

The Natural Management Of Menopause, PMS And Related Hormonal Imbalance Problems

The Natural Management Of Menopause

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In recent years, many women across North America have demonstrated a reluctance to rely upon hormone replacement therapy (HRT) as a means to reduce menopausal symptoms, due primarily to concerns about the potential risk of breast cancer. In fact, only about 20% of women who are given a prescription for HRT actually follow through and take it faithfully. A growing number of postmenopausal women have been seeking out the use of herbal remedies as an alternative to HRT, as reflected by the rapid growth in herbal supplement sales during the past decade. Interest in natural therapies to control menopausal symptoms is expected to escalate due to two recent alarming reports, which confirm previous suggestions that hormone replacement therapy increases the risk of breast cancer and that unopposed estrogen (usually given to women who have undergone a hysterectomy) substantially increases the risk of ovarian cancer.^{1,2} On July 9, 2002, researchers announced that they were stopping the American Women's Health Initiative (WHI) trial of 16,000 women taking hormone replacement therapy (HRT), as results showed that after 5.2 years there was a 26% increased risk of breast cancer in the women using hormone replacement than in women receiving the placebo. Women taking HRT also showed a 41% increased risk of stroke and a 29% increased risk of heart attack (myocardial infarction), compared to women receiving the placebo. Prior to this, many doctors promoted HRT as a means to reduce the risk of heart disease in postmenopausal women, but the findings of the WHI trial provide unequivocal evidence that, in fact, HRT greatly increases the risk of both heart attack and stroke in this population.^{1,3} More bad news regarding estrogen replacement therapy appeared in the July 17th, 2002, issue of the *Journal of the American Medical Association*. In a follow-up study of 44,241 former participants in the Breast Cancer Detection Demonstration Project, researchers discovered that the use of estrogen replacement therapy (without concurrent use of progesterone) increased risk of ovarian cancer, with a relative risk of 1.8 in women who used estrogen replacement therapy for 10-19 years and a 3.2 relative risk in women using estrogen replacement therapy for 20 or more years.²

Previous data from the Nurses' Health Study demonstrated that for each year a woman remained on HRT, her risk of developing breast cancer increased by 2.3%. Thus, a postmenopausal woman taking HRT for 10 years had a 23% increased risk of developing breast cancer, compared to women who were non-users of HRT. After 20 years of HRT use, a woman's risk of developing breast cancer would be 46% greater than a woman who never used HRT during the menopausal years, according to evidence provided by the Nurses' Health Study.^{37,38,39} As the results of these studies get reported by the popular media, a growing number of women are giving up their HRT medications and searching for credible alternative means to optimize their feeling of well being, reduce hot flashes and other menopausal symptoms, maintain an active sex life and a healthy appearance, and reduce their risk of osteoporosis, heart disease and other degenerative conditions.¹

In order to help patients arrive at a prudent course of action, health practitioners should be informed about the current research status of various natural interventions that have a proven and safe record in the management of menopausal complaints, and health conditions affecting menopausal women.

In today's world, women live one-third of their lives in the postmenopausal years. Helping them maximize their quality of life, and lifespan, should be the intent of any nutrition, supplementation, or lifestyle recommendations, which should be customized to an individual's needs. In addition to controlling hot flashes and other menopausal symptoms, there are three major health concerns that must also be factored in to the decision-making process. It is well established that postmenopausal women are at increased risk for breast cancer, osteoporosis, and heart disease.

- Heart disease is the number one killer of postmenopausal women
- Osteoporosis affects one in four women by age 50
- Breast cancer incidence rates have increased by 40% in the last 50 years, with one in every 403 women afflicted between ages 50-59, one in 266 women afflicted between ages 60-69, and one in 220 women afflicted at age 70 and over. ⁴

Heart Disease

After menopause, women become less able to clear cholesterol from their blood stream. During the pre-menopausal stage of life, high circulating estrogen levels increase the production of LDL-cholesterol receptors, which enable cells to extract LDL-cholesterol (low density lipoprotein-cholesterol, which is known to increase risk of heart attack and stroke) from the blood stream and use it for various purposes. In menopause, there is a 90% drop off in circulating estrogen levels, which appears to reduce the ability of cells to produce LDL-cholesterol receptors. As a result there is a strong tendency for cholesterol to accumulate in the blood stream, stick to the walls of the arteries and cause narrowing of coronary blood vessels; leading to heart attack. ⁴ As a high saturated fat diet is the main culprit in raising LDL-cholesterol levels, postmenopausal women should adjust their diet to lower their saturated fat intake (results from the Framingham Heart Study suggest individuals should ingest no more than 10 – 28 gms per day of saturated fat, based upon the presence of other risk factors such as family history, diabetes, smoking, high blood pressure etc), in order to keep their blood cholesterol levels below 200 mg per dL. This implies that the use of animal protein foods consist of chicken, turkey, Cornish hen and fish, and that all milk and yogurt products consumed are non-fat or 1% varieties. No cheese above 3% milk fat should be consumed and butter, ice cream, whipping cream, regular chocolate products, items containing coconut or palm oil, and deep fried products of all types, be avoided. ⁵ Increasing soluble dietary fiber intake can also reduce blood cholesterol levels by dragging cholesterol out of the body, as well as bile acids, which can serve as precursors (building block) to the synthesis of cholesterol in the liver. Soluble fiber is found in most fruits and vegetables, oat bran, psyllium husk fiber, ground flaxseeds, and in beans and peas. ⁶ Remaining physically fit and at or near one's ideal weight, are also important lifestyle factors in preventing cardiovascular disease in the postmenopausal years. ^{7,8}

