Black Cohosh: Not Effective for Relieving Postmenopausal Symptoms

Newton KM, Reed SD, LaCroix AZ, et al. Treatment of vasomotor symptoms of menopause with black cohosh, multibotanicals, soy, hormone therapy, or placebo: a randomized trial. Ann Intern Med 2006;145:869–79.

Study Overview

Objective. To compare the efficacy of placebo versus 3 herbal regimens containing black cohosh and hormone replacement therapy for control of vasomotor symptoms in postmenopausal women.

Design. Randomized, double-blind, placebo-controlled trial.

Setting and participants. 351 postmenopausal women (aged 45–55 years) with vasomotor symptoms were enrolled from a health maintenance organization in Washington State from May 2001 to September 2004. Participants were randomized into 1 of 5 groups: (1) black cohosh 160 mg daily (n = 80); (2) multibotanical 200 mg daily that included black cohosh and 9 other ingredients (n = 76); (3) multibotanical plus dietary soy counseling (n = 79); (4) conjugated equine estrogen 0.625 mg daily, with or without medroxyprogesterone acetate 2.5 mg daily (n = 32); or (5) placebo (n = 84). Participants were assessed at 3, 6, and 12 months. Black cohosh and multibotanical supplementation were supplied as single batches and independently verified to contain specified levels of the active, ethanol-extracted triterpene glycosides.

Main outcome measure. Changes in rate and intensity of vasomotor symptoms and Wiklund Vasomotor Symptom Subscale scores.

Main results. There were no differences in the rate of vasomotor symptoms per day, symptom intensity, or the Wiklund Vasomotor Symptom Subscale scores between the herbal interventions groups and the placebo group at 3, 6, or 12 months' follow-up ($P > 0.05$ for all comparisons). However, symptom intensity was significantly worse with the multibotanical plus soy intervention compared with placebo at 12 months ($P = 0.016$). On average over all the follow-up time points, the difference in rate of vasomotor symptoms between placebo and any of the herbal treatments was less than 0.55 symptoms per day. In constrast, the difference for hormone therapy versus placebo was –4.06 vasomotor symptoms per day for the average over all the follow-up time points (95% confidence interval, –5.93 to –2.19 symptoms per day; $P < 0.001$).

Conclusion. Black cohosh alone or in combination with other herbal treatments did not reduce postmenopausal vasomotor symptoms in this cohort of well-educated, predominantly white women.

Commentary

While menopause is a normal part of aging for women, some women experience more severe vasomotor symptoms (eg, hot flashes, night sweats) and require pharmacologic management [1]. Estrogen replacement has long been the most effective treatment, but recently the Women's Health Initiative (WHI) study has raised serious safety concerns and has led many women to adopt reputedly safer, although unproven, alternative therapies [1,2]. In particular, black cohosh is one of the most popular herbs used for menopausal symptoms [3]. To date, most studies of herbal supplements have significant experimental flaws that limit their usefulness; hence, Newton and colleagues' current study is of timely importance.

This study was rigorously designed and adequately powered and followed participants for 12 months, with a 92% trial completion rate. After results from the WHI were published, current participants were given the chance to find out if they had been assigned to hormone therapy and to withdraw from the study, and new participants were given the choice of being randomized into nonestrogen arms only. Despite the fact that it had fewer participants, the estrogen arm was the only arm that demonstrated a statistically significant effect of treatment on vasomotor symptoms, which is consistent with prior studies [1]. Interestingly, the multibotanical plus soy diet intervention showed a small but statistically significant worsening of vasomotor symptoms only as a yearly aggregate. This occurred with only a relatively low increased intake of 1 additional daily serving of soy and should be treated as a spurious result. Lastly, too few serious adverse events (1 breast cancer, 1 endometrial cancer) occurred to make meaningful comparisons, although those in the estrogen arm noted more breast pain ($P < 0.001$) and menstrual disorders ($P = 0.04$).

This study by Newton and colleagues refutes the hypothesis that black cohosh is effective for vasomotor symptom control in postmenopausal women. Because the

population studied (ie, white, middle-aged, relatively well-educated women) is precisely the group that tends to use herbal supplements in the United States [1], it may be difficult to generalize the results to other populations whose rates and severity of vasomotor symptoms and response to black cohosh may be different.

Applications for Clinical Practice

Clinicians should inform their menopausal patients that using black cohosh as primary vasomotor symptom management is no more effective than placebo and that these symptoms do naturally decline over time.

—Review by Mark S. Horng, MD, MPH

References

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