Original Article

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The Comparison of Fennel and Mefenamic Acid Effects on Post-Partum after Pain

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ABSTRACT

BACKGROUND AND OBJECTIVE: Postpartum pain and painful uterine contractions normally occur after childbirth and are regarded as one of the most common problems after delivery. Postpartum pain is significantly intensified by increased parity. Therefore, mothers are forced to use chemical drugs to inhibit this pain. Considering the side-effects of chemical drugs and the growing tendency towards herbal medicines, we aimed to compare the effects of fennel extracts and mefenamic acid on postpartum pain.

METHODS: This single-blind, clinical trial was conducted on 86 mothers with postpartum pain after vaginal delivery at Baharloo Hospital in Tehran, Iran in 2014-2015. Subjects were randomly divided into two groups (43 cases per group), receiving fennelin (fennel extracts) and mefenamic acid capsules. Postpartum pain was measured two hours after childbirth, using Visual Analogue Scale (VAS). Volunteers with scores higher than four were included in the study. Pain intensity was measured by VAS before and one hour after each round of intervention. Subjects used the medicines four times a day (with 4-6 hour intervals). The collected data were statistically analyzed. IRCT: 2014020515338N2

FINDINGS: The mean score of pain before the intervention was 6.47±0.797 in the mefenamic acid group and 6.35±0.752 in the fennel group. In both groups, pain score significantly reduced one hour after using medicines in comparison with the pre-treatment period (1.90±0.56 and 1.70±0.74 in the mefenamic acid and fennel groups, respectively) ($p<0.05$). During the study, fennel was more effective than mefenamic acid in pain reduction. The same finding was reported after the study during the fourth round of intervention (88±0.70 and 1.19±0.76 in the fennel and mefenamic acid groups, respectively).

CONCLUSION: According to the results of this study, fennel, similar to mefenamic acid, could be suggested as an effective herbal medicine for pain reduction in mothers with complaints of postpartum pain.

KEY WORDS: Postpartum Pain, Fennel, Mefenamic Acid.

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Introduction

Due to physical and mental stress, postpartum period may be accompanied by various problems such as pain (1). In primiparous women, tonic contractions occur in the uterus after childbirth, while in multiparous women, severe uterine contractions happen with intervals and lead to postpartum pain, which is similar to the pain caused by labor contractions (although milder). This type of pain normally persists for 2-3 days after delivery (2,3). Postpartum pain with a prevalence rate of 77% is the most commonly reported pain, following childbirth in multiparous women. Unlike the pain during the first and second stages of delivery, little attention has been paid to postpartum pain (4,5).

In fact, uterine contractions in postpartum period are as painful as contractions during labor and dysmenorrhea (6). In order to explain postpartum pain, several theories have introduced the secretion of prostaglandins and arachidonic acid from the endometrium as the major contributing factor. Therefore, the aim of programmed treatments is to reduce the level of prostaglandins (7). Overall, postpartum pain has harmful consequences for the mother and infant and interferes with childcare, mothers' exclusive breastfeeding and their sleep pattern (8). One of the available methods for pain management is the use of non-steroidal anti-inflammatory drugs (NSAIDs) or opioids, with relatively significant side-effects. However, use of NSAIDs should be limited, considering their adverse side-effects (9).

The most important side-effects of prostaglandin inhibitors include digestive disorders such as gastrointestinal bleeding, indigestion, nausea and vomiting (10). Common analgesics for women, which are prescribed for labor pain management, include mefenamic acid and ibuprofen (11). However, mothers are often concerned about the possible side-effects of medicines and seek complementary treatments for the management of their symptoms. Generally, complementary medicine is widely accepted, especially among women (12). One of the factors affecting the intensity of postpartum pain is parity. The intensity of postpartum pain is significantly associated with the frequency and duration of breastfeeding (5). In fact, higher parity is correlated with more severe postpartum pain. In this regard, in a previous study, the majority of women, who used complementary medicines during their pregnancy, introduced fast recovery and effectiveness of medicines for their infants as the major reasons for selecting complementary treatments (13).

