Integrative Medical Clinic
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MANAGEMENT OF PERIMENOPAUSE AND MALE ANDROPAUSE WITH BIO-IDENTICAL HORMONE REPLACEMENT (BHRT) – A BRIEF INTRODUCTION

There is some confusion about the words 'natural' and bio-identical – these are hormones derived from plant sources generally and then synthesised into exact human hormones. So are most pharmaceutical hormones but they are then generally further altered to increase potency and be patented for financial advantages.
Pharmaceutically compounded hormones (BHRT) are not 'natural' ie from humans, they're still synthesised, but they do remain naturally bio-identical. Most, but not all, are used in a transdermal form - for good reason. There are some pharmaceutical products which also use bio-identical hormones – estrogen patches are one example.

SOME REASONS FOR CONTROVERSY

"IT IS NOT AN 'APPROVED' OR 'GUIDELINE' MEDICINE"

Most drugs by their synthetic and non-human nature require extensive (RCT) testing and long expensive approval processes. 'Bio-identical Replacement Hormones' (BHRT) have already been 'proven' biologically for ever. That's common sense. Moreover, these natural hormones have been used by many doctors world-wide for at least 2 decades now. There is no evidence of any higher risk than in the non-treated population when prescribed correctly.

What is up for discussion is long term exposure to even natural hormones. Are we designed to have minimal hormones from mid-life for some safety reason or is it just that we are living beyond fertility 'use-by-date'? It is unlikely that continuation of *low dose* replacement would be harmful when used according to natural cycles and in appropriate dosage.

UNFAMILIARITY WITH THE METHOD.

There are no drug reps or promotional materials. Information is via doctor personal education, international conferences, workshops etc.

THERE ARE NO LARGE RCTS (RANDOMISED CLINICAL TRIALS)

No pharmaceutical company or other agency is willing to fund the high expense for no return. No RCT's - means just that - that large trials just haven't been done – it does not mean the treatment may not be effective.

BHRT HASN'T BEEN PROVEN TO BE OF BENEFIT?

Actually there is good data and clinical experience showing effective benefits.

In my own experience using BHRT over 18 years, I have no doubt at all of the efficacy and safety. I listen to the patients, they know.

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STUDIES SHOW THE RISKS OF PAST HRT – PARTICULARLY THE 2002 WHI DATA.

Bio-identical hormones are NOT the same as the hormones used in the damning WHI studies, and many other HRT studies. Here the estrogens (CEE) were equine (horse) derived and the 'progesterone' was very synthetic MPA progestin – neither has been in the human before. Progesterone (the only form in the human) is NOT a 'progestin'. Whilst the biochemical steroid composition may appear similar, the effects can be very different just as estrogen (female) and testosterone (male) – with their subtle substitutions, have totally different physiological responses. So results of non-identical hormone studies should NOT be applied to human-identical hormones – yet it is very common practice in medical circles.

Cohort WHI studies actually showed that using *natural progesterone* instead of MPA (progestin) was not associated with the risks in the WHI data (CEE and Progestin). Moreover, substituting human estrogen for the horse type, *did not show the risk*.

Its very salient to examine even the WHI data itself – in fact the risks even with oral equine HRT were still extremely low considering the benefits. It is just that the reporting method as % risk rather than absolute was emotive and caused panic. 25% increase in breast cancer is far more compelling news than expressing it as only an additional 7 chances in 10,000 risk. (the risk with no hormones is 26/10,000 so it only went up another 7 cases).

FOR EXAMPLE, ASK A WOMAN WHOSE LIFE HAS TURNED UPSIDE DOWN FROM MENOPAUSE THE QUESTION OF RISK ACCEPTANCE USING STANDARD PHARMACEUTICAL HRT IN TWO DIFFERENT WAYS – WHAT WOULD BE YOUR REACTION?

- You have a 25% increased risk of breast cancer – is that OK? - Most are aghast.
- Or, you have about 7 more chances in 10,000 of breast cancer risk – is that OK? That sounds minimal.

Same thing, different wording.

Women I pose this question to, usually respond quite differently to the use of HRT. Using bio-identical products the risk is almost certainly very minimised but the gains in life quality are very significant.

