

Effect of Low Level Laser Therapy and Anti-Inflammatory Diet on Primary Dysmenorrhea: A Randomized Controlled Trial

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Abstract

Background: Primary dysmenorrhea (PD) is the most common gynecological problem in women during the menstruation, its associated complications have a negative effect on well-being and quality of life of women.

Aim of Study: This study was conducted to ascertain whether combining low-level laser therapy (LLLT) with anti-inflammatory diet (AID) have an effect on primary dysmenorrhea (PD).

Patients and Methods: The study involved 35 females diagnosed with PD, aged 20-35 years, with body mass indices between 18-29.9 kg/m². Participants were randomly assigned to two groups: Group A (n=17) received LLLT alone, while Group B (n=18) received both LLLT and AID. Both interventions were administered over three consecutive menstrual cycles. The outcome measures, including serum levels of C-reactive protein (CRP), scores of menstrual distress questionnaire (MDQ), and visual analogue scale (VAS), were evaluated at baseline and after treatment.

Results: A statistically significant improvement was observed in CRP, MDQ, VAS in both groups after treatment compared to before treatment ($p < 0.05$), by comparing both groups post-treatment there was no significant difference between both groups ($p > 0.05$) but the percentage of improvement in CRP and MDQ was high in group B than in group A (15.46% versus 17.89%), (20.25% versus 26.32%) respectively.

Conclusion: A program of combined LLLT and AID has a better effect on management of PD rather than LLLT alone.

Key Words: Primary dysmenorrhea – Low level laser therapy – Anti inflammatory diet – CRP – Menstrual distress questionnaire – Visual analogue scale.

Introduction

PRIMARY dysmenorrhea (PD), defined by painful menstrual cramps with no identifiable pelvic pathologies, is a widespread condition impacting women worldwide [1].

PD affects 60% of reproductive-age women, ranking as their most common health concern [2,3]. This condition and its associated symptoms like headache, fatigue, gastrointestinal disturbances, and muscular cramps can substantially affect young women's quality of life and social engagement [4,5].

PD can disable individuals and render them inefficient, leading to significant absences from educational and professional settings. Specifically, this condition is associated with a loss of 1-3 workdays monthly for approximately 1% of women in their reproductive years. Moreover, painful uterine contractions cause around 14% of girls to miss school [6,7]. Additionally, it can disrupt social relationships due to associated mood changes and shame, while also incurring economic costs from medication use [8]. Consequently, dysmenorrhea's socioeconomic impact on women is substantial.

Research on healthy women revealed a positive correlation between C-reactive protein (CRP) concentrations and menstrual symptom severity (mental state, behavioral patterns, pain perception, and physical indicators), suggesting low-grade inflammation's role in dysmenorrhea etiology [9]. A subsequent study found significant positive correlations between CRP levels and various premenstrual symptoms, including mood changes, cramps in the abdomen, greater appetite, bloating, and pain in the breasts [10].

Despite the common use of analgesics, oral contraceptives, and non-steroidal anti-inflammatory drugs (NSAIDs) for PD, such treatments fail in 20–25% of cases due to side effects or loss of efficacy [11]. Consequently, alternative pain relief methods have gained popularity.

Recent years have seen growing interest in complementary approaches, including transcutaneous electrical nerve stimulation, acupuncture, herbal medicine, and mind-body practices like meditation and yoga [12,13].

Low level laser therapy (LLLT), a non-invasive physiotherapeutic modality, offers anti-inflammatory, septic, and analgesic benefits. It effectively treats dysmenorrhea by inducing endorphin production and suppressing prostaglandin E and F synthesis [14].

Additionally, healthy nutrition plays a crucial role in managing dysmenorrhea severity [15,16] with pre-menstrual and menstrual food choices significantly impacting menstrual outcomes [17,18].

Anti-inflammatory diets (AIDs) have emerged as a novel approach for preventing and treating diseases. These include various traditional eating patterns like the Mediterranean, Okinawan, Nordic, and Mexican diets, as well as the Dietary Approaches to Stop Hypertension (DASH) diet. Such dietary approaches emphasize abundant fruit and vegetable consumption, often recommending 1–2 servings at each meal. They also prioritize whole grains, healthy fats like olive oil, and lean protein sources such as legumes, fish, and poultry. Red meat consumption is limited to occasional servings [19,20] and other scientific bodies now endorse the Mediterranean diet (MD) as the most health-promoting dietary pattern, as it has been shown to lower the risk of various chronic illnesses.

