Available online at **www.ijmrhs.com**

ISSN No: 2319-5886

International Journal of Medical Research & Health Sciences, 2016, 5, 8:257-263

The effect of salvia officinalis tablet on hot flashes, night sweating, and estradiol hormone in postmenopausal women

SimaKiani rad[1], Sedighe Forouhari[2]*, Alamtaj Samsami Dehaghani[3], HomeiraVafaei[4], Mehrab sayadi[5] and Maryam Asadi[1]

[1]Student Research Committee, Shiraz University of Medical Sciences, Shiraz, Iran
[2]Infertility Research Center, Shiraz University of Medical Sciences, Shiraz, Iran
[3] Infertility Research Center, Reproductive Endocrinology and Infertility Division, Department of OB-GYN, School of Medicine Shiraz University of Medical Sciences, Shiraz, Iran
[4]Department of Obstetrics and Gynecology, Shiraz University of Medical Sciences, Shiraz, Iran
[5] Student of biostatistics, Student Research Committee, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran
**Corresponding E-mail: forouharism@yahoo.com*

ABSTRACT

Hot flashes and night sweats associated with menopause are the most annoying symptoms among premenopausal women and have been ranked as the first reason for referral to medical centers. The common treatment for this symptom is administration of Hormone Replacement Therapy (HRT) that has some adverse effects and is sometimes contraindicated. Therefore, use of herbal drugs that have fewer side effects needs to be investigated. This study aimed to investigate the influence of salvia tablets on hot flashes, night sweats, and estradiol hormone in postmenopausal women referring to healthcare centers in Shiraz. This double-blind randomized clinical trial was performed on 100 qualified postmenopausal women with hot flashes. The study women were divided into two groups daily treated with 3 salvia or placebo tablets (100 mg) for 8 weeks. Estradiol hormone and menopause symptoms were evaluated using Menopause Rating Scale(MRS)1 week before and 8 weeks after the beginning the intervention. Besides, duration, intensity, and frequency of hot flashes and night sweats were evaluated every week, and the two groups were compared in terms of these variables. The results showed no significant difference between the two groups regarding demographic information, hot flashes, night sweats, and other menopause symptoms in MRS scale before the intervention. After 8 weeks, however, hot flashes, night sweats, and MRS scores significantly decreased in the saliva group compared to the control group. However, no significant difference was observed between the two groups concerning the estradiol levels. Yet, the results of intra-group analysis showed that the level of this hormone increased in the sage group. Sage tablets were effective in treatment of hot flashes, night sweats, and other menopausal symptoms in postmenopausal women. Thus, they can be considered as an alternative therapy for the individuals who are not able to use HRT.

Keywords: Saliva, Hot flashes, Night sweating, Estradiol

INTRODUCTION

Vasomotor symptoms, including hot flashes and night sweats, are the most common clinical symptoms in postmenopausal women[1]. The most frequent symptom; i.e., hot flashes, is experienced by up to 88% of the menopausal women[2]. This symptoms is the most annoying symptom among premenopausal women and has been ranked as the first reason for referral to medical centers[1]. Hot flashes are defined as the subjective feeling of

