Journal of
Babol University of Medical Sciences
JBUMS
e-ISSN: 2251-7170 p-ISSN: 1561-4107

Comparing the Effect of "Ginger-Lavender Capsule" and "Mefenamic Acid" on Postpartum Pain

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Article Type

Research Paper

Received:
Jan 12nd 2023
Revised:
Mar 13rd 2023
Accepted:
May 10th 2023

ABSTRACT

Background and Objective: Although chemical drugs are effective for postpartum pain, herbal medicines with relative safety and fewer side effects are more suitable. The aim of the present study was to compare the impact of "Ginger-Lavender" and "Mefenamic acid" capsules on postpartum pain.

Methods: This triple-blind clinical trial study enrolled 94 multiparous women complaining of moderate to severe postpartum pain in Valiasr Hospital, Fasa, in 2021. They randomly divided into 2 groups (n=47): the "Ginger-Lavender" 300 mg capsules (A) and the "Mefenamic acid" 250 mg capsules (B). Measuring the pain score started 2 hours after delivery and continued every 6 hours, before and 1 hour after receiving the related drugs, until 24 hours using VAS.

Findings: The demographic information of the two groups, including mothers' age and BMI, weight of newborns, breastfeeding, receiving oxytocin and the number of pregnancies and deliveries, were not significantly different. Before the intervention, there was no significant difference in pain severity between the two groups (A=5.02±1.24, B=4.72±0.97). Consuming "Ginger-Lavender" and "Mefenamic acid" capsules at different hours decreased pain severity significantly ($p<0.05$). No significant differences were found between the "Ginger-Lavender" and "Mefenamic acid" groups for the mean postpartum pain severity at different hours after the first (A=2.38±0.922, B=2.553±0.928), second (A=2.0217±1.242, B=2.021±1.188), third (A=1.55±0.97, B=1.61±1.07), and fourth (A=1.42±1.01, B=1.38±0.99) interventions.

Conclusion: Since "Ginger-Lavender" capsules reduced postpartum pain, it is recommended to use them instead of standard drug, "Mefenamic acid" capsules, as an effective and safe herbal medicine.

Keywords: *Pain, Postpartum Care, Ginger, Lavender, Mefenamic Acid*.

Cite this article: Salehi F, Jannesari Sh, Nasiri M, Sahranavard Sh. Comparing the Effect of "Ginger-Lavender Capsule" and "Mefenamic Acid" on Postpartum Pain. *Journal of Babol University of Medical Sciences*. 2024; 26: e1.

[DOI: 10.22088/jbums.26.1.1]

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Introduction

Parturition is defined as the birth of a newborn (1). One of the major causes of maternal mortality worldwide is postpartum hemorrhage (2). The most important factor that inhibits bleeding is uterine contraction (1). Postpartum pain is caused by rapid and intermittent contractions of the uterus after the placenta and fetal membranes are removed (3). In primiparous women, the uterus remains contracted after childbirth, but in multiparous women, these contractions occur at intervals. The intensity of these pains usually decreases by the third day (4). Postpartum pain relief affects the mother's comfort and improves mother-child interactions (5), and finally, better care of the child (6). The main cause of pain is the production of prostaglandins (7). Demographic, personality, cognitive, social, and economic factors, as well as the number and type of delivery can affect postpartum pain (8).

Although chemical drugs positively affect postpartum pain recovery, they bring some side effects (9). Mefenamic acid and Ibuprofen are common painkillers used for postpartum pain relief (10). Mefenamic acid is a non-steroidal anti-inflammatory drug. This medicine is used for mild to moderate pain (10, 11). More information still needs to be provided about the safety of non-steroidal anti-inflammatory drugs in breastfeeding (10). Chemical drugs have some side effects and their costs are increasing, so it is necessary to use less dangerous drugs (12). One of the ways to reduce postpartum pain of vaginal delivery is the use of medicinal plants (9). Herbal medicines are accepted in developed and developing countries due to their natural origin, relative safety, better compatibility with the human body, and fewer side effects (13).

