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Bioidentical Hormone Therapy in Menopause: What Does "Bioidentical" Really Mean?

Mertihan Kurdoğlu[1*]

Menopausal symptom management has undergone a pivotal shift over the last two decades. Following the initial alarm raised in 2002 by the results of the Women's Health Initiative study regarding the risks of conventional hormone therapy, a significant portion of the patient population turned away from synthetic options. This gap was filled by the concept of "bioidentical" hormone replacement therapy (BHRT), often marketed as a safer and more "natural" alternative.

However, for both clinicians and patients, the term "bioidentical" has become a significant source of confusion because it conflates molecular structure with manufacturing processes. As we move toward a personalized medicine approach in menopause management, it is imperative to distinguish between FDA-approved bioidentical therapies and unregulated custom-compounded preparations.

Strictly defined, a "bioidentical" hormone is a molecule that is both structurally and chemically identical to the hormones secreted by the human ovary—specifically 17-beta estradiol and progesterone. This stands in contrast to conjugated equine estrogens or synthetic progestins, such as medroxyprogesterone acetate.

Clinical findings indicate that molecular structure is essential. Observational data, such as the E3N cohort study from France, showed that while synthetic progestins were associated with an increased breast cancer risk, micronized progesterone (a bioidentical molecule) was not associated with a significantly increased risk when used in combination with transdermal estradiol for up to five years (1). Furthermore, transdermal estradiol bypasses first-pass hepatic metabolism and potentially reduces the risk of venous thromboembolism compared to oral regimens (2).

Therefore, the physiological preference for biologically identical molecules is a scientifically valid phenomenon. The danger lies in how these molecules are delivered.

A common misconception in consumer health circles is that the term "bioidentical" is synonymous with "custom-made". Many patients believe that to receive bioidentical hormones, they must utilize a compounding pharmacy to create a tailored mixture based on salivary hormone testing.

Major medical societies, such as the Endocrine Society and the North American Menopause Society (NAMS), have taken a firm position against this practice. The 2022 NAMS Position Statement clarifies that there is no evidence to support the efficacy and safety of custom-compounded bioidentical hormone therapy (cBHRT) (3).

The risks of cBHRT are threefold. Firstly, in contrast to FDA-approved products, compounded preparations are not subject to testing for dose consistency, purity, or bioavailability. A 2020 report of the National Academies of Sciences, Engineering, and Medicine found substantial variability in the potency of compounded hormones (4). Secondly, the salivary testing often used to "tailor" these dosages creates a false sense of precision. Hormone levels fluctuate wildly, and salivary pharmacokinetics do

Mertihan Kurdoğlu graduated from Hacettepe University Faculty of Medicine, Department of Medicine (English). He completed his specialty in Obstetrics and Gynecology at Gazi University, Faculty of Medicine, Department of Obstetrics and Gynecology between 2001 and 2005. In 2006, he worked as a specialist at Çankırı State Hospital. Between 2007 and 2014, he worked at Van Yüzüncü Yıl University, Faculty of Medicine, Department of Obstetrics and Gynecology. Between 2014 and 2016, he worked in the Gazi University Faculty of Medicine, Department of Obstetrics and Gynecology. During this period, he was assigned by Gazi University to the Division of Minimally Invasive Gynecology and Research, Department of Obstetrics and Gynecology, at the University of Texas Medical Branch in Galveston, Texas, USA, where he received training in robotic surgery under the supervision of Associate Professor Gökhan Sami Kılıç. He is currently working in the field of urogynecology at Gazi University Hospital in Ankara, Turkey. He has published more than 150 scientific papers in national and international journals, receiving nearly 2,700 citations, and has contributed 10 book chapters to national and international textbooks. He has previously served as a member of the editorial board of the Van Medical Journal, as editor of the *Turkish Journal of Obstetrics and Gynecology*, and as editor-in-chief of the *Eastern Journal of Medicine*. Currently, he serves as editor-in-chief of the *International Journal of Women's Health and Reproduction Sciences*, alongside Prof. Dr. Arash Khaki.

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[1]Department of Obstetrics and Gynecology, Faculty of Medicine, Gazi University, Ankara, Türkiye.
***Corresponding Author:** Mertihan Kurdoglu, Email: mkurdoglu@gazi.edu.tr

not necessarily reflect tissue receptor activity. Thirdly, compounded products lack the "black box" warnings required on commercial products, leading patients to erroneously believe they carry zero risk for breast cancer or hyperplasia of the endometrium.

The publication policy of modern menopause medicine should not be against bioequivalent hormones; instead, it should support their regulation and oversight.

Physicians have access to FDA-approved, commercially available bioidentical hormones. These include micronized progesterone capsules and various forms of 17-beta estradiol (patches, gels, sprays, and rings). These products offer the physiological benefits of being "body-identical" while also guaranteeing safety through regulatory oversight and consistent dosing.

In conclusion, the appeal of "natural" treatments is strong; however, in the context of endocrinology, precision and purity are of utmost importance. We must educate patients that "bioidentical" describes a molecule, not a marketing strategy. By prescribing FDA-approved bioequivalent formulations, physicians can offer the best of both worlds: the physiological compatibility of natural hormones and the rigorous safety standards of evidence-based medicine.

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