Breast Cancer Risk Test Trumps Gail Model

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SAN ANTONIO — The investigation of OncoVue breast cancer risk test provided a 2.4-fold improvement over the Gail model in accurately identifying women at elevated risk of breast cancer in a blinded validation study. This is the third independent study demonstrating that the OncoVue individualized breast cancer risk estimator provides more accurate estimates than does the widely used Gail model, Dr. Kathie M. Daleassen said at the San Antonio Breast Cancer Symposium.

OncoVue integrates genetic testing for 22 single nucleotide polymorphism variants located on 19 genes with classic Gail model personal risk factors, such as age at first menses and first live birth and the number of first-degree relatives having breast cancer. The genetic test uses DNA from a saliva sample, explained Dr. Daleassen of the University of California, San Francisco, and the Buck Institute for Age Research in Novato, Calif. She reported on 169 women diagnosed with breast cancer during 1997-1999, when they were a mean of 54 years old, and 177 age-matched controls. All were enrolled in the Marin County Study of Breast Cancer Adolescent Risk Factors.

OncoVue proved to be a 2.4-fold more accurate than the Gail model at identifying women with a 12% or greater risk of developing breast cancer between ages 30 and 69, which is 1.5 times the national average risk.

The Gail model identified as high risk 37 of the 177 women who went on to develop breast cancer. OncoVue identified 56 of the women, a 51% improvement.

The Food and Drug Administration has yet to approve any tests such as those from for BRCA1 and BRCA2. The OncoVue test, developed by InterGenetics Inc. of Oklahoma City, is available at roughly three dozen breast care centers around the country.

The study was supported by the California Breast Cancer Research Program and InterGenetics. Dr. Daleassen reported having no financial conflicts of interest.

Test Tags HER2 Patients Who Are at Low Risk

S A N A N T O N I O — The gene MammmPrint signature independently identified the low-risk subgroup of HER2-positive early breast cancer patients likely to have a good long-term clinical outcome, even without adjuvant trastuzumab and chemotherapy.

Dr. Michael Knauer of the Netherlands Cancer Institute, Amsterdam, reported a validation study of 169 women with HER2-positive unilateral breast cancer drawn from six partially published studies. All of the women had T1-3 N0 disease; 46% received chemotherapy and 15% got trastuzumab.

MammmPrint classified 16% of the tumors as having a “good prognosis” signature, Dr. Knauer said at the San Antonio Breast Cancer Symposium. Those 27 patients had a 10-year distant disease-free survival rate of 89%. The 142 patients classified by MammmPrint as having a high genomic risk had a 10-year distant disease-free survival of 64%.

In a multifactorial analysis adjusted for the conventional prognostic factors along with adjuvant therapies, the MammmPrint signature and tumor size were the only independent predictors of 10-year distant disease-free survival. MammmPrint was the stronger predictor of the two; a “poor prognosis” MammmPrint result was associated with a 5.4-fold increased risk of distant recurrence within 10 years, compared with a favorable MammmPrint signature.

In the subset of 90 patients who didn’t receive adjuvant trastuzumab or chemotherapy, a poor prognosis MammmPrint result conferred a 4.7-fold greater risk of distant relapse within 10 years. Again, MammmPrint, which markets MammmPrint, supported the study. Dr. Knauer said he has no financial conflicts of interest regarding the study.