

The Effect of *Foeniculum Vulgare* (Fennel) on Body Composition in Postmenopausal Women with Excess Weight: A Double-blind Randomized Placebo-controlled Trial

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Objectives: The goal of this study was to evaluate the effect of fennel on body composition.

Methods: This study is a secondary analysis of a double-blind, randomized, placebo-controlled trial. Fifty-four out of 60 patients were able to successfully complete the original study. Seven out of 54 patients were excluded because they were not overweight and obese. Thus, 47 women were included in this secondary analysis. Of these 47 women, 22 were in the fennel group and 25 were in placebo group. Body weight, body mass index (BMI) as well as fat distribution was measured at the baseline and after a three-month follow-up.

Results: Comparison of fennel and placebo groups did not reveal any significant effect in terms of body weight, BMI, waist and hip circumferences and fat distribution. Also, the results of paired *t*-test did not show variation of these parameters across groups before and after 12-week treatment.

Conclusions: Menopausal women in fennel group experienced a slight increase in body weight and fat distribution, which was not significant. Further studies with larger sample sizes are recommended to validate the results of this study. (**J Menopausal Med 2017;23:166-171**)

Key Words: Body fat distribution · Body mass index · Body weight · *Foeniculum* · Postmenopause

Introduction

It has been shown that estrogen deficiency induced by menopause causes a number of changes in body composition, including reduced lean mass and increased body weight or abdominal fat.¹ The central distribution of body fat is associated with increased risk of cardiovascular disease.² Use of hormone therapy (HT) in menopausal women prevents

the central distribution of body fat and loss of lean mass.^{3,4} However, postmenopausal women undergoing hormone replacement therapy (HRT) tend to abandon due to HRT-related side effects, such as breast swelling/tenderness, spotting, bloating and bleeding.⁵ As such, a large number of postmenopausal women have a preference for compounds with non-hormonal materials such as phytoestrogens, which offer a safer option. Fennel is regarded as phytoestrogen-

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a type of herb belonging to the apiaceae family which is assumed to be an ancient medicinal plant and has been used in Iranian traditional medicine for ages. It has known antioxidant, cytotoxic, anti-inflammatory, antimicrobial estrogenic, hypotensive and antithrombotic features.⁶ One animal study on the effect of fennel on body weight, feed intake food efficiency rate and serum leptin found that it could reduce the rate of food efficiency in rats.⁷ One human study in South Korea demonstrated its remarkable effect in controlling appetite in overweight women.⁸ However, there is a paucity of studies assessing the effect of fennel on body composition among postmenopausal women. The goal of this secondary analysis is to assess the effect of fennel on body composition in post-menopausal women.

Materials and Methods

A secondary analysis was conducted on data derived from a randomized controlled trial that was intended to assess the effect of fennel on lipid profile and bone density in Iranian postmenopausal women. The ordinal protocol was approved by Ethics Committee of Mashhad University of Medical Science (No. 930804). Fifty-four out of 60 patients were able to successfully complete the original study. Seven out of 54 patients were excluded because they were not overweight and obese. Thus, 47 women were included in this secondary analysis. Of these 47 women, 22 were in the fennel group and 25 were in placebo group. Body weight, body mass index (BMI) as well as fat distribution was measured at the baseline and after a three-month follow-up.

1. Inclusion and exclusion criteria

Inclusion criteria were: healthy postmenopausal women (no vaginal bleeding for 1 year) aged above 40 years who had a normal mammogram over the last year. The exclusion criteria included using any fluoride or bisphosphonates, current (or over the past 6 months) use of estrogen or calcitonin, endometrial thickness >5 mm, regular ingestion of phytoestrogen or soy-based products, regular physical exercise and allergy to fennel.

2. Intervention

All participants signed informed consent forms regarding the voluntary basis of their participation in the study and that they could abandon the trial at any time. To ensure allocation concealment, researchers printed random numbers on non-transparent sealed envelopes. The envelopes contained soft capsule for 30 days. All subjects were requested to take soft capsules three times a day. The soft 100-mg fennel capsules were standardized to 71 to 90 mg anethole. Placebo group received capsules with identical shape and size. Both fennel and placebo were filled with sunflower oil (mineral oil). The sequence and concealment of allocation was carried out by a research assistant, who was not directly involved in the study. The degree of compliance was evaluated in terms of the number of capsules given back by the patients at the end of trial.

