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Original Article

High-intensity laser therapy versus pulsed electromagnetic field in the treatment of primary dysmenorrhea

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Abstract. [Purpose] To determine the efficacy of high intensity laser therapy (HILT) versus pulsed electromagnetic field (PEMF) in the treatment of primary dysmenorrhea. [Subjects and Methods] This was a randomized clinical trial that included 52 girls diagnosed with primary dysmenorrhea and who were assigned randomly into two groups of equal numbers. The treatment was three sessions every cycle for three consecutive cycles where group (A) included those participants treated with HILT 15 min/session and group (B) those who were treated with PEMF 30 min/session. All patients were evaluated before starting the treatment as well as after the end of treatment by present pain intensity scale and the prostaglandin level in blood and pain relief scale at the end of treatment for both groups. [Results] The results showed a significant decrease in the severity of pain, statistically significant decrease in prostaglandin level in blood, and a statistically significant pain alleviation in both groups. With comparison between both groups there was a statistically significant decrease in the severity of pain, significant decrease in the blood levels of PGF2α, in group (A) than group (B). [Conclusion] Both HILT and PEMF are effective in the treatment of primary dysmenorrhea with HILT being superior to PEMF.

Key words: Dysmenorrhea, High intensity laser therapy, Pulsed electromagnetic field

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INTRODUCTION

Dysmenorrhea can be defined as painful menses in females that represent a common gynecologic problem worldwide affecting about 60% of women among adolescent and young adult females. It categorized into two types: primary and secondary dysmenorrhea[1, 2]. Primary dysmenorrhea is a painful menstrual cramp that felt in lower abdomen and pain can transfer downwards into the inner thighs. Common symptoms displayed by females suffering from the condition include nausea, diarrhoea, vomiting, lethargy, and headaches, many of which can have an adverse impact on daily life[3]. Primary dysmenorrhea usually happen in earlier age but may be remained until 50 years old. It begins around the time that a female's initial menstruation begins. Specifically, it appears one to two years following the start of menarche (first menstruation), and this notably corresponds to the incidence of consistent ovulatory cycles. Typically, the discomfort associated with the

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condition starts several hours prior to or following the beginning of menstruation, and its duration is two to three days[4].

The etiology of primary dysmenorrhea is not exactly understood, but can be explained by excessive or imbalanced secretion of uterine prostaglandins form endometrium during menstruation with falling progesterone level during the luteal phase brings about these elevations, particularly PGF2α[5]. These levels reach their peak during the initial two days of menstruation and, as such, facilitate myometrial contractions characterised by ischemia and dysrhythmic behaviour, with increased basal tone and increased active pressure. Uterine hyper-contractility, reduced uterine blood flow, and increased peripheral nerve hypersensitivity are effective in inducing pain[4]. Prostaglandin (PG) increases the level of tension and contraction strength of uterus and blood vessels, and this process may induce pain, thus, the measure of PG level can be an indicator of intensity of dysmenorrhea. PG level can show the therapeutic effect on dysmenorrhea objectively[6]. Drugs therapy centring on PG inhibitors, which include non-steroid anti-inflammatory drugs (NSAIDs), result in hepatic, renal, hematologic, and gastrointestinal pain, along with central nervous system (CNS) toxicity, which includes indigestion, nausea, constipation, diarrhoea, headache, abdominal pain, dizziness, rashes, impaired renal blood flow, renal papillary necrosis, and vertigo[7, 8].

A range of treatment options have been examined in the literature, including TENS, heat application, pelvic floor and aerobic exercises, and acupuncture, with several producing effective outcomes[9]. Low level laser therapy (LLLT) has an effective results in the treatment of acute pain and it helps in pain reduction in the short term through alleviating the inflammation[10, 11]. In comparison with other modalities LLLT is an effective method in the treatment of dysmenorrhea[12]. It reduces both prostaglandin E and F production, and stimulates inhibition of the synthesis of prostaglandin synthetase[13]. Pulsed High Intensity Laser Therapy (HILT) has been used in many fields of physical therapy as sports, traumatology and pain therapy with high excellent results[14–16].