intense heat in the upper part of the body that may last from 30 seconds to 5 minutes. This symptom occurs mostly at night, and may lead to awakening the patients and poor sleep quality, eventually leading to fatigue, irritability, impaired memory, and poor concentration [1,2]. The prevalence of vasomotor symptoms in women has been reported to be74% in Europe, 38% in the United States, 36% in Canada, 50-68.9% in Latin America, and 22.1%-63.1% in Asian countries[3,4].In Iran, the prevalence rates of hot flashes and night sweats have been reported as 50-60% and 38.2%-53.1%, respectively[5, 6]. The etiology of hot flashes is still unknown. Nonetheless, Hormone Therapy (HT) is the most effective method to treat or reduce the symptoms of menopause, including hot flashes [1, 7].Unfortunately, these treatments have side effects, such as increased risk of breast cancer, thrombophlebitis, hypertension, vaginal bleeding, and gallbladder disease[8, 9].A steady decline was observed in the use of HT among the postmenopausal women at recruitment in the United Kingdom between April 2001 and September 2005.Between April 2001 and June 2002, the rate of HT use was 29% which was followed by a steady monthly decline; such a way that only 10-11% of the newly recruited women used HT from February to September 2005 [10]. In Iran, only 8.75% of postmenopausal women used HT[11].It has been estimated that 3–5 billion dollars annually spent on hormone replacement and physician monitoring by 2005[12]. Among the alternative treatments, herbs are the most common and popular methods. World Health Organization (WHO) considered complementary and alternative medicine approaches for prevention and treatment of diseases. These approaches may be effective in alleviating the menopausal symptoms and improvement of the long-term sense of well-being[13, 14]. Saliva, a member of the Labiacee family native to Mediterranean Europe, has been used in traditional medicine to treat excessive perspiration and sweating during menopause. Sage has a combination of the properties needed for a promising alternative to treat hot flashes and the associated climacteric complaints[15, 16]. However, its efficiency has not been confirmed via published clinical studies. Therefore, the present study aims to investigate the effects of salvia on menopausal symptoms.

MATERIALS AND METHODS

The present randomized clinical trial (Identifier: IRCT2014062218187N1) aimed to investigate the effect of salvia tablets on hot flashes, night sweats, and estradiol hormone in postmenopausal women referring to healthcare centers in Shiraz in 2014. This double-blind randomized clinical trial was performed on 100 postmenopausal women with hot flashes who were qualified for the study. The study women were divided into two groups, A and B, each containing 50 patients using randomized block permutation. Members of group A took medicine A and members of group B took medicine B. The women were well aware that they were divided into the study groups randomly. The study data were collected using a questionnaire including demographic information and Menopause Rating Scale (MRS) answered by the researcher. The participants' levels of plasma estradiol hormone were measured. Initially, the women were asked to complete the questionnaire that included the number, severity, and duration of hot flashes and number and severity of night sweats in the first week before the intervention. Then, they received three oral tablets (100mg) of sage+ or placebo per day for 8 weeks, and continued filling out the forms every week. At the end of the 8 weeks, MRS was completed by the researcher and estradiol test was repeated. After all, the collected data before and after the intervention were compared and statically analyzed.

RESULTS

This study was conducted on 93 patients (46 patients in the intervention group and 47 ones in the control group).Three patients in the control group and four patients in the intervention group were excluded from the study. The study results revealed no significant difference between the two groups regarding the demographic characteristics, including age, age at menopause, duration of menopause, body mass index, parity, education level, employment status, socioeconomic status, and marital status. Also, the results of independent t-test indicated no significant difference between the two groups with respect to the duration of hot flashes before the intervention. However, significant differences were observed between the two groups in this regard during the eight-week intervention ($P<0.001$).The mean duration of hot flashes in the saliva group was 3.54 ± 1.64 prior to the intervention, declined per week, and reduced to 1.38 ± 0.68 at the eighth week. Although significant changes were observed in the placebo group, the changes did not follow a descending trend (Figure 1).

