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The Effect of Evening Primrose (Oenothera biennis) Oil Capsule on Postpartum Pain in Multiparous Women: A Triple-Blind Randomized Clinical Trial

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ABSTRACT

Background & aim: Postpartum pain is a problem of women after delivery, which increase in multiparous women. Due to the side effects of chemical drugs to control postpartum pain and the individuals' tendency to use herbal medicine, the present study aimed to investigate the effect of evening primrose (Oenothera biennis) oil capsule on postpartum pain in multiparous women.

Methods: This triple-blind randomized clinical trial examined 90 multiparous women two hours after a normal vaginal delivery, who had a moderate to severe postpartum pain at maternity ward of Ommolbanin Hospital, Mashhad, Iran in 2021. The participants were randomly assigned to three groups including intervention, placebo, and control group. A capsule of evening primrose oil or placebo was given to the subjects every 8 hours for up to 4 doses. The control group received routine medication (acetaminophen). Pain severity was measured one hour before and after each intervention using the Visual Analogue Scale (VAS), and McGill Pain Questionnaire. Data analysis was carried out by Kruskal-Wallis, one-way analysis of variance (ANOVA), Chi-square and exact Chi-square tests using SPSS software (Ver. 16).

Results: The mean severity of postpartum pain after intervention in the group received evening primrose oil capsule had a significant decrease versus placebo and control groups ($P < 0.001$) and no side effects in the intervention group was observed.

Conclusion: Evening primrose oil was effective in reducing the severity of postpartum pain in multiparous. So it seems that it could be recommended as a safe medication for postpartum pain relief in multiparous women.

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Introduction

Women may experience a variety of pain and discomfort after delivery (1). The causes of pain in the first days after vaginal delivery include uterine contractions, perineal tears, and breast congestion. Uterine contraction is the most common causes of pain at the first days after vaginal delivery (2). Rapid and intermittent uterine contractions after delivery cause cramps in the uterus to constrict large arteries of the uterus and prevent postpartum hemorrhage. This uterine pain is called postpartum pain and its severity is similar to menstrual cramp pain to severe discomfort and sometimes much more severe than labor pain (2). Postpartum pain is mostly felt in the lower back and lower abdomen (3). Uterine contractions release

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chemical pain mediators such as Bradykinin, Leukotrienes, Serotonin, Lactic acid, and Prostaglandins (1). The release of prostaglandins seems to be the main cause of postpartum pain (4). The prevalence of postpartum vaginal pain is about 70% that is not considered compared to the pain of the first and second stages of labor (5). Postpartum pain usually persists for two to three days after delivery and its prevalence is 77% in multiparous women (6). Postpartum pain increases with multiple deliveries and usually lasts 3 to 4 days and rarely up to one week after delivery. In primiparous women, the uterus contracts well after delivery, but in multiparous women, after multiple deliveries, the number and duration of postpartum uterine contractions increase due to reduced uterine muscle strength following multiple pregnancies and increased central nerve sensitivity (2). Heldcraft et al. (2003) reported that 50% of primiparous women and 86% of multiparous women experience postpartum pain, and 50% of cases is associated with low back pain (4). Brito et al. (2021) found that 54.6% of women reported postpartum pain during the first 24 hours after delivery (7). Various factors affect postpartum pain, including multiparousity, breastfeeding, over-expansion of the uterus, length of labor, instrumental delivery, intra- and postpartum medication to expedite labor, or to prevent postpartum hemorrhage, painless delivery, maternal physical and mental disorders, a history of painful menstruation, history of low back pain during pregnancy, maternal weight, and cultural factors (8, 9). If in the case of non-treatment of postpartum pain, the risk of postpartum depression increases, leading to disruption of communication between mother and infant. Furthermore, postpartum pain can cause the mother's inability to breastfeed, improper body position during breastfeeding, sleep disorders, confusion, anxiety, anorexia, inability to perform daily tasks, and risk of deep vein thrombosis in cases of severe pain and immobility (10).