Ginger (*Zingiber officinale*) belongs to Zingiberaceae family (14). This plant contains substances such as gingerol, gingerdiol, gingerdione, beta-carotene, capsaicin, caffeic acid, curcumin and shogaol (15, 16). Gingerol and gingerdione are potent inhibitors of prostaglandins. Their analgesic, anti-inflammatory, and antibacterial properties have been observed in animals; inhibition of cyclooxygenase and lipoxygenase cause the reduction of leukotriene and prostaglandin, and finally, lead to anti-inflammatory and analgesic effects (17, 18). The anti-inflammatory role of ginger is determined by stimulating prostaglandin synthesis and increasing the activity of uterine smooth muscles (19).

Lavender (*Lavandula angustifolia*) is also one of the old medicinal plants (20). The most critical components of the lavender extract are linalyl acetZate, borneol, nerol, linalool, and cineol. It also contains butyric acid, propionic acid, valeric acid, free linalool, gerambol, tannin, and flavonoids (21). The analgesic effects of lavender extract (linalool) have been investigated and confirmed in various cases (22). Kazeminia et al. confirmed the effectiveness of lavender scent on childbirth (20). Buckle showed that lavender reduces labor pain (23). Linalool and linalyl in lavender can stimulate the parasympathetic system (24). Therefore, lavender has sedative, analgesic, and antispasmodic effects (25). Linalyl acetate and linalool have narcotic and sedative properties, respectively (24). Other features of linalool are analgesic properties, relieving smooth muscle spasms, increasing local blood flow, and decreasing muscle tone (26).

Generally, ginger has analgesic and anti-inflammatory properties; lavender also has sedative, analgesic and pain-relieving properties. Besides, the effect of the oral lavender extract on postpartum pain has not been studied yet. Moreover, Mefenamic acid is a standard and effective medicine for postpartum pain, but it shows significant side effects, such as affecting the liver, kidney, and digestive system. Also, reducing postpartum pain is very important and necessary for better care and more effective interaction between mother and child after delivery. Hence, the present study used a combination of ginger and lavender in the form of "Ginger-Lavender" oral capsules to investigate the effect on postpartum pain and also compare it with the standard treatment, i.e. "Mefenamic acid" capsules, in women referred to Valiasr Hospital, Fasa, in 2021.

[DOI: 10.22088/jbums.26.1.1]

Methods

This study is a three-blind randomized controlled clinical trial. After being approved by the ethics committee of Shahid Beheshti University of Medical Sciences with the code IR.SBMU.PHARMACY.REC.1400.167 and registered in the Iranian clinical trial system with the number IRCT20200525047565N3, it was performed on 94 multiparous women in the maternity and postpartum department of Valiasr Hospital, Fasa, in 2021. First, interviews were done by filling out the questionnaires by 120 mothers hospitalized in the postpartum ward to select the cases; sampling was done in a non-random and purposive method. 103 mothers, who met the study inclusion criteria and complained of moderate to severe postpartum pain, were randomly divided into 2 groups, including group A (n= 51) and group B (n=52). Random allocation of samples was done using Excel software and the random numbers (RAND) function.

According to the obtained list, participants were randomly assigned to two groups: "Ginger-Lavender" capsule and "Mefenamic acid" capsule. Sampling was done based on the study of Pourmaleky et al. with the type I error $\alpha = 0.05 \rightarrow Z_{\alpha/2} = 1.96$, the probability of the type II error $\beta = 0.20 \rightarrow Z_{\beta} = 0.85$ and power $\beta\text{-}1 = 0.80$, and the observed effect was $(\mu_1\text{-}\mu_2)/\sigma = 0.60$ (27). The number of samples in each group was calculated to be 43 people. Considering the probability of 10% sample drop, 47 people were determined in each group, and 94 people participated in the study. Data collection tools in this research included a personal and demographic information questionnaire, midwife profiling questionnaire, checklist of observations related to birth information registration, scale, visual analog scale (VAS) and side effects questionnaire. There were individual midwifery information forms, observation checklists, and drug side effect forms that did not need validity and reliability. The numerical pain measurement scale is a reliable tool whose validity and reliability have been proven in various studies. Farrer et al. mentioned the reliability of this tool as 0.83, which was done by the test-retest method ($p<0.001$) (28). A 2 kg calibration weight was first considered to ensure the scale's reliability. According to the manufacturer's manual, it was calibrated with the same weight after every 10 uses.

