Adjuvant Chemo for Postmenopausal Women With Early Breast Cancer

By Mark L. Fuerst

Postmenopausal women with the most common form of early breast cancer may see no added benefit by receiving adjuvant chemotherapy; however, their premenopausal counterparts may show improved invasive disease-free survival (IDFS) from adjuvant chemotherapy.

Hormone receptor (HR)-positive, HER2-negative is the most common form of breast cancer, comprising about two-thirds of all invasive breast cancers. The SWOG S1007 (RxPONDER) clinical trial, designed and run by SWOG Cancer Research Network with support from the National Cancer Institute, set out to determine which patients with HR-positive, HER2-negative breast cancer, and 1-3 positive axillary lymph nodes benefit from adjuvant chemotherapy and which patients could safely avoid adjuvant chemotherapy and still achieve similar outcomes with endocrine therapy alone.

"Up until now, there were no data from a large randomized clinical trial to guide this decision," said Kevin Kalinsky, MD, MS, Director of the Glenn Family Breast Center at Winship Cancer Institute of Emory University, at the 2020 San Antonio Breast Cancer Symposium (Abstract GS3-00).

"At the time of this analysis, our data show that postmenopausal women with HR-positive, HER2-negative breast cancer with 1-3 positive nodes and a recurrence score of 25 or lower can safely avoid receiving adjuvant chemotherapy. On the other hand, premenopausal patients with HR-positive, HER2-negative breast cancer with 1-3 positive nodes and a recurrence score of 25 or lower should consider adjuvant chemotherapy. IDFS improved by 5 percent with chemotherapy in this group."

Study Details

The prospective, randomized clinical trial included 5,083 patients with stage 2-3 breast cancer involving 1-3 axillary lymph nodes and whose tissue had a recurrence score of 25 or lower. They were randomly assigned to endocrine therapy alone or endocrine therapy plus chemotherapy. About two-thirds of the patients were postmenopausal.

Data were stratified by recurrence score (0-13 vs. 14-25), menopausal status, and axillary nodal dissection versus sentinel node biopsy. The recurrence score, which can range from zero to 100, was determined using the Oncotype Dx test, a genomic test that measures the expression of cancer-related genes in a patient's tumor. The test provides a genome-based individualized risk assessment by evaluating 16 cancer-related genes for early-stage invasive breast cancer.

The study was designed to assess whether the difference in IDFS for patients treated with chemotherapy, compared with no chemotherapy, was related to the recurrence score. The investigators found no association between chemotherapy benefit and recurrence score values between 0 and 25 when evaluating the entire study population. However, there was a significant association between chemotherapy benefit and menopausal status, triggering further analyses of the data by menopausal status.

In postmenopausal patients with recurrence scores of 25 or lower, there was no difference in the 5-year IDFS between those who received chemotherapy (91.6%) and those who did not (91.9%). In premenopausal patients with recurrence scores of 25 or lower, 5-year IDFS was 94.2 percent for those who received chemotherapy versus 89 percent for those who did not. Data also showed a 53 percent overall survival benefit in premenopausal patients, although this result is considered early due to the limited number of events at the time of evaluation, Kalinsky said.

The results were similar in premenopausal women with recurrence scores 0-13 and those with recurrence scores 14-25. "For premenopausal patients with node-positive breast cancer, we know from other studies that the most effective adjuvant endocrine therapy is ovarian suppression combined with an aromatase inhibitor. We also know that chemotherapy induces ovarian suppression that is often permanent in premenopausal women," he explained.

Among the premenopausal women in this study, ovarian suppression was performed in 15.9 percent of those in the endocrine therapy alone arm versus 3.7 percent of those in the chemotherapy plus endocrine therapy arm. "To what extent the chemotherapy benefit observed in our trial is due to chemotherapy-induced menopause remains unknown," said Kalinsky.

Future studies will allow for additional subset data analyses and time for continued follow-up, he said, adding that future analyses will include quality of life among other outcomes.

In conclusion, Kalinsky said: "At the interim analysis at 54 percent of anticipated IDFS events in the overall population, postmenopausal women with recurrence score of 0-25 did not benefit from adjuvant chemotherapy in any subgroup. A 5-year IDFS improvement was seen with the addition of chemotherapy to endocrine therapy in all premenopausal subgroups. An overall survival improvement was seen at 5 years with chemotherapy in premenopausal women."

