The Controversy of Hormone Replacement

Hormone replacement became controversial after the initial results of the Women's Health Initiative Study (WHI Study) were released in 2002.

Background of Hormone replacement:

Synthetic hormones were routinely offered for perimenopausal and menopausal symptoms since the 1960's. The medical literature provided strong evidence for the use of estrogen and progesterone for women's health and wellness, most specifically the cardiovascular system and bone health. Our medical knowledge was based on bioidentical hormones (molecularly identical to what the human body produces). However, mainstream physicians prescribed synthetic hormones, not bioidentical hormones. The pharmaceutical industry manufactures synthetic hormones, which are created by altering the molecular structure of the original hormones, which unlike bioidentical hormones can be patented.

WHI Study - Hormone section

The groundbreaking events in hormone history were the initial results of the *Women's Health Initiative Study* (WHI Study) in 2002. These results not only made hormone replacement controversial, but created enormous confusion among health care professionals. The results were never clearly explained to the lay public or to health care professionals.

The hormone section of the WHI study involved about 28,000 women. The goal was to see the benefits of estrogen and progesterone, specifically for cardiovascular health. There was a concern of estrogen causing an increase in breast cancer, even though there was no previous credible evidence.

Over 2/3 of the women were above age 60, about 1/4 were above age 69. The average age of menopause is 51. Perimenopause occurs about 10 years earlier, at which time hormones start to decline.

Women were divided into two main placebo controlled groups. One group (consisting of women with no uterus) was assigned to synthetic estrogen (Premarin). The other group (consisting of women with a uterus) was assigned to Prempro, a combination of synthetic estrogen (Premarin) + synthetic progesterone (Provera). The federal government funded the study and the participants were monitored in the top 40 US clinical centers. Wyeth-Ayerst, the manufacturers of Premarin and Prempro donated these synthetic hormones for the study.

The Prempro (synthetic estrogen + synthetic progesterone) arm of the study was halted in 2002 due to an increase in blood clots and increase in breast cancer.

The Premarin (synthetic estrogen) arm of the study was halted in 2004, due to an increase in blood clots. No increase in breast cancer was seen.

There was a lot of discussion on the lack of cardiovascular protection, but people were not told that the heart attacks, strokes and clots in the lungs were due to estrogen given by mouth, and mainly in women who had no hormone balance for over 10-15 years.

CONCLUSIONS FROM THE HORMONE PART OF THE WHI STUDY

1. The Prempro (oral synthetic estrogen + synthetic progesterone) arm had increased breast cancer and increased blood clots.
2. The Premarin (oral synthetic estrogen) arm had increased blood clots, but a DECREASE in breast cancer.
3. Synthetic progesterone, NOT synthetic estrogen was associated with an increase in breast cancer

WHAT WE ALREADY KNEW

1. Oral estrogen (synthetic or bioidentical) causes an increased risk of blood clots due to the first pass effect of the liver, a well-known effect, which has also been declared on every package insert of oral birth control pills for decades!
2. The molecular structure of synthetic progesterone is significantly different than our own (bioidentical) progesterone. Our own progesterone is believed to be protective to our breasts.

STUDIES BEEN DONE ON HORMONES SINCE THE WHI STUDY

The *Kronos Early Estrogen Protection Study (KEEPS)* was initiated after 2002. Although, the primary focus was on heart disease, after 4 years, no increase in breast cancer has been seen.

Summary:

1. No study to date has shown a link between any form of estrogen and an increase in breast cancer. If there were any studies before the WHI study showing a link between estrogen (in any form) and breast cancer, it is unlikely that the hormone part of the WHI study would have taken place. Everyone, including Wyeth-Ayerst, the manufacturers of Premarin and Prempro, would have far too much to lose.
2. No study has ever been done on bioidentical hormones. There is no financial incentive.
3. Synthetic Progesterone is the only hormone shown in studies to be linked to an increase in breast cancer. First from the British data (Million Women's Study), then from the WHI study.
4. Bioidentical Progesterone has long been believed to be protective for the breast, but again, has never been studied.
5. **Oral** estrogen causes an increased risk of blood clots, which can present in many ways such as heart attacks, stroke, pulmonary embolism etc. This information has been known for decades.
6. Women have an inherent risk of breast cancer, which escalates after menopause and continues to increase with age. Without a family history of breast cancer, women have ~ 10% lifetime risk of breast cancer. The risk of breast cancer is about 1 in 233 in the 30's, and 1 in 8 at age 85. Risk is much higher if there is a family history of breast cancer.
7. Health and wellness of women declines predictably, parallel to the loss of hormone balance. If intervention of the natural aging process is considered, then it is more natural to restore hormone balance than to treat symptoms with prescription medications
8. It is unlikely we will ever have studies on bioidentical hormones. Most likely, years from now, we will retrospectively analyze the data on women who used bioidentical hormones. The women of this generation can only make educated choices.