The participants were selected voluntarily and purposefully, according to the conditions required and effective on the studied variables, and based on the inclusion criteria. After explaining the research objectives to the participants, the researcher assured them about the confidentiality of the information and that the researcher will be available during the study. To enter the study, written consent was obtained from the participants. The inclusion criteria were age of 15-44 years, having minimum reading and writing literacy, vaginal delivery, pregnancy age between 37-42 weeks, complaining of moderate to severe pain, no instrumental delivery, no 3rd and 4th degree tears, no history of chronic and systemic diseases such as diabetes or hypertension, no record of cesarean section and intra-abdominal surgery, no use of epidural and spinal anesthesia during labor, no drug addiction, no history of allergy to herbal medicines, the successful start of breastfeeding, a healthy and singleton child, the absence of complications of childbirth such as bleeding, fever, and high blood pressure, the second or subsequent childbirth. Exclusion criteria were unwillingness to continue participating in the study, lack of relief with the studied painkillers and the need for further evaluation, the occurrence of drug sensitivity during use, the use of chemical and herbal painkillers other than the studied painkillers, and the occurrence of complications after childbirth, such as bleeding, fever and increased blood pressure during the intervention.

In this research, ginger was placed in capsules as powder. High-quality ginger with characteristics including firmness, very pale brown color with few and short roots, without wrinkles on its surface and free of any threads or roots inside, purchased from the market, was peeled and cut into very thin slices. The ginger slices were arranged on a flat surface and exposed to sunlight for 3-4 days. Then they were powdered by the machine. Each capsule contained 250 mg of ginger powder and 50 mg of lavender extract; the extract

[DOI: 10.22088/jbums.26.1.1]

was prepared from the clean lavender flowers which were recognized, powdered and extracted. The capsules were identical in shape, appearance, smell, and color to the Mefenamic acid capsules manufactured by Amin Pharmaceutical Company. "Ginger-Lavender" capsules were prepared with the cooperation of pharmaceutical experts in Shahid Beheshti School of Traditional Medicine laboratory under all sanitary standards. "Ginger-Lavender" and "Mefenamic Acid" capsules were placed in similar cans, but the researcher, statistical consultant, and participants did not know the type of drug. In this way, blinding was achieved.

Two hours after delivery, capsules were taken with an interval of 6 hours until 24 hours (i.e. 4 capsules). The pain score was measured with a visual assessment scale (VAS) before and one hour after the first intervention, and once every 6 hours (maximum 4 times) before and one hour after each intervention, until 24 hours after delivery. Mothers were asked to mark their pain intensity on a scale from 0 to 10. The average pain intensity during 24 hours was calculated and compared with the baseline value. Those who had a pain score of more than 4 while meeting other inclusion criteria were included in the study.

During the study, 5 people were excluded from the intervention group; 1 person had stomach irritation, 3 people had taken "Mefenamic acid" capsules at the same time, and 1 person had taken only one capsule out of the 4 prescribed capsules. Also, in the control group, 2 people were excluded from the study due to not observing the prescribed times correctly, 1 person due to postpartum bleeding, and 1 person due to unwillingness to cooperate (Figure 1).