Given the established analgesic and anti-inflammatory properties of LLLT and AID, it is surprising that no previous research has explored the potential benefits of combining these two interventions on CRP levels, a key indicator of inflammation and pain severity, in patients with PD. This study aimed to fill this knowledge gap by investigating the effects of LLLT-AID combination therapy on CRP levels in PD.

Patients and Methods

Study design:

The study adhered to a prospective, randomized, controlled trial design. Ethical approval was secured from the Research Ethics Committee of the Faculty of Physical Therapy, Cairo University [No: P.T.REC /012/005370] adhered to the Declaration of Helsinki's Principles for the ethical conduct of

human research. This study was conducted between October 2022 and August 2024.

Participants:

This study involved 35 women diagnosed with PD at the gynecological outpatient clinic of El-Mataria Teaching Hospital in Cairo, Egypt. Participants were aged 20–35 years, with BMIs ranging from 18 to 29.9 kg/m². All subjects had regular menstrual cycles, characterized by 3–8 days of menstruation and 21–35-day intervals between cycles. Exclusion criteria encompassed a history of uterine myomas or tumors, ovarian cysts, pelvic infections or inflammatory disease, other gynecological conditions, hormonal imbalances, psychological disorders, and contraindications for LLLT like malignancies, epilepsy, pacemaker use, or hemorrhagic conditions.

Randomization:

Following a thorough explanation of the study protocol, all female participants provided informed consent before being randomly assigned to one of two groups (A or B) using computer-generated randomization cards. Notably, no participants dropped out of the study following randomization.

Interventions:

Low level laser therapy (LLLT):

Group A participants underwent LLLT treatment for three consecutive menstrual cycles, with three sessions per cycle. The initial session was administered when pain became intolerable, typically shortly before menstrual flow onset. The subsequent two sessions followed on the next two days. Treatment began with the patient supine, applying LLLT to the suprapubic region for 4 minutes using a wavelength of 808–905 nm, 1500 Hz frequency, and 4 J/cm² energy density. The device was held perpendicular to the skin. Patients then turned prone for a 4-minute application to the L4–S3 paravertebral area. This protocol was consistent across all three menstrual cycles [21].

Anti-inflammatory diet:

All participants in group (B) were treated with LLLT, three monthly sessions over a period of three consecutive menstrual cycles like group (A) in addition to an individualized structured dietary plan considering participants nutritional needs. We include the regular diet rich in fruits, vegetables, olive oil, white meat, fish, legumes, and whole grain, in addition, limiting refined carbohydrates, white sugar, red meats, processed meats and salt to assess the influence of a simple modification that patients might find easy to adopt in their everyday lives.

Outcome measures:

Serum CRP level (primary outcome measure): Serum CRP levels, reflecting inflammation and menstrual symptoms, were measured from blood

samples taken from females in both groups, with lower CRP levels indicating a reduction in both inflammation and menstrual discomfort [10].

Menstrual distress questionnaire: It is a reliable and validated method for evaluating the physical and psychological manifestations of PD and their effects on daily functioning [22]. This multi-dimensional assessment tool encompasses eight key factors, consisting of 47 items, including pain, concentration, behavioral adaptations, autonomic responses, fluid retention, negative effect, arousal, and control. Participants in both groups completed the MDQ at pre- and post-treatment intervals, using a 4-point Likert scale to rate their symptoms, where 0, 1, 2, and 3 corresponded to symptom-free, mild symptoms, moderate symptoms, and severe symptoms, respectively [23].

Visual Analogue Scale (VAS):

It was employed to assess and quantify the pain experienced by each female participant in both groups (A and B) at the beginning and end of the study. As a well-established and reliable tool for pain measurement, the VAS features a 10-cm straight line that represents the continuum of pain intensity, with one end indicating “no pain” and the other end indicating “worst pain”. The scale is further divided into four distinct segments, each corresponding to a 2-cm distance, and labeled with descriptive phrases such as “mild pain”, “moderate pain”, “severe pain”, and “very severe pain” [24].

Sample size calculation:

The sample size for this study was determined using a pilot study and a priori power analysis with G*Power software (version 3.1.9.2) for a mixed-design MANOVA. With CRP as the primary outcome, an effect size of 0.57 was assumed, and the type I error was set at 0.05. To achieve a power of 0.80, the initial sample size was calculated to be 27. To account for a potential 20% dropout rate, the final sample size was increased to 35.

