

UTILIZATION OF PERSONALIZED TESTS & TREATMENTS FOR BREAST CANCER J.S. Haas; K.A. Phillips; S. Liang; M.J. Hassett; C.A. Keohane; J. Armstrong; M. Toscano. Brigham and Women's Hospital, Boston, MA; University of California, San Francisco, San Francisco, CA; Dana Farber Cancer Institute, Boston, MA; Aetna, Hartford, CT. **3Z415CD2R**

OBJECTIVE: To determine the use of genomic tests and treatments for breast cancer in clinical practice outside of a trial setting, including the use of HER2 testing, trastuzumab, and gene expression profiling (GEP).

METHODS: Cross-sectional medical record review of women aged 36 – 64 years, with a new diagnosis of invasive breast cancer in 2006 – 2007, who were identified using claims data from a large, US health plan (n = 392 to date). Because of debate about the availability and performance of the two types of HER2 tests, immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH), we specifically examined the type of HER2 test received.

RESULTS: Almost all women had documentation of a HER2 test (97.7%): 56.2% had IHC alone, 17.4% had FISH alone, and 24.0% had both (the remaining 2.4% had documentation of a test but the type of test was not documented). Of women with a negative or intermediate IHC result, 17.4% and 59.1% respectively had a positive FISH. Using the maximum of all available HER2 test results, 24.9% had a positive HER2 result, 11.1% had an intermediate result, and 63.9% were HER2-negative. Only 55.2% of women who were HER2-positive received trastuzumab, compared to 16.7% of women with an intermediate score, and no women with a negative HER2 result. The majority of women (85.7%) did not have a GEP test. Among women with GEP, 58.9% of tests indicated a low risk of recurrence, 21.4% medium risk, and 5.4% a high risk. Adjuvant chemotherapy was received by 27.3%, 91.7%, and 100% of women with a low, medium and high risk of recurrence respectively ($p < 0.001$).

CONCLUSION: HER2 tests, primarily IHC, are widely used in clinical practice in the US. There are discrepancies in classification of HER2 status based on IHC vs. FISH that are clinically important. We did not find evidence of overuse of trastuzumab by women who were HER2-negative. Further work should clarify whether the lack of trastuzumab for HER2-positive women is clinically appropriate. We found modest adoption of GEP, and GEP score was associated with the use of adjuvant chemotherapy, as women with a low score were significantly less likely to receive this treatment.

Similarly, almost nothing is known about utilization of gene expression profiling (GEP - e.g., OncotypeDx®) for breast cancer, which offers the possibility of better recurrence estimation to tailor the use of adjuvant chemotherapy.