Clinical Perspective

Addressing the Challenges of Online Misinformation and Unregulated Products in the Clinical Management of Menopause

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The volume of menopause content on social media has increased exponentially. Although some information is evidence based, the reality is much of what has proved popular is not. Social media exposes health care professionals and patients alike to misleading terminology as well as products and services that are unsupported by the literature and guidelines or, in some cases, harmful. Health care professionals committed to evidence-based medicine should be aware of myths and misleading menopause-related content on social media so they can answer questions and provide anticipatory guidance regarding what their patients may have been or will be exposed to on social media.

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Although bioidentical estradiol and estradiol are the same hormone, many patients erroneously believe that bioidentical implies safety and efficacy or more desirable formulations that are different from U.S. Food and Drug Administration (FDA)–approved products.[1,2] Consequently, many patients request a bioidentical hormone for menopausal hormone therapy (MHT). The ideal approach is to explain that *bioidentical* means hormones that are chemically and structurally the same as those produced by the body and that, in the context of MHT, the two most common bioidentical hormones are estradiol and progesterone. In addition, clinicians should provide assurance that many bioidentical hormones are approved by the FDA or, outside of the United States, respective government authorities.[1–3] Clarity here is essential because some health care professionals and patients erroneously believe that bioidentical hormones are inherently safer, and this belief may be used to support the practice of prescribing unstudied, ultra-high doses of estradiol or compounded hormones.

"Plant-based" is also a marketing term that uses the health halo of something found in nature to imply improved safety or other health benefits where neither exists. The estradiol and progesterone found in MHT are made by semi-synthesis, meaning they are synthesized from a chemical, or chemicals found in nature–the source material is typically soybeans.[1–3] Although "plant-based" evokes an image of grinding up plants for encapsulation, the reality is that semi-synthesis is a multistep process that occurs in a laboratory.

COMPOUNDED HORMONES

According to the FDA, "Compounding is generally a practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[4] Compounded drugs exist to find alternatives for patients with medical needs that FDA-approved pharmaceuticals cannot meet and should be restricted to situations where a government-approved hormone is not suitable due to a documented allergy to a pharmaceutical or excipient or a requirement for a commercially unavailable dose.[1,3,4] For example, compounding oral progesterone for someone with a peanut allergy (in the United States, the only FDA-approved progesterone contains peanut oil) or compounded testosterone for hypoactive sexual

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desire disorder when a government-approved product is not available.

Compounded MHT has clearly expanded far beyond the niche it was meant to occupy—approximately one-third of current prescriptions for MHT in the United States are compounded products.[5] Some who promote these products falsely imply that they contain "FDA-approved hormones," but this is misleading because the FDA does not approve hormones; the pharmaceutical that contains the hormone is approved. Compounded hormones have less regulatory oversight; they do not have to contain the boxed warning label required of FDA-approved estrogens and have incomplete adverse event reporting, which supports the illusion of greater safety.[1]

There is an erroneous belief among some that compounded hormones offer improved efficacy or reduced side effects through customization, either in the amount of hormone or by combining estrogens, such as estradiol and estriol.[1,3,4] Compounded hormones for MHT have not been appropriately studied in terms of formulations and absorption. This is especially concerning, because estrogens and progesterone have low aqueous solubility and are challenging to formulate consistently.[6] There are reports of concerning deviations in potency between the claims on the label and the amount of hormone in some compounded products, and the FDA has found numerous compounding facilities to be in violation of regulations related to compounding, with concerns regarding potency as well as unsanitary conditions of equipment and the environment.[1,3,6–8] At least two studies found less estradiol absorption than expected with compounded transdermal estrogen.[9,10]

Clinicians and patients should know that no compounded systemic MHT has been adequately proven to safely treat vasomotor symptoms, prevent menopause-related bone loss, or address any other symptom or health issues related to menopause.[3,7,11,12] An increased risk of endometrial cancer is a concern due to issues with formulation or absorption or both that could result in supraphysiologic levels of estrogen, inadequate progesterone, or both.[1,3] Compounded topical progesterone has never been shown to provide endometrial protection.[1,3] Despite these serious concerns, 86% of consumers are unsure or unaware that compounded MHT is not FDA-approved, so they may not know about the concerns regarding safety and efficacy.[13]

