

RESEARCH HIGHLIGHTS FROM THE 38TH ANNUAL MEETING OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ORLANDO, FL MAY 18-21, 2002

CLINICAL RESEARCH

Docetaxel Shows Benefit for Patients With Early-Stage Breast Cancer

Researchers from the Breast Cancer International Research Group in Los Angeles, CA, presented the interim (33 months) analysis of a phase III trial comparing docetaxel, doxorubicin, and cyclophosphamide (TAC) with 5-fluorouracil, doxorubicin, and cyclophosphamide (FAC) for adjuvant therapy in patients with node-positive breast cancer. The study involved 1,491 patients, with 745 randomized to TAC (75/50/500 mg/m² every three weeks x six) and 746 to FAC (500/50/500 mg/m² every three weeks x six). The design included stratification by nodes less than or equal to three or four or more. Patients with estrogen- or progesterone-receptor positive tumors received tamoxifen for five years following surgery. The percentage of patients able to receive all six cycles of chemotherapy was 96% for FAC and 91% for TAC. Cox analysis showed significantly improved disease-free survival and overall survival for the patients who received TAC. Febrile neutropenia (24% versus 2%) and grades 3 or 4 infection (2.8% versus 1.3%) occurred more frequently in patients receiving TAC. Other significant toxicities occurring in more than 5% of patients were nausea (9%), vomiting (7%), and asthenia (5%) in patients receiving FAC, and asthenia (11%) and stomatitis (7%) in patients receiving TAC.

Chemotherapy Offers Possible Improved Benefit for Early-Stage Breast Cancer

A multicenter collaborative study presented by researchers from Loyola University Breast Care Center at the Cardinal Bernardin Cancer Center in Chicago, IL, suggested that outcomes may be improved if patients with early-stage breast cancer begin taking tamoxifen after completing chemotherapy. In a phase III trial, 1,477 women with hormone-receptor positive tumors were treated with oral cyclophosphamide, Adriamycin® (Pharmacia Corporation, Peapack, NJ), and 5-fluorouracil (CAF) for six cycles. Tamoxifen was given simultaneously (n = 550) or following chemo-

therapy (n = 566) and continued for five years. Some patients were treated only with tamoxifen (n = 361). Eight years after treatment, the groups began to diverge in terms of disease-free survival. To date, the differences when adjusted for other contributing factors are not significant (disease-free survival of 67% for tamoxifen following chemotherapy versus 62% for simultaneous with chemotherapy); however, a possible benefit from delaying tamoxifen therapy rather than giving it concurrently was suggested. Both groups receiving CAF had higher percentages of women with disease-free survival than the tamoxifen-alone group (55%). The data supported the hypothesis that tamoxifen may antagonize chemotherapeutic agents and support a practice standard of starting tamoxifen after chemotherapy is completed.

Tamoxifen Standard of Care Recommended for Prevention of Breast Cancer Recurrence

A panel of leading breast cancer experts examined the results of the ATAC (anastrozole, tamoxifen, alone or in combination) study that was presented at the San Antonio Breast Cancer Symposium in 2001 and the related medical literature. The study, designed to compare the benefits of anastrozole and tamoxifen over a five-year period, involved 9,000 women with early-stage breast cancer following surgery. All were candidates for adjuvant hormonal therapy. In the preliminary analysis, with a median follow up of 33 months, 317 of 3,125 women taking anastrozole either suffered a relapse of their breast cancer or died. This was compared with 379 of 3,116 women taking tamoxifen. The impact of anastrozole on long-term survival has not been evaluated yet. A five-year course of tamoxifen is required to identify the maximum clinical benefit. The expert panel determined that because of the lack of long-term efficacy and tolerability data, it will not recommend routine use of anastrozole because it is too early. Long-term data are extensive regarding the safety and tolerability of tamoxifen. In addition, the panel found no data to support switching from tamoxifen to anastrozole or other aromatase inhibitors. For some women, tamoxifen may be contraindicated and, in these cases, anastrozole may be an option. Further panel recommendations included the following.

- Women aged 35 and older with a five-year projected breast cancer risk greater than 1.66% should be considered candidates for tamoxifen.

- Insufficient evidence exists for the use of raloxifene for breast cancer risk reduction.

Smoking During Cancer Therapy Reduces Survival for Patients With Lung Cancer

Researchers from the Dana-Farber Cancer Institute in Boston, MA, and London Regional Cancer Centre in London, Canada, presented the results of a study examining the effects of smoking on outcomes for patients with limited small cell lung cancer (LSLC). From 1989–1999, 215 patients with LSLC were treated with six cycles of alternating cyclophosphamide, Adriamycin® (Pharmacia Corporation, Peapack, NJ), and vincristine and etoposide and cisplatin. Thoracic radiation started at etoposide and cisplatin cycle two or three (either 50 Gy/15 fractions per three weeks or 50 Gy/25 fractions per five weeks). Smoking status was noted at the onset of chemoradiation therapy for 186 patients (107 nonsmokers and 79 smokers). The prognostic variables for the two groups were similar, as were toxicity breaks in therapy. Overall survival was significantly better for the nonsmokers. For example, at two years, 28% of the nonsmokers compared to 18% of the smokers still were living. At five years, 9% and 4%, respectively, still were living. The researchers concluded that patients should stop smoking to achieve maximal benefit from LSLC chemoradiation therapy.

Vitamin A May Help Prevent Lung Cancer in Former Smokers

The results of a randomized, placebo-controlled, clinical trial of two forms of vitamin A, 9-cis and 13-cis retinoic acid, for the reversal of preneoplasia in former smokers, was presented by a collaborative group including researchers from the University of Texas M.D. Anderson Cancer Center in Houston, National Cancer Center Hospital in Tokyo, Japan, and Southwestern Medical Center in Dallas, TX. Retinoic acid targets the retinoic acid receptor-beta and is needed for normal growth and development of epithelial cells that line the lung membranes. Former smokers were identified as those who had smoked at least 20 pack years and

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