3. Outcome measures

Following the overnight fasting, the waist circumference of participants was measured using a soft measuring tape, which was placed directly on the narrowest point between iliac crest and lower rib margin. Also, the hip circumference was measured at the widest area over the great trochanters and the waist-hips circumference ratio was calculated. The weight and height were measured by one of the researchers. Subjects were barefooted and had light indoor clothing on during bodyweight measurements (it weighed about 100 g). The BMI was also computed by dividing weight (kg) by height (m³).

4. Statistical analysis

Data were checked for normal distribution using the Kolmogorov-Smirnov test of normality. The paired *t*-test was used to determine the difference before and after treatment. The student *t*-test (between groups), was utilized to compare the two treatment groups. Statistical tests were two-sided, and a *P* < 0.05 was considered statistically significant. Covariance analysis was performed to compare the effect of intervention on post treatment scores after controlling BMI difference at the baseline. Since this was a secondary analysis, the sample size was not determined, but post-hoc calculation of statistical power was conducted by PASS/NCSS software (NCSS, Kaysville, UT, USA) to

assess the power of findings.

Results

The mean age of menopausal women was 57.36 years in fennel group and 56.72 in the placebo group. The mean

length of menopause was 8.61 years in the fennel group and 7.39 years in the placebo group. Women in the experimental and control groups had 4.55 and 3.86 children. Moreover, the mean BMI in the fennel and placebo groups was 29.50 ± 2.98 and 32.04 ± 4.1 respectively. The two groups were identical in variables such as age, length of menopause, history of hysterectomy; number of children, body weight, level

Table 1. Baseline characteristics of subjects in the group

Items	Fennel group (n = 22)	Placebo group (n = 25)	P value
Weight			0.027
Overweight	15 (68.2)	9 (36.0)	
Obesity	7 (31.8)	16 (64.0)	
Age (years)	57.36 ± 5.6	56.72 ± 4.6	0.670
Years since menopause	8.61 ± 6.7	7.39 ± 5.12	0.441
No. of children	4.55 ± 2.24	3.86 ± 1.79	0.237
History of hysterectomy			0.354
Yes	1 (4.5)	4 (16.0)	
No	21 (95.5)	21 (84.0)	
Educational levels			0.547
Illiterate	4 (18.2)	1 (4.0)	
Primary school	10 (45.5)	12 (48.0)	
Middle school	1 (4.5)	2 (8.0)	
High school	4 (18.2)	6 (24.0)	
University	3 (13.6)	4 (16.0)	
Income			0.194
<150 \$	2 (9.1)	2 (8.0)	
150-300 \$	19 (86.4)	16 (64.0)	
300-450 \$	0 (0.0)	2 (8.0)	
>450 \$	1 (4.5)	5 (20.0)	
Marital status			0.136
Married	18 (81.8)	25 (100.0)	
Divorced/Widow	4 (18.2)	0 (0.0)	
Total cholesterol (mg/dL)	2	225.12 ± 35.66	0.321
LDL-cholesterol (mg/dL)	236.82 ± 44.1	131.4 ± 28.66	0.072
HDL-cholesterol (mg/dL)	148.77 ± 35.83	50.4 ± 8.66	0.193
Triglycerides (mg/dL)	46.95 ± 9.29	129.44 ± 51.17	0.887

The data is presented as mean ± standard deviation or n (%)
 LDL: low-density lipoprotein, HDL: high-density lipoprotein

of educational, marital status income level and lipid profile at the baseline except for BMI, as show in Table 1 and 2.

Of 60 patients, 5 in the fennel group and 1 in the placebo group abandoned the trial. The former group complained of allergic rash (n = 1), weight gain (n = 1), hypertension (n = 1) and vaginal bleeding (n = 2). One patient in the placebo group complained of stomachache. However, none of these (vaginal bleeding) was related to malignancy or endometrial proliferation. Also, 7 patients were excluded because they did not meet the obesity criteria. Comparison of fennel and placebo groups did not show any significant change in body weight, BMI, waist and hip circumferences and fat distribution, as shown in Table 2. Also, the results of paired *t*-test did not reveal any variation in these parameters in both groups before and after the 12-week trial. In both groups,

high compliance was observed.

At the baseline, BMI was assessed either as a continuous or categorized variable. There was a significant difference between the two groups in this regard, with subjects in the placebo group having more BMI. As such, we used covariance analysis, with the results indicating that if BMI difference was controlled at the baseline, the effect of intervention would not be statistically significant ($P = 0.356$) (data were not showed).

