Hormone Replacement Therapy

A Guide for Patients

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Myths vs. Facts

A lot of confusing and even contradictory information has been published on the topic of hormone replacement therapy (HRT). The following is intended to provide you with the most up-to-date and accurate information about current HRT practice.

Myth: ***All women going through menopause experience the same "classic" symptoms and just need an estrogen supplement.***

Fact: Patients with a hormone imbalance or deficiency can present with a variety of symptoms, and many of those symptoms overlap. An above-normal level of one hormone can produce the same symptoms as a below-normal level of another. Therefore, testing via saliva or blood is the only way to obtain an accurate assessment of a patient's hormone levels in order to determine the best treatment plan.

Myth: ***All hormone replacement therapy is the same.***

Fact: There are many different types of hormone replacement therapies. Most hormone replacement therapies can be grouped into one of two main categories: synthetic (conventional) or bio-identical. Hormone supplements such as Premarin®, Prempro®, and Celestin® are synthetic, meaning they are not true hormones. Though they may claim to be "natural" because they contain products found in nature, synthetic hormones are pharmaceutical drugs that only mimic some hormonal functions. Side chains are added to the substance to create synthetic products. The resulting product lacks the full effects of true hormones and may even cause unwanted side effects. Bio-identical hormones, however, are identical to those found in the human body and therefore perform the same physiological functions.

Myth: ***Hormone replacement therapy is unsafe and causes breast cancer, cervical cancer, stroke, and cardiovascular disease.***

Fact: In the 1990s and early 2000s, the Women's Health Initiative conducted its first large-scale clinical trial to examine the effects of hormone replacement therapy. When the study was prematurely halted due to safety concerns, many practitioners panicked and stopped prescribing hormone therapy altogether. However, the study (like many of the large trials that have been conducted on HRT) focused only on oral synthetic hormone therapy and failed to consider the inherent weaknesses of synthetic estrogens and oral dosage forms. Although no corresponding large trial has been conducted on bio-identical hormone therapy (BHRT), numerous smaller studies involving BHRT, along with decades of successful use, all point to it as a well-tolerated and effective therapy option.

The Truth about BHRT

Myth: ***Bio-identical hormone replacement therapy (BHRT) is unregulated.***

Fact: Bio-identical hormones—like all compounded medications—are made from FDA- and USP-registered materials—the same used by pharmaceutical manufacturers—and their preparation is well regulated by state boards of pharmacy that have responsibility for overseeing all pharmacy practice in each state. Pharmacies that compound medications, including bio-identical hormones, are regulated by state pharmacy boards—similar to the relationship doctors have with state medical boards. In addition, there are also national standards and guidelines for compounded medications.

Myth: ***Compounded bio-identical hormones are unsafe because they aren't FDA-approved.***

Fact: Compounded medications are regulated by state boards of pharmacy and are not subject to federal laws designed to regulate mass-produced drugs. This is because they are customized to meet the unique needs of patients based on the specific orders of a physician. The FDA approval process is designed for mass-produced, manufactured drugs; it is universally recognized that holding compounded medications to these standards would completely eliminate their availability. Compounded medications are in a similar position as manufactured products prescribed for off-label use, which constitutes about a fifth of all prescriptions. They are not approved by the FDA for such use, and yet it is well accepted that physicians should be able to use their discretion to prescribe medications for off-label use.

Myth: ***Bio-identical hormones are just as risky as products like Premarin® and Prempro®.***

Fact: There are no studies comparing the two types of therapies, so we cannot make any direct comparisons. The Women's Health Initiative study examined only Premarin® and Prempro®, which do not use the same ingredients that are used to compound bio-identical hormones. To date, there have been no studies that show a link between BHRT and cancer/strokes/heart attack. However the pharmacy community supports and funds studies to better determine the risk profile of BHRT. A physician is trained and licensed to diagnose disease and to determine appropriate therapy for patients. Premarin® and Prempro® may be appropriate for some patients; bio-identical hormones may be appropriate for others. It is up to prescribers to make that determination.

Myth: ***BHRT is not necessary.***

Fact: Prescribers often prescribe manufactured synthetic hormone products such as Premarin® and Prempro®. When they determine those products are inappropriate, prescribers sometimes prescribe bio-identical hormones tailored to meet each patient's unique needs. For many patients, manufactured synthetic products are effective, but for some, they are not.

Source: "The Truth about Bio-identical Hormones," International Academy of Compounding Pharmacists.

The Endocrine Hormones

The hormones commonly involved in hormone replacement therapy are produced by the glands of the endocrine system—the hypothalamus, thyroid, pituitary, adrenals, pancreas, and ovaries (or testes). They include:

- Estrogen (3 Types)
    - Estrone (E1)
        - 50-70% less active than Estradiol
        - Converts to Estradiol
    - Estradiol (E2)
        - Most potent and active estrogen
        - Most studied
        - Formed from testosterone
    - Estriol (E3)
        - Biologically the most weak estrogen
        - Most abundant estrogen in the body (60-80%, compared to 10-20% of estrone and estradiol)
        - "Protective"— it protects from effect of estradiol
        - Cannot be converted to estrone or estradiol
- Progesterone
- Pregnenolone
- Testosterone
- Cortisol
- DHEA
- Thyroid
    - T3
    - T4

Signs of a Hormone Imbalance

The effects and benefits of hormones in the human body are well studied. Hormones affect many areas of your health, including mood, metabolism, as well as cardiovascular, sexual, and reproductive functions. A hormonal imbalance can affect your health and quality of life.