It should also be noted that soy products and soy extract supplements are known to reduce blood cholesterol levels by 9 – 12% in patients with high cholesterol levels. ⁹ The same is true for a supplement known as gamma-oryzanol, which is derived from rice bran oil. ^{10,11} Both soy extract and gamma-oryzanol have been shown to reduce hot flashes and other menopausal symptoms and are excellent alternative therapies to the use of HRT in postmenopausal women. Gamma-oryzanol is an approved drug for the management of menopausal symptoms in Japan, where the research on this natural agent has been performed. ¹² It is very convenient that soy extract and gamma-oryzanol can help reduce menopausal symptoms, reduce cholesterol levels, and in the case of soy isoflavones, help to maintain bone mineral density. ^{13,14,15}

Osteoporosis

The decline in estrogen levels that accompanies the menopausal years also permits calcium to leak out of bone into the blood stream, where it will eventually become filtered by the kidney and exit the body in the urine. This of course, leads to osteoporosis, which increases risk of fractures. Osteoporosis is reaching epidemic proportions in our society largely due to insufficient calcium intake and accumulation in bone, especially between ages 11 and 24, and loss of calcium from bone during the menopausal years. ^{16,17} It should be noted that Canadian statistics indicate that complications from osteoporotic hip fractures (e.g., the development of pneumonia) result in more deaths each year than the combined mortality rate from breast and ovarian cancers. ¹⁸ The lifestyle recipe to prevent osteoporosis during the menopausal years is as follows:

1. Ingest 1,500 mg per day of calcium, if not taking HRT. This can be through a combination of calcium from diet and supplements (note that calcium carbonate and

calcium citrate are absorbed equally as well if taken with meals). As calcium carbonate is less expensive, it represents a more cost-effective intervention for patients. However, if the patient has had a previous history of kidney stones, calcium citrate may be preferred due to its greater solubility.¹⁶

2. Supplement with 600 to 1,000 IU of Vitamin D. For general health reasons women should consider taking a high potency multiple vitamin and mineral, which normally includes 400 IU of Vitamin D. Studies show that postmenopausal women ingesting an additional 200 to 400 IU of Vitamin D per day may reduce their risk of hip fractures by approximately 50%. A high potency multiple vitamin and mineral (including extra antioxidant protection and a B-50 complex) contains other nutrients important to bone health (calcium zinc, magnesium, copper) as well as providing comprehensive micronutrient support for other aspects of health optimization. As we age, our kidneys reduce their ability to convert 25-hydroxyvitamin D to 1,25-dihydroxyvitamin D, which is twice as powerful a form of Vitamin D, than is 25-hydroxyvitamin D. However, studies indicate that by increasing blood levels of 25-hydroxyvitamin D, through the intake of Vitamin D supplements (600 – 1,000 IU per day), a postmenopausal women can compensate for the drop off in 1,25-hydroxyvitamin D synthesis, and thereby, significantly reduce her risk of osteoporotic fractures.^{19,20}
3. Perform weight-bearing and/or resisted exercises 4 to 7 times per week. Weight bearing exercise such as walking or jogging, and weight training exercises, place increased stress on the spine and femurs, which respond by holding their calcium in bone to help withstand the physical stresses acting on the bone structures. Some studies reveal that postmenopausal women can increase their bone density, without using HRT, by simply ingesting more calcium and performing a series of 5 weight training exercises, twice per week.²¹
4. Supplement with a product that contains Black Cohosh and Soy Isoflavones. As will be discussed later, the standardized grade of Black Cohosh and Soy Extract have been shown to reduce menopausal symptoms and evidence exists to show that they can also help to preserve bone mineral density via their estrogenic effects on bone receptors.^{22,23}

Breast Cancer

It is well documented that women who are overweight during the postmenopausal years have approximately a three times greater risk of developing breast cancer.^{24,25,26} This is likely due to the fact that as fat mass increases there is a greater conversion of androstenedione to estrone within the stromal tissue of adipose tissue. Higher circulating estrone hormone (one of three types of estrogens made by the female body) levels are associated with increased risk of breast cancer, as estrone is known to increase the cell division rate of breast cells. In turn, this leads to a greater chance of genetic mutations occurring, which may be cancerous. This is exactly the same mechanism through which HRT has been shown to increase breast cancer risk. Thus, postmenopausal women would be well advised to attain and maintain an ideal body weight and a body mass index below 25 (24.87).²⁴

