Black Cohosh-HealthProfessional

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Black Cohosh  
Fact Sheet for Health Professionals  
  
Introduction  
Black cohosh (Actaea racemosa or Cimicifuga racemosa), a member of the buttercup family, is a perennial plant native to North America. Other, mostly historical, names for this herb include snakeroot, black bugbane, rattleweed, macrotys, and rheumatism weed [1,2]. Black cohosh has a long history of use. Native Americans used it, for example, to treat musculoskeletal pain, fever, cough, pneumonia, sluggish labor, and menstrual irregularities [3]. European settlers used black cohosh as a tonic to support women s reproductive health [4].  
  
Today, black cohosh is most commonly used for menopausal symptoms, including hot flashes (also called hot flushes) and night sweats (together known as vasomotor symptoms), vaginal dryness, heart palpitations, tinnitus, vertigo, sleep disturbances, nervousness, and irritability [5,6]. Menopause, which typically occurs in women at about 51 years of age, is the cessation of menstruation and the end of a woman s reproductive period [5].  
  
This fact sheet provides an overview of the use of black cohosh to relieve menopausal symptoms.  
  
Black Cohosh Dietary Supplements  
Preparations of black cohosh are made from its roots and rhizomes (underground stems). They are sold as dietary supplements in such forms as powdered whole herb, liquid extracts, and dried extracts in pill form [7].  
  
Available preparations vary considerably in their chemical composition, in part because the compounds in black cohosh that may be responsible for any relief of menopausal symptoms are not known. Substances in black cohosh that may account for its activity include triterpene glycosides such as actein, 23-epi-26-deoxyactein, and cimicifugoside; resins, such as cimicifugin; and aromatic acid derivatives such as caffeic, isoferulic, and fukinolic acids [8,9].  
  
Products containing black cohosh extract are frequently standardized to provide at least 1 mg triterpene glycosides per daily dose [10]. Remifemin, a commercial black cohosh product used in several studies included in a 2012 Cochrane Review described below, is an extract currently standardized to be equivalent to 40 mg black cohosh root/rhizome (extracted with isopropyl alcohol) per daily dose of two tablets, but it is not standardized to triterpene glycoside content [7,11]. The product has been on the market for years and has been reformulated over time [10].  
  
Black Cohosh and Menopausal Symptoms  
Studies using various designs since the 1950s have attempted to determine whether black cohosh affects menopausal symptoms [12]. Complicating efforts to understand the efficacy of black cohosh for treating menopausal symptoms is the wide variation in the chemical compositions of formulations. Black cohosh s active ingredients and potential mechanism(s) of action are unknown. Studies have found varying results for the plant s effects on human physiology as to whether, for example, it raises the body s levels of estrogen, which is present in lower levels in menopausal women than in premenopausal women, or whether it affect levels of luteinizing hormone or follicle-stimulating hormone [13,14]. It is not clear whether black cohosh affects the structure and activity of vaginal and uterine tissues [5,15]. Some researchers believe that black cohosh might exert its effects through a brain-related action, such as modulation of serotonergic pathways, or through its potential ability to act as an antioxidant, anti-inflammatory, or selective estrogen receptor modulator [5,15-17].  
  
Two high-quality randomized controlled trials investigating black cohosh for menopausal symptoms are described here. One, published in 2006, assigned 351 women age 45 55 years experiencing daytime hot flashes and night sweats into one of five groups to take one of the following [18]:  
  
160 mg/day black cohosh (70% ethanolic extract standardized to contain 2.5% triterpene glycosides)  
A multibotanical preparation containing 200 mg black cohosh along with Siberian ginseng, dong quai, and other ingredients  
The same multibotanical preparation plus two daily servings of soy foods providing 12 20 g soy protein  
Hormone therapy (estrogen with or without progesterone)  
A placebo  
After 3, 6, and 12 months of supplementation or placebo, the number and intensity of hot flashes and night sweats did not differ between the herbal-intervention groups and the placebo group, with one exception. At 12 months, participants consuming the multibotanical preparation plus soy foods had significantly worse symptom intensity than those consuming the placebo.  
  
Another randomized controlled trial published in 2009 assigned 88 perimenopausal and postmenopausal women (mean age 53 years; 55% from underrepresented minority groups) who were experiencing at least 35 hot flashes and night sweats per week into one of four groups to take one of the following [19]:  
  
128 mg/day black cohosh (75% ethanolic extract standardized to contain 5.7% triterpene glycosides)  
398 mg/day red clover (ethanolic extract of the aerial parts standardized to 120 mg isoflavones)  
Hormone therapy (estrogen and progesterone)  
A placebo  
After 3, 6, 9, and 12 months of supplementation or placebo, the number of vasomotor symptoms declined significantly in all groups. However, there were no statistically significant differences between the black cohosh and red clover groups compared to placebo, with one exception. The black cohosh group showed worse symptom intensity at 6 and 9 months. This study also investigated secondary endpoints such as somatic symptoms (e.g., insomnia and fatigue), mood changes (e.g., depression and anxiety), and sexual dysfunction (e.g., vaginal dryness). For most of these outcomes, no significant differences were observed between any of the treatment groups at any time.  
  
