

Cool Flare: An Herbal Approach to Cool Hot Flashes Associated with Menopause

By Geoff D'Arcy, Lic. Ac., D.O.M.

[Cool Flare Formula](#)



I was asked by a group of medical doctors to use the following format, to review the literature of one of my favorite herbal formulas. I would like to share this article with you, regarding what I found in the conventional databases.

Overview

The side effects and dangers associated with Hormone Replacement Therapy (HRT) have led millions of peri-menopausal and menopausal women to search for herbal alternatives. Patients often question their medical doctors about these issues. Two thousand years ago, physicians of Traditional Chinese Medicine (TCM) began looking for botanical answers and documenting their findings. Cool Flare is an herbal formula with a TCM base of (5:1) extracts with organic western 1:1 herbs and is formulated to treat the hot flashes of peri-menopause and menopausal crises. This formula is often used in conjunction with another formula, Meno-Peace for treatment of severe menopausal crises.

The "hot flash" (HF), or vasomotor instability, is experienced by 75% of peri-menopausal and menopausal women in the United States. The experience for some women is minor, yet for others, the HF is an extremely unpleasant sensation that is disruptive to their sleep patterns and daily living. The HF is believed to be triggered by a number of external and internal stimuli including anxiety, stress, high temperatures, caffeine and alcohol. Thinner women tend to experience more severe and frequent HFs than do women with more adipose tissue, probably due to the ability of adipose tissue to transform androstenedione to estrone and estradiol.

Smoking history also tends to be associated with the experience of HFs at an earlier age. The etiology of HFs in the pattern of decreasing estrogen levels is related to the downward resetting of the hypothalamic thermoregulating mechanism, probably by the action of norepinephrine, which is usually modulated by estrogen. The body attempts to dissipate unwanted body heat via vaso-dilation thereby causing the sensation of the HF.¹

The risks and potential side effects of HRT can include: vaginal bleeding (starting or returning), breast tenderness (which often goes away after three months), nausea (which may resolve spontaneously), fluid retention, changes in the shape of the eye (sometimes leading to contact lens intolerance), headache, dizziness, depression, an increased risk for reduced tolerance to sugar and other carbohydrates, and an increased risk for gallbladder disease.¹ Studies have not confirmed that estrogen causes weight gain, yet, in some women, HRT causes water retention, and thus temporary weight increase.¹ Some scientists have pointed out that there is an increased risk of breast or uterine cancer with HRT, especially when used without progesterone.¹

These side effects and risks associated with HRT have led millions of peri-menopausal and menopausal women to seek out herbal alternatives. Robert Rister, in his book, *Japanese Herbal Medicine*, reports that in Japan, the usefulness of herbal medicine is growing rapidly among conventionally trained medical doctors. In 1976 only 42 herbal formulas had been approved by the Japanese FDA, with only 19.2% of Japanese medical doctors utilizing herbal medicine.^{2,5} In 1996 148 formulas had been approved by the Japanese FDA, and it is estimated today that almost 77% of Japanese medical doctors, who have every method of modern medicine



available to them, prescribe herbal formulas.^{2,3} This increased use of herbal medicine has been driven by hundreds of scientific studies validating the effectiveness of herbal formulas. Sixty percent of these Japanese doctors consider herbal formulas to be the first choice for some diseases.⁴ Rister reports, "In cases where standard medications deliver predictable results without side effects, Japanese doctors prefer synthetic drugs to Kampo (herbal medicine). These doctors, however, note seven situations for which Kampo (herbal formulas) are especially suitable, and menopause is most definitely one of them."