As well, avoiding the use of HRT is emerging as a significant strategy upon which to help prevent breast cancer in postmenopausal women. The best alternative approaches include a combination of Black Cohosh, Soy Isoflavones and Gamma Oryzanol, as each of these natural interventions has been shown to reduce menopausal complaints and, their use in human populations over many years suggest that they do not increase risk of breast cancer. In fact, in Japan, where soy isoflavone intake is customarily between 50 and 75 mg per day, breast cancer incidence is 75% lower than in the U.S.¹⁴ Recent experimental studies involving black cohosh have shown that it exerts an anti-proliferative effect on breast cells and human breast cancer cell lines, which is consistent with a reduced risk of breast cancer, according to available scientific evidence.²⁷ Therefore, in women without a previous history of breast cancer, the use of black cohosh, soy isoflavones and gamma-oryzanol, can be considered safe and effective alternatives to the use of HRT.^{28,14,12} In patients with a

previous history of breast cancer, the jury is still out as to whether or not these natural agents should be used. However, in a recent survey, women with a previous history of breast cancer were 7.4 times more likely to use alternative treatments for menopause symptoms than were women with no previous history of breast cancer. Soy products, herbal remedies (including black cohosh and gamma-oryzanol) and Vitamin E were the most common alternatives to HRT. ²⁹

In addition to these devastating statistics, the decline in estrogen and progesterone production that accompanies menopause, triggers a broad range of physical, psychological and aging-related signs and symptoms that can significantly interfere with a woman's feeling of well-being. ⁴ Although underutilized by medical doctors in this part of the world, substantial evidence from European and Asian studies provides convincing support that the herbal agent known as black cohosh, along with soy extract and gamma-oryzanol, can significantly reduce menopausal symptoms, help support bone density, reduce high cholesterol, prevent atrophy and dryness of vaginal tissues, and improve a woman's feeling of well being and vitality. Unlike HRT, these natural substances are not associated with an increased risk of breast cancer, ovarian cancer or heart disease. As such, in most cases they can be employed as a significant part of a natural lifestyle program, aimed at enhancing the health and quality of life of postmenopausal women. The scientific evidence to support the concurrent use of these natural agents is as follows:

Dietary Supplements in the Management of Menopausal Symptoms

1. Black Cohosh:

The most widely used and thoroughly studied natural supplement for the management of menopausal symptoms is the herbal agent known as black cohosh (*cimifuga racemosa*), which must be standardized to 2.5% triterpene content. Four major human studies have demonstrated the ability of black cohosh to help manage menopausal signs and symptoms. In the first study (open study) involving 131 doctors, who together recruited 629 female patients, 80% of patients experienced improvement of physical and psychological symptoms, associated with menopause, within 6 to 8 weeks of treatment with black cohosh extract. Significant improvement was noted in the following symptoms:

- Hot flashes
- Profuse sweating
- Headache
- Vertigo
- Heart palpitations
- Tinnitus
- Nervousness / Irritability
- Sleep disturbances
- Depressive moods

Only 7% of patients reported mild transitory stomach complaints. ^{22,30,6}

A second study (controlled study) compared the effects of black cohosh to estrogen replacement therapy (0.625 mg C.E.E.) or diazepam (2 mg) for 12 weeks. Black cohosh out-performed both Premarin (C.E.E.) and Valium (diazepam) using the Kupperman Menopausal Index.

This index is one of the most utilized assessments in clinical studies of menopause. This quantitative assessment of menopausal symptoms is achieved by grading of severity:

Severe = 3

Moderate = 2

Mild = 1

Not present = 0

After grading each symptom, the total score is achieved by adding all of the symptom scores together.

Symptoms assessed are:

- Depressive moods
- Feelings of Vertigo
- Headache
- Heart Palpitations
- Hot flashes
- Joint Pain
- Loss of Concentration
- Nervousness / Irritability
- Profuse sweating
- Sleep disturbances ³¹

The third study (double-blind) compared the effects of black cohosh to estrogen replacement therapy (0.625 mg C.E.E.) or a placebo for 12 weeks. In this study, black cohosh produced better results in controlling menopausal symptoms (Kupperman Menopausal Index), the Hamilton Anxiety Test, and produced greater improvement in the vaginal lining than estrogen or the placebo. In the black cohosh group, the number of hot flashes per day dropped from an average of 5 to less than 1. In the estrogen group, this number dropped from 5 to 3.5 hot flashes per day on average. ²⁸

In a fourth study, (double-blind) black cohosh was compared to a placebo in a study following 110 women. The black cohosh group demonstrated significant improvement in menopausal symptoms and blood hormone measurements. In addition to relieving hot flashes, it once again produced impressive age-reversal results on the vaginal lining as confirmed by vaginal smear analysis.