Therefore, controlling postpartum pain is very important and has important effects on a woman's return to normal life and caring for the infant (2). Pharmacological and non-pharmacological treatments are important for postpartum pain management (11).

Pharmacological methods for relieving postpartum pain include simple analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), and narcotic analgesics (12). Nonsteroidal anti-inflammatory drugs (NSAIDs) have side effects such as nausea and vomiting, diarrhea, abdominal cramps, gastrointestinal bleeding, drowsiness, dizziness, vertigo, seizures, and deep coma in some cases (2, 13). The mothers' tendency to use alternative medicine has increased due to the drug transfer to breast milk (14, 15). In addition to therapeutic and analgesic effects, herbal medicines have fewer side effects and are cost-effective (16).

Evening primrose with the scientific name, Oenothera biennis, is a plant that has been used in this field (17, 18). The oil called Huiledonager is obtained from seeds of this plant and consists of various acids such as Palmitic acids (5.6%), Stearic acid (1.5%), Oleic acid (11%), Linoleic acid (omega 3) (72%), Alpha Linoleic acid and Gamma Linoleic Acid (omega 6) (7% to 14%), and Arachidonic acid (19). Omega-3 and omega-6 acids reduce the production of some arachidonate metabolites and increase the level of anti-inflammatory eicosanoids (18). This plant contains some antimicrobial, anti-inflammatory, analgesic, and antioxidant compounds (20). Evening primrose contains sterols that modulate the effects of cytokines, nitric acid (NO), Interleukin B1, Interferon gamma (IFNγ), and Thromboxane B2, and suppresses expression of COX-2 gene; hence, it has more anti-inflammatory activity than other analgesic herbs (18). Masoumi et al. (2017) in their study on the effects of evening primrose on premenstrual syndrome, used 1000 mg capsule of evening primrose oil 3 times a day, 14 days before menstruation for two months. The results of their study showed that evening primrose was effective on relieving the symptoms of premenstrual syndrome (21). Also in the study by Jafarnejad et al. (2016) on the effects of evening primrose for female mastalgia, it was found that the use of evening primrose oil capsule (1000 mg) twice daily for two months was effective in reducing the severity of mastalgia (22). According to a systematic review by Faghani et al. (2019), the positive effects of

evening primrose can improve premenstrual syndrome, reduce the hormonal effects of polycystic ovary syndrome, decrease postpartum pain and could be used instead of HRT in menopausal symptoms and mastalgia (17). Evening primrose oil has the most biologically active form of gamma linoleic acid and has more gamma linoleic acid (more than 70%) than other plants. Therefore, this plant is known as an important therapeutic agent with anti-inflammatory and analgesic effects (18). Evening primrose causes no serious side effects during pregnancy and lactation (23, 24).

Given the numerous side effects of chemical drugs and the acceptance of herbal medicines, and high prevalence of postpartum pain and its various side effects on mothers and infants, and the compounds available in evening primrose, it is likely to be helpful in postpartum pain. Therefore, this study was performed to investigate the effect of evening primrose oil capsules on postpartum pain in multiparous women.

Materials and Methods

The present triple-blind clinical trial examined 90 multiparous women who visited the maternity ward of Ommolbanin Hospital in Mashhad in 2021. The subjects were selected using the convenience sampling method and were divided into three groups of intervention, placebo, and control, based on random allocation.

