Original Study

The Effect of Fennel on Pain Quality, Symptoms, and Menstrual Duration in Primary Dysmenorrhea

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A B S T R A C T

Study Objectives: To assess the effectiveness of fennel on primary dysmenorrhea symptoms and menorrheal duration.
Design: Clinical trial study.
Setting: Islamic Azad University, Toyserkan.
Participants: 80 female students were randomly divided in to two groups of intervention (n = 40) and control (n = 40).
Interventions: The intervention group was given one soft capsule Fennel (30 mg) every 4 hours, 3 days before menstruation till the 5th day and continued for 3 months. The control group received no medication.
Main Outcome Measures: The severity of samples pain was graded using a visual analogue scale. 5 standard questionnaires include of Visual analog scale pain (VAS), McGill pain questionnaire, the range of stress about dysmenorrheal (VASA), Perceived stress scale, Well being scale were filled out in intervals of before, during and after fennel capsule uptake. Data were analyzed by SPSS 17 software. $P < .05$ was considered to be statistically significant.
Results: The mean of nausea intensity and weakness decreased to 1.93, and 2.88 after 3 months, whereas they were 2.37, 6.65 in control group which indicated a significant difference. Reduce the duration of menstrual period, a significant difference was found after two and three months of use. Concern in terms of quality and feelings of well-being after 1 and 3 months, was observed significant difference compared with before using.
Conclusion: Considering the safety of herbal medicines, this drug can use to relieve dysmenorrheal signs and menstrual duration.
Key Words: Fennel soft capsule, Menorrheal duration, Pain quality, Symptoms

Introduction

Dysmenorrhea is one of the most common gynecologic conditions in women regardless of nationality.[1] Primary dysmenorrhea often starts shortly before or just after the onset of the menstrual flow and usually the pain duration is commonly 48-72 hours.[2] Associated general symptoms, such as nausea and vomiting (89%), malaise, weakness (85%), lower backache (60%), diarrhea (60%), and headache (45%), may be present with primary dysmenorrhea.[2] The prevalence of dysmenorrhea among youth is about 60%-96%.[3,4] It occurs only in ovulatory cycles and in women with high levels or increased sensitivity to prostaglandins.[5,6] High levels of prostaglandin stimulate myometrial contractions, ischemia, and sensitization of pain fibers, which lead to pelvic pain.[5]

Studies have shown that dysmenorrhea is one the most disruptive factors affecting life quality and social activity of young women; it makes the person weak and lethargic, especially if there are symptoms like headaches, weakness, vomiting, and spasm.[7] Nonsteroidal anti-inflammatory drugs (NSAID) and oral contraceptive pills, both of which work by reducing uterine contractions, are the most common pharmacologic treatments for dysmenorrhea.[8] NSAIDs act by blocking prostaglandin production.[7] The efficacy of conventional treatments such as nonsteroidals is considerable; however, the failure rate is still often 20%-25%.[9,10] Most women do not seek medical treatment because they believe it would not help to reduce dysmenorrhea.[11] In addition, side effects may not be well tolerated by some women with primary dysmenorrhea.

Many consumers are now seeking alternatives to conventional medicine.[10] Many Americans, nearly 40%, use health care approaches developed outside of mainstream Western, or conventional, medicine for specific conditions.[12] Complementary and alternative medicine (CAM), such as acupuncture, homeopathy, nutritional therapies, and herbal products with low toxicity, refers to medical interventions and techniques that are not a part of medical system.[9] In 51 reports from 49 surveys conducted in 15 countries, prevalence of use of any CAM was 9.8%-76%.[13]

Herbal and dietary therapies are more popular complementary medicines, are suitable for dysmenorrhea, and are classified in the US as supplements.[11] There are many studies that show efficacy on primary dysmenorrhea of herbal therapies such as acupuncture, aromatherapy, and heat therapy or dietary therapy such as vitamin E.[9,14,15] A recent study in America showed that the use of vitamin E taken at 800 IU per day significantly decreases the pain of primary dysmenorrhea[16] and that it may even be helpful for decreasing bleeding during menstruation.[17] A recent study

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of 120 Iranian students found that treatment of primary dysmenorrhea with ginger for 5 days has a statistically significant effect on pain relief.[18] Another studies showed more efficacy of herbal drugs compared to mefenamic acid.[18,19]

Research has shown that sweet fennel, *Foeniculum vulgare,* can reduce menstrual pains by lowering the level of prostaglandins in blood circulation.[20,21] Drug information center recommends the daily uptake of 1 up to 1.5 cup of fennel powder to reduce dysmenorrhea.[20] Recently, a new form of sweet fennel in a capsule of 30 mg is prescribed for pain reduction in case of dysmenorrhea.[21] Information on the effectiveness of soft capsule of fennel on primary dysmenorrhea and symptom is limited. The aim of the present study was to determine the effect of soft fennel capsules on primary dysmenorrhea.