Pulse Electromagnetic field (PEMF) has been used in the physical therapy field as a useful modality for treatment of many diseases, it shows vasodilatation, analgesic effect, anti-inflammatory action and anti-edematous activity[17]. PEMF offers a non-invasive, harmless, and simple method to directly treat the site of lesion, the source of pain and inflammation in a wide range of diseases and pathologies[18]. The beneficial effects of PEMF on body tissues include: pain reduction, decrease of inflammation, improving the number and action of white blood cells and fibroblast in the wound, increase rate of edema reduction, absorption of hematoma, stimulates osteogensis, anti-infective activity, and increases the healing of peripheral and central nervous system[19]. Study to investigate the effect of PEMF in treatment of primary dysmenorrhea concluded that PEMF appears to be effective in treatment of primary dysmenorrhea, providing an effective, safe, low-cost and successful alternative rather than pharmacological treatment[20]. The purpose of this study was to investigate the effect of pulse HILT versus PEMF in treatment of primary dysmenorrhea.

SUBJECTS AND METHODS

Randomized clinical trial study was carried out after full explanation of the treatment protocol and signing of a consent form. A research approval was obtained from the Ethics Review Committee of the Faculty of Applied Medical Sciences, Umm Al-Qura University. Inclusion and exclusion criteria were set as follows:

- The body mass index of participants should not exceed 29 kg/m^2 with no medical or psychological problems.
- None of them received any medical treatment regarding their menstrual pain during the study course.

Sample size analysis was conducted before the study to calculate the adequate sample size according to previous research results of LLLT in primary dysmenorrhea[21]. Using G-power analysis version 3.1 after setting the effect size to 0.8 (large effect size based on Cohen's d and to detect even low differences among the study groups), high power of 0.8 and type 1 error of 0.05; 52 patients was needed to conduct the study.

A total of 52 female participants aged between 18–24 years and diagnosed with primary dysmenorrhea were randomized into two groups (HILT group, and PEMF group) using a GraphPad program (San Diego, USA). HILT group consisted of 26 female, received pulsed HILT program for ten minutes three sessions every cycle for three consecutive cycles and PEMF group consisted of 26 female, received PEMF program for ten minutes sessions every cycle for three consecutive cycles.

Present Pain intensity scale (PPi): Participants were asked to show the severity of pain on PPi[22]. It is a graphic rating scale with numerical values placed equidistantly along a line in which 0 equal no pain, 1 equal mild pain, 2 equal moderate pain, 3 equal severe pain and 4 mean unbearable pain. It was done before and after treatment course for both groups. Pain relief scale (PR)[22] was used after treatment course to indicate the rate of pain relief. The PR is similar to present pain intensity scale in which 0 equal no relief, 1 equal slight relief, 2 equal good relief, 3 equal excellent relief and 4 equal complete relief.

Blood samples (5 ml) were collected from each participant Sample before and after three months of treatment application to measure the concentrations of serum PGF2α using commercially available ELISA kit (Abcam, MA, USA). All serum samples were processed in duplicate on a fully automated ELISA system (Human Diagnostics) and according to the manufacturer's instructions. As reported by the manufacturer, the kit had a sensitivity of 0.98 pg/ml together with inter and intra-assay coefficient of variation of 7.1% and 10.1%, respectively.

Each group received the intended treatment for three sessions every cycle for three consecutive cycles when the subject complained of unbearable pain a day before the beginning of menstrual flow, and the treatment was repeated on the first and second days after the menstrual flow. Participants in HILT group received pulsed HILT with pulsed Nd:YAG laser produced by a HIRO 3 device (ASA, Arcugnano, Vicenza, Italy). The HILT apparatus used postulates (Nd:YAG), with pulsed emission

(1,064 nm), very high peak powers (3 kW), high levels of energy density (fluency from 810–1,780 mJ/cm), very short pulse duration of (120–150 μs), a duty cycle of approximately 0.1%, and frequency (10–40 Hz). The HILT was applied with total energy of 880 J, which was administered through three phases. During the initial phase, laser fluency was set to 510 mJ/cm^2 for total 350 J that include fast scanning for suprapubic and paravertebral regions from L_4–S_3 and, the intermediate phase was applied using a headpiece to nine point, three points supra-pubically while the patient in crock lying position, and six points over the lumbosacral region from L_4–S_3 three shoots for each side while the patient in prone lying position with 20 J and fluency of 610 mJ/cm^2 and 14 sec for each point for total of 180 J. The final phase was the same as initial phase but with slow scanning with total application time of 15 min. Participants in PEMF group received PEMF using EASY quattro PRO (ASA, Arcugnano, Vicenza, Italy). The treatment was applied while the participant was lying in a comfortable modified side lying position with small paddings under her body curves. Then, PEMF was applied for 30 min with one electrode above suprapubic region and another electrode on the lumbosacral region from (L4−S3) supported by long strap with frequency of 50 Hz and intensity of 60 gauss. The device was calibrated for constant output thorough out the experiment at the Department of physical therapy, faculty of Applied Medical Science, Umm Al-Qura University.

