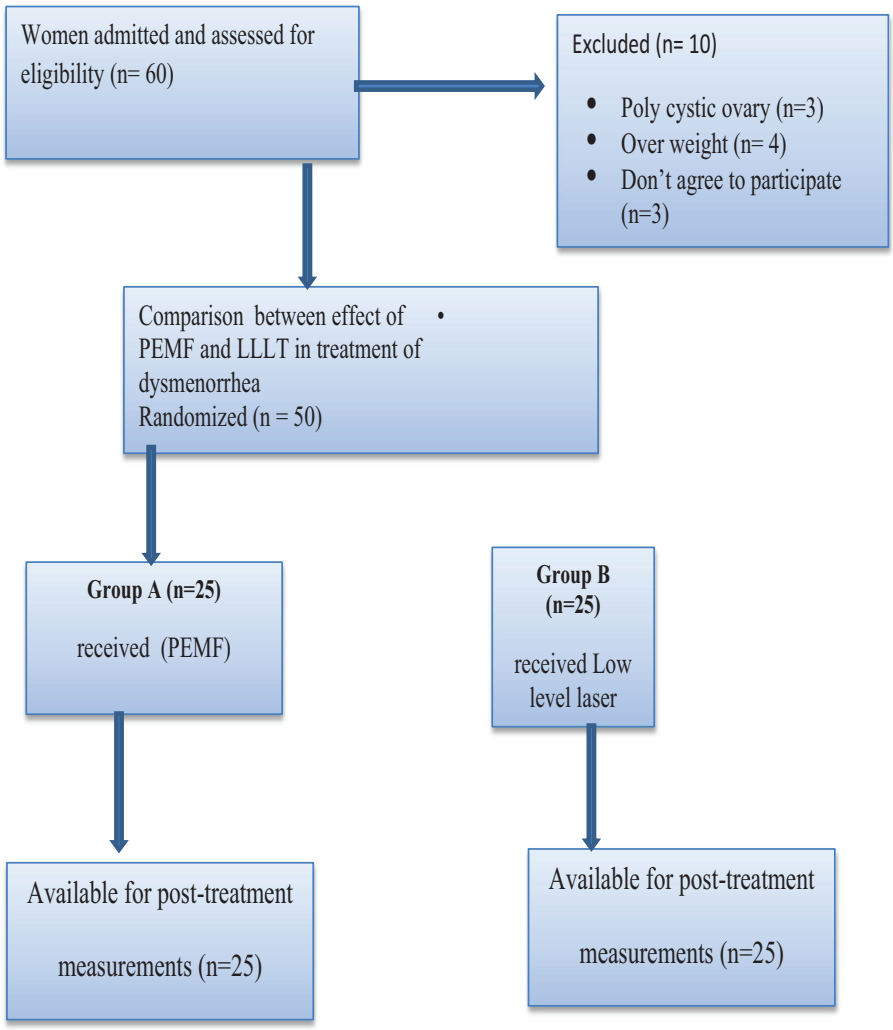
The median of the present pain intensity scale in the 'pretreatment' and the 'post-treatment' for both groups are presented in Table 3. Wilcoxon's signed-rank tests revealed that there was a significant reduction in pain intensity scale after treatment in comparison with before treatment in groups A and B ($Z=-4.562$, $P=0.0001$ and $Z=-4.134$, $P=0.0001$), respectively. However, between groups, 'Mann–Whitney *U*-test' revealed that the median of the present pain intensity scale of the 'pretreatment' between both groups revealed that there was no significant difference ($U=267$, $Z=-0.971$, $P=0.331$), whereas Mann–Whitney *U*-test revealed that the median of the present pain intensity scale of the 'post-treatment' between group A versus B showed significant differences ($U=112.5$, $Z=-4.06$, $P=0.0001$), and this significant reduction in present pain intensity scale is in favor of group A, as shown in Table 3.

Discussion

Painful menstruation or dysmenorrhea is a cramp in the lower abdomen that radiates to the back; it affects about 90% of adolescent girls and about 50% of women [14]. The current study was conducted to investigate the effect of PEMF versus LLLT in treatment of primary dysmenorrhea. Results of this study revealed that there was significant reduction ($P<0.05$), in prostaglandin level in both PEMF and LLLT groups at post-treatment; when comparing between groups there was no statistical significant difference ($P>0.05$), whereas there was a clinical difference in favor of the PEMF group. In addition, there was a statistically significant reduction ($P=0.0001$) post-treatment in Ppi scale in both groups. When comparing between both groups, there was a significant reduction ($P=0.0001$), in Ppi and this significant reduction was in favor of PEMF.

Painful menses explained by the action of prostaglandins on uterine muscles. PGF2α is

Figure 1



Flow of study participants. LLLT, low-level laser therapy; PEMF, pulsed electromagnetic field.