HORMONE PELLETS

Hormone pellets are a form of compounded hormones where the hormone, typically estradiol or testosterone, is formulated as a small pellet that is implanted subcutaneously. Once implanted, it cannot be removed, and it may take up to 9 months or longer for hormones to return to pre-pellet levels. In a review of 92 women who received more than one 50 mg estradiol implant, the median return to pretreatment estradiol levels after two implants was 311 days (range 108–1,228 days).[14]

Unlike FDA-approved pharmaceuticals, hormone pellets are not batch-tested for dose or purity.[1] Instead, practitioners who insert these pellets rely on the blood levels to plan for subsequent insertions, although this method has not been adequately studied.[1,3] In 2019, the FDA uncovered more than 4,000 adverse events from hormone pellets (implanted in women and men) marketed by BioTe that had gone unreported to the agency.[15] The adverse events included cancers, strokes, heart attacks, blood clots, and infections at the implantation site.[15]

A retrospective review of women who received testosterone or estradiol pellets or both showed that 58% had side effects compared with 15% of those receiving standard FDA-approved MHT; side effects included mood swings, anxiety, hair loss, acne, abnormal uterine bleeding, and needing a hysterectomy for abnormal uterine bleeding.[16] In this study, the mean peak and mean nadir testosterone levels were 194.04 ng/dL and 66.91 ng/dL, respectively; 38.5% of women using testosterone pellets had testosterone levels greater than 200 ng/dL (reference range for a postmenopausal woman for this study was 3–41 ng/dL).[16] Estradiol levels were significantly elevated, with a mean peak of 237.70 pg/mL for patients with pellets compared with 93 pg/mL for those receiving FDA-approved MHT (the postmenopausal reference range for this study was less than 6.0–54.7 pg/mL).[16]

Safety data for FDA-approved MHT cannot be applied to pellet therapy, so providing informed consent about risks such as heart attack, stroke, blood clots, dementia, and breast cancer is not possible. Given the potential for significantly elevated levels of estradiol, it is unknown how to dose a progestogen to protect against endometrial cancer; hence, health care professionals who choose to implant these pellets are exposing patients with a uterus to a risk of endometrial cancer. Anecdotally, many obstetrician–gynecologists who do not implant pellets report seeing patients with significant bleeding issues as well as balding and clitoromegaly related to pellet therapy if they were referred from non-obstetrician–gynecologist clinicians, such as plastic surgeons, radiologists, or emergency medicine doctors, as well as naturopaths and nurse practitioners.

Given that more than 90% of women who have used pellets have not tried FDA-approved MHT, there are clearly clinicians who are not adequately informing women about FDA-approved options.[16] Health care professionals who fail to warn patients about the risks of hormone pellets or who fail to accurately inform them about the differences between FDA-approved therapies and hormone pellets have not provided informed consent and could risk malpractice concerns when complications arise. In addition, overdosing patients with estrogen or testosterone or both could lead to complaints to respective medical boards with potential negative effects on licensure.

ESTROGEN FACE AND BODY CREAM

Currently, two types of estrogen products are promoted outside of evidence-based recommendations for anti-aging indications for face and body use or both: traditional pharmaceutical estradiol vaginal cream and compounded estriol alone or combined with other ingredients such as dehydroepiandrosterone (DHEA) and vitamin C.

Menopause is associated with various skin changes, such as decreased sebum production, epidermal thinning, and decreased collagen and elastin. For some, this may result in an acceleration of skin aging, such as dryness, decreased elasticity, and an increase in fine wrinkles. Several observational studies and small clinical trials have evaluated topical estrogens in various formulations and shown an increase in skin thickness, prevention of collagen loss, prevention of wrinkles, and restored skin hydration.[17–24] Unfortunately, most of the studies are smaller and of relatively short duration, and the formulations, doses, and application methods vary; in addition, some studies don't disclose the amount of estrogen per application.[18–24] In some studies, systemic MHT is allowed; in others, it is a reason for exclusion. In addition, none of these studies compare topical estrogen against FDA-approved topical tretinoin. However, one prospective study that was not placebo-controlled found equal benefit from topical 0.01% estradiol cream (compounded) and a commercial 15% glycolic acid.[24] Given these limitations and the wide variety of formulations, especially because many are compounded, it is impossible to draw any conclusions about the efficacy of any specific product.