The outcome measures were pain and PG level. The pain, which was measured pre and after treatment intervention, was assessed by PPi and PR scale, while PG level was assessed prior to the treatment and three months after treatment by taking a blood sample to detect its level. Descriptive statistics were used in the form of means, standard deviations (SD), and qualitative variable analytical experimentations, including the use of a student t-test to comparatively examine means prior to and following the treatment. A significance level of 0.05 was applied across each statistical examination.

RESULTS

The outcomes for each treatment variable being presented as follows:

Present pain intensity scale: As indicated in Tables 1, 2, and 3, pain severity in the HILT group prior to the application of treatment was moderate for 4 cases (15.4%), severe for 13 (50%), and unbearable for 9 (34.6%). While after treatment there was no pain was reported after treatment for 11 cases (42.3), mild pain for 12 (46.2%), and moderate pain for 3 (11.5%). This indicates an enhancement percentage of 78.1%. While for the PEMF group prior to the application of treatment, pain severity was moderate for 3 cases (11.5%), severe for 13 (50%), and unbearable for 10 (42.3%), while after treatment no pain was reported for 6 cases (23.1%), mild pain for 8 (30.8%), and moderate pain for 12 (46.2%). This indicates an enhancement percentage of 62.4%. Hence, the PPi score mean fell considerably following the application of treatment for both groups when considered in relation to the base values ($p<0.0001$). The mean difference with respect to the groups prior to the treatment was non-significant ($p>0.05$), while it indicated statistical significance following the treatment ($p<0.05$) in favour to the HILT group.

Present relief scale: As indicated in Table 4, after the end of treatment course Group (A) participants reported complete relief for 11 cases (42.3%), excellent relief for 10 (38.5%), good relief for 4 (15.4%), and slight relief for 1 (3.9%). While in PEMF group after the end of treatment course there was complete relief in 6 cases (23.1%), excellent relief in 9 cases (34.6%), good relief in 7 cases (26.9%) and slight relief in 4 cases (15.1%). The comparison between post mean value of pain relief after treatment showed that the mean value was 3.2 ± 0.85 for HILT group and 2.65 ± 1.02 for PEMF, there was a significant ($P<0.05$) difference between the two groups in favour to the HILT group.

Prostaglandin level blood: As indicated in Tables 5 and 6, the mean for PG blood level for Group (A) and Group (B) displayed a high level of statistical significance ($p<0.001$) regarding its fall from prior to treatment to following treatment. For Group (A), the mean concentration for serum PGF2α was 32.85 ± 3.92 pg/ml prior to treatment, while this fell considerably to 13.50 ± 2.80 pg/ml following treatment with a mean difference of 19.35 and 59% enhancement. For Group (B), the mean concentration for was 32.77 ± 3.89 pg/Ml, while this fell following treatment to 15.19 ± 2.38 pg/ml with a mean difference of 17.58 and 54% enhancement. There was highly significant ($p<0.001$) decrease of prostaglandin level in blood in both groups, the mean difference between the two groups was non-significant ($p>0.05$) before treatment while it was significant ($p<0.05$) after treatment in favour to the HILT group.

DISCUSSION

Dysmenorrhea is one of the most frequent gynecological conditions of pain around the pubic bone and in the lower abdomen during menstruation. Affecting from 50% to over 70% of women of childbearing age[23, 24], its symptoms can be described by the increase release of uterine prostaglandins, particularly PGF2α that causes over activity of myometrium, ischemia and stimulation of nerve endings[5]. The purpose of this study has been to investigate the effect of Pulsed HILT versus PEMF in treatment of primary dysmenorrhea. Results of this study illustrated highly statistically significant decrease in pain severity in the study groups ($p<0.0001$), also, there was highly statistically significant decrease in serum prostaglandin level in both groups ($p<0.0001$); while in comparing both groups there was significant decrease in both pain and prostaglandin serum level in HILT group more than PEMF group ($p<0.05$).

