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Who gets genomic testing for breast cancer recurrence risk?

Jessica T. DeFrank¹, Talya Salz², Katherine Reeder-Hayes^{3,4}, and Noel T. Brewer^{1,3}

¹UNC Gillings School of Global Public Health, Department of Health Behavior, University of North Carolina at Chapel Hill

²Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center

³UNC Lineberger Comprehensive Cancer Center

⁴Division of Hematology/Oncology

Abstract

Background/Aims—Our study examined whether patient characteristics, beliefs, and decision-making styles were associated with uptake of genomic testing for breast cancer recurrence risk.

Methods—Participants were 132 early-stage breast cancer patients eligible for the Oncotype DX genomic test. We interviewed patients in 2009–2010 and obtained information from medical charts.

Results—Half of women eligible for genomic testing for breast cancer recurrence risk received it. The most common reason for not getting the test was that women’s physicians did not offer it (80%). Test recipients were more likely to be unsure about receiving chemotherapy treatment compared to women who did not receive the test ($p < .05$). Women who received the test had less advanced disease pathologies, recalled a lower objective recurrence risk, perceived lower recurrence risk and were slightly younger (all $p < .05$). Most women who described their decision-making style as active received the test (75%) whereas few women who described their style as passive received the test (12%) ($p < .01$).

Conclusion—In the university clinic we studied, genomic testing appeared to more common among patients who may benefit most from the information provided by results, but confirmation in larger studies is needed.

Keywords

Cancer; Oncology; Risk Recurrence; Genomics; Oncotype DX; Patient Decision Making

INTRODUCTION

Genomic testing has become an important part of clinical cancer care. One increasingly used test, Oncotype DX, estimates 10-year risk of breast cancer recurrence and predicts chemotherapy benefit among early stage, hormone-receptor positive patients by examining the activity of 21 genes in breast tumors [1, 2]. Test results offer additional insight beyond standard clinicopathological markers such as tumor size and grade for assessing risk, and offer more precise risk estimates [3–6]. One of the potential promises of Oncotype DX testing is to allow women with low recurrence risk scores to safely forgo chemotherapy and its potential side effects. A recent systematic review of 10 studies of the impact of Oncotype

DX test results on clinical treatment found that test results were associated with changes in about 20% to 40% of treatment recommendations, most often in the direction of declining adjuvant chemotherapy [7].

Guidelines from several major professional groups, including the National Comprehensive Cancer Network, recommend that physicians consider Oncotype DX testing for eligible women. Patients also have a strong interest in genomic testing to assess their breast cancer recurrence risk [8]. These factors likely have contributed to the rapid adoption of the test. However, little is known about determinants of which eligible patients receive this test in clinical settings. It is unclear whether genomic testing is being offered by physicians to women who may benefit from the information provided by test results, whether there are socio-demographic disparities in uptake of the test, and the extent to which patient preferences and beliefs influence test receipt.

Our study team conducted individual interviews with women who were undergoing treatment for early stage breast cancer and met eligibility criteria to receive Oncotype DX testing. The purpose of our study was to examine whether medical and demographic characteristics, beliefs, and decision-making styles of women eligible for the Oncotype DX test were associated with receipt of the test. We also assessed patient-reported reasons for not getting the test.

METHODS

Participants and recruitment

Participants were women being treated for early-stage breast cancer at the University of North Carolina Breast Clinic (Chapel Hill, NC) between May 2009 and November 2010, who were eligible to receive genomic recurrence risk testing by Oncotype DX (diagnosed with stages I or II, hormone-receptor positive breast cancer). We obtained a temporary waiver of HIPAA authorization to determine women's receipt of the test prior to approaching them for participation. We included both node-negative and node-positive women, as studies have validated the test for both groups of women [1, 3]. We excluded women who were non-English speaking, were incarcerated, had a second primary cancer diagnosis or other life-threatening co-morbid disease, or had a history of a serious psychiatric diagnosis. Approaching these women for participation would have been inadvisable by physicians due to other health concerns or their limited ability to comprehend study materials.

