Review: Most herbal therapies have no benefit for menopausal symptoms

Kronenberg F, Fugh-Berman A. **Complementary and alternative medicine for menopausal symptoms: a review of randomized, controlled trials.** Ann Intern Med. 2002;137:805-13.

QUESTION

In women with menopausal symptoms, are complementary and alternative medicine (CAM) therapies effective and safe?

DATA SOURCES

Studies were identified by searching MEDLINE (1966 to March 2002), the Alternative and Complementary Database (AMED) (1985 to 2000), and personal files.

STUDY SELECTION

Studies in any language were selected if they were randomized controlled trials (RCTs) of CAM therapies in menopausal women. Studies of single symptoms or conditions that were not associated with menopause were excluded.

DATA EXTRACTION

Data were extracted on study year, country, design, patient characteristics, dose and duration of treatment, outcome measures, and results. Study quality was not assessed.

MAIN RESULTS

29 RCTs were included. The Table summarizes the RCT findings. 3 of 4 short-term RCTs on black cohosh reported no difference in symptoms compared with control. 6 of 11 RCTs with dietary phytoestrogens (soy or isoflavone supplementation) showed some improvement in hot flashes or menopausal symptoms. Red clover, evening primrose oil, ginseng, dong quai, a Chinese herbal formula, vitamin E, and wild yam cream did not reduce hot flashes. For nondrug therapies, unblinded trials suggest acupuncture was not effective, paced respiration was superior to biofeedback, and relaxation therapy was more beneficial than reading (4 small trials). The product, dosage, scoring systems for hot flashes, and menopausal cause and status of patients varied across studies. No data on long-term safety for any of the products have been published.

CONCLUSIONS

No consistent evidence exists that complementary therapies benefit women with menopausal symptoms. Harm has not been studied.

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Complementary and alternative medicine therapies for menopausal symptoms*

Treatment	Number of RCTs	Length of follow-up	Results for menopausal symptoms
Black cohosh	4	2 to 6 mo	3 RCTs showed no difference between black cohosh and control
Red clover	2	3; 7.5 mo	No difference between red clover and placebo
Dong quai	1	6 mo	No difference between dong quai and placebo
EPO	1	6 mo	Placebo better than EPO for hot flashes
Ginseng	1	4 mo	No difference between ginseng and placebo
Chinese herbal formula	1	3 mo	No difference between the Chinese herbal formula and placebo
Soy and soy extracts	11	6 to 28 wk	6 RCTs showed some difference in hot flashes (e.g., severity, frequency, or symptom score)
Vitamin E	2	3 y; 4 wk	1 RCT (3 y) showed no difference; 1 showed clinically insignificant benefit
Wild yam cream	1	3 mo	No difference between wild yam cream and placebo

*EPO = evening primrose oil; RCT = randomized controlled trial.

COMMENTARY

Although the use of CAM has increased dramatically over the past decade in North America (1–3), the evidence supporting its efficacy for menopausal symptoms is sparse. Kronenberg and Fugh-Berman identified black cohosh and soy as promising therapies in their systematic review. Few studies examined symptoms, such as vaginal dryness, sleep, or mood disturbances. The studies' methodological weaknesses include lack of placebo control, short duration, no reporting of statistical significance, high dropout rates, and no intention-to-treat analysis. The 1 placebo-controlled trial that found black cohosh to be effective for hot flashes did not find estrogen to be effective, which casts doubt on the study's validity. Most soy studies were reported as placebo-controlled and double-blind; however, the blinding is questionable because soy and rice beverages taste different. Many studies also found an effect in the placebo groups, which emphasizes the importance of placebo-controlled trials.

Menopausal women commonly use CAM therapies, and many use herbal therapies for long-term periods as alternatives to hormone therapy. In view of recent data from the Women's Health Initiative (4), it is crucial to establish the long-term safety of herbal therapies, especially compounds that may have estrogenic activity. Of interest, relaxation techniques, such as paced respiration, decreased hot flashes and were safe.

The review's take-home message is that paced respiration may be effective and safe for management of menopausal symptoms; most herbal therapies do not have efficacy or safety data supporting their use. Soy and soy extracts are promising but require further studies. Currently, many herbal therapies are expensive and have no guarantee that they contain the supposed active ingredient or that contaminants do not exist. As health care providers and researchers, we should advocate for more standardization and regulation of CAM therapies and more vigorous research into their long-term efficacy and safety.

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