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Herbal Remedy for Premenstrual Syndrome with Fennel (*Foeniculum vulgare*) – Randomized, Placebo-Controlled Study

Ziołowy lek na zespół napięcia przedmiesiączkowego z kopru włoskiego (*Foeniculum vulgare*) – badanie randomizowane, kontrolowane placebo

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Abstract

Objectives. To find the remedial effect of fennel (*Foeniculum vulgare*) in women suffering from moderate-to severe premenstrual syndrome (PMS).

Material and Methods. A prospective, double-blind, placebo-controlled clinical trial design was employed over three menstrual cycles. A total of 250 women underwent an initial screen by means of a Daily Record of Severity of Problem Questionnaire (DRSP-Q). Eligible patients were randomly assigned into active (treatment) or placebo groups and had treatment with fennel extract. Symptoms were documented with the DRSP-Q scores.

Results. All the symptoms showed a significantly greater improvement with the fennel extract than placebo ($P < 0.05$) except bloating which was unaffected by the treatment.

Conclusions. Fennel (*Foeniculum vulgare*) is an effective and well-tolerated herbal remedy for the relief of symptoms of women with moderate to severe PMS (*Adv Clin Exp Med* 2011, 20, 4, 509–512).

Key words: premenstrual syndrome (PMS), fennel, herbal drug.

Streszczenie

Cel pracy. Ocena skuteczności kopru włoskiego (*Foeniculum vulgare*) stosowanego u kobiet cierpiących na umiarkowaną lub ciężką postać zespołu napięcia przedmiesiączkowego (PMS).

Materiał i metody. Przeprowadzono prospektywne, z podwójnie ślełą próbą, kontrolowane badanie kliniczne z użyciem placebo w ciągu ponad 3 cykli miesięczkowych badanych kobiet. U 250 z nich wykonano wstępną analizę za pomocą kwestionariusza Daily Record of Severity of Problem Questionnaire (DRSP-Q). Zakwalifikowane pacjentki losowo przydzielono do grupy aktywnej (leczenia) lub grupy z użyciem placebo. Grupa aktywna była leczona wyciągiem z kopru włoskiego. Objawy udokumentowano wynikami DRSP-Q.

Wyniki. Zanotowano istotnie większą poprawę wszystkich objawów w grupie leczonej wyciągiem z kopru włoskiego w porównaniu z placebo ($p < 0,05$) z wyjątkiem wzdęć, na które leczenie nie miało wpływu.

Wnioski. Koper włoski (*Foeniculum vulgare*) jest skutecznym i dobrze tolerowanym lekiem ziołowym do łagodzenia objawów umiarkowanego lub ciężkiego PMS (*Adv Clin Exp Med* 2011, 20, 4, 509–512).

Słowa kluczowe: zespół napięcia przedmiesiączkowego (PMS), koper włoski, ziołowy lek,

Premenstrual syndrome (PMS) is a complex combination of psychological symptoms including irritability, aggression, tension, anxiety, and depression, and somatic changes [1]. PMS occurs cyclically during the luteal phase of the menstrual cycle and is relieved quickly after menstrual flow begins [2]. Epidemiologic surveys have estimated

that frequency of PMS symptoms is quite high (80–90%) [3]. According to the American College of Obstetricians and Gynecologists (ACOG) there is no specific laboratory test for diagnosis of PMS but it can be diagnosed if at least one of the effective and one of the somatic symptoms is reported five days prior to the onset of the menses in the

three prior menstrual cycles [4]. The etiology of PMS remains unknown but it has been attributed to hormonal change, neurotransmitters, prostaglandins, diet, drugs and lifestyle [1].

In spite of the lack of established efficacy, many women with PMS use alternative therapies [5]. While most of these treatments are successful in relieving symptoms for some of the women treated, to date no therapeutic interventions has been proven to be effective for all [6].

The essence of fruits of a fragrant plant known as *Foeniculum vulgare*, from the umbelliferae species, has long been used to relieve painful menstruation [7]. Fennel is a grassy plant, 70–200 cm in height and has thin, stringy leaves with yellow flowers. The plant has been used to relieve dysmenorrhea (a common gynecological complaint), however its effects on the treatment of PMS have not been determined. This study aimed to find the remedial effect of fennel in women suffering from moderate to severe PMS in a randomized, placebo-controlled study over three consecutive menstrual cycles.

Material and Methods

The study was randomized, double-blind and placebo-controlled. The study was approved by the ethics committee of Shahrekord University, Iran. A total of 250 women underwent an initial screen by means of a Daily Record of Severity of Problem Questionnaire (DRSP-Q). The questionnaire included 21 items and described both emotional and physical effects of PMS. Women with moderate or severe PMS were selected. In sum, 60 women were included. All volunteers included gave their informed consent before entering the study. The sample was randomly assigned into the active group (30) or the placebo group (30) and had treatment with fennel extract. Following Borenstein [8], eligible participants were asked to complete a daily diary. Diaries were kept for three consecutive cycles. The DRSP-Q scores were calculated: women rated each item and summed up for the assessment of PMS, ranging from 0 (no symptoms) to 4 (severe PMS). The study medication consisted of either active (30 drops of fennel extract every 8 hours for 3 days) or placebo during three menses. Inclusion criteria for both groups were regular menstrual cycles and sleep-wake schedules and good health. Exclusion criteria for PMS were chronic disease, pelvis inflammation, pregnancy and dementia. Fennel extract is obtained by the Bareej Pharmaceutical Company (BPC) through distillation with steam from dried ripe fruit. Statistical analyses were conducted using SPSS version 14.0. A paired t-test

was used to calculate the difference within groups. Chi-square and Mann-Whitney tests were used to evaluate whether there was any difference between the two groups.