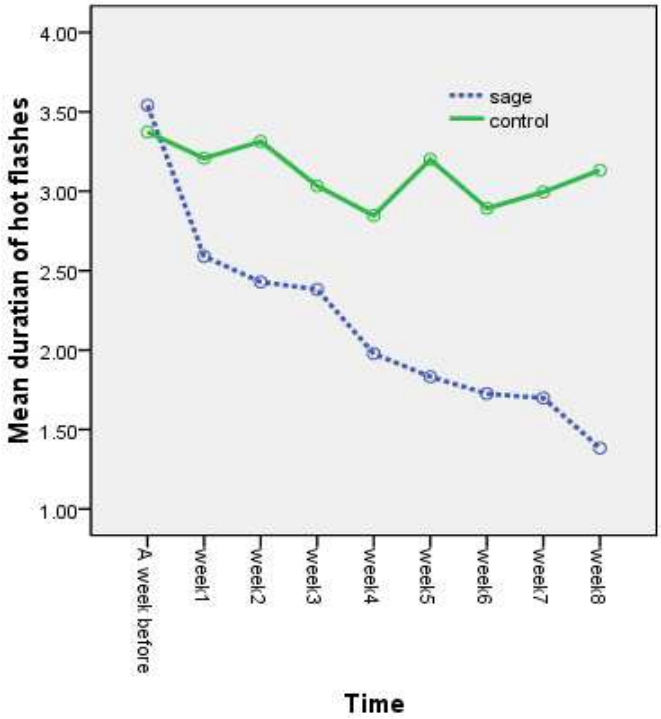

Fig. 1: Mean duration of hot flashes decrease strongly in sage group but in control group approximately plated after 8 week

The mean number of hot flashes was 5.74±2.62 in the intervention group and5.98±2.84 in the control group a week before the intervention. Although no significant difference at 5% level was observed between the two groups in this regard a week after the intervention (P=0.092), the difference was statistically significant in the following weeks (weeks 2-8) (P<0.001).Moreover, within group comparisons using repeated measures ANOVA showed a significant reduction in the mean number of hot flashes in the intervention group (P<0.001).Accordingly, the intervention group's mean number of hot flashes decreased from 5.74±2.62 a week before the intervention to 2.31±0.84 at the end of the intervention(Figure 2).

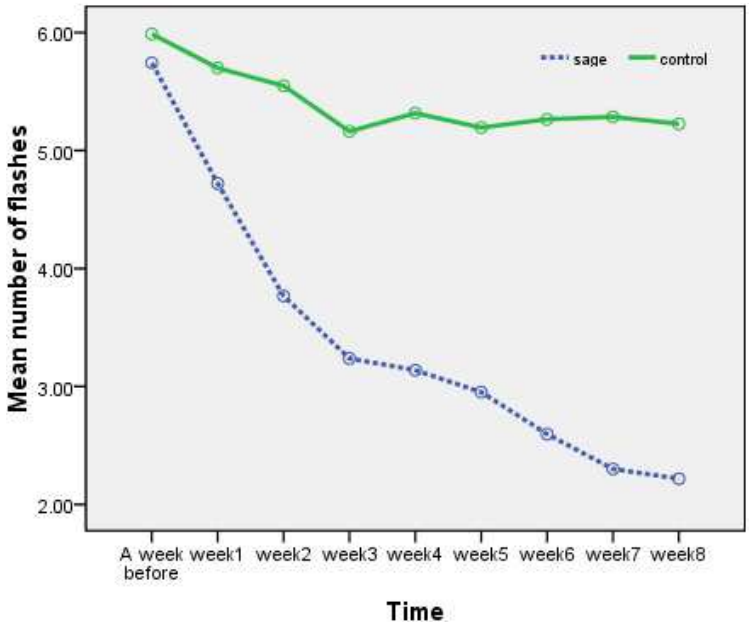

Fig. 2: Mean number of hot flashes decrease strongly in sage group but in control group approximately is plated after 8 week

In the intervention group, the mean severity of hot flashes decreased from 2.25 a week before the intervention to 2 in the first and second weeks, 1.75 in the third week, 1.5 in the fourth week, 1.25 in the fifth to seventh weeks, and 1 in the eighth week, and the differences were statistically significant (Figure 3).

