Many Breast Cancer Patients May Not Be Receiving Recommended Test

October 14 2009, By Robin Hindery

A new report finds widespread variations and frequent errors in HER2 testing -- a procedure recommended for all patients with invasive breast cancer.

For more than a decade, doctors have had access to a simple genetic test that can help determine the best course of treatment for patients with breast cancer.

However, a new UCSF-led report reveals that as many as two-thirds of women with invasive breast cancer had no documentation of having received this test. In addition, one in five tests performed in local labs proved inaccurate when the same tissue was retested in larger labs.

The report, published in September in the journal Cancer, stemmed from the increasing use of patient-specific, targeted therapies for cancer treatment and prevention, said lead author Kathryn Phillips, PhD, the founder, director and principal investigator of UCSF's Center for Translational and Policy Research on Personalized Medicine (TRANSPERS).

"Once these therapies, and the tests associated with them, receive FDA approval or begin to be adopted, it is important to understand whether they are used effectively and efficiently in routine clinical practice," said Phillips, a UCSF professor of clinical pharmacy.

Phillips and her fellow researchers chose to focus specifically on HER2,

a protein that is widely recognized as an important predictive factor in breast cancer.

In about one of every three breast cancers, a gene mutation causes the cancer cells to produce an excess of HER2, creating a form of the disease that is more aggressive and less responsive to hormone treatment.

For those patients, treatment with the drug trastuzumab — marketed as Herceptin — has proven to be highly effective.

The American Society of Clinical Oncology recommends that all patients with invasive breast cancer undergo HER2 testing, and the FDA has approved three types of tests to determine HER2 status.

In addition to benefitting women with HER2-positive cancer, testing also prevents women with normal HER2 expression from taking a drug that could actually cause them more harm than good, Phillips and her colleagues noted in their report. Overuse of Herceptin can expose a patient to "an unnecessary risk of heart failure" and can cost the health care system $100,000 per year, the report said.

Widespread Variations Reported

Despite the clear advantages of testing, there appear to be widespread variations in testing practices and key gaps in knowledge, the report concluded.

One study the researchers examined found that only 32 percent of patients newly diagnosed with invasive breast cancer had documentation indicating that they had undergone a HER2 test.

Another study found that up to 20 percent of women already receiving Herceptin had no record of having been tested for HER2 abnormalities.

“It appears that some clinicians and payers assume that all eligible patients are being tested, tests are accurate, and only patients with positive test results are receiving trastuzumab,” the report’s authors wrote. “Our review suggests that gaps in the literature are substantial, and that these important assumptions cannot yet be verified.”

The report also made note of a troubling finding when HER2 test results from local labs were compared to results from large, higher-volume labs using the same tissue sample. Up to 20 percent of the smaller labs’ test results were disproven by the larger labs.

Those disparities may be due to differences in how labs perform and interpret tests and lack of consensus about accepted procedures, the report said.

“Considering the serious implications of inaccurate tests for patients’ lives and the impact on the health care system, it is essential to have more data on test quality and interpretation,” the authors concluded.

In order to limit mistakes and increase knowledge and efficiency when it comes to HER2 testing—or any other emerging clinical testing technology—Phillips and her colleagues recommend building a solid evidence base to support effective decision making.

This can be accomplished in a number of ways, including by standardizing testing procedures; encouraging clinicians to carefully document the tests their patients receive, as well as the results; and promoting the widespread use of electronic medical records, Phillips said.

Phillips’s report, funded by grants from the National Cancer Institute (NCI) and the Blue Shield Foundation of California, is one of the early studies to emerge from the TRANSPERS Center, which UCSF and the

Department of Clinical Pharmacy launched in 2008 to explore questions of access, utilization, cost-effectiveness, and preferences when it comes to personalized medicine. Through its work, the center aims to bring together stakeholders from academia, industry and government, and to speed the translation of new personalized medicine technologies into clinical practice and policy — a key objective of UCSF's campuswide strategic plan. Phillips and her colleagues are currently expanding their study to include thousands of patients in two national health plans. They are also shifting their focus to a newer targeted therapy for breast and colon cancers: diagnostic tests that analyze patterns of gene behavior in order to determine the likelihood of disease recurrence.

More information: Journal paper: www3.interscience.wiley.com/jo … ct?CRETRY=1&SRETRY=0

Source: UCSF