New Test Predicts Risk for Recurrence for Patients With DCIS

AACR

- Multigene assay predicts risk for local recurrence for patients with DCIS.
- This advance combines knowledge of the genome and new molecular technologies.
- Test allows physicians to individualize treatment so that lower-risk patients avoid radiation.

SAN ANTONIO - In a significant advance for patients with ductal carcinoma *in situ*, researchers have developed and prospectively validated a multigene test to identify the risk for recurrence of breast cancer.

The method combines measuring tumor gene expression with a gene expression algorithm to decipher the genetic underpinnings of a patients cancer and determine whether the individual patient should be treated with surgery (usually lumpectomy) or a combination of surgery and radiation.

This is the first time a multigene test has been used to differentiate lower-risk and more aggressive forms of ductal carcinoma *in situ* (DCIS) and will allow physicians to spare many patients the need to undergo radiation, according to researchers.

Lawrence J. Solin, M.D., FACR, FASTRO, chair of the department of radiation oncology at Einstein Medical Center in Philadelphia, presented the results at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), held Dec. 6-10, 2011.

"Using a molecular-based assay, we have successfully identified patients at higher risk for recurrence and patients at lower risk," said Solin. "This is an important advance for women with newly diagnosed DCIS. By predicting individual risk, physicians can provide a more tailored treatment program for each patient."

The validation study of the DCIS Score was a collaboration among the Eastern Cooperative Oncology Group (ECOG), North Central Cancer Treatment Group and Genomic Health. The validation utilized patient tumor samples from E5194, an ECOG-led, multi-institutional study of patients with low-, intermediate- or high-grade DCIS who had been treated surgically but had not received radiation. E5194 was the first prospective study of local excision alone for DCIS, and its five-year results were reported at SABCS in 2006 (L. Hughes).

Researchers tested and scored tumors from 327 patients to determine their risk for recurrence. The DCIS validation study team used the Oncotype DX breast cancer assay, which has been available for invasive breast cancer since 2004, and a DCIS

Score algorithm to study these tumor samples.

The test uses reverse transcriptase-polymerase chain reaction technology, which quantitates the level of RNA in the individual tumor sample to reveal its underlying biology. The level of RNA is then used by a prespecified algorithm to calculate a DCIS Score, which predicts the likelihood of local recurrence, defined as either the development of a new invasive breast cancer or the recurrence of DCIS.

Solin also reported 10-year results of E5194, in which 46 patients had an ipsilateral breast event (IBE; defined as ipsilateral local recurrence of DCIS or invasive cancer) at a median follow-up of 8.8 years. Continuous DCIS Score was significantly associated with IBE when adjusted for tamoxifen use and provided value beyond the traditional measures of tumor size, tumor grade and margin status.

Numerous studies, including the current study, have shown that routine, microscopic pathology grading is not a reliable indicator of the risk for recurrence.

"The DCIS Score will help physicians understand the underlying biology of DCIS for an individual patient and accurately gauge the risk for that person," said Solin. "As a result, the patient and physician can decide on the appropriate course of treatment based on a more complete understanding of the risk involved."

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The mission of the CTRC-AACR San Antonio Breast Cancer Symposium is to produce a unique and comprehensive scientific meeting that encompasses the full spectrum of breast cancer research, facilitating the rapid translation of new knowledge into better care for patients with breast cancer. The Cancer Therapy & Research Center (CTRC) at The University of Texas Health Science Center at San Antonio, the American Association for Cancer Research (AACR) and Baylor College of Medicine are joint sponsors of the San Antonio Breast Cancer Symposium. This collaboration utilizes the clinical strengths of the CTRC and Baylor and the AACRs scientific prestige in basic, translational and clinical cancer research to expedite the delivery of the latest scientific advances to the clinic. The 34th annual symposium is expected to draw nearly 8,000 participants from more than 90 countries.

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