

Osteoporosis and 'Bioidentical/Bioequivalent' Hormones



Compounded preparations

So called 'bioidentical' or 'bioequivalent' hormones are increasingly being sold direct to women on the internet or through laboratories by compounding chemists who encourage patients to obtain prescriptions for these unregistered and unproven concoctions from their doctor.

'Bioidentical' hormones, unsupported by scientific evidence, are said to alleviate menopausal symptoms and treat or prevent osteoporosis without side effects. Some doctors write prescriptions at the request of suppliers who have supposedly assessed the woman's hormonal needs by salivary hormone testing.

Women are being falsely informed through internet sites and other media advertisements that 'bioidentical' hormone therapy has all the good effects of Hormone Replacement Therapy (HT) with none of the severe side effects that have caused so many women, looking for menopause relief, to steer away from traditional HT.

The risks of pharmaceutical HT may be misrepresented in the media whilst pharmacy mixed hormones may be promoted as having similar or greater benefits with no risk or no mention of risk. Quite correctly, they state that hormone therapies are best tailored to the individual and her needs. Incorrectly, they claim that a woman's clinical need can be calculated from her saliva and that their hormonal mixtures are somehow safer than conventional HT.

'Bioidentical' hormone compounds may contain hormones that are not approved by the Australian Therapeutic Goods Administration and have no proven efficacy or safety.

No scientific evidence

There is no scientific evidence for claims that 'bioidentical' hormones have any advantage over conventional therapies and there is no evidence that

they reduce the risk of osteoporotic fractures. However, there is evidence that they may sometimes be dangerous.

So-called 'bioidentical' oestrogens are claimed to be synthesised from the same sources as some traditional HT e.g. yams. Hormone made by the 'bioidentical' manufacturer is often claimed to be 'natural' and it is implied that the identical oestradiol produced by the regulated pharmaceutical industry, from the same yam source, is somehow different and not natural.

There are no published peer reviewed data to show that salivary hormone tests can accurately show the hormonal status or needs of a woman. Neither blood levels nor salivary levels have been shown to be useful in adjusting hormonal therapies nor have they been correlated with clinical response. Most experienced clinicians realise that hormone regimens are best tailored by the clinical response and not by biochemistry reports.

Unregulated industry

'Bioidentical' hormonal mixtures are simply the same hormones, often with additional hormones, given in a different way.

'Bioidentical' hormones are made up as lozenges or troches and creams. They are sucked in the cheek and absorbed through the lining of the cheek or absorbed through the skin. They may contain oestrogens, thyroxine, growth hormone and melatonin.



'Bioidentical' hormones are imported and manufactured by an industry which is unregulated and which permits them to be sold without evidence of the chemistry, clinical effectiveness, side effects and drug interactions associated with these particular hormonal regimens.

Costly therapy, unknown patient

The cost of unproven 'bioidentical' hormones is usually several times greater than traditional menopausal hormone therapies and patients often have to pay dearly for salivary tests. Both the patient and her doctor may receive results of these tests from 'hormone consultants', whose qualifications are unknown, who have not seen the patient, and who give unvalidated interpretations of the results.

Unproven therapy

Doctors must inform patients when a therapy is unproven. The patient must be fully informed of any risks associated with such therapy, access to proven therapies should not be denied and a second medical opinion should be offered if there are potential risks to an unproven and unconventional therapy.

Unregulated industry

In Australia and the USA, there has been a recent proliferation of compounding chemists who have taken advantage of postmenopausal women's need for and anxiety about conventional HRT and the loopholes in current legislation in these



countries. These compounding pharmacies have become an unregulated pseudo-pharmaceutical industry. It is time for the international drug regulatory authorities to regulate them for the interests and health of the consumer.

In conclusion

'Bioidentical or bioequivalent' hormones should not be used or prescribed for the prevention or treatment of osteoporosis. There are many other managements from which to choose which are both evidence-based and effective.

References are available on request from Osteoporosis Australia.

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