The take-home message, said Kalinsky, is "postmenopausal women with 1-3 positive nodes and recurrence score 0-25 can likely safely forego adjuvant chemotherapy without compromising IDFS. This will save tens of thousands of women the time, expense, and potentially harmful side effects that can be associated with chemotherapy."

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Black & Hispanic Patients Used Telehealth Less During Pandemic

BY MARK L. FUERST

During the peak of the COVID-19 pandemic in early spring of 2020, fewer Black and Hispanic cancer patients in New York City used telehealth as compared with White patients, according to an analysis of data from one of the city’s large hospital systems.

New York City was one of the early epicenters of the COVID-19 pandemic. Public concern about exposure and policies to “flatten the curve” led to abrupt curtailment of health care service use, including cancer. While innovative strategies to mitigate the disruption, including telemedicine, were put in place, the use of phone encounters and video visits was less accessible to minority populations.

“In a world where telehealth is needed because patients don’t have in-person access to routine and follow-up cancer care—such as during the COVID-19 pandemic—it is important to recognize the gaps that exist among racial and ethnic minorities,” said lead study author Cardinale B. Smith, MD, PhD, Associate Professor of Medicine and the Chief Quality Officer for Cancer Services at Mount Sinai Health System. “We know that many patients have not been seeking medical attention or continuing routine care because of fear about the virus.”

Smith presented the results of the study at the 2020 ASCO Quality Care Symposium.

The Mount Sinai researchers evaluated data on race/ethnicity and visit type collected from electronic medical records of patients with cancer from the Mount Sinai Health System, which includes a National Cancer Institute-designated cancer center and eight ambulatory sites across New York City. They collected data from electronic medical records on all cancer patients with an in-person or telehealth visit during the peak of the pandemic between March 1 and June 1, 2020.

Key Findings
A total of 7,681 patients, mean age 65 years, had a telehealth visit during the study period. Three-quarters of the telehealth visits were video visits. Of these patients, 48 percent were White, 19 percent Black, 6 percent Hispanic, and 7 percent Asian. In comparison, of all patients seen at the health system in 2019, 42 percent were White, 23 percent Black, 14 percent Hispanic, and 7 percent Asian. In 2019, less than 1 percent of all patients used telehealth.

This study is limited to a single center in an urban environment and did not compare results to in-person visit frequency and did not capture the type of video platform used, she said. Additional research is needed to determine whether these results are generalizable beyond the population studied.

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—Cardinale B. Smith, MD, PhD, Chief Quality Officer for Cancer Services at Mount Sinai Health System

In conclusion, Smith said: “Telehealth utilization increased exponentially, but significantly decreased video visit utilization was seen among minorities. Awareness of these disparities is important.”

Next Steps
The researchers are currently exploring ways to improve patient access to telehealth. They have obtained a grant that will allow them to provide in-home remote monitoring of patients. Individuals enrolled in the study will be provided with a Wi-Fi booster or enabler, depending on their home situation, and a tablet so they can have video visits with their clinician and participate in patient-reported outcome measures.

Significant disparities in the use of telehealth not only limit access to quality cancer care for these patients during the pandemic, but will continue to hinder patient care as telehealth use becomes more integrated into standard cancer care.

ASCO Expert Sonali M. Smith, MD, Professor of Medicine at the University of Chicago Medicine, commented: “Telehealth is an important part of cancer care, especially in the era of COVID-19. It is important for health care providers, patients, and caregivers to think about how we can help increase use of these kinds of services to ensure all patients can access high-quality cancer care.”

Mark L. Fuerst is a contributing writer.

C. Kent Osborne, MD, Professor, Department of Medicine and Hematology Oncology at Baylor College of Medicine, commented: “This interim analysis of an important randomized trial clearly shows no benefit in adding chemotherapy to endocrine therapy in postmenopausal women with positive nodes. Nodal disease is an important prognostic marker biologically, but is not a marker of chemotherapy sensitivity. I’m still skeptical that chemotherapy works differently in premenopausal and postmenopausal women. It could be an ovarian suppression effect.”

Mark L. Fuerst is a contributing writer.