Data analysis:

Independent *t*-test was applied to test homogeneity of difference between the two tested groups A and B. A two-way (2×2) mixed-design Multivariate Analysis of Variance (MANOVA) was then conducted to assess the impact of two interventions on three outcome measures. Our study incorporated two independent variables: The tested group (between-subjects factor) with two levels - Group A receiving LLLT and Group B receiving both LLLT and AID; and the assessment time point (within-subjects factor), comprising pre- and post-intervention measurements. There were three dependent variables: Serum C-reactive protein levels, pain intensity as measured by the VAS, and MDQ score. All analyses were performed using SPSS version 20, with statistical significance set at $p \leq 0.05$.

Results

Demographic test measures:

As shown in a table 1 the results revealed insignificant differences between both groups regarding age, weight, height and BMI ($p > 0.05$).

Effect of low-level laser therapy and anti-inflammatory diet on serum CRP:

Pair wise comparisons revealed that both groups A and B experienced statistically significant decreases in mean CRP levels following intervention ($p < 0.05$). Group A showed a 15.46% reduction in mean CRP, while Group B demonstrated a 17.89% decrease. However, when comparing the two groups, no statistically significant differences in mean CRP values were observed either before or after the intervention period ($p > 0.05$).

Effect of low-level laser therapy and anti-inflammatory diet on VAS:

Pair wise comparisons indicated that both treatment groups experienced statistically significant reductions in mean VAS scores following intervention ($p < 0.05$). Group A exhibited a 39.69% decrease in mean pain intensity, while Group B showed a 35.21% reduction. However, when comparing both groups directly, no statistically significant differences in mean pain intensity scores were observed either at baseline or post-intervention ($p > 0.05$).

Effect of low-level laser therapy and anti-inflammatory diet on MDQ score:

Pair wise comparisons revealed that both intervention groups experienced statistically significant decreases in mean MDQ scores from pre- to post-treatment ($p < 0.05$). Group A demonstrated a 20.25% reduction in mean MDQ values, while Group B showed a more pronounced decrease of 26.32%. However, when comparing the two groups directly, no statistically significant differences in mean MDQ scores were observed at either pre- or post-intervention ($p > 0.05$).

Table (1): Independent *t* test for the demographic data of the two tested groups in females with primary dysmenorrhea.

	X ± SD		p-value of significance
	Group (A)	Group (B)	
Age (years)	28.87±4.29	28.95±4.57	$p=0.956$
Weight (kg)	74.00±11.09	72.40±11.90	$p=0.685$
Height (cm)	164.93±8.46	166.1±6.85	$p=0.665$
Body mass index (kg/m ²)	27.34±2.12	26.17±3.83	$p=0.293$

Table (2): Two-way mixed design MANOVA of CRP in females with PD.

CRP X 1SD			
Group (A)		Group (B)	
Pre test	Post test	Pre test	Post test
6.47 \pm 1.60	5.47 \pm 1.51	5.70 \pm 1.59	4.68 \pm 1.38
Tests of within subject effect (time)		F=21.70, η^2 =0.397	p =0.000*
Tests of between subject effect (group)		F=2.715, η^2 =0.076	p =0.109
Interaction (group* time)		F=0.002, η^2 =0.000	p =0.968
Pairwise comparisons tests			
<i>Pre test vs. Post test:</i>			
Group (A)		p = 0.004*, CI = (0.334-1.666)	
Group (B)		p = 0.001*, CI = (4.35-7.73)	
<i>Group (A) vs. Group (B):</i>			
Pre test		p = 0.169, CI = (-1.88-0.342)	
Post test		p = 0.119, CI = (-1.78-0.212)	

 \bar{X} : Mean.

CI: Confidence interval.

SD: Standard deviation.

*Significant at alpha level <0.05.

 η^2 : partial eta squared.

Table (3): Two way mixed design MANOVA of VAS in females with PD.

Pain intensity score (VAS)			
X 1SD			
Group (A)		Group (B)	
Pre test	Post test	Pre test	Post test
6.40 \pm 1.24	3.86 \pm 1.47	7.13 \pm 1.84	4.61 \pm 1.46
Tests of within subject effect (time)		F=76.995, η^2 =0.700	p =0.000*
Tests of between subject effect (group)		F=2.792, η^2 =0.078	p =0.104
Interaction (group* time)		F=0.001, η^2 =0.000	p =0.976
Pairwise comparisons tests			
<i>Pre test vs. Post test:</i>			
Group (A)		p = 0.004*, CI = (1.651-3.242)	
Group (B)		p = 0.001*, CI = (1.753-3.288)	
<i>Group (A) vs. Group (B):</i>			
Pre test		p = 0.169, CI = (-1.850-0.394)	
Post test		p = 0.119, CI = (-1.763-0.273)	

 \bar{X} : Mean.