Some who promote these products claim that, because FDA-approved vaginal estrogen formulations are safe for vaginal use, they are safe to apply to the skin elsewhere for cosmetic benefits. The absorption of transdermal estradiol varies by site of application and is also affected by excipients, so health care professionals and patients should not assume that absorption of estrogen applied to the face, forearm, or leg will be the same as that of vaginal application of government-approved products, which, when used as directed, do not require a progestogen for endometrial protection and do not affect the risk of breast cancer, blood clots, or cardiovascular disease.[25] It is unknown how additional ingredients in compounded products, such as DHEA and vitamin C, affect absorption, and some studies of topical estrogen for cosmesis use doses of estrogen that could achieve systemic levels if absorbed.[18,19] In addition, there are no long-term studies that evaluate the effect of facial or whole-body application of transdermal estradiol, estriol, or Premarin on serum hormone levels or the endometrium, which is concerning because these products could be used for decades and, in the case of estrogen body lotion, may be used over a large surface area. There also are insufficient data about local complications, such as spider angioma and melasma. However, there is a case report of melasma in the area of application (arm) associated with a 0.025 mg estradiol and 0.1 g estriol compounded cream applied twice daily to treat photoaging.[26]

SUPPLEMENTS

There is an ever-growing number of menopause-related supplements, and some products are even promoted as bespoke offerings by individual physicians or telemedicine companies. Unlike financial associations with the pharmaceutical industry, no financial disclosure is required for a physician selling their own line of supplements or of money made on social media from advertising these products. There is significant money to be made here. For example, selling 8,333 bottles of a turmeric supplement at $35 a bottle can net a profit of $195,302 (the product is obtained from a private labelling company).[27] It can all be done through virtual staffing; there are services that will take care of manufacturing, warehousing, and product shipping.[27] Another revenue stream is partnering with a company that sells a menopause supplement to provide consulting work and content for social media. One of the companies that brokers these arrangements claimed that a physician with several hundred thousand followers on Instagram can make $15,000–20,000 monthly for approximately 10 hours of work each month (personal communication).

In the United States, supplements are not FDA-approved and do not have the safety and efficacy data of FDA-approved pharmaceuticals. In addition, many studies have shown that these products can vary significantly in dosing or even be adulterated with other

products, some of which could be dangerous.[28–33] For example, a study of black cohosh supplements showed that 25% of the supplements contained no black cohosh and, instead, contained material identical to that of three Asian Actaea species, which are toxic to humans.[32] Supplements for weight loss and those that claim to boost metabolism appear to be at particular risk for adulteration; bacterial and fungal contamination are also serious and common concerns.[28,31]

Supplements are a growing cause of liver failure, with some estimates suggesting supplements may cause up to 43% of nonacetaminophen drug-induced liver injury in the United States and 19% of nonacetaminophen drug-induced acute liver failure.[33,34] This is not surprising–one study estimates that 15.6 million U.S. adults have used at least one potentially hepatotoxic supplement within the past 30 days. However, the number is likely higher because this study addressed only six potentially hepatotoxic products.[34]

Galantamine is an ideal way to evaluate the difference in quality between an FDA-approved prescription and a supplement, because it is available as both. When 11 FDA-approved products were tested, the amount of galantamine was within an acceptable margin of error with regard to the labeling, and there was no bacterial contamination. In comparison, with 10 brands of dietary supplements, the galantamine ranged from less than 2% to as much as 110% of what was printed on the label, with only one demonstrating the same margin of error as the FDA-approved products.[31] Also, 30% of the supplements were contaminated with genes for the enterotoxin produced by *Bacillus cereus sensu stricto*.[31]

Some supplements, such as calcium, vitamin D, or iron, may be recommended to compensate for a nutritional shortfall or to treat a deficiency. In addition, multivitamins may be recommended for specific populations, such as postbariatric surgery. Currently there are inadequate data to recommend any supplement for symptoms of menopause. Patients who need to take supplements for dietary insufficiency, those who require multivitamins for specific indications, and those who wish to explore supplements for symptoms should be advised of the following safe practices:

- Choose products with proof of independent third-party verification, such as a USP Verified label, an NSF label, or a product verified by ConsumerLabs.com.
- Avoid products with potentially hepatotoxic botanicals such as turmeric, green tea extract, ashwagandha, *Garcinia cambogia*, red yeast rice, and black cohosh.[34,35]
- Avoid ayurvedic medicines; contamination with lead is a significant concern.[36–38]
- Avoid products with proprietary blends; the exact amount of each ingredient is unknown, and these "secret formulas" are also associated with hepatotoxicity.
- Avoid products that claim to aid with weight loss or boost metabolism; they have a greater likelihood of adulteration or contamination.[39]

HOME URINE HORMONE TESTING

There are home urine hormone testing products that purport to do one or more of the following: diagnose menopause, help women identify where they are in the menopause transition, or provide information about sex hormones and metabolites to monitor, "HRT management of symptoms related to hot flashes, vaginal dryness, and osteoporosis."[40] Some of these tests are available over the counter; others are offered by physicians, chiropractors, naturopaths, and even health coaches. Home urine tests are based on levels of follicle-stimulating hormone, and the DUTCH (Dried Urine Test for Comprehensive Hormones) test reports levels of sex hormones and metabolites and involves collecting a sample at home and sending it back for analysis.

Patients may be exposed to much misinformation regarding hormone testing on social media. For example, physicians and celebrities have been involved in promoting urine follicle-stimulating hormone testing as valuable in understanding "the menopause journey." A chiropractor with more than 2.85 million followers across the four largest social media platforms in the United States has claimed, "I think we could end breast cancer if every woman ran a DUTCH test every single year."[41] Anecdotally, some women have been led to believe that they cannot take MHT for vasomotor symptoms because they have been told they are a "poor estrogen metabolizer" based on the results of these tests.

Currently, there is no proven role for urine hormone testing, including hormone metabolites, in the diagnosis of menopause, evaluating the menopause transition, predicting the age of menopause, prescribing MHT, calculating breast cancer risk, managing symptoms of menopause, or in the diagnosis or management of osteoporosis.

SUMMARY

Key recommendations regarding misinformation about menopause:

- Be proactive about explaining the definitions of bioidentical and plant-based regarding MHT.

- Assure patients that bioidentical and plant-based hormones are available in a wide variety of government-approved formulations.
- The safety and efficacy of MHT is known only for government-approved formulations; this does not include compounded hormones and pellets.
- Currently there is insufficient evidence to support the safety or efficacy of estrogen face and body cream for antiaging purposes.
- Avoid compounded hormones based on preference; they are appropriate in cases of allergy or when a dosing need cannot be met with a government-approved formulation.
- Hormone pellets are not recommended and have significant safety concerns.
- Urine testing of hormones or metabolites or both is not currently indicated for any aspect of menopause care.
- When supplements are needed (eg, to make up a dietary shortfall or if patients wish to try them for other reasons), practitioners should recommend products with verified third-party testing.

Patients are exposed to a wide variety of products on social media that are promoted for various aspects of menopause health with inadequate data regarding efficacy and safety. The terminology is often confusing. Further confounding the picture is the promotion of a variety of these products by health care professionals and celebrities, many of whom have a financial interest in these products or in promoting them to create viral content. It is important to listen to patients' concerns and desires about MHT, educate about the importance of government-approved products, and assure them that these products have the safety and efficacy data that they deserve.

The American College of Obstetricians and Gynecologists' Committee Opinion No. 709, "Commercial Enterprises in Medical Practice," from 2017 states that, "Obstetrician–gynecologists should not sell or promote agents or devices as being therapeutic without an adequate evidence base for medical benefit" and that, "The sale of prescription or nonprescription medication or devices directly to patients from obstetrician–gynecologists' offices is discouraged when reasonably convenient, alternative vendors exist."[42] Obstetrician–gynecologists and American College of Obstetricians and Gynecologists leadership should consider how the promotion on social media and personal profit from the commercial enterprises discussed in this article align with Committee Opinion No. 709.

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