Inclusion criteria of the study were as follows: signing the written consent to participate in the study, maternal age of 18-35 years, singleton pregnancy with a gestational age of 37-42 weeks, live and seemingly healthy infant with 2500-4000 grams weight, being in the second to fifth vaginal delivery, having no substance abuse, or spinal and epidural anesthesia during labor, no cesarean section or previous uterine surgery, being in the second and third stage of normal delivery, having no medical diseases (cardiovascular diseases, respiratory diseases, overt diabetes, renal disease, chronic hypertension, epilepsy, thyroid diseases, blood diseases, mental health problems, and maternal depression), having no grade 3 and 4 of perineal and vaginal tears, no allergy to medicinal plants (itching, urticaria or skin lesions, shortness of breath, runny nose, nausea, and vomiting), no allergy to acetaminophen (skin rash, hives, itching, nausea and vomiting, abdominal cramps, anorexia, sudden decrease in urine volume), the onset of lactation up to the first two hours after delivery and continuation of breastfeeding, the severity of postpartum pain of 4 and more (based on the Visual Analogue Scale). Exclusion criteria included consumption of other herbal or chemical drugs to relieve pain, allergy to evening primrose (gastrointestinal problems, including nausea, increased bowel movements), mother's suffering from serious complications after delivery (increased postpartum hemorrhage, temperature more than 38 °C, blood pressure more than 140/90 mm Hg), breastfeeding discontinuation for maternal or neonatal reasons and the woman's willingness to withdraw from the study.

Considering that no similar study was found on the effect of evening primrose on postpartum pain, the sample size was estimated based on the study of Ramezani Motlagh et al. (2017) who studied the effect of Purslane seed capsule in prevention of postpartum pain in multiparous mothers. The results showed that Purslane seed is similar to evening primrose in terms of compounds (linoleic acid and gamma linoleic acid). Using the formula to compare the mean with the coefficient, sample size was estimated to be 12 per group with a 95% confidence interval, and 80% test power. A total of 90 individuals were studied in the three groups for a higher certainty and prediction of possible exclusion of 30 individuals per group.

To collect data, researcher-made demographic and obstetric questionnaire, the form of delivery and post-delivery data, checklist for recording medication use, its possible side effects and satisfaction of medication, Visual Analogue Scale (VAS) and short-form McGill Pain Questionnaire (SF-MPQ) were used after confirming their validity and reliability. Visual Analogue Scale (VAS) is a standard tool for assessing the pain severity in the form of a 10-cm ruler in which a score of

