



MENOPAUSE TREATMENT OPTIONS

Making the Right Choice for *YOU*



sigma

CANADIAN MENOPAUSE SOCIETY
SOCIÉTÉ CANADIENNE DE LA MÉNopause

TABLE OF CONTENTS

Foreword	1
Lifestyle Based Changes for the Management of Menopausal Symptoms	2
Over -the-counter and Natural Health Products for the Management of Menopausal Symptoms	4
Non-Hormonal Prescription Medications	6
Menopausal Hormone Therapy (MHT)	8
Tissue Selective Estrogen Complex (TSEC)	10
Compounded Bioidentical Hormone Therapy	12
Acknowledgement	13



FOREWORD

Although each woman's experience with menopause is unique, there are a few elements which are very common. Among North American women, about 75% will experience hot flashes. These are usually most bothersome in the first two years after the final menstrual period, but for some women they may last 7-10 years or longer. While the cause of hot flashes is not completely understood, it is known that a fall in estrogen levels plays an important role.

But--menopause is about a lot more than hot flashes. Other commonly reported symptoms include an increase in muscle aches and joint pain, lack of energy, mood changes such as depression, memory changes, sexual problems, sleep disturbances, and bladder control problems.

For some women, these symptoms are mild and not troublesome. For others, the symptoms may be severe and have a large impact on quality of life.

There are many options available for treatment, for those who wish, and not all options require consultation with a care provider or a prescription. It is our hope that this pamphlet will help you to fully understand all your treatment options.



LIFESTYLE BASED CHANGES FOR THE MANAGEMENT OF MENOPAUSAL SYMPTOMS:

When faced with bothersome symptoms of menopause, many women choose to use lifestyle based changes. For some, this is a first-line approach; they try these first, in hopes of achieving relief. Other women use these options in order to avoid the use of over-the-counter or prescription medications altogether. Below is a summary of how well each of these options works.

1. Cooling and Avoiding Triggers:

For many women this is a practical and common-sense approach to feeling more comfortable while having a hot flash. Dressing in layers, wearing breathable fabrics such as cotton, and avoiding any known personal triggers (for example, wine or spicy foods) are things many women do to stay comfortable. Many health care professionals will suggest women try these tactics first, as they are seldom harmful. Using a fan, or an over the counter cooling product (spray, wipe or cooling device) may also help. However, there are no scientific studies to prove that these approaches work, and they may be inadequate for many women.

2. Exercise and Yoga:

There are many health benefits to regular exercise and yoga, such as improvements in balance, strength and flexibility. Some women who practice regularly will have fewer menopausal symptoms than those who do not. However, most scientific studies that have tried to prove yoga or exercise treats hot flashes do not show these as a specific benefit. The women who were exercising did not have any fewer or less intense hot flashes compared to the women who were not exercising. Individual women may try these approaches to see if they achieve their own personal benefit.

3. Weight loss:

Maintaining a healthy body weight, especially in menopause, has many important health benefits. These include reducing the risk of diabetes, heart disease and many cancers, like breast and colon. When it comes to weight loss and symptoms of menopause, there seems to also be a benefit. In studies, women were generally found to have relief from menopausal hot flashes when they lost weight. A large amount of weight loss is not required to see a benefit; however, the benefit tends to be greater the more weight that is lost. Fat is a very good insulator, and may hold heat in.

LIFESTYLE BASED CHANGES FOR THE MANAGEMENT OF MENOPAUSAL SYMPTOMS:

4. Acupuncture

Acupuncture, originating from traditional Chinese medicine, is the insertion of fine, thin needles into specific points in the body to change energy flow in the body to a healthier balance. Acupuncture is used for many health conditions including chronic pain, migraines, allergies, and digestive problems. Acupuncture has been shown to reduce the frequency of hot flashes compared to not using anything, however in some studies the benefits have been no better than using a placebo version of acupuncture (called sham acupuncture). It is unclear if acupuncture should be recommended for the treatment of hot flashes at this time. Acupuncture is relatively safe, but some mild bruising can occur at the injection site.

5. Mindfulness

Mindfulness is awareness of one's thoughts and feelings in the present moment in a non-judgmental manner. Mindfulness training involves specific meditation practices and other techniques to help one respond to thoughts and feelings and handle stress. Mindfulness has been shown to decrease the intensity of hot flashes and make them less bothersome. Mindfulness may be more useful for women with mild hot flashes or when a quick response is not required.

6. Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) involves learning skills to manage one's thoughts, feelings and behaviours to help control symptoms. The benefits are seen through changes in how a woman perceives and copes with her symptoms. CBT uses a combination of strategies such as individualized or group therapy, imagery and stress reduction. Research has shown that CBT is an effective way to treat hot flashes in menopausal women, as well as women who have hot flashes after breast cancer treatment. In studies, CBT programs that have shown benefit have included education either in a group with a psychologist or self-guided, breathing exercises and relaxation techniques.