In developing countries, use of herbal medicines is not only popular among public, but also among healthcare providers (14). Fennel is among herbal medicines with similar effects as NSAIDs (7). This plant with the scientific name "Foeniculum vulgare" belongs to the Apiaceae family (15). Fennel contains protein, fat, insignificant amounts of sugar, mucilage, calcium, phosphorus, iron, potassium, vitamin A, vitamin C and 4-5% volatile oil (16). According to conducted research, fennel extracts can inhibit uterine smooth muscle contractions and reduce pain in rats (17). Nazarpour et al. showed that fennel extracts were effective in reducing menstrual pain, similar to mefenamic acid (18).

Moreover, Asgari Nematian et al. showed that methanolic extracts from fennel leaves have analgesic effects (19). Based on the available data about natural products, dietary amounts of fennel can be harmless during pregnancy (20). Therefore, this study was conducted to evaluate the effects of fennel and mefenamic acid on postpartum pain.

Methods

In this single-blind, clinical trial, 90 nulliparous and multiparous women with postpartum pain after natural delivery at Baharloo Hospital, affiliated to Tehran University of Medical Sciences, were recruited in 2014-2015.The inclusion criteria were as follows: 1) giving natural birth; 2) gestational age of 38-40 weeks; 3) singleton live birth; 4) fetal weight of 2500-4000 g; 5) no severe bleeding; 6) no sensitivity to prescribed medicines; 7) no drug addiction or dependence on psychotropic drugs; 8) absence of recognized diseases;

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9) minimum educational level (primary education at least); 10) spontaneous rupture of membranes; 11) undergoing no interventions such as abortion or assisted vaginal delivery (by using vacuum devices or forceps); 12) absence of grade III or IV tears; and 13) minor or severe postpartum pain.

On the other hand, the exclusion criteria were as follows: 1) severe bleeding; 2) long, difficult labor; 3) prior history of gastrointestinal laceration or bleeding; 4) cardiovascular diseases; and 5) unwillingness to continue the study.After obtaining written consent forms from the participants, they were randomly divided in two groups (A & B). For this purpose, 90 cards with the same size and shape were prepared. Letters A and B were each written on 45 cards. The cards were put inside an envelope and eligible mothers were asked to pick a card. Mothers were divided into A and B groups, based on the card they had selected.For selecting the medicines, mothers were asked to select among 45 pockets containing four fennel capsules or 45 pockets containing mefenamic acid capsules (Barij Essence Pharmaceutical Company, Iran) in similar envelopes, labeled as A and B. Mothers had no information about the type of medicines, whereas both the researcher and pharmacist were fully aware of the content of envelopes.

At first, data collection forms including subjects' demographic characteristics and obstetric history were distributed among mothers and completed via interview. The participants were able to leave the study anytime they pleased.In both groups (A & B), before receiving the first doses of medicines, pain score was measured, using Visual Analogue Scale (VAS) and was recorded in the designed checklist. VAS is a measurement tool (10 cm in length), graded from zero to ten. In this scale, zero indicates "no pain" and ten is indicative of "severe pain". The scores were categorized as follows: scores 0-3 (mild pain), scores 4-7 (medium pain) and scores 8-10 (severe pain). The reliability and validity of VAS have been confirmed in previous studies (21). In the present study, those with pain scores lower than four were not enrolled. To record pain intensity, the VAS ruler was given to mothers. After giving the required explanations, the participants were asked to describe the severity of their pain by a number on the ruler. The number was recorded on the pain registration checklist. Also, one hour after using the medicines, patients' pain intensity was re-evaluated with the ruler and recorded in the checklist.The intervention continued for 24 hours after childbirth. During this period, both groups received the capsules four times within 4-6 hour intervals. The same procedure was performed for each round of intervention. Pain intensity was measured and recorded before and one hour after taking the medicines. In addition, the amount of mothers' abnormal bleeding was determined, based on national guidelines (22) and visual estimation.Two subjects in group A (fennel group) were excluded from the study due to early discharge from the hospital (less than 24 hours) and unwillingness to continue the intervention. Also, two patients in group B (mefenamic acid) were excluded from the study, given their need for stronger medicines and lack of consent to continue the intervention. At the end of the study, the possible side-effects of medicines were recorded in a checklist by the researchers. For data analysis, independent t-test, Chi-square and Fisher's exact test were performed, using SPSS version 18. $p<0.05$ was considered statistically significant