CI: Confidence interval.

SD: Standard deviation.

*Significant at alpha level <0.05.

 η^2 : partial eta squared.

Table (4): Two-way mixed design MANOVA of MDQ in females with PD.

MDQ X 1SD			
Group (A)		Group (B)	
Pre test	Post test	Pre test	Post test
80.20±129.18	63.96±126.69	76.75±132.69	56.55±132.27
Tests of within subject effect (time)		F=431.34, η²=0.929	p=0.000*
Tests of between subject effect (group)		F=0.271, η²=0.008	p=0.606*
Interaction (group* time)		F=5.087, η²=0.134	p=0.0.31
Pairwise comparisons tests			
Pre test vs. Post test:			
Group (A)		p = 0.000*, CI = (13.544-18.941)	
Group (B)		p = 0.000*, CI = (17.863-22.537)	
Group (A) vs. Group (B):			
Pre test		p = 0.749, CI = (-18.266-25.166)	
Post test		p = 0.475, CI = (-28.274-13.459)	

Discussion

Menstrual-related issues, particularly PD, significantly impact the well-being and life quality of reproductive-age women [25].

A range of non-medicinal strategies have been developed to alleviate menstrual discomfort, including nutritional interventions, adjustments to daily routines, use of herbal products, and dietary supplements [26]. Food choices before and during menstruation can play a crucial role in influencing menstrual experiences and outcomes [17,18].

Since menstruation involves inflammatory processes [27], it is hypothesized that the chronic, low-level inflammatory state resulting from the inflammatory response may be implicated in the pathogenesis, clinical presentation, and severity of dysmenorrhea [28,29]. Research on adult women has revealed that CRP levels, a widely researched inflammatory marker, fluctuate significantly throughout the menstrual cycle [30].

CRP is a widely investigated inflammatory marker, [31] and recent research has also established its role as a novel and trustworthy indicator of acute phase response to infection and inflammation [32,33].

So, the present study was conducted to examine the influence of AID with LLLT on PD.

Our research revealed that administering AID with LLLT for three successive menstrual cycles led to a significant reduction in CRP, VAS, and MDQ levels post-treatment compared to pre-treatment values. Although a statistical analysis of both groups post-treatment showed no significant difference ($p>0.05$), a clinical difference emerged, with the study group exhibiting a greater percentage of improvement in CRP (15.46% vs 17.89%) and MDQ (20.25% vs 26.32%) outcomes.

The observed reductions in dysmenorrheal pain, CRP levels, and MDQ scores following LLLT treatment can be explained by its multifaceted effects. As a non-invasive therapy, LLLT exhibits antiseptic, anti-inflammatory, and analgesic properties. Its pain-relieving mechanism involves both reducing inflammation and altering serotonin metabolism, as evidenced by increased urinary 5-hydroxyindoleacetic acid levels [14].

Our study's findings concur with the conclusions of [34] who explored the role of physical activity alongside LLLT in alleviating PD pain, noting that 76.67% of participants reported complete relief from pain.

Additionally [21] concluded that both LLLT and Pulsed electromagnetic field (PEMF) are effective modalities in treatment of PD by decreasing levels of serum cortisol and decreasing menstrual symptoms, using MDQ.

However, our findings contrast with, [35] who employed laser needle acupuncture for PD. Despite using different acupuncture points, that study observed pain reduction without statistically significant changes.

The observed greater improvements in CRP and MDQ scores in the group receiving both AID and LLLT, compared to LLLT alone, can be explained by the inflammation-reducing effects of the Mediterranean-inspired diet. This eating pattern, emphasizing leafy greens, fruits, whole grains, olive oil, and fish, has demonstrated anti-inflammatory benefits [36]. Additionally, anti-inflammatory food consumption seems to optimistically impact various aspects of well-being, including stress levels, mood, cognitive function, and sleep quality, [37] potentially through mechanisms involving reduced inflammation and oxidative stress [38].

Our findings are confirmed by Fung et al., [39] who displayed that following Mediterranean style eating patterns is linked to notably reduced levels of inflammatory markers, including CRP. In addition, a cross-sectional study by Byung-Joon Ko demonstrated that a DASH-style diet is inversely related to circulating CRP levels [40].

