

**Complementary Treatments for Hot  
Flashes in Postmenopausal Women:**  
An evidence based review of the literature

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**Question**

- In postmenopausal women ages 48-55, how do complementary and alternative treatments compare in terms of efficacy and safety to hormone therapy and/or placebo in the treatment of hot flashes?

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**Background**

- **Menopause**-a period of time women experience 12 months after amenorrhea and cessation of ovulation.
- Signs and symptoms of menopause: hot flashes, night sweats, depressed mood, sleep disturbances, decreased libido, cognitive difficulties, vaginal dryness, and body aches
- **Hot flash**-a sudden and uncomfortable sensation of warmth that begins in the chest and moves through the face and neck lasting anywhere from a few seconds up to several minutes

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## Background

- Current treatment
  - Hormone replacement therapy (combination estrogen/progestin)
    - ✦ Adverse effects-increased incidence of breast cancer, coronary heart disease, stroke, pulmonary embolism
    - ✦ Up to 45% of women on HRT discontinue their prescription after one year

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## Background

- Alternative therapies:
  - **Black cohosh**-popular herb used extensively in the Native American culture for the treatment of a number of gynecologic conditions.
    - ✦ Mechanism of action involves a dopaminergic effect on the CNS which may decrease hot flashes
  - **Soy isoflavones**-plant derived diphenolic compounds that exhibit both hormonal and nonhormonal properties.
    - ✦ Bind to estrogen receptors and alter physiological hormonal processes.

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## Incidence/Prevalence

- 1.3 million women reach menopause annually in the United States
- 20% of all women will experience symptoms for less than one year while approximately 50% will experience the for up to five years
- Hot flashes are experienced by up to 80% of women going through menopause

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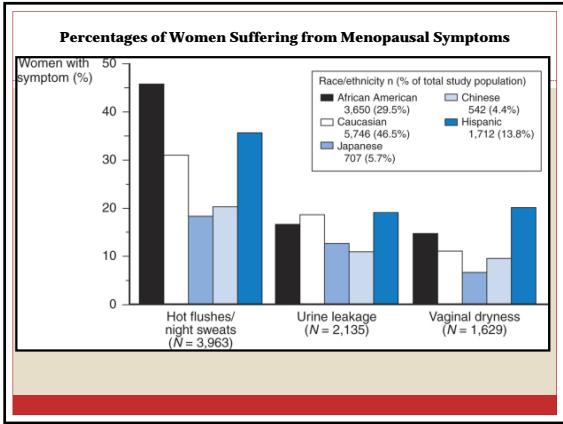
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**Etiology/Risk Factors**

- **Etiology**-As women age, the number of ovarian follicles decrease. Ovarian production of estrogen and inhibin decreases and LH and FSH secretion increases. Without estrogen, endometrial development fails and menstrual cycles cease.
- **Risk Factors**-increasing age, oophorectomy, sex chromosome abnormalities

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**Key Evidence/Results**

- **Six articles reviewed**
  - Located by PubMed search, evidence based reviews, and AAPA journal
  - Journal articles dated between the years 2000-2007
  - Search restricted to randomized controlled studies published in English including women in their 40s and 50s who had naturally transitioned into menopause.

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## Results: Black Cohosh

- **STUDY 1:** A 2005 randomized, multicenter, double-blind clinical trial compared the efficacy and tolerability of isopropanolic black cohosh extract in the treatment of climacteric complaints compared with placebo. The study concluded that isopropanolic black cohosh extract was significantly more effective than placebo.
- **STUDY 2:** A 2006 randomized double blind, trial compared black cohosh with a number of additional treatment options including multibotanicals, estrogen replacement therapy, and placebo. It was concluded from this study that black cohosh alone or in combination showed little potential for relief of vasomotor symptoms.
- **STUDY 3:** Another 2006 randomized double blind study explored the efficacy of black cohosh in the form of Cimicifuga racemosa compared with placebo in the treatment of hot flashes. This trial failed to provide any evidence that black cohosh reduced hot flashes more than placebo.

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## Results: Soy isoflavones

- **STUDY 4:** A 2002 randomized double blind placebo controlled trial explored the change in menopausal symptoms and cardiovascular risk factors in response to soy isoflavone in postmenopausal women. This study suggests that isoflavone may be a safe and effective alternative therapy for menopausal symptoms and may offer a benefit to the cardiovascular system.
- **STUDY 5:** A 2002 multicenter randomized double blind placebo controlled study investigated the effect of an oral soy isoflavone extract on hot flashes in menopausal women. It was concluded that soy isoflavone extract may help to reduce the frequency of hot flashes in climacteric women and provides an attractive alternative to hormone replacement therapy.
- **STUDY 6:** A 2003 multicenter double blind randomized study evaluated the effect of soy isoflavones and melatonin in relieving menopausal symptoms. Treatment groups included 1) soy isoflavones + melatonin 2) soy isoflavones alone 3) melatonin alone 4) placebo. The study concluded that there is no advantage of isoflavones or melatonin over placebo for the relief of menopausal symptoms.

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## Conclusion

- Black cohosh and soy isoflavone both have the potential to be effective when administered orally for the treatment of menopausal symptoms in healthy adult females.
- The alternative regimes have low toxic profiles and are well tolerated by patients when taken correctly.
- Hormone replacement therapy remains the therapeutic standard for preventing menopausal symptoms but this is not always a safe or effective option.
- Primary care providers should take into consideration patient specific concerns and utilize these proven helpful products in reducing the duration and severity of symptoms.
- Regardless of the management strategy adopted, treatment should be periodically reassessed as menopause related vasomotor symptoms will abate over time without any intervention in most women.

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### Clinical Pearls

- Essentials of menopause diagnosis:
  - 1. Cessation of menses due to aging or bilateral oophorectomy
  - 2. Elevation of FSH and LH levels
  - 3. Hot flushes and night sweats (80% of women).
  - 4. Decreased vaginal lubrication, thinned vaginal mucosa with or without dysparunia

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### Clinical Pearls

- Treatment options:
  - Oral conjugated estrogens or transdermal estrogen in combination with progesterone are the first line treatment option for menopausal symptoms.
  - Women who are at risk for cardiovascular disease, cerebrovascular disease, and breast cancer should use caution when using HRT.
  - Data from the Women's Health Initiative study suggest that women should not use combination progestin-estrogen therapy for more than 3 to 4 years.
  - Alternative treatment options include paroxetine or venlafaxine as well as gabapentin and clonidine.
  - Other potential "natural" alternatives may include Vitamin E, black cohosh, and soy isoflavone.

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Carol found her own way of coping with the hot flushes



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