AUSTRALASIAN MENOPAUSE SOCIETY
EMPOWERING MENOPAUSAL WOMEN

Information Sheet

Complementary and Herbal Medicines for Hot Flushes

Key points:

- Any product used for the treatment of menopausal symptoms should have been shown in clinical studies to be safe and effective.
- There have been many trials of complementary and herbal medicines for the relief of menopausal symptoms.
- No complementary therapies are as effective as oestrogen therapy for menopausal symptoms
- Use of phytoestrogens may be helpful but long-term data is lacking and they may not be safe in some women
- There is currently insufficient evidence to support the use of herbal therapies.
- Compounded bioidentical hormonal preparations are not recommended due to major concerns about the safety and efficacy of these products.
- Comprehensive information can be found under Additional Reading at the bottom of this sheet – the position statement from the North American Menopause Society (1) and evidence summaries and recommendations from Cancer Australia's Management of menopausal symptoms in women with a history of breast cancer (2).

Many women experience hot flushes and night sweats around the time of menopause. Menopausal hormone therapy (MHT), also known as hormone replacement therapy (HRT) has been proven to be effective in alleviating these symptoms (3). Some women however, choose to explore complementary or herbal therapies for relief of symptoms. There have been a great many trials of complementary and herbal medicines and some of these have suggested benefits from certain therapies and others have shown no benefit. It can be difficult for consumers and for doctors to interpret this mixed information (4). This information sheet provides a brief overview of the current evidence for complementary and herbal therapies.

Complementary and herbal therapies are sometimes referred to as "natural" and may be derived from plants and other sources. Some people believe that these products are safer than prescription products. However, scientific studies of these compounds have not supported this belief (4). Extracts from plants and other so-called "natural" products may actually cause harm and can interact with prescribed medicines (5). They do not

necessarily act like the hormones normally produced by women. Some over the counter treatments, including plant extracts, are not subject to the rigorous testing for content, safety and effectiveness that prescription treatments are subject to. Herbal products may contain heavy metals, illegal ingredients and toxic chemicals as well as naturally occurring organic toxins.

Any product used for the treatment of menopausal symptoms should have been shown in clinical studies to be effective. This usually requires a placebo-controlled trial or a head to head comparison with a known effective treatment or both. The placebo comparison is particularly important, because there is often a temporary placebo effect of most menopause treatments which commonly lasts around three months. Unless the product is tested for more than three months, it is not possible to say that it is truly effective for menopausal symptoms. This short-term placebo effect is quite different from the prolonged improvement in menopausal symptoms demonstrated by treatments such as MHTs which reduce hot flushes by around 90% and continue to be effective for as long as they are used (6). Prescription drugs cannot be licensed until they have been shown to be safe and effective. This is not the case for over the counter remedies for menopausal symptoms. The AMS advocates that all therapies whether prescription or alternative should not be used unless there is good research evidence for effectiveness and safety in the short and long term.

Herbal and Botanical therapies

Black Cohosh (Cimicifuga racemosa or Actaea racemosa)

A recent systematic review concluded that there is currently insufficient evidence to support the use of black cohosh for hot flushes. The effect of black cohosh on other important outcomes, such as health-related quality of life, sexuality, bone health, night sweats and cost-effectiveness is not yet established (7).

There were originally reports of liver toxicity (8), but these have not been seen in larger studies, and appear to be due to contaminants, though the longest study was only for six months (9).

Phytoestrogens including Red Clover (Trifolium pratense)

A wide range of products containing plant or phytoestrogens, including soy products, are available as over the counter remedies for hot flushes. Studies have varied widely in the dose and nature of compounds tested and the active product of these is thought to be isoflavones which bind to the oestrogen receptor and possess both oestrogen agonist and antagonist properties (1).Varied outcomes have been demonstrated with some short-term studies suggesting that there may be some benefit in using these products early in menopause but we are still lacking good long

term studies. The available evidence suggests that isoflavones do not relieve long term menopausal vasomotor symptoms any better than placebo (10).

There is some evidence that questions the safety of these products in patients with breast cancer and phytoestrogen supplements may interfere with treatments for breast cancer (11).

Wild Yam Cream

There is very limited data on the use of wild yam cream for hot flushes. Existing studies do not show any efficacy in reducing menopausal symptoms (12) .