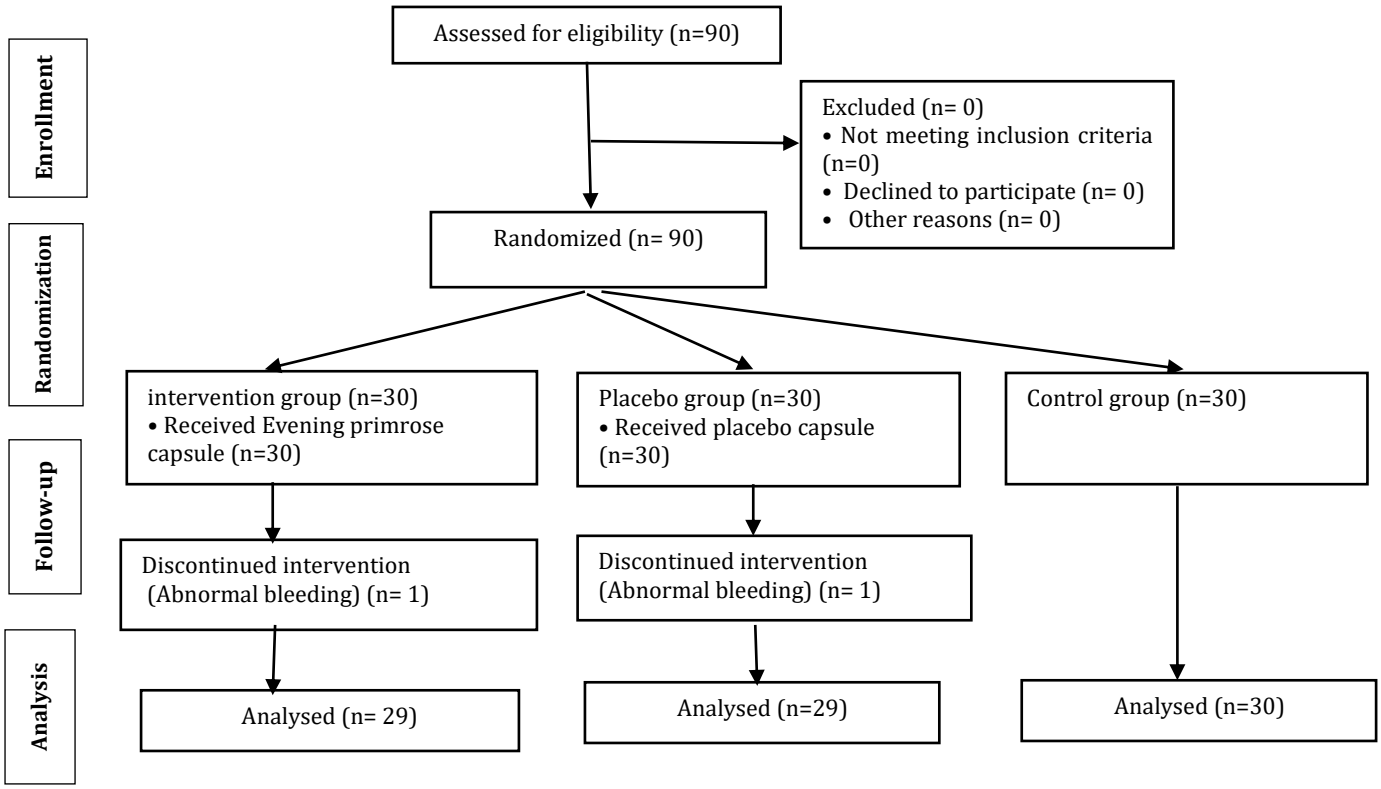
zero indicates the absence of pain, and a score of 10 is the maximum pain. A score of 1-3 indicates mild pain, 4-7 is moderate pain, and 8-10 is severe pain. The validity and reliability of this tool have been confirmed in several studies (25, 26, 27, 28). Its reliability was confirmed by Phan et al. using the test-retest with a correlation coefficient of 0.83 (29).

McGill Pain Questionnaire is a pain measurement tool in which the reliability was calculated by Dworkin et al. using Cronbach's alpha, and the alpha coefficients of all dimensions were from 0.83 to 0.87 (28).

To collect data, the researcher received written permission to start sampling after approval of the ethics committee under code of IR.MUMS.NURSE.REC 1399.083, and registration in the Iranian Registry of Clinical Trials (IRCT) under code of IRCT20210217050394N1. Random allocation was carried out using Randomization software.

The researcher identified the subjects in the maternity ward in the morning and evening at the beginning of the active labor, and then explained the research purpose and method. The subjects' selection questionnaire form was completed after obtaining written and informed consent. Maternity information was recorded by referring to the mother's file and by observation. After delivery, if breastfeeding started up to the first two hours after delivery and breastfeeding continued, pain score was measured using a visual analogue scale during two hours after delivery before taking the first dose of the drug. Those with pain severity of 4 or higher were included in the study, and the McGill Pain Questionnaire was completed and recorded for them. The drugs were coded in exactly the same package with the same labels by the pharmacist consultant.

