Ibuprofen Versus Fennel for the Relief of Postpartum Pain: A Randomized Controlled Trial

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Abstract
Objective: The present study aimed to compare the value of ibuprofen and fennel for postpartum pain relief in women with normal vaginal delivery.
Materials and methods: In this randomized clinical trial we studied 90 women referring to obstetrics ward for Normal Vaginal Delivery (NVD) in Assali hospital in Khorramabad. Women were randomly allocated to receive either oral ibuprofen or oral fennel by stratified random sampling technique. All women were asked to give pain score by visual analogue scale before and at 1, 2, 3 and 4 hours after treatment.
Results: Difference between fennel and ibuprofen groups was not significant considering severity of pain before (P=0.22). Difference between two groups considering mean severity of pain one hour after treatment (P=0.57) was not significant. But comparing the mean of pain severity in two groups, showed significant difference after two (p<0.023), three (p<0.001) and four (p<0.001) hours after treatment.
Conclusion: Ibuprofen and fennel were effective for relief of postpartum pain without any notable side effects, but in general ibuprofen was more effective than fennel. More studies are needed to confirm the efficacy of fennel in pain relief especially in postpartum women which must be compared to a no treatment control group.

Keywords: Ibuprofen, Fennel, postpartum, pain

Introduction
Postpartum pain is a common complaint among women after vaginal delivery (1). In the majority of cases, pain management is needed during the post-partum hospitalization period(2). In Iran there is no national protocol for post-partum pain management. A variety of drugs such as acetaminophen, Ibuprofen, Naproxen, etc are used for postpartum pain treatment. In clinical practice nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used for moderate to severe pains. Ibuprofen inhibits prostaglandin synthesis, and compared with other NSAIDs, has a comparable efficacy and less adverse side effects (3, 4).

Foeniculum vulgare (fennel) is an annual plant, which belongs to family of Umbelliferae (Apiaceae). Fennel fruits have 1-3% volatile oils, which have disinfectant and anti-inflammatory effects on the respiratory and gastrointestinal system, also have an antispasmodic effect on smooth muscle(5). Ruberto et al in a study has also reported antioxidant and antimicrobial activity of fennel (6). Moreover, Alexandrovich et al in a case control study showed that fennel eliminated colicin infants in case group (treated with fennel) more effectively than control group(7). Namvar Jahromi et al showed that fennel can be used as a safe and efficient
herbal drug for primary dysmenorrheal (8). According to our Knowledge effectiveness of Ibuprofen and Fennel for postpartum pain relief have not studied formerly, so the present study aimed to compare the value of ibuprofen and fennel for in postpartum pain relief in women with normal vaginal delivery.

Methods & Materials
In this randomized clinical trial we studied 90 NVD (Normal Vaginal Delivery) women referring to obstetrics ward in Assali hospital in Khoramabad. Inclusion criteria comprised: postpartum pain, multiparity, duration of pregnancy (38-42 weeks), NVD, livefetuse, singleton pregnancy, cephalic presentation and birth weight 2500-4000. Exclusion criteria included: Epiostomy, perineal laceration, prolonged delivery, cesarian section, drug sensitivity, regular use of NSAID and opioids during and after pregnancy, severe postpartum bleeding and other severe disease. Then the qualified women were randomly allocated to receive either ibuprofen or Fennel orally by stratified random sampling technique. Each treatment pack contained ibuprofen (400 mg) 1 tablet and ranitidine (150 mg) 1 tablet or Fennel essence 20% (Golghatre Company). All women were asked to give pain score by visual analogue scale before ibuprofen or fennel taken and at 1, 2, 3 and 4 hours after treatment. Patients were allowed to use a supplemental analgesic after 4-hour evaluation as a rescue drug. Severity of pain, rated on a 10-cm visual analogue scale from 0 (“no pain”) to 10 (“worst pain ever”). An initial rating was recorded before the subject took the first dose of drug and at 1, 2, 3 and 4 hours after the first dose by one of the investigators. All the data were collected and analyzed using the SPSS statistical package. Demographic and clinical characteristics were compared between the groups using analysis of variance and Chi-square test. P-value < 0.05 was considered statistical significance.

