

- Medscape 
- eMedicine
- MedscapeCME
- Medscape Connect
- Find a Physician...

Medscape MedscapeCME eMedicine Drugs MEDLINE All

SEARCH

O Eichhorn
Account Settings | Log Out | Newsletters

LATEST | NEWS | CONFERENCES | JOURNALS | RESOURCE CENTERS | VIEWPOINTS

From Medscape Medical News

HER2 Testing May be Underutilized in Breast Cancer

Roxanne Nelson

Authors and Disclosures

 Print This  Email this



RELATED ARTICLES

News

Gene Variants Affecting Response to Clopidogrel Not a Factor With Prasugrel

CDC Releases Recommendations for Molecular Testing

Gemcitabine/docetaxel After Anthracycline Advised for Advanced Breast Cancer

Articles

The Genetic Information Nondiscrimination Act (GINA): What it Means for Your Patients and Families

Disclosure of APOE Genotype for Risk for Alzheimer's Disease

Association Between Cyclooxygenase-2 Expression in Atypical Hyperplasia and Risk of Breast Cancer

September 16, 2009 — Cancer therapies are increasingly being tailored to fit the genetic profile of the patient, but new research suggests that human epidermal growth-factor receptor (HER)2 gene testing may be underused. A literature review found only scant information about the actual use of HER2 testing in clinical practice, suggesting that there are "important variations in testing practices and key gaps in knowledge about those practices."

The review was published online September 14 in *Cancer*.

It concludes that a large percentage of breast cancer patients who might benefit from trastuzumab (*Herceptin*) treatment appear not to be receiving it. Up to 66% of women eligible for HER2 testing had no documentation of a test in their health-insurance records, and up to 20% of patients receiving trastuzumab were not tested or had no documentation of a positive test.

The researchers also note that 20% of HER2 test results might be incorrect.

There are important knowledge gaps regarding the real-world use of HER2 testing and trastuzumab.

"Our review of the literature suggests that there are important knowledge gaps regarding the real-world use of HER2 testing and trastuzumab," study author Elena Elkin, PhD, a researcher at Memorial Sloan-Kettering Cancer Center in New York City, said in a statement.

"Filling these gaps may help optimize limited healthcare resources and improve care for women with breast cancer," she added.

Genomic testing continues to evolve and can add significant prognostic and predictive information to standard parameters for breast cancer patients, as [previously reported](#) by *Medscape Oncology*.

HER2 testing was developed to identify patients with breast cancers that overexpress HER2, which occurs in 20% to 30% of cases. Trastuzumab, a humanized monoclonal antibody, binds strongly and selectively to the extracellular portion of HER2, and is highly effective in women with breast cancers that overexpress the HER2 gene, the authors explain.

Testing for HER2 is now recommended for all patients with invasive breast cancer, and the US Food and Drug Administration has approved 3 types of tests for this purpose: immunohistochemistry (IHC), fluorescence in situ hybridization (FISH), and, most recently, chromogen in situ hybridization (CISH).

But despite the proven efficacy of trastuzumab in patients with HER2-positive breast cancer, the authors point out that there is still uncertainty regarding the best approach to selecting patients for treatment. There is also uncertainty about the most appropriate and efficient testing strategy and the reliability and interpretation of test results.

The goal of this study was to evaluate what is currently known about the use and cost-effectiveness of HER2 testing in clinical practice in the United States, the authors explain.

The researchers, led by Kathryn A. Phillips, PhD, professor of health economics and health services research at the University of California-San Francisco, conducted a literature review and examined available evidence about the percentage of eligible patients tested for HER2, the test methods used, concordance of test results between community and central/reference laboratories, the use of trastuzumab by HER2 test result, and the cost-effectiveness of testing strategies.

Limited Information Available About HER2 Testing

Overall, they found that there was very little information about the use of HER2 testing in routine clinical practice. "The limited evidence available suggests that there are important variations in testing practices and key gaps in knowledge about those practices," the authors write.

The studies also tended to include selected populations, used outdated information, and were frequently not published in peer-reviewed journals.

Of the studies that assessed the percentage of patients tested for HER2, 1 reported that 52% of metastatic breast cancer patients at a single facility received testing in 1999/2000. Another study reported testing in 32% of Medicare

enrollees with newly diagnosed breast cancer in 2005; among these women, 93% received only IHC, 0.3% received only FISH, and 6% received both tests.

Possible Inappropriate Use of Trastuzumab

The authors also identified 1 study that demonstrated the potentially inappropriate use of trastuzumab. About 12% to 20% of the women enrolled in a large health plan who received trastuzumab had not been tested or did not have conclusive evidence of a positive test. In that example, an estimated 8% of the patients who received trastuzumab underexpressed HER2, 4% had not been tested at all, and the details were unknown for 8% because the physician did not provide the record.

The researchers were unable to find any studies that examined laboratory concordance in routine practice. However, several studies did assess concordance in conjunction with enrollment in clinical trials, and an American Society of Clinical Oncology/College of American Pathologists guideline review of these studies found that approximately 20% of IHC tests performed by community laboratories are incorrect, based on comparison with central or reference laboratory results.

Of 621 studies that were reviewed, 4 contained information about the cost-effectiveness of HER2 testing or trastuzumab treatment in the United States. However, only 1 paper examined HER2 testing strategies in an American population by analyzing 7 possible test-treat strategies, and there were no studies that analyzed testing strategies in the adjuvant setting.

There were also no studies that assessed the way testing use has changed since 2005, when indications for HER2 testing were expanded.

"Our findings regarding HER2 testing illustrate both the challenges and the opportunities in building an evidence base to support effective and efficient decision making about emerging testing technologies in cancer care," they conclude. "HER2 testing provides an example of a test that is clinically beneficial but that faces quality and implementation challenges, and such challenges will increasingly become relevant as more new testing technologies and targeted therapies emerge."

This study was funded by 2 grants to Dr. Phillips from the National Cancer Institute and a grant from the Blue Shield Foundation of California (unrestricted). Dr. Phillips and coauthor Jennifer S. Haas, MD, MSPH, from Brigham and Women's Hospital in Boston, Massachusetts, report having received an unrestricted grant from the Aetna Foundation to examine the use of HER2 testing and gene-expression profiling for breast cancer. Dr. Haas also reports receiving a research grant from Pfizer for unrelated work.

Cancer. Published online before print September 14, 2009.

 [Print This](#)  [Email this](#)

MORE ON THIS TOPIC

eMedicine Clinical Reference

- [Breast Cancer, Mammography \(Radiology\)](#)
- [Breast Cancer Evaluation \(Obstetrics and Gynecology\)](#)
- [Breast Cancer, Male \(Radiology\)](#)

Medscape Resource Centers

- [Biologic Therapies in Cancer](#)
- [Breast Cancer Resource Center](#)

Medscape Medical News © 2009 Medscape, LLC
Send press releases and comments to news@medscape.net.

[Medscape](#) [MedscapeCME](#) [eMedicine](#) [Drugs](#) [MEDLINE](#) [All](#)

[SEARCH](#)

[About Medscape](#) | [Privacy Policy](#) | [Terms of Use](#) | [WebMD Health](#) | [WebMD Corporate](#) | [Help](#) | [Contact Us](#)

All material on this website is protected by copyright. Copyright © 1994-2009 by Medscape. This website also contains material copyrighted by 3rd parties.