Table 1 Participant demographic characteristics

Items	Group A (mean±SD)	Group B (mean±SD)	*P*-value
Age (years)	18.04±1.33	17.84±1.24	0.587
Body mass (kg)	63.54±6.99	62±4.1	0.347
Height (cm)	163.28±3.96	161.84±4.71	0.248
BMI (kg/m^2)	23.72±1.95	23.61±1.76	0.841

released from disintegrating endometrial cells in endometrial sloughing. PGF2α makes stimulation of myometrial tissue lead to ischemia and compression on nerve endings, and it increases the frequency and amplitude of uterine contraction and this leads to compression on the uterine blood supply in turn leading to lower abdominal cramps [15]. Drugs used to decrease pain during menses such as prostaglandin inhibitor drugs have many side effects on the liver, kidney, stomach, and central nervous system, which may lead to difficulty in digestion, nausea, abdominal cramps, abnormal bowel action, vomiting, headache, dizziness, vertigo, and visual disturbances such as blurred vision. There are contraindications of prostaglandin inhibitor drugs such as ulcers in the gastrointestinal system, respiratory diseases, and allergy to aspirin and similar agents [16]. The superior improvements that were recorded in the PEMF group are attributable to the effects of PEMF on pain perception by altering nerve impulses, increasing endorphins, reducing edema, or fluid retention [17], and magnetic therapy may enhance circulation by vasodilatation of blood vessels, increase blood oxygen, alkalinize bodily fluids, and remove toxic materials from the wall of blood vessel or through effects on cellular calcium channels [7,18]. The result of the study agrees with Fouda *et al.* [19], who suggested that PEMF has short-term beneficial clinical effects above laser in decreasing myofascial pain symptoms by increasing blood supply, which heats and vibrates the tissue, leading to muscle relaxation. In addition, PEMFs were designed to produce voltages similar to those present normally during dynamic mechanical deformation of

Table 2 Mean±SD, *t*, and *P* values of prostaglandin level in blood before and after treatment in both groups

Prostaglandin level in blood	Before treatment (mean±SD)	Post-treatment (mean±SD)	Mean difference	*P*<
Group A	76.01±10.59	61.79±12.08	14.21	0.05
Group B	74.98±10.12	65.68±10.89	9.29	0.05
Mean difference	1.03	–3.89		
P-value	0.721	0.228		

Table 3 Descriptive statistic and comparison tests (within and between groups) for the present pain intensity scale before and after treatment in both groups

Median (interquartile range) and within groups (pre vs. post) of the present pain intensity scale		
Present pain intensity scale	Group A	Group B
Before treatment	3 (1)	3 (1)
After treatment	0 (1)	2 (1)
P-value	0.0001*	0.0001*
Between groups (group A vs. B)		
Present pain intensity scale	Before treatment	After treatment
P-value	0.331	0.0001*

IQR=75th percentile–25thpercentile. *$P<0.05$, significant at the α level.

connective tissues [7]. In addition, the effects of PEMF on biological tissues include analgesic effect through stimulation of endorphins, reduction in inflammation, increasing the number of white blood cells and fibroblast in the wound, absorption of edema and hematoma, stimulates osteogensis, anti- infective activity, and improves the healing of peripheral and central nervous system [20]; the results are in line with Hutchinson *et al.* [21], who mention that pelvic pain of gynecological origin such as ruptured ovarian cysts, postoperative pelvic hematomas, chronic urinary tract infection, uterine fibrosis, dyspareunia, endometriosis, and dysmenorrhea can be treated by a different high-voltage, high-frequency system. Treatment times varied from 15 to 30 min on subsequent or alternate days. 90% experience marked rapid relief from pain and pain subsiding within 1–3 days. Most patients do not require supplementary analgesics.

In addition, the results of this study were supported by Strugatskii *et al.* [22], who stated that the application of constant magnetic field in combination with other treatment modalities led to significant effects in cases of acute endometritis following abortion. In addition, the results of this study agree with Markov and Colbert [6], who stated that magnetic field therapy has analgesic characteristics by increasing pain threshold, stimulating production of opioid peptides, anti-inflammatory, vasodilatation, and anti-edematous activity without side effects, and accompanied by activation of the anticoagulation system. PEMF treatment activates mast cells and increases electric capacity of muscular fibers.Despite the intergroup superior effect of PEMF, the LLLT group also exhibited significant intragroup improvements. These improvements are attributable to anti-inflamatory and analgesic effect of LLLT; it is an effective method to treat a variety of soft tissue injuries and painful conditions through an increase in B endorphin. Also, the results of the study agree with Low and Reed [11] and Basford *et al.* [23], who stated that LLLT reduces pain by its effect on serotonin metabolism by increasing 5 hydroxyindoleacetic in urine. Also, LLLT has an anti-inflammatory effect by reducing the production of prostaglandin E and F, consequences of accumulation of superoxide dismutase, which acts as an inhibitor in the production of prostaglandins. LLLT also stimulates the production of endorphins [11] and inhibition of the synthesis of prostaglandin [24].

Conclusion

PEMF and LLLT are useful modalities in the treatment of primary dysmenorrhea by decreasing the level of prostaglandin in blood and decreasing sensation of pain with a better improvement using PEMF.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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