EFFECT OF LOW-INTENSITY LASER ACUPUNCTURE AND REFLEXOLOGY IN RELIEVING DYSMENORRHEA: A RANDOMIZED CONTROL TRIAL

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Abstract

Background: Dysmenorrhea is defined as painful contractions which arise directly earlier/throughout menstruation time. Dysmenorrhea could be primary or secondary. These cramps are considered the most familiar complaints seen in 50% of women in their fertility time. Owing to the negative influence of medications and their 20-25% failure percentage, many women search for new adjunctive therapeutic approaches.

Objective: The present study attempts to detect the influence of low-intensity laser acupuncture therapy (LILT) and foot reflexology in treating primary dysmenorrhea (PD) in female students.

Methods: 50 females with PD participated in this trial; their ages ranged from 19-28 years; they were allocated randomly into two groups; intervention and controls. The intervention group received laser acupuncture and foot reflexology for 24 sessions 3 times per week for (2 consecutive menstrual cycles), and the control group received Ibuprofen (400 mg), 1/8h for 3 days during cycles.

Results: There was a significant improvement in pain level and functional ability after treatment in each group in favor of the intervention group.

Conclusion: laser acupuncture combined with foot reflexology effectively reduces pain and improves functional ability in treating PD.

Key words: Dysmenorrheal symptoms**.** Laser. Acupuncture**.** Foot reflexology

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Introduction

Dysmenorrhea: is defined as menstrual pains or cramping during menstruation. They were starting habitually since starting the first menstrual cycle. Its warning signs and symptoms usually stay for one or two days. Pains are commonly in the pelvic or low abdominal area. Additional symptoms might include feeling dizzy and fainting, cramps, feeling nauseating, desire to vomit, diarrhea, headache, and exhaustion [1].

Dysmenorrhea commonly initiates throughout puberty and continues with age, and its probable incidence is 40% to 50% [Dawood 2006]. PD classically occurs during adolescence, approximately 6 to 12 months following the first menstruation, commonly whenever ordered ovulations are started. PD is habitually managed using drugs as analgesics. Non-steroidal anti-inflammatory drugs (NSAIDs) as ibuprofen, acetylsalicylic acid (ASA), and naproxen are used by many women discover for pain reduction [2].

Reduction of symptom severity by using oral contraceptive drugs is reported. Antinausea tablets (antiemetics) might relieve nausea and vomiting; however, they commonly fade spontaneously if spasms decrease. Intrauterine devices (IUD) that discharge low progesterone levels are helpful for pain reduction [3].

On the other side, one review focused on modifying lifestyle to relieve pain signs and symptoms in women complaining of PD. Entirely complimentary and adjunctive therapeutic interventions aiming at modifying lifestyles were approved via adequate evidence-based data [4].

They included nutrition, physical activity, weight control, herbals, natural oils, medicinal flowers, less used therapies, related social and cultural problems, and psychologic status. Acupuncture, acupressure, and reflexology are also mentioned, as those approaches are alternate forms of treatment that signify an altered daily life and inspire persons to change their daily life and behaviors. All these are centered on diverse philosophies and procedures than the western routine [5].

Another atypical method for managing PD symptoms is the low-level laser skin-adhesive therapy (LLLT), approaching a decreased percentage of 83% compared to placebo. Researchers had suggested that the warming resulting from these procedures increases the circulation in the abdomen, and the effects could be securely equaled to using any oral pain killers [6].

Comparatively, a recent laser technique stimulates acupuncture points via low-intensity laser therapy (LILT). Effects of LILT were studied through functional magnetic resonance imaging studies. It was found that activation of the cerebral cortex occurs by stimulating specific acupuncture points via a needle or laser. The extremely varying laser application parameters found in earlier experiments have prohibited establishing a strong recommendation regarding management considerations [7].

Picture receptors accomplish the effects of light on the cell at cell molecules that, whenever elicited, stimulate a series of biologic responses like DNA/RNA production, higher cAMP concentrations, connective tissue collagen and protein production, and cell multiplication. Resulting in quick renewal, control, and curing the injured soft tissues. Consequently, light can trigger the readjustment of cell metabolic rate [8].

