TruBalance Healthcare Inc. (Canada)

The Truth About Hormone Therapy

The Women's Health Initiative Study

Interview Aug 22, 2011 by Neal Rouzier, MD https://www.youtube.com/watch?v=3xym2ylmZ3M

Scared and concerned. That pretty much sums up how most women using or considering using hormone therapy felt after part of the Women's Health Initiative (WHI) was halted prematurely in 2002. Television and other media dramatically publicized that hormone therapy increased a postmenopausal woman's risk of heart disease, breast cancer, stroke and blood clots. Millions of women abandoned hormone therapy, deciding they would live with hot flashes and osteoporosis if that's what it took to survive.

BEWARE OF MEDIA SENSATIONALISM

Since then, critics have gradually chipped away at the sensationalism with which the media portrayed WHI study results. In the calm after the highly-publicized storm, the FDA and critics, including Dr. Wulf Utian, Executive Director of the North American Menopause Society (NAMS), have urged women and healthcare providers to not over-react. "Significant damage has resulted from the way the WHI results were originally reported," said Dr. Utian. "Women have walked away from treatments often necessary for their health and well-being."

NAMS and other healthcare organizations now advise that women need not abandon bio identical (natural) hormone therapy, but that therapy should be individualized and delivered at the lowest effective dose for menopausal symptoms.

HORMONE THERAPY STUDY OR PREMPRO® STUDY?

The problem with media coverage of the portion of the WHI study halted in 2002 is that outcomes were discussed as if they applied to all hormone therapy when they really only applied to the one type of hormone medication given to participants — Prempro®,a synthetic hormone derived from horse urine. **Dr. Edward Klaiber, a Massachusetts endocrinologist and lead author of a paper published in the December 2005 Fertility and Sterility, which re-evaluates the WHI, said "I looked at the way they designed the study, and they did make some major mistakes**. ... The results might have been different if they had used a different form of estrogen that resembled a normal cycle ... Prempro® was a mistake." "WHI outcomes told us a lot about what happens when you give the same oral dose of Prempro® to an older group of post-menopausal women." But you can't extrapolate these outcomes to women of all ages, to other estrogen/progestin formulations or to formulations that use bioidentical hormones and/or other routes of administration such as the patch, creams or vaginal therapies."

AGE OF STUDY PARTICIPANTS AFFECTED OUTCOMES

A 2004 Yale study also published in the journal *Fertility and Sterility* said the age of WHI participants, which ranged from 50 to 79 was too high. The average age was 63 — ten years or more beyond when women typically seek hormone therapy help for hot flashes or osteoporosis. 67% of the women were over age 60 and 20% were between 70 and 79.

"The vast majority of women who are starting hormone replacement in this country are doing it around the time of menopause, and they have been unnecessarily scared to death about HRT," said researcher Richard H. Karas, MD. Researchers also say many of the women in the WHI study may already have been in the early stages of heart disease or were unhealthy when the trial started.

• 35% were being treated for high blood pressure (risk factor for stroke).
• 35% were overweight with 34% of that group obese (risk factor for breast cancer).
• 50% were or had been smokers (risk factor for stroke).
• 12.5% were using medication for high cholesterol (risk factor for heart attack).

Age and health may be the reason why WHI results regarding hormone therapy and cardiovascular health vary from those in other studies. In many other studies, including the Nurses' Health Study begun in 1976 and still underway, women who used estrogen plus progestin experienced an overall reduction rather than an increase in heart disease risk. Clearly, more study is needed to fully understand the cardiovascular benefits and risks associated with hormone therapy.

BREAST CANCER RISK WAS GROSSLY INFLATED

Dr. Klaiber's paper and an Australian study published in the *British Medical Journal* in 2005 also say the breast cancer risk associated with taking hormones is much smaller than publicity of the WHI study indicates. While the media reported a 26% increase in the risk of breast cancer associated with hormone therapy, what they didn't say was the 26% increase is over the normal rate of 0.1%. Multiplied out (0.1% times 26%), researchers call the increased risk for the individual woman "miniscule" and not significant statistically.

♥ ♥ WHAT YOU WEREN'T TOLD

The media also did little to report details of positive outcomes in other parts of the WHI study. These included:

• 37% decrease in colon cancer by those using hormone therapy (HT).
• 34% decrease in hip fracture and 24%decrease in total fractures with HT.
• Lower breast cancer incidence in a group taking Premarin® than in nonusers of HT, and there was no increase in heart disease. Therefore the National Institute of Health recommends no change in the management of hysterectomized patients using estrogen therapy. Likewise, the media has given little publicity to revisions of hormone therapy position statements issued by various healthcare groups since the initial WHI publicity. For example, in 2004 NAMS revised an earlier statement. Revisions include:

• Placing no limit on estrogen therapy (ET) or estrogen/progesterone therapy (EPT) duration, provided it is consistent with treatment goals and monitored regularly. • Noting that the role of both ET and EPT in the prevention of coronary heart disease remains unclear, especially in younger women starting therapy early and continuing for a number of years.

