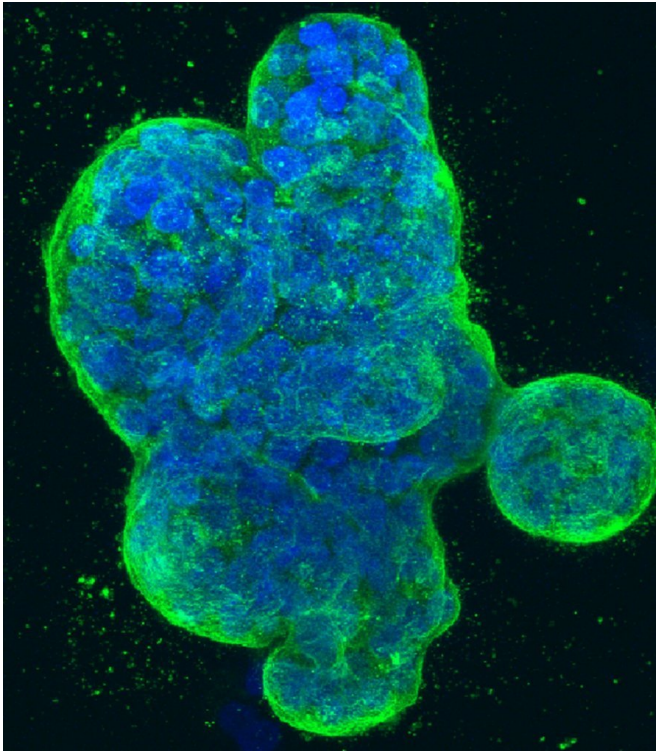


Trastuzumab achieves slight reduction in recurrence for women with HER2-positive DCIS

29 May 2020



Three-dimensional culture of human breast cancer cells, with DNA stained blue and a protein in the cell surface membrane stained green. Image created in 2014 by Tom Misteli, Ph.D., and Karen Meaburn, Ph.D. at the NIH IRP.

The addition of the monoclonal antibody therapy trastuzumab to radiotherapy did not reach the protocol objective of a 36% reduction in the ipsilateral breast tumor recurrence rate for women with HER2-positive ductal carcinoma in situ (DCIS) on the *NRG Oncology* clinical trial NSABP B-43. The trial did find a statistically non-significant, modest (19%) reduction in the rate of recurrence among women that received trastuzumab, but this difference was not statistically significant. These

results were recently exhibited during an oral presentation at the virtual Annual Meeting of the American Society for Clinical Oncology.

The Phase III NRG-NSABP B-43 trial accrued 2014 women and randomly assigned trial participants in a 1:1 fashion to receive either whole-breast [radiotherapy](#) alone or radiotherapy with two doses of [trastuzumab](#) following lumpectomy. The goal of the trial was to determine if the addition of trastuzumab can assist in preventing [recurrence](#) of ipsilateral breast cancer, ipsilateral skin cancer, ipsilateral DCIS, or ipsilateral breast tumor recurrence in women with DCIS. This hypothesis was developed in response to data from previous preclinical studies that suggested that trastuzumab can boost the effectiveness of radiotherapy.

Of the 2014 patients that were accrued to the trial, 1998 patients (99.2%) had follow up information available at the median follow up time point of 79.2 months. 2001 women had radiotherapy information; 98.2% of patients completed radiotherapy treatment on the radiotherapy alone treatment arm (RT) and 98.1% completed radiotherapy on the radiotherapy plus trastuzumab arm (RT+T). In the RT+T group, 94.3% patients completed both doses of trastuzumab therapy, while 2.5% had only one dose of the therapy. Another 3.2% did not start trastuzumab.

The NRG-NSABP B-43 protocol required that 163 in-breast tumor recurrence (IBTR) events be confirmed or that all patients be on study for at least five years to trigger a definitive analysis. Since less than 163 IBTR events were confirmed, analysis was performed because all patients were on the trial for five years or longer.

At this preliminary analysis based on information through December 31, 2019, 114 IBTR events were

confirmed with 63 being in the RT arm and 51 in the RT+T treatment arm. In those that had a recurrence, 38 were invasive including 18 in the RT arm and 20 in the RT+T treatment arm. The remaining 76 IBTR events were DCIS with 45 in the RT treatment arm and 31 in the RT+T treatment arm. Annual IBTR event rates were 0.99% per year in the RT group and 0.80% per year in the RT+T group. There were 48 deaths on the trial with 26 in the RT arm and 22 in the RT+T arm.

"This is the first prospective, randomized study of HER2-targeted treatment for HER2-positive DCIS. It provides important insight into the [natural history](#) and impact of HER2-targeted treatment on outcomes," stated Melody Cobleigh, MD, of Rush University Medical Center and the lead author of the NRG-NSABP B-43 abstract.

More information: Cobleigh, M et al. Primary results of NRG Oncology/NSABP B-43: Phase III trial comparing concurrent trastuzumab (T) and radiation therapy (RT) with RT alone for women with HER2-positive ductal carcinoma in situ (DCIS) after lumpectomy. Abstract presented at the virtual Annual Meeting of the American Society of Clinical Oncology (ASCO).

Provided by NRG Oncology

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