Actions of Individual Constituents

Rehmannia Six Formula

Chinese name: *Liu Wei Di Huang*; Japanese name: *Rokumi-Jio-Gan* Ingredients: *Rehmannia glutinosa*, *Alisama alisma orientale*, *Cornus cornus officinalis*, *Dioscorea dioscorea opposita*, *Poria poria cocos*, *Moutan paeonia suffruticosa*

This is a classic women's formula, dating back to the 12th century in China; it is a combination of six herbs commonly used in Traditional Chinese Medicine (TCM) and Japanese (Kampo). This formula is classified as enriching the *yin* and nourishing the *kidneys*. The traditional concept of the *kidneys* in TCM is that they nourish marrow and the strength of bones. When the *kidney yin* fails to nourish and contain the *liver* energies, *fire* spreads upward, resulting in hot flashes, night sweats, heat in the palms and chest, spontaneous sweating, headache, sore hot dry throat. This condition can go on to create whole body dryness, vaginal dryness, etc. The Rehmannia Six formula makes up one third of the Cool Flare formula and modern science is starting to verify some of its ancient anecdotal results. Studied recently in China and Japan for its use in treating menopausal problems,^{8,9} there is some evidence from animal studies that this formula, plus a derivative formula Rehmannia Eight, may have a positive, preventive effect for osteoporosis as well as the hot flashes of menopause.^{7,10} The preventive effects produced by traditional Chinese (Kampo) medicines, *Hachimi-jio-gan*, (Rehmannia Eight), which has two more ingredients than *Rokumi jio gan*, (Rehmannia Six), on the progress of bone loss induced by ovariectomy in rats were investigated by studying the bone mineral density (BMD) of tibia in ovariectomized (OVX) rats. The results of this study strongly suggest that the gynecological Kampo medicines are as effective as 17 beta-estradiol in preventing the development of bone loss induced by ovariectomy in rats.⁷

In another study, after a relatively long-term injection of hydrocortisone into rats, the strength of bone (anti-stress capacity) reduced evidently, while the rigidity (anti-deformity capacity) increased markedly (i.e., bone fragility elevated). At the same time, the content of serum 25(OH) D3 decreased remarkably. After oral administration of *Liu Wei Di Huang Wan* (Rehmannia Six), the anti-stress capability of bone increased evidently and its anti-deformity capability returned to normal; however, there was no elevation of serum 25(OH) D3 content. The experiments suggests that *Liu Wei Di Huang Wan* is beneficial to preventing and curing osteoporosis, but no correlation between its mechanism and the metabolism of 25(OH) D3 was demonstrated.¹⁰

In another study, *Liu Wei Di Huang Wan* (Rehmannia Six), not only increased plasma estradiol levels, but also increases the leucocytic estrogen receptors (ER) levels. The number of ER in human peripheral leucocytes in 22 women with climacteric syndrome were measured by radioligand method. The results were compared with those of 12 normal child-bearing aged women and showed that the contents of leucocytic ER in climacteric syndrome patients were significantly lower than those of normal child-bearing aged women. The authors used a Chinese prescription --*Liu Wei Di Huang Wan* (Rehmannia Six), to treat the patients for 2 months. The numbers of leucocytic ER were significantly increased after treatment. The data indicate that decrease of ER levels in cells may be involved in the pathogenesis of climacteric syndrome. *Liu Wei Di Huang Wan* (Rehmannia Six), not only increases plasma estradiol levels, but also increases the leucocytic ER levels. This may be the basis of the therapeutic effect on the disease.¹¹



Dong Quai Root, *Angelica Chinensis*

This well known herb increases circulation, protects the heart, and increases the effectiveness of other herbs in the formula.¹⁷ It has been used for thousands of years by Traditional Chinese Medicine and has long been considered the *women's ginseng*. It is rarely used alone and is often used in prescriptions for menstrual and menopausal problems. It may be effective for PMS through its antispasmodic action especially on smooth muscle.¹⁶ Traditionally used in formulas for hot flashes with peri-menopause, it also has a record in the treatment of cardiovascular disease, including high blood pressure and circulation for men and women.¹⁵

Black Cohosh Root, *Cimicifuga Racemosa*

Considered 80% effective in relieving the symptoms of menopause when taken for four weeks or longer, it increases vaginal lubrication as effectively as estrogen replacement therapy.²⁵ It also relieves headaches and muscle pain and stops irregular bleeding.²¹