Results

The mean age of participants was 27.97±5.003 years in the mefenamic acid group and 27.26±5.37 years in the fennel group; however, no significant difference was observed between the two groups. In terms of occupational status, 95.3% of participants were housekeepers in both groups. Overall, 44.2% of participants in the mefenamic acid group and 55.8% of subjects in the fennel group had high school education. In both groups, the majority of participants had experienced their second birth (or more). There was no significant association between parity and study groups (table 1). Frequency distribution of pregnancy status, onset of pain, infant gender, and episiotomy showed no significant difference between the two groups (table 1). Pain score was 6.47±0.8 in the mefenamic acid group and 6.35±0.75 in the fennel group before the

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intervention. There was no significant difference in the mean pain score between the groups before the first intervention; in fact, the two groups were similar in terms of pain score. One hour after the first round of intervention, pain scores reduced to 1.91±0.65 and 1.70±0.75 in the mefenamic acid and fennel groups, respectively; however, no statistical difference was observed between the two groups. Both medicines during each round of intervention caused pain reduction, although fennel was more effective during the treatment period (table 2). Before the final round of intervention, the mean pain score was 5.35±0.84 in the mefenamic acid group and 4.95±0.79 in the fennel group (p=0.027). In addition, the mean pain score one hour after the fourth round of intervention was 1.19±0.63 in the mefenamic acid group and 0.88±0.70 in the fennel group (p=0.037). According to the findings of this study, no case of bleeding was found in neither of the groups. In addition, no side-effects were reported in these groups.

Table 1. Comparison of maternal and neonatal characteristics between the two groups

Variables \ Groups		Mefenamic acid N(%)	Fennel N(%)	p-value
Status of pregnancy*	Wanted	38(88.4)	37(86.0)	0.747
	Unwanted	5(11.6)	6(14.0)	
The onset of pain*	Spontaneous	33(76.7)	28(65.1)	0.235
	Induced	10(23.3)	15(34.9)	
Episiotomy*	Yes	33(76.7)	27(62.8)	0.159
	No	10(33.3)	16(37.2)	
Infant gender*	Female	26(60.5)	21(48.80	0.279
	Male	17(39.5)	22(51.2)	
Gestational age**	39.30±1.206	39.88±1.028		0.018
Number of abortions**	0.33±0.57	0.16±0.53		0.173
Infant weight**	3214.19±258.51	3203.95±262.66		0.858
Parity*	First pregnancy	12(27.9)	6(14.0)	0.154
	Second pregnancy	16(37.2)	24(55.8)	
	Third or more	15(34.9)	13(30.2)	

***Number (percentage), **Mean±SD**

Table 2. Comparison of pain score before and one hour after the intervention in the mefenamic acid and fennel groups

Pain score \ Groups		Mefenamic acid (Mean±SD)	Fennel (Mean±SD)	p-value
First round	Before the intervention	6.47±0.8	6.35±0.75	0.489
	After the intervention	1.90±0.56	1.70±0.74	0.167
Second round	Before the intervention	5.88±0.83	5.86±0.76	0.893
	After the intervention	1.35±0.65	1.28±0.77	0.650
Third round	Before the intervention	5.47±0.98	5.40±0.98	0.743
	After the intervention	1.21±0.74	1.02±0.71	0.273
Fourth round	Before the intervention	5.35±0.84	4.95±0.79	0.027
	After the intervention	1.19±076	0.88±0.7	0.037

