FDA Approves Test for HER2 Gene in Breast Ca

BY ELIZABETH MECHCATIE

A test that measures the number of copies of the HER2 gene in breast tumor tissue has been approved by the Food and Drug Administration.

If the Inform Dual ISH test is positive, then the patient is a candidate for treatment with trastuzumab, the recombinant monoclonal antibody directed against HER2 that is marketed as Herceptin by Genentech for the treatment of HER2 overexpressing breast cancer. The test is manufactured by Tucson, Ariz.–based Ventana Medical Systems, a member of the Roche group, as is Genentech.

"When used with other clinical information and laboratory tests, this test can provide health care professionals with additional insight on treatment decisions for patients with breast cancer," Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostic Device Evaluation and Safety in the FDA's Center for Devices and Radiological Health, said in the statement announcing the approval. The test makes it possible "to see and count copies of chromosome 17 and HER2 genes on the same slide, similar to HER2 amplification measurements that have traditionally only been available using fluorescence microscopes," the statement said.

But the new test, "allows lab staff to see the HER2 and chromosome 17 signals directly under a microscope, for longer periods of time."

Approval is based on a study conducted in the United States that evaluated the test in 510 women with breast cancer. The test confirmed that the tumor sample contained more than the normal number of copies of the HER2 gene, located on chromosome 17, in 96% of the HER2 positive samples, according to the statement.

About 20% of women diagnosed with breast cancer are HER2-positive, according to the FDA. ■

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transfusion if they had a greater estimated blood loss during the surgery. Age, body mass index, and prior history of surgeries did not influence this outcome, he said at the meeting.

Further analyses showed that the odds of transfusion were also higher for women whose indication for surgery was fibroids and/or menorrhagia versus prolapse, and for women having an abdominal hysterectomy versus women who had a transvaginal or laparoscopic procedure.

In the case of menorrhagia, women usually have a known history of anemia, according to Dr. Mangel. But the anemia can be much more severe preoperatively than anticipated, possibly related to a longer time between deciding to have the surgery and actually having it.

There are no formal guidelines when it comes specifically to managing anemia in patients undergoing hysterectomy, he said, but a general surgical principle is that the healthier a patient is going into surgery, the better the likelihood of a good outcome.

"I'm not advocating to have a hard and fast guideline published because I do think you need to leave room for patient counseling, discussion of what matters to the patient, and for there to be some physician judgment involved regarding the risks of postponing this person's surgery versus not," he said. For instance, a patient who is unlikely to return for a rescheduled hysterectomy in 2 to 3 months may get into an emergent situation where, ironically, she needs a transfusion.

"But if given the opportunity, surgeons should consider intervening," he recommended. "I think we are all a little bit guilty of this, that we have become a little bit lax with our concern about transfusing patients in general. … To the extent we don't have to give people blood, we are better off not giving them blood. And while this may pose inconvenience to patients and surgeons, if they are willing to consider doing this type of an intervention, blood transfusion rates will go down for hysterectomy. So sometimes, the right thing to do is not always the most convenient thing to do." ■