

# Comparison of the effectiveness of fennel and mefenamic acid on pain intensity in dysmenorrhoea

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مقارنة بين فعالية الشُمرة وحمض الميفيناميك في تخفيف آلام عسر الطمث

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**الخلاصة:** أُجريت دراسة في عام 2002 في مدينة كرمان الإيرانية، للمقارنة بين فعالية الشُمرة وحمض الميفيناميك في تخفيف آلام عسر الطمث الأولي. وفي إطار هذه الدراسة، تم أخذ مجموعتين عشوائيتين من طالبات المدارس الثانوية (متوسط عمرهن 13 عاماً) ممن يعانين من عسر الطمث، وأُعطين خلاصة الشُمرة (55 طالبة) أو حمض الميفيناميك (55 طالبة) لمدة شهرين. ولوحظ أن الآلام قد خفت أو زالت تماماً لدى 80% من الطالبات اللاتي تلقين خلاصة الشُمرة، ولدى 73% ممن تلقين حمض الميفيناميك، في حين لوحظ أن 80% ممن تلقين خلاصة الشُمرة و62% ممن تلقين حمض الميفيناميك لم يحتجن إلى الخلود إلى الراحة. ولم يُلاحظ فرق جوهري بين المجموعتين في مستوى تخفيف الآلام.

**ABSTRACT** A study in Kerman, Islamic Republic of Iran in 2002 compared the effectiveness of fennel and mefenamic acid on pain relief in primary dysmenorrhoea. Two groups of high-school girls (mean age 13 years) suffering dysmenorrhoea were randomized to receive fennel extract ( $n = 55$ ) or mefenamic acid ( $n = 55$ ) for 2 months. In the fennel group, 80% of girls and in the mefenamic acid group, 73% of girls showed complete pain relief or pain decrease, while 80% in the fennel group and 62% in the mefenamic acid group no longer needed to rest. There was no significant difference between the 2 groups in the level of pain relief.

## Comparaison de l'efficacité du fenouil et de l'acide méfénamique sur l'intensité de la douleur dans la dysménorrhée

**RÉSUMÉ** Une étude réalisée à Kerman (République islamique d'Iran) en 2002 a comparé l'efficacité du fenouil et de l'acide méfénamique pour soulager la douleur dans la dysménorrhée primaire. Deux groupes d'élèves du secondaire (âge moyen 13 ans) souffrant de dysménorrhée ont été randomisés pour prendre un extrait de fenouil ( $n = 55$ ) ou de l'acide méfénamique ( $n = 55$ ) pendant 2 mois. Quarante-vingt pour cent (80 %) des filles du groupe ayant pris l'extrait de fenouil et 73 % des filles du groupe ayant pris l'acide méfénamique ont eu un soulagement total de la douleur ou une diminution de la douleur ; 80 % du groupe ayant pris l'extrait de fenouil et 62 % des filles du groupe ayant pris l'acide méfénamique n'avaient plus besoin de repos. Il n'y avait aucune différence significative entre les deux groupes dans le niveau de soulagement de la douleur.

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## Introduction

Dysmenorrhoea is pain with lower abdominal cramps during menstruation [1,2]. It is a common gynaecologic disorder affecting up to 50% of menstruating women [1]. Primary dysmenorrhoea usually starts 1–2 years after menarche and is associated with normal ovulatory cycles without pelvic pathology, whereas secondary dysmenorrhoea is defined as painful menses associated with underlying pathology [1,2]. Primary dysmenorrhoea is more common in young women but may persist throughout the years of menstruation [1]. It is associated with ovulatory cycles and is due to myometrial contractions induced by prostaglandins originating in the secretory endometrium that occurs mostly in the first 48 hours of menses [2].

