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Role of soy isoflavones on hotflashes in menopause women

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Abstract

Background: Menopause is a biological process that can cause various troublesome symptoms such as hot flashes and emotional changes, but can also increase mortality risk due to subsequent osteoporosis and reduced metabolism. Soy isoflavones are structurally similar to 17 β -estradiol, the primary female sex hormone. It is expected that isoflavones supplement will improve menopause-related health outcomes.

Aim of the study: To study role of soy isoflavones on hotflashes in menopause women.

Materials and methods: The present study was conducted at Sardar Patel Medical College, Bikaner, Rajasthan, India. For the study, 120 women over 40 yr of age with body mass index in the range of 20–35Kg/m² who complained of hot flushes were selected. The patients were divided into 2 groups equally based on their arrival order to clinic; the first group received soy extracts as 50 mg isoflavone in form of a tablet, one before lunch and one before dinner and the second group were given placebo resembling the active drug in size and shape in the same manner. Both groups had the regimen for 12 wk.

Results: We observed that mean age of Group 1 patients was 52.36 years and of Group 2 was 53.65 years. Mean BMI of group 1 was 28.26 kg/m² and of group 2 was 27.69 kg/m². Mean age of menopause for group 1 was 48.26 years and for Group 2 was 48.69 years. The results on comparison were found to be statistically non-significant for all the variables. It was observed that the frequency of hotflashes decreased significantly for Group A over the period of follow up. However, Group B had minimal efficacy for improvement in hotflashes. The results on comparison were found to be statistically significant.

Conclusion: Within the limitations of the present study, it can be concluded that soy isoflavones are significantly efficacious in improvement of hot flashes in menopausal women.

Keywords: Menopause, Soy isoflavone, breast cancer, HRT

Introduction

Menopause is a biological process that can cause various troublesome symptoms such as hot flashes and emotional changes, but can also increase mortality risk due to subsequent osteoporosis and reduced metabolism. Hormone replacement therapy (HRT) would be the most intuitive way to combat these changes; however, the 2002 Women's Health Initiative (WHI) study showed that hormone replacement therapy increased the risk of breast cancer, stroke, and coronary heart disease in healthy postmenopausal women [1]. Since then, healthcare professionals and women have been seeking alternative therapies. In Canada for example, it has been found that 60% to 90% of women would consider taking complementary and/or alternative medicine (CAM) for menopausal symptoms, but are concerned about the efficacy and cost [2]. Many patients taking CAM choose not to tell their doctors because they feel doctors are not knowledgeable enough or are biased against CAM [3]. Soy and soy products have been studied in menopausal women for decades. Soy isoflavones are structurally similar to 17 β -estradiol, the primary female sex hormone. It is expected that isoflavones supplement will improve menopause-related health outcomes [4]. However, the question remains whether isoflavones have effects on climacteric symptoms, bone biochemical markers, and menopause-related quality of life. Previous studies have shown that climacteric symptoms including hot flashes were improved in the isoflavones group compared to the placebo group [5]; in contrast, other studies showed no benefit to isoflavones over placebo [6]. Hence, the present study was conducted to study role of soy isoflavones on hotflashes in menopause women.

Materials and methods

The present study was conducted at Sardar Patel Medical College, Bikaner, Rajasthan, India from 2009 to 2011. The ethical clearance for the study was approved from the ethical committee

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of the hospital. For the study, 120 women over 40 yr of age with body mass index in the range of 20–35Kg/m² who complained of hot flushes were selected. Women with previous history of cancer, diabetes mellitus or renal, hepatic, and heart failure or abnormal uterine bleeding, myoma, ovarian cyst, Poly Cystic Ovarian Syndrome (PCOS), endometriosis, hormone therapy during the last three months, consumption of drugs interacting with intestinal absorption, a known history of breast disease or the detection of breast mass or nodules in breast examination were excluded. In addition, patients who had a suspicious history of probable sensitivity to soy products, disability or known history of drug or alcohol consumption, cigarette smoking, and caffeine consumption were excluded. The patients were divided into 2 groups equally based on their arrival order to clinic; the first group received soy extracts as 50 mg isoflavone in form of a tablet, one before lunch and one before dinner and the second group were given placebo resembling the active drug in size and shape in the same manner. Both groups had the regimen for 12 wk. At the first visit, patients underwent breast examination (BE) and breast sonography (BS). Breast examination was performed by two board-certified general surgeon oriented with the aim of the study. Prior to the study, breast tenderness and nodularity in BE were scored. The hot flushes were assessed by a chief resident of gynecology and were categorized in mild, moderate and severe. Each patient was followed for a period of 12 weeks, with evaluations being made after 6 weeks, and then at 12 weeks. At each checkpoint, the patients were asked to record the daily number of hot flushes and describe its severity.

The statistical analysis of the data was done using SPSS version 11.0 for windows. Chi-square and Student's t-test were used for checking the significance of the data. A p-value of 0.05 and lesser was defined to be statistical significant.

Results

Table 1 shows demographics of the study population. We observed that mean age of Group 1 patients was 52.36 years and of Group 2 was 53.65 years. Mean BMI of group 1 was 28.26 kg/m² and of group 2 was 27.69 kg/m². Mean age of menopause for group 1 was 48.26 years and for Group 2 was 48.69 years. The results on comparison were found to be statistically non-significant for all the variables. Table 2 shows severity of hot flushes over follow up period. It was observed that the frequency of hotflushes decreased significantly for Group A over the period of follow up. However, Group B had minimal efficacy for improvement in hotflushes. The results on comparison were found to be statistically significant. ($p < 0.05$)

Discussion

In the present study, we observed that soy isoflavone have significant effect on the improvement of hot flushes in patients with menopause. These can be efficaciously used for hot flushes in menopausal women. The results were compared with previous studies and was found to be statistically significant. Ahsan M et al studied the effect of soy isoflavone supplementation on the menopausal symptoms in perimenopausal and postmenopausal women. An observational pilot study was done involving 29 perimenopausal and 21 postmenopausal women prescribed 100 mg soy isoflavones for 12 weeks. Menopause Rating Scale (MRS) questionnaire was administered to the patients before starting soy isoflavone therapy and at the end of treatment. Total score of both the groups were comparable at baseline. Among perimenopausal women highest score was given to symptoms of psychological domain. Urogenital symptoms were the worst

among postmenopausal women. After 12 weeks of treatment, total scores improved significantly by 19.55% and 12.62% in the perimenopausal and postmenopausal women respectively. The greatest improvement was seen in scores of hot flushes for both the groups and the least improvement was shown by symptoms of urogenital subscale. They concluded that soy isoflavone improves the MRS score among both the perimenopausal and postmenopausal women. As they are most effective for somatic and psychological symptoms, their use could be beneficial during perimenopause. Li L et al. studied the efficacy of soy isoflavones in the treatment of menopausal hot flushes. Model based meta-analysis (MBMA) was used to quantitate the efficacy of soy isoflavones. We conducted a systemic literature search to build a time-effect model for placebo and soy isoflavones in treating menopausal hot flushes. Studies were identified, subjected to inclusion and exclusion criteria, and reviewed. From 55 articles, 16 studies of soy isoflavones met the inclusion criteria, and contained 65 and 66 mean effect values in placebo and soy isoflavone groups, respectively, from about 1710 subjects. Interestingly, the developed model was found to describe adequately the time course of hot flushes reduction after administration of placebo and soy isoflavones. Using this model, we found that the maximal percentage change of hot flushes reduction by soy isoflavones was 25.2% after elimination of the placebo effect, accounting for 57% of the maximum effects of estradiol (Emax-estradiol = 44.9%). However, a time interval of 13.4 weeks was needed for soy isoflavones to achieve half of its maximal effects, much longer than estradiol, which only required 3.09 weeks. These results suggest that treatment intervals of 12 weeks are too short for soy isoflavones, which require at least 48 weeks to achieve 80% of their maximum effects. They concluded that soy isoflavones show slight and slow effects in attenuating menopausal hot flushes compared with estradiol [7, 8].

Vahid Dastjerdi M et al conducted randomized clinical trial in 204 patients who complained of hot flushes in Arash Women's Hospital, Tehran, Iran from 2013–2015. The first group received 50 mg isoflavone (group A) once daily and the second group received placebo (group B) in the same regimen. Patients were evaluated for breast examination (BE) and breast sonography (BS) as well as vaginal sonography at initial presentation and at 6th and 12th week follow-ups. Patients were educated to record frequency and severity of hot flushes. Group A experienced less hot flushes attack which was also less severe. Isoflavone had no effect on neither breast density nor nodularity and neither breast tenderness nor nipple discharge. There were no significant differences in endometrial thickness in 6 and 12wk. They concluded that effects of isoflavone on frequency and severity of hot flushes in perimenopausal women is observed. Thomas AJ et al conducted review controlled clinical trials of isoflavones and amino acid preparation effects on hot flushes and at least one other symptom including mood, sleep, pain, and cognitive function that women report during the menopausal transition and early postmenopause. An experienced reference librarian searched PubMed/Medline, CINAHL Plus, PsycInfo, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Web of Science, EMBASE, AMED, and Alt-Health Watch for English-language randomized controlled trials between 2004 to July 2011. Seventeen trials of isoflavones and amino acid effects on hot flushes and one additional symptom were identified. In five trials of soy isoflavone preparations, two (6g soy germ extract and 25g soy protein in soy nuts) significantly decreased hot flushes, but no other symptoms. In the seven trials of other isoflavones, six significantly reduced hot flushes; in addition, Red Clover (80 mg) significantly

reduced mood symptoms; Rexflavone (350 mg) for women with Kupperman Index > 20 significantly reduced sleep symptoms; two trials had significant reductions for pain: Isoflavone powder (90 mg) and Red Clover (80 mg). The only trial in this systematic review that significantly reduced cognitive symptoms was Red Clover (80 mg). In one trial, Red Clover isoflavone (80 mg/d) significantly relieved hot flashes, mood, pain, and cognitive symptoms. Amino acids yielded no significant results.

