

BIO-BALANCE 4 WOMEN

Menopause Treatment Options

Estrogen was first synthesized in the 1920 and was used to treat postmenopausal hot flashes in the 1930's. The role of estrogen in osteoporosis prevention was not understood until the 1940's. The positive cardiovascular effects to estrogen were then discovered in the 1950's. Three decades later, further data concerning the beneficial effects of estrogen incognizant of function became available.

Testosterone, an androgenic or male hormone, is produced naturally in the ovaries. The effect of testosterone on menopausal symptoms was first studied in the 1930's. By the 1940's the medical literature described the positive enhancement of testosterone on sexual well-being. Ten years later, improvement in the quality of life by administering testosterone to menopausal women was demonstrated. By the 1970's the adrenal and ovarian source of testosterone were described more accurately with data showing that the ovaries produce the majority of testosterone in women. In the 1980's further studies confirmed that testosterone was the main sex drive motivator. More recently the beneficial effects of testosterone on bone, lipids, and hot flashes have been studied. Today there is ample evidence regarding the value of estrogen/testosterone replacement in postmenopausal women. This appears to be particularly valuable for women who have undergone a surgical menopause. Even when ovaries are preserved during hysterectomy, approximately 25% will cease producing hormones within in six months. There are many forms of estrogen therapy today, including natural hormones, oral tablets, injectable hormones, transdermal patches and gels as well as subcutaneous pellets. Currently only 10 to 15% of American women have prescribed hormonal replacement therapy. Often patients do not understand the beneficial effects of HRT in reducing heart disease, osteoporosis, Alzheimer's and menopausal symptoms such as hot flashes, insomnia, irritability, decreased libido, and depression. Many do not fill their initial prescription and about half stop their therapy within one year.

Currently, 50 million women may be considering the use of hormone replacement therapy HRT, 85% truly have hot flashes. HRT is about 90% effective in relieving vasomotor instability which causes hot flashes. Hormonal replacement therapy also offers long-term protection against cardiac disease, osteoporosis and Alzheimer's disease. Only 8% of women who have undergone a natural menopause take HRT for longer than a year. Nearly 40% of Americans use alternative medical therapies primarily herbal remedies. There is growing evidence that isoflavones from food can have beneficial health effects in treating menopause. In contrast to prescription medication, there is little scientific substantiation regarding the safety and effectiveness of herbal remedies commonly available today. As opposed to prescribed estrogen, testosterone and progesterone, quality control is often absent and hormone content can vary extensively in these over-the-counter herbal products. Exceptions to this rule include the Rexall or Unicity Network vitamins and herbals which are prescribed by your physician. Some foods which are rich in isoflavones may reduce the risk of cardiac disease and osteoporosis. These foods include soy, such as tofu, sweet potatoes, pumpkin, beans, carrots, garlic, red wine, barley, green beans and oats. Promensil is a red clover isoflavone extract and may also be helpful in reducing hot flashes.

Herbal remedies include St. John's Wort which may act as an antidepressant but may reduce estrogens effectiveness. DHEA may increase energy, improve well-being, reduce sleep disturbances and aid in handling stress. Adverse effects include hypertension and insulin resistance. Black Cohosh appears to have estrogenic effects and may be effective in treating menstrual cramps. Damquai is claimed to relieve all menstrual symptoms but research findings failed to substantiate all of these claims. Gingko Biloba is marketed to improve memory and reverse aging. Ginseng is promoted as an aphrodisiac and an aid to relieve menopausal symptoms based on animal research. Uterine bleeding to endometrial cancer may occur if it is used in high doses.

Yearly, you should have the following tests: Pap smear, breast exam, mammogram, and possibly a vaginal ultrasound or an endometrial biopsy. Every three years, you should have a lipid profile and a thyroid function test. Every three to five years, you should have a bone density test unless you have osteoporosis or osteopenia and then you should monitor your bone density on a yearly basis.

To empower you, you should also learn about hormone treatments and read as much as you can from reliable sources. You may turn your attention to the website Biobalance4Women.com. This website will have links to reliable information sources such as Web MD and the American College of Obstetrics and Gynecology. It is very important that you become an informed consumer and make decisions in conjunction with discussions with your physician. When you are informed, you can enjoy menopause and decide on the appropriate hormone replacement that is for you.