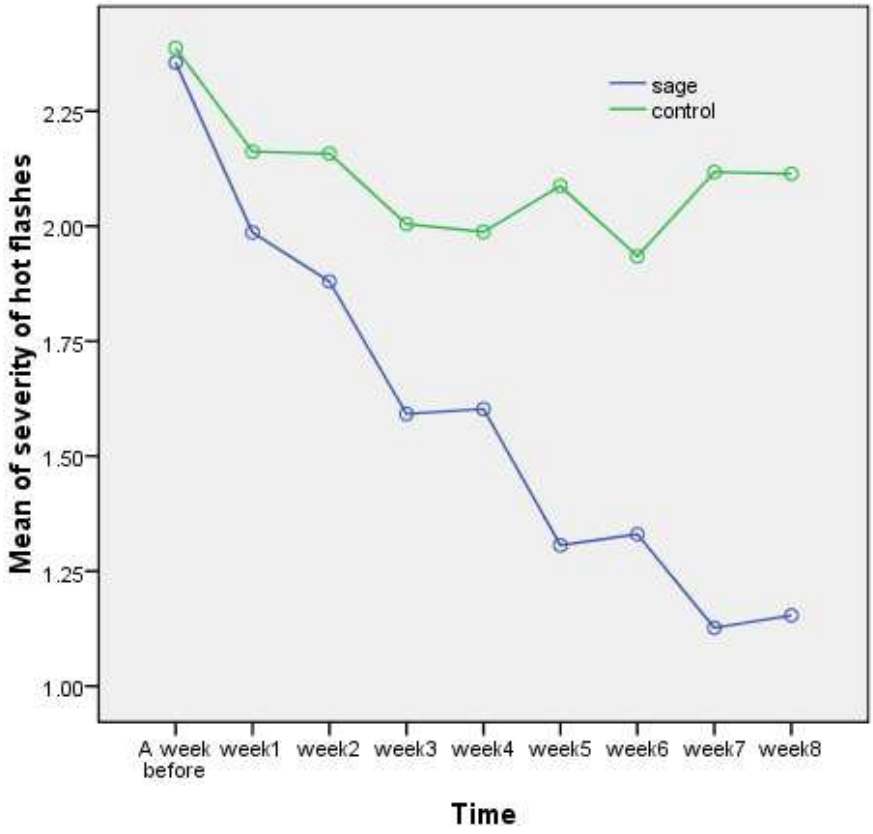

Fig. 3: Mean number of severity of hot flashes decrease strongly in sage group but in control group approximately plated after 8 week

The study results revealed no significant difference between the two groups regarding the mean number of night sweats a week prior to the intervention(P=0.717). The mean number of night sweats was 1.95±1.05 in the intervention group and 1.88±0.98 in the control group. However, the mean number of night sweats significantly decreased in the intervention group (P<0.001) (Figure 4).

The results showed no significant difference between the two groups concerning the severity of night sweats a week before and one and two weeks after the intervention. After three weeks, however, significant differences were found between the two groups in this regard. The severity of night sweats significantly decreased in the sage group, but showed no significant changes in the control group.

The study findings demonstrated no significant difference between the two groups regarding MRS total score before the intervention. Nevertheless, MRS scores reduced by 25.36% in the sage group after the intervention (P<0.001).

In this study, no significant difference was found between the two groups with regards to the mean serum estradiol levels (pg/ml) before and after the intervention. Nonetheless, the intervention group's mean estradiol level increased from 32.49±79.76 to 38.74±68, and the results of intra-group analysis showed that this increase was statistically significant (P=0.014).