Discussion

As far as we know, this is the first study to assess the effects of fennel on body composition in post-menopausal

Table 2. Comparison of anthropometric parameters between fennel and placebo group

Variable	Fennel (n = 22)	Placebo (n = 25)	P value (between groups)
Weight (kg)			
Start point (0 week)	69.27 ± 8.83	73.50 ± 10.81	0.153
End point (12 weeks)	69.45 ± 8.83	73.22 ± 11.23	0.212
P value before and after	0.550	0.529	
Body mass index (kg/m ²)			
Start point (0 week)	29.50 ± 2.98	32.04 ± 4.1	0.022
End point (12 weeks)	29.53 ± 3.07	31.84 ± 4.2	0.041
P value before and after	0.834	0.296	
Fat distribution (cm)			
Start point (0 week)	0.91 ± 0.055	0.90 ± 0.06	0.888
End point (12 weeks)	0.96 ± 0.18	0.92 ± 0.07	0.337
P value before and after	0.122	0.303	
Waist circumference (cm)			
Start point (0 week)	95.23 ± 7.96	96.40 ± 9.19	0.645
End point (12 weeks)	96.27 ± 9.43	96.60 ± 8.56	0.901
P value before and after	0.491	0.842	
Hip circumference (cm)			
Start point (0 week)	104.7 ± 9.85	106.12 ± 8.89	0.607
End point (12 weeks)	101.27 ± 12.97	104.40 ± 10.44	0.365
P value before and after	0.125	0.182	

The data is presented as mean ± standard deviation

women with excess weight. According to the results of this study, fennel did not have any significant effect on body weight, BMI, waist and hip circumferences and waist–hip ratio (WHR) over a three–month period. All variables except for BMI were identical in both groups. However, the researcher was blind to BMI findings at the baseline. The fact that fennel did not have any positive effect on body composition rejects our hypothesis, which was based on the study of Bae et al.⁸ The results of two studies by Bae et al.⁸ showed that taking fennel as tea (containing 2 g of dried tea) or as aromatherapy (2–4 drops of fennel oil on dried cotton)⁹ could suppress appetite in overweight women.

This effect was attributed to the content of trans-anethole, which acted on amphetamine and helped appetite control.⁸ The results of this study are consistent with recent data derived from animal models according to which inhalation of essential oils has no effect on decreasing body weight in rats.⁷ Similarly, our findings did not show any significant increase in body weight of subjects. One possible justification for the results reported by Bae et al.⁸ and the present study is that fennel may suppress appetite, but it also slightly increases in body weight and fat distribution. Further studies are required to examine the effect of fennel on both appetite and body composition. Our review of literature showed the paucity of human studies about the effects of fennel on body composition. However, considering that phytoestrogens are an active biological compound in fennel, we incorporated studies that assessed phytoestrogen effects such as flaxseed and soy on body composition.^{10–14} Five out of 10 studies reviewed in the meta–analysis of Zhang et al.¹⁵ suggested that soy intake led to an increase in body weight, though this reduction was not statistically significant. In another study by Machado et al.¹⁶ 75 overweight adolescents were randomly assigned to three groups of brown flaxseed (28 g/day), golden flaxseed (28 g/day), and control group. The results showed a body weight increased from 59.28 to 61.25 ($P < 0.001$) in the brown flaxseed group and from 63.84 to 64.88 ($P = 0.010$) in the golden flaxseed, though it remained unchanged in the control group.¹⁶ These findings are consistent with our study, according to which phytoestrogens may lead to a slight increase in body weight. Part of discrepancy between our findings and those reported in other studies may be due to different ingredients of pill (tablet) and teas.

Another reason could be that fennel might have varying effects on menopausal compared to others age group. One limitation of this study was its failure to control lifestyle habits like physical activity and diet. However, subjects were asked not to change their usual diet and physical activity over a three–month period. Moreover, although previous study showed that fennel might suppress appetite, we only assessed the effect of fennel on body composition. Further research studies should address the change of diet pattern during the treatment. The results of a post–study power analysis indicated that the current sample size had only 22% and 15% power in identifying the difference between placebo and fennel groups in terms of body weight and fat distribution.

Conclusion

Menopausal women in the fennel group demonstrated a slight increase in body weight and fat distribution. The study power was not sufficient to detect a significant effect. Therefore, further studies with larger sample sizes are recommended to assess the findings of this study.

Conflict of Interest

The Barij Essence Pharmaceutical Company supported this study by providing soft fennel capsules. However, the design of protocol, analysis, and research implementation were undertaken by the author.

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