New Lancet MHT Study May Not Be Relevant to Modern Body-Identical Formulas

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Reference

Collaborative Group on Hormonal Factors in Breast Cancer. Type and timing of menopausal hormone therapy and breast cancer risk: individual participant meta-analysis of the worldwide epidemiological evidence. *The Lancet* 2019. Epub 2019 Aug 29.

Design and participants

A meta-analysis of epidemiological studies and randomized trials on long-term follow-up of post-menopausal women prescribed menopausal hormone therapy (MHT). The analysis looked at 58 studies published between 1992 and 2018 and more than 100,000 women who received a breast cancer diagnosis during that time. The majority of the data was derived from prospective studies.

Key findings

A slight but statistically significant increased risk of breast cancer was detected for every type of MHT except vaginal estrogen. For a woman of average weight who has never used MHT, the absolute risk of breast cancer in the age range of 50 to 69 years is 6.3%. According to this analysis, that risk increases to 6.8% for estrogen-only MHT; 7.7% for formulations with intermittent progestin; and 8.3% for formulations with daily progestin.

Practice implications

The first takeaway is that no cancer risk was detected for topical vaginal estrogen, a reassuring finding for patients who require vaginal estrogen for dryness and other symptoms of the genitourinary syndrome of menopause (GSM).

The second takeaway is that the highest cancer risk was for estrogen plus progestin, suggesting that at least some of the risk is attributable to the progestin. Given the duration of MHT before diagnosis (average of ten years) and the timing of the diagnoses (median-year of 1999 for North America participants and 2007 for European participants), most of the participants were exposed to estrogen in the form of oral conjugated equine estrogen and progestins such as medroxyprogesterone acetate and norethisterone. The higher risk associated with such formulations may not be relevant to MHT in the form of body-identical transdermal estradiol and oral micronized progesterone — a combination increasingly preferred by clinicians and recommended by expert MHT prescribing guidelines.[1, 2]

Oral micronized progesterone (OMP) is different from progestins in that it is identical to the body's progesterone. OMP is available in Canada as Prometrium® (not accessible by all ND prescribers) or as a compounded capsule. It can be prescribed together with estrogen or *on its own*, a treatment strategy proposed by Canadian researcher Jerilynn Prior. In two randomized controlled trials,[3, 4] Professor Prior found that OMP-alone may relieve the symptoms of both perimenopause and menopause. Both studies were small and of short duration and did not assess for the long-term safety of progesterone.

To understand the safety of OMP, we have to look to other studies such as the 2018 systematic review "The impact of micronized progesterone on breast cancer risk."[5] Conducted by an international expert panel, the review acknowledged the relative scarcity of data for body-identical progesterone and did not conduct a meta-analysis. Instead, they reviewed the data of 19 studies and made the following recommendations: "(1) estrogens combined with oral (approved) or vaginal (off-label use) micronized progesterone do not increase breast cancer risk for up to 5 years of treatment duration; (2) there is limited evidence that estrogens combined with oral micronized progesterone applied for more than 5 years are associated with an increased breast cancer risk; and (3) counseling on combined MHT should cover breast cancer risk - regardless of the progestogen chosen." They found no evidence for the effectiveness or safety of transdermal progesterone.

In conclusion, the new *Lancet* study demonstrates that non-body-identical types of MHT such as oral conjugated equine estrogen and medroxyprogesterone acetate probably do increase the risk of breast cancer, albeit slightly. We should, of course, advise patients of that risk within the broader conversation of risks versus benefits. We should also make patients aware that other types of MHT, such as body-identical transdermal estradiol and OMP, may not carry the same risk. Finally, we could inform patients of the work of Professor Prior, and her recommendation that OMP can be used on its own, without estrogen.

About the Author

Dr. Lara Briden, ND graduated from CCNM in 1997. She is author of the bestselling book "Period Repair Manual" and is a passionate communicator about women's health.

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