Evening Primrose Oil

Very few studies have addressed whether evening primrose oil improves hot flushes. Existing data shows no benefit (5, 13). Evening primrose oil lowers the seizure threshold in people with epilepsy and interferes with the actions of ant-epileptic medication (5).

Flaxseed

No evidence of benefit for vasomotor symptoms (1).

Ginseng (Panax ginseng or Panax quinquefolius)

No evidence of benefit for vasomotor symptoms (1). Ginseng reduces the effects of immunosuppressive drugs, increases the effect of oral hypoglycaemic agents, potentiates the side effects of monoamine oxidase inhibitors and has an additive effect with benzodiazepines. Ginseng can also potentiate the action of warfarin (5).

Maca (Lepidium Meyennii Walp or Lepidium peruvianum Chacon)

Maca is a traditional foodstuff from South America with oestrogenic effects seen in vitro but not in vivo. Poor quality trials indicate improvement in menopausal symptom scores but there is insufficient evidence to support the use of Maca at this time (1).

Pine bark (Pycnogenol)

Pine bark derived from the Mediterranean pine (Pinus pinaster) is a source of proanthocyanidins (also found in grape seed). Pycnogenol is promising as improvement in menopausal symptom scores were observed in 3 short term RCTs using different doses but the effective dose and long term safety needs to be established (1).

Pollen extract

There is insufficient evidence to support the use of pollen extract currently with only one small RCT reporting improvement in menopausal symptoms. Potential safety concerns relate to pollen allergy (1).

Siberian rhubarb

Siberian rhubarb is used for gastrointestinal complaints with some evidence that the hydrostilbenes in rhubarb act as serum oestrogen receptor modulators. Limited evidence form one small short term study indicated improvement in menopausal symptom score but further research is need to establish efficacy and safety (1).

Combination botanical therapies

Combination botanical therapies are purported to be superior as they address multiple menopausal symptoms (as does oestrogen in MHT). However, difficulties may arise in determining the potential for adverse events and drug-herb interactions. There is insufficient evidence regarding efficacy and safety to recommend their use currently (1).

Compounded bioidentical menopausal hormone therapy

Compounded "bioidentical" hormones contain hormonal preparations which are aimed at correcting "hormonal imbalances" which may occur at menopause. However, there is no evidence to support the effectiveness or safety of these products. Not only is evidence lacking to support superiority claims of compounded bioidentical hormones over conventional MHT, these claims also pose the additional risks of variable purity and potency, and lack efficacy and safety data. The Committee on Gynecologic Practice of the American College of Obstetricians and Gynecologists, the Practice Committee of the American Society for Reproductive Medicine and the US Endocrine Society have raised major concerns about the safety and efficacy of these products and recommend that patients be counselled to avoid their use (14) . (Please refer to AMS information sheet *Bioidentical custom compounded hormone therapy*)

Progesterone Cream

Progesterone cream alone is not effective for the treatment of hot flushes because of unreliable absorption. (15).

Progesterone cream also does not provide sufficient endometrial protection if used in conjunction with exogenous oestrogen.

Non-Herbal Therapies

Vitamin E

Vitamin E has not shown benefit in the treatment of menopausal hot flushes after breast cancer, and very limited efficacy in other women (16).

Omega-3

No evidence of benefit for vasomotor symptoms in short term studies (2).

Magnesium

No evidence of benefit for vasomotor symptoms in one RCT in women with breast cancer.

Homeopathy

No evidence of benefit (2).

Prescription medicines

A number of prescribed medications have been shown in randomised clinical trials to be more effective than placebo in the treatment of hot flushes and night sweats. A summary of these treatments can be found in the AMS information sheet *Nonhormonal treatments for menopausal symptoms*).

Lifestyle and Behavioural Modifications for Menopausal Symptoms

See AMS information sheet *Lifestyle and Behavioural Modifications for Menopausal Symptoms* for a summary of the evidence (under production and available soon).

Additional Reading:

Cancer Australia's Management of menopausal symptoms in women with a history of breast cancer https://canceraustralia.gov.au/publications-and-resources/clinical-practice-guidelines/menopausal-guidelines

Nonhormonal management of menopause-associated vasomotor symptoms: 2015 position statement of The North American Menopause Society. *Menopause* 2015; 22(11): 1155-72; quiz 73-4.

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