

New study suggests 21-gene recurrence score may help in radiation decision-making

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A new study shows that a test physicians commonly used to guide chemotherapy treatment for post-breast cancer surgery patients may also help them decide whether radiation therapy may be of benefit.

Known as the 21-gene [recurrence](#) score, the test is a personalized analysis of the activity of 21 genes found in a patient's [breast](#) tumor tissue. The score can be used to predict whether, after undergoing surgery, that patient's breast cancer is likely to return in another part of their body, like the bones or lungs, and whether that patient will likely benefit from [chemotherapy treatment](#).

Study results suggest patients with an intermediate or high 21-gene recurrence score are more likely to see their cancer return to the breast and nearby lymph nodes and, thus, could benefit from [radiation](#). Findings appear today in *JAMA Oncology*. The study was conducted by the SWOG Cancer Research Network, a cancer clinical trials network funded by the National Cancer Institute (NCI), part of the National Institutes of Health, and part of the oldest and largest publicly funded research network in the nation.

The Canadian Cancer Trials Group, with co-sponsorship by the NCI, is enrolling patients on a trial called TAILOR RT, which will confirm whether the recurrence score—all by itself—can identify low risk node positive patients who do not need radiation. Because randomized trials represent the gold standard in [clinical research](#), TAILOR RT results could change the standard of cancer care. Until that data is in, the

SWOG findings provide evidence that the recurrence score can be an effective, additional tool—along with tumor size or stage—that physicians can use to determine whether to recommend radiation therapy, particularly for patients whose cancer presentation makes the need for radiation uncertain.

"For a decade, radiation oncologists have been banging on the doors of precision medicine, looking for genomic tools they can use to personalize treatment for their patients," said Wendy Woodward, MD, Ph.D., lead investigator of the SWOG study and chief of the clinical breast radiotherapy service at the University of Texas M.D. Anderson Cancer Center. "Radiation oncologists want these tools because they can help their patients. Radiation treatment can help wipe out local disease, saving or lengthening a patient's life. And omitting radiation treatment could spare other patients pain, time, and cost."

The 21-gene recurrence score test is sold as the Oncotype DX Breast Recurrence Score and was developed by the California-based company Genomic Health, Inc. In multiple research studies, the test has been proven to predict the likelihood of disease recurrence—and chemotherapy benefit—in patients with invasive, early-stage breast cancer.

The test made international headlines in June 2018 when the results of the Trial Assigning Individualized Options for Treatment, or TAILORx, were released at the annual meeting of the American Society of Clinical Oncology. Results from TAILORx, the largest randomized post-surgery breast cancer trial ever mounted, showed that the test could predict who would, and would not, benefit from chemotherapy.

Woodward and her team wanted to see if the 21-gene recurrence score could also be useful in predicting the local breast cancer recurrence that radiation can prevent. Radiation is much more targeted than

chemotherapy, focusing on specific areas in and around the breast.

Woodward was particularly interested in how recurrence scores might help add to the clinical tools that currently guide radiation for patients—especially when the need isn't clear. Breast cancer patients who have undergone mastectomy, have low-risk clinical factors, and cancer-free lymph nodes often do not require radiation treatment after their cancer surgery. However, those with large tumors and cancer in four or more lymph nodes almost definitely get radiation. But what about patients with a more ambiguous presentation—say, a smaller tumor and one to three cancer-positive lymph nodes? Can scores help safely guide radiation decisions?

To find out, Woodward and her team dove into data generated by S8814, a long-closed SWOG trial that compared post-surgery treatments in postmenopausal women with breast cancer. In this randomized trial, postmenopausal women with node-positive breast cancer were randomly assigned to one of three treatments. Physicians recommended radiotherapy based on clinical factors, such as tumor size and the number of lymph nodes that contain cancer.

As part of S8814, 367 patients took the 21-gene recurrence score test. Woodward and her team reviewed all these records to see which patients had [radiation therapy](#) and which had what's known as locoregional recurrence (LRR), when cancer returns after treatment close to the site of the original tumor—in this case, the breast, chest wall, or lymph nodes. After winnowing out certain patients, the SWOG team wound up with a pool of 316 patient records. They logged every patient's recurrence score, and also whether and when LRR occurred. In all, after a median of eight years of follow-up, 34 patients went on to have an LRR event—27 with intermediate or high recurrence scores and seven with low recurrence scores. Regardless of other factors, such as number of cancer-positive lymph nodes, the recurrence score proved to be an

independent predictor for LRR.

"We believe these data support using recurrence scores—along with standard clinical factors like age or tumor size—to determine risk of recurrence and radiotherapy decisions for patients," Woodward said.

"Our findings are clearly limited, as we had some small patient numbers and looked at data retrospectively. But these results provide additional evidence of the value of this test in node positive patients. And they suggest it might be possible to skip radiation in patients with low recurrence scores and one to three [cancer](#)-positive nodes, a question now being rigorously tested in TAILOR RT.

"There are large [clinical trials](#) going on looking at radiation care for [breast cancer](#) patients, like TAILOR RT, and I encourage people to enroll. The more data we have, the more we'll know how to use this new precision medicine tool."

More information: Wendy A. Woodward et al, Association Between 21-Gene Assay Recurrence Score and Locoregional Recurrence Rates in Patients With Node-Positive Breast Cancer, *JAMA Oncology* (2020).
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Provided by SWOG

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