Patterns of 21-Gene Assay Testing and Chemotherapy Use in Black and White Breast Cancer Patients

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Abstract

Studies suggest that not all women with early-stage, hormone receptor (HR)-positive disease receive recurrence score (RS) testing. In this study we examined the influence of sociodemographic, clinical, and attitudinal factors associated with receipt of RS testing and the effect of RS testing on chemotherapy use in black and white patients. The study sample consisted of 270 HR-positive women. Among those who were node-negative, 43% received RS testing. No differences were found in RS testing according to race but testing varied according to age. The results of this study contribute to the body of knowledge regarding RS testing in a diverse clinical sample by including self-reported psychosocial and attitudinal factors in patient's interactions with their providers.

Background: In women with early stage, hormone receptor (HR)-positive (HR^+) breast cancer, the 21-gene recurrence score (RS) assay quantifies recurrence risk and predicts chemotherapy responsiveness. Recent data suggest that not all women with early-stage, HR^+ disease receive this testing. We examined sociodemographic, clinical, and attitudinal factors associated with RS testing receipt and the RS testing effect on chemotherapy use in black and white patients. **Patients and Methods:** Women with newly diagnosed invasive, nonmetastatic breast cancer were recruited and interviewed to collect sociocultural and health care process data; clinical data were collected from charts. Of the sample (n = 359), 270 had HR^+ disease. Primary analysis focused on those with HR^+ node-negative disease (n = 143); secondary analyses included node-positive women. Logistic regression models evaluated factors associated with receipt of RS testing and chemotherapy. **Results:** Among women eligible for the 21-gene assay, 62 patients [43%] received RS testing. In multivariable analysis, older age (odds ratio, 1.04 per 1 year increase; 95% confidence interval, 1.01-1.08) was associated with RS testing after adjustment for covariates. Chemotherapy use was 23%. In multivariable analysis, positive attitudes about chemotherapy and greater risk of recurrence were associated with chemotherapy use ($P < .05$). **Conclusion:** Patterns of genomic testing might vary according to age. Efforts to understand factors associated with low testing rates will be important.

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Introduction

Breast cancer remains the most common cancer among US women, with more than 230,000 new diagnoses and 40,000 deaths each year,[1] along with decrements in quality of life.[2-4] Half of newly diagnosed patients present with estrogen-receptor positive and early-stage disease.[5] Increased clinical genomic profiling of breast tumors, in combination with traditional factors such as age, tumor size, and grade, determine recurrence estimates and guide adjuvant treatment decisions.[6] The 21-gene recurrence score (RS) assay (Onco*type* DX; Genomic Health Inc, Redwood City, CA) is a

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validated test that quantifies risk of recurrence and predicts benefit from chemotherapy in patients with early stage, estrogen receptor and progesterone receptor-positive (HR^+) node-negative breast cancer treated with tamoxifen.[7] The use of RS testing has been integrated into 3 sets of clinical guidelines.[6,8,9]

Several studies demonstrated that the RS affects treatment utilization.[10-14] Specifically, RS alters oncologists' chemotherapy treatment recommendations in 25% to 44% of cases,[11,13,15] usually from combined chemohormonal therapy to hormone therapy alone.[10,12,16-18] Beyond decreasing chemotherapy, testing also results in more specific reclassification of women. With an accurate understanding of the severity, treatment can be tailored to a patient's specific tumor.[19] Ultimately, the RS can become one of the first commonplace genomic tests that shift patterns of care in routine practice.[19]

Recent studies suggest that not all women with early-stage, hormone-positive disease receive RS testing. Studies using large cohorts have demonstrated that black women are less likely to be tested than white women.[19,20] Lund and colleagues (2012)[20] found that testing bias might attenuate racial differences in RS, and disparate outcomes might be explained in part by differences in RS, although compliance and pharmacogenomics might also play a role. Because of persistent disparities in breast cancer survival,[21,22] even among HR-positive women,[23] it might be critical to understand potential racial disparities in RS testing. Because sociocultural factors such as religiosity and medical mistrust have been associated with receipt of genetic risk assessment in minority women, we examined these factors in our study.[24,25] Such factors are regarded to influence patient–provider interactions and decision-making in minority women.[26]