Various treatments have been suggested for dysmenorrhoea, among them non-steroidal anti-inflammatory drugs (NSAIDs), which have been shown to be effective in 80% of cases [1–3]. Other treatments are oral contraceptives, transcutaneous electrical nerve stimulation, presacral neurotomy and even hysterectomy [1–3]. Some studies have shown the effectiveness of herbal drugs in the treatment of dysmenorrhoea [4–6]. One of the suggested herbal drugs is fennel extract, produced by distillation of fennel seeds with water vapour, which is believed to have anti-spasmodic and analgesic properties. Studies on the isolated mouse uterus have demonstrated an antispasmodic effect of fennel on spasms induced by oxytocin and prostaglandin  $E_2$  [4].

NSAIDs such as mefenamic acid have a number of adverse effects (digestive disorders, diarrhoea, haemolytic anaemia and seizures) [7]. In view of the apparent safety of fennel in patients, with the exception of epileptic patients [6], the present study was

designed to study the effectiveness of fennel for the treatment of dysmenorrhoea. This case–control semi-experimental study was carried out on 110 young women at a school in the Islamic Republic of Iran to compare the effects of fennel and mefenamic acid on pain intensity in primary dysmenorrhoea during 2 consecutive menstrual cycles.

## Methods

The participants were selected randomly from 2 high schools in Kerman city. All were 13 or over years old and suffering from primary dysmenorrhoea. The inclusion criteria were: a history of 1 year regular menses, starting dysmenorrhoea 1–3 years after menarche, and no history of epilepsy, digestive disorders or other diseases. Informed consent for participation was obtained from the participants and their parents.

After interviewing the students, 120 who consented to participate were randomly divided into 2 groups of 60 students.

The case group received 30 drops of fennel extract (Barij Extract Co., Tehran, Islamic Republic of Iran) to be used at the onset of menses and then continuously every 6 hours for the first 3 days of menses. The effective dose of fennel extract was established from the manufacturer's instructions. The control group received 250 mg mefenamic acid (Alhavi Co., Tehran, Islamic Republic of Iran) to be used at the onset of menses and repeated every 6 hours during the first 3 days of menses.

The fennel extract and mefenamic acid were distributed in similar packages and both the participants and the researcher distributing the treatments were blind to the type of treatment. Students were supplied with written instructions for treatment use and a questionnaire that included the scor-

ing sheet for pain symptoms. All students were also given face-to-face instructions for drug use and filling the questionnaire by a trainer not included in the research group. Participants were requested not to use any other drug during the study period and anyone who reported using other drugs was excluded from the study. Compliance with treatment use was checked regularly via phone calls and visits to subjects. One of the researchers was in direct contact with the trainer in order to control the project's progress.

The treatments were used in 2 consecutive menstrual cycles and subjects assessed the effectiveness of the treatments at the end of each menstrual cycle. Pain intensity was reported by subjects according to a verbal multidimensional scoring system taking account of 3 dimensions (need for analgesics, limitation of activities and need for rest):

- severe pain (need for analgesics, unable to carry out routine activities and complete need for rest);
- moderate pain (need for analgesics, limitation in activities and limited need to rest);
- mild pain (no need for analgesics, no limitation in routine activities or no need to rest).

Data analysis was made using through *Epi-Info*, version 6 and by using descriptive statistics, distributional indexes and chi-squared tests.

## Results

Of the 120 students, 10 did not complete the treatments and were excluded. There were no significant differences between the 2 groups of students in terms of mean age, age at menarche or age when dysmenorrhoea started (Table 1).

Overall, there was no significant difference in pain intensity between the 2 groups before treatment (Table 2). In the fennel group 65% had severe pain and 35% had moderate pain, and in the mefenamic acid group 62% had severe pain and 38% had moderate pain. The majority also suffered limitation of activities and a need to rest completely.