For women who received the genomic test, we attempted to survey them in clinic during the appointment at which they received their test results. For women who did not receive the test, we surveyed them at their next scheduled medical oncology appointments after their initial visit to the breast clinic. We mailed study materials to women who consented to be in the study but did not complete baseline questionnaires in clinic.

Patients read and signed a written informed consent form. They had the option to complete a HIPAA authorization form to allow a review of their medical records to abstract additional information on their cancer (e.g. stage, grade). Women received \$15 and a parking pass for participating. The University of North Carolina Institutional Review Board approved the study.

Measures

We collected patient data primarily through study questionnaires and supplemented data collection through review of medical charts for patients who provided consent. All but 6 women consented to review of their medical charts. Three team members abstracted data

from medical charts and a program manager reviewed abstracted chart information for accuracy. Study questionnaires varied slightly according to whether or not women received the test.

Medical chart review—For patients who consented to medical chart review, study staff recorded pathology information (tumor stage and grade, number of positive nodes), menopausal status, number of co-morbidities and other information related to prognosis and treatment. We used patient pathology information to calculate women’s 10-year risk of distant cancer recurrence using Adjuvant! Online version 7. For patients who refused medical chart review, these data were treated as missing.

Demographics—The questionnaires assessed patients’ demographic characteristics (race, education, income, health insurance status, employment status, and marital status). The questionnaires assessed numeracy with a validated three item scale, [9] and we dichotomized responses as “low” (0–1 correct items) or “high” (2–3 correct items). A single, validated health literacy item assessed how often respondents need help with written health-related materials [10]. We dichotomized responses as “high” literacy (“never” or “rarely” needs help) and “low” literacy (“sometimes” to “always” needs help).

Plans for treatment and recurrence risk—The questionnaire assessed patients’ plans to receive chemotherapy treatment in the future (“yes”, “no” or “unsure”). Three questionnaire items assessed women’s beliefs about their recurrence risk. One risk perception item assessed patients’ recall of what their doctors said their recurrence risk was by asking, “What did your doctor say was the chance of your breast cancer coming back in the next 10 years based on the test?” A 5-point response scale ranged from “very low chance” to “very high chance”; these response options were similar to the 3 Oncotype DX recurrence risk categories. Another risk perception item assessed patients’ recall of their numerical recurrence risk and read “Here is the same question asked in a different way. What did your doctor say was the percent chance that your cancer will come back in the next 10 years based on the test?” The questionnaire provided a space to fill in a percentage (0–100%). For women who did not receive the test, these two risk perception items did not include the phrase “based on the test”. A third risk perception item assessed patients’ perceived recurrence risk: “Aside from what your doctor said, what do you think is your percent chance of your breast cancer coming back in the next 10 years?” The questionnaire provided a space to fill in a percentage (0–100%).

Psychosocial variables—The questionnaire assessed breast cancer worry using previously validated items asking how often women worried about or thought about their chances of getting breast cancer again and how often these thoughts affected their mood or ability to engage in daily activities [11]. The 4-point response scale ranged from “rarely or never” to “(almost) all the time.” We calculated a mean for the 4 items with higher scores reflecting more worry. The questionnaire assessed women’s beliefs that their breast cancer could recur using one item that read “Breast cancer could possibly come back in another part of my body.” This item had a 5-point response scale, coded such that higher scores reflected a stronger belief that their cancer could come back. One item assessed perceived effectiveness of chemotherapy treatment: “How much do you think chemotherapy will help lower the chance of your breast cancer coming back?” The 5 point response scale ranged from “none at all” to “completely”, coded such that higher scores reflected higher perceived effectiveness. Two items assessed whether women felt their standard test results (e.g. tumor stage and size) could be trusted and were accurate. The 5 point response scale ranged from “strongly disagree” to “strongly agree”, coded such that higher scores reflected greater trust and perceived accuracy.