The latest WHI study which was featured on the front of many newspapers and in many magazines was a tainted study because it was done on women over 60 who had never taken hormonal therapy and who had been given Premarin and Provera and no natural form of estrogen and progesterone. We suggest bioidentical estrogen and bioidentical testosterone which is similar to what the body makes itself and women who have plenty of these two hormones such as women in their late 30's and early 40's do not have higher risk of cancer or heart disease than women past menopause with these same hormones will not increase their risk for heart disease or breast cancer.

Other readings that may bring you closer to understanding so that you can make informed decisions include the book *Natural Hormone Balance* by Uzzi Reiss and a new book by Dr. Gino Tuteria who is responsible for the training and use of bioidentical hormone pellets. Other good readings include the Carbohydrate Addicts Healthy Heart program and *Guidelines for Women's Health Care* by the American College of OB/GYN.

Estrogen:

Plant-based estrogen from Mexican wild yams may be administered orally in tablet form, transdermally by patch or gel and IM by injection or by subcutaneous pellet insertion. Each treated delivery has advantages and disadvantages which should be weighed in determining what the best mode of therapy is for you. The most common side effect expressed regarding oral estrogen is weight gain and water retention. This side effect has not been proven by a double blind study, however, it is

clinically appearing in 10 to 15% of patients. This same percentage of patients will not even absorb oral estrogen and will continue to have low estrogen levels and high FSH levels leading to continuing hormonal symptoms. Estrogen is metabolized by the liver when it is taken orally and is literally taken apart by the liver and made into several degradation products which are then used by the body. Because of this first pass effect, many hormones are inactivated when taken orally and cause a great deal of side effects. Therefore, women choose to take their hormones in another manner.

Laboratory testing to check FSH and estradiol is required to detect lack of absorption or high first pass effect in many women. Transdermal and IM or pellet administration will usually solve this problem. Some patient's have poor circulation to their skin and therefore do not absorb through the skin. Most patient's above the age of 70 will not absorb through a transdermal patch and therefore will require either shots or pellets to achieve relief of their symptoms. Many women do well on the patch but some allergic to the glue or cannot keep it on and many need to change their patch more often than twice a week as is directed by the pharmaceutical company that makes the patch. Intramuscular estrogen requires a visit to the doctor once a month to receive the shot and also may cause a drop in estrogen immediately prior to the injection which would cause mood swings and headaches.

Subcutaneous pellets usually produce stable hormone levels in a bioidentical fashion to what the body produced at an earlier time. Subcutaneous pellets also increase their absorption when you are awake and blood flow is high and decrease their absorption at night when you do not need your hormones quite as much while you are sleeping. Increased exercise and metabolism will use up the pellets more quickly and a low metabolism will cause patients to use their pellets slowly and not need reinsertion quite as often.

Some hormones that are produced orally include Estrace which is a 17 beta estradiol, a natural estrogen obtained from Mexican wild yams and the level of Estrace can be followed easily by monitoring blood tests. The patch features several delivery systems to achieve adequate tissue levels but some of my patients have noted that the patch comes off, they are very hard to get refilled as the insurance company will only give you exactly enough for a month and if one comes off, you cannot get a refill.

Patient management that is necessary for estrogen therapy include yearly Pap smears, pelvic exams and in some instances blood levels. Some side effects of estrogen are breast tenderness, swelling in the hands, feet and face, bloating of the abdomen, nausea, migraine headaches and some times weight gain and increased hunger.

Progesterone:

If you have a functioning uterus, progesterone is needed to reduce the chance of malignancy of the uterine lining. A daily or two week per month dose of progesterone may be given. Sometimes progesterone can be given on a daily basis with your estrogen if you are taking it orally.

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A natural progesterone such as Prometrium can be given orally or a progesterone vaginal suppository is sometimes recommended. Progesterone prevents PMS and also stabilizes the endometrial lining. I do not recommend any form of Provera as it is broken down on the first pass through the liver into multiple smaller molecules that have side effects such as hunger, increase in cholesterol, irritability and make PMS worse instead of better. If you have a functioning uterus, it is important to take progesterone cyclically or daily to prevent hyperstimulation of the uterine lining which may lead to endometrial hyperplasia or even endometrial cancer. If you are finished with childbearing and would like to take estrogen and cannot tolerate progesterone or choose not to take it, you may undergo a procedure called ThermaChoice which ablates or removes the lining of the uterus so that you do not have periods any more. This is a one day stay procedure with the usual risks of surgery but few risks in terms of threat to life or damage of other accompanying organs such as the bladder and the rectum which risks are involved with hysterectomy. ThermaChoice can be scheduled through your gynecologist's office and after that procedure is done, you may be able to take estrogen without progesterone if you choose. Progesterone therapy side effects, if given a natural progesterone, may cause withdrawal bleeding, sleepiness, bloating, headaches, depression and irritability. If Provera is considered, all of these same risks would be increased by the risk of fluid retention, PMS and highly increased irritability and abdominal bloating in addition to an increase in hunger. Natural progesterone should not cause bloating and acts as a diuretic in your body. It certainly should not cause headaches or breast tenderness but we often give it to counteract the effects of estrogen on the breast.