Reflexology is a treatment technique which had been used in different nations since thousands of years. Reflexology is a remedy established for stimulating nerves and circulation via reflex points that correspond to specific body parts, structures, and organs [9].

Reflexology is one of the complementary treatments, amongst all non-pharmacological approaches, is applied for treating diseases. It is a finger pressure practiced by our hands. Many reflex points are found in both hands and feet that resemble all tissues, zones, body parts, and systems all over our body. Through reflexology, self-management of our body can be triggered, and biological cure can be boosted [10].

Reflexology must not be misunderstood with massaging as reflexology is a procedure of figure pressure that is frequently applied over the foot since the foot has high sensitivity compared to other areas in the body. Applying regular reflexology sessions might reduce nervousness, let subjects feel relaxed, and reserve well-being [11].

Aim of the Study

This study was done to assess low-intensity laser acupuncture and foot reflexology effects on primary dysmenorrhea.

Methods

Subjects

A randomized control trial was done on 50 females were suffering from PD who were referred to the physiotherapy outpatient clinic of a private hospital. The study was approved by the faculty of physical therapy Cairo university ethical committee letter No. P. REC/012/003238. Age range between 19-28 years and BMI did not exceed 25 Kg/m^2. The treatment course applied for females was 24 sessions (one every other day) 3 times per week for (2 consecutive menstrual cycles). All participants agreed voluntarily and filled out a consent form. All participants were informed that their data would be confidential and only used for research purposes.

Exclusive criteria: Secondary dysmenorrhea, gynecological disorders, chronic disease (diabetes mellitus, hypertension, cardiovascular or respiratory diseases) and any dermatological diseases.

The participants were randomly allocated equally into two groups (A and B).

Study group (A): 25 females were suffering from PD. All received foot reflexology (20 minutes) and laser acupuncture (12 minutes) 3 sessions per week starting during menstruation for 24 sessions for (2 consecutive menstrual cycles).

Control group (B): 25 females were suffering from PD. All received ibuprofen capsules (400-milligram) and were instructed to take them once every eight hours for three days, one day earlier than the start of their menstruation cycle and repeated on the first two days of menstruation for (2 consecutive menstrual cycles).

Materials

Assessment procedures

Pain assessment through Visual analog scale (VAS): VAS is a tool used for subjective evaluation of clinical painful signs or symptoms. It is commonly a 10 cm straight line, with the limits of zero-till 10. The two edges of the line are regarded by stated grading representing the minimum and maximum values of the clinical sign/symptom that is to be assessed (for making it easy for the person to allocate midway levels); thus, the person points the line at a point expressing the severity of the sign/symptom. A 0 to 100 mm mark is given to measure the line's distance (in mm) lengthways as the person blot is marked [12].

Functional ability assessment

Scoring system for assessment of dysmenorrhea: It measures the disability of dysmenorrhea, sign a 3-items scale, and these are evaluated by 0-3 grades. The categories are working ability, systemic symptoms, and analgesic requirements. The extreme score is 9, which means 100% disability [13].

Treatment procedures

Low-level laser: Low-level laser acupuncture classically targets a ray of light existing out of a laser tube on top of a laser acupuncture point, exciting it similarly as a laser acupuncture needle does. The observable red laser ray radiates from either helium or neon gases, typically raising the point temperature. Through this process, practitioners can hold the beam gradually for a duration ranging from ten seconds to two minutes maximum. Ray duration generally be determined by the extent of soft tissue the laser must pierce and power the specialist wants to use on a point. We focused precisely on triggering laser acupuncture points for moving fluids & circulation inside the qi and blood in the channels [7].

Parameters: Wavelength: It denotes the exit of laser shade, and it is stated in nanometers (nm). The violet and ultraviolet are at the higher edge of the color range in the 400 nm scope. While the lower edge is the infrared light at 700 nm and more. The standard wavelengths of red laser acupuncture are 635-650 nm range. Additional colors might be found as blue, ultraviolet, and green. Diverse wavelengths have dissimilar uses [7].