One item assessed women's preferred role in treatment decision making [12] and had the following response options: "I prefer to make the final selection about which treatment I will receive"; "I prefer to make the final selection of my treatment after seriously considering my doctor's opinion"; "I prefer that my doctor and I share the responsibility for deciding which treatment is best for me"; "I prefer that my doctor makes the final decision about what treatment will be used, but seriously considers my opinion"; and "I prefer to leave all decisions regarding my treatment to my doctor." Following standard methods[13–15], we coded the first two responses as indicating "active decision-making", the third as "shared decision-making", and the last two as "passive decision-making"

Reasons for not getting the test—For women who did not receive the test, a brief description of Oncotype DX appeared at the end of the questionnaire followed by a question on whether women had heard about the test before and whether their doctors had offered them the test. The questionnaire also listed other possible reasons for not receiving the test (e.g., I already knew I wanted chemotherapy) and an open-ended "other" response option. Women could check as many reasons as applied.

Data analysis

Percentages in text refer to the final sample ($n=132$) unless noted due to missing data. We used bivariate logistic regression to model the probability of receiving the test; analyses provided unadjusted odds ratios and 95% confidence intervals. We then conducted sensitivity analyses excluding 23 women who were node-positive according to their medical charts, because of questions regarding the usefulness of genomic testing for this group (node-positive women often receive chemotherapy treatment). All tests were two-tailed with a critical alpha of .05. We analyzed data using SAS v 9.2 (Cary, NC).

RESULTS

Of 246 women eligible to receive Oncotype DX testing, 225 were eligible for our study (Figure 1). Of these women, 143 participated in the study (64%). Participation was higher for women who received the test (70%, 66/94) compared to those who did not (51%, 77/151). Women completed the questionnaires in clinic (22%, 31/143), at home (56%, 80/143), or in both locations (22%, 32/143). We excluded 11 women from analyses who received neoadjuvant chemotherapy according to their medical charts, as these women generally should not be offered the test. The final sample of 132 women was predominately white (88%), insured (95%) and married (69%) (Table 1). About one-half worked for pay (48%), and over one-half had annual household incomes over \$60K (61%) and had college degrees (64%).

Sixty six women (50%) received genomic testing and 66 (50%) did not receive the test. Women who did not receive the test often reported that their doctors did not offer them the test (80%, 53/66) and that they had not heard of the test (65%, 43/66) (Table 2). Other reasons were that women already knew that they either wanted (14%, 9/66) or did not want (14%, 9/66) chemotherapy or their doctors advised against the test, because the information would not have been useful (8%, 5/66). Cost of the test was not a common concern for this population (2%, 1/66).

Demographic and medical characteristics

Receipt of the test did not differ by demographic characteristics (all $p>.05$; Table 1), with the exception of slightly younger age for women who received the test (Table 3, $p=.01$). Women who received and did not receive the test were about 3 months post-diagnosis according to medical charts (Table 3). Women were less likely to receive the test if they

were diagnosed with slightly later-staged cancers (stage IIb compared to I), were post-menopausal (compared to pre-menopausal), had one or more positive nodes or had medium-sized tumors (compared to small) (all $p < .05$). Women who received the test were similar to those who did not with regard to receipt of breast conserving surgery, mastectomy, radiation, level of comorbidity, tumor grade, progesterone receptor status and self-reported family history of breast cancer (all $p > .10$).

Risk of recurrence

Risk of recurrence scores estimated through Adjuvant! Online were similar for women who received and did not receive the test (Table 3, mean=28% and 32% respectively). Women's self-reported risk category (e.g. "low") as conveyed to them by their physicians was not associated with receipt of the test. However, women who received the test recalled slightly lower numerical recurrence risk scores (e.g., 0–100%) as conveyed to them by their physicians compared to those who did not receive the test (mean= 10% and 16% respectively, $p = .05$). Only about one-half of women (55%; 73/132) said they knew their numerical recurrence risk number as reported by their physicians, whereas more women (80%; 106/132) recalled being told their recurrence risk category. Women who received the test perceived their recurrence risk as lower than those who did not receive the test (mean=12% and 18% respectively, $p = .05$). Also, women who received the test less strongly endorsed the belief that their cancers could come back than women who did not receive the test ($p = .02$).

