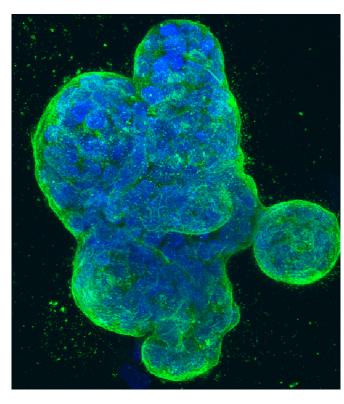


Some breast cancer patients with high responses to chemotherapy may not need surgery

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Three-dimensional culture of human breast cancer cells, with DNA stained blue and a protein in the cell surface membrane stained green. Credit: NCI Center for Cancer Research, National Cancer Institute, National Institutes of Health

Patients with early-stage breast cancer who had a pathologic complete response (pCR) to neoadjuvant chemotherapy may be able to skip surgery and receive standard radiation treatment with a low chance of disease recurrence, according to a new study from researchers at The University of Texas MD Anderson Cancer Center.

The Phase II trial <u>results</u>, <u>published today</u> in Lancet Oncology, evaluated the likelihood of breast cancer returning in patients who are in complete remission after receiving chemotherapy and radiation without surgery. Each of the 31 patients followed had a complete response to chemotherapy and none had a breast tumor recurrence after a median follow-up of 26.4 months.

"The ultimate form of breast-conserving therapy is completely eliminating breast surgery for invasive disease," said principal investigator Henry Kuerer, M.D., Ph.D., professor of Breast Surgical Oncology. "This research adds to growing evidence showing that newer drugs can completely eradicate cancer in some cases, and very early results show we can safely eliminate surgery in this select group of women with breast cancer."

This is the first modern prospective trial of surgery omission in patients with <u>early-stage breast cancer</u> who respond favorably to chemotherapy. High responses are indicated by state-of-the-art breast imaging-guided, vacuum-assisted core biopsy (VACB). These results build on Kuerer's previous research using an MD Anderson-developed biopsy protocol to accurately identify patients achieving a pCR after chemotherapy. Those patients, known as "exceptional responders," are at a lower risk of breast cancer recurrence and are candidates for avoiding breast surgery.

Improved chemotherapy agents have increased pCR rates significantly, and patients with triplenegative or HER2-positive breast cancer now are achieving a pCR in 60% to 80% of cases. Combining these high response rates with selective image-guided VACB and stringent histologic processing has improved physicians' ability to determine which patients may not need surgery.

The multicenter trial enrolled 50 women older than 40 with early stage triple-negative or HER2-positive



breast cancer and a residual breast lesion less than 2 centimeters as determined by imaging after standard chemotherapy treatment. Patients had one image-guided VACB. If no disease was identified on biopsy, breast surgery was omitted, and patients proceeded to standard whole-breast radiotherapy.

The mean age of participants was 60.4 years; 21 patients had triple-negative breast cancer and 29 had HER2-positive breast cancer. Thirty-eight participants were white, 10 were Black and 2 were other ethnicities/races. The VACB identified a pCR in 31 patients. No serious biopsy-related adverse events or treatment-related deaths occurred.

"For the time being, standard breast cancer surgery is still necessary," Kuerer said. "While these results are remarkable and quite promising, it's important for patients to know this is the very beginning of a new type of treatment for select patients. Much longer follow-up and further studies will be necessary before this approach can be integrated into routine breast cancer care."

The investigators will continue to follow trial participants for long-term outcomes. As a secondary aim of the study, the researchers also are measuring minimal residual disease from liquid biopsies to determine if they correlate with pCR.

Although this was a small, non-randomized study, it shows the feasibility of this approach. A larger randomized study is needed to directly compare the treatments before any changes to standard of care are considered.

More information: Henry M Kuerer et al, Eliminating breast surgery for invasive breast cancer in exceptional responders to neoadjuvant systemic therapy: a multicentre, single-arm, phase 2 trial, *The Lancet Oncology* (2022). DOI: 10.1016/S1470-2045(22)00613-1, www.thelancet.com/journals/lan... (22)00613-1/fulltext

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