Subjects and Methods

The research was conducted on 80 female students who provided informed written consent, from January 12 to April 12, 2012. First, the ethics confirmation was received from the Research Ethics Committee of Toyserkan Azad University. After access to medical students and explaining the survey, the researcher asked students if they have premenstrual pain, and willingness to participate in research to be investigated.

All student applicants underwent general physical examinations for the diagnosis of secondary and primary dysmenorrhea. Students with primary dysmenorrhea and pain scoring higher than 3, based on visual analog scales (VAS) entered the study and were divided randomly into 2 equal groups of intervention (n = 40) and control (n = 40). The inclusion criteria were the willingness to take part in the study, age range of 18-23, and showing dysmenorrhea more than 3 based on the score of pain ruler. The exclusion criteria were mild dysmenorrhea, student transferring to another university, unwillingness to attend the research, irregular uptake of capsules; any similar analgesic drug uptake, the occurrence of unbearable side effects, and cases with the following diagnosis: pelvic inflammatory disease, endometriosis, and any pelvic tumor.

The intervention group received 30 mg fennel capsules each 4 hours (8 am to 12 midnight) from about 3 days before menstruation till end of fifth day for 3 months. There was no treatment for control group and they did not receive any placebo. The same questionnaires were given to intervention and control group.

The data sampling tools were a demographic form including age, menstruation cycle, intensity of dysmenorrhea, the level of social activity disturbance, the intake of painkillers during menstruation and the background of menstruation, and 5 standard questionnaires as follows:

Visual analog scale pain
McGill pain questionnaire
The range of stress about dysmenorrhea
Perceived stress scale
Well being scale and item

VAS used in first visit to grade pain severity, by marking on a 10-cm vertical line with a range of 0 (no pain) to 10 (severe pain). Also, VAS was used to measuring 3 symptom include of nausea and weakness before fennel intake, and after 1, 2, and 3 months of use in 2 groups. The short-form McGill pain questionnaire (SF-MPQ) of 15 questions was used in order to measure pain quality before fennel intake, and after 1 and 3 months of use. The range of stress or worry about dysmenorrhea, perceived stress scale comprising 10 questions, and WELL being scale comprising 12 questions all were used for the other symptoms including levels of anxiety, stress, and well-being. To determine the validity of research tools, content validity test and for justifiability of tools, retests have been applied. Two questionnaires with a 1-week interval were given to 10 similar participants with case studies to complete. The confidence level of questionnaire was 94%. SPSS version 17 was used for statistical analysis.

Results

Two participants of the control group were excluded due to unwillingness to continue participation in the study, so the control group consisted of 38. The resulting age averages in intervention and control groups were 20.8 and 20.5, respectively. The average age of menstruation initiation was 13.1 years and the average age for the initiation of dysmenorrhea were14.7 and 14.4, respectively. No significant differences have been observed regarding the variables. The majority of intervention (67.5%) and control (60.5%) groups experienced menstruation pain in more half of the cycles in last year. 57.5% of intervention and 63.2% of control groups used pain killers for dysmenorrhea pain during the day before.

No significant difference was observed for nausea between the 2 groups before intervention and 1 month after treatment. The averages of nausea points of most students in both groups were mild. The mean change in nausea score (from 2 to 3 months of treatment) in the fennel group was significantly greater than the other group. The level of weakness was equal in both groups at the beginning of the experiment. The drug uptake in duration of 1 up to 3 months decreased weakness point and showed statistical significant difference after 3 months in both groups (Table 1).

Fig. 1 shows the changes of bleeding duration before and after drug uptake. The majority of intervention group menstruation duration decreased from about 7 to 6 days. However, drug uptake did not have any effect on decrease of bleeding amount.

Table 2 shows a statistical significant different of worries points between before and after intervention. The pain

Table 1
Comparison of Nausea and Weakness in the 2 Groups

Variable	Time	Intervention (mean ± SD)	Comparison (mean ± SD)	*P* value
Nausea	Before use	2.85 ± 2.98	2.63 ± 2.54	.95
	After use	1.93 ± 2.80	2.37 ± 2.55	.03
Weakness	Before use	6.65 ± 2.76	6.39 ± 2.71	.68
	After use	2.88 ± 2.20	6.39 ± 2.71	.001