Psychosocial characteristics

Women who said they were "unsure" about getting chemotherapy treatment were much more likely to get the test compared to women who said they already planned on getting chemotherapy (Table 4, 87% and 37% respectively, $p < .01$). Compared to women who described their decision-making style as passive, women who described their decision-making styles as active were dramatically more likely to have received the test (Table 4, 12% for passive vs. 75% for active, $p < .01$). Additional analyses showed that age, race, education and measures of recurrence risk were not associated with preferred decision-making styles (all $p > .05$). Women who received the test also reported slightly lower trust and perceived accuracy in their standard (non-genomic) test results than women who did not receive the test ($p = .03$ and $p = .05$ respectively). Both groups of women reported equal levels of worry about breast cancer and belief in the effectiveness of chemotherapy ($p > .05$).

Sensitivity Analyses

We conducted the same analyses described above excluding the 23 lymph node-positive women, given questions about the appropriateness of the test for this group. As expected, exclusion of node-positive women explained many of the clinical differences between the two cohorts: after exclusion of the node-positive patients, women who received and did not receive the test no longer differed according to the recurrence risk they recalled their doctors telling them ($p = .29$), perceived recurrence risk ($p = .34$), or cancer stage ($p = .45$ for comparison between stage IIb and I patients). However, even after exclusion of node-positive patients, differences in the other psychosocial variables remained. Women who got the test still reported less concern about their cancer coming back ($p < .05$), and less trust and perceived accuracy in their standard test results (both $p < .05$) compared to those who did not get the test. Women who got the test were still more likely to report being "unsure" about receiving chemotherapy treatment ($p < .05$) and were dramatically more likely to describe themselves as active ($p < .01$) or shared ($p < .05$) decision makers.

DISCUSSION

Findings from our study in a single university clinic suggest that women receiving genomic testing were those who may benefit the most from the information provided by the test results, but confirmation in a larger study of multiple clinics is needed. Women who, at the time of their surveys, said they were unsure about whether or not to get chemotherapy were much more likely to have had the test than women who had already decided to have the treatment. This finding is appropriate, as women who are uncertain about treatment may derive more benefit from the test in terms of decision making support compared to women who have already made treatment decisions. Among patients who did not receive the test, 80% said the reason was because their doctor did not offer it. This finding may suggest that physicians are reluctant to order or discuss the test with patients who have already made treatment decisions or reluctant to offer the test to women they perceived *a priori* to be at higher risk, such as node-positive patients. This hypothesis is supported by a qualitative study of physicians where most said they would not order the test if a patient was certain to have or forgo chemotherapy [16]. Alternatively, women who did not recall being offered the test may have received unclear information or not understood what test they were being offered, as for instance when the brand name of the test was not mentioned. Whether patients who did not recall being offered the test in the current study could have benefited from information provided by the results is unclear.

Test recipients recalled that their doctors conveyed lower recurrence risk to them and perceived lower recurrence risk, compared to those who did not get the test. This finding might suggest that women who believe they have a lower recurrence risk and thus a more favorable prognosis are more likely to get the test, perhaps using test results to inform potential decisions to forgo chemotherapy. Conversely, women who have higher perceived recurrence risk might already have decided to have chemotherapy; test results might not change their treatment decisions. However, our cross-sectional data preclude us from determining whether risk beliefs motivated behavior. While our objective measure of recurrence risk (Adjuvant Online! scores that incorporated non-genomic pathology information) did not differ between women receiving and not receiving genomic testing, we found that those who got the test had slightly less advanced disease according to some pathological markers such as stage and node involvement. Our sensitivity analyses demonstrated that when node-positive women were removed from the study sample, the difference between tested and untested women in clinical measures largely disappeared. This result may indicate that physicians or patients remain uncomfortable relying on the results of genomic testing to forgo chemotherapy in a group usually categorized as at high risk of recurrence.

