Bioidentical Hormones for Menopause: What Should We Tell Our Patients?

Désirée A. Lie, MD, MSEd
December 15, 2015

Case Resolution

Our goal is to provide Mrs Miller with up-to-date and accurate information about the use of bioidentical hormones to address her desire to manage her menopausal symptoms and concerns about the myriad of products that claim to address these symptoms. Because she may have pre-existing assumptions and biases about different hormonal formulations, it is important to address her current beliefs and concerns before providing information. Women, in particular, have been reported to be reluctant to discuss the use of complementary or alternative therapies with their physicians.[17]

Clarifying Myths About Bioidentical Hormones

Some myths that should be addressed in a conversation about bioidentical hormones are[18]:

Myth: Bioidentical hormone therapy is natural and therefore superior to CHT. Fact: Hormones used in bioidentical hormone therapy may be derived from plant products such as yams, but they need to be commercially processed to become bioidentical and hence may not be "natural." Many FDA-approved estrogen products including pills, patches, gels, sprays, and creams are, in fact, bioidentical products that may be derived from equine or other sources. The term "bioidentical" is not synonymous with "natural." "Bioidentical" refers to the structure of the product, whereas "natural" refers to its source and processing.

Myth: Compounded bioidentical hormones are better than CHT. Fact: Compounding is simply a process of mixing different hormonal preparations. Compounded therapies may consist of FDA-approved as well as non-FDA-approved products. Compounded products cannot be individually FDA regulated because of the variation in types and proportion of hormones in each product.

Myth: Custom compounding individualized to the patient using salivary hormone assessment is superior to CHT because it mimics the patient's own natural hormone levels. Fact: Individualizing hormonal therapy by monitoring hormone levels has not been shown to be efficacious. Salivary levels do not necessarily reflect tissue levels and can depend on time of day, meal times, and dietary intake. Women with similar salivary or serum levels of hormones may metabolize the hormones differently. Hormone therapy should be individualized by symptom relief and side-effect profile and not laboratory test results.

So How Does This Patient Conversation Go?

A technique called "beneficent persuasion"[19] engages the patient's existing framework of understanding to encourage the best decisions for the long term. Among the strategies suggested are:

- Vivid depictions: use of specific cases and stories to demonstrate another patient's story and outcomes;
- Framing: explaining benefits first, then the risks, then repeating the benefits;

- Regret: asking patients how they would feel if they missed an opportunity for the best treatment and outcome; and
- Refocusing: allowing patients to imagine positive outcomes and a better view of the future.

Another communication strategy is to adopt the cross-cultural care model, in which the clinician first elicits the patient's health belief model and then negotiates and frames the suggested treatment recommendation to fit into the patient's belief system.[20]

Patients often conceive of bioidenticals and compounded therapies as superior because they are "natural" and "individualized." Our conversation with Mrs Miller could start with: "What is your understanding of bioidentical hormone therapy compared with CHT?" This open question allows us to address any misconceptions about superiority of commercially marketed bioidenticals or the meaning of the term "natural" when applied to hormonal therapy. Next, we could turn to her treatment goal and ask: "Which troublesome symptoms are you most concerned about?" This allows us to offer specific therapies and to discuss the pros and cons of each. This could be followed by a discussion of risks and benefits of CHT and the need for surveillance (lipid levels, blood pressure, breast cancer, colorectal cancer, osteoporosis) as a good long-term preventive care strategy. Asking her about other unanswered questions will help raise potential misconceptions about salivary hormone assays and the use of different formulations of hormones. Explaining the underpinnings of the FDA approval process for hormonal products may help to persuade her of the predictability and efficacy of FDA-approved bioidenticals compared with non-FDA-approved products. The standard that should guide her is the seal of FDA approval rather than the terms "bioidentical" or "custom compound." NAMS provides an excellent summary of different types of FDA-approved hormonal therapies.[21]

Mrs Miller should also be encouraged to read and to do her own research and to bring in further questions and concerns for future discussion before making an informed decision on her choice of treatment for her symptoms. Treatment efficacy and monitoring should be based on symptom control and side-effect profile.

