S20. Tamoxifen or Raloxifen for chemoprevention of breast cancer in high risk women: The NSABP-experience

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Background and Objective: The NSABP Study of Tamoxifen and Raloxifene (STAR), launched in 1999, compared tamoxifen with raloxifene in a population of healthy postmenopausal women at increased risk for breast cancer to determine the relative effects on the risk of invasive breast cancer.

Methods and Patient characteristics: To be eligible for participation, a woman had to be healthy with at least a 5-year predicted breast cancer risk of 1.66% based on the Gail Model or a history of lobular carcinoma in situ (LCIS) treated by local excision alone. All participants were at least 35 years of age and postmenopausal. Between July 1999 and November 2004, 19,747 participants were randomized to receive either tamoxifen, 20 mg, plus placebo or raloxifene, 60 mg, plus placebo daily for a 5-year period. The mean age of the participants was 58.5 years. 93% were white and 51.6% had a hysterectomy prior to entering the study. 71% of the women had one or more first degree female relatives (mother, sister, daughter) with a history of breast cancer and 9.2% of the women had a personal history of LCIS. A history of atypical hyperplasia of the breast was noted in 22.7% of the participants. The mean predicted 5-year risk of developing breast cancer among the study population was 4.03% (SD, 2.17%) with a life time predicted risk of just over 19%. The mean time of follow-up is 3.9 years (SD, 1.6 years).

Results: There was no difference between the effect of tamoxifen and the effect of raloxifene on the incidence of invasive breast cancer; there were 163 cases of invasive breast cancer in the tamoxifen-treated group and 168 cases in those women assigned to raloxifene (incidence 4.30 per 1,000 vs 4.41 per 1,000; RR 1.02; 95% CI, 082–1.28). There were fewer cases of noninvasive breast cancer (LCIS and DCIS) in the tamoxifen group (57 cases) then in the raloxifene group (80 cases), although the difference is not yet statistically significant (incidence 1.51 vs 2.11 per 1,000; RR, 1.40; 95% CI, 0.98–2.00). There were 36 cases of uterine cancer with tamoxifen and 23 cases with raloxifene (RR, 0.62; 95% CI, 0.35–1.08). There was no difference in the total number of deaths (101 tamoxifen vs 96 raloxifene) or in causes of death.

Conclusions: Raloxifene is an effective option for postmenopausal women to reduce their risk of invasive breast cancer. The drug has fewer serious side effects then tamoxifen, making it a more attractive option as well.