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Thank you for entrusting in the compounding services at Madison Medical Compounding Pharmacy to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to working with you. Please don't hesitate to let us know how we can assist you and your practice.

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Compounded Bioidentical Hormone Therapy (cBHT)

Compounded hormone therapy is a form of bioidentical hormone therapy that is individually formulated for patients by professional compounding pharmacists. The popular term “bioidentical” refers to hormones that have “the same molecular structure as a hormone that is endogenously produced and circulates in the human bloodstream”. Bioidentical hormone therapy can be manufactured in standard doses and routes of administration by drug companies or may be individually prescribed and formulated for patients as compounded bioidentical hormone therapy (cBHT). cBHT is available in a variety of strengths and dosage forms for various routes of administration (e.g., capsules, creams, troches, and vaginal suppositories) and has emerged as a popular alternative to manufactured hormone therapy. Commonly compounded formulations include estradiol and/or estriol, progesterone, and testosterone.[1]

Women have been attracted to CBHT because they perceive it manages menopausal symptoms, is tailored to their individual bodies and needs, and is often accompanied by enhanced clinical care and attention. 1 Women have sought physicians and compounding pharmacists who listen to their concerns, consider individualized options versus the conventional medical approach to managing menopause, and work together to customize their care. A national population-weighted survey in 2015 determined that 35% of U.S. women currently using hormone therapy, and 41% of U.S. women aged 40–49 who had never used manufactured hormones, were using cBHT.[2]

According to a systematic review and meta-analysis of randomized controlled trials and existing evidence related to the safety and efficacy of commonly prescribed cBHT preparations in perimenopausal and postmenopausal women, compounded estradiol, estriol, progesterone, and testosterone were not associated with increased risk of adverse effects compared with either placebo or therapies using FDA-approved hormone products. This deep and thorough literature search identified some studies that have not been cited by others in this field, including the NASEM committee. In this systematic review and meta-analysis of 29 randomized controlled trials involving 1,808 perimenopausal and postmenopausal women, the analyzed safety outcomes included endometrial thickness, two risk factors of cardiovascular disease, and adverse events. The primary efficacy outcome was vaginal atrophy symptoms. Changes in serum hormone levels were also evaluated as a secondary outcome to provide information on absorption. cBHT was not significantly associated with altered lipid profile and glucose metabolism, which are risk factors for cardiovascular disease. No significant change of endometrial thickness was observed with cBHT in studies lasting 2 months to 1 year. cBHT in the form of compounded vaginal androgen was found to significantly improve vaginal atrophy symptoms. This finding was supported by the association between compounded vaginal androgen and improved female sexual function scores.[3]

Balanced Estradiol and Progesterone: A Paradigm-Shifting Concept in Women's Health

Estradiol is commonly considered the "prototypic" sex hormone in women. Estradiol modulates mood and cognition and is strongly associated with hormonal shifts throughout the life of a woman, ranging from puberty and the onset of the menstrual cycle, pregnancy and the postpartum period, as well as perimenopause and eventually menopause. Yet, women have another important hormone, which is often overlooked: progesterone.[4]

Reasons for progesterone's lack of attention as part of balanced hormone therapy may be that a form of orally active progesterone did not exist for decades. While synthetic progestins were developed as a "replacement" for progesterone and even incorrectly termed "progesterone", synthetics do not have the same biological effects. Progesterone was available as a painful intramuscular injection in the mid-1900s, but "was not micronized and marketed as a bioavailable, readily accessible, oral therapy until decades later; Prometrium® (micronized progesterone in peanut oil in oral capsules) was not approved in Canada until 1996, and in the USA until 1998."[1]

"Fundamental, descriptive, quantitative and experimental data all show that estradiol's important cellular action is to promote growth and proliferation; by contrast, despite short-term proliferative effects, progesterone's dominant actions are to inhibit proliferation, to enhance differentiation and promote maturation. Estradiol and progesterone variably interact in every cell and tissue in women's bodies and across the life cycle… Women's reproductive and overall health becomes optimal when premenopausal menstrual cycle estradiol and progesterone actions are balanced within this complex system… The classical scenario described above plays out very typically in the human endometrium: estradiol thickens the uterine lining during the follicular phase creating a proliferative endometrium. During the luteal phase, however, progesterone inhibits proliferation and causes differentiation of the endometrium into a secretory organ into which a fertilized ovum could implant."[5]

In contrast to current practice guidelines, Jerilynn C. Prior, MD of the University of British Columbia, recommends that a menopausal woman who has undergone a hysterectomy and is suffering from hot flushes and night sweats would be treated with both estradiol and progesterone. This new model illustrates that progesterone does more for women than prevent endometrial cancer.[5]

We recommend testing hormone levels at baseline and during therapy and monitoring symptom profiles to determine optimal doses of each hormone. Hormone testing can be done as blood or saliva tests; saliva testing is often recommended when hormones are administered topically.

Our compounding pharmacy customizes hormone therapy to comply with FDA recommendations, using the lowest dose needed to achieve treatment goals. Your questions are welcome. We work together with patients and their healthcare providers to individualize therapy.

References:

[1] Thompson JJ et al. Why women choose compounded bioidentical hormone therapy: lessons from a qualitative study of menopausal decision-making. BMC Women's Health. 2017; 17:97

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[3] Liu Y at al. Safety and efficacy of compounded bioidentical hormone therapy (cBHT) in perimenopausal and postmenopausal women: a systematic review and meta-analysis of randomized controlled trials. Menopause. 2022 Feb 14;29(4):465-482.

[4] Inger Sundström-Poromaa et al. Progesterone – Friend or Foe? Frontiers in Neuroendocrinology. 59(Suppl 3); 2020 October:100856

[5] Jerilynn C. Prior, MD. Women’s reproductive system as balanced estradiol and progesterone actions—A revolutionary, paradigm-shifting concept in women’s health. Drug Discovery Today: Disease Models. Volume 32, Part B, Winter 2020:31-40