References

1. Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. JAMA. 2013;310:1353-1368. Abstract
2. Sprague BL, Trentham-Dietz A, Cronin KA. A sustained decline in postmenopausal hormone use: results from the National Health and Nutrition Examination Survey, 1999-2010. Obstet Gynecol. 2012;120:595-603. Abstract
3. Steinkellner AR, Denison SE, Eldridge SL, Lenzi LL, Chen W, Bowlin SJ. A decade of postmenopausal hormone therapy prescribing in the United States: long term effects of the Women's Health Initiative. Menopause. 2012;19:616-621. Abstract
4. Jewett PI, Gangnon RE, Trentham-Dietz A, Sprague BL. Trends of postmenopausal estrogen plus progestin prevalence in the United States between 1970 and 2010. Obstet Gynecol. 2014;124:727-733. Abstract
5. Iftikhar S, Shuster LT, Johnson RE, Jenkins SM, Wahner-Roedler DL. Use of bioidentical compounded hormones for menopausal concerns: cross-sectional survey in an academic menopause center. J Womens Health (Larchmt). 2011;20:559-565.
6. US Food and Drug Administration. Bio-identicals: sorting myths from facts. April 8, 2008.http://www.fda.gov/forconsumers/consumerupdates/ucm049311.htm Accessed Nov 15, 2015.
7. North American Menopause Society. The 2012 hormone therapy position statement of the North American Menopause Society. Menopause. 2012;19:257-271. Abstract
8. McBane SE, Borgelt LM, Barnes KN, Westberg SM, Lodise NM, Stassinos M. Use of compounded bioidentical hormone therapy in menopausal women: an opinion statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy. Pharmacotherapy. 2014;34:410-423. Abstract
9. De Villiers TJ, Pines A, Panay N, et al; International Menopause Society. Updated 2013 International Menopause Society recommendations on menopausal hormone therapy and preventive strategies for midlife health. Climacteric. 2013;16:316-337. Abstract
10. Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee. Committee opinion no. 532: compounded bioidentical menopausal hormone therapy. Obstet Gynecol. 2012;120:411-415. Abstract
11. Moyer VA, US Preventive Services Task Force. Menopausal hormone therapy for the primary prevention of chronic conditions: US Preventive Services Task Force recommendation statement. Ann Intern Med. 2013;158:47-54.Abstract
12. Cobin RH, Petak SM, Bledsoe MB, et al. American Association of Clinical Endocrinologists (AACE) Reproductive Medicine Committee position statement on bioidentical hormones. Updated July 15, 2007.https://www.aace.com/files/position-statements/aacebhstatement071507.pdf Accessed November 18, 2015.
13. Harvard Women's Health Watch. Bioidentical hormones: help or hype? http://www.health.harvard.edu/womens-health/bioidentical-hormones-help-or-hype Accessed November 18, 2015.
14. Wheeler RB, Stewart K. Is bioidentical hormone therapy safe? Everyday Health.http://www.everydayhealth.com/menopause/bio-identical-hormone-treatment.aspx Accessed November 18, 2015
15. Boothby LA, Doering PL. Bioidentical hormone therapy: a panacea that lacks supportive evidence. Curr Opin Obstet Gynecol. 2008;20:400-407. Abstract
16. Cirigliano M. Bioidentical hormone therapy: a review of the evidence. J Womens Health. 2007;16:600-631.
17. Ge J, Fishman J, Vapiwala N, et al. Patient-physician communication about complementary and alternative medicine in a radiation oncology setting. Int J Radiat Oncol Biol Phys. 2013;85:e1-e6. Abstract
18. Sood R, Shuster L, Smith R, Vincent A, Jatoi A. Counseling postmenopausal women about bioidentical hormones: ten discussion points for practicing physicians. J Am Board Fam Med. 2011;24:202-210. Abstract
19. Swindell JS, McGuire AL, Halpern SD. Beneficent persuasion: techniques and ethical guidelines to improve patients' decisions. Ann Fam Med. 2010;8:260-264. Abstract

20. Teal CR, Street RL. Critical elements of culturally competent communication in the medical encounter: a review and model. Soc Sci Med. 2009;68:533-543. Abstract
21. North American Menopause Society. Hormone products for postmenopausal use in the USA and Canada.http://www.menopause.org/docs/default-document-library/htcharts.pdf?sfvrsn=2 Accessed December 7, 2015.

Sources:
http://www.medscape.com/familymedicine
http://www.medscape.com/index/section_3089_0