



Hormone Replacement Therapy

This information sheet is to inform women of the latest research regarding Hormone Replacement Therapy (HRT) and help each woman determine if HRT is right for her. HRT are the female hormones - estrogen and progesterone - that a woman can take for menopausal symptoms such as hot flashes, moodiness, insomnia, and vaginal dryness. (Please read the handout on Menopause for further information). After reading this update, it is very important that each woman discuss her individual case, concerns, and questions with her health care provider. What is best for your sister or friend may not be best for you.

The Recent Study:

The Women's Health Initiative (WHI) is a long-term study sponsored by the National Institute of Health (NIH) that is looking at ways to prevent heart disease, breast and colon cancer, and osteoporosis. One arm of the study followed 16,608 healthy postmenopausal women (with a uterus), ages 50-79. Women in this arm of the study were randomly put into one of two groups: one group of women took Prempro (which is Premarin or conjugated equine estrogen 0.625 mg/day and Provera or medroxyprogesterone acetate 2.5 mg/day) and the other group took placebo (sugar pill). The other arm of the study is looking at women with no uterus and taking estrogen-only therapy. The study is designed to assess the major benefit and risks of HRT with regard to heart disease, blood clots in the lungs, breast cancer, colon cancer, and osteoporosis/bone fractures. Other factors, such as reduction in hot flashes, moodiness, and vaginal dryness, are not assessed.

During the study, the data collected the first 3-4 years indicated a small increase in heart attacks, strokes, and blood clots in women taking hormones. But it was not until the 5th year of the study that the data indicated for the first time that the number of cases of invasive breast cancer in the Premarin (estrogen) and Provera (progestin) group had crossed the boundary established as a signal of increased risk. The study was halted in May 2002 with this group in the study; however, the other part of the study with the groups of women taking estrogen-only therapy and placebo continues.

Putting the Risks for Women Who Take Estrogen and Progestin as Indicated by the WHI Study into Perspective

The data indicated that if 10,000 women take the studied HRT regimen for one year, as compared to 10,000 women taking placebo, the following risks would occur:

The negative predictions:

- 8 more women will develop breast cancer
- 7 more women will have a heart attack

- 8 more women will have blood clots in the lungs
- 8 more women will have a stroke

The positive predictions:

- 6 fewer women will have colorectal cancer
- 5 fewer women will have hip fractures

The increased breast cancer risk did not appear in the first 4 years of use. Increased risk for blood clots was greatest during the first 2 years of hormone use. The reduced risk of colorectal cancer occurred after 3 years of hormone use.

Limitations of the Study

The study does not look at the benefits of HRT to relieve menopausal symptoms, such as hot flashes, moodiness, insomnia, and vaginal dryness. For many women, these benefits are very important! (See handout on Menopause for treatments of these symptoms).

The study used only ONE preparation of HRT (Premarin 1.625 mg/day and Provera 2.5 mg/day). The data from the WHI cannot be applied to ALL of the different HRT therapies containing estrogen and progestin, such as Estrace, Prometrium, and the HRT patch (these contain different types of estrogens and progestins). However, other HRT therapies have NOT been studied in this way, so it cannot be assumed that they are different (better or worse) than those studied.

Until more studies are completed on other HRT therapies, it is recommended women using all types of HRT talk to their health care provider and weigh the risks and benefits as discussed in this update.

Applying Accounts of Risk to Individual Situation

The percentage of women in the WHI study who actually had negative effects from HRT was small, as was the size of the risk for each individual woman taking HRT. For example, with breast cancer, while the increase risk for the group taking HRT was 26%, an individual woman's increased risk for breast cancer with HRT use was *less than one tenth of the percent a year*, according to the study authors. However, this small increase in individual risk goes up over time. In other words, the longer a woman stays on HRT, the more risk she has for developing breast cancer – even a higher risk than would normally occur with advancing age.

Recommendations for Women Who Want to Take HRT:

Short-term relief of menopausal symptoms:

- For women taking HRT for short-term relief of menopausal symptoms, the benefits of HRT are likely to outweigh the risks.

Long-term relief of postmenopausal symptoms:

- Women may find that longer-term use of HRT to relieve symptoms such as vaginal dryness, hot flashes, and insomnia coupled with the proven benefits of prevention of fractures and reduction of colon cancer may outweigh the risks of HRT. Alternative treatments for these symptoms need to be discussed and an assessment of the woman's individual risks for heart disease, stroke, and breast cancer needs to be addressed with her health care provider.

Consider Alternative Treatments for Symptoms:

- Lifestyle changes that can *reduce* (not eliminate) symptoms of menopause:
- Stop smoking; avoid triggers to hot flashes such as spicy foods, caffeine, and alcohol
- Decrease stress; exercise regularly, and wear loose clothes

Other medications:

- Clonidine (high blood pressure medication); particular antidepressants; and estrogen vaginal cream.
-there have been few studies regarding herbal preparations and effective treatment for menopausal symptoms and the results are conflicting and inconclusive. Some women have found the following to be helpful: soy products and black cohosh (to help with hot flashes), chaste-tree or vitex (to help with loss of sexual interest and vaginal dryness), and others. Remember, many herbal preparations are not well-studied and *none* are regulated by the government – so you cannot be certain what or how much of an herb or contaminant you are getting in a given bottle. It is recommended you talk to your health care provider about alternative methods to relieve menopausal symptoms.

Cardiac Protection:

Women who are taking or considering HRT *only* for the prevention of heart disease should talk to their health care provider about other methods to lower their risks.

Osteoporosis:

Women who are taking HRT *only* for the prevention of osteoporosis should talk to their health care provider about their personal risks and benefits for continuing the drug therapy. There are alternatives to long-term prevention of osteoporosis that should be considered for these women.

Individualizing Your Care:

You need to talk with your health care provider about your particular symptoms, risk factors, options, and the benefits that best suit your needs at this point in time. If you are presently taking HRT, it is very important to talk to your health care provider before

changing your therapy or stopping HRT. Together, you can determine what is best for you in regard to HRT!

Taking Estrogen-Only Therapy – For Women with a Hysterectomy:

So far, that arm of the WHI study continues. The same proportion of risks to benefits has not appeared. Complete results probably will not be known until 2005. Individual consideration should apply to these women, as well: talk to your health care provider.

NOTE: Women who have a uterus should NOT take estrogen alone – it has been proven to increase risk for cancer of the uterus.

Also, if a woman had a hysterectomy and had endometriosis, she may still need progesterone to control growth of implants. 16 cases in literature have been reported in which malignancy developed in endometrial tissue of women when treated with unopposed estrogen.

References

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Other Resources

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