

Short Communication

Utilization of BRCA1/BRCA2 Mutation Testing in Newly Diagnosed Breast Cancer Patients

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Abstract

Background: Among newly diagnosed breast cancer patients who are at risk for carrying a BRCA1 or BRCA2 mutation, knowledge of mutation status can influence local breast cancer treatment decisions. Thus, genetic testing at the time of diagnosis is increasingly considered an option for such patients. In this study, we evaluated factors associated with the decision to undergo BRCA1/BRCA2 gene testing at the time of initial breast cancer diagnosis.

Methods: Participants were newly diagnosed breast cancer patients who had not yet received definitive local breast cancer treatment and who had a family history consistent with hereditary breast cancer. Participants were offered genetic counseling and BRCA1/BRCA2 testing with results in 2 to 3 weeks.

Results: Of 231 patients who referred to the study, 20 (9%) declined the baseline interview, 34 (15%) completed a

baseline interview but declined genetic testing, and 177 (76%) underwent BRCA1/BRCA2 testing. Physician recommendation for BRCA1/BRCA2 testing and indecision about definitive local treatment were both associated with undergoing testing. Among patients who were tested, 38 (21%) proceeded with definitive local treatment before receiving test results. Delay in the availability of test results and low levels of anxiety were associated with the decision to proceed with definitive local treatment before receiving test results. **Conclusions:** These results suggest that if rapid testing is available and genetic referrals are made