Medications effective in reducing risks for breast cancer can also cause serious side effects

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Three drugs that reduce a woman's chance of getting breast cancer also have been shown to cause adverse effects, according to a new report from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health & Human Services.

The report is based on a study led by Heidi D. Nelson, M.D., M.P.H., research professor in the Oregon Evidence-Based Practice Center at Oregon Health & Science University and medical director of the Women and Children's Program and Research Center at Providence Health & Services. It is published online in the Sept. 15 issue of the *Annals of Internal Medicine*.

The study is the first to make a direct, comprehensive comparison of drugs that reduce the risk of breast cancer so that women and their health care providers can assess their potential effectiveness and adverse effects. It compares the use of tamoxifen, raloxifene and tibolone to reduce the risks of getting breast cancer in women without pre-existing cancer.

Tamoxifen, raloxifene and tibolone can be prescribed to women with a family history of breast cancer or other risk factors, but prescribing practices vary widely. According to the study, all three drugs significantly reduce invasive breast cancer in midlife and older women, but benefits and adverse effects can vary depending on the drug and the

patient.

Breast cancer is the second most commonly diagnosed cancer among women (after skin cancer), with more than 190,000 new cases diagnosed each year in the United States. It is estimated to cause more than 40,000 deaths per year. The National Cancer Institute estimates that nearly 15 percent of women born today will develop breast cancer in their lifetimes. Most cases of breast cancer occur in women with no specific risk factors other than age and gender, although family history of breast and ovarian cancer is associated with higher risk.

Tamoxifen, a selective estrogen receptor modulator (SERM), was approved by the Food and Drug Administration in 1998 to reduce risk for breast cancer in women at high risk of developing the disease. Its use to reduce the risk of breast cancer is accepted clinical practice, although it is primarily used for treatment rather than risk reduction.

The study compared tamoxifen with another SERM, raloxifene, which is primarily used to prevent and treat osteoporosis and was approved by the FDA for breast cancer risk reduction in 2007. A third drug, tibolone, which has not been approved by the FDA for use in the United States but is commonly used in other countries to treat menopausal symptoms and osteoporosis, also was included in the study.

The study found that all three drugs reduce the occurrence of breast cancer but have various side effects. The most common side effects for tamoxifen are flushing and other vasomotor symptoms (e.g., night sweats, hot flashes), vaginal discharge and other vaginal symptoms such as itching or dryness; for raloxifene, side effects include vasomotor symptoms and leg cramps; and for tibolone, side effects include vaginal bleeding.

The study also found that each drug carried risks of adverse effects.

Tamoxifen increases risks of endometrial cancer, hysterectomies and cataracts compared with the other drugs. Tamoxifen and raloxifene increase risk of blood clots, although tamoxifen's risk is greater. Tibolone carries an increased risk of stroke, according to the study.

The study also examined the drugs' effectiveness and harms based on age, menopausal status, estrogen use and family history of breast cancer, and sought to identify the kinds of women who might be good candidates for therapy, although the evidence is limited in this area. The investigators called for more research to more clearly identify characteristics of patients who would benefit from these drugs while suffering the least harm.

"Before applying the findings of the report to practice, clinicians must ensure that women understand their individual risks for breast cancer and can favorably balance these with the unwanted effects of risk-reducing medications," explained Nelson.

Source: Oregon Health & Science University (news : web)