Since 1956, over 1.5 million menopausal women in Germany have used black cohosh extract with noted success and without significant side effects. Physiologically, black cohosh extract appears to mimic the effects of estriol, which is a form of estrogen made by the body. Estriol is a weaker form of estrogen than estrone or estradiol, and is not associated with an increased risk of reproductive cancers. Like other forms of estrogen, estriol helps to maintain bone density and aids cholesterol removal from the blood stream. Black cohosh extract has also been shown to inhibit the over-secretion of leutinizing hormone (L.H.), providing proof of its estrogen-like properties. ^{28,32}

Remarkably, the triterpene saponins, unique to black cohosh, have also been shown to serve as a precursor (building block) for the synthesis of progesterone in the body. ³³ As there is a 66% decline in progesterone levels at menopause, black cohosh supplementation may help to preserve progesterone balance, which is important to preserving bone health, maintaining libido and psychological well being. ⁴ The dosage that is proven to be beneficial in the treatment of menopausal symptoms, is 40 or 80 mg, taken twice per day (standardized grade containing 2.5% triterpene glycoside content). ²⁸

2. Soy Isoflavones:

Soy extract, yielding a minimum of 50 mg of soy isoflavones, has been shown to reduce hot flashes and other menopausal symptoms in various clinical trials. ^{14,34,36} Some studies show up to a 40% reduction in hot flashes with the use of soy isoflavone products.

¹⁴ Soy isoflavones also possess phytoestrogen activity (plant-based estrogen). Like the triterpene saponins found in black cohosh, soy isoflavones are a type of “selective estrogen receptor modulator” or SERM, which preferentially stimulates beta estrogen receptor on reproductive and other tissues. In turn, this provides weak estrogenic support to reproductive tissue and bones, without over stimulating breast and endometrial cells, as may HRT. HRT stimulates the alpha receptors on breast tissue, which increases their rate of cell division, and the likelihood of developing cancerous mutations. Stimulation of the beta receptors, by soy isoflavones and black cohosh triterpenes, has been shown to slow down the rate of cell division of breast and endometrial cells, in the presence of the body’s own estrogen; an effect associated with a decreased risk of reproductive cancers.
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Investigation into the biological actions of soy isoflavones suggests that they provide a number of additional protective effects. These include antioxidant protection against free radicals, the slowing of cellular proliferation, reducing the synthesis of estrone hormone by inhibiting the estrogen synthase (aromatase) enzyme in fat tissue, increasing the detoxification of potentially harmful chemicals and hormones, and by competing with the body’s more powerful estrogen for attachment and stimulation of estrogen receptors on the breast, and other tissues expressing estrogen receptors.

Soy isoflavones have also been shown to support bone mineral density in postmenopausal women, and help keep cholesterol levels within a safer range, as mentioned earlier. ¹⁴

3. Gamma-oryzanol:

Supplementation with gamma-oryzanol (150 mg, twice per day) has been shown to reduce the secretion of leutinizing hormone (LH) by the pituitary gland and promote endorphin release by the hypothalamus. Hot flashes and other menopausal symptoms (profuse sweating, mood changes) result indirectly from the over-secretion of LH, which is attempting to initiate the start of another ovulatory cycle. The lack of response by the immature egg cells in the ovaries at the outset of menopause results in over-secretion of follicle stimulating hormone (FSH) and LH by the pituitary, contributing to the onset of hot flashes and related symptoms. Clinical trials reveal that 67 – 85% of women treated with gamma-oryzanol have experienced a significant reduction in menopausal symptoms.

¹² As noted previously, gamma-oryzanol, supplemented at the above noted dosage, is also known to reduce high cholesterol by up to 12%. ^{10,11,15}

Summary of Daily Dosage

It is now possible to find combination supplement products that provide all three nutrients (black cohosh, soy isoflavones and gamma-oryzanol) in a single product formulation. As these three nutrients work synergistically, recommending a combination formula of this nature gives the patient the best possible opportunity to control their symptoms and improve their state of well being, without having to rely on HRT. Not all cases respond to the use of natural supplementation, however, studies suggest that the majority of patients report extremely positive results. To summarize the doses and standardized grades of each nutrient the following guide should prove helpful:

1. Black cohosh extract – consider 80 mg, twice per day (standardized to 2.5% triterpene content)
2. Soy extract – 250 mg (yielding 25 mg of soy isoflavones), twice per day
3. Gamma-oryzanol – 150 mg, twice per day

This combination of nutrients can be used safely by low-risk menopausal women as a viable alternative to HRT (monitoring of bone density and blood lipids should be performed periodically), and by women who

have contraindications to estrogen replacement therapy (fibrocystic breast disease, endometriosis, uterine fibroids, liver or gallbladder disease, pancreatitis, or unexplained uterine bleeding).^{28,14,12} As well, women taking HRT may want to use a combination formula such as this for general nutrient support, in order to acquire important isoflavones and related phytoestrogens.

As stated previously, due to bothersome side effects and fear of breast cancer, less than 20% of North American postmenopausal women were currently using estrogen replacement therapy prior to this most recent report in July 2002.⁴ It is anticipated that many users will choose to quit HRT or be advised to do so by their physician, based upon the latest findings of the American Women's Health Initiative trial.¹

It should be noted however, that several studies using lower doses of estrogen (0.33 mg vs 0.625 or 1.25 mg as occurs in standard HRT preparations), have provided some evidence that lower doses of estrogen may be beneficial in preventing osteoporosis without increasing risk of breast cancer. As such, some concerned doctors have been prescribing lower doses of estrogen in combination with 200 mg of natural progesterone, over the past several years in light of previous evidence linking standard HRT doses with an increased risk of breast cancer. More study is required to know if these lower doses are safe, but they may represent a viable alternative for the time being for women who absolutely need this type of intervention.⁴⁰

Through proper guidance directed towards nutrition, exercise, and supplementation, practitioners can greatly influence a woman's quality of life and health risk profile during the menopausal years. Many of the proven principles of natural menopausal management have been largely overlooked by traditional medicine and thus, it is incumbent upon more holistic practitioners to enlighten their female patients in regards to these matters, particularly in light of the recent negative outcomes associated with HRT.

