JOHN R. WOODWARD, M.D., P.A.
Gynecologic Endocrinology, Urology and Surgery
7777 Forest Lane, Suite A-338
Dallas, Texas 75230

SPECIAL BULLETIN

Women's Health Initiative Study Revisited

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In July, 2002, the first results of the Women's Health Initiative were published in the national media. These apparently negative results hit the concept of hormone replacement (HRT) like a bombshell. As a result, half the women who were taking hormones in one way or another stopped them over the next year. This was an unfortunate outcome, and as more information about the study has emerged, not a well-reasoned one. So let us consider a more rational approach.

Armed with six hundred twenty eight million tax payer dollars, the National Institutes of Health began the recruiting in 1993 in 40 centers around the country of what became 161,809 postmenopausal women between ages 50 and 79 for a randomized, double-blind study which was to be completed in 2005. The object was to find out once and for all whether hormones (estrogen and progesterone) really did protect women from developing heart problems and other chronic diseases (osteoporosis, colon cancer, Alzheimer's, etc.). The main evidence in support of HRT came from an ongoing study of more than 48,000 nurses, which in 1991 showed a 50% reduction in heart attack rates.

The Women's Health Initiative contained two huge hurdles that, in retrospect, severely limited its usefulness. If the study had too many young women, it would take years for them to get old enough to generate enough "events" like heart attacks and fractures to provide a statistically meaningful analysis. Another problem was finding enough women willing to risk a placebo. Women with severe menopausal problems such as hot flashes and night sweats were specifically discouraged from participating in the study because they probably would know almost immediately whether they were getting a sugar pill instead of the real thing.

As a result, the study, at it's inception, was designed to be a study primarily of older, geriatric women well past menopause and would include only a small portion of younger women (ages 50 to 54), most of whom did not suffer from severe menopausal problems. The average age of a woman in the WHI was 63; 67% were over the age of 60, and only 1,700 women were between the ages 50 to 54. How important is the timing of hormone replacement? The major rise of heart disease and osteoporosis seen in women occurs between 45 and 55. Once that damage is done, it cannot be reversed. Studies in monkeys show, for instance, that delayed hormone replacement does not protect against plaque build-up in arteries.

Another major source of concern with the WHI is that hormone substitution (Premarin, Provera, Prempro) was used rather than real hormone replacement with human estradiol and progesterone. Also, the route of administration was oral (tablets) rather than non-oral (transdermal or subdermal), resulting in a first pass effect through the liver, not a good thing. No blood levels of estrogen or progesterone were measured.

In August, just to complete the debacle, earlier heart data from the WHI was revised and showed that the initially reported 24% increase in heart risk was not really statistically significant.

Basing one's decision as to whether to use hormone replacement should not be determined by one study, particurarly one as poorly conceived and carried out as the Women's Health Initiative Study. It should be made in conjunction with the woman's physician, preferably a board certified specialist in Gynocology, and the doctor's advice should be based upon the results of numerous studies combined, not just one severely flawed analysis innacurately reported in the media.

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