Treatment Decision Guided by Circulating Tumor Cell Count May Improve Long-Term Outcomes for Patients with Metastatic Breast Cancer

Patients whose treatment was guided by measurement of tumor cells in the blood had improved survival outcomes.

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The use of circulating tumor cell (CTC) count to guide the choice between chemotherapy and endocrine [hormone] therapy as first-line therapy for patients with metastatic, estrogen receptor (ER)-positive/HER2-negative breast cancer provided overall survival benefit, compared with physician's choice of treatment, according to data from the STIC CTC trial presented at the San Antonio Breast Cancer Symposium, held December 6-10, 2022.

"The validity of CTC count has been studied extensively in metastatic breast cancer in the past two decades, and we and others have previously demonstrated its clinical validity as a biomarker of prognosis," said study presenter François-Clément Bidard, MD, PhD, a professor of medical oncology at Institut Curie and Versailles Saint-Quentin University, Paris, France. "We hypothesized that the CTC count could drive and help standardize the difficult treatment decision between endocrine therapy, which appears more suited for patients with good prognosis, and chemotherapy, which may benefit patients with worse prognosis."

As Bidard explained, in the absence of any recent trial comparing the two treatment strategies, the consensus among experts is to exhaust all endocrine therapy options before switching to chemotherapy to treat patients with metastatic breast cancer. Such recommendation is based on the limited side effects of endocrine therapy compared to chemotherapy. However, treatment decisions are highly heterogenous among physicians and centers.

To test the ability of the CTC count to improve patient outcomes when used to drive the treatment decision between chemotherapy and endocrine therapy in women with metastatic, ER-positive/HER2-negative breast cancer, Bidard and colleagues designed the STIC CTC trial, in which 755 patients were randomly assigned (1:1) to having their treatment decided by the investigator or by their CTC count.

“We anticipated that most patients would have their treatment unchanged, while some would have their treatment escalated from endocrine therapy recommended by investigators to chemotherapy based on high CTC count, or vice versa, de-escalated from chemotherapy to endocrine therapy if their CTC count was low,” said Bidard.

The primary results of this trial, reported at SABCS in 2018, showed a progression-free survival benefit in patients whose treatment was escalated from endocrine therapy to chemotherapy based on their CTC count.

After a follow-up of nearly five years, the authors now report the overall survival analysis of the trial, showing that, in patients with discordant recommendations between the investigator’s choice of therapy and the CTC count, the strategy based on CTC count resulted in better long-term outcomes.

Among a subgroup of patients representing 25% of the study population, for whom endocrine therapy was the recommended treatment by investigator’s choice but who displayed high CTC count, those who were treated with chemotherapy had an absolute gain of 16 months in median overall survival and experienced a 47% reduction in their risk of death compared to patients in the same group who received endocrine therapy.

Among the subgroup of patients who were assigned to chemotherapy by investigator’s choice but had low CTC count, corresponding to 14% of the study population, those who received endocrine therapy had a comparable overall survival to those who received chemotherapy.

“The STIC CTC trial is the first to establish the clinical utility of the CTC count as a biomarker in breast cancer care, indicating that a single assessment of the CTC count before the start of treatment can guide the treatment decision between chemotherapy and single agent endocrine therapy in ER-positive/HER2-negative metastatic breast cancer,” said Bidard. “Our study demonstrates that integrating prognostic biomarkers into the treatment algorithm can improve the management and outcomes of metastatic breast cancer patients.

“Interestingly, the subgroup of patients with concordant favorable estimates by clinician assessment and CTC count, representing 48% of the study population, had a median overall survival of about five years, even though these patients did not receive cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors as part of their first-line treatment,” added Bidard.

The limitations of this study include that it was conducted before the introduction of CDK4/6 inhibitors, which are now widely used for the first-line treatment of metastatic ER-positive/HER2-negative breast cancer.

“When the trial was designed, the question related to the choice between single-agent endocrine therapy and chemotherapy pertained to first-line therapy,” said Bidard. “Endocrine therapy with CDK4/6 inhibitors is the preferred option for treatment-naïve patients, but the dilemma between endocrine therapy and chemotherapy remains after disease progression on adjuvant or first-line therapy with CDK4/6 inhibitors, where current guidelines advocate in favor of endocrine therapy

despite its short-lived efficacy.

“In that scenario, based on the STIC CTC trial results, the CTC count, in combination with predictive biomarkers, whenever available, may help customize the early use of chemotherapy or antibody-drug conjugates, which are becoming more and more attractive,” continued Bidard.

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