

BIO-IDENTICAL HORMONES – THE FACTS

Some doctors, working with compounding chemists, produce hormonal mixtures and call them “bio-identical hormone therapy.” Typically these treatments are presented as troches or lozenges that are sucked, or sometimes prescribed as creams to be rubbed into the skin.

There are many potential problems with these products.

WHAT ARE BIO-IDENTICAL HORMONES?

Bio-identical hormones are hormones that are produced by the female human body. The controversy dates back to the times (1960's) when pharmaceutical companies introduced the contraceptive and other hormone pills. Oestrogen is a difficult chemical compound when it comes to taking it in a pill form, which needs to travel through the gut. For that reason the molecule of oestrogen was modified to enable better absorption (ethinyl-estradiol; estradiol-valerate etc.)

THE OPPORTUNITY

The modified compounds, which need to travel through the gut and the liver before reaching the general blood stream, can cause nausea and other symptoms of gastro-intestinal upset. There was therefore initially a genuine drive to help these patients by providing a different modality to take hormones. From this the term 'bio-identical' has over time taken on a near-mythical connotation, which it certainly does not deserve.

Some doctors, working with compounding chemists, produce hormonal mixtures and call them “bio-identical hormone therapy (HT).” Typically these treatments are presented as troches or lozenges that are sucked, or sometimes prescribed as creams to be rubbed into the skin. They usually contain three oestrogens, progesterone, DHEA, testosterone and sometimes other steroids such as pregnenolone.

For many women 'bio-identical' means 'better' or 'non-pharmaceutical'. None of this has any merit.

As a matter of fact the initial difficulty of providing bio-identical hormones through classical pharmaceutical means has largely dissipated and many products on the market currently are truly bio-identical. Oestradiol patches (and gel), testosterone cream or implants are “bio-identical” HT. The difference is that pharmaceutical products have been tested and most are of high quality. Pharmaceutical grade progesterone pessaries are available in Australia, but capsules of progesterone have to be compounded.

WHAT ARE THE PROBLEMS WITH THESE PRODUCTS?

The products are commonly not subjected to quality control

Pharmacies, which produce compounded formulations, are not subject to the same rigorous checks and controls as the pharmaceutical industry. Often, faced by increasing competition, there is a tendency to cut corners. It is almost impossible for the consumer to ascertain that the troches for example, do indeed contain the products the label says they contain. There is likely a great variability from one troche to another and from one batch of troches to another.

The absorption profile is largely unknown and there are no long-term safety studies

There are problems with the troche as a method of delivering medication in itself. It is not clear how long you need to suck on the troche. Also, many of the hormones are absorbed with a large peak blood level 30-60 minutes later; which is not physiological, and can trigger side effects such as migraines; only to drop to very low blood levels a few hours after that.

Oestrogens and testosterone can be delivered as a cream but progesterone is much more problematic. Progesterone is best given as a capsule or a pessary.

Cirigliano (1) reviewed the scant medical literature on these products. These treatments do not undergo stringent quality control, their absorption profile is largely unknown and there are no long-term safety studies.

Exploitation of public fear and misinformation

Some healthcare providers will add a good dose of cancer fear, irrelevant information of dubious scientific value and a few laboratory tests, all for a fee of course.

- The FDA in the USA has produced an excellent patient information sheet "Bio-Identicals: Sorting Myths from Facts" is well worth a read.

Often these expensive treatments are monitored using salivary and blood hormones levels, which have not been validated (1). It is well known in clinical practice that, unlike monitoring thyroid function where blood tests are exquisitely sensitive and useful, many of the main symptoms of menopause relate to effect of the hormones on the brain, rather than blood levels of any particular hormone at any particular point in time. Therefore 'spot' measurements of a whole host of hormones is of little, if any value in the management of menopausal symptoms (assuming that is the reason for taking bio-identical hormones).

Lack of adequate medical supervision

Many physicians prescribing bio-identical hormones have little expertise in gynaecology in general and will omit basic surveillance of hormone therapy.

Three cases of uterine cancer were described in Australian women using troches (2).

The Australasian Menopause Society does therefore not recommend the use of bio-identical HT.

In Summary

The traditional pharmaceutical industry has now achieved formulations, which are bio-identical and are far better products than most compounded medication due to rigorous quality control.

Some people may still benefit from compounded formulations in the few instances that the commercially available products do not address their needs. WHRIA can recommend a trusted compounding chemist in your area.

Women should be wary of any health practitioner aggressively 'selling' their 'bio-identical' and 'natural' methods.

More Information:

See our Video Gallery for Associate Professor John Eden's talk on Testosterone and Bio-identical Hormones

Web links:

Australasian Menopause Society

- Information sheets (<https://www.menopause.org.au/for-women/information-sheets>)
 - Bioidentical hormone preparations– history of development
 - Bioidentical hormones for menopausal symptoms

US Food and Drug Administration

- "Bio-Identicals: Sorting Myths from Facts."
 - <http://www.fda.gov/downloads/forconsumers/consumerupdates/ucm049312.pdf>
- Compounded Menopausal Hormone Therapy Questions and Answers
 - <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm183088.htm>

References

1. Cirigliano M. Bioidentical Hormone Therapy: A Review of the Evidence. *Journal of Women's Health* 2007; 16(5): 600-31.
2. JA, Hacker NF, Fortune M. Three cases of endometrial cancer associated with "bioidentical" hormone replacement therapy. *Medical Journal of Australia* 2007; 187 (4): 244-5.