From my experience the combination of black cohosh, soy isoflavones and gamma-oryzanol, as outlined above, can be used for the following conditions and concerns:

1. As a natural alternative to estrogen replacement or HRT for postmenopausal women, who demonstrate normal bone density and cholesterol levels
2. As an important source of phytoestrogens and phytonutrients for women of all ages to help reduce the risk of female-related diseases throughout their lifetime (cut the dosage in half for premenopausal women and teenagers)
3. As a supplement for women with PMS, fibroids, endometriosis and fibrocystic breast disease
4. As an alternative treatment for postmenopausal women with contraindications to estrogen replacement therapy
5. As a dietary adjunct to estrogen replacement therapy or the birth control pill, in order to help tone down the over-stimulation effect of these drugs on breast and uterine tissues.

Final Comments

By age 50 all women should have a bone mineral density test to determine their bone status. If osteoporosis is not found to be present, then most women can simply follow the lifestyle program outlined in this review. If there has already been significant bone loss, then the attending physician may wish to consider the use of bisphosphonate drugs, which have been shown to slow the loss of calcium from bone, or the use of Raloxifen or other SERMs such as Tamoxifen. The point is that all postmenopausal women should have their bone density tracked periodically to monitor the effectiveness of the program to which they are subscribing, be that the use of lifestyle and natural substances and/or the use of conventional drugs. Blood work to determine fasting cholesterol and triglyceride levels and other biomarkers of cardiovascular disease should also be included as part of regular screening. What is now clear, however, is that the use of HRT as a means to manage menopausal symptoms and prevent heart disease in postmenopausal women has fallen out of favor, even in the most traditional medical circles. Patients are seeking the help of knowledgeable professionals, who are able to guide them to evidence-based natural interventions that are proven to be safe and effective. With a baby boomer turning 50 years of age every seven seconds, there is tremendous need for allied health practitioners to disseminate credible wellness information that can enhance the quality of people's lives and help individuals avoid illness and other maladies, where science has shown that such conditions can be prevented, postponed and/or safely and effectively managed. The information contained in this report should enable health care

professionals, interested in wellness management, to provide scientifically sound advice to their female clients in regards to the natural management of menopausal symptoms and the prevention of serious and often life threatening health conditions, that are common in the postmenopausal stage of life.

For more information on this or other related topics, visit Dr. Meschino's website at: www.renaissance.com.

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THE NATURAL MANAGEMENT OF PREMENSTRUAL SYNDROME

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The Premenstrual Syndrome (PMS) is a recurrent, variable cluster of troublesome physical and emotional symptoms that develop during the 7-14 days before the onset of menses and subside when menstruation occurs. Approximately one-third of all premenopausal women are affected, primarily those 25-40 years of age. In about 10% of affected women, the syndrome may be recurrent and severe.¹

Symptoms can be classified as:

- Behavioral (nervousness, anxiety, irritability, mood swings, fatigue, lethargy, depression)
- Gastrointestinal (abdominal bloating, diarrhea and/or constipation, appetite changes with cravings for such things as sugar, salt or chocolate)
- Reproductive Tissue (breast tenderness and swelling, uterine cramping, altered libido)
- Other (headache, backache, acne, ankle and finger swelling)²

Although not every woman experiences all the symptoms or signs at one time, many consistently complain of bloating, breast pain, ankle swelling, a sense of increased weight, skin disorders, irritability, aggressiveness, depression, libido changes, lethargy and food cravings.¹

Causative Factors

One of the underlying factors that has been linked to PMS is an elevated estrogen to progesterone ratio five to ten days prior to menses. This can arise from excess estrogen synthesis, decreased estrogen clearance (liver detoxification of circulating estrogen) or reduced secretion of progesterone from the corpus luteum. (After ovulation the corpus luteum is formed in the ovaries, which secretes progesterone. If fertilization does not take place, the corpus luteum shrinks and progesterone secretion drops off until approximately day 14 of the next menstrual cycle, when a new corpus luteum is formed in the ovaries.)^{3,4,5}

Typically, this derangement is caused by a combined mild estrogen excess and mild progesterone deficiency.²

Evidence exists to show that an elevated estrogen to progesterone ratio is associated with a decline in brain endorphin levels, which in all likelihood, is a contributing factor to mood swings in the premenstrual syndrome. Brain endorphin levels are known to increase the feeling of psychological well being.^{6,4}

Elevated estrogen levels are also known to adversely affect Vitamin B6 status. Vitamin B6 levels are often low in depressed patients, especially women taking estrogens (birth control pills or estrogen replacement therapy).^{7,8}