Below are some of the common symptoms of hormone imbalance. Notice the significant overlap in symptoms between several of the conditions, making testing via saliva or blood the only way to obtain an accurate assessment of a patient's hormone levels and develop the best treatment option.

Estrogen/Progesterone Deficiency

- Hot flashes
- Night sweats
- Vaginal dryness
- Foggy thinking
- Memory lapses
- Incontinence
- Tearfulness
- Depression
- Sleeplessness
- Palpitation
- Headaches

Estrogen Excess/Progesterone Deficiency

- Decreased libido
- Weight gain
- Sugar cravings
- Sleeplessness
- Fibrocystic breasts
- Mood swings
- Irregular/heavy menses
- Headaches
- Anxious
- Irritable
- Edema
- Bloating

Androgen (Testosterone) Excess

- Sleeplessness
- Increased triglycerides
- Ovarian cysts
- Anxious
- Rage/aggression
- Oily skin
- Acne
- Loss of scalp hair
- Hirsutism
- Depression
- Weight gain
- Changes in libido

Androgen (Testosterone) Deficiency

- Thinning skin
- Fibromyalgia
- Headaches
- Palpitation
- Decreased muscle mass
- Sleeplessness
- Depression
- Foggy thinking
- Memory lapses
- Aches/pains
- Fatigue
- Vaginal dryness
- Decreased libido

Synthetic vs. Bio-Identical

There are many types of hormone replacement therapies (HRT), some of which are listed below. However, most can be grouped into one of two main categories: synthetic (conventional) or bio-identical based on their chemical properties. Both are described more fully below:

Bio-Identical

The term "bio-identical" indicates that the chemical structure of the replacement hormone is ***identical*** to that of the hormone that exists intrinsically in the human body. The chemical structure must match that of our natural hormones produced in the body in order to fully replicate the functions of the hormone in the body. Additionally, doses of bio-identical hormones are individually tailored to the biochemical individuality of the patient.

Synthetic

Though they claim to be "natural" because they are derived from items found in nature (i.e. plants such as yams or soy), synthetic hormones are not the same as those found naturally in the human body.

- Synthetic hormones are pharmaceutical drugs that only mimic some hormonal functions. Side chains are added to the substance to create synthetic products. This creates drugs that lack the full effects of true hormones and can cause unwanted and even dangerous side effects.
- Conjugated equine estrogen and synthetic progesterone-like molecules (progestins) are not true hormones. They also only mimic *some* hormone functions.
    - Premarin® is promoted as natural because its source—pregnant mare's urine—is found in nature.
    - Celestin® is promoted as natural because it comes from a plant source, yet it matches horse estrogens instead of human estrogens.
- Additionally, molecular differences between synthetic progestins and natural progesterone result in differences in their side effects and potential health risks. As an example, some of the carcinogenic effects of synthetic progestins contrast with the anti-carcinogenic properties of progesterone.

HRT
Hormone Replacement Therapy

ERT
Estrogen Replacement Therapy

CHRT
Conventional (Synthetic) Hormone Replacement Therapy

BHRT
Bio-identical Hormone Replacement Therapy

Treatment Guidelines

The goal of hormone replacement therapy (HRT) is not to replicate the hormonal levels of a 25-year-old in a 45-year-old's body. Rather, the goal of any HRT is to optimize function, minimize symptoms, and prevent morbidity, without causing harm. The same is true of bio-identical hormone replacement therapy (BHRT).

BHRT Model of Care

- Test patient via blood or saliva to obtain an accurate assessment of endogenous hormones
- Prescribe individualized doses of bio-identical hormones, along with nutritional and lifestyle counseling
    - Replenish only the hormones that are necessary
    - Correct cortisol, thyroid, and progesterone first
    - Use the lowest amount required to alleviate the symptoms and achieve the desired physiologic effect
    - Start bio-identical estrogen dosage at mid-range
        - Never use unopposed estrogen
    - Start low and adjust slowly
        - Efficacy can be improved by changing timing application, and/or delivery route
    - Monitor symptoms
        - If symptoms not resolved, consider other hormonal and behavioral causes
- Re-test to ensure levels remain within normal physiologic levels

Dosage Forms

- Most synthetic (conventional) hormones are delivered orally
    - Oral dosage forms are not well absorbed by the body
    - Limits to the amounts that can be taken
    - Patients may be taking more to get less or may be unable to take the amount really needed
    - Injections can be expensive, inconvenient, and painful
    - Many of the gels available have unpleasant scents

- Compounded BHRT can be prepared in a variety of dosage forms
    - Vaginal delivery forms (suppositories/creams/gels) provide excellent systemic absorption
        - Non-irritating bases are hypo-allergenic and petrolatum-free
        - Vaginal delivery of estrogens and progesterone is vastly superior
    - Troches (lozenges) provide fast dissolution, rapid onset, and avoid GI destruction
        - May require more frequent dosing (up to 3x/day)
        - Saliva testing considerations
    - Sustained Release Capsules
        - Provide higher production of metabolites and more level response than commercially-produced pills
        - Can be dispensed in controlled release over 10-12 hours
        - Requires only 1-2x/day