CODEN [USA]: IAJPBB ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

http://doi.org/10.5281/zenodo.1157977

Available online at: http://www.iajps.com Research Article

EFFECT OF EVENING PRIMROSE ON PREMENSTRUAL SYNDROME: A RANDOMIZED CLINICAL TRIAL

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Abstract:

Premenstrual syndrome is a set of physical and emotional psychological symptoms which occur periodically during the secretory phase of the menstrual period. This study was done to effect of Evening Primrose on premenstrual syndrome. This clinical double-blind study was conducted on 80 girls student suffered from premenstrual syndrome at Hamadan University of Medical Sciences, Hamadan, Iran. The samples were then randomly divided in two 40-member groups, Evening Primrose (1000 mg, 2 times per day) and placebo (2 times per day) groups. The subjects were received the therapeutic regimen for 2 months. Data collection tools were collected using questionnaires, daily symptom records (DSR) questionnaires and adverse drug reaction questionnaires of participants before and after intervention were registered and compared. Analyses were carried out by Chi-square, paired t-test using SPSS /21.The result showed that after intervention, severity of premenstrual syndrome was reduced in Evening Primrose group (61.45±21.25 to 21.38±9.05) ($P<0.05$).

Findings revealed that taking Evening Primrose can reduce severity of premenstrual syndrome. So, regarding the little side complications, consumption of Evening Primrose has a useful effect on premenstrual syndrome.

Key words: *Premenstrual Syndrome, Evening Primrose, Iran*

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*Please cite this article in press as Shobeiri et al., **Effect of Evening Primrose on Premenstrual Syndrome: A Randomized Clinical Trial**, Indo Am. J. P. Sci, 2018; 05(01).*

INTRODUCTION:

Premenstrual syndrome (PMS) refers to physical and emotional symptoms that occur in the one to two weeks before a woman's period. Symptoms often vary between women and resolve around the start of bleeding. Common symptoms include acne, tender breasts, bloating, feeling tired, irritability, and mood changes, depression, crying, mood swings, and oversensitivity. In case group received (1,2). Premenstrual syndrome (PMS) is commonly regarded as a menstrual-related disorder that occurs in 30–40 % of women reproductive age. It encompasses a complex series of emotional, physical and behavioural symptoms that periodically arise in the late luteal phase and resolve soon after the onset of menstruation (1-4). Notably, PMS is characterized by negative emotional and physical symptoms during the lutealphase(5). Aberrant amygdala structural and functional connectivity were found in PMS patients(5). The most common symptoms in PMS include abdominal bloating, breast tenderness, anxiety, crying spells, depression, fatigue, lack of energy, anger and irritability, changes in appetite, and varying degrees of edema (6). Etiology of PMS still remains unknown; however, it is understood as a psychoendocrine disorder. Involvement of sex steroids is supported by the relief of PMS symptoms with the suppression of ovulation; however, no strong evidence is provided to confirm that reproductive hormones are the sole cause of PMS(7). Today, in the treatment of diseases and disorders, the use of herbal therapies and complementary medicine has been considered due to their low level of complications (8). Evening primrose oil (Oenotherabiennis) is a commonly used alternative therapy and a rich source of omega-6 essential fatty acids. It is best known for its use in the treatment of systemic diseases marked by chronic inflammation, such as atopic dermatitis and rheumatoid arthritis. It is often used for several women's health conditions, including breast pain (mastalgia), menopausal and premenstrual symptoms, cervical ripening, and labor induction or augmentation. Evening primrose oil is generally well tolerated, with reported minor adverse effects, including gastrointestinal upset and headaches(9). More severe psychological symptoms have been described for the premenstrual dysphoric disorder (PMDD). No single treatment is universally recognized as effective and many patients often turn to therapeutic approaches outside of conventional medicine. A systematic review reported the effects of herb remedies in the premenstrual conditions(10).The present study examined the efficacy of Evening Primrose on reduction of PMS symptoms among students of Hamadan University of Medical Sciences, in west of Iran.