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Conclusion

The findings of the present study showed that fennel extracts had similar effects to mefenamic acid. In addition, these extracts were more effective in reducing postpartum pain, compared to mefenamic acid. The only study which investigated the effects of fennel on postpartum pain was conducted by Asti and colleagues. As they indicated, both 400 mg ibuprofen capsules and 25% fennel drops were effective in pain relief; however, fennel was less effective than ibuprofen after 1, 2, 3 and 4 hours of intervention (7). The results of the study by Asti and colleagues were not in accordance with our findings; in fact, the lower effect of fennel in reducing pain can be associated with its low dosage. In the present study, higher doses of fennel and longer hours of treatment were considered. Tafazoli et al. also investigated the effects of cumin and mefenamic acid on postpartum pain and showed that cumin was more effective in pain reduction, compared to mefenamic acid (6).

Pourmaleky et al. investigated the effects of ginger and mefenamic acid and showed that ginger is more effective in reducing postpartum pain, compared to mefenamic acid (23); this finding was in accordance with our results. Among similar research on the effects of fennel on pain, we can mention studies which focused on inhibiting prostaglandins and uterine contractions in menstrual pain. A study by Khorshidi et al. on the effects of 1% and 2% fennel essences on dysmenorrhea showed that both essences could reduce menstrual pain, compared to the placebo (24). In addition, Moslemi and colleagues showed that in the fennel group, the mean duration of pain in the first and second months of use significantly reduced, compared to the pre-treatment period (25). A study by Nazarpoor et al. showed that the intensity of menstrual pain was not significantly different between groups using fennelin drops and mefenamic acid; in fact, both groups experienced pain reduction. However, the difference in the mean pain score showed that fennelin was more effective than mefenamic acid in pain reduction (18). The results of the mentioned studies were aligned with the present research. The possible mechanism of fennel effectiveness may be related to the structural similarity of anethole in fennel to dopamine; anethole attaches to dopamine receptors and leads to pain reduction (25). Yazdani et al. investigated the effects of fennel and chamomile on primary dysmenorrhea and showed that both are significantly effective in reducing pain (26). Other conducted studies on fennel have shown that the essence of this plant is able to inhibit uterine smooth muscle contractions and is more effective during the treatment period.Delaram et al. showed that the mean pain score reduced not only by the end of the first month of prescribing medicines, but also by the end of the second month after treatment. Moreover, at greater time intervals, pain reduction was more evident, and both medicines (fennel and Phacelia platyloba) could reduce pain during the treatment; however, the effect of fennel in reducing pain was more significant than Phacelia platyloba (27).

In the present study, fennel became more effective than mefenamic acid as the treatment continued. It should be mentioned that the half-life of mefenamic acid is approximately two hours and its administration should be repeated every 4-6 hours. Therefore, we can state that the analgesic effects and sustainability of fennel improved, compared to mefenamic acid, as the treatment continued. This is why the difference was statistically significant in the final round of intervention. In the present study, no case of abnormal bleeding was observed in the mefenamic acid and fennel groups. In this regard, in a study by Nazarpoor and colleagues, which aimed to investigate the effects of fennelin and mefenamic acid on dysmenorrhea, fennelin was more effective in reducing bleeding intensity, compared to mefenamic acid (18).In addition, in a study by Akhavan-Amjadi et al., which evaluated the effects of fennel seed extracts on the severity and duration of menstrual bleeding, the severity and duration of menstrual bleeding increased in none of the groups (28).

However, the results reported by Khorshidi et al. showed that 1% and 2% fennel drops caused an increase in the severity of menstrual bleeding (24). In this study, none of the participants in the two groups had any complaints. Similarly, in the study by Asti et

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al., participants receiving fennel and ibuprofen had no complaints about the side-effects of medicines (7). Considering the inadequacy of conducted studies and contradictory results about the effects of fennel on the severity of bleeding, it is suggested that in future studies, the effects of fennel on the severity of postpartum bleeding be taken into consideration. Based on the present findings and previous research on the analgesic effects of fennel, we can conclude that fennel has analgesic properties and could be used along with chemical compounds for pain relief

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