

# RESEARCH HIGHLIGHTS

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### Clinical and Epidemiologic Research

#### Women With Node-Positive Breast Cancer Obtain Benefits From Adjuvant Chemotherapy

Researchers from the University of Vermont in Burlington presented results from the analysis of data from the Cancer and Leukemia Group B trials for the effects of adjuvant chemotherapy in younger and older women. The purpose of the study was to determine the benefits and toxicities of adjuvant chemotherapy for women with node-positive breast cancer. Data from 6,489 patients were analyzed for all four trials by age group. Sixty-one percent of the biopsies were estrogen-receptor positive and 56% were progesterone-receptor positive. Fifty-seven percent of the women received tamoxifen therapy in addition to chemotherapy regimens. Women older than 65 had more positive lymph nodes ( $p < 0.05$ ). Multivariate analysis demonstrated that small tumor size, a low number of positive lymph nodes, higher doses of chemotherapy agents, and the use of tamoxifen all were associated with longer relapse-free survival. No correlation with age existed. The researchers concluded that older women had similar dose-related benefits from adjuvant chemotherapy as younger women in reducing breast cancer-related relapse and mortality. They also noted that older women had a higher mortality rate because of more deaths related to causes other than breast cancer. In addition, women older than 65 were greatly underrepresented in clinical trials.

#### Older Patients Are Underrepresented in Cancer Clinical Trials

Investigators from the U.S. Food and Drug Administration's Center for Drug Evaluation and Research analyzed data from clinical trials for cancer drugs involving 29,350 patients, comparing cancer statistics and percentages of patients involved in clinical trials by age group. Older patients were defined as

those older than 65. The percentage of patients older than 65 who were diagnosed with specific types of cancer were 49% for breast cancer, 67% for lung cancer, 70% for colorectal cancer, 71% for pancreatic cancer, 44% for ovarian cancer, and 54% for leukemias. However, the percentages of patients older than 65 who were enrolled in clinical trials were 45% for breast cancer, 35% for lung cancer, 41% for colorectal cancer, 33% for pancreatic cancer, 31% for ovarian cancer, and 24% for leukemias. The disparity increased with increasing age. The researchers concluded that underrepresentation of older patients in clinical trials hampers efforts to assess the risks and benefits of therapies for older patients. They recommended developing strategies to increase the enrollment of older patients in cancer clinical trials and designing prospective trials specifically for older adults.

#### Paclitaxel Plus Standard Therapy May Improve Outcomes for Patients With Head and Neck Cancer

The results of a multicenter, phase III trial comparing standard cisplatin and 5-fluorouracil with cisplatin, 5-fluorouracil, and paclitaxel for the treatment of locally advanced head and neck cancer were presented by researchers from Hospital 12 de Octubre in Madrid, Spain. The trial involved 384 patients randomly assigned to one of the two treatment arms. Pretreatment patient characteristics were well balanced between the two treatment groups. Patients who received paclitaxel had no signs of tumor progression at a median of 23 months compared to 18 months for those who received standard therapy. For patients who received paclitaxel, tumor growth was halted in 33% compared to 14% of those who received standard therapy. The organs involved in speaking and swallowing (larynx, pharynx, and tongue) were preserved in 88% of the patients who received paclitaxel compared to 75% of those who did not receive paclitaxel. Side effects were similar in the two groups, although those who received standard therapy were more likely to experience severe mucositis. Follow-up is continuing; those who received paclitaxel are surviving significantly longer than the median 38 months associated with the standard chemotherapy regimen.

#### Antiangiogenesis Drug May Benefit Patients With Metastatic Colorectal Cancer

Bevacizumab (Avastin™, Genentech Inc., South San Francisco, CA) inhibits vascular endothelial growth factor (VEGF), a protein that enhances blood vessel growth (angiogenesis) necessary for tumor survival. Researchers from Duke University Medical Center in Durham, NC, presented the results of a phase III trial of standard chemotherapy (irinotecan, 5-fluorouracil, and leucovorin) compared to standard therapy plus bevacizumab. In this study, 800 patients were randomized to one of the two treatment arms. Tumors were shown to shrink by half in 45% of the patients who received bevacizumab and 35% of the patients who received the standard therapy. Furthermore, patients who received bevacizumab survived a median of 20.3 months compared to 15.6 months for those who did not receive it. Cancer progression was delayed for a median of 10.6 months for patients who received bevacizumab and 6.2 months for those who did not. Phase II trials of bevacizumab suggested that bleeding, thrombosis, proteinuria, and hypertension were possible safety issues. However, in this phase III trial, only hypertension was identified as a potential problem and it was readily treatable with oral medications. The researchers also noted that the risk of gastrointestinal perforation, although rare, may be increased with the addition of bevacizumab to standard therapy.

#### Adjuvant Oxaliplatin May Reduce Risk of Disease Recurrence in Patients With Colorectal Cancer

Researchers from Hospital Saint Antoine in Paris, France, presented the results from an international phase III trial of oxaliplatin for the treatment of locally advanced colorectal cancer. The study involved 2,248 postsurgical patients diagnosed with stage II or III colon cancer who were assigned randomly to

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