Output: It denotes the intensity or ray illumination, stated in milliwatts (mW). Furthermost, generally, the 5mW laser for laser acupuncture is categorized as IIIa agreeing with the FDA. However, these lasers are of lower-power output and fit best for laser acupuncture.

Many laser companies validate a higher-power methodology, whereas others validate low power. The high-power (Class IIIb) infrared lasers pierce deeper and add much energy to penetrated tissues. That is called a shouting methodology. The 5mW laser is similar to whispers; however, it only requires a few drives or whispers as we deal with meridians' power. In order to do that, we operate with the body vitality for helping to do this; thus, it did not require a tack hammer. Knowing the characteristic security of Class IIIa, we favored the low-power method [14].

Methods

Intervention: Essential information for each female was taken includes (name, age, the level of pain, BMI), foot reflexology, and laser acupuncture applied on classical dysmenorrhea point. The treatment began as soon as the symptoms of dysmenorrhea started, three sessions per week.

Assessment of pain: Pain level documented by using (VAS) before starting the sessions and after the ending sessions. There is no pain in a score (0) and the troubling pain in (10). An increased score that a female gives means increased intensity of her pain [12].

Assessment of function ability: Every participant answered the questionnaire of scoring system for assessing dysmenorrhea before and after treatment to detect functional disability. If the patient had a higher, score usually associated with severe pain and debility.

Procedure: All subjects were brief and precise about the nature of treatment and effect to respect their conviction and collaboration through the period of application. The subject was divided randomly into two groups, one experimental group (A) underwent reflexology and laser acupuncture, and the control group (B) used ibuprofen capsules (400-milligram) and were instructed to take them once every eight hours for three days.

Foot reflexology: It was applied in 15 stages precise reflexology comprising the zones responsible for dysmenorrhea comprising liver, spleen, kidney, pituitary, as well as the solar plexus for (20 mins) all [15].

Laser acupuncture: Was applied in classical points, participants assumed a supine position, the parameters of laser were: LLLT (Chattanooga Gallium Aluminum Arsenide Diode Laser - Italy) with a wavelength of wavelength (905 nm), power (5 milliwatts), shoot (for 60 secs), duration (12 mins) each point take two shoots alternatively of a total (960 J) 3 sessions per week for 24 sessions for (2 consecutive menstrual cycles) [14].

- Bladder 21 [T12]: Point is located 1.5 cm sideways of the lower border of the 12th thoracic spinous process (T12)
- Bladder 29 [S3]: Point is located in the sacral area, 1.5 cm sideways of the middle sacral crest, at the level of the 3rd posterior foramen of the sacrum.
- Spleen 6: Point is located four finger spaces above the ankle in the depression under the bone [just above medial malleolus].
- Stomach 36 [fibula]: Point is located on the lower leg anterior part, 3 cm below ST 35, one finger-span (middle finger) beside the anterior tibial crest [16].

Randomization

Patients have efficiently been allocated randomly to 2 categories to eliminate bias through an envelope produced by an independent subject via randomly generated numbers of 25 participants in each group with an allocation ratio of 1:1. The participants were blinded to treatment allocation.

Sample size calculation

Preliminary power analysis was performed using G*Power 3.1.9.2 software to prevent a type II error with the following parameters [power (1−α error P) = 0.95, α = 0.05, effect size = 1.187]. Analysis was determined as a sample size of 50 individuals divided into two groups (25 each). For the sake of this calculation, we used pain intensity as the main outcome measure in 12-subject pilot research.

Statistical procedures

Data were analyzed using SPSS version 20 and found that:

- The arithmetic mean, standard deviation (SD)
- Comparison of mean: paired t-test of pain level and function ability in each group before and after the treatment, unpaired t-test for comparison of means pre-and post-treatment.
- Significance: *P*-value >0.05 specifies non-significant result, *P*-value <0.05 specifies significance, *P*-value <0.01 specifies high significance.

Results

This research was aimed to detect the effect of low-intensity laser acupuncture and foot reflexology in PD. Data were collected from participants before and after treatment and then were statistically studied. Both descriptive and analytic statistical tests were applied.

1) The Subjects General Characteristics

Thirty females were included; divided randomly into two groups, study group (A), control group (B). The data are summarized in table 1 (Table 1).

