

Oncotype DX test can now spare chemotherapy use in early-stage breast cancer

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RxPONDER study results demonstrate that the great majority of postmenopausal women can be spared unnecessary chemotherapy and receive only hormone therapy



Exact Sciences Corp. on 9 Dec 2020 announced that data from the **Rx** for **Positive Node, Endocrine Responsive Breast Cancer**, or RxPONDER, trial successfully defined the benefit of chemotherapy in early-stage, node-positive breast cancer patients with Oncotype DX Breast Recurrence Score[®] results of 0 to 25. First results from the study, led by the independent SWOG Cancer Research Network, and sponsored by the National Cancer Institute (NCI), identified the majority of women with 1-3 positive nodes who received no benefit from chemotherapy. The data presented at the 2020 San Antonio Breast Cancer Symposium (SABCS).

RxPONDER showed a different effect of chemotherapy based on Recurrence Score[®] results for postmenopausal and premenopausal women. Postmenopausal women with Recurrence Score results 0-25 were not observed to show benefit from chemotherapy and may avoid the associated side effects of the treatment. Importantly, no chemotherapy benefit was observed regardless of the number of affected nodes, tumor grade, or size. Two-thirds of the women in the trial were postmenopausal.

The first results also demonstrated, after a median of five years of follow-up, that premenopausal women with Recurrence Score results 0-25 were observed to have a statistically significant chemotherapy benefit, with an average improvement in distant recurrence rates at 5 years of 3%.

Study lead author Kevin Kalinsky, MD, a long-time SWOG investigator and director of the Glenn Family Breast Center at the Winship Cancer Institute of Emory University, said “These results are practice changing and demonstrate that the great majority of postmenopausal women can be spared unnecessary chemotherapy and receive only hormone therapy. This should bring more clarity to physicians and some relief for patients.”

Of the total patients enrolled in the study, 231 were Korean. “The first results of this study will open the way for many Korean lymph node positive, HR+/HER2- breast cancer patients to make a more informed decision about whether to undergo

chemotherapy or not ", said Eun Sook Lee., local study coordinator, M.D.,Ph.D., Staff Surgeon, Center for Breast Cancer, National Cancer Center and Professor, NCC Graduate School of Cancer Science and Policy in Korea.

Approximately 25% of patients diagnosed with hormone receptor (HR)-positive, HER2-negative early breast cancer have tumor that has spread to their lymph nodes and two out of three are postmenopausal. The vast majority of these patients currently receive chemotherapy.

"With the RxPONDER and TAILORx trials, there is now definitive and undeniable clarity on who does and who does not benefit from chemotherapy among early-stage breast cancer patients, with either node-negative or node-positive disease," said Steven Shak, MD, chief medical officer at Exact Sciences.

One of the largest clinical trials in women with node-positive HR+, HER2- early breast cancer, RxPONDER is a prospective, randomized Phase III study conducted at 632 sites in nine countries – the United States, Canada, Mexico, Colombia, Ireland, France, Spain, South Korea, and Saudi Arabia. The study enrolled more than 5,000 women with up to three positive nodes.

The use of the Oncotype DX test in early-stage breast cancer is supported by prospective outcomes from more than 17,000 patients with node-positive disease and more than 83,000 patients with node-negative disease, including the TAILORx study. Results from TAILORx, published in 2018, showed that the Oncotype DX test identifies the vast majority of women with node-negative disease who receive no substantial benefit from chemotherapy (approximately 80%), as well as the important minority for whom chemotherapy can be life-saving.