OVER-THE-COUNTER AND NATURAL HEALTH PRODUCTS FOR THE MANAGEMENT OF MENOPAUSAL SYMPTOMS:

Many women choose to try over-the-counter and natural health products for the relief of their menopausal symptoms. Some people feel these products offer a safer alternative to prescription medications. However, it is important to remember that even when a product is labelled as “natural” or found in a health food store, that does not necessarily guarantee it is safe. Many of the scientific studies conducted on these products cannot prove they are safe, or that the products work well.

Below is a listing of specific remedies and how well they work.

1. Soy products:

Soy is derived from plants, and acts similarly to estrogens in some people. Soy is present in a diverse group of food products and supplements. Soy products do not seem to work for all women; only certain people are able to process soy in their bodies to make its active ingredient. This is because not everyone has the enzymes necessary to do this. In some studies, soy products work well to reduce hot flashes related to menopause. Some experts recommend soy supplements to women as a first choice for relief from hot flashes. Therefore, women may choose to trial soy products to see whether they are right for them.

2. Black cohosh:

Black cohosh is one of the most popular over-the-counter remedies for the treatment of menopausal symptoms. It has also been widely studied scientifically to test for its effectiveness. Despite it being a very popular choice for women, black cohosh has not been consistently shown to work better than placebo (sugar pills) in studies. It is not recommended for the relief of menopausal symptoms.

3. Dong quai:

Dong quai is popular in traditional Chinese medicine to help a variety of female health complaints. It has not been shown to be effective at treating symptoms of menopause when studied scientifically. There are also some concerns about its safety. It may slow blood clotting, and if taken with medications that prevent blood clots (for example, blood thinners), it may cause bleeding or bruising. There may also be concern about cancer risk.

OVER-THE-COUNTER AND NATURAL HEALTH PRODUCTS FOR THE MANAGEMENT OF MENOPAUSAL SYMPTOMS:

4. Wild yam, primrose and flaxseed

There are no good scientific studies that prove wild yam, evening primrose, or flaxseed can successfully improve symptoms of menopause, when compared to a placebo (sugar pill). Wild yam creams in particular are not recommended, as the products have been found to sometimes contain additional ingredients which may prove to be unsafe. Importantly, the human body cannot convert the active ingredient in wild yam (diosgenin) into progesterone, contrary to claims. Flaxseed may help symptoms of hot flashes in some women.

5. Combination products

Combination products may be popular with traditional medical practitioners, but are very difficult to study scientifically. How well these products work, as well as their safety, is largely unknown. For those that have been studied scientifically, none have proven to work better than a sugar pill. Women should be cautious when using any sort of combination product.

6. Fermented soy bean extract

Fermented soy bean extract is a relatively new product to Canada, and is approved by Health Canada as a Natural Health Product for relief of menopause symptoms. It is a pill taken twice daily. The active ingredient in it comes from soy beans. The product tends to lessen the number of hot flashes women have, when compared with a placebo. So far, there is no safety data for breast cancer risk, as trials looking at this risk have not been conducted. It is available for purchase at most Canadian pharmacies, without a prescription.



Non-hormonal Prescription Medications

General Comments

Non-hormonal prescription medications for hot flashes include antidepressants (SSRI/SNRI), gabapentinoids (gabapentin, pregabalin) and clonidine. These medications are not as effective as estrogen, however may be useful in women who are not able to take hormone therapy. In general, these agents have shown to decrease hot flashes by 50 – 60%, though response can vary among women. All of these drugs have different mechanisms of action therefore if one medication does not work or is not tolerated, another one can be tried.

1. Antidepressants

Antidepressants such as Selective Serotonin Reuptake Inhibitors (SSRI) and Serotonin-Noradrenaline Reuptake Inhibitors (SNRI) can help reduce hot flashes. Among the different SSRI antidepressants, paroxetine, citalopram, and escitalopram have the best evidence for treating hot flashes. Venlafaxine and desvenlafaxine are SNRI antidepressants that are used for hot flashes. The doses of the antidepressants used for hot flashes are often lower than the doses used for depression, and therefore may be better tolerated. Side effects of SSRI antidepressants include dry mouth, nausea, jitteriness, fatigue, insomnia or drowsiness, diarrhea, sexual problems and weight gain or loss. Side effects of SNRI antidepressants include nausea, loss of appetite, dry mouth, trouble sleeping, and constipation. As we are all unique, not everyone is going to experience the same side effects with a specific medication or to the same degree.

