



Hormone Replacement Therapy and Bio-Equivalents: Looking at the Options



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Presented at the University of Calgary's Wednesday Evening Course Program, Edmonton, Alberta.

Since the publication of the Women's Health Initiative study in 2002, the use of estrogen and progestin (hormone replacement therapies [HRTs]) in the treatment of menopause has declined significantly due to fears of cardiovascular events and cancer. However, a large number of women continue to suffer from menopausal symptoms and are seeking treatment. New treatments are sought in response to patient and doctor anxiety regarding the prescription of standard estrogen and progestin formulations. More and more patients are asking their doctors about bio-equivalent hormones and alternative therapies for treating menopausal symptoms.

When to use HRT

The Society of Obstetricians and Gynecologists of Canada has advised the use of standard estrogen and progestin for the treatment of menopausal symptoms only for the shortest duration necessary. There is no specified timeline, nor cutoff point for this treatment.¹

Estrogen

While there is still continuing debate in the scientific and marketing communities, topical estrogen may be superior to the oral route because there is no first-pass effect through the liver and, theoretically, there is less risk of deep vein thrombosis.

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Topical vaginal estrogen therapy is considered to be safe in the usual prescribed dose of 0.5 gm once or twice per week and does not require the accompaniment of progesterone therapy as low systemic blood levels have been recorded when it is used at this dosage. Topical vaginal estrogen therapy should not be confused with topical systemic estrogen therapy which will provide much higher estrogen blood levels.

Progesterone

There are no respected randomized clinical trials which show that topical progesterone is superior to oral progesterone. While there are many claims for the different benefits of progesterone, it is only universally accepted as an adjunct to estrogen therapy in order to prevent endometrial cancer.

Female libido

The treatment of a diminished female libido is complex. The decline in female libido is not likely due to menopause, but rather to the natural aging process and a decline in natural hormone production. Certainly psychosocial issues need to be addressed by family doctors before considering medical therapy, as they are often the cause of the diminished libido.

Treatment

Both oral and topical testosterone treatments have been helpful in selected patients, but studies on these treatments have been poorly designed and produce inconsistent results.²

Bio-equivalents

Bio-equivalent hormones have been touted to be safer than traditional hormonal preparations by the medical community that has an interest in using the phrase "alternative medicine." The use of alternative medicines is hard to quantitate but may be equal to established prescribed therapies. However, we do not have a good definition of what a "bio-equivalent preparation" is and, unfortunately, there are no good studies to show that they are effective. There are also no studies to show that they are safer. Bio-equivalent estrogens should be looked at in the same light as standard estrogen preparations. Yet, patients are drawn to alternative therapies, both by the failure of established therapies and by effective marketing.

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Take-home message

- Use standard estrogen formulations to treat menopausal symptoms for as short a duration as possible
- The use of bio-equivalent estrogens should be done with a patient's consent and understanding that their safety and efficacy have not been confirmed in good studies
- Topical estrogen may be superior to oral estrogen
- Vaginal estrogen treatment is efficacious and safe

Phytoestrogens

Phytoestrogens are a type of bio-equivalent hormone. There are no respected randomized control trials that show their efficacy in treating menopausal symptoms. As well, there are no studies to show they are safer.

Conclusion

The number of menopausal women using traditional HRT has dropped significantly just as the use of alternatives to traditional HRT has increased. Clearly, there is a continuing need for the treatment of menopausal symptoms. We need to provide a safe and effective treatment for these women while looking for better modes in the future. 

References

1. SOGC Clinical Practice Guideline: Canadian Consensus Conference on Menopause, 2006 Update. No. 171, February 2006.
2. Davis SR, McCloud P, Strauss BJ, et al: Testosterone Enhances Estradiol's Effects on Postmenopausal Bone Density and Sexuality. *Maturitas* 1995; 21(3):227-36.