Health care practice setting also appears to play a role in the receipt of testing.[27] Other health care-related factors such as patient–provider communication might also affect receipt of RS testing. Patient–provider communication has been associated with receipt of cancer screening tests,[28] cancer treatment,[26,29] and other genomic tests.[30] Patients with better communication with their providers might be more likely to request the test, have a better understanding of the purpose and/or rationale of the test, and thus be more likely to make decisions to have the test.[31,32] In a small sample of mostly white patients, Tzeng and colleagues[32] found that receiving information about RS testing from an oncologist was associated with women's willingness to receiving testing. We will expand knowledge in this area by including attitudinal and sociocultural variables that are hypothesized to affect cancer behaviors, particularly in black women, but have not been empirically examined within the RS testing context.

We hypothesized that black women and those of lower socioeconomic status (SES) would be less likely to receive RS but that this would be attenuated after controlling for tumor characteristics. We also expected that women without RS would be more likely to have chemotherapy compared with those with RS, but that RS would be correlated with chemotherapy use among those with RS.

Patients and Methods

Setting and Population

This report is a part of a larger study that has been detailed elsewhere.[33] Briefly, after institutional review board approval from all institutions, a convenience sample was recruited via hospitals in Washington, DC (n = 3), in Detroit (n = 1), and self-referrals from outreach activities (eg, fliers, posters, mailings) between July 2006 and April 2011. Since recommendations for Oncotype DX testing were added to National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology guidelines in 2007 we focused only on women who were diagnosed when the guidelines had integrated RS testing. Thus, participants diagnosed in 2006 were excluded from the analysis.[6,34]

Eligible women were ≥ 21 years old and diagnosed with invasive nonmetastatic disease for whom systemic adjuvant therapy would be considered with curative intent. Black women were oversampled to facilitate race comparisons and to investigate within race group differences. Women with ductal and lobular carcinoma in situ, distant metastasis, recurrent disease, second primaries, who were not English speakers, who did not self-identify as black or white, or who were unable to provide informed consent were excluded.

A total of 678 potentially eligible patients were screened for the study, 477 were eligible and of that number 395 [82.8%] were interviewed and 350 [90.9%] had complete medical records. Women with HR-negative cancers and those with stage III breast cancer were excluded from analyses. There were 270 women with HR-positive disease and 146 who were HR-positive and node-negative; the latter group was the primary focus of this study.[34] We also explored RS patterns in the overall group of women recruited that included node-negative and node-positive disease (n = 270). The reason for including patients with node-positive tumors was to explore use of RS among women for whom testing was not standard practice to assess if some women might have requested or sought testing regardless of NCCN guidelines and/or recommendations.[35]

Data Collection

Clinical research assistants confirmed eligibility and obtained consent for interviews and chart reviews. Interviews were conducted by trained staff using a standardized computer-assisted telephone survey that lasted approximately 50 minutes. The survey included information about sociodemographic factors, attitudes about therapy, sociocultural factors, and interactions with providers. On average, interviews were conducted within 14 weeks after definitive surgery. Treatment and clinical variables (eg, 21-gene assay, etc) were abstracted from medical records 12 to 18 months after interviews. Participants received a $25 incentive.

Measures

Outcomes were obtained from medical records and included RS (yes or no), hormonal use (yes vs. no), and chemotherapy use of any regimen (yes or no).[26] Among women with RS, we abstracted patients' recurrence risk score and 10-year recurrence risk from medical records.

Sociodemographic variables were self-reported race, age, education, marital status, employment, education, and insurance type (private vs. public) status. Clinical factors abstracted from medical records were HR status (positive vs. negative), surgery type (lumpectomy or mastectomy), nodal status (positive or negative), pathological tumor size, and breast cancer stage categorized from I to III, which was categorized similar to other reports as positive,