THE TRUTH ABOUT HORMONE THERAPY

So where can the truth about hormone therapy be found? Certainly not in media sensationalism. Each woman must look for the truth in the clinical data available and in her own health history. We advise that each woman work with her healthcare provider and/or a bio-identical hormone specialist to make an individual decision based on the severity of her symptoms, her family and personal health history and her personal risk factors. In all cases, **treatment should be individualized using the lowest effective dose** as determined and monitored through periodic measurement of hormone levels. And it only makes sense that supplemental hormones should be bioidentical, chemically the same as those your body produces naturally. The truth is that if your going to decide to go on bio identical (natural) hormone therapy (BHRT) - your medical doctor should perform baseline hormone testing via saliva or blood and Urine: NTx bone loss testing, and then after reviewing

test results with create an individualized bio-identical hormone program for you. If you are scared or concerned, call us - telephone 647.884.0663 for additional information. We can help.

MAJOR HORMONE THERAPY STUDIES

1976-present Nurses' Health Study (NHS)

The single largest cohort study of women, the ongoing NHS was established in 1976 to study the relationship between oral contraceptive use and cigarette smoking and risk of major illnesses. The scope and range has since broadened to include implications of various lifestyle factors (i.e. exercise and diet) on women's health. Initially comprised of 127,000 nurses, 30 to 55, participants receive detailed questionnaires every 2 years in which they report medical histories, daily diet habits and major life events that have occurred in the previous 24 months. Response rate averages 90 percent. Major findings include: 1) Birth control pills do not increase non-smoking women's risk of heart disease 2) Women who take oral contraceptives for more than 5 years have less than half the risk of ovarian cancer than women who have never used birth control pills 3) Women who take estrogen after menopause decrease risk of heart disease, but raise risk of breast cancer. For more information, visit www.nurseshealthstudy.org.

1987-1990 Post-menopausal Estogen/Progestin Interventions (PEPI) Trial

This three-year study involved 875 postmenopausal women aged 45 to 64 years. 32% previously had a hysterectomy. The study's purpose was to test the effects of estrogen therapy on four factors that affect a woman's risk of heart disease: HDL (good) cholesterol, systolic blood pressure, fibrinogen and insulin. Women were randomly assigned to five treatment groups: 1) A placebo (no hormone), 2) Estrogen (0.625 mg Premarin®), 3) Estrogen (0.625 mg Premarin) and progestin (2.5 mg Provera®) taken daily, 4) Estrogen (0.625 mg Premarin) taken daily and progestin (10 mg) taken 12 days each month, 5) Estrogen (0.625 mg Premarin) and micronized progesterone (200 mg progesterone USP) taken daily. In the study, all of the estrogen/progestin combinations produced significantly greater increases in HDL (good) cholesterol levels than the placebo. Estrogen combined with bioidentical, micronized progesterone provided the best cardiovascular protection of all the combined regimens, nearly equal to taking estrogen alone. Combining estrogen with progesterone or progestin was shown to help protect women against endometrial cancer. The study also discovered postmenopausal women taking hormones gained less weight than if not taking hormones.

1995-1998 Heart and Estrogen/Progestin Replacement Study (HERS)

This three year study of 2,300 postmenopausal women with coronary heart disease (CHD) studied the role of hormone therapy on heart disease risk. After 6.8 years, those randomly assigned to take supplemental estrogen and progestin showed no cardiovascular benefit or harm. The study recommended women not start estrogen/progestin to prevent future heart attacks, but if already using estrogen therapy, to continue as there may be a long-term benefit. Results of the 1998-2002 HERS II follow-up study concluded that postmenopausal with CHD not use combination hormone therapy to reduce the risk of CHD events, such as heart attacks.

1991-2005 Women's Health Initiative Study (WHI)

Involving over 161,000 women ages 50-79, the WHI had two components. The primary component, a randomized controlled trial on hormone therapy in postmenopausal women with breast cancer as a primary endpoint, had three arms. 1) Administration of oral, single dose Prempro® synthetic estrogen and progestin 2) Administration of oral, single dose Premarin® synthetic estrogen 3) Administration of calcium/vitamin D to evaluated the effect on prevention of osteoporosis- related fractures and colorectal cancer. The second component examined the relationship between lifestyle, health and risk factors and specific disease outcomes.

This 15-year project ended March 2005. For complete information and results, visit *www.whi.org*.