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File: ■ Sage (*Salvia officinalis*)
■ Menopause
■ Hot Flashes

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RE: Fresh Sage Extract Shows Promise for Alleviation of Menopausal Symptoms

Bommer S, Klein P, Suter A. First time proof of sage's tolerability and efficacy in menopausal women with hot flushes. *Adv Ther.* 2011;28(6):490-500.

Menopausal symptoms are divided into 3 types: vasomotor (sweating, hot flashes, and palpitation), psychic and physical (fatigue, depression, decreased libido, cardiovascular, etc.), and urogenital (vaginal dryness, incontinence, and cystitis). The most frequent symptom of menopause is hot flashes. Sage (*Salvia officinalis*) is used traditionally to treat hot flashes, night sweats, and hyperhidrosis (excessive sweating). The purpose of this open-label, multicenter study was to evaluate the efficacy and safety of sage for the treatment of hot flashes and other symptoms of menopause.

Women (n = 69, aged 50-65 years) were recruited from 8 general practices in Switzerland from January 17, 2008 to December 16, 2008. Included patients had a time period of ≥ 12 months since their last menstruation and ≥ 5 hot flashes/day. Patients were excluded if they used medications, hormones, supplements, and/or herbs that influence menopausal symptoms within the last month before study commencement, had surgical or medical menopause, or had serious illnesses. For 56 days, patients were treated with 280 mg/day thujone-free sage spissum (dried) extract (Bioforce AG; Roggwil, Switzerland). The extract was equivalent to 3400 mg of a 1:17 strength tincture of fresh sage leaves. Patients recorded the number and intensity of hot flashes over 24 hours in a daily diary. Efficacy was assessed by evaluating the change in intensity and frequency of hot flashes, and the change of the total score of the mean number of intensity-rated hot flashes (TSIRHF). Also, at baseline and on day 56 (week 8), the patients completed the Menopause Rating Scale (MRS), which is a validated questionnaire that measures as a sum of 3 subscales (somato-vegetative, psychological, and genitourinary) the severity of 11 symptoms and quality-of-life of women with menopause. Blood pressure and laboratory values of blood drawn on these 2 days were used to evaluate safety.

After 8 weeks of treatment, the number of hot flashes/day significantly decreased from an average of 9.3 to 3.8 hot flashes/day (P = 0.0001). The number of mild hot flashes decreased 46% from baseline to week 8 (3.7 to 2.0 hot flashes/day, P > 0.05 [according

to the text]). The number of moderate hot flashes decreased by 62% from baseline to week 8 (3.9 to 1.5 hot flashes/day, $P = 0.0001$). The number of severe hot flashes decreased 79% from baseline to week 8 (1.4 to 0.3 hot flashes/day, $P = 0.0001$), and very severe hot flashes were reduced 100% (0.3 to 0 hot flashes/day, $P < 0.05$). TSIRHF significantly decreased by 64% at 8 weeks ($P = 0.001$ [noted in abstract]). A total of 56% of physicians and 54% of patients rated efficacy as very good or good, while 23% of physicians and 25% of patients rated efficacy as poor. The mean global MRS score significantly decreased by 43% ($P < 0.0001$), while for subscales the somato-vegetative was reduced by 43% ($P < 0.0001$), the psychological decreased 47% ($P < 0.0001$), and the urogenital decreased by 20% ($P < 0.01$). The largest decreases were for hot flashes and sleep problems.

There were only 2 adverse events (abdominal pain and mild diarrhea in 1 patient) that were considered related to the study medication. Tolerability was rated very good or good by 90% of the physicians and patients. There were no abnormal laboratory parameters that were considered clinically significant.

According to the authors, this was the first published study to demonstrate clinical efficacy of a sage mono-preparation in treating menopause symptoms. A limitation of the study was that there was no control group. This is a weakness of the study. The study design could have easily included a natural history control arm, where an untreated group is evaluated, or a placebo control group. Also, the authors did not discuss the fact that one-fourth of the physicians and patients considered sage as having poor efficacy. Nonetheless, the authors conclude that this sage extract was safe and effective in treating hot flashes and many other symptoms of menopause. The authors concede that additional rigorous research is needed to confirm the findings.

—Heather S. Oliff, PhD

The American Botanical Council has chosen not to reprint the original article.

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