It is recommended to start antidepressants at a low dose to see how they are tolerated and then gradually increase. These drugs work relatively quickly for the treatment of hot flashes, typically showing effects within a couple of weeks. When stopping antidepressants it is important to slowly decrease the dose to prevent any withdrawal symptoms such as flu like symptoms, nausea, changes in senses and trouble sleeping. For some women it may take up to two weeks or longer to discontinue the medication.

Antidepressants are also helpful in women who have hot flashes from breast cancer treatment. Women on tamoxifen therapy should avoid using paroxetine and fluoxetine because of a drug interaction with tamoxifen. These drugs block the breakdown of tamoxifen to a metabolite that is active, causing the tamoxifen not to be as effective.

Non-hormonal Prescription Medications

2. Gabapentinoids (gabapentin, pregabalin)

Gabapentin is a medication used for seizures and other health conditions such as pain, migraines and psychiatric conditions. Studies have shown that gabapentin can reduce hot flashes; however the exact way it works is unknown. The dose of gabapentin to treat hot flashes is different than for treating other conditions. It is recommended to start gabapentin once daily and increase the dose gradually to allow the body to get used to the effects. It may take one or two weeks to reach the effective dose. The main side effects of gabapentin are drowsiness, dizziness, fatigue, disorientation, headache and altered balance. Since drowsiness is a side effect, gabapentin may be useful for women who have trouble sleeping because of night sweats. Pregabalin is used to treat fibromyalgia and neurologic pain. It is less well studied for menopausal symptoms compared to gabapentin. The side effects of pregabalin include dry mouth, dizziness, sleepiness, blurry vision, altered balance and trouble concentrating.

3. Clonidine

Clonidine is a blood pressure medication that has been used for years to treat hot flashes. Clonidine may be less effective than SSRI/SNRI antidepressants and gabapentin. Clonidine has a number of side effects that can limit its use, including light-headedness, dizziness, drowsiness, dry mouth, headache, constipation and decrease in blood pressure. Clonidine should be started at a lower dose and increased gradually. It is important to decrease the clonidine dose slowly over time when discontinuing, as there is the potential for increased blood pressure if it is stopped too quickly.



Menopausal Hormone Therapy (MHT)

When estrogen levels fall at the time of menopause, temperature regulation is disrupted. Because of this, many women will experience hot flashing and night sweats. Not surprisingly replacement of the missing hormones is a highly effective treatment for hot flashes and night sweats, often referred to as vasomotor symptoms (VMS). Estrogen, even in low doses, will significantly reduce hot flashes in over 90% of women.

Additional benefits from the use of estrogen include improved sleep resulting in less fatigue and irritability, improved concentration, and, in some women, relief from depression symptoms. Estrogen plays an important role in the prevention of bone loss and reducing the risk for osteoporosis and fractures. In addition, estrogen therapy has been shown to reduce joint pain and to offer some protective benefit to the development of heart disease. Loss of estrogen in the bladder and vagina can also lead to bladder irritability and gradual onset of vaginal dryness and painful intercourse.

In women with a uterus, if estrogen is administered alone, it can lead to overgrowth of the lining of the uterus (endometrium) and ultimately put a woman at risk for uterine cancer. This effect is counteracted by the addition of a progestogen (a progesterone-like hormone). This medication, by counteracting the effects of estrogen on the uterine lining, actually reduces the risk of uterine cancer below the normal population risk.

Estrogen alone seems to have little impact on breast cancer risk and only with prolonged use is there even a slight increase observed. The combination of estrogen and progestogen, however, may gradually increase the breast cancer risk with longer durations of use (an additional 8 cases for every 10,000 women using MHT per year). This very small risk is equivalent to the increased risk of breast cancer resulting from failure to exercise regularly, development of obesity after menopause, and regular alcohol use.

Like birth control pills, the oral estrogen in MHT seems to cause a very slight increase in the risk for a blood clot which is greatest in the first year of use and falls back towards normal thereafter.

Menopausal Hormone Therapy (MHT)

Estrogen can be administered by mouth (orally) or through the skin (transdermally). To date all estrogens when given orally seem to slightly increase the risk of a blood clot. Recent research suggests that estradiol, which is the estrogen produced in our bodies, may have a lower risk of blood clots than other estrogen formulations. Transdermal estrogen, in standard low doses, is believed to carry little, if any, risk of blood clots and therefore is the preferred route in women with a known increased risk of clots (obesity, inactive lifestyle, known clotting disorder). Since the actual risk of blood clots is very low the choice of route of delivery for most women is often left to personal preference. Oral estrogen has less beneficial effects in cigarette smokers and in smokers the transdermal route may be preferred.

Progesterone is not reliably absorbed through the skin in its natural state and may not protect the uterine lining against overgrowth. Natural progesterone is not recommended for transdermal use. Natural progesterone is available as an oral capsule, which is better absorbed, and has been shown in studies to protect the uterine lining from overgrowth. Certain chemically altered progestogens can be absorbed transdermally or orally.