Results

Demographic and clinical characteristics such as the age, BMI (body mass index), weight, age at menarche and menstrual variables of each group are shown in Table 1. No statistical difference was found between the two groups. Table 2 shows the results at the end of herbal remedy with the drug. Women who received the fennel extract had a significant improvement in combined symptoms compared with those on placebo. The reduction percentages of all symptom scores in the active (treatment) group were significantly higher than that in the placebo group except bloating which was unaffected by the treatment. There were few adverse events related to the fennel extract (Table 3), nevertheless no generalization can be made due to the small sample sizes of the two groups [1]. The study suggests that the use of fennel *Foeniculum vulgare* may reduce the severity of symptoms of women with PMS.

Discussion

The survey tested the efficacy of fennel *Foeniculum vulgare* on PMS by conducting a prospective, double-blind, placebo-controlled study. The

Table 1. Demographic and clinical characteristics of 60 women at entry of fennel extract herbal medicine for premenstrual syndrome (active treatment n = 30; placebo n = 30)

Tabela 1. Demograficzne i kliniczne cechy 60 kobiet, u których leczono zespół napięcia przedmiesiączkowego ziołowym lekiem z wyciągiem z kopru włoskiego (aktywne leczenie n = 30; placebo n = 30)

	Active (Aktywne)	Placebo
Age – years (Wiek – lata)	20 ± 5.6	22 ± 3.9
BMI	19.85 ± 2.2	19.69 ± 2.5
Weight – kg (Masa ciała – kg)	55.4 ± 5.6	57.3 ± 6.8
Age at menarche – lata (Wiek menarche – lata)	13.6 ± 2.2	13.7 ± 1.7
Cycle length – days (Długość cyklu – dni)	28.8 ± 1.5	29.3 ± 1.2
Bleeding length – days (Długość krwawienia – dni)	6.0 ± 1.3	5.9 ± 1.7

Table 2. Results at the end point (end of three consecutive cycles) in 60 women with premenstrual syndrome (active treatment $n = 30$; placebo $n = 30$)**Tabela 2.** Wyniki na końcu badania (po 3 kolejnych cyklach) u 60 kobiet z zespołem napięcia przedmiesiączkowego (aktywne leczenie $n = 30$; placebo $n = 30$)

	Active (Aktywne)	Placebo	<i>P</i> –Value
Stress (Stres)	14.10 ± 6.10	23.44 ± 5.49	< 0.001
Depression (Depresja)	17.80 ± 8.93	21.16 ± 10.04	0.04
Excitement (Pobudzenie)	12.63 ± 5.26	14.22 ± 7.98	0.15
Bloating (Wzdęcia)	13.52 ± 5.47	12.96 ± 6.13	0.075
Somatic symptoms (Objawy somatyczne)	5.11 ± 3.60	6.35 ± 5.63	0.04
Cluster symptoms (Objawy grupowe)	64.40 ± 29.36	79.10 ± 28.1	0.01

Table 3. Adverse events reported for fennel extract**Tabela 3.** Objawy niepożądane podczas stosowania wyciągu z kopru włoskiego

	Active (Aktywna)	Placebo
Allergic reactions (Reakcje alergiczne)	0	1
Acne (Trądzik)	0	0
Gastric upset (Niestrawność)	0	1
Visual symptoms (Zaburzenia widzenia)	1	0
Neurological symptoms (Objawy neurologiczne)	0	0
Respiratory symptoms (Objawy pochodzące z układu oddechowego)	0	1

results show that fennel extract is an effective treatment for women with PMS.

PMS, being one of the most common disorders in women, is defined by an array of predictable physical, cognitive, effective, and behavioral symptoms that occur cyclically during the luteal phase of the menstrual cycle and are resolved quickly at or within a few days of the onset of menstruation [3, 4, 9–11]. It is estimated that 70–90% of menstruating women have some degree of symptoms before menses. The prevalence of moderate to se-

vere PMS that needs to be treated is around 8–30% in different ethnic groups [12]. The symptoms of PMS are identified in adolescence and can begin around age 14, or 2 years post-menarche, and persist until menopause [13].

To date, no universally acceptable treatment for PMS has been reported. Most therapies have yielded conflicting results. Herbal medicine is a recent favorable therapeutic approach owing to fewer side-effects. Fennel is a fragrant herbal medicine and this study used fennel extract for the treatment of women with PMS. Because safety is of primary concern with any medication, the essence of fennel has previously been used as a safe and effective herbal drug for dysmenorrhea-associated PMS [7]. Dysmenorrhea (a common gynecological complaint) can be relieved by fennel extract [14–16]. As fennel has an inhibitory effect on the production of oxytocin and prostaglandin E2 (PGE2) [17], the mode of action of fennel appears to be hormonal.

Patient acceptance and tolerability aspects are crucial in treatment [18]. While the effects of other herbal drugs on PMS gradually decreased over time [19], the effect of fennel in the present study was clear to both the women and physicians, for at least as long as three cycles after treatment [1, 18].

The present study provides an herbal remedy in women suffering from moderate to severe PMS. Further investigations with more subjects and longer duration of therapy should be carried out to clarify the detailed benefits of fennel extract in women with PMS.

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