

Pathologic complete response to neoadjuvant therapy in breast cancer patients predicts low risk for local metastases

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Select breast cancer patients who achieved pathologic complete response (pCR) after chemotherapy may be able to avoid follow-up breast and lymph node, or axillary, surgery, according to new findings from researchers at The University of Texas MD Anderson Cancer Center. The study, published today in *JAMA Surgery*, identifies the exceptional responders who are at lowest risk for local metastases and thereby are candidates for less invasive treatment options.

Worldwide, triple negative (TN) and HER-2 positive [breast](#) cancers account for about 370,000 women diagnosed annually, explains Henry Kuerer, M.D., Ph.D., professor of Breast Surgical Oncology and the study's principal investigator. In as many as 60 percent of these patients, neoadjuvant chemotherapy (NCT), given as the primary treatment, can result in pCR, or absence of residual disease, in both the breast and axillary lymph nodes.

"This high rate of pCR naturally raises the question of whether [breast surgery](#) is required for all patients, particularly those who will receive adjuvant radiation," said Kuerer. "An important secondary question in these exceptional responders is whether we can also omit axillary [surgery](#) to remove lymph nodes."

In order to determine those patients for whom surgery may be avoided, it is necessary to accurately identify those with a pCR following NCT.

However, standard breast imaging techniques were not capable of accurately predicting residual disease.

Recently Kuerer completed a clinical feasibility trial investigating the utility of image-guided biopsies to predict breast pCR. The preliminary results of that study, originally presented at the 2016 San Antonio Breast Cancer Symposium, revealed the technique to have 100 percent accuracy and 100 percent predictive value for determining residual disease following NCT.

"By doing the same image-guided, percutaneous needle biopsies after NCT that we do at time of diagnosis, our preliminary research revealed we can accurately predict which women will have a complete response," said Kuerer. "With that knowledge, there's an obligation to test whether no surgery, or 'ultimate breast conserving therapy,' is safe."

The current study sought to determine if patients achieving a pCR following NCT also may avoid axillary surgery for nodal metastases in addition to breast surgery. The prospective single-institution cohort study enrolled 527 women with T1-T2/N0-N1 stage triple negative (264) or HER-2 positive (263) [breast cancer](#) treated at MD Anderson between January 2010 and December 2014.

All participants received NCT followed by standard breast and nodal surgery. Clinical staging was determined prior to NCT by core biopsy or fine-needle aspiration, followed by clinical examination, mammography and ultrasound of the breast and axilla. Breast pCR was defined as no [residual disease](#) at the time of surgery. Axillary pCR was defined as no evidence of metastatic carcinoma.

Overall, 36.6 percent of patients achieved a breast pCR, with a slightly higher rate among TN (37.5 percent) than HER-2 positive (35.7 percent) patients. Of patients presenting with N1 disease, 77 (32.5 percent)

achieved a breast pCR compared to 116 of those with N0 stage disease (40 percent).

All 116 N0 stage patients with a breast pCR also achieved axillary pCR. Similarly, 89.6 percent of patients with N1 disease and a breast pCR were also free of nodal metastases. Overall, there were no significant differences between patients with TN and HER-2 positive breast cancers.

"In our study, patients achieving a breast pCR were more than seven times less likely to have residual nodal disease, with even more pronounced differences among patients presenting with N0 stage disease," said Audree Tadros, M.D., fellow in Breast Surgical Oncology and the study's lead author. "Based upon these findings, we anticipate women with initial node-negative disease may avoid breast and axillary surgery if they achieve a pCR after NCT and move on to standard radiotherapy."

To investigate the efficacy and safety of this approach, MD Anderson's Institutional Review Board has approved a Phase II clinical trial, which is now open at MD Anderson and will soon open within the MD Anderson Cancer Network. The study is enrolling women with Stage I and II HER2-positive and TN breast cancer. Study participants who achieve image-guided, biopsy-proved pCR after NCT will undergo whole-breast radiation, without surgery. In those with initial, ultrasound-proven node-negative disease, axillary surgery will also be avoided. The trial will be the first using image-guided biopsies in this setting and not include surgery.

"There is an urgency to test whether surgery is needed. In conversations with my patients, many express concerns about overtreatment. They want the most personalized care with as minimal treatment as possible," said Kuerer. "If some women are able to avoid unnecessary surgery, it

would be groundbreaking for [patients](#) - both physically and psychologically."

Provided by University of Texas M. D. Anderson Cancer Center

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