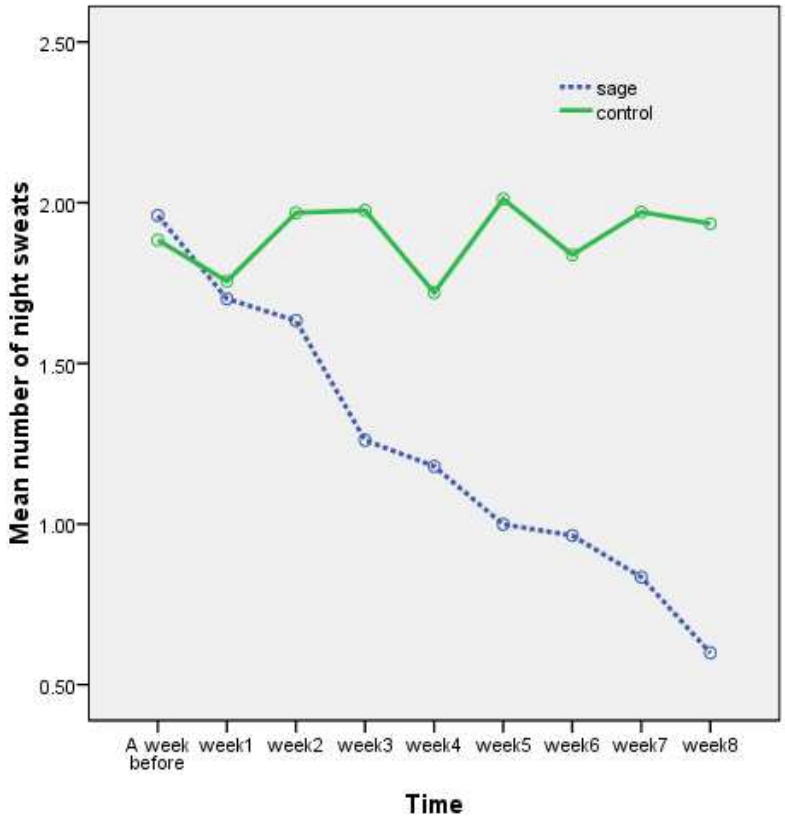

Fig. 4: Mean number of severity of night sweats decrease strongly in sage group but in control group approximately plated after 8 week

DISCUSSION

The findings of the current study showed that sage reduced hot flashes and night sweats and, thus, could improve the symptoms of menopause.

Bommer et al. performed a similar study to investigate the efficacy and safety of sage extract on hot flashes and other menopausal symptoms for 8 weeks. The findings of that study disclosed that daily use of salvia extract tablets significantly reduced the severity and frequency of hot flashes and menopausal symptoms. Also, no adverse events or laboratory abnormalities were observed during the study. These findings were in agreement with those of the current research [16].

Furthermore, De Leo and colleagues conducted a study on the effect of the combination of sage and alfalfa on menopausal symptoms. The results showed this compound to be effective in two-third of the menopausal women under study. Besides, estradiol basal levels remained unchanged. The findings of that research were consistent with those of the present study [17].

Gallagher et al. also assessed the effect of sage vs. placebo on the frequency of hot flashes in premenopausal complaints. The study results revealed no significant differences between sage and placebo groups with respect to frequency, duration, and severity of hot flashes. Nonetheless, a larger number of the patients taking sage rated their overall clinical conditions as improved compared to those taking the placebo [18].

A study by Vandecasteele et al in 2012 evaluated the efficacy and safety of sage in controlling hot flashes in patients with prostate cancer. The results is consistent with the present study and significantly reduce the number and severity of the symptoms [19].

Mohaisen and colleagues investigated the effect of a mixture of alfalfa and sage on the reproductive system of adult female mice. As a result of this study, a significant increase were detected in estradiol level in the treated group than in the control group. Histological studies showed a significant increase in the number of ovarian follicles and increasing the diameter of the endometrial glands. The researchers concluded that these findings may be due to a combination of plant phytoestrogens [20].

CONCLUSION

The findings of the current study showed that extracts of sage significantly reduced the frequency, severity, and duration of hot flashes and night sweats and improved the menopausal symptoms in menopausal women. Hence, this safe and effective herb can be recommended for treatment of menopausal symptoms.

Acknowledgment
This study was part of a Master of Science thesis and approved by the Shiraz University of Medical Sciences (the research project and grant No. 6942-92).