The results of this study agree with Bjordal et al., who stated that laser is effective in the treatment of acute pain and results in pain reduction in the short term through alleviating the inflammation[10]. These results also, in line with England and Sabour

Table 1. The present pain intensity score before and after treatment in pulsed HILT group

	Present pain intensity (PPi) score			
	Before treatment		After treatment	
	No.	%	No.	%
No pain	0	0.0	11	42.3
Mild pain	0	0.0	12	46.2
Moderate pain	4	15.4	3	11.5
Severe pain	13	50.0	0	0.0
Unbearable pain	9	34.6	0	0.0
Mean	3.2		0.7	
SD	0.7		0.7	
MD	2.5*			
Improvement %	78.1			

SD: standard deviation; MD: mean difference; *p<0.05

Table 2. The present pain intensity score before and after treatment in PEMF group

	Present pain intensity (PPi) score			
	Before treatment		After treatment	
	No.	%	No.	%
No pain	0	0.0	6	23.1
Mild pain	0	0.0	8	30.8
Moderate pain	3	11.5	12	46.2
Severe pain	13	50.0	0	0.0
Unbearable pain	10	42.3	0	0.0
Mean	3.3		1.2	
SD	0.7		0.8	
MD	2.1*			
Improvement %	62.4			

SD: standard deviation; MD: mean difference; *p<0.05

Table 3. The comparison between pre & post-mean values of the present pain intensity score between both groups

		HILT	PEMF	MD
Pre-treatment	Mean	3.2	3.3	0.1
	SD	0.7	0.7	
Post-treatment	Mean	0.7	1.2	0.5*
	SD	0.7	0.8	

SD: standard deviation; *p<0.05

Table 4. PR scores prior to and following treatment, Group (A) and Group (B)

	Pain relief Score			
	Group A (HILT)		Group B (PEMF)	
	No.	%	No.	%
No Relief	0	0.0	0	0.0
Slight Relief	1	3.9	4	15.4
Good Relief	4	15.4	7	26.9
Excellent Relief	10	38.5	9	34.6
Complete Relief	11	42.3	6	23.1
Mean	3.2		2.7	
SD	0.9		1.0	
MD	0.6*			

SD: standard deviation; MD: mean difference; *p<0.05

Table 5. PG blood level mean values prior to and following treatment, Group (A) and Group (B)

		Pre-treatment	Post-treatment	MD	Improvement %
Group A (HILT)	Mean	32.9	13.5	19.4*	59.0
	SD	3.9	2.8		
Group B (PEMF)	Mean	32.8	15.2	17.6*	54.0
	SD	3.9	2.4		

SD: standard deviation; MD: mean difference; *p<0.05

Table 6. Comparative presentation of PG blood level mean values prior to and following treatment, Group (A) and Group (B)

		Group A (HILT)	Group B (PEMF)	MD
Pre-treatment	Mean	32.9	32.8	0.08
	SD	3.9	3.9	
Post-treatment	Mean	13.5	15.2	1.69*
	SD	2.8	2.4	

SD: standard deviation; *p<0.05

who stated that LLLT is an effective method in the treatment of dysmenorrhea in comparison with other modalities. LLLT reduces the production of prostaglandin E and F, consequences of accumulation of superoxide dismutase, which acts as an inhibitor in the production of prostaglandins[11, 13]. This study's findings are also consistent with Thabet et al., which examined a 30-participant sample group to examine the impact that physical activity paired with LLLT has on the pain experienced during PD. The researchers employed a Gallium-arsenide laser (wavelength of 635–670 nm and a 5 mv power), and a McGill Pain Questionnaire (MPQ) was responded to by the participants prior to and following treatment. The researchers also assessed serum cortisol levels prior to the research, and this was conducted once again after the 3-month treatment. LLLT was employed on the day prior to menstruation in addition to the first and second days of menstruation, and 3 shots (lasting 60 seconds) were implemented to the suprapubic region. The paravertebral region in prone position and the L4–S3 region

were also targeted with similar 60-second shots. As indicated by the results, pain severity was reduced, with 23 participants (76.67%) experiencing complete relief[21].

Furthermore, the present findings are also supported by the results of Shin et al., who used laser instead of needle for acupuncture. The researchers employed a laser rather than an acupuncturist's needle to examine a 31-participant sample group, consisting of females experiencing PD. Two groups were created from the sample, with 21 participants being administered with LLLT and 10 participants being administered with a placebo laser. Prior to the emergence of the monthly menstruation period, the participants underwent a 5-day treatment course of either LLLT or the placebo laser, which lasted for a period of 20 minutes. The visual analogue scale (VAS) was employed to gain insight into pain intensity, and this was utilised each month for a period of 6 successive months. Of the total 31 participants, 16 females experienced satisfaction in the initial month, while 5 experienced satisfaction in the second LLLT cycle. Notably, pain alleviation was reported by 83% of the participants[25]. In addition, the current study agrees with Kempf et al., double-blind study performed acupuncture with laser. Laser performed more effectively than the placebo laser for the treatment of dysmenorrhea, with the method used by the researchers involving the bilateral stimulation of 8 acupuncture points (SP6–LV3–LI4), and CV3–ST36 (on the right side of body) using a 20-minute laser for three menstrual cycles. The VAS scale was employed to determine pain intensity, and the results clearly evidenced pain alleviation for the laser group[26].