A 2012 Cochrane Review evaluated 16 randomized clinical trials on the effectiveness of black cohosh in reducing menopausal symptoms, including hot flushes, night sweats, vaginal dryness, and combinations of symptoms measured by validated rating scales [5]. (The two trials discussed above were included in this Cochrane Review.) The 16 included trials randomized a total of 2,027 women (mean age 50.5 to 56.4 years), and their samples ranged from 23 to 351 participants. Study durations were 8 to 54 weeks, with a mean duration of 22.8 weeks. Participants received a daily dose of various formulations of 8 to 160 mg/day black cohosh extract, with a median dose of 40 mg/day. In some cases, the authors of the original study reports indicated that the extract they used came from the root/rhizome, they had extracted the product using isopropyl alcohol or ethanol, and/or they had standardized the extract to contain a specific amount of triterpene glycosides. The studies were highly heterogeneous with respect to such factors as design, duration, type and amount of black cohosh used, and main findings. The review s authors concluded that there was insufficient evidence from these trials to either support or oppose the use of black cohosh for menopausal symptoms.   
  
A 2016 systematic review and meta-analysis of randomized clinical trials examined four studies of herbal and plant-based therapies that included black cohosh (three of which were examined in the Cochrane Review described above) to treat menopausal symptoms [20]. The trials randomized a total of 511 women to a daily dose of various formulations of 6.5 to 160 mg/day black cohosh extract or placebo. There were no significant associations between supplementation with black cohosh and reduction in the number of vasomotor symptoms, such as hot flashes. Furthermore, there were no beneficial associations between black cohosh use and relief of menopausal symptoms using self-reported rating scales.  
  
The American College of Obstetricians and Gynecologists, in its 2015 clinical guidelines for managing menopausal symptoms, concluded that data do not show that herbal dietary supplements like black cohosh are efficacious for the treatment of vasomotor symptoms [21]. The North American Menopause Society advises clinicians against recommending herbal therapies such as black cohosh because they are unlikely to be beneficial (italics in original) in alleviating vasomotor symptoms [15].  
  
The Cochrane Review found adequate justification for conducting further studies on black cohosh s use to treat menopausal symptoms [5]. Its authors recommended that researchers conduct higher quality trials with larger samples and provide more details about their experimental protocols. Others have recommended that researchers should completely and comprehensively describe the black cohosh preparation they used so that other researchers could use the same or similar products [22]. It is also important to independently analyze and verify the product s composition to ensure its identity and quality [23].  
  
Health Risks  
Clinical trials using various black cohosh preparations to treat menopausal symptoms have shown that its use is associated with a low incidence of adverse effects. The most commonly reported side effects are gastrointestinal upset and rashes, both of which are mild and transient [1,24]. Other reported adverse effects in clinical trials have included breast pain/enlargement, infection, vaginal bleeding/spotting, and musculoskeletal complaints, although their incidence was similar in women taking black cohosh and those taking placebo [5]. Most studies have examined black cohosh use for short periods, typically 6 months or less, so no published studies have assessed the long-term safety of black cohosh in humans.  
  
Across the world, reports have described at least 83 cases of liver damage including hepatitis, liver failure, elevated liver enzymes, and assorted other liver injuries associated with black cohosh use [1,25]. However, there is no evidence of a causal relationship. It is possible that at least some reported cases of hepatotoxicity were due to impurities, adulterants, or incorrect Acteae species in the black cohosh products used. However, no one independently analyzed these products to confirm the existence of these problems [3,26-28].  
  
In 2007, the Australian Department of Health began requiring that products containing black cohosh carry the following label statement: Warning: Black cohosh may harm the liver in some individuals. Use under the supervision of a healthcare professional [29]. In 2008, the U.S. Pharmacopeia (a nonprofit standard-setting organization for foods and drugs) recommended labeling black cohosh products with the following cautionary statement: Discontinue use and consult a healthcare practitioner if you have a liver disorder or develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice [30]. However, the U.S. Food and Drug Administration does not require such a warning on black cohosh product labels.  
  
The American Herbal Products Association recommends that pregnant women not take black cohosh except under the supervision of their health care provider because studies have not rigorously evaluated its use during pregnancy [1]. The U.S. Pharmacopeia advises that individuals with liver disorders should also avoid black cohosh [30]. It adds that users who develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice, while taking the supplement should discontinue use and contact their doctor.  
  
Interactions with Medications  
Black cohosh is not known to have any clinically relevant interactions with medications, although this has not been systematically studied [1].  
  
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