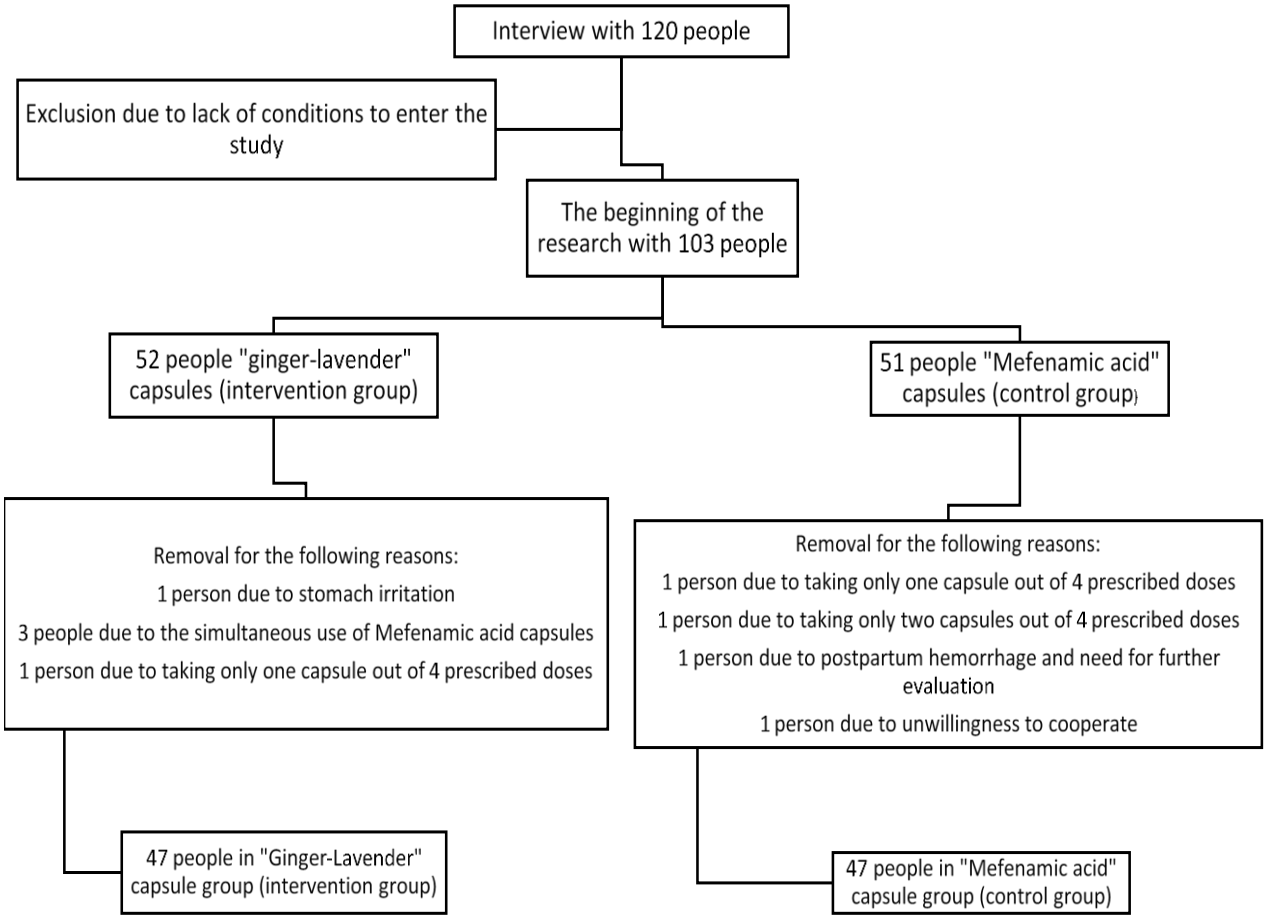


Figure 1. Flowchart of the study process

[DOI: 10.22088/jbums.26.1.1]

During the study, the possible side effects form of drugs was completed by the researcher to check side effects such as increased bleeding, nausea, vomiting, dizziness, and other cases. To control the bleeding, when the mothers received their drug dose, their pads were controlled every 6 hours, and the amount of bleeding after delivery was evaluated.

The data was analyzed using SPSS version 26. Descriptive statistics included tables, graphs, central and dispersion indices, and absolute and relative frequency distribution. Independent t-test, paired t-test, chi-square, and Mann-Whitney tests were used to compare the results. The significance level of the trial was considered 0.05.

Results

Demographic information included mothers' age, body mass index and education, parents' occupation, family income, sex and weight of newborns, breastfeeding, receiving or not receiving oxytocin, number of pregnancies and deliveries, number of abortions, episiotomy, 1st to 4th degree tears and participation or non-participation in physiological childbirth classes. The results of the two groups did not show any significant difference**.**

There was no significant difference in the mean intensity of pain before the intervention in the two groups. The mean pain intensity for the ginger-lavender group was 5.02±1.24 and for the mefenamic acid group was 4.72±0.97. The intensity of pain before and after each time of taking the drug compared to the previous dose showed a decrease for both the ginger-lavender capsule and the mefenamic acid capsule, and the difference was statistically significant ($p<0.05$) (Table 1). The mean pain intensity after taking the first and fourth doses for the ginger-lavender group was 2.38±0.92 and 1.42±1.06, respectively, and for the mefenamic acid group was 4.72±0.97 and 3.00±1.31, respectively (Table 1).