Of interest was the finding that, regardless of node-involvement, women who received the test reported slightly lower trust and perceived accuracy in their standard non-genomic results for recurrence risk compared to women who did not receive the test. These findings are consistent with evidence showing that genomic testing provides more precise recurrence risk estimates compared to standard non-genomic markers [5, 17] and with our previous research suggesting that women place more emphasis on genomic over standard risk information when test results conflict [18]. Also regardless of node-involvement, women who received the test were less concerned that their cancer would come back compared to women who did not receive the test. However, the sources of this finding are unclear. Women who received the test likely would have discussed recurrence risk during their clinic appointments, perhaps receiving some reassurance from their doctors.

Consistent with an increased emphasis on patient participation in medical decisions, our study found that most participants said they preferred some role in treatment-related

decisions. However, the robust association of patient decision-making style with uptake of genomic testing warrants consideration. Uptake of the test was dramatically higher for women who reported an active compared to passive decision making style. Over 70% of women who said they preferred a more active role in their treatment decisions received the test; in comparison, only 12% of women who said they preferred that their physicians make decisions about their treatment received the test. While studies show that younger age and higher educational status are consistent predictors of the desire to participate in shared decision making [19], these factors were not associated with decision making styles for our study, suggesting that other psychosocial factors may account for women's decision-making preferences. However, caution must be used in interpreting the association between test uptake and decision-making style. Our analyses used cross-sectional data, which precludes us from knowing, for example, whether women's decision making styles influenced uptake or if the behavior of receiving the test influenced responses about preferred decision-making styles. Regardless, best practices for clinical communication between physicians and patients about the utility of such tests remains unclear [16].

There were minimal socio-demographic disparities in uptake of genomic testing for this population of early stage breast cancer patients. Women who received the test did not differ by race, income, or education, although women who received the test were slightly younger in age than those who did not receive the test. However, these findings should be interpreted with caution, as our study was limited to a single institution, and almost all study participants had health insurance. Also, we were not able to assess whether study participants differed from other patients as this information was not available to us. Thus, it is possible that the absence of socio-demographic differences in uptake for our study population is obscured due to low participation by certain subgroups. Other studies have pointed to potential racial and ethnic disparities in uptake of genomic testing [20–22]. The question of whether the test is being applied equivalently among diverse populations remains an area of future research.

Our study is one of the few to describe uptake of genomic testing for breast cancer recurrence risk in a clinical setting and was successful in recruiting women who did and did not get the test. Our findings suggest that women receiving genomic testing for breast cancer recurrence were those who may benefit the most from the information provided by the test results, although future research on use of such tests in more diverse settings and patient populations is warranted.