MATERIALS AND METHODS:

This clinical double-blind study was conducted on 80 girls student suffered from premenstrual syndrome at Hamadan University of Medical Sciences, Hamadan, Iran. All participants were informed about the experimental procedure and provided written informed consent. Eighty women were stratified randomly in to two groups and each had 40 members of cases and control, in order to access a uniform sample in terms of social, economic and cultural conditions. The recruitment took place between December 2016 and September 2017. A standard questionnaire was used to collect data according to Daily Record of Severity of Problems scale in menstruation daily symptom records (DSR). While absence of the symptom was scored as 0, score of 1indicated mild symptoms, which did not interfere with daily activities such as education and work. Score of 2 represented moderate symptoms, which affected daily activities to some extent. However, score of 3 was indicative of severe symptoms, which prevented the patient from daily activities. On admission to clinic, all relevant information was collected by interviewing, including demographic characteristics, marital state, occupation, educational level, characteristics related to premenstrual syndrome such as its time and duration, characteristics related to menstrual cycles, results of diagnostic interventions, and also, previous history of psychological disorders including depression or anxiety. In case group received Evening Primrose (1000 mg, 2 times per day); and in control group received placebo (2 times per day), for 15 day before the start of the cycle until the fifth day.

Severity of symptoms was determined based on Daily Record of Severity of Problems scale in one menstrual cycle before the intervention and two menstrual cycles after the intervention. Each group was assayed for three cycles, one without any drugs and then two cycles with them.At the end we compared the results obtained in these three steps and analyzed the collected data. The research was conducted based on the protocol of Helsinki declaration. The aims of the research were clarified to females who participated in the study and asked them to fill informed consent. Women could leave the study at any time. The Ethical Committee of Hamadan university of Medical Sciences approved the research (approval number: 9311205855). In this randomized trial registration code of project was IRCT201610289014N127.

Analysis of the data was performed by SPSS/21, using t test and chi square test. P-value <0.05 was considered as significant.

RESULTS:

Eighty participants aged 18-22 years who complained of primary dysmenorrheal were enrolled in this research. As shown in Table 1, the two groups treated with Evening Primrose and placebo were comparable in terms of baseline characteristics including age, Menarche age, Menstruation time, Weigh, Height. There was no significant difference in the mean of severity of premenstrual syndrome before the intervention (cycle 0) between the Evening Primrose and placebo groups (61.45±21.25 and 61.21±30.12, respectively) (P=0.967), but the difference was significant in the two groups during the first cycle (30.11±10.07 and 62.32±18.15, respectively) and the second menstrual cycle (21.38±9.05 and 62.48±19.17, respectively) after the intervention (P < 0.001). The trend of changes in pain severity score showed significant downward trend of severity of premenstrual syndrome score within the study period in both the treatment groups (P < 0.001)(Table 2).

Table 1: Baseline characteristics and clinical data of the study Population

Characteristics	**Mean (SD)**		**P value (t-test)**
	Evening Primrose (n=40)	**Placebo (n=40)**	
Age**(yr)**	21.4±1.2	21.5±1.3	0.9
Menarche age**(yr)**	14.4±1.2	13.8±2.1	0.2
Menstruation time**(yr)**	5.9±0.8	5.8±1.1	0.2
Weight(kg)	59.34±7.5	59.1±8.5	0.7
Height(cm)	164.8±3.8	162.8±4.4	0.6

SD: Standard deviation

Table 2: Mean and SD of premenstrual syndrome (cycle 0, 1, and 2) in the groups of study according to the type of drug

Characteristics	**Mean (SD)**		**P- Value [a]**
	Evening Primrose (n=40)	**Placebo (n=40)**	
On admission (cycle 0)	61.45±21.25	61.21±30.12	0.967
One month later (cycle 1)	30.11±10.07	62.32±18.15	P<0.001
Two months later (cycle 2)	21.38±9.05	62.48±19.17	P<0.001
(cycle 0 &1) Paired t-test , P value	P<0.001	0.842	
(cycle 0 &2) Paired t-test , P value	P<0.001	0.823	

[a] Comparison between experimental and control (Independent t- test).