Figure 1. CONSORT Flow Diagram



The subjects, the researcher and the statistical consultant were unaware of the type of intervention and placebo groups, and the researcher was informed of the naming of the codes after the end of the data analysis stage and showing the results to the professor of the specialized drug consultant. In this study, the intervention and placebo groups were triple-blind, but due to the nature of the control group, blinding was not possible in this group. In the intervention and placebo groups, one capsule (1000 mg evening primrose oil capsule ready to market and made by Barich Essential Oil Company or a placebo capsule containing 1000 mg paraffin) was given every 8 hours for up to 4 doses at least two hours after delivery, and the pain was measured again one hour before and after taking the drug. A 500-mg acetaminophen tablet was given one hour after each intervention if the pain persisted and the mother requested analgesia. The 1000-mg evening primrose oil capsules were used in the present study. The drug was in the form of a clear soft gelatin capsule containing 70-140 mg of gamma linoleic acid. The placebo capsules containing paraffin, which were exactly in the same size, color, and shape as the evening primrose capsule, were placed in the same packaging with the same label. The control group received routine care (500 mg acetaminophen) and the pain score was measured using a visual analogue scale during the two hours after delivery, and then every 8 hours for one hour before and after the intervention. At the end of the study, the McGill Pain Questionnaire was completed by three groups. Side effects were assessed and recorded based on a checklist after each intervention, and no side effects were observed. In the intervention and placebo groups, a person was excluded from the study (due to abnormal bleeding). Data analysis was performed using SPSS 16 software. Chi-square test, the exact Chi-square test, one-way analysis of variance, and Kruskal-Wallis test were used to evaluate the homogeneity of the three groups in terms of intervening variables and also examine other research variables at a significance level of 5%. The following diagram shows the method of collecting and conducting research (Figure 1).

Results

Based on the test results, participants in the three groups were not significantly different in terms of demographic characteristics, including age, education level, job, family income level, and some midwifery characteristics such as gestational age, number of pregnancies, number of abortions, frequency of breastfeeding, and duration of breastfeeding (P>0.05) (Table 1).

But according to Kruskal-Wallis test, the mean number of consumed analgesics during 24 hours was lower in the intervention group than the other groups; the three groups were significantly different in this regard (p <0.001) (Table 1).

Table 2 presents mean scores of postpartum pain based on visual analogue scale before the intervention (first dose), and one hour before and after the second to fourth doses of evening primrose oil capsule and placebo in the three groups.

Based on the results, the severity of postpartum pain was not significantly different in the three groups before starting the first dose (p>0.05). The severity of postpartum pain one hour after the first dose, and the second, third, and fourth doses indicated that the postpartum pain scores were significantly lower in the evening primrose oil capsule group (p<0.001).

The results of mean postpartum pain severity based on McGill pain severity score before the intervention (first dose) and after the intervention (after the fourth dose) indicated that the severity of postpartum pain was significantly lower in the evening primrose oil capsule group after the intervention (p<0.001) (Table 3).

Also, the results of intergroup comparison of pain intensity before and after the intervention based on McGill pain intensity score in the three groups based on Wilcoxon test were significant in all groups (P <0.001) (Table 3).

Table 1. Frequency distribution of demographic and obstetric characteristics of subjects in three groups

Variable	Evening primrose capsule	Placebo	Control	Significance level
age (year)	30.2±5.7	29.5±5.6	28.7±5/5	*P=0.59
Education level	**Number (%)**	**Number (%)**	**Number (%)**	
Primary school	5(16.7)	6(20.0)	10(33.3)	
High school	14(46.7)	14(46.7)	9(30.0)	**P=0.49
High school diploma and higher	11(36.7)	10(33.3)	11(36.7)	
Job				
Housewife	28(93.3)	27(90.0)	29(96.7)	***P=0.86
Employee	2(6.7)	3(10.0)	1(3.3)	
Family income level	**Number (%)**	**Number (%)**	**Number (%)**	
Sufficient	28(93.3)	28(93.3)	26(86.7)	
Less than sufficient	2(6.7)	2(6.7)	4(13.3)	***P=0.72
Gestational age (Week)	39.5±0.51	39.1±0.85	39.3±7.7	****P=0.52
Number of pregnancies	2.83±0.83	2.73±0.86	2.96±0.99	****P=0.65
History of abortion				
Yes	2(6.7)	7(23.3)	7(23.3)	**P=0.15
No	28(93.3)	23(76.7)	23(76.7)	
Pregnancy care				
Yes	29(96.7)	27(90.0)	27(93.1)	***P=0.86
No	1(3.3)	3(10.0)	2(6.9)	
Pregnancy status				
Unwanted	19(63.3)	18(60.0)	13(43.3)	
Wanted	5(16.7)	6(20.0)	11(36.7)	**P=0.39
Unplanned	6(20.0)	6(20.0)	6(20.0)	
Frequency of breastfeeding	1.33±0.47	1.46±0.50	1.46±0.50	****P=0.48
Breastfeeding duration (minutes)	24.16±5.88	24.66±4.72	26.0±7.35	****P=0.55
Duration of the last breastfeeding until Taking the drug (minutes)	12.83±5.82	13.10±4.51	13.51±4.76	****P=0.73
number of consumed analgesic	0.25±0.52	2.9±1.33	2.7±0.94	****P<0.001