At the same time, studies reveal that Vitamin B6 supplementation can improve many symptoms of PMS.^{9,10}

Excess estrogen may also give rise to elevated levels of prolactin hormone, which is implicated in breast pain and fibrocystic breast disease.^{11,12}

Elevated estrogen levels may also result in higher levels of aldosterone, which is the hormone that increases sodium and water retention.² Thus, an elevated estrogen to progesterone ratio has been shown to alter endorphin, neurotransmitter (brain chemicals) prolactin and aldosterone levels, which contribute to many of the psychological and physical symptoms of PMS.²

Correcting the Estrogen to Progesterone Ratio Naturally

A number of dietary, lifestyle and supplementation practices have been shown to improve the estrogen to progesterone ratio and provide relief to women who suffer from PMS:

- A. A low fat, high fiber diet can help reduce circulating estrogen levels. Vegetarian women, who are known to have higher intakes of fiber excrete two to three times more estrogen in their feces and have fifty percent lower levels of free estrogen in their blood than omnivores.^{13,14} Other studies reveal that when women lowered their fat intake from 40 percent to 25 percent of their total calories and increase their fiber consumption from 12 gms to 40 gms per day, there was a 36 percent reduction in blood estrogen levels. A low fat diet alone has also been shown to relieve PMS symptoms.^{15, 16, 17}
- B. Exercise has also been shown to have a favorable modifying influence on PMS frequency and severity. Several studies demonstrate that women who engage in regular exercise programs do not suffer from PMS nearly as often as sedentary women. In addition to lowering free-estrogen blood levels, exercise also raises brain endorphin levels, improving mood and reducing anxiety and feelings of depression.^{18,19,20}
- C. Specific dietary supplements have proven value in normalizing the estrogen to progesterone ratio and markedly improving PMS frequency and severity:

- Black Cohosh – contains triterpene or saponin compounds that serve as a natural building block of progesterone synthesis. It is the only known natural substance that can raise blood progesterone levels. Additionally, black cohosh triterpenes help to block the effects of excess estrogen on breast tissue and the uterus, toning down the PMS-promoting impact on these tissues. Studies on women with PMS reveal that the standardized grade of black cohosh can improve PMS symptoms when taken at a daily dosage of 40 or 80 mg, twice daily (std to 2.5% triterpene content).^{21,22}
- Other botanical substances have also been shown to reduce PMS symptoms, such as Angelica Species (dong quai), Red Clover, and Licorice Root. The problem is, however, that Angelica Species and Red Clover contain coumarins and thus predispose patients to photosensitivity-induced dermatitis and internal bleeding disorders. They are both contraindicated with concurrent use of any anti-coagulant drug and reports of bleeding disorders appear in the scientific literature in reference to the use of Angelica Species. Active ingredients in Licorice are known to cause high blood pressure as a common side effect of its use.^{23,24}

Overall, black cohosh offers a safe and effective natural approach to the treatment of PMS. It has no well-known drug-nutrient interactions with few and minimal side effects reported. Black cohosh has even been shown to provide antispasmodic and pain relief in PMS sufferers.²¹

Chasteberry is another herbal agent that has proven value in the treatment of PMS as a further option. The usual daily dosage is 175-225 mg (std to 0.5 percent agnuside content).^{25,26}

- Soy isoflavones – have been shown to tone down the effects of the body's estrogens. Soy isoflavones act as phytoestrogens (plant-based estrogens), which can attach to estrogen receptors on the breast, endometrium and other tissues. As such, they can partially block the entrance into these tissues of the body's estrogens, helping to reduce estrogen overstimulation to the breast and uterine tissues. Soy isoflavonoids also enhance estrogen detoxification by the liver and slow down the synthesis of estrogen by inhibiting estrogen synthase enzyme (aromatase) in adipose tissue. Through these mechanisms, the ingestion of 45-75 mg per day of soy isoflavonoids has demonstrated therapeutic benefits in the management of menopausal symptoms, bone density support and modulating female reproductive health, including menstrual cycle regulation.^{27,28,29,30}

- B-Vitamins – More than a dozen double-blind clinical trials suggest that Vitamin B6 supplementation is useful in the treatment of PMS. Vitamin B6 is a co-factor in estrogen detoxification in the liver, a co-factor in the synthesis of mood elevating neurotransmitters (brain chemicals) and a co-factor in the formation of anti-inflammatory prostaglandin hormones. In some of these applications, Vitamin B6 works synergistically with other B-Vitamins, such as niacin, folic acid, Vitamin B12 and Vitamin B2. Thus, it is likely best to use a B-50 complex as a more comprehensive B-Vitamin approach to the management of PMS.^{9,10} Some studies suggest that Vitamin B6 taken in conjunction with 300-400 mg of magnesium per day is beneficial in PMS management.³¹ Vitamin B6 works together with magnesium in many enzyme systems and thus, are considered to be synergistic nutrients with proven value in the treatment of PMS.³²
- Vitamin E – Double-blind studies also suggest that Vitamin E supplementation at 400 I.U. per day can reduce various symptoms of PMS, including nervous tension, headache, fatigue, depression, insomnia, breast tenderness, anxiety and food cravings. Vitamin E is known to modulate prostaglandin hormone synthesis and directly affects cellular differentiation (maturation) and proliferation rates (cell division rate) of breast and other epithelial tissues.^{33,34,35,36,37} Vitamin E supplementation (400-600 I.U. per day) has also been shown to help regulate circulating hormones in PMS and fibrocystic breast disease.^{34,38}