DISCUSSION:

Adding an antioxidant agent to first line therapeutic regimes for treatment of premenstrual syndrome has been shown to be an effective schedule. Recently, direct attention has been paid
toward using herbal drug to facilitate pain relief in these patients(11). premenstrual syndrome are the common problems occurring in women during childbearing age. Many studies have been conducted on finding the best treatment for these conditions. Most researches have proved the positive effects of different drugs (11). The findings of this study demonstrated significant effects of Evening Primrose (1000 mg/2 times per day) on reduction of PMS symptoms and among menstrual cycles (0, cycle 1, cycle 2). The obtained results corroborate those of previous studies regarding the positive effect of some supplementation on premenstrual symptoms(11, 12).Salehi et al. (13) reported that comparison of the results obtained before and after intervention revealed that depression and sadness were significantly reduced in the women receiving *Evening Primrose* in comparison with those receiving placebo. After intervention, severity of premenstrual syndrome was reduced in *Evening Primrose* group (60.58±30.6 to 34.09±19.81), Vitexagnus (61.23±30.54 to 25.25±17.78) and the vitamin E group, (61.24±32.04 to 54.9±19.24). Severity of premenstrual syndrome were reduced in the *Evening Primrose* and *Vitexagnus* groups in compared to vitamin E group ($P<0.05$)(13).

These results were similar to those reported by Dante and Facchinetti(10). The mentioned study revealed that Evening Primrose supplements alleviated concentration problems, and affective and behavioral variations related to PMS ($P=0.01$). Vitexagnuscastus was the more investigated remedy, and it was reported to consistently ameliorate PMS better than placebo. Evening primrose oil showed an effect different than placebo. None of the herbs was associated with major health risks, although the reduced number of tested patients does not allow definitive conclusions on safety. Some herb remedies seem useful for the treatment of PMS(10).
In another study conducted in this regard, intake of herbs supplement modestly reduced PMS symptoms, although the improvements did not exceed the placebo(14).
In a review study conducted in 2015, reported that combined oral contraceptives and serotonergic antidepressants are effective drugs, each is a different option for treating PMS/PMDD. Other treatment options include lifestyle modification, cognitive behavioral therapy, and herbal medicine (e.g., chasteberry,Evening Primrose) (1, 15).

The present study reported that daily intake of 1000 mg Evening Primrose was effective in reducing PMS symptoms. Furthermore, daily intake of Evening Primrose for longer duration was caused that the symptoms more were relieved. Overall, the results of the mentioned studies suggest that treatment with Evening Primrose supplements is an effective technique for reducing mood disorders observed in PMS. Furthermore, Evening Primrose supplementation is a cost-effective, beneficial, and effective treatment for reducing symptoms of PMS. The main limitation of the present study was small sample size of the study groups. If the sample size was large enough, the differences between the trial groups would be indicated more clearly with less random error. In addition, the present study was conducted addressing a single group of adolescents; therefore, the results may not be generalizable to females outside that age range.

CONCLUSION:

The results of this study showed that the taking Evening Primrose can reduce severity of premenstrual syndrome. So, regarding the little side complications, consumption of Evening Primrose has a useful effect on premenstrual syndrome.

ACKNOWLEDGEMENT:

The authors would like to thank the Hamadan University of Medical Sciences in Iran for their valuable support and participation. This article is the result of a research project that was approved by the Research Deputy of Hamadan University of Medical Sciences, Hamadan, Iran.

CONFLICT OF INTEREST:

No potential conflict of interest relevant to this article was reported.

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