The American College of Obstetricians and Gynecologists



Women's Health Care Physicians



PFS003: Hormone Therapy APRIL 2013

Hormone Therapy

The average age when a woman has her last menstrual period is 51 years. **Menopause** is defined as the absence of menstrual periods for 1 year. The years leading up to menopause often are called **perimenopause**. This is a time of gradual decrease in **estrogen** levels and changes in the menstrual cycle. In general, perimenopause lasts from age 45 years to age 55 years, although the timing varies among women. Changing estrogen levels can bring on symptoms such as hot flashes and sleep changes. After menopause, the lack of estrogen can increase the risk of **osteoporosis** (bone loss). To manage the symptoms of perimenopause, some women may choose to take **hormone therapy**.

Your Body's Hormones

During your childbearing years, monthly changes in the production of two hormones—estrogen and *progesterone*—bring about your menstrual period. Estrogen has other effects in the body. It helps keep bones strong and helps protect against heart disease. It also keeps the tissues of the vagina moist and elastic.

Estrogen and progesterone are made by the *ovaries*. The ovaries also make other hormones, including the male hormone testosterone. Estrogen causes the *endometrium*—the lining of the uterus—to grow and thicken to prepare the uterus for pregnancy. In the middle of the cycle, one of the ovaries releases an egg (*ovulation*). Following ovulation, levels of progesterone begin to increase. If the woman does not become pregnant, estrogen and progesterone levels decrease. The decrease in progesterone triggers menstruation, or shedding of the lining.

During perimenopause, the ovaries begin to make less estrogen. Some months your ovaries may release an egg; some months they may not. As a result of these changes, your period may become irregular. The number of days between periods may increase or decrease. Your periods may become shorter or longer. Menstrual bleeding may get heavier or lighter. You may begin to skip periods. The event known as menopause happens when you have not had a menstrual period for 1 year.

Perimenopausal Signs and Symptoms

The signs and symptoms that many women experience during perimenopause are caused by gradually decreasing levels of estrogen. You may have only a few symptoms, or you may have many. Symptoms may be mild, or they may be severe.

Hot Flashes

About 75% of all women have hot flashes during perimenopause. A hot flash is a sudden feeling of heat that spreads over the face and body. The skin may redden like a blush. You also may break out in a sweat. Hot flashes may last from a few seconds to several minutes or longer. They can occur a few times a month or several times a day, depending on the woman. Hot flashes can happen anytime—day or night. When they occur at night, they can disrupt your sleep. Hot flashes at night also can cause night sweats.

Vaginal Dryness

Loss of estrogen causes changes in the vagina. The lining may become thin and dry. These changes can cause pain during sexual intercourse. They also can make the vagina more prone to infection, which can cause burning and itching.



The urinary tract also changes with age. The urethra (the tube that carries urine from the bladder during urination) can become dry, inflamed, or irritated. In some women, this irritation may lead to frequent urination. Women may have an increased risk of bladder infection after menopause.

Bone Changes and Osteoporosis

Bones are constantly changing throughout life. Old bone is removed in a process called resorption. New bone is built in a process called formation. During the teen years, bone is formed faster than it is broken down. The amount of bone in the body (sometimes called the "bone mass") reaches its peak during the late teen years. In midlife, the process begins to reverse: bone is broken down faster than it is made. After menopause, the decrease in estrogen triggers a period of rapid bone loss in women that starts 1 year before the final menstrual period and lasts for about 3 years. The natural effects of aging on bones may contribute to this bone loss as well. These changes can lead to a condition known as osteoporosis. In osteoporosis, the bones are weak and fragile and can break (fracture) more easily.

Hormone Therapy

Hormone therapy means to take estrogen, and in many cases, *progestin* as well. Progestin is a form of progesterone. Estrogen taken by itself increases the risk of cancer of the endometrium. Taking progestin along with estrogen reduces this risk. If you do not have a uterus (you have had a *hysterectomy*), estrogen generally is given alone, without progestin. Estrogen plus progestin is sometimes called "combined hormone therapy."

Systemic Therapy

Hormone therapy can be either "systemic" or "local." These two terms describe where and how the hormones act in the body. With systemic therapy, the hormones are released into your bloodstream and travel to the organs and tissues where it is needed. Systemic forms of estrogen include pills, skin patches, gels and sprays that are applied to the skin, and vaginal rings. If progestin is prescribed, it can be given as a pill, patch, gel, or in an *intrauterine device*. Progestin can be taken separately or combined with estrogen in the same pill or in a patch.

For women taking estrogen-only therapy, estrogen may be taken every day or every few days, depending on the way the estrogen is given. For women taking combined therapy, there are two types of regimens:

- 1. Cyclic therapy: Estrogen is taken every day, and progestin is added for several days each month or for several days every 3 or 4 months.
- 2. Continuous therapy: Both estrogen and progestin are taken every day.

