Serum HER2/neu Change Predicts Clinical Outcome to Trastuzumab-Based Therapy

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Model for Personalized Medicine
The findings allowed the 307 metastatic breast cancer patients who had the serum HER2/neu test before and after trastuzumab-based treatment to be divided into those with a greater than 20% decrease in serum HER2/neu levels and those with a less than 20% decrease. The patients whose serum HER2/neu levels decreased by less than 20% had a lower response rate, shorter duration of response, shorter time to progression, and decreased overall survival rate. "In this analysis, measuring serum HER2/neu levels provided an early predictor of the outcome of trastuzumab-based therapy in metastatic breast cancer patients," said Allan Lipton, MD, professor of medicine and oncology, Penn State College of Medicine, Penn State Milton S. Hershey Medical Center, and a coauthor of the pooled analysis. "For instance, patients with less than a 20% decrease in serum HER2/neu have a decreased disease-free and overall survival with trastuzumab-based therapies. Patients with less than 20% should be considered for investigative agents in addition to trastuzumab. The serum HER2/neu test represents a model for the future of personalized medicine in which a serum biomarker is used to direct therapy at an individual level."

Unique Test
The standard method for determining HER2/neu status is by testing tissue from the primary tumor, usually involving an invasive procedure. A simple blood test to determine serum HER2/neu levels during the course of therapy is complementary to tissue testing because continuous monitoring of serum concentrations of HER2/neu allows physicians to follow disease progression and therapy response, thereby guiding ongoing treatment decisions. The serum HER2/neu test is the only test that can track a woman's HER2/neu level once she is diagnosed with metastatic breast cancer regardless of whether the treatment is hormone therapy, chemotherapy, or trastuzumab-based therapy because it is a serum biomarker for HER2/neu-positive tumors. "We are moving toward a new paradigm in the monitoring and management of breast cancer patients," said Dr. Ali. "There are patients on trastuzumab who are achieving great results from the therapy and some who are not receiving the maximum benefit. It is important for doctors to know about the latter group as early as possible so they can optimize treatment regimens."

Pooled Analysis
The study included a pooled analysis of seven trials of first-line trastuzumab therapy (with or without chemotherapy) in metastatic breast cancer patients. Pretreatment and posttreatment (16 to 120 days) serum tests were conducted on 307 patients. Patients whose serum HER2/neu levels decreased by less than 20% had a lower response rate (28.4% vs 56.5%, \( P < .001 \)), shorter duration of response (230 vs 369 days, \( P = .008 \)), shorter time to progression (182 vs 320 days, \( P < .001 \)), and decreased overall survival rate (593 days or 1.6 years vs 898 days or 2.5 years, \( P = .018 \)).
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