

BIO-IDENTICAL HORMONE THERAPY

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Great controversy exists around whether hormone therapy is “safe” for peri-menopausal women. The short answer is: it depends on the woman.

The debate continues, especially since the results of the NIH Women’s Health Initiative trials released in 2002 indicated that post menopausal women who took Premarin and Provera or “Prempro” seemed to be at more risk to develop heart attacks, strokes, blood clots, breast cancer and dementia than those who did not. They were less likely to develop osteoporotic fractures and colon cancer, however. And women on Premarin alone, those without a uterus, didn’t seem to have the breast cancer risk that women on Prempro did.

Many wonder if taking “bio-identical hormones” such as estradiol or progesterone, made in the laboratory from the soy bean or Mexican yam root to be identical to human estrogen and progesterone, might be “safer” and not confer the same risks as Premarin, which is made from pregnant mares’ urine. That remains to be studied, but the current thinking is that if estrogen is used, it is best to be used in women under age 55 for preventing hot flashes and protecting bones from loss in density, and that it be used for as short a time as possible to decrease the risks that come with aging.

There are those who disagree. Suzanne Somers writes in her book, *The Sexy Years*, that endocrinologist Diana Schwartzbein believes that women should take carefully measured “bio-identical hormones” and continue to have menstrual periods throughout their lives. This implies that menopause is a deficiency disease to be treated rather than a natural process that all women experience. It also ignores the belief that estrogen may contribute to cellular breakdown through inflammation along with the aging process, which was thought to have brought the Women’s Health Initiative trials to an early end.

This NIH study was designed to answer the question: does estrogen help prevent heart attacks in post menopausal women? Should it be used for prevention? If all post menopausal women were given hormones, what would be the long-term benefits and risks? In order to include the number of women necessary for statistical significance, the study needed 700 million dollars which the NIH budget could not manage. The money was raised separately by Congress, and Wyeth Pharmaceutical contributed all the Premarin and Prempro pills and placebos. Twenty-seven thousand women were enrolled at forty clinical centers throughout the United States, one-third between the ages of 50-59 and two-thirds between the ages of 60-79. Many of the women (almost half) between 50 and 59 dropped out of the study because of bleeding and breast tenderness which occurs

when a woman is estrogen dominant, or has too much estrogen unbalanced by progesterone. The average age of participants was 63.

Every study run by NIH has a Data Safety and Monitoring Board, a group of independent experts that are advisory to the NIH. The WHI Board met every six months to revise the data presented to them as Group A and Group B, since the study was double blind and neither the participant, the doctor, or the researcher knew what pill the patient was taking. The board had certain rules called monitoring boundaries, and if any group exceeded those boundaries, the group had the responsibility to stop the study. The study did not test for whether hormones caused breast cancer, but it monitored for it. They noted blood clots and heart disease rates were significantly higher in one group, then strokes climbed in that group. The breast cancer rate crossed the monitoring boundary for that same group (which could have been the placebo group, implying the hormone group was indeed protected) and the recommendation was made to stop the study for that group. The unblinding revealed it was indeed the Prempro group that showed the risks outweighed the benefits.

For women taking Prempro compared to those taking placebo per 10,000 study participants:

	Premarin	Placebo	
	37	30	Heart Attacks
	29	21	Strokes
	34	16	Venous Blood Clots
	38	30	Breast Cancer
Benefits	10	15	Hip Fractures
	10	16	Colon Cancer

Since the Premarin-only group had not exceeded the monitoring boundary for breast cancer, speculation occurred about the role of Provera. Two years later, and one year before its planned completion, the Premarin-alone study was stopped because there was an increased risk of stroke and no overall benefits: 12 more strokes and 6 fewer fractures per 10,000 women compared to 8 more strokes and 5 fewer fractures in the Prempro group.

As a result of these trials, the FDA recommends that estrogens alone or with progestogens should be used for as short a period of time and in as low a dose as possible for the indications of either menopausal symptoms or osteoporosis and not to prevent heart attacks.

It is a well-established fact that the risk of heart attacks in women does not rise until after their periods cease. In observational studies such as The Framingham Trials and the Nurses Health Study, women who took estrogen in peri-menopause or after hysterectomy had 30 to 50% fewer heart attacks compared to non-users. The questions remain: Do the results of the WHI transfer to women under age 55 who take hormones? Are women who take hormones that mimic their own estrogen and progesterone (rather than Prempro) equally vulnerable to these same risks? The Kronos Institute has started a seven-year trial on women 45-55 years old using bio-identical hormone to answer these questions. In the meantime, what's a woman to do?

Many of us who work with women in the peri-menopausal and post menopausal years will help translate all this information into a risk-benefit equation for the individual woman. We know that estrogen molecules vibrate with individual receptors on each of our cells stimulating that cell to increase its performance, whatever that cell does. If it's a brain cell, it helps our memory, our reaction time. If it's a skin cell, it helps with resilience. If it's a bone cell it helps strength. Any estrogen whether it's estradiol, estrone (our body fat estrogen) or estriol (our pregnancy estrogen) will do that. Premarin, Cenestin, Estratest and Estrace will also do that to varying degrees. All of the estrogens will also increase our cells' susceptibility to inflammation and self-destruction. Our cells' ability to repair themselves is much more efficient when we're 45-55 years old than when we're over 55. With aging comes vulnerability to cell destruction that estrogen in any form can enhance. Only further study will delineate the difference in effect of estradiol versus Premarin on individual estrogen receptors.

If you're wondering whether you're a candidate for bio-identical hormones, visit a doctor or nurse practitioner who is knowledgeable about how to formulate your risk-benefit equation and about the various patches, creams, gels, and pills that are available for your use.

Susan Doughty is founder of the New England WomenCenter and has presented workshops on physical, emotional and spiritual issues on a national level. She is published in the areas of pacemakers, nurse-managed centers and advanced practice nursing. For more information please phone New England WomanCenter in South Portland at 207-761-4700.