After treatment, 80% in the fennel group and 73% in the mefenamic acid group had no pain. In regard to the limitation of activities, 80% in the fennel group and 62% in the mefenamic acid group were returned to the normal state and 83% in the fennel group and 71% in the mefenamic acid group needed no rest after treatment. There was no

Table 1 Age of the 2 treatment groups

Variable	Fennel group (n = 55) Mean (SD)	Mefenamic acid group (n = 55) Mean (SD)	P-value
Age (years)	15.5 (1.5)	15.5 (1.4)	NS
Age at menarche (years)	13.1 (0.9)	13.2 (0.9)	NS
Age at starting dysmenorrhoea (years)	13.7 (1.1)	13.7 (1.1)	NS

NS = not significant; SD = standard deviation.  
n = total number of participants.

**Table 2 Comparison of the 2 treatment groups in regard to dysmenorrhoea symptoms before and after treatment**

Variable	Before treatment				After treatment			
	Fennel group (n = 55)		Mefenamic acid group (n = 55)		Fennel group (n = 55)		Mefenamic acid group (n = 55)	
	No.	%	No.	%	No.	%	No.	%
<i>Need to rest</i>								
No need	0	0	0	0	46	83	39	71
Limited	37	67	33	60	8	15	13	24
Complete	8	33	22	40	1	2	3	5
	$\chi^2 = 0.63, df = 1, NS$				$\chi^2 = 2.77, df = 2, NS$			
<i>Activity state</i>								
Normal	0	0	0	0	44	80	34	62
Limited	15	27	20	36	9	16	18	33
No activity	40	73	35	64	2	4	3	5
	$\chi^2 = 1.5, df = 1, NS$				$\chi^2 = 4.48, df = 2, NS$			
<i>Pain intensity</i>								
No pain	0	0	0	0	44	80	40	73
Moderate	19	35	21	38	10	18	11	20
Severe	36	65	34	62	1	2	4	7
	$\chi^2 = 0.16, df = 1, NS$				$\chi^2 = 2.04, df = 2, NS$			

NS = not significant.

n = total number of participants.

df = degrees of freedom.

significant difference between the 2 treatments in any of the dimensions of pain after treatment (Table 2).

## Discussion

Dysmenorrhoea is the most common gynaecological disorder among adolescent girls reducing their quality of life and causing missed school or work [7]. NSAIDs, especially mefenamic acid, are the treatment of choice for dysmenorrhoea, showing 80% effectiveness. However, there is still a 20%–25% failure rate [1–3], and side-effects such as diarrhoea and rashes [8], immunohaemolytic anaemia [9] and nephrotoxicity; overdose is accompanied by central nervous system toxicity and convulsions [8]. Herbal remedies may be a

safer way to treat many common ailments including dysmenorrhoea. Fennel has been shown to be effective in the treatment of dysmenorrhoea [4]. Although one report has suggested that fennel extract can stimulate uterine contractions and lead to abortion [3], this claim has not been verified and is unlikely at treatment dose.

In the present study, fennel extract and mefenamic acid (250 mg, 4 times a day) were equally effective in reducing pain intensity, limitations in activity and the need for rest among adolescent girls with primary dysmenorrhoea. The effectiveness of NSAIDs such as mefenamic acid in dysmenorrhoea has been reported to be about 75%–80% in previous studies [5,6,10–13]. In the present study 73% of participants taking fennel extract recorded a decrease or complete absence of pain. The failure

rate of NSAIDs is still 20%–25% study [1–3]. In the present study about 20% of the mefenamic acid group reported moderate pain and 7% severe pain after treatment. In a study carried out in 1999 comparing the effectiveness of fennel with placebo, a significant decrease in pain symptoms was observed [4]. In the present study too, 80% of fennel-treated subjects had either pain decrease or pain relief after treatment and there was no significant difference in any of the dimensions of pain symptoms compared with the mefenamic acid-treated group.

Half of the workforce in society is women and the loss of well-being due to dysmenorrhoea diminishes the quality of life of women and the loss of several working days every month during the years of fertility is a potential problem for the economy of any society. The effectiveness of herbal and dietary treatments in dysmenorrhoea are still under investigation and need more careful studies. However, any attempt to find treatments for dysmenorrhoea with less adverse effects is highly desired.

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