Bio-identical hormones

Dear Editor

Helena Teede, Amanda Vincent[1] and Emma Wernecke[2] (*AFP* May 2011) are wrong to dismiss bio-identical hormones as having no benefit over conventional hormone therapy. A comprehensive review published in 2009 concluded that 'physiological data and clinical outcomes demonstrate that bio-identical hormones are associated with lower risks, including the risk of breast cancer and cardiovascular disease, and are more efficacious than their synthetic and animal derived counterparts. Until evidence is found to the contrary, bio-identical hormones remain the preferred method of HRT'.[3]

My own personal experience in treating hundreds of patients with bio-identical hormones over the past 15 years or so leads me to the same conclusion.

Peter Lewis
Manly, NSW

References

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2. Warnecke E. What works? Evidence for lifestyle and nonprescription therapies in menopause. Aust Fam Physician 2011;40:286–9.
3. Holtorf K. The bioidentical hormone debate: are bioidentical hormones (estradiol, estriol, and progesterone) safer or more efficacious than commonly used synthetic versions in hormone replacement therapy? Postgrad Med 2009;121:73–85.

Reply

Dear Editor

The purpose of the article by Teede and Vincent[1] was to present the current evidence based conclusions regarding hormone therapy (HT), including risks and benefits. At the present time, National Health and Medical Research Council (NHMRC) Level I and Level II evidence (meta-analysis and/or randomised clinical trials) regarding 'bio-identical hormone therapy' is lacking.[2] Indeed, the final sentence of the conclusion of the review by Holtorf, quoted by Dr Lewis, calls for 'more randomised trials of substantial size and length'[3] regarding bio-identical hormones and we would strongly support this conclusion. The review by Holtof[3] predominately deals with studies comparing progesterone (as oral micronised progesterone), which is available in the USA in tablet form as a component of conventional HT, to synthetic progestagens, and we would agree that there are differences between these agents.

Yet this specific comparison avoids the key issues in the bio-identical hormone debate. Much of the controversy around bio-identical hormones appears fuelled by inconsistent use of terminology, inappropriate marketing and lack of regulation, as well as inadequate research. The U.S. Food and Drug Administration (FDA) has determined that the term 'bio-identical' is primarily a marketing term.[4] 'Bio-identical' hormone preparations referred to in the article by Teede and Vincent refers to those HT products that are marketed as 'bio-identical'. These bio-identical HT products are generally compounded individually by pharmacists in Australia and are not currently subject to the rigorous research requirements, regulations and monitoring that applies to conventional HT produced by pharmaceutical companies. Furthermore, products marketed as 'bio-identical' may contain a range of hormones of variable doses and do not necessarily contain the preparations reviewed in the article by Holtorf.

Also, it is important to note that anecdotal experience, as presented by Dr Lewis, is considered the lowest level of evidence and as such we strongly encourage the proponents of 'bio-identical' HT to conduct placebo controlled randomised clinical trials to evaluate efficacy and safety. Until this data is provided we would continue to support the conclusions of the FDA, US Endocrine Society,[5] North American Menopause Society[6] and Australasian Menopause Society[7] that there is no evidence supporting the proposition that 'bio-identical' hormone therapy is safer and more effective than conventional HT.

We would also encourage relevant authorities to consider appropriate regulation and monitoring, as well as review the accuracy of product information and marketing claims surrounding bio-identical hormone preparations.

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References

1. Teede HJ, Vincent A. Hormone therapy – where are we now? Aust Fam Physician 2011;40:280–5.
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3. Holtorf K. The bioidentical hormone debate: are bioidentical hormones (estradiol, estriol, and progesterone) safer or more efficacious than commonly used synthetic versions in hormone replacement therapy? Postgrad Med 2009;121:73–85.
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7. Australasian Menopause Society. Available at www.menopause.org.au.

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