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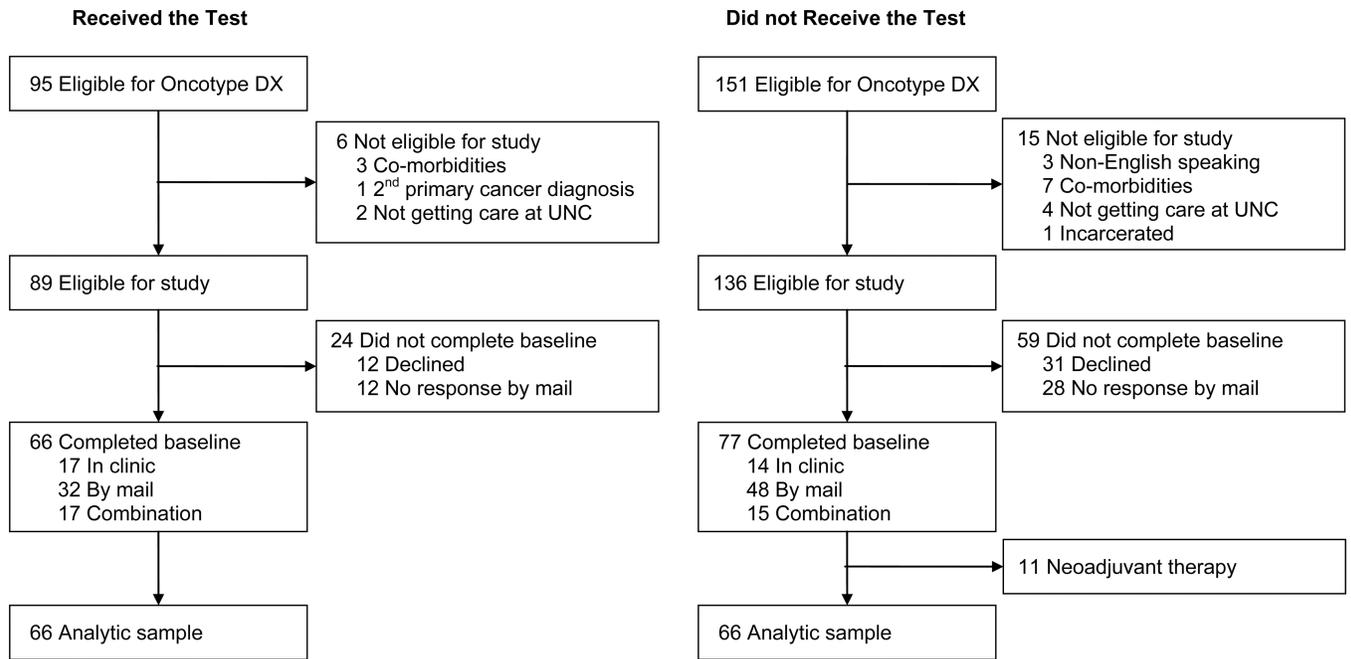


Figure 1.
Flow diagram

Table 1Demographic characteristics of sample ($n=132$).

	Overall Sample <i>n</i> (%)	Received the Test <i>n</i> (%)	Unadjusted <i>OR</i> (95% <i>CI</i>) ^a
Race			
Other	15/130(12)	6/15 (40)	
White	115/130 (88)	59/115 (51)	1.58 (0.53, 4.73)
Marital Status			
Not married	40/130 (31)	17/40 (43)	
Married/living as married	90/130 (69)	49/90 (54)	1.61 (0.76, 3.43)
Education			
Less than college	46/129 (36)	20/46 (44)	
College or more	83/129 (64)	46/83 (55)	1.62 (0.78, 3.34)
Annual household income			
<\$60,000	47/120 (39)	25/47 (53)	
\$60,000	73//120 (61)	35/73 (48)	0.81 (0.39, 1.69)
Worked for pay			
No	66/128 (52)	30/66 (45)	
Yes	62/128 (48)	36/62 (58)	1.66 (0.83, 3.34)
Insured			
No	7/130 (5)	3/7 (43)	
Yes	123/130 (95)	63/123 (51)	1.40 (0.30, 6.52)
Literacy			
Low	17/131 (13)	5/17 (29)	
High	114/131 (87)	61/114 (54)	2.76 (0.91, 8.36)
Numeracy			
Low	39/132 (30)	20/39 (51)	
High	93/132 (70)	46/93 (49)	0.93 (0.44, 1.96)

Note. Ns differ due to missing data. None of the ORs are statistically significant.

^aModeling probability of receiving the test compared to not having received the test.

Table 2Reasons patients gave for not having received the test ($n=64$)

	%
Doctor did not offer the test	80
Patient had not heard of the test	65
Patient already knew she wanted chemotherapy	14
Patient already knew she did not want chemotherapy	14
Doctor said the test was not necessary/ information was not needed	8
Could not afford	2
Don't know	14
Other	6

Note. Patients checked all reasons that applied. 2 subjects did not respond to these survey items.

