

Team publishes initial data from TAILORx breast cancer trial

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Mammograms showing a normal breast (left) and a breast with cancer (right).
Credit: Public Domain

Initial results were announced today from the Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, a multi-center prospectively conducted trial of more than 10,000 women with early stage breast cancer sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) with support from

Genomic Health, Inc. The study demonstrated that a group of trial participants with low 21-gene recurrence score (Oncotype DX Recurrence Score) results of 10 or less who received hormonal therapy alone without chemotherapy had less than a one percent chance of distant recurrence at five years.

This finding, published online today by the *New England Journal of Medicine*, provides evidence that other women in the future may effectively use hormonal therapy alone if the Recurrence Score is 10 or less. Second primary cancers exceeded recurrences of the original [breast cancer](#), resulting in 93.8 percent five year disease free survival, the primary trial endpoint.

These results, also presented at the 2015 European Cancer Congress (ECC2015, abstract #5BA) today, which involve the group of 1,626 patients with a Recurrence Score between 0 and 10, demonstrated that 99.3 percent of node-negative, estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative patients who met accepted guidelines for recommending [chemotherapy](#) in addition to hormonal therapy, had no distant recurrence at five years after treatment with hormonal therapy alone. Outcomes were excellent irrespective of patient age at diagnosis, tumor size, and tumor grade.

TAILORx was designed and conducted by ECOG-ACRIN in association with all of the cancer research groups of the NCI-sponsored National Clinical Trials Network that address cancer in adults; these include the Alliance for Clinical Trials in Oncology, NCIC-Clinical Trials Group, NRG Oncology, and SWOG. Together, these groups enrolled 10,273 patients across 1,182 sites in the United States and five additional countries (Australia, Canada, Ireland, New Zealand, and Peru).

"The compelling results seen in this global study provide unequivocal evidence supporting the clinical utility of Oncotype DX to risk-stratify

patients with early stage breast cancer, and indicate that the findings are generalizable to everyday clinical practice," said lead author Joseph A. Sparano, MD, vice-chairman of medical oncology at Montefiore Einstein Center for Cancer Care, and professor of medicine and of obstetrics, gynecology, women's health at Albert Einstein College of Medicine.

Dr. Sparano continued: "This is the first prospectively conducted clinical trial evaluating this assay—or any multigene expression assay for that matter—in which patients with early stage breast cancer were uniformly treated based on their assay results. The findings provide the highest level of evidence supporting expert-derived clinical practice guidelines which have recommended Oncotype DX in patients with early stage ER-positive breast cancer. The risk of developing a second primary cancer was about three-fold greater than having a recurrence of the original breast cancer, but we wouldn't expect chemotherapy to prevent these cancers from developing. Further follow-up of the trial is ongoing to determine whether chemotherapy may also be effectively spared in patients who have a mid-range Recurrence Score between 11 and 25."

The trial used the Oncotype DX test on every patient to quantify individual risk of recurrence in order to assign them to treatment. This trial continues to evaluate the effect of chemotherapy only for those with a mid-range Recurrence Score, as previous Oncotype DX studies have already confirmed the benefit of adjuvant chemotherapy for those in the high Recurrence Score range.

In the TAILORx trial, women with a Recurrence Score of 10 or less received hormonal therapy alone; women with a Recurrence Score greater than 25 received hormonal therapy plus chemotherapy; and those with a mid-range Recurrence Score from 11 to 25, the primary study group, were randomized to receive hormonal therapy with or without chemotherapy. The data safety monitoring board of the trial, as

mandated by the study protocol, continues to monitor outcomes in patients with a Recurrence Score of 11 to 25 randomized to chemo-endocrine therapy or endocrine therapy alone.

"To date, more than 170,000 breast cancer patients have changed their treatment decision based the Oncotype DX test. Many of these women who received high Oncotype DX scores were able to choose chemotherapy as a potentially life-saving treatment, while the majority were able to effectively pursue [hormonal therapy](#) alone and avoid the unnecessary side-effects of chemotherapy," said Steven Shak, MD, chief scientific officer, Genomic Health. "The rigorous TAILORx trial led by ECOG-ACRIN provides level 1A evidence supporting Oncotype DX as the only multigene expression assay that can identify the tens of thousands of patients each year who can effectively forego chemotherapy."

Oncotype DX is the only test that has been validated to predict the likelihood of chemotherapy benefit and the only test incorporated in all major international clinical guidelines including those of the American Society of Clinical Oncology, National Comprehensive Cancer Network, St. Gallen, and the European Society of Medical Oncology.

"These findings will give women with [early stage](#) breast cancer greater certainty that anti-estrogen therapy will decrease their risk of recurrence and increase their chance for survival whereas chemotherapy will not," said breast cancer survivor Mary Lou Smith, JD, MBA, who helped design the study as a leader in the ECOG-ACRIN Cancer Research Advocates Committee.

Provided by ECOG-ACRIN Cancer Research Group

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