ADVANTAGES IN USING BHRT

This communication is meant to be brief so the discussion is limited for that reason. There are many publications on the subject of 'natural' hormone supplementation for women and men.
It replaces deficient levels that may be causing symptoms, with the exact same human substance. The dosing is low, never reaching the physiological levels of younger fertile women – those levels are not necessary to resolve menopause or andropause symptoms. This is in line with WHI later recommendations.
Most BHRT hormones are in transdermal cream applications. Hence avoiding liver first-pass. The evidence for the benefits over oral routes, especially estrogens, is well documented in mainstream literature. Certain hormones can be given safely orally, such as DHEA and Progesterone (the latter with some advantages in certain cases).

IS THERE A PLACE FOR SINGLE UNOPPOSED HORMONE REPLACEMENT?

With intact uterus, micronized oral progesterone is used to reduce risk of endometrial neoplasia (cancer) as with traditional estrogen treatments.

In post hysterectomy cases – contrary to conventional guidelines, we still advocate the addition of progesterone as the philosophy is to mimic nature as close as possible. Also we may add testosterone and DHEA where these are sub-optimal. There is ample evidence of improved QOL in so doing. Hard data on prevention of disease is less robust as there is little gain in this research.

Some women have hormone 'imbalance' for example estrogen dominance as evidenced by characteristic symptoms and lab workup. She may do very well on transdermal progesterone only. Or at least adding it to 'balance' the low dose estrogen.

Some women may have very low testosterone and clinical symptoms supporting this – she may respond to gentle T supplementation for libido, muscle strength, vitality and so on.

SO ARE THERE RISKS?

Nothing is guaranteed in medicine. It is good practice to screen for risk factors, to ensure a 'healthy woman' ongoing screening program.

I ask patients on BHRT to ensure they work with their GP for regular checks.

There is still some belief that long term exposure to estrogen may enhance risk of breast cancer. The data on this when considering protection with concomitant progesterone, healthy diet, exercise etc is still being worked on. It may be a very, very minimal risk in at risk women. As always, consider the risks/benefits.

TESTOSTERONE REPLACEMENT FOR MEN – A FEW WORDS

Another large discussion point, which I will not cover other than to say, similar principles apply. Refer to my website for more information. The major criticisms are again not supported by the literature:

Testosterone supplementation especially bio-identical does NOT cause prostate cancer. Sure, if PCa occurs, and statistically it does as we age, then T replacement is contra-indicated.

T does not cause or aggravate heart disease – in fact it is PROTECTIVE.

Recent literature has pointed to higher risk of cardiac events for older men on T replacement. It appears to contradict all the other studies. This year (2015) there have been criticisms of the study with major flaws in design. We await further analysis. To date T appears protective when used in sufficient dose to place T in the upper protective centiles.

So for men the data on testosterone replacement efficacy is well established.

What formulation is less clear. As a general rule in integrative medicine, we prefer to use exact biological equivalents where possible. So T is available as bo-identical testosterone, applied

transdermally. Six months use will determine efficacy. Some men will prefer the injectables when T creams are not effective. This is not BHRT but will convert into natural T.

ONGOING SURVEILLANCE

As mentioned above, serum levels are useless when using transdermals. Urine is better. In fact I have access to a US lab that can determine what we do with our testosterone metabolically - DHT, aromatising to E2 etc.

We want to avoid excess aromatisation to non-methylated estrogens and treat to prevent this.

Regular prostate checking especially in first 12 months.
CBC for Hb.

When we look at the long list of potential loss of vitality symptoms for men as we age and lose testosterone production, as evidenced by the loss of vitality, depression, increased abdominal size, metabolic syndrome, libido etc – it seems to me astounding that conventional medicine avoids this area of health optimisation. Women have long understood the huge benefits of HRT for them.

SUMMARY

1. The overarching factor is that with diminished quality of life, and it can vary from nuisance level to serious, bio-identical hormone replacement can be very effective.
2. The answer to these questions, which to me is logical, is to replace, using safe, physiological dosing, transdermal where possible, bio-Identical hormones.
3. Maintain healthy patient surveillance using meaningful lab and imaging methodology.
4. I always recommend patients be their own advocates and read as widely on the subject as they can. We doctors can guide, treat and at best do no harm.

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