



Evaluating the evidence for over-the-counter alternatives for relief of hot flashes in menopausal women

Kristi W. Kelley and Dana G. Carroll

Abstract

Objective: To review the literature on alternative over-the-counter (OTC) therapies for the treatment of hot flashes in menopausal women.

Data sources: A literature search was conducted using PubMed, International Pharmaceutical Abstracts, and Medline from inception to June 2010, combining the term *hot flash* individually with *black cohosh*, *isoflavones*, *red clover*, *soy*, *vitamin E*, *ginseng*, *dong quai*, *evening primrose oil*, *wild yam*, *kava*, and *melatonin*. All publication types including human participants and published in English were eligible for review. These articles, relevant abstracts, and additional references were used to collect pertinent data.

Study selection and data extraction: Clinical trials comparing the above single-ingredient agents with placebo or active treatment were selected. In addition, only studies assessing the effects of these single-ingredient agents on vasomotor symptoms in menopausal women were included.

Data synthesis: Since the Women's Health Initiative and Heart and Estrogen/Progestin Replacement Study II, women have sought lifestyle changes and other drug therapies as alternatives to menopausal hormone therapy to relieve hot flashes associated with menopause. The currently available literature is conflicting in regard to efficacy and does not support the use of alternative OTC therapies for hot flash management associated with menopause. In addition, long-term safety data are lacking for any of these therapies.

Conclusion: Women should be encouraged to implement therapeutic lifestyle changes to assist them with hot flash management. Based on the current literature, alternative OTC therapies do not have consistent, beneficial data to support their use in hot flash management.

Keywords: Hot flashes, menopause, pharmacotherapy, OTC products, nonprescription medications.

J Am Pharm Assoc. 2010;50:e106–e115.

doi: 10.1331/JAPhA.2010.09243

Received December 31, 2009, and in revised form July 2, 2010. Accepted for publication July 12, 2010.

Kristi W. Kelley, PharmD, BCPS, CDE, is Clinical Associate Professor, and **Dana G. Carroll, PharmD, BCPS**, is Clinical Associate Professor, Harrison School of Pharmacy, Auburn University, Alabama.

Correspondence: Kristi W. Kelley, PharmD, BCPS, CDE, Continuity Clinic at Trinity Medical Center/Baptist Health System, Inc., 840 Montclair Rd., Suite 122, Birmingham, AL 35213. Fax: 205-979-2980. E-mail: wat-sokm@auburn.edu

Disclosure: The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

Published concurrently in *JAPhA* and *Pharmacy Today*.

This article is part of a larger CPE activity, Today's Focus on Women's Health. To view all activity content and earn CPE credit, go to the Online CPE Quick list at www.pharmacist.com/education and click on the title, Today's Focus on Women's Health, to complete and submit the CPE exam online. A Statement of Credit will be awarded for a passing grade of 70% or better. You will have two opportunities to successfully complete the CPE exam. Pharmacists who successfully complete the activity before August 15, 2013, can receive credit.

Evidence shows that 75% to 85% of perimenopausal women experience vasomotor symptoms^{1,2} and that 75% of postmenopausal women experience hot flashes.^{2,3} Women usually begin experiencing these symptoms in the perimenopausal period, with a peak incidence in the first 2 years postmenopause.² Hot flashes result from peripheral vasodilation, causing increases in body temperature, especially in the extremities.² Women usually notice warmth over their upper body and face that may also be accompanied by sweating and increases in heart rate. Although hot flashes usually last 1 to 5 minutes, it may take up to 30 minutes for body temperature to return to normal. Although most women cannot predict the occurrence of hot flashes, the early evening hours tend to be when activity peaks.² These vasomotor symptoms usually last 6 months to 2 years; however, they may continue up to 5 years, with a small percent of women experiencing symptoms for 15 years.²⁻⁴

