Major Study Shows Risks/Benefits of Osteoporosis Drug Use in Postmenopausal Women

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The drug may help prevent breast cancer and vertebral fractures, but raise the risk of blood clots and fatal strokes

A study in the July 13 issue of the *New England Journal of Medicine,* reporting the results of a 5-1/2 year-long trial of more than 10,000 postmenopausal women with a history of heart disease or at high risk for heart disease, shows that patients given raloxifene therapy had a reduced incidence of vertebral fractures and breast cancer, but an increased incidence of blood clots and fatal strokes. The multi-site international study was headed by Elizabeth Barrett-Connor, M.D., Professor of Family and Preventive Medicine at the University of California, San Diego (UCSD) School of Medicine.

The study showed mixed results. On the positive side, raloxifene therapy reduced invasive breast cancer by 44 percent with 1.2 fewer cases per 1000 women treated for one year. Raloxifene has anti-estrogenic effects in the breast, inhibiting the growth of estrogen-stimulated breast cancer. It also reduced painful vertebral fractures by 35% with 1.3 fewer cases per 1000 women.

On the other hand, use of raloxifene was shown to raise the risk of blood clots by 44%, or 1.2 cases per 1000 women treated for one year. Additionally, 59 of the 5,044 raloxifene users had fatal strokes, compared to only 39 of the half on placebo, an absolute increase of 0.7 cases per 1000 women treated for one year, or a 49 percent greater risk of stroke-related death – though there was no significant difference in the total number of stroke episodes.

"The breast cancer prevention benefits may not justify the risks of taking raloxifene for some patients, especially those already prone to heart problems, because of the risk related to other diseases," said Barrett-Connor, who added that women should talk about risks with their doctors.

Doctors had thought that the drug might help prevent heart problems, because it lowers cholesterol levels. However, the study showed that raloxifene therapy did not significantly reduce the risk of coronary events such as heart attack, hospitalization or death in the clinical trial group assigned to raloxifene therapy, made up of women with previous established or proven risk of heart disease.

Raloxifene is a non-steroidal selective estrogen-receptor modulator (SERM) produced by Eli Lilly. The drug is sold as Evista for preventing and treating osteoporosis, and has also been tested by doctors as an alternative to tamoxifen for preventing breast cancer in a previous trial.

The Raloxifene Use for the Heart (RUTH) trial began in 1998 to determine the effects of the drug on clinical coronary events in women with or at increased risk for coronary heart disease. Eligible participants were women age 55 years or older, who were at least one year postmenopausal, and had established or risk factors for heart disease such as clogged arteries, high blood pressure or cholesterol level, smoking or diabetes. Women at 177 sites in 26 countries were randomly assigned to treatment or placebo.

After an average of five years, the RUTH study showed that deaths and major heart problems were about the same in both the group receiving raloxifene and those taking a placebo. Raloxifene users experienced one-third fewer cases of breast cancer and about half the number of invasive breast cancers.

The mixed results of the study make it vital that women talk with their doctors about treatment options, and weigh the risk/benefit ratio in light of their own health history, according to the study's authors.

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