There is a patch that is available that has both Estradiol and a form of progesterone called Norethindrone acetate which is the same progesterone as is available in birth control pills. The CombiPatch is an excellent form of combined treatment which delivers both estrogen and progesterone for people with an intact uterus who do not want to undergo ThermaChoice or have the side effects or risks of estrogen without progesterone. The good news about CombiPatch is that after a year of therapy patients usually stop having periods because the lining of their uterus becomes so thin from the combined balance treatment. This can also be obtained with the use of natural progesterone with estrogen and testosterone pellets.

Your physician can assess the uterine effects of your hormonal replacement therapy by doing a vaginal probe ultrasound or an endometrial biopsy or a D&C and hysteroscopy. Our office chooses to begin with the least risky treatment which is a vaginal probe ultrasound and if the lining of the uterus is less than 4 mm and there is postmenopausal bleeding there is no risk of uterine cancer and no other treatment needs to be undertaken. If an endometrial biopsy is done in the office, there is a short period of pain during the procedure and for an hour or so thereafter. However, that office procedure can avoid a D&C to rule out malignancy or premalignancy.

If a D&C and hysteroscopy is done, a ThermaChoice treatment can be combined with that procedure so no more bleeding occurs in the future. A follow up ultrasound will be done two months after the ThermaChoice to prove that the lining is in fact gone.

Testosterone:

Testosterone is an androgenic or male hormone that women naturally make in their ovaries and in their adrenal glands. Some women make more than others which explains the discrepancy in sex drive and body hair distribution prior to the age of 40 in the normal population.

Testosterone can be administered orally by gel or in an IM injection or through subcutaneous pellets. The need for testosterone can be considered when you experience a lack of concentration, exhaustion, depression, absent or reduced libido; all of which can be improved with the addition of the proper type of testosterone. The current data suggests that testosterone added to estrogen for hormone replacement therapy may aid postmenopausal bone formation and reduce osteoporosis and lower LDL and triglycerides to reduce the risk of heart attacks. Testosterone, in fact, is the best bone builder and can reverse osteoporosis more quickly than estrogen, Fosamax or any other biphosphate including Evista marketed to improve osteoporosis. How many men have you known at the age of 60 who have osteoporosis? Not many unless they are on chronic steroids. Men make a lot of testosterone and their bones reflect that physiologic fact.

Testosterone prescribed without estrogen may adversely effect lipids as well as induce acne, hair growth and deepening of the voice. The addition of estrogen attenuates the side effects of testosterone alone and in a recent study of estrogen combined with testosterone there were no reports of serious liver or cardiovascular events. Prior to prescribing testosterone in any form, we will order a total and free testosterone level as well as a cardiovascular panel to see if you are at risk for heart disease and we will make sure that there are no co-existing diseases that might be made worse with testosterone. Testosterone can improve hot flashes, bladder symptoms, vaginal atrophy, depression, libido and osteoporosis. It also improves a condition known as dry eyes which is very severe in women after menopause and can keep you from having the option of wearing contact lenses.

Androgens also are the primary hormone that effects balance in both men and women and when testosterone decreases so does the incidence of falls in the elderly. The decrease of testosterone in women occurs beginning at age 35 and along with that decrease comes a decrease in vitality, sex drive and aging. The forms that are offered through normal oral or sublingual medications are either not well absorbed or have severe side effects because they have a methylated group attached to them.

This methylated group causes male side effects in women severe enough to discontinue treatment. Estrogen and testosterone pellets, however, do not have this methylated group and they are bioidentical to what women produce throughout their lifetime. The goal in therapy with testosterone is not only to get rid of all of the signs of testosterone deprivation but to improve quality of life to the point where patients have the same energy level and libido as they did when they were less than 35 years of age. Men tend to lose their testosterone starting at age 50 but it is a much slower drop and they rarely go through the type of libido drop that women do in their 40s.