*One-way analysis of variance, **Chi-square test, ***Exact Chi-square test, ****Kruskal-Wallis test

Table 2. Mean scores of post-pains before and after each intervention in three groups based on visual pain criteria

Variable	Evening primrose capsule	Placebo	Control	Significance level
	Mean ± standard deviation	**Mean ± standard deviation**	**Mean ± standard deviation**	
Severity of Postpartum pain before the first dose	5.40 ± 1.32	5.16 ± 1.11	4.73 ± 0.44	P=0.050
Severity of Postpartum pain after the first dose	0.96 ± 1.54	4.10 ± 1.56	5.43 ± 0.67	P<0.001 P<0.001
Difference	- 4.43 ± 1.13	- 1.03 ± 1.23	0.70 ± 0.65	
Wilcoxon test result	P<0.001	P=0.001	P<0.001	
Severity of Postpartum pain before the second dose	4.93 ± 1.77	6.89 ± 1.17	6.86 ± 0.93	P<0.001
Severity of Postpartum pain after the second dose	1.13 ± 1.02	5.79 ± 1.49	7.53 ± 1.04	P<0.001 P<0.001
Difference	- 3.79 ± 1.78	- 1.10 ± 1.14	0.66 ± 0.80	
Wilcoxon test result	P<0.001	P<0.001	P<0.001	
Severity of Postpartum pain	4.31 ± 2.01	7.20 ± 1.04	7.33 ± 0.80	P<0.001

Variable	Evening primrose capsule	Placebo	Control	Significance level
	Mean ± standard deviation	Mean ± standard deviation	Mean ± standard deviation	
before the third dose				P<0.001
Severity of Postpartum pain after the third dose	0.55 ± 1.24	6.31 ± 1.41	7.66 ± 0.80	P<0/001
Difference	- 3.75 ± 2.02	- 0.89 ± 0.85	0.33 ± 0.80	
Wilcoxon test result	P<0.001	P<0.001	P=0.033	
Severity of Postpartum pain before the fourth dose	2.79 ± 2.22	7.00 ± 1.13	6.96 ± 0.88	P<0.001
Severity of Postpartum pain after the fourth dose	0.27 ± 0.75	5.93 ± 1.51	7.36 ± 0.85	P<0.001
Difference				P<0.001
Wilcoxon test result	- 2.51 ± 2.01 P<0001	- 1.06 ± 1.53 P<0.001	0.40 ± 0.67 P=0.004	

Kruskal-Wallis test (data are described by standard deviation ± mean)

Table 3. Mean and standard deviation of McGill post-pain intensity score before and after intervention of subjects by group

Variable	Evening primrose capsule	Placebo	Control	Significance level
	Mean ± standard deviation	Mean ± standard deviation	Mean ± standard deviation	
Intensity score of postpartum pain before intervention	0.99 ± 0.25	0.99 ± 0.40	0.96 ± 0.24	**P=0.89
Intensity score of postpartum pain after intervention	0.12 ± 0.81[a]	1.36 ± 0.44[b]	1.43 ± 0.27[b]	*P<0.001
Difference between postpartum pain, before and after intervention	-0.87 ± 0.27[a]	0.37 ± 0.62[b]	0.47 ± 0.17[b]	**P<0.001
Wilcoxon test result	P<0.001	P<0.001	P<0.001	