It is common to have irregular bleeding the first few months of combined therapy use, but within 1 year, bleeding usually stops for most women. If you are postmenopausal, it is important to tell your health care provider if you have bleeding. Although it is often an expected side effect of hormone therapy, it also can be a sign of endometrial cancer. All bleeding after menopause should be evaluated.

Local Therapy

Women with vaginal dryness and thinning of the vaginal lining may be prescribed "local" estrogen therapy in the form of a low-dose vaginal ring, vaginal tablet, or vaginal cream. These forms release small doses of estrogen into the vaginal tissue. The estrogen helps restore the natural thickness and elasticity to the vaginal lining while relieving dryness and irritation. The tablets and creams usually are used daily at first, then twice or three times a week. The ring is inserted and left in the vagina for 3 months, after which it is removed and a new ring is inserted. You do not have to remove the ring for sexual intercourse.

Benefits and Risks of Hormone Therapy

Hormone therapy has many benefits, but it also has risks. Beginning in 2002, findings of the Women's Health Initiative, a study by the National Institutes of Health, raised concerns about the risks of both estrogen-only and combined hormone therapy for postmenopausal women. In the years since this study, efforts to clarify the findings have been ongoing. The following sections summarize the latest information about hormone therapy.

Benefits

- Both types of hormone therapy (combined and estrogen-only) remain the most effective treatment for the symptoms of perimenopause.
- Both types of hormone therapy help prevent the rapid bone loss that occurs early in menopause. It also has been shown to prevent hip and spine fractures.
- Low doses of local estrogen help relieve vaginal dryness and irritation.
- Estrogen-only therapy (but not combined therapy) appears to reduce the risk of developing or dying from breast cancer.

Risks

- Combined hormone therapy (specifically, a combination of oral conjugated equine estrogen and a progestin called medroxyprogesterone acetate) is associated with an increased risk of stroke, breast cancer, *deep vein thrombosis (DVT)*, gallbladder disease, and urinary incontinence. It does not prevent heart disease.
- · Estrogen-only therapy increases the risk of endometrial cancer.
- Estrogen-only therapy is associated with an increased risk of stroke, gallbladder disease, DVT, and urinary incontinence. It does not prevent heart disease.

Researchers are continuing to look closely at the risks and benefits of hormone therapy. The average age of the women who were studied in the WHI was 64 years, which is well past the age when menopause starts. Most women who take hormone therapy are in their 40s and 50s and are experiencing perimenopausal symptoms. Research is underway to study whether the risks associated with hormone therapy are related to when therapy is started, how long it is used, and how the therapy is given.

Current Recommendations

If you currently have or have a history of DVT or blood clots in the lungs; have active or recent *cardiovascular disease*, such as a stroke or heart attack; have estrogen-related cancer (such as breast cancer); have liver disease; or have undiagnosed uterine bleeding, you should not take hormone therapy. If you are healthy, it is recommended that use of hormone therapy be limited to the treatment of perimenopausal symptoms and for the prevention of osteoporosis in women at increased risk of osteoporosis or fractures. Hormone therapy is not currently recommended for the prevention of other chronic health conditions, such as heart disease. You should use the lowest effective dose for the shortest amount of time possible. Continued use should be reevaluated on a yearly basis. Some women may require longer therapy because of persistent symptoms.

In addition to seeing your health care provider regularly, you should contact your health care provider if you are taking hormone therapy and have abnormal uterine bleeding.

Other Options

Many women are interested in options other than hormone therapy that can be used to relieve symptoms of menopause. Keep in mind that for some of these options, there are concerns about their safety and effectiveness. It is important to talk with your health care provider about the risks and benefits of taking any of these alternatives to hormone therapy.

Medications

Some drugs that have been approved by the U.S. Food and Drug Administration (FDA) to treat other conditions also have been found to be effective in relieving hot flashes in some women. When a drug is used for another condition in addition to the medical problem it is approved for, it is called "off-label use." For example, *antidepressants* are primarily used to treat *depression*. Some antidepressant drugs also help to relieve hot flashes and can be prescribed for this purpose by your health care provider. Gabapentin, an anti-seizure medication, is another prescription drug that can be prescribed for off-label use to reduce hot flashes and ease sleep problems associated with menopause.

Vaginal Moisturizers and Lubricants

Vaginal moisturizers and lubricants can be used to help with vaginal dryness and painful sexual intercourse. They do not contain hormones, so they do not have an effect on the vagina's thickness or elasticity. They are used to relieve symptoms and make intercourse more comfortable.

Vaginal moisturizers are available over the counter. They come prepackaged in one-dose applicators. They are absorbed into the lining of the vagina and do two things: 1) they coat the vaginal lining to replenish moisture, much as your natural secretions do, and 2) they restore the natural acidity of the vagina. These effects last a few days. You can use a moisturizer every 2–3 days as needed.