Table 1. Comparison of the average intensity of postpartum pain before and after each intervention in the two groups of ginger-lavender capsules and mefenamic acid capsules

Group / Variable	Ginger-lavender capsules Mean±SD	Paired t-test	Mefenamic acid capsules Mean±SD	Paired t-test
Pain intensity before the first dose	5.02±1.24	T=19.19 df=46 p-value=0.00	4.72±0.97	T=14.77 df=46 p-value=0.00
Pain intensity one hour after the first dose	2.38±0.92		2.55±0.92	
Pain intensity before the second dose	4.40±1.61	T=17.50 df=46 p-value=0.00	4.10±1.25	T=16.71 df=46 p-value=0.00
Pain intensity one hour after the second dose	1.97±1.27		2.02±1.18	
Pain intensity before the third dose	3.55±1.50	T=15.94 df=46 p-value=0.00	3.46±1.28	T=14.36 df=46 p-value=0.00
Pain intensity one hour after the third dose	1.55±0.97		1.61±1.07	
Pain intensity before the fourth dose	3.34±1.64	T=13.79 df=46 p-value=0.00	3.00±1.31	T=14.44 df=46 p-value=0.00
Pain intensity one hour after the fourth dose	1.42±1.06		1.38±0.99	

[DOI: 10.22088/jbums.26.1.1]

No statistically significant difference was observed between the mean intensity of postpartum pain at different hours and after each intervention in the two groups of ginger-lavender capsule and mefenamic acid. Therefore, the effect of ginger-lavender capsule in reducing afterpain was similar to that of mefenamic acid capsule (Table 2). The mean intensity of postpartum pain in different hours, after the first (A=2.38±0.92, B=2.55±0.92), second (A=2.02±1.24, B=1.02±1.18), third (A=1.55±0.97, B=1.61±1.07) and fourth (A=1.42±1.01, B=1.38±0.99) intervention, showed no statistically significant difference in the two groups of ginger-lavender capsule and mefenamic acid (Table 2).

Table 2. Comparison of the mean intensity of postpartum pain after each intervention in the two study groups

Variable / Group	Ginger-lavender capsules Mean±SD	Mefenamic acid capsules Mean±SD	Paired t-test
Pain intensity one hour after the first dose	2.38±0.92	2.55±0.92	T=-0.89 df=92 p-value=0.37
Pain intensity before the second dose	4.40±1.61	4.10±1.25	T=1 df=92 p-value=0.32
Pain intensity one hour after the second dose	2.02±1.24	2.02±1.18	T=0.002 df=92 p-value=0.99
Pain intensity before the third dose	3.55±1.50	3.55±1.50	T=0.29 df=92 p-value=0.76
Pain intensity one hour after the third dose	1.55±0.97	1.61±1.07	T=0.30 df=92 p-value=0.76
Pain intensity before the fourth dose	3.34±1.64	3±1.31	T=1.10 df=92 p-value=0.27
Pain intensity one hour after the fourth dose	1.01±1.42	1.38±0.99	T=0.20 df=92 p-value=0.83

In the two groups, there was no significant difference in terms of pain relief time after the first, second, third and fourth dose (Figure 2). Bleeding severity variable was determined by visual estimation of the amount of blood spread on the pad, based on national guidelines, and the amount of postpartum bleeding in the two groups did not show a statistically significant difference. In general, the amount of bleeding in both groups decreased after taking the drug (Figure 3). The result of the Mann-Whitney test showed that there was no statistically significant difference between the ginger-lavender capsule and the mefenamic acid capsule in terms of nausea, stomach irritation and stomach irritation with diarrhea.

[DOI: 10.22088/jbums.26.1.1]

