Development of a Benefit/Risk Assessment Tool for Breast Cancer Chemoprevention

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Abstract

PURPOSE: The Study of Tamoxifen and Raloxifene (STAR) demonstrated that raloxifene was as effective as tamoxifen in reducing the risk of invasive breast cancer (IBC) in postmenopausal women and had lower risks of thromboembolic events, endometrial cancer, and cataracts, but a nonstatistically significant higher risk of noninvasive breast cancer. We developed a risk assessment tool to summarize the risks and benefits of these agents.

PATIENTS AND METHODS: Baseline incidence rates of IBC and other health outcomes, absent raloxifene and tamoxifen, were estimated from breast cancer chemoprevention trials, the Surveillance, Epidemiology, and End Results Program, and the Women's Health Initiative. Effects of raloxifene and tamoxifen were estimated from STAR and the Breast Cancer Prevention Trial. We assigned weights to health outcomes to calculate the net benefit from: raloxifene compared with placebo and tamoxifen compared with placebo.

RESULTS: The risks and benefits depend on age, race, breast cancer risk, and history of hysterectomy. Over a 5-year period, postmenopausal women with an intact uterus had a better benefit/risk index for raloxifene than for tamoxifen. For postmenopausal women without a uterus, the benefit/risk ratio was similar. Tables describe the benefits and risks of raloxifene and tamoxifen and can help identify groups of women for whom the benefits outweigh the risks.

CONCLUSIONS: We developed a benefit/risk index to quantify benefits from chemoprevention with tamoxifen or raloxifene. This index can complement clinical evaluation in deciding whether to initiate chemoprevention and in comparing the benefits and risks of raloxifene versus tamoxifen.

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