Summary

In many cases, PMS can be managed naturally through dietary modification, exercise, and nutritional supplementation. Some of the recurring abdominal cramping and pain is also responsive to hands-on chiropractic care and acupuncture. With respect to dietary and supplementation practices, the following practical recommendations simplify the daily course of action to be considered by PMS sufferers:

1. Eat less animal fat.
2. Consume more grain fiber (wheat bran, psyllium) and vegetables (especially cruciferous vegetables such as cabbage, cauliflower, broccoli and brussels sprouts).
3. High Potency Multi Vitamin and Mineral – containing a B-50 complex, Vitamin E (400 I.U.) — from natural sources, Magnesium (200-300 mg), Calcium (500 mg), and all vitamins and minerals from “A to Zinc.”
4. Black Cohosh – 80 mg, once or twice per day (std to 2.5 percent triterpene content)
5. Soy Extract – 500 mg per day (std to 10% isoflavones), yielding 50 mg of isoflavones
6. Supplement diet with other soy-based foods, such as soy milk, soy cheese, veggie burgers, etc.

Finally, it is beneficial to participate in an aerobic-based exercise program 3 to 6 times per week for 20-45 minutes per session (on average), and have the lower spine and pelvis checked by a Doctor of Chiropractic in cases where abdominal pain and cramping is a recurring PMS symptom.

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Black Cohosh and Breast Cancer: A Review of the Scientific Studies

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Human observational studies (Epidemiological studies) and experimental evidence suggest that soy isoflavones, which act as phytoestrogens (plant-based estrogens) in the body, help reduce risk of breast cancer. In Asia, where soy isoflavone intake is high, the incidence of breast cancer in women is 75% lower than in North America. (1,2) Soy isoflavones have been shown to slow the cell division rate of breast cells, an effect that is associated with a lower risk of developing cancerous mutations. (3)

The herb known as black cohosh also contains an isoflavone known as formononetin, which has been shown to act as a phytoestrogen in human studies. (4) In Europe, black cohosh has been used routinely with great success for the past 40 years as a treatment for menopausal symptoms, PMS and other female reproductive disorders (i.e., dysmenorrhea), in place of conventional hormone replacement therapy and oral contraceptives. (5) Black cohosh has also been recommended or prescribed in the United States for more than 100 years and was an official drug of the U.S. Pharmacopoeia from 1820 to 1926, which was the era prior to the political movement that allowed patented drugs, manufactured by pharmaceutical companies, to dominate the drug market, in concert with the growing influence that pharmaceutical companies have been allowed to exert on the prescribing practices of medical practitioners.

Over the years many studies have documented black cohosh's effectiveness and safety. Published reports from Germany, where black cohosh has been used as a primary mode of treatment for menopausal symptoms for the past 40 years, indicate that it has a high safety profile and is associated with few and infrequent side effects, which include nausea, vomiting, headaches, dizziness, breast pain (mastalgia). No drug interactions are reported in the medical literature for black cohosh, adding to the evidence that it is a safe intervention for the management of menopausal symptoms, as well as PMS, dysmenorrhea and other female reproductive complaints. (5,6) Throughout its documented use by millions of women over the past 40 years, there has been no indication that supplementation with black cohosh increases risk of breast cancer or any other female reproductive cancer. (7) Moreover, black cohosh has been shown to have a safety profile that is superior to that of hormone replacement, in that hormone replacement therapy is known to increase the risk of breast cancer by 2.3% per year and has been shown to increase risk of other conditions (heart disease and stroke), according to the recently published results of the Women's Health Initiative Study in the U.S. (8,9)

Intrigued by the physiological effects of black cohosh on female reproductive tissues, a number of researchers have designed experimental studies to examine the influence of black cohosh on breast cancer risk. As stated previously, its long historical use in Europe and the United States, as an effective and natural treatment for menopausal symptoms, PMS and other female conditions, has shown that it is not associated with an increased risk of breast cancer, or any other cancer. (10) Additionally, all of the experimental studies performed to date, involving the use of human breast cells and human breast cancer cells have shown that standardized extracts of black cohosh actually block the development of breast cancer and/or decrease the ability of breast cancer cells to divide and multiply. The assumption made by many investigators was that black cohosh might encourage the growth of breast cancer cells because it has a weak estrogenic effect, which is likely to promote proliferation of these cells. However, in vitro studies, using human breast cells and

