

Skipping adjuvant radiotherapy may not impact risk of recurrence or progression in patients with low-risk DCIS

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Patients with low-risk ductal carcinoma in situ (DCIS) who skipped adjuvant radiotherapy after breast-conserving surgery had comparable

five-year outcomes to those with high-risk DCIS who received adjuvant radiotherapy, according to results from the [E4112](#) clinical trial presented at the [San Antonio Breast Cancer Symposium](#), held December 5–9, 2023.

"Nearly all women with DCIS—a noninvasive form of [breast cancer](#)—will have their cancer successfully removed, but some women will have a high risk of the disease returning or progressing to invasive breast cancer," said Seema A. Khan, MD, a professor of surgery and the Bluhm Family Professor of Cancer Research at the Feinberg School of Medicine and Lurie Comprehensive Cancer Center of Northwestern University.

She explained that most patients with DCIS undergo breast-conserving surgery followed by adjuvant radiotherapy, which is intended to reduce the likelihood that the disease returns as DCIS or as invasive breast cancer. About a quarter of patients with DCIS undergo mastectomy instead.

"There is an increasing realization that DCIS carries an unnecessary treatment burden for many women," Khan noted. "Using personalized diagnostic tools to predict the risk of recurrence or progression may prevent excessive treatment for some patients."

Khan and colleagues conducted the E4112 clinical trial to assess the potential of bilateral magnetic resonance imaging (MRI) coupled with a DCIS gene profile to guide treatment for patients with DCIS. Previously reported results from this trial indicated that MRI could help to identify patients who could opt for the less intensive breast-conserving surgery instead of a mastectomy, Khan noted.

The latest analysis aimed to determine if some of those patients who underwent breast-conserving surgery based on MRI results could also

safely forego subsequent radiotherapy based on a DCIS gene expression profile. This approach could help reduce treatment in patients whose DCIS carries a low risk of recurrence, she explained.

The analysis included 171 patients with DCIS who underwent breast-conserving surgery and whose tumor tissue was profiled using the Oncotype DX Breast DCIS Score test.

The Oncotype DX Breast DCIS Score is a laboratory test that examines expression levels of cancer-related genes in DCIS tissue. The results of the test are reported as a score between zero and 100, with higher scores associated with higher expression of cancer-related genes and a greater likelihood of disease recurrence in the same breast, either as DCIS or as invasive cancer.

In this study, patients who received a score lower than 39 were considered to have low-risk DCIS and were eligible to skip adjuvant radiotherapy, while patients with scores 39 or higher were recommended to receive adjuvant radiotherapy.

The adherence to the score-based treatment recommendations was 93%: 75 of 82 patients with low-risk DCIS elected to skip adjuvant radiotherapy, and 84 of 89 patients with high-risk DCIS opted to undergo adjuvant radiotherapy.

After a median follow-up of five years after surgery, 5.1% of the 82 patients with low-risk DCIS and 4.5% of the 89 patients with high-risk DCIS experienced disease recurrence in the same breast as the primary DCIS.

Similar results were found when comparing only those patients who adhered to the score-based recommendations: 5.5% of the 75 patients with low-risk DCIS who skipped radiotherapy experienced disease

recurrence, as compared with 4.8% of the 84 patients with high-risk DCIS who received radiotherapy. The differences were not statistically significant nor influenced by patient age in either analysis.

"Our results indicate that the Oncotype DX Breast DCIS Score was an effective tool to stratify patients for adjuvant radiotherapy following breast-conserving [surgery](#). Women who skipped radiation based on this score did not experience an excess risk of recurrence in the same breast during the five-year follow-up period," said Khan.

"These findings reveal a new approach to guide treatment decisions by determining which patients may benefit from [radiotherapy](#) and which patients may safely forego it."

Combined with previously reported data from the trial, the results demonstrate the potential of MRI and the Oncotype DX Breast DCIS Score to guide surgical and [adjuvant](#) treatment, respectively, for patients with DCIS, she added.

Limitations of the study include the short follow-up time, the [small sample size](#), and the nonrandomized design.

Study E4112 was designed and conducted by the ECOG-ACRIN Cancer Research Group. Other participating cooperative groups included the Alliance for Clinical Trials in Oncology, NRG Oncology, and SWOG Cancer Research Network.

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