

COMET Trial Finds Active Monitoring Is a Viable Option for Low-Risk DCIS

Recurrence risk was similar for women who received active monitoring and those who underwent surgery for “Stage 0” breast cancer.

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Among patients with hormone receptor (HR)-positive, HER2-negative, low-risk ductal carcinoma in situ (DCIS), those who underwent active monitoring had similar two-year invasive ipsilateral breast cancer recurrence rates as those who underwent guideline-concordant treatment, according to results from the [COMET](#) clinical trial presented at the [San Antonio Breast Cancer Symposium \(SABCS\)](#), held December 10-13, 2024.

The results of this study were [simultaneously published in JAMA](#).

“Active monitoring” is a strategy in which patients are monitored closely, with surgery reserved for those patients who develop cancer.

A steady increase in mammography and other breast cancer screening methods has led to the identification of more cases of DCIS, a noninvasive form of breast cancer. However, DCIS poses little risk to the patient unless it progresses to invasive disease, explained [E. Shelley Hwang, MD, MPH](#), the Mary and Deryl Hart Distinguished Professor of Surgery, Vice-Chair of Research in the Department of Surgery, and a Professor of Radiology at the Duke University School of Medicine, who presented the study.

“All current treatments for DCIS aim to reduce the risk of future invasive cancer, despite a growing body of evidence that not all DCIS is destined to progress,” Hwang said. “Thus, current practice may result in the overtreatment of women whose tumors are at low risk of progression, leading to chronic pain, altered body image, reduced quality of life, and other side effects that may be avoidable.”

The COMET team sought to assess whether active monitoring is as effective as upfront treatment among patients whose DCIS has a low risk of progressing to invasive cancer. They conducted a multicenter, randomized clinical trial that enrolled 995 patients with grade 1 or 2, HR-positive, HER2-negative DCIS with no evidence of invasive cancer. They randomly assigned 484 patients to undergo active monitoring and 473 patients to receive guideline-concordant care consisting of surgery with or without adjuvant radiation. Patients in the active monitoring arm could elect to

have surgery at any time, and surgery was required if the tumor showed signs of invasive progression. Patients in both treatment arms were allowed the option to receive endocrine therapy.

After 24 months of follow-up, 27 patients in the guideline-concordant care arm and 19 in the active monitoring arm had been diagnosed with invasive ipsilateral (same breast) breast cancer. The two-year cumulative rate of invasive ipsilateral breast cancer was 5.9% in the guideline-concordant care arm and 4.2% in the active monitoring arm; the difference met the threshold for noninferiority, meaning that neither treatment was deemed inferior to the other.

Because 29% of patients overall did not adhere to their randomized treatment arm, the researchers performed a separate analysis of 673 patients who received their assigned treatment. The two-year rate of invasive ipsilateral breast cancer was 8.7% in the guideline-concordant care arm and 3.1% in the active monitoring arm.

Slightly more patients received endocrine therapy in the active monitoring arm compared to the guideline-concordant care arm—71.3% versus 65.5%, respectively. Among patients who received endocrine therapy, the rate of invasive ipsilateral cancer was 7.15% in the guideline-concordant care arm and 3.21% in the active monitoring arm.

Hwang noted that these results may help patients and their providers make informed decisions about DCIS treatment. “Omission of surgery has been highly controversial, with both patients and providers fearing that it might result in an unacceptably high rate of patients who develop invasive cancer,” Hwang said. “Our findings are reassuring, and longer-term follow up will have important implications for the future inclusion of active monitoring as a treatment option for low-risk DCIS.”

Limitations of this study include the inability to blind treatment arms to either the provider or the patient. Further, while the researchers prospectively balanced patient characteristics between the two treatment arms, differences in characteristics that were unaccounted for are possible.

Data on patient-reported outcomes from the COMET trial are available in [another press release](#).

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