Table 3

Continuous correlates of genomic testing receipt.

	Did Not Receive the Test	Received the Test	UnadjustedOR (95%CI)^a
	mean (SD)	mean (SD)	
Medical			
Age at diagnosis, years (n=126)	62.2 (11.1)	57.5 (10.2)	0.96 (0.93, 0.99)*
Months since diagnosis, median (n=126)	3.0 (35.1)	3.0 (31.3)	n/a
Recurrence Risk			
Objective recurrence risk, from Adjuvant! Online, 0–100% (n=126)	31.7 (16.3)	28.3 (11.3)	0.98 (0.96, 1.01)
Patient reported recurrence risk, category (n=106)	1.8 (.70)	1.7 (.68)	0.77 (0.44, 1.35)
Patient reported recurrence risk, 0–100% (n=73)	15.7 (16.3)	10.0 (3.5)	0.98 (0.95, 1.00)*
Perceived recurrence risk, 0–100% (n=126)	18.4 (22.4)	11.7 (12.7)	0.98 (0.95, 1.00)*
Psychosocial			
Belief that cancer could come back (n=129)	4.0 (0.87)	3.5 (1.11)	0.64 (0.44, 0.92)*
Worry about breast cancer (n=128)	1.7 (0.64)	1.5 (0.56)	0.67 (0.37, 1.22)
Trust in standard (non-genomic) test results (n=125)	4.1 (.80)	3.8 (.65)	0.58 (0.35, 0.95)*
Perceived accuracy of standard (non-genomic) test results (n=124)	4.1 (.81)	3.8 (.61)	0.60 (0.36, 1.00)*
Perceived effectiveness of chemotherapy (n=124)	2.8 (1.22)	2.5 (1.13)	0.82 (0.60, 1.12)

Note. Ns differ due to missing data or withheld consent to review medical chart.

^a Modeling probability of receiving the test compared to not receiving the test

* $p < .05$

Table 4

Categorical correlates of genomic testing receipt.

		Overall Sample <i>n</i> (%)	Received the Test <i>n</i> (%)	Unadjusted <i>OR</i> (95% <i>CI</i>) ^a
Planning to get chemotherapy	No	69/130 (53)	36/69 (52)	1.86 (0.87, 3.99)
	Unsure	15/130 (12)	13/15 (87)	11.09 (2.23, 55.17)**
	Yes	46/130 (35)	17/46 (37)	Ref
Stage	I	72/126 (57)	42/72 (58)	Ref
	IIa	38/126 (30)	19/38 (50)	0.71 (0.32, 1.57)
	IIb	16/126 (13)	4/16 (25)	0.24 (0.07, 0.81)*
Menopause status	Pre	22/125 (18)	17/22 (77)	Ref
	Current	8/125 (6)	7/8 (88)	2.06 (0.20, 20.99)
	Post	95/125 (76)	41/95 (43)	0.22 (0.08, 0.66)**
Positive lymph nodes	0	103/126 (82)	58/103 (56)	Ref
	1–3	23/126 (18)	7/23 (30)	0.34 (0.13, 0.90)*
Tumor size	1cm	33/124 (27)	11/33 (33)	Ref
	1.1–2 cm	52/124 (42)	36/52 (69)	4.50 (1.77, 11.44)*
	>2 cm	39/124 (31)	17/39 (44)	1.55 (0.59, 4.04)
Patient's decision-making style	Passive	26/130 (20)	3/26 (12)	Ref
	Shared	64/130 (49)	33/64 (52)	8.16 (2.23, 29.92)*
	Active	40/130 (31)	30/40 (75)	23.00 (5.67, 93.23)**

Note. Ns differ due to missing data or withheld consent to review medical chart.

^aModeling probability of receiving the test compared to not receiving the test.

* $p < .05$

** $p < .01$