No studies have been yet carried out to investigate the efficacy of HILT on pain associated with primary dysmenorrhea. Our results of HILT may cause hopeful new therapeutic tool in the treatment of primary dysmenorrhea as our findings showed that HILT is more effective in alleviating pain associated with dysmenorrhea than PEMF. The pulsed Nd:YAG laser or pulsed HILT has a wavelength of 1,064 nm and acts in a therapeutic window that permits it to infiltrate and spread easily through human tissues, as the skin does not absorb this wavelength due to lack of proper concentration of endogenous chromophores. Although HILT has a peak power of up to 3 kW, the duty cycle of a brief duration limits heat accumulation inside tissues and quickly produces a photothermal and photochemical effect[27]. Several studies have proven the ability of pulsed Nd:YAG laser in the treatment of various musculoskeletal and neurological problems, and it is thought to have anti-inflammatory, anti-edematous, reparative and analgesic effects[16, 28, 29]. The sedative effect of HILT may be as a result of various mechanisms of action, involving its capability to decrease the conduction of the pain impulses and to raise the rate of morphine-mimetic substances production in the human tissues[28]. Furthermore, it may have the ability to block pain transmission through Aδ- and C-fiber, increases blood flow, vascular permeability, and cell metabolism[30, 31].

This study's results are consistent with those of Markov and Colbert, who found that magnetic field therapy produces a range of impacts associated with inflammation reduction, sedation, vasodilation, and the reduction of oedematous impacts, paired with an increase in the pain sensitivity limits[17]. The findings published in Khamaganova et al. are similarly consistent with the present research in that the previous researchers found evidence to suggest that high-frequency PEMF (with more than 10–15 individual treatments at 2-day intervals) is effective in treating back pain (89%), postoperative pain (80%), endometriosis (40%), the pain experienced due to pelvic inflammatory disease (80%), and various forms of lower abdominal pain (83%)[32].

The outcomes of the present study are consistent with a double-blinded clinical study evaluated the effectiveness of PEMF for treating knee pain in osteoarthritis. Treatment was applied for eight sessions, 6-minutes each over a 2 weeks period. Each patient recorded perceived pain on a 10-point scale before and after each treatment session. The group treated with PEMF showed a 46% decrease in pain vs. an average 8% in the placebo group. Two weeks after the study, pain diminished by 49% versus the placebo group, which demonstrated 9% pain decrease[33]. The results are supported by Strauch et al., who indicated that PEMF was an effective therapeutic tool in alleviating pain, muscle spasm and associated swelling during tooth removal and used effectively in postsurgical pain, treatment of chronic wounds and assisting in angiogenesis and vasodilation[34]. Hutchinson et al.'s results are supportive of this study's findings, with their research investigating pain alleviation associated with burst ovarian cysts, long-term urinary tract infections, uterine fibrosis, endometriosis, dyspareunia, and postoperative pelvic hematomas[35]. The study's participants responded positively and enhancements were observed regarding analgesic, anti-inflammatory, and immune-enhancing impacts.

Numerous mechanisms including inflammatory mediators might explain the pain-relieving effects of PEMF treatment. It has been shown that PEMF treatment increases the anti-inflammatory cytokine interleukin (IL)-1 and decreases the pro-inflammatory cytokine IL-1b, which is a strong hyperalgesic mediator and a nociceptors stimulator through direct and indirect pathways[36–38]. Animal studies have shown that IL-1b might trigger nociceptive fibres in a brief time in sensory transmission, and IL-1b receptors were found in many sensory neurons[38–40]. In addition, IL-1b also modifies neuronal excitability via its effect on neuronal receptors such as gamma-aminobutyric acid receptors, sodium channels, glutamate receptor and ion channel protein found in nerve cells, and through its influence on the release or the triggering of nociceptive molecules such as IL-6, and prostaglandins, and substance-P[41, 42]. Furthermore, PEMF may also cause analgesic effects by increasing the synthesis and release of nitrous oxide (NO). This, in turn, enhances the analgesic effects in the periphery in early stages of inflammation, and pain severity has been shown to inversely correlate with NO levels[43]. PEMF has been also suggested to enhance the endogenous opioid precursor proteins[44].

It was concluded that HILT and PEMF are effective modalities in the treatment of primary dysmenorrhea, with HILT being more effective modality which can be used as an alternative conservative therapy rather than medication that have numerous side effects.

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