REFERENCES

[1] Berek J, Novak E. Berek and Novak's Gynecology. Lippincott Williams & Wilkins 2012.
[2] Freeman E, Sherif K. Prevalence of hot flushes and night sweats around the world: a systematic review. Climacteric. 2007;10(3):197-214.
[3] Ghaemi SZ, Forouhari S, Dabbaghmanesh MH, Sayadi M, Bakhshayeshkaram M, Vaziri F, et al. A prospective study of selenium concentration and risk of preeclampsia in pregnant Iranian women: a nested case–control study. Biological trace element research. 2013;152 (2):174-9.
[4] Archer D, Sturdee DW, Baber R, De Villiers T, Pines A, Freedman R, et al. Menopausal hot flushes and night sweats: where are we now? Climacteric. 2011;14(5):515-28.
[5] ASADI MOJGAN JZ, Nayebzadeh F. Prevalence of menopause symptoms among Iranian women. Journal of Family and Reproductive Health. 2012;6(1):1.
[6] Ashrafi M, Kazemi Ashtiani S, Malekzadeh F, Amirchaghmaghi E, Kashfi F, Eshrati B, et al. Symptoms of natural menopause among Iranian women living in Tehran Iran. Iranian journal of reproductive medicine. 2010;8(1):29-32.
[7] Shayan, A., Forouhari, S., Ahmadi Nia, H. The Effect of Body Mass Index on Sexual Function. Research Journal of Pharmaceutical, Biological and Chemical Sciences. 2015; 6(6):811-816.
[8] Pachman DR, Jones JM, Loprinzi CL. Management of menopause-associated vasomotor symptoms: Current treatment options, challenges and future directions. International journal of women's health. 2010;2:123.
[9] Hickey M, Elliott J, Davison SL. Hormone replacement therapy. BMJ. 2012;344:e763.
[10] Menon U, Burnell M, Sharma A, Gentry-Maharaj A, Fraser L, Ryan A, et al. Decline in use of hormone therapy among postmenopausal women in the United Kingdom. Menopause. 2007;14(3):462-7.
[11] Forouhari S,Khajehei M, Moattari M , Mohit M,Safari Rad M, , , Ghaem H. The effect of education and awareness on the quality-of-life in postmenopausal women.Indian Journal of Community Medicine. 2010; 35(1): 116-121.
[12] Borrelli F, Ernst E. Alternative and complementary therapies for the menopause. Maturitas. 2010;66(4):333-43.
[13] Gollschewski S, Kitto S, Anderson D, Lyons-Wall P. Women's perceptions and beliefs about the use of complementary and alternative medicines during menopause. Complement Ther Med. 2008;16(3):163-8.
[14] Huntley AL, Ernst E. A systematic review of herbal medicinal products for the treatment of menopausal symptoms. Menopause. 2003;10(5):465-76.
[15] ESCOP Monographs. The Scientific Foundation for Herbal Medicinal Products. European Scientific Cooperative on Phytotherapy. Stuttgart: Thieme Press; 2003:452-455.
[16] Bommer S, Klein P, Suter A. First Time Proof of Sage's Tolerability and Efficacy in Menopausal Women with Hot Flushes .Springer Healthcare. 2011;28(6):490-500.
[17] De Leo V, Lanzetta D, Cazzavacca R, Morgante G. Treatment of neurovegetative menopausal symptoms with a phytotherapeutic agent. Minerva Ginecol. 1998;50(5):207-11.
[18] Gallagher J. Salvia officinalis for menopausal hot flushes: a pilot study. Focus on Alternative and Complementary Therapies. 2002;7(1):92-3.

[19] Vandecasteele K, Ost P, Oosterlinck W, Fonteyne V, De Neve W, De Meerleer G. Evaluation of the efficacy and safety of Salvia officinalis in controlling hot flashes in prostate cancer patients treated with androgen deprivation. Phytotherapy Research. 2012;26(2):208-13.
[20] Mohaisen H. Adaay SSA-D, Ferial K. Khazzal. Effect of aqueous extract of Medicago sativa and Salvia officinalis mixture on hormonal, ovarian and uterine parameters in mature female mice. J Mater Environ Sci. 2013;4(4):424-33.