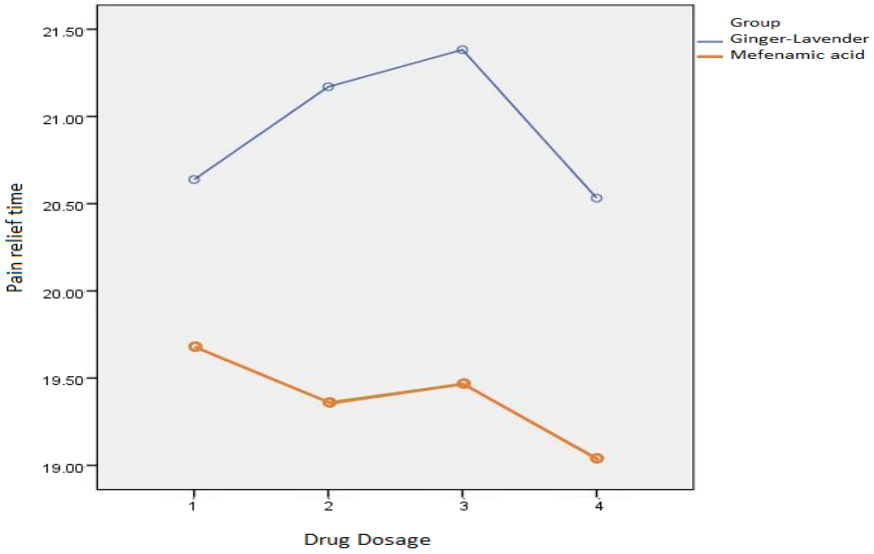


Figure. 2 the process of feeling pain relief after each intervention in two groups participating in the study

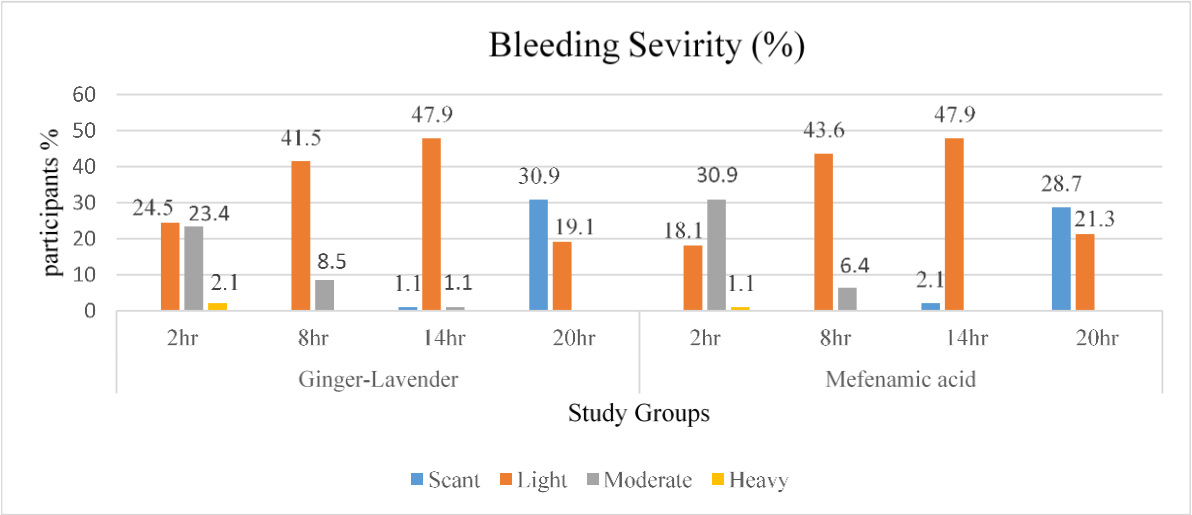


Figure 3. The amount of bleeding in the first 24 hours after delivery in the two studied groups

Discussion

Based on the results, the pain intensity, in general, decreased significantly in both intervention and control groups at different hours**.** The effect of the “Ginger-Lavender” capsules and “Mefenamic acid” capsules on reducing postpartum pain was similar, and no statistically significant difference was observed between these two groups.

The results of study conducted by Ozgoli et al. on the effect of anise plant on postpartum pain also showed that anise significantly reduces the pain score compared to Mefenamic acid (5). It is not in line with the results of the present study. Because, they have studied both primiparous and multiparous women. Although the intensity of after-pain in multiparous women is higher and pain relief is more complicated, effects of "ginger-lavender" capsules in reducing the intensity of postpartum pain was similar to "Mefenamic

[DOI: 10.22088/jbums.26.1.1]

acid" capsules. Ahmadi et al. investigated the effect of the “Ginger-Lavender” capsules compared to the “Mefenamic acid” capsules on student girls who had a history of primary dysmenorrhea. The reduction in pain intensity between the two groups was significant and the results showed that the effect of the “Ginger-Lavender” capsules on primary dysmenorrhea relief was greater than that of “Mefenamic acid” capsules (29). The results of the mentioned study are not consistent with the present research. The perception of pain is subjective and relative and people's mental and emotional conditions greatly affect the pain intensity, so the mental states and stresses imposed on the mother after childbirth cannot be ignored. Also, during breastfeeding, due to the release of oxytocin, the mechanism of causing pain and contractions is strengthened, and it causes the aggravation of after pain. On the other hand, considering the possibility of receiving oxytocin before and after childbirth, which can cause contractions and pain intensification, the difference in the results of the aforementioned study with the present study in terms of reducing pain intensity is not far from expected.