Progestogens, although typically administered for protection of the uterus, may also help the beneficial effect of estrogen on hot flashes and bone protection. A variety of progestogens are available for commercial use and these may have slightly different effects. Some research suggests that natural progesterone may have less of an adverse effect on breast cancer risk however this is not yet proven.

Side effects of estrogen include some short term nausea, breast tenderness, and water retention when first started, as well as occasional headaches.

Progestogens may cause breast tenderness, headache and mood changes. Women with a uterus may choose to take their medication in a continuous fashion (to avoid monthly bleeding) or in cyclic fashion (to get a predictable bleed every one to two months). Irregular bleeding may occur in the first months after initiation of continuous MHT.

Tissue Selective Estrogen Complex (TSEC)

The most recent innovation in menopause therapy is called a TSEC. It is a therapy that acts in different ways on different tissues. It pairs, in a single tablet, an estrogen with a SERM (selective estrogen receptor modulator). A SERM is a medication that blocks the effects of estrogen in certain tissues. The TSEC available in Canada combines an estrogen (conjugated equine estrogen) with a SERM called bazedoxifene. The estrogen can help reduce hot flashes and prevent bone loss while the SERM blocks the effects of estrogen on the uterine lining (endometrium) and breast.

This TSEC is highly effective in reducing both the number and severity of hot flashes. In studies, the number of hot flashes in women using this TSEC was noticeably improved by week 3, and there was a 75% reduction in 12 weeks. This is compared to a 35% reduction in the number of hot flashes in women using placebo.

Women who took this medication also had an increase in the density of their bones. Bone density is used to predict risk of osteoporosis.

Women who used this medication reported higher quality of life scores compared to placebo. This is most likely due to better sleep.

Breast cancer risk on this medication has not been fully evaluated. Clinical trials up to two years in length have not shown an increased risk of breast cancer compared to placebo. Two years is probably not a long enough time to assess breast cancer risk, as most cancers related to hormones take a long time to grow. Both ingredients in this TSEC are known to reduce breast cancer risk when used separately. Mammograms show that women who use this TSEC do not have an increase in breast density. Women who use certain estrogens and progestogens may show an increase in breast density. Breast density is one predictor of breast cancer risk.

Endometrial (uterine) cancer is a risk when estrogen is taken by itself. This TSEC, in clinical trials, shows no increase in the risk of endometrial cancer or pre-cancerous changes.

Tissue Selective Estrogen Complex (TSEC)

Blood clots may be a risk when estrogen is taken. They tend to occur most frequently in the first year of use, and are increased with older age, obesity, and an inactive lifestyle. In clinical trials lasting 2 years, there was no increased risk of blood clots seen with use of this TSEC.

Heart disease data with this medication is reassuring. The risk of stroke and heart attacks for women on this TSEC was similar to those on placebo. These are very rare events for women in their 50's.

Bleeding is a nuisance while taking menopause hormone therapy, and is one of the most common reasons that women stop. It is estimated that about 25% of women taking estrogen/progestogen therapy will experience some vaginal bleeding during 12 months of use.

With use of this TSEC, that number is around 6%, which is the same as women NOT taking any hormone therapy.

Breast tenderness is another common reason that women taking estrogen/progestogen therapy discontinue. With TSEC therapy, the rate of breast pain and tenderness is the same as for women taking no hormone therapy.

Weight gain is a common question women ask when discussing hormone therapy. Weight gain after menopause is common, even when not taking menopause therapy. Over a two year clinical trial period, compared to placebo, women taking this TSEC did not gain more weight.

Overall, this TSEC offers another choice for women choosing hormonal management of their symptoms. The single pill once a day dosing may be more convenient for some women. It is effective for relief of hot flashes, has shown to have a positive effect on bone and quality of life. There may be advantages with less bleeding and less breast tenderness compared to other hormone therapy. The studies show no increased clot risk, no increased heart disease risk, and no increased uterine cancer risk. The data on breast cancer, although reassuring, will need to be followed as more information becomes available.

Compounded “Bioidentical” Hormone Therapy

There has been considerable media attention around custom compounded bioidentical hormone preparations, which have been aggressively marketed as being natural and safer than Health Canada approved products. Although the compounded formulations may contain the same active ingredients as Health Canada approved preparations, the custom compounded products have not been rigorously tested for quality, safety, and how well they work. There can be considerable variation in dosing between batches, as well as lack of standards and oversight for quality control.

There is little scientific evidence about the effects, good or bad, about these products. As they have not been tested to the high scientific standards of safety required by Health Canada, these custom compounded products are NOT Health Canada approved.

All scientific societies universally recommend that these products not be used until further evidence of safety and efficacy are made available.



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