Traditional hormone therapy, which is known to reduce hot flashes in 80% to 90% of women, has been the treatment of choice for vasomotor symptoms.^{1,3} Before findings of the Wom-

en's Health Initiative (WHI) were published,⁵ hormone therapy prescriptions reached a peak of 91 million in 2001.⁶ After WHI and the Heart and Estrogen/Progestin Replacement Study II (HERS II),^{7,8} which was published in July 2002, the number of prescriptions dispensed for hormone therapy declined to an estimated 56.9 million.⁶

Recent evidence from WHI has shown that menopausal hormone therapy should be used for the shortest length of time to limit the risk of coronary events, venous thromboembolism, strokes, and invasive breast cancer.^{3,9-11} In light of WHI, many women are skeptical of using menopausal hormone therapy. Reports indicate that as many as 30% to 45% of women will not fill their prescriptions for hormone therapy or may decide to stop menopausal hormone therapy within the first 12 months of therapy.³

Since the results of WHI and HERS II were published, women have sought lifestyle changes and other drug therapies as alternatives to hormone replacement therapy to relieve hot flash symptoms associated with menopause. Current estimates indicate that women use alternative treatments more frequently than men.¹² Alternative treatments (also called herbal remedies and/or natural medications by the lay public) are regulated as dietary supplements, which means that the content of active ingredients, purity of ingredients, and health claims are not regulated by the Food and Drug Administration (FDA). However, many patients do not realize this and view these products as "natural," believing them to be harmless. Another concern with alternative products is that they are available for patients to purchase without a prescription (over the counter [OTC]) and often without guidance from a health professional. Because patients consider these products "natural" and do not view them as medications, they often neglect to tell health care providers that they are taking alternative OTC products. Patients will often read about alternative therapies on their own; therefore, health care providers should remain informed about the products so that they can provide appropriate counseling.

At a Glance

Synopsis: In light of recent evidence indicating that hormone replacement therapy should be used for the shortest length of time to limit the risk of coronary events, venous thromboembolism, strokes, and invasive breast cancer, many women are seeking alternative therapies for hot flashes. A search of the literature was therefore conducted to determine whether various over-the-counter (OTC) therapies, such as soy, black cohosh, and vitamin E, were effective at relieving hot flashes in menopausal women. The current literature suggests that alternative OTC therapies do not have consistent, beneficial data to support their use in managing hot flashes. Lifestyle changes (e.g., exercise, healthy eating, smoking cessation, limiting alcohol consumption, using paced respiration) should be initially encouraged for women seeking relief from hot flashes.

Analysis: Based on available evidence, the American College of Obstetricians and Gynecologists concluded in 2004 that "treatment with wild yam extract, black cohosh or dietary phytoestrogen supplements derived from the isoflavone red clover has no significant effects on vasomotor symptoms," and no studies have appeared since that time to contradict these recommendations. Health care providers should remain familiar with alternative therapies claiming to relieve hot flashes in order to educate patients about potential benefits and risks of these therapies. Alternative non-prescription products are not without risk; however, neither are prescription products. Therefore, patients should be counseled so that they can make the best decision to relieve hot flashes and to minimize adverse events.

Study selection

Many studies have been published in the past 2 decades on alternative OTC therapies for hot flashes associated with menopause. A literature search was conducted using PubMed, International Pharmaceutical Abstracts, and Medline from inception to June 2010, combining the term *hot flash* individually with *black cohosh*, *isoflavones*, *red clover*, *soy*, *vitamin E*, *ginseng*, *dong quai*, *evening primrose oil*, *wild yam*, *kava*, and *melatonin*. The search was limited to English language and human studies. Additional reports were identified via the reference citations of articles retrieved. Clinical trials comparing the above single-ingredient agents with placebo or active treatment were selected. In addition, only studies assessing the effects of these single-ingredient agents on hot flash/vasomotor symptoms in menopausal (natural, surgical, or chemical) women were included.

Below we discuss menopausal hot flashes, describe lifestyle changes for managing hot flashes, and provide an in-depth review of the literature for alternative OTC therapies for treating hot flashes in menopausal women.

Download English Version:

<https://daneshyari.com/en/article/2543841>

Download Persian Version:

<https://daneshyari.com/article/2543841>

[Daneshyari.com](https://daneshyari.com)