

Herbal supplements did not relieve vasomotor symptoms of menopause

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.

Clinical impact ratings: GIM/FP/GP ★★★★★☆☆

QUESTION

Do herbal supplements relieve vasomotor symptoms of menopause in women?

METHODS

Design: Randomized placebo-controlled trial (Herbal Alternatives for Menopause Trial [HALT]).

Allocation: Concealed.*

Blinding: Blinded (clinicians, participants, {data collectors, and outcome assessors}†).*

Follow-up period: 12 months.

Setting: Washington State, United States.

Patients: 351 women 45 to 55 years of age (mean age 52 y, 93% white) who were in menopausal transition or were postmenopausal with ≥ 2 vasomotor symptoms per day for 2 weeks (≥ 6 moderate-to-severe symptoms). Exclusion criteria included contraindications to hormone therapy (HT), use of HT or oral contraceptives in the past 3 months, use of herbal medicines in the past month, bilateral oophorectomy, or history of breast cancer.

Intervention: Black cohosh (*Actaea racemosa* or *Cimicifuga racemosa*), 160 mg/d, triterpene glycosides, 2.5%, and ethanol extract, 70% ($n = 80$); multibotanical (MB) ($n = 76$); MB plus dietary soy ($n = 79$); conjugated equine estrogen (CEE), 0.625 mg/d, with (uterus) or without (no uterus) medroxyprogesterone acetate (MPA), 2.5 mg ($n = 32$); or placebo ($n = 84$).

Outcomes: Frequency and intensity of vasomotor symptoms (hot flashes and night sweats) and Wiklund Vasomotor Symptom score rating (0 [none] to 10 [severe]).

Patient follow-up: 93% (intention-to-treat analysis).

MAIN RESULTS

At 12 months, the black cohosh and MB groups did not differ from the placebo group for any outcome; the MB-plus-soy group had higher intensity of vasomotor symptoms but did not differ from the placebo group for frequency of symptoms and Wiklund score (Table). The CEE-with-or-without-MPA group had lower frequency of symptoms and lower Wiklund scores than did the placebo group (Table).

CONCLUSIONS

Herbal supplements did not relieve vasomotor symptoms of menopause in women. Hormone therapy reduced the frequency and severity of symptoms more than did placebo.

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*See Glossary.

†Information provided by author.

Herbal supplements or conjugated equine estrogen (CEE) with or without medroxyprogesterone acetate (MPA) vs placebo in women during menopause at 12 months†‡

Outcomes	Treatment	Difference in mean change between groups (95% CI)
Frequency of vasomotor symptoms (hot flashes and night sweats)	Black cohosh	-0.2 (-1.3 to 0.9)
	Multibotanical	0.09 (-1.0 to 1.2)
	Multibotanical + soy	0.5 (-0.6 to 1.6)
	CEE with or without MPA	-3.8 (-5.8 to -1.8)
Intensity of vasomotor symptoms (hot flashes and night sweats)	Black cohosh	0.05 (-0.07 to 0.2)
	Multibotanical	0.1 (-0.02 to 0.2)
	Multibotanical + soy	0.2 (0.03 to 0.3)§
	CEE with or without MPA	0.05 (-0.2 to 0.3)
Wiklund vasomotor symptom score	Black cohosh	0.1 (-0.7 to 0.9)
	Multibotanical	0.4 (-0.3 to 1.2)
	Multibotanical + soy	0.6 (-0.2 to 1.4)
	CEE with or without MPA	-1.8 (-2.8 to -0.8)

†CI defined in Glossary. Based on a mixed model and adjusted for age, body mass index, hysterectomy, previous hormone therapy, menopausal status, and randomization.

§Intervention had worse intensity of symptoms than did placebo.

||Severity of sweats, hot flashes, sleep disturbance, fatigue, vaginal dryness, depression, headache, irritability, muscle or joint pain, breast tenderness, nervousness, palpitations, and dizziness or fainting.

COMMENTARY

The study by Newton and colleagues fails to support the use of popular complementary and alternative medicine (CAM) treatments for menopausal symptoms, a condition for which such treatments are often recommended. The study was well designed and executed and has many strengths. HALT was blinded, randomized, and controlled and had several treatment groups, including those given black cohosh, soy, and MB. Only women with ≥ 2 hot flashes/d were included, representing the 20% of menopausal women considered to have at least moderate symptoms (1). Reliable symptom scales were used to measure response. Most important, alternative treatments were compared not only with placebo but also with HT, the standard treatment for menopausal symptoms.

Newton and colleagues found that alternative therapies did not differ from placebo, while HT was considerably better than placebo. Yet women are reluctant to take HT because of understandable concerns that include increased risk for breast cancer, heart disease, and thrombosis (2). What can doctors recommend? While all CAM therapies

have not been tested as rigorously as those in HALT, it is unlikely that other CAM agents, from red clover to Chinese herbs to magnet therapy, will be more successful. Various pharmaceuticals (including the antidepressants venlafaxine, paroxetine, and fluoxetine; the antihypertensives clonidine and methyldopa; and the anticonvulsant gabapentin) have, at best, modest benefit in treating hot flashes (3, 4).

What remains uncontested is that HT is the best treatment for menopausal symptoms. If other measures do not ameliorate disruptive symptoms, most authorities continue to recommend estrogen (with or without progesterone) at the lowest possible dose for the shortest possible time.

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References

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