Traditional Chinese and Japanese herbal medicines classify this herb as *cold*, as it relieves the symptoms of heat during menopause. Black cohosh is considered a leading phytoestrogen for menopausal problems by some authors.^{18,19,20,21,22,23,24,25} Clinical studies from Germany demonstrate that black cohosh decreases Luteinizing Hormone (LH), which can be responsible for hot flashes and other menopausal and perimenopausal problems.¹⁹ A review of eight human studies on the effectiveness of *Cimicifuga racemosa* (black cohosh) for the symptoms of menopause concludes it is a safe and effective alternative to estrogen.¹⁸ Menopausal women taking *Cimicifuga* ethanol extract for 8 weeks had lower LH and unchanged FSH. Fractions tested showed both competitive binding at estrogen receptors and reduction of LH secretion.¹⁹ In another study, sixty post-hysterectomy menopausal women randomized to *Cimicifuga* or 3 types of estrogen all had a lower Kupperman-Index but no significant differences in serum FSH and LH.²⁰ Black cohosh may be debunked as a phytoestrogen at least in animal studies (as has dong quai) its actions may lie in two mechanisms: 1) Compounds bind to receptor sites in the reproductive tract, brain and other organs that otherwise would receive estrogen, therefore reducing overall estrogen activity when estrogen levels are high. 2) These compounds block the formation of LH, which stimulates a surge of estrogen production during the first fourteen days of the menstrual cycle. This stimulates estrogen production when levels are low, thus giving a dual stabilizing action of the body's estrogen fluctuations and the problems they cause.²² Black Cohosh has demonstrated its ability to provide balance and prevent nervousness, hot flashes, depressed moods and vaginal dryness associated with menopause.²³ A recent study suggests that black cohosh actually protects animals from osteoporosis.²⁴ Human studies have not yet confirmed this action.

Chaste Tree Berry, *Vitex Agnus-Castus*

The whole fruit contains several different components thought to be medicinally active.¹ *Vitex*, as it is commonly known, does not contain hormones. Its benefits come from its action on the pituitary gland and the production of estrogen and progesterone. *Vitex* increases the hormone levels to help balance and regulate the menstrual cycle.²

Cool Flare may be used by patients concerned with maintaining healthy hormone levels during peri-menopause and menopause. This is especially pertinent for those individuals with a family history or a significant risk profile for HRT.

Side Effects:

When taken according to the recommended dosage and schedule, and for individuals with no other predisposing medical conditions or sensitivities to any of the constituents, the potential for serious side effects is minimal or none.

Potential side effects from constituents:

Rehmannia Six Formula

These herbs may exacerbate patients already suffering with indigestion and diarrhea.

Dong Quai, *Angelica Chinensis*

Only a few mild side effects have been reported sensitivity to sunlight for a small percentage of fair skinned people.

Black Cohosh Root, *Cimicifuga Racemosa*

Headache, dizziness, abdominal pain and nausea have been reported, usually with high dosages.

Chaste Tree Berry, *Vitex Agnus-Castus*

Side effects of *Vitex* are extremely rare and usually consist of minor gastrointestinal upset and a minor skin rash, reported in less than 2% of women.²⁸

Contraindications:

As with the use of conventional medications, known hypersensitivity or allergy to any one of the constituents in this product is an absolute contraindication. Case reports are suggestive of interaction between *warfarin* and dong quai at much higher dosages when used as a single herb.¹⁴ In this formula the dosage is much lower than in those cited.

Pregnancy and nursing: Due to the known effects of some constituents and unknown effects of many other constituents on fetal and neonatal growth and development, this product should be avoided during pregnancy and breast-feeding.

Dosage : Two capsules, three times daily, on an empty stomach with warm water. Take at least two hours after any medication. When results are achieved and held for two weeks, drop to a maintenance dosage of one capsule three times daily, on an empty stomach with warm water.

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*The statements contained in this article have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease

