A Hormone Foundation Update on the WHI Study Results

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Estrogen + Progestin Effects on Breast Cancer and Mammograms

The latest release of information from this important national study sheds some new light on the effects of combination hormone therapy (estrogen + progestin, E+P) in healthy older (over age 55) postmenopausal women. The results of this latest breast cancer study support the conclusion recommending against the long-term use of the combination hormone therapy in older healthy postmenopausal women. However, younger women (ages 45-55) that have severe menopausal symptoms can still consider combination hormone therapy after full discussion with their physician about the associated risks and benefits that apply to their individual situation. All WHI Study results stress the need for more discussion between physician and patient and emphasize the need for use of the lowest dose of hormone therapy that relieves symptoms for the shortest possible time.

A Summary of the Key Findings in the Breast Cancer Study

Participants in this study were divided into two groups – one group that took the combination hormone therapy (E+P) and another group that took an inactive pill (placebo) that looked exactly like the hormone medication. Conclusions are based on the comparison of results between these two groups.

In the group taking the combined hormone therapy, the following results were found:

1. Increased number of those found to have breast cancer. The increased risk of breast cancer due to the hormone combination therapy was 8 additional cases detected for every 10,000 women over one year.
2. Tumor size of the cancer was larger.
3. Increased involvement of lymph nodes when breast cancer was detected. lymph node involvement was nearly 10% more in those taking the hormone combination, indicating more regional spread.
4. No increase in number of women having metastatic breast cancer (metastatic cancer is a more serious type where the cancer spreads to other parts of the body).
5. Increased number of abnormal mammogram results seen after one year of therapy. The increase in abnormal results continued during the length of the study. The incidence of regional cancer spread was 10% more in those taking the hormone combination.
6. There was a 4% increase in the number of abnormal mammograms seen in those on the hormone combination at one year and continuing throughout the study.

Important Facts to Keep in Mind Concerning These Results:

- The increase in women diagnosed with breast cancer so far appears only to be in those taking the hormone combination (E+P), not in those taking the estrogen-only form of therapy. The portion of the study that follows the estrogen-only group is continuing and is expected to end in 2005.
- It is well known that combined hormone therapy causes an increase in breast density which can make the interpretation of mammography results more difficult. Use of digital mammogram instead of standard mammogram techniques may help with the interpretation of results. It has also been shown that going off of the combined hormone therapy for a period of two weeks clarifies many abnormal mammogram results.
- Breast tumors in those on combined hormone therapy may be more difficult to find due to the increase in breast density. This may allow tumors present to grow for a period of time before being detected. In addition, this may explain why there was an increase in the involvement of regional lymph nodes in those on E+P.
- It is still not known whether the increase in breast cancer rate for those on combined hormone therapy results in a higher occurrence of death. So far, there is no reportable difference in survival rate between those on the combination hormone therapy and those taking the inactive pill (placebo). Conclusive information about whether hormone therapy is more harmful will require a longer period of investigation of all groups of the study participants.

More Details on the WHI Study Design – Breast Cancer

- Participant eligibility – postmenopausal women between the ages of 50 and 79 with no prior history of hysterectomy, breast cancer, or other medical condition likely to result in death within 3 years.
- Participants taking menopausal hormones were required to stop taking them for 3 months before entering the study.
- All participants had a baseline mammogram and breast exam at the beginning of the study. Any abnormal findings were cleared up before continuation in the study.
- Participants were randomly assigned to a study group. A total of 8506 women were placed in the group that received the hormone combination (E+P) and 8102 women were placed in the group that received the inactive (placebo) pill.
- The hormone combination pill contained 0.625 mg/dL of conjugated equine estrogens plus 2.5 mg/dL of medroxyprogesterone acetate (Prempro®, Wyeth Pharmaceuticals).
- Participants were contacted every 6 months and were evaluated once a year by mammography and clinical breast exam at one of 40 study center sites.
- Follow up continues in those that developed breast cancer in order to determine and compare the survival rates of both groups.