Also, Lahoz et al., [41] concluded that following a Mediterranean style eating pattern is linked to reduced CRP levels, with particular emphasis on

higher vegetable, fruit, fish, and dairy product intake.

Moreover, a systematic review of Bajalan et al., [42] indicated that an increased intake of vitamin and mineral-rich fruits and vegetables, as well as fish, milk, and dairy products, is positively correlated to a reduction in menstrual pain.

Likewise, Szymanska et al., [43] observed that a diet centered around unprocessed foods like the MD or AID, led to a reduction in pain intensity and menstrual distress.

Mukherjee et al., [44] highlighted the potential of dietary choices in modulating inflammatory markers, with particular emphasis on the MD components like extra virgin olive oil, nuts, and fish, when consumed in specific amounts.

This agrees with Sala-Climent et al., [45] who concluded that anti-inflammatory food intake can help relieve chronic pain and enhance stress management, depression, and sleep quality.

The study's results align with Ciołek et al., [46] who explored the effects of dietary and lifestyle factors on menstrual symptoms. This study identified specific eating patterns that may either alleviate or worsen menstrual discomfort. The results indicated that women following an AID rich in minimally processed foods like vegetables, fruits, whole grains, dairy, and legumes experienced notably reduced menstrual pain. Conversely, a diet high in ultra-processed foods, including sweet food, processed meats, and items low in fiber and high in saturated fats, was linked to increased menstrual pain and overall discomfort.

This study has several limitations that warrant consideration. First, we did not assess a broader range of inflammatory markers like white blood cell count or mean platelet volume, which could provide a more comprehensive understanding of the inflammatory processes involved. Future research should explore these additional markers to elucidate the mechanisms by which an anti-inflammatory diet may outperform LLLT in reducing serum CRP levels in dysmenorrhea. Second, the absence of long-term follow-up prevents us from drawing conclusions about the sustained effects of the interventions. Third, adding some antioxidant supplements and herbs with AID for further decrease of serum CRP such as (vitamin E, Omega3, vitamin D, vitamin C, ginger, green tea). Lastly, educational programs aimed at reproductive aged women and healthcare professionals should be introduced to spread awareness about how diet and lifestyle choices can help relieve PD.

Conclusion:

Both LLLT and AID are effective methods in PD treatment rather than LLLT alone, by decreas-

ing levels of serum CRP and decreasing menstrual symptoms, with a better impact of combining LLLT with AID.

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Conflict of Interest:

No conflicts of interest are disclosed by the authors.

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تأثير العلاج بالليزر منخفض الشدة والنظام الغذائي الغني بمضادات الالتهاب على آلام عسر الطمث الأولى

الخلفية: يعد عسر الطمث الأولى من المشكلات النسائية الشائعة التي تؤثر سلباً على جودة الحياة.

الهدف: تقييم تأثير الجمع بين الليزر المنخفض الشدة والنظام الغذائي الغني بمضادات الالتهاب في علاج عسر الطمث الأولى.

الأشخاص والطرق: شملت الدراسة ٣٥ سيدة تم تقسيمهن إلى مجموعتين؛ تلقت المجموعة (أ) (١٧ سيدة) علاج الليزر المنخفض الشدة لمدة ٣ دورات شهرية، بينما تلقت المجموعة (ب) (١٨ سيدة) العلاج نفسه بالإضافة إلى نظام غذائي غني بمضادات الالتهاب. تم التقييم بقياس مستويات بروتين سى التفاعلى بالدم، استبيان اضطراب الدورة الشهرية، ومقياس النظير البصرى للألم قبل وبعد العلاج.

النتائج: أظهرت النتائج تحسناً ملحوظاً في جميع المقاييس بعد العلاج في كلتا المجموعتين، لكن بدون فرق إحصائي بينهما. ومع ذلك، كانت نسبة التحسن في المجموعة (ب) أعلى في مستويات بروتين سى التفاعلى بالدم (١٧, ٨٩٪ مقابل ١٥, ٤٦٪) ونتائج استبيان اضطراب الدورة الشهرية (٢٦, ٣٢٪ مقابل ٢٥, ٢٠٪) مقارنة بالمجموعة (أ).

الخلاصة: الدمج بين الليزر المنخفض الشدة والنظام الغذائي الغني بمضادات الالتهاب أكثر فعالية في تخفيف عسر الطمث الأولى مقارنة باستخدام الليزر وحده.