Equol supplements of 30 mg/d for non-Equol producing women significantly reduced mood symptoms in one trial. The Magnolia Bark Extract combination significantly reduced hot flashes, mood, and sleep symptoms. They concluded that isoflavone trials yielded significant reductions on hot flashes and co-occurring symptoms during the menopausal transition and postmenopause, but studies require replication with larger sample sizes and attention to measurement of outcomes^[9, 10].

Table 1: Demographics of the study population

Variables	Group 1 (n=60)	Group 2 (n=60)	p-value
Mean Age (years)	52.36	53.65	0.23
Mean BMI (kg/m ²)	28.26	27.69	0.9
Mean age of menopause (years)	48.26	48.69	0.25
Mean duration of menopause (years)	2.35	2.46	0.09

Table 2: Severity of hot flashes over follow up period

Frequency of hotflashes	Baseline time		6 weeks		12 weeks		p-value
	Group A	Group B	Group A	Group B	Group A	Group B	
-2>	10	11	18	12	24	13	0.25
-2-5	16	14	9	13	5	12	0.001
-5<	4	5	3	5	1	5	0.03

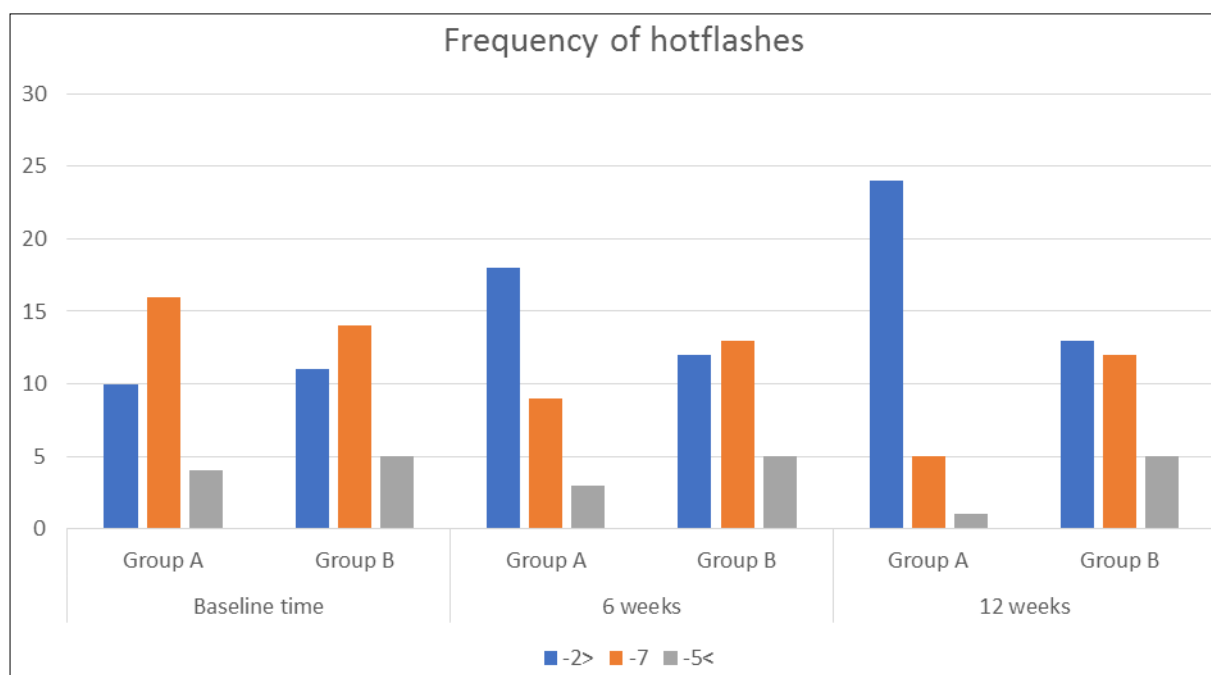


Fig 1: Frequency of hotflashes in Group 1 and 2

Conclusion

Within the limitations of the present study, it can be concluded that soy isoflavones are significantly efficacious in improvement of hot flashes in menopausal women.

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