Continued from previous page

The Kaiser study is important because it replicates the NSABP validation study findings in a real-world community-based population. Nearly one-third of participants in the Kaiser study had tumors of 1 cm or less, as is increasingly the case in the contemporary era of widespread mammographic screening, she added.

The Oncotype DX assay uses reversetranscriptase PCR to measure expression of 16 genes involved in cancer proliferation, cancer invasion, estrogen receptor activity, and HER2, along with five reference genes. At a cost of \$3,460, the test is pricey, although Steven Shak, M.D., chief medical officer at Genomic Health, is quick to add that it's a highly complicated assay requiring 1,000 individual steps. For reasons of quality control, it must for the time being be performed on samples shipped to the company's core laboratory.

Despite the test's high price tag, a costbenefit analysis reported at the meeting by Gary H. Lyman, M.D., concluded that routine use of the assay in early-stage breast cancer patients who are estrogen receptor-positive, node-negative, and tamoxifen-treated is cost-effective.

Taking into account the costs of five commonly used chemotherapy regimens,

the use of empiric chemotherapy in such patients costs an average of \$12,923 per year of life gained, compared with \$5,124 per year of life gained with the use of a strategy of selective chemotherapy guided by the Oncotype DX score. The potential savings through routine use of the 21-gene assay were greatest among patients at least 50 years of age, for whom empiric chemotherapy cost an average of \$28,742 per year of life gained, compared with \$16,108 using a selective strategy of Oncotype DX-guided chemotherapy, according to Dr. Lyman of the University of Rochester (N.Y.).

He added that his figures understate the

test's true value because they don't factor in the quality-of-life issues that further enhance the attractiveness of a test that safely enables many patients to avoid chemotherapy. Patients dread the toxicities of chemotherapy, including nausea and vomiting, hair loss, profound fatigue, and infections. His study was funded by Genomic Health, as was the Kaiser epidemiologic study.

Future projects will include tweaking the 21-gene assay so it can be applied to patients with node-positive breast cancer, and research on the value of chemotherapy in patients with an intermediate score on the Oncotype DX.

Blood Test **Predicts Breast** Ca Outcome

SAN ANTONIO - An elevated circulating tumor cell count at any point during systemic therapy for metastatic breast cancer indicates a high likelihood of rapid disease progression and mortality from that time on, Daniel F. Hayes, M.D., said at a breast cancer symposium sponsored by the Cancer Therapy and Research Center.

This implies that circulating tumor cell count, as measured by a commercially available blood test, may have an important role in patient monitoring and treatment. A randomized prospective clinical trial is now underway to evaluate the impact of switching therapy in patients who develop an elevated circulating tumor cell (CTC) count during therapy, added Dr. Hayes, clinical director of the breast cancer program at the University of Michigan Comprehensive Cancer Center, Ann Arbor.

In a previously reported double-blind multicenter study of 177 women who were about to start a new therapy for metastatic breast cancer, Dr. Hayes and his coinvestigators showed that the presence of at least 5 CTCs per 7.5 mL of whole blood using the CellSearch test was associated with significantly reduced progression-free and overall survival.

The same held true for patients with a positive test at their first follow-up visit after treatment initiation. They had a median 2.1-month progression-free survival from that time, compared with 7.0 months in women with 0-4 CTCs on the test. Their median overall survival was 8.2 months, compared with more than 18 months in those with a negative CellSearch test, said Dr. Hayes, a consultant to Immunicon, the company that developed the test.

In a multivariate regression model, CTC count at baseline and first follow-up visit were the strongest predictors of progression-free and overall survival, outperforming HER2/neu status, tumor receptor status, type of therapy, and other standard predictors (N. Engl. J. Med. 2004;351:781-91).

In Dr. Hayes's new analysis of the same patient cohort, he demonstrated that patients who developed an elevated CTC count at the second, third, or fourth follow-up visit also fared significantly worse than those who continued to have fewer than 5 tumor cells at their blood draw. -Bruce Jancin



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