Group (A) : Twenty-five females were treated by laser acupuncture and foot reflexology techniques. Their mean age (23.4 ± 3.1) years, their mean BMI (23 ± 4.3) kg/m^2, and their mean of regularity (3.70 ±1.64).

Group (B) : Twenty-five females were treated with Ibuprofen. Their mean age (22.3 ± 2.9) years, their mean BMI (24 ± 4) kg/m^2, and their mean of regularity (4.52 ± 1.21).

2) Pain Assessment

Table 2 demonstrated the pain level in the Visual Analog Scale (VAS) before and after management in both groups. A high significant variance was noted in the paired t-test in pain intensity after treating both study and control groups, with a mean value of the study group (A) of (4.8± 1.2), with t-value of (8.113), a P-value of (0.001). For the control group (B), mean (7.1± 1.1), with t-value of (1.029), with a *P* (0.001) (Table 2).

Table 1: Physical characteristic of subjects in each group.

Item	Group (A) n=25	Group (B) n=25	Comparison	
	Mean ± SD	Mean ± SD	t-value	*P*-value
Age (year)	23.4 ± 3.1	22.3 ± 2.9	1.3	0.388
BM (KG/M2)	23 ± 4.3	24 ± 4	0.245	0.7
Regularity	3.70 ±1.64	4.52 ± 1.21	1.12	0.17
SD: standard deviation, t-test, p> 0.01				

Table 2: Means, SD, t- and P- values in groups A and B.

Item	Group (A) n=25	Group (B) n=25	Comparison	
	Mean ± SD	Mean ± SD	t-value	*P*-value
Group (A)	7.9 ±0.7	4.8 ±1.2	8.1137	0.001
Group (B)	7.5 ±0.9	7.1± 1.1	1.0293	0.001
SD: standard deviation, t-test, p> 0.01				

Table 3: Pain intensity means, t and P values between group A and B.

Item	Mean differences	Comparison	
		t-value	*P*-value
Pain before treatment	3.887	5.23	*P*-0.01
Pain after treatment	1.200	1.3	0.3132
t-test, p> 0.01			

In addition, we found a very slight variance of the unpaired t-test between the two groups as the mean difference was (0.400 - 1.200) 0.389, with a t-value of (1.3) and a *P* (0.3132) (Table 3).

3) Functional Ability

Table 4 demonstrates the functional disability in the form of a questionnaire for both groups. There was a slight difference before and after treatment in the paired t-test in the study and control groups with study group (A) mean value of (6.3±5.8), with a t-value of (13.11) & a *P* (0.00). Control group (B) mean (7.47±4.1), with t-value of (11.5) & *P* (0.001). While a non-significant difference was seen in the unpaired t-test between the two groups as the mean difference was (0.433), with t-value of (1.856) & *P* (0.05) (Tables 4 & 5).

Discussion

This randomized clinical trial investigated the effect of laser acupuncture combined with foot reflexology in treating primary dysmenorrhea (PD). The result showed improvement in pain and functional ability for all groups. However, a highly significant difference was noted among groups in pain level after treatment.

Acupuncture is considered one of the recommended methods for relieving PD. Complementary and alternative medicine (CAM) interventions nowadays are extensively conventional to women. Worldwide researches deliver debated scientifically evidence-based resources; for that reason, more research must be directed for proving or disregarding their effectiveness in treating PD [5].

Many types of research on laser acupuncture were done in the last two decades, as controlled clinical trials were conducted for applying laser acupuncture and reflexology. LLLT seems to be effective for treating acute pains. As well it reduces pain in the short term via alleviation of inflammation. Compared with many interventions, LLLT showed effectiveness in treating dysmenorrhea. It decreases prostaglandin E and F secretion, besides lowering prostaglandin synthetase production [17].