Estrogen and testosterone pellets:

In 1937, subcutaneous estrogen pellets were first implanted in laboratory animals. Two years later, the first subcutaneous pellet insertion of Estradiol in humans was reported by Dr. Mishell in the American Journal of OB/GYN. With his conclusions that the subcutaneous pellets were safe and effective with no untoward side effects. In England, Greenblatt popularized the method of hormonal replacement therapy in 1949. If you are an OB/GYN, you know that Dr. Mishell and Dr. Greenblatt have always been forerunners in the field of endocrinology for women.

Lobo and other researchers under his direction use the pellets in an attempt to avoid the possible side effects of oral estrogen such as hypertension, blood clots and gallbladder disease. They compared serum levels of estradiol from the pellets to the newly developed Estraderm patch in 1988. Their data shows that the pellets provided a more reproducible delivery system than the patch, the stable estrogen levels for four months.

Holland regarded the pellets as the most effective treatment for postmenopausal osteoporosis because of the high estradiol levels achieved. He found a correlation between the serum estradiol levels and spinal bone density in postmenopausal women. He stated that there are no published data describing any ill effects from high estradiol levels. He reported also the most commonly administered doses of implants are 50, 75 and 100 of estradiol with the addition of 100 mg of testosterone for subcutaneous HRT. Studd found an 8.3% increase in spinal bone mineral density using pellets. The average estrogen level increased more than five fold from 80 to 453 using 75 mg of estradiol and 100 mg of testosterone.

Barlow studied the long-term hormonal and clinical effects of the pellets for up to three years. He documented rising estradiol and testosterone baseline levels from repeated insertion. Her surmised that even a small initial decrease in estrogen initiates hot flashes even though the estrogen level remains in the physiologic range. Thom demonstrated that the pellets give very consistent hormone levels which plateau for four to five months. She too noted that when symptoms return in four to six months the estrogen level had fallen only to within the normal premenopausal range. It is clear that reimplanting the pellets alleviates the menopausal symptoms. Reimplantation when the previous pellet is still functioning would explain the accumulated hormonal levels. Reported data has shown no change in weight, blood pressure, liver functions or other adverse metabolic effects during the therapy. If you think logically, this makes total sense because these hormones are bioidentical to the hormones you made prior to menopause or prior to having your ovaries removed.

Pellets should be considered for women not tolerating oral hormone replacement therapy. The hormone levels achieved with pellets more closely resembles stable levels experienced prior to menopause. Since women are more tolerant of pellet therapy better compliance is achieved resulting in the prevention of long-term disease such as osteoporosis, heart disease and Alzheimer's disease. Biobalance 4 Women in St. Louis and the Biobalance 4 Women in Kansas City was started by Dr. Kathy Maupin under the direction of Dr. Gino Tutera who has been treating menopause with hormone

therapy through pellet therapy in California for over 16 years. He has now centered his practice on relieving the ills and progressive decline of menopause in women throughout the United States. He currently is opening a new center for hormonal balance in Beverly Hills and is publishing a new book on Bioidentical hormones used by women and men via pellets.

As a woman physician, I, Dr. Kathy Maupin, have been confused by the disability and aging process that occurs at the time of ovarian imbalance. I have been searching for the answer to my patients complaints of hot flashes, night sweats, irritability, memory loss, insomnia and reduced sex drive. I felt that all of this could be tied together somewhere but none of the present literature or suggestions by the mainstream GYN endocrinologists could satisfy my quest to find an answer to this problem.

I have found my answer in being able to replace bioidentical hormones to postmenopausal women to bring them back to a state of hormone balance only found prior to menopause. With pre and postoperative blood evaluations and discussions with my patients, I have found that pellet replacement therapy is the only hormone therapy that actually leaves women satisfied, feeling younger and more energetic.

During my first year of developing this practice, I have had phone calls from husbands of my patients thanking me for repairing their marriages through reigniting their wives sex drives. I am extremely pleased and satisfied with these outcomes and plan on continuing bioidentical pellet therapy and all of the other metabolic therapy that is necessary at the time of menopause and beyond. My other interests include insulin resistance and prediabetes, adrenal abnormalities and growth hormone reduction after the age of 40. Many of these problems are only touched on by current mainstream therapy and I plan to assist in remedying current lack of information with my Biobalance 4 Women.

Kathy Maupin, M.D.