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NEWS REPORT

Adjuvant Chemotherapy Provides Survival Benefit for Women With Lymph Node-Negative, Estrogen Receptor-Negative Breast Cancer

By Kara A. Nyberg, PhD

January 28, 2005 — Updated findings from 3 National Surgical Adjuvant Breast and Bowel Project (NSABP) trials verify a favorable survival rate for women with axillary lymph node-negative, estrogen receptor (ER)-negative breast cancer who receive adjuvant chemotherapy following surgery, according to a report in the *Journal of the National Cancer Institute*.

The 3 randomized phase 3 trials (B-13, B-19, and B-23), which began in 1981, were conducted sequentially. Notably, the treatment given to the experimental group of each trial served as the control for the next trial.

The first trial, B-13, compared the value of postoperative methotrexate plus 5-fluorouracil (MF) chemotherapy with surgery alone. The second trial, B-19, compared an adjuvant chemotherapy regimen of MF to that of cyclophosphamide plus MF (CMF). And the final trial, B-23, assessed whether doxorubicin plus cyclophosphamide (AC) was more effective than CMF postoperatively, and whether the addition of tamoxifen to either AC or CMF enhanced treatment outcome.

A survival benefit for chemotherapy was confirmed at 16, 13, and 8 years of follow-up for trials B-13, B-19, and B-23, respectively, especially for CMF and AC vs surgery alone among women with lymph node-negative breast cancer. The absolute recurrence-free survival benefit for those treated with CMF and AC was approximately 16%, equal to a 58% reduction in disease recurrence. The absolute overall survival benefit conferred by these treatments was about 8%, corresponding to a mortality reduction of 40%.

However, after 5 years, the B-23 findings demonstrated no statistically significant differences in the outcomes of AC- and CMF-treated patients, and no advantage with tamoxifen with either chemotherapy regimen over the benefit achieved with chemotherapy alone.

Chemotherapy benefits were greatest for women younger than 49 years and decreased with advancing age, note Bernard Fisher, MD, the lead investigator of the NSABP study group, and colleagues. However they

point out that the use of AC in women aged 60 or more years who have ER-negative tumors and negative axillary lymph nodes cannot be totally dismissed. "In older women who have pathologic and other biomarkers that are indicative of rapidly proliferating tumors, for example, unfavorable histologic or nuclear grade and high thymidine labeling index, and who are more likely to benefit from chemotherapy, the use of an anthracycline-containing regimen, and perhaps CMF, might be considered."

"It is clear that the benefit of chemotherapy (vs surgery alone) extends to women of all ages who fit the eligibility criteria of these trials," writes Kathy S. Albain, MD, in an editorial accompanying the study.

Reference

Fisher B, Jeong J-H, Anderson S, Wolmark N. Treatment of axillary lymph node-Negative, Estrogen Receptor-Negative Breast Cancer: Updated Findings From National Surgical Adjuvant Breast and Bowel Project clinical trials. JNCI. 2004;96:1823-1831.

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