

## New test predicts risk for recurrence for patients with DCIS

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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 <u>gene expression</u> with a gene expression algorithm to decipher the <u>genetic underpinnings</u> of a patient's 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 lowerrisk and more aggressive forms of <u>ductal carcinoma</u> 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 <u>radiation oncology</u> 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 <u>recurrence</u> 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 <u>patients</u> 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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