human breast cancer cells, have demonstrated the opposite effect. In these studies black cohosh has been shown to have an antiproliferative effect on a number of human breast cancer cell lines. Reporting in the journal, *Breast Cancer Research and Treatment* (2002), C Bodinet and J Freudenstein, showed that black cohosh extract significantly inhibited human breast cancer cells (MCF-7 breast cancer cell line) from proliferating (dividing and spreading). They also showed that black cohosh extract enhanced the effectiveness of the anti-cancer breast cancer drug Tamoxifen, in regards to its ability to suppress the proliferation of breast cancer cells. These researchers concluded that black cohosh extract treatment may be a safe, natural remedy for menopausal symptoms in patients who have had breast cancer. Tamoxifen is a drug given to patients who previously had estrogen receptor positive breast cancer, to help prevent a recurrence or spread of their condition. Experimental data suggest that black cohosh should be considered as a component of the treatment protocol when Tamoxifen is administered to patients who have had breast cancer in the past and may further help to prevent the recurrence of breast cancer in patients who previously had breast cancer cells displaying estrogen-receptor-positive phenotype. (11) In the study by Foster, the authors concluded that extracts of black cohosh can be taken safely by patients who are susceptible to breast cancer (and possibly should be used as a means of chemoprevention [cancer prevention]). (12)

The study by D Dixon-Shanies and N Shaikh (1999), published in *Oncology Report*, also demonstrated that black cohosh extract blocks the growth of human breast cancer cells (T-47D human breast cancer cell line), and these researchers surmise that in vitro studies suggest that certain herbs, such as black cohosh extract and soy (particularly the genistein isoflavone) may have potential in the prevention of breast cancer. (13)

As one in nine women in the U.S. develops this disease, some experts suggest that it may be prudent for North American women to use a well-designed black cohosh- and soy isoflavone-containing supplement as a preventive measure throughout adult life (unless contraindications are present), as a means to discourage the development and/or spread of breast cancer. Theoretically, the anti-proliferative effects of these natural herbal agents acting on breast cells, would give the immune system a better chance to destroy any cancer cell before it has an opportunity to thrive; at least this is the current thinking.

A recent study funded by Susan G. Komen Foundation showed that a specific strain of mice, who are bred to be more susceptible to the development of spontaneous breast cancer (transgenic mouse model of breast cancer), were no more likely to develop breast cancer during one full year of supplementation with black cohosh, at a dosage comparable to that used in women. This study showed that even mice that are at high risk for breast cancer development, due to genetic reasons, are no more likely to develop breast cancer during black cohosh supplementation than are the non-black cohosh supplemented mice. This study did show, however, that there was an increase in lung metastasis in mice that developed breast cancer in the black cohosh group (27%), compared to the non-supplemented mice (11%). Whether or not this is an incidental or significant finding needs to be confirmed by further studies. (14) Studies in humans and experimental studies, using human breast cancer cells (not breast cells from mice), suggest that in humans black cohosh does not increase breast cancer risk and may, in fact, reduce risk of this disease, and may provide additional protection against the recurrence of breast cancer (while managing the hot flashes induced by the drug Tamoxifen) in patients with a previous history of breast cancer. (11,12,13) In fact, Freudenstein and Bodinet, mentioned above, concluded that extracts of black cohosh can be taken safely by patients who are susceptible to breast cancer. (12) Additionally, a recent study by JE Burdette and fellow researchers demonstrated that many natural ingredients present within black cohosh extract were shown to inhibit free radical damage (mutations) to the DNA of human breast cancer cells (S30 breast cancer cell line), upon exposure to a potent free radical source (menadione). The results showed that many substances contained within black cohosh (methyl caffeate, caffeic acid, ferulic acid, cimicifugic acid, fukinolic acid) exhibited powerful antioxidant effects, significantly reducing free radical damage and mutations within the DNA of human breast cells. The researchers state that this data suggest that black cohosh can protect against cellular DNA damage caused by reactive oxygen species (free radicals) by acting as antioxidants. (15) The standardized grade that demonstrates clinical efficacy involves the use of black cohosh extract providing 2.5% triterpene content. A usual daily dosage for menopausal women and younger women experiencing PMS and/or dysmenorrhea (painful menstruation) is 40 or 80 mg, twice per day. (7) Active ingredients in black cohosh extract also exhibit anti-spasmodic effects upon smooth muscle, which may account for its ability to relieve menstrual cramps. The triterpene glycosides found in this herb are also the only known precursor (building block) from which the body can increase synthesis of progesterone, a factor that likely contributes to the success of this herb in the management of PMS where corpus luteum failure, resulting in low secretions of progesterone, has been shown to be a contributing factor. (16)

In regards to black cohosh and risk of breast cancer, the cumulative human evidence of more than 100 years, as well as the experimental investigative studies on this herb, strongly suggest that it does not promote the development of breast cancer. According to studies using human breast cells and human breast cancer cells, black cohosh extract may, in fact, reduce risk of breast cancer development, and may be a consideration to help reduce hot flashes in women on Tamoxifen, who have had a previous history of breast cancer. (11,12,13)

Studies examining the toxicity of black cohosh, which have used high dosages of this herb in rats for long periods of time, suggest that black cohosh is very non-toxic and can be used safely for long-term use. Black cohosh should not be taken during pregnancy. (17)

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