Lubricants can be used each time you have sexual intercourse to make penetration easier and to decrease discomfort caused by friction. Many types of lubricants are available. Water-soluble lubricants are less sticky than other types. They are easily absorbed into the skin and may have to be reapplied frequently. Silicone-based lubricants last longer and tend to be more slippery than water-soluble lubricants. Oil-based lubricants include petroleum jelly, baby oil, or mineral oil. Oil-based lubricants should not be used with condoms. They can dissolve the latex and cause the condom to break.

Botanical Products

Botanical products either contain plant material or contain chemicals made in a lab that are based on plant materials. Many botanical products are sold over the counter to help relieve symptoms of perimenopause and menopause. These products can come in many forms, including pills, herbs sold in bulk, teas, tinctures, and oils.

Few studies have been done to test whether these substances actually are effective in treating perimenopausal and menopausal symptoms. Of those that have been tested, results do not show that they actually work consistently. Although a few people may find relief with a botanical product, this result is not the norm for the majority of people who participated in the studies.

There are a number of safety concerns as well. Just because a product is labelled "natural" does not mean it is safe. These products are not regulated by the FDA and there are no formal manufacturing standards. They may contain unsafe ingredients or they may be made in unsafe conditions. It also is important to know that some menopause products contain botanicals that act like estrogen in the body. Like standard hormone therapy, they may increase the risks of serious medical conditions. There also is a risk of drug interactions and side effects.

Bioidentical Hormones

Bioidentical hormones are hormones manufactured from plants that are combined together (compounded) by a pharmacist based on instructions from a health care provider. They are not approved by the FDA. There is no evidence that bioidentical hormones are more effective or safer than standard hormone therapy. These hormones have the same risks as hormone therapies approved by FDA. They may have additional safety risks as well, such as questionable quality or too much or too little of the drug.

Follow-up

The decision about how long to take hormone therapy depends on many factors and involves balancing individual risks and benefits. If you choose to take hormone therapy, regular follow-up is important. Your need to take hormone therapy may change. Benefits and risks also may change over time. Your health care provider should evaluate your continued use of hormone therapy on a yearly basis. At your yearly visits, let your health care provider know if you have any new symptoms and how well your therapy is working. Report any side effects, especially vaginal bleeding, to your health care provider right away.

Symptom Checklist

, ,						
Your age:						
At what age did your symptoms start?						
Irregular menstrual periods (circle the appropriate description)						
Cycle has gotten shorter or longer						
Bleeding has become heavier or lighter						
Number of days of bleeding has increased or decreased						
Hot flashes						
Number per day						
Severity (circle the term that best describes your hot flashes):						
Mild	Medium		Severe			
Night sweats						
Number per night						
Severity (circle the term that best describes your night sweats):						
Mild	Medium Severe					
Sleep problems (check all that apply)						
Problems falling asleep						
Waking too	Waking too early					
🗅 Waking up a	Waking up at night					
Mood swings (cha Irritability Crying spells Depressed m Other (descr	s nood					
Dizziness	🗅 Yes 🕻	🗅 No				
Fatigue	🗅 Yes 🕻	⊐ No				
Memory lapses						
lf yes, number p						
Difficulty concentrating						
If yes, how frequent (eg, a few times a week, once a day):						
	aont (og, a re		, u woo	K, 011		
Sexual desire (circle the appropriate description) Increased Decreased Has stayed the same						
Vaginal dryness			Yes		No	
Pain during or afte	er intercours	e 🗆	Yes		No	
Bleeding after int	ercourse		Yes		No	

Glossary

Antidepressants: Medications that are used to treat depression.

Cardiovascular Disease: Disease of the heart and blood vessels.

Deep Vein Thrombosis: A condition in which a blood clot forms in veins in the leg or other areas of the body.

Depression: Feelings of sadness for periods of at least 2 weeks.

Endometrium: The lining of the uterus.

Estrogen: A female hormone produced in the ovaries.

Hormone Therapy: Treatment in which estrogen, and often progestin, is taken to help relieve some of the symptoms caused by low levels of these hormones.

Hysterectomy: Removal of the uterus.

Intrauterine Device: A small device that is inserted and left inside the uterus to prevent pregnancy.

Menopause: The time in a woman's life when menstruation stops; defined as the absence of menstrual periods for 1 year.

Osteoporosis: A condition in which the bones become so thin that they break more easily.

Ovaries: Two glands, located on either side of the uterus, that contain the eggs released at ovulation and produce hormones.

Ovulation: The release of an egg from one of the ovaries.

Perimenopause: The period before menopause that usually extends from age 45 years to 55 years.

Progesterone: A female hormone that is produced in the ovaries and that prepares the lining of the uterus for pregnancy.

Progestin: A synthetic form of progesterone that is similar to the hormone produced naturally by the body.

PFS003: Designed as an aid to patients, this document sets forth current information and opinions related to women's health. The information does not dictate an exclusive course of treatment or procedure to be followed and should not be construed as excluding other acceptable methods of practice. Variations, taking into account the needs of the individual patient, resources, and limitations unique to the institution or type of practice, may be appropriate.

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