The present study results are similar to Thabet et al., 2008 who studied a 30-applicant to inspect the influence of physical activity combined with LLLT on pain throughout PD. The investigators used gallium-arsenide laser (with 635–670 nm wavelength and a 5 mv power) and McGill Pain Questionnaire pre- and post-laser. They also measured the cortisol concentrations before the study. Then this was repeated one time yet again after the 3-month therapy. LLLT was applied one day before the menstrual cycle, and at the first two days of the menstrual cycle, three shots (fixed for one minute) were applied on the suprapubic area. Prone lying was used for the paravertebral area, and L4–S3 area was also targeted with similar one-minute shots. The severity of pain was declined, as shown in the results, with 23 applicants (76.67%) experiencing total relief [18].

Additionally, our results are moreover reinforced by Shin et al., 2012 results. The investigators applied a laser as a substitute to the acupuncturist's needle to examine 31-female applicants with PD. They divided the sample into two groups, with 21 applicants being managed via LLLT and 10 applicants being managed via placebo laser. Preceding the emerging of the menstrual cycle, the applicants experienced a 5-day therapy of LLLT or placebo, lasting for 20 minutes. VAS was used for detecting the intensity of pain, and this was applied every month for six consecutive months. Of the 31 applicants, 16 were satisfied in the first month, whereas five had this in the second LLLT cycle. Markedly, 83% of applicants described pain reduction [19].

Table 4: Group A and B t-test mean, SD, t, and P-value.

Item	Pre	Pre	Comparison	
	Mean ± SD	Mean ± SD	t-value	*P*-value
Group (A)	8.5 ± 5.9	6.3 ± 5.8	13.11	0.001
Group (B)	8.5 ± 4.2	7.47 ± 4.1	11.5	0.001
SD: standard deviation, t-test, p> 0.01				

Table 5: t-test mean difference, t and P values between group A and B.

Item	Mean differences	Comparison	
		t-value	*P*-value
Functional disability before treatment	0.245	-1.202	0.2
Functional disability after treatment	0.433	1.856	0.05
t-test, p> 0.01			

Furthermore, the present study approves that of Kempf et al.,2009 who started a double-blind study executing acupuncture in addition to the laser. The laser was further effective than placebo in treating dysmenorrhea; the investigators involved a two-sided stimulus of eight points (SP6–LV3–LI4) and CV3–ST36 (on the body's right side) via a 20-minute laser in place of three consecutive menstruations. Evaluating the intensity of pain was done via VAS. Pain reduction was evident in the laser group [20].

There is inadequate evidence to show that acupuncture or acupressure helps treat primary dysmenorrhea, and no evidence of side effects has been given for most comparisons. For all evaluations, the quality of the evidence was low or extremely low. The principal constraints included the possibility of distortion, poor reporting, incoherence, and bias in publication [21].

Barbara& Kevin 2001 claimed that laser acupuncture reduces pain and modifies uterine motility for facilitating menstruation and promoting pain relief. Laser acupuncture helps treat PD. In a controlled study, most patients treated with laser acupuncture reported symptoms reduction without relapse during a-6- months follow-up [22].

Reflexology might reduce premenstrual symptoms (PMS), with the aim of global scores, PMS somatic and psychological symptoms were reduced by application of reflexology. Moreover, increasing reflexology session duration amplified its effectiveness. Reflexology can be applied as a beneficial interference in patient care, and its effectiveness may be improved by cumulative interference duration in every reflexology therapeutic setting [23].

Kirsch 2011 did a clinical trial study on 68 students with PD, equally distributed; one group was treated with reflexology sessions, while the other group used Ibuprofen. The reflexology approach was concomitant with a further decline in the severity and extent of the menstruation pain compared to the Ibuprofen treatment [24].

Jones. J and S. Leslie. 2012 study aimed to classify aroma-foot-reflexology influence on PD disorder and lesser abdominal skin temperature degree. Using quasi-experimental study design for applicants separated into two groups: one control and the other for treatment, who received aroma-foot-reflexology treatment. The outcomes displayed the significance of aroma-foot reflexology in decreasing dysmenorrheal pain and elevated abdominal skin temperature [25].

Limitations

One of the limitations of the study can be recognized as the subjective description of pain by participants. This can be recognized as a possible source of bias. The second limitation can be considered the limited duration to follow up the influence of laser or reflexology on the physiological parameters of the participants.

Conclusion

Laser acupuncture combined with foot reflexology is considered effective in reducing pain and improving functional ability in treating PD.

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