** One-way analysis of variance test * Kruskal-Wallis. (Non-identical letters are significantly different)

Discussion

Postpartum uterine contractions are a very common problem that can trigger a neuro-hormonal stress response and has far-reaching physiological effects. Uterine pain and contractions stimulate pain receptor chemical mediators which are the source of postpartum pain (1). In this study, consumption of evening primrose oil capsules reduced postpartum pain. Literature research found no internal or external study similar to the present study, so we referred to the studies that had been performed on the effect of similar medicinal plants in terms of composition and mechanism of action on postpartum pain. The results of all these studies were consistent with the present study.

In the present study, the mean severity of postpartum pain after the intervention indicated that the severity of postpartum pain was less in the evening primrose capsule group than the control and placebo groups. Furthermore, the mean scores of postpartum pain were lower one hour after taking the capsules than one hour before taking in the evening primrose oil capsule group.

Ramezani Motlagh et al. (2019) studied the effect of Poppy seed capsules on postpartum pain and found that the mean severity of postpartum pain was significantly lower in the

Poppy seed capsule group than placebo (p<0.001) (30). Poppy (Portulaca) is effective in relieving postpartum pain after delivery due to the presence of gamma linoleic acid, linoleic acid, and phenolic compounds. The results of their study were consistent with the results of the present study.

Ozgoli et al. (2017) studied the effects of Anise (Pimpinella anisum) capsules on postpartum pain and found that anise was significantly effective in reducing postpartum pain (31). A reason for the effectiveness of anise on postpartum pain is the presence of compounds such as phytoestrogens, phenol, and sterol that relieve pain and inflammation by inhibiting cyclooxygenase and Lipoxygenase (32). The results of their study was consistent with the findings of the present study. In the study conducted by Ozgoli, anise was compared with mefenamic acid, while in the present study, the effects of evening primrose on reducing postpartum postpartum pain were examined; also in the above study, the intervention was performed on all women with normal delivery, while in the present study, the subjects were multiparous women, which is inconsistent with the present study.

Shayan et al. (2019) and Masoumi et al. (2017) also studied the effect of evening primrose on symptoms of premenstrual syndrome and found that compounds such as gamma linoleic acid and linoleic acid caused by evening primrose relieved pain and inflammation (21, 33).

In the study by Chananeh et al. (2018) on the effect of Nigella Sativa on postpartum pain, the results indicated a decrease in the severity of postpartum pain in the Nigella Sativa group (p<0.001) (34). Analgesic and anti-inflammatory effects of Nigella Sativa through inhibition of uterine smooth muscle contractions were mentioned as the reasons for the effectiveness of Nigella Sativa on postpartum pain. Their results were consistent with the findings of the present study.

Mehravar et al. (2021) also reported that germinated wheat was effective in relieving postpartum pain due to its anti-inflammatory and analgesic effects (35). Due to its anti-inflammatory properties, germinated wheat could inhibit prostaglandins and relieve pain (36). The results of their study were consistent with the present study. In their study, the intervention was performed on all women with normal delivery, while the present study was performed only on multiparous women.

Women did not report any side effects for the capsule in the present study.

One of the strengths of the present study is that the study was performed with placebo and control group and also this is the first study in Iran and the world that has investigated the effect of evening primrose oil on postpartum pain. The limitations of the present study were that to avoid asymmetry in taking the drug in the middle of the night, the researcher tried to ensure that the majority of the samples were delivered in the early morning hours so as to have the least interference with the mother's sleep, and the intervention is short-term (24 hours).

According to extensive research, since there is no study on the effect of evening primrose on postpartum pain, the results of the present study may pave the way for further research in this field.

Conclusion

Evening primrose oil was effective in relieving postpartum pain. Therefore, its use is recommended as an herbal medicine without side effects in relieving postpartum pain.

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Conflicts of interest

Authors declared no conflicts of interest.

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