Results
Totally ninety women were enrolled in the present trial, with 45 randomized to receive ibuprofen and 45 fennel. Two groups were similar in demographic data and clinical characteristics. We did not detect significant difference between two group in the case of age, education level, job, duration of pregnancy, birth weight also duration of second and third phase of labor (P>0.05). Difference between fennel and ibuprofen groups was not significant considering severity of pain before treatment (P=0.22). In this survey we observed patients for 4 hours and showed that difference between two groups considering mean severity of pain one hour after treatment (P=0.57) was not significant. But comparing the mean of pain severity in two groups, showed significant difference after two (p<0.023), three (p<0.001) and four (p<0.001) hours treatment. We did not discern any notable adverse side effects related to fennel or ibuprofen intake. 80% of women in both groups did not need any extra analgesics after 4 hours (Table 1).

Discussion
This clinical trial demonstrated that ibuprofen 400 mg and fennel (essence 20%, 18 drops) administered as single oral doses are effective analgesic agents in relieving postpartum pain. Comparing two groups showed ibuprofen is more effective than fennel in postpartum pain relief and difference between ibuprofen and fennel groups was significant after 2 (p=0.023), 3 (p=0.001) and 4 hours (p=0.001) treatment. This may be due to low dose of fennel that we used in this survey. Numerous studies compared the efficiency of drugs on postpartum pain relief (9,10). However none of these surveys compared efficacy of fennel with ibuprofen on postpartum pain relief and according to our knowledge this is the first study in this field. ModaressNejad a study compared the efficiency of fennel and Mefenamic acid on pain relief of primary dysmenorrheal. 80% in the fennel group and 73% in the Mefenamic acid group showed complete pain relief or pain decrease (11). Also other study in Iran in this field by Manochehri et al, showed fennel

Table 1: Mean ratings (±SD) of pain intensity

<table>
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<tr>
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<th>Fennel Essence</th>
<th>Ibuprofen</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Before taking analgesia</td>
<td>5.66(±0.95)</td>
<td>5.42(±0.94)</td>
<td>0.22</td>
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<tr>
<td>1 h after taking analgesia</td>
<td>3.88(±1.24)</td>
<td>3.8(±1.42)</td>
<td>0.75</td>
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<tr>
<td>2 h after taking analgesia</td>
<td>2.88(±1.005)</td>
<td>2.28(±1.4)</td>
<td>0.023</td>
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<tr>
<td>3 h after taking analgesia</td>
<td>2.28(±1.05)</td>
<td>1.53(±1.89)</td>
<td>0.001</td>
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<tr>
<td>4 h after taking analgesia</td>
<td>0.800(±0.99)</td>
<td>0.222(±0.99)</td>
<td>0.001</td>
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Ibuprofen and fennel in postpartum

(essence 2%) had comparable effect as ibuprofen on primary dysmenorrheal pain relief in high school students (12). Moreover Porter and Janssen in a survey compared acetaminophen with codeine and ibuprofen in postpartum pain and showed that subjects receiving ibuprofen experienced fewer side effects; also, overall satisfaction between two groups did not differ (13). In other study, Schachtel et al. showed that ibuprofen (400 mg) was more efficient than acetaminophen (1000 mg) for total pain relief and for reduction of pain by more than 50%, with faster onset and prolonged period (14). As well, Behotas et al. have studied the relief of post episiotomy pain by comparing a single dose of 400 mg of ibuprofen, 1 g of acetaminophen and placebo. They showed that ibuprofen was more efficient after 1 hour than the other two groups (15). In conclusion, ibuprofen and fennel were effective for relief of postpartum pain without any notable side effects, but in general ibuprofen was more effective than fennel. More studies need to confirm the efficacy of fennel in pain especially in postpartum pain in women.

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Conflict of interest

None

References