In general, no statistically significant difference was observed between the time of pain relief after receiving “Ginger-Lavender” capsules and “Mefenamic acid” capsules. Chenaneh et al. investigated postpartum pain relief time between the group receiving *Nigella sativa* and Mefenamic acid and the group receiving placebo and Mefenamic acid. The overall result showed that there was a significant difference in the relief time between these two groups (3). The mentioned results are not in line with the present study’s findings. Maybe because in the mentioned study, if the pain was not relieved after one hour of receiving the medicine, an additional Mefenamic acid was prescribed for the mothers who wished, but in the present study, mothers who requested to receive extra painkillers were excluded from the research, and in their study, Mefenamic acid capsules were prescribed for both intervention and control groups.

In the present study, the amount of bleeding decreased after taking “Ginger-Lavender” capsules and “Mefenamic acid” capsules in both groups and no statistically significant difference was observed. Chenaneh et al. investigated the rate of postpartum bleeding in two groups of *Nigella sativa* and Mefenamic acid after receiving 4 doses of the medicines. They showed that there is no statistically significant difference between the two groups and none of the mothers had abnormal bleeding after delivery (3). Therefore, the results of this study are consistent with the present study’s findings. Even though lavender, like *Nigella sativa*, has the property of relaxing smooth muscles, it did not increase postpartum bleeding. This result can be attributed to the appropriate dose of medicine in the "Ginger-Lavender" capsule.

In the present study, there was no statistically significant difference between the “Ginger-Lavender” capsules and the “Mefenamic acid” capsules in terms of nausea, stomach irritation, and stomach irritation with diarrhea. By investigating the effect of *Nigella sativa* and Mefenamic acid on postpartum pain, Chenane et al. showed that the side effects of these two medicines did not occur in any mothers. There was no statistical significant difference between the two groups (3). These results are consistent with the findings of the present study. The results of a study by Golian Tehrani et al. comparing the effect of fennel plant with mefenamic acid on postpartum pain showed that fennel is as effective as mefenamic acid on postpartum pain (30), which is in line with this study.

One of the strengths of this study is the use of lavender extract orally for the first time as a simple and accessible method to reduce the intensity of postpartum pain and the fact that this medicinal form, in combination with ginger powder, has not been used in previous studies. Another strong point of the study is the comparison of "Ginger-Lavender" capsules with the standard medicine for postpartum pain treatment, “Mefenamic acid”, because in most of the previous studies, “Mefenamic acid” capsules were also used in the intervention group for comparison. In this study, blinding is also one of the strengths. Factors such as the difference in pain threshold, the difference in the social, cultural, and economic level of people, as well as the environmental conditions at the time of sampling, such as light, noise, crowding, etc., can affect pain.

[DOI: 10.22088/jbums.26.1.1]

So, they can be considered as some of the limitations of this research. However, it was controlled to some extent by sampling randomly in different shifts.

The present study's findings showed that "Ginger-Lavender" capsules reduced postpartum pain without side effects. Therefore, according to the high prevalence of postpartum pain, this medicinal combination is healthy and safe for both mother and child compared to the chemical drugs, and the use of "Ginger-Lavender" herbal medicine is recommended to reduce postpartum pain. The present study showed no significant statistical difference in terms of the amount of pain reduction in the two studied groups. Therefore, this herbal capsule can be introduced as a suitable alternative to the "Mefenamic acid" capsule, which is a chemical medicine. Investigating the effect of the "Ginger-Lavender" capsule on reducing pain after abortion and curettage, as well as cesarean and gynecological surgeries, in future studies in recommended.

Acknowledgment

We would like to thank the Department of Obstetrics and Reproductive Health and Faculty of Traditional Medicine of Shahid Beheshti University of Medical Sciences and also, the officials and personnel of Valiasr Hospital, Fasa, for their sincere cooperation.

[DOI: 10.22088/jbums.26.1.1]

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[DOI: 10.22088/jbums.26.1.1]