

TAILORx Results Suggest About 70% of Women With Early-Stage, Hormone-Receptor-Positive, HER2-Negative Disease Can Skip Chemotherapy

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The Oncotype DX test is a genomic test that analyzes the activity of a group of 21 genes from a breast cancer tissue sample that can affect how a cancer is likely to behave and respond to treatment.

Doctors use the Oncotype DX test to help figure out a woman's risk of early-stage, estrogen-receptor-positive, HER2-negative breast cancer coming back (recurrence), as well as how likely she is to benefit from chemotherapy after breast cancer surgery.

The Oncotype DX test results assign a Recurrence Score -- a number between 0 and 100 -- to the early-stage breast cancer. You and your doctor can use the following ranges to interpret your results for early-stage invasive cancer:

- Recurrence Score lower than 18: The cancer has a low risk of recurrence. The benefit of chemotherapy is likely to be small and will not outweigh the risks of side effects.
- Recurrence Score of 18 up to and including 30: The cancer has an intermediate risk of recurrence. It's unclear whether the benefits of chemotherapy outweigh the risks of side effects.
- Recurrence Score greater than or equal to 31: The cancer has a high risk of recurrence, and the benefits of chemotherapy are likely to be greater than the risks of side effects.

Results from the TAILORx (Trial Assigning Individualized Options for Treatment) study published in 2015 showed that women with a Recurrence Score of 10 or lower could safely skip chemotherapy.

Still, the researchers, as well women and their doctors, wondered about women with an intermediate Recurrence Score of 11 to 25 -- could they also skip chemotherapy?

New results from the TAILORx study strongly suggest they can. The findings show that about 70% of women diagnosed with hormone-receptor-positive, HER2-negative breast cancer that has not spread to the lymph nodes do not need chemotherapy after surgery.

The results were presented on June 3, 2018 at the 2018 ASCO Annual Meeting and published at the same time in the *New England Journal of Medicine*:

- Read the abstract of "[TAILORx: Phase III trial of chemoendocrine therapy versus endocrine therapy alone in hormone receptor-positive, HER2-negative, node-negative breast cancer an intermediate prognosis 21-gene recurrence score.](#)" presented at the ASCO annual meeting.
- Read the abstract of "[Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer](#)".

"These data confirm that using a 21-gene expression test to assess the risk of cancer recurrence can spare women unnecessary treatment if the test indicates that chemotherapy is not likely to provide benefit," lead author Joseph A. Sparano, M.D., associate director for clinical research at the Albert Einstein Cancer Center, said in a statement.

Sparano estimated that the findings will apply to about 60,000 women per year in the United States.

"This is very good news for most women who want to avoid therapies that are unlikely to produce any benefit, especially chemotherapy," said Marisa Weiss, M.D., Breastcancer.org founder and chief medical officer. "But the study also helps identify those women who are most likely to benefit. Of course, anyone who is facing breast cancer wants the most effective therapy possible, even if it means accepting chemotherapy. At least this way they know that they are the ones who are most likely going to benefit."

The TAILORx study is a prospective study. A prospective study follows a group of similar people who are different in terms of the factors being studied to see how the factors affect the rates of a certain outcome.

The TAILORx study included 10,273 women diagnosed with hormone-receptor-positive, HER2-negative breast cancer that had not spread to the lymph nodes. The researchers performed Oncotype DX tests on tissues samples from all the cancers, and all the women were then assigned an Oncotype DX Recurrence Score:

- 6,711 of these women (69%) had a Recurrence Score between 11 and 25

These women were randomly assigned to receive either:

- chemotherapy plus hormonal therapy (3,312 women); 18.4% of these women didn't comply with treatment
- hormonal therapy alone (3,399 women); 5.4% of these women didn't comply with treatment

About half the women took hormonal therapy for fewer than 5.4 years and half took hormonal therapy for longer periods of time; 35% of the women took hormonal therapy for longer than 5 years.

The most common chemotherapy regimens were:

- Taxotere (chemical name: docetaxel)-Cytoxan (chemical name: cyclophosphamide); 56% had this regimen
- regimens with an anthracycline, such as Adriamycin (chemical name: doxorubicin), Doxil (chemical name: doxorubicin), and Ellence (chemical name: epirubicin); 36% had this regimen

The hormonal therapy medicines used depended on the women's menopausal status:

- 91% of postmenopausal women took an aromatase inhibitor
- 78% of premenopausal women took tamoxifen alone or tamoxifen followed by an aromatase inhibitor
- 13% of premenopausal women had ovarian suppression

Half the women were followed for longer than 8.5 years and half were followed for a shorter amount of time.

The researchers found that invasive disease-free survival rates -- how long the women lived without the invasive breast cancer recurring -- between the two groups were almost identical:

- 83.3% of women treated with hormonal therapy alone were alive with no invasive recurrence
- 84.3% of women treated with chemotherapy and hormonal therapy were alive with no invasive recurrence

Still, when the researchers did more detailed analysis, they found there were some women with intermediate scores who might benefit from the addition of chemotherapy after surgery:

- Women age 50 or younger with a Recurrence Score between 16 and 25 appear to have fewer distant recurrences (breast cancer coming back in a part of the body away from the breast) if they had chemotherapy and hormonal therapy after surgery.

Overall, results from the TAILORx study strongly suggest that three groups of women diagnosed with hormone-receptor-positive, HER2-negative, node-negative breast cancer can safely skip chemotherapy:

- women with a Recurrence Score between 0 and 10
- women older than 50 with a Recurrence Score between 11 and 25
- women 50 and younger with a Recurrence Score between 11 and 15

"With results of this groundbreaking study, we now can safely avoid chemotherapy in about 70% of patients who are diagnosed with the most common form of breast cancer," said Kathy Albain, Huizenga Family Endowed Chair in Oncology Research at Loyola University and one of the study's authors. "For countless women and their doctors, the days of uncertainty are over."

"It allows us to individualize treatment based on extraordinary science that now has tremendous prospective validation," said ASCO expert Harold Burstein, M.D., of the Dana-Farber Cancer Center. "The most challenging decisions we make with these patients is whether or not to recommend chemotherapy with all its side effects and its potential benefits. [Now the] vast majority of women who have this test performed on their tumor can be told they don't need chemotherapy, and that can be said with tremendous confidence and reassurance."

If you've been diagnosed with early-stage, hormone-receptor-positive, node-negative, HER2-negative breast cancer and are weighing the pros and cons of adding chemotherapy to your treatment plan, the Oncotype DX test may help you and your doctor make that decision. Besides any genomic test results, you and your doctor will consider other factors when developing your treatment plan, such as:

- your age
- the size of the cancer
- hormone receptor protein levels
- the grade of the cancer
- any other health conditions you have
- your family history of cancer
- your personal preferences

Together, you can make the best treatment decisions for YOU!

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