

Evidence Based Practice Critically Appraised Topic

Black cohosh for Hot Flashes

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Clinical Scenario:

A 51 year old female presents to the clinic with complaints of hot flashes that continue to be getting progressively worse. She reports having multiple hot flashes on a daily basis, she recalls them starting in August or September of 2010. She states that this has affected her sleep, work, and even social gatherings. She has been informed by her physician that she is not a candidate for hormone replacement therapy. As a result of that information she would like to know if the herbal product black cohosh will help alleviate the vasomotor symptoms she is currently experiencing accompanied by menopause.

Clinical Question:

Can the herbal product black cohosh help alleviate hot flashes in menopausal women?

Articles:

Newton, K., Reed, S., LaCroix, A., Grothaus, L., Ehrlich, K., & Guiltinan, J. (2006). Treatment of vasomotor symptoms of menopause with black cohosh, multibotanicals, soy, hormone therapy, or placebo: a randomized trial. *Annals Of Internal Medicine*, 145(12), 869-879.

Shams, T., Setia, M., Hemmings, R., McCusker, J., Sewitch, M., & Ciampi, A. (2010). Efficacy of black cohosh-containing preparations on menopausal symptoms: a meta-analysis. *Alternative Therapies In Health And Medicine*, 16(1), 36-44.

The Search: Cochrane Database of Systemic Reviews

Search Terms: black cohosh, women, AND menopause

Critical Review of Study:

Newton et al. (2006) performed a one-year double blinded, placebo-controlled trial to assess the efficacy of black cohosh on vasomotor symptoms offering Level 2b evidence. Sham et al. (2010) completed a meta-analysis providing Level 1a evidence.

Newton et al. study consisted of 351 women between the ages of 45-55 years with 2 or more vasomotor symptoms per day. The controlled trial was designed to investigate the effects

of 3 naturopathic approaches for vasomotor symptom relief and hormone therapy compared with a placebo. The interventions consisted of : 1) Black cohosh, 160 mg daily; 2) multibotanical with black cohosh, 200 mg daily, and 9 other ingredients; 3) multibotanical plus dietary soy counseling; 4) conjugated equine estrogen, 0.625 mg daily, with or without droxyprogesterone acetate, 2.5 mg daily; or 5) placebo. The intensity of vasomotor symptoms were graded by (1 mild to 3 severe), and Wiklund Vasomotor Symptom Subscale.

Sham et al. (2010) completed the review of literature in PubMed, Embase, and Cochrane library aimed on evaluating the efficacy of herbal preparations containing black cohosh for treatment of menopausal symptoms. The data search included black cohosh, cimicifuga racemosa, actacea racemosa and menopause. Inclusion and exclusion criteria were established, studies that met the following criteria was included: study design was an RCT, population comprised perimenopausal/ postmenopausal women, intervention was a preparation containing black cohosh, at least one of the control groups was placebo, and at least one of the outcomes was the frequency of vasomotor symptoms. Studies that were conducted exclusively in women with a history of breast cancer were excluded. The first search results consisted of 223 abstracts and 31 potential studies for review. Then out of 22 RCTs, 13 did not meet the inclusion criteria. As a result, nine RCTs were retained for the meta-analysis.

Results:

Newton et al. study results revealed that there was no difference between the herbal interventions and placebo at 3, 6, or 12 months or for the average over all the follow-up time points ($P > 0.05$ for all comparisons) with 1 exception: The difference in vasomotor symptoms per day between placebo and any of the herbal treatments at any time point was less than 1 symptom per day; for the average over all the follow-up time points, the difference was less than 0.55 symptom per day. Some limitations to this study were its small patient population size of only 315 patients. Newton et al. results indicated that black cohosh used in isolation, or as part of a multibotanical regimen, showed little potential as an important therapy for relief of vasomotor symptoms.

Sham et al. (2010) meta-analysis of placebo-controlled RCTs with preparations containing black cohosh in healthy perimenopausal women between the ages of 40 and 60 years. The overall results determined that black cohosh-containing preparations were found to be

efficacious in reducing the symptoms of menopause in comparison to placebo. The meta-analysis also revealed that black cohosh in combination with other multibotanicals and St John's wort appeared to be more efficacious in treating menopausal symptoms compared with black cohosh alone. The results also conveyed some of the commonly reported side effects in the black cohosh group were gastrointestinal symptoms (0.7%-15%), musculoskeletal and connective tissue conditions (4%-9.8%). Strengths of the systematic review are the inclusion of only randomized double-blind placebo-controlled trials of black cohosh, so limitations of the meta-analysis are the small number of trials and the dose and formulation of black cohosh were different in the RCTs. Overall, the results were unvarying with those of previous reviews that suggested a benefit of black cohosh in reducing the frequency of vasomotor symptoms.

Clinical Bottomline:

After reviewing the level of evidence (Level1A and Level2B) I would support the use of black cohosh to help alleviate vasomotor symptoms caused by menopause. The two articles did vary in level of evidence, but reviewing Level1A evidence that black cohosh can reduce the frequency of vasomotor symptoms helps me conclude my clinical decision. The data is limited on the dosage of black cohosh that would be effective warrants me to research further to suggest a appropriate daily dosage. The evidence also discloses that black cohosh is safe but can have possible adverse effects, so I would inform patients of this when developing a treatment plan. Therefore in the clinical case involving the 51 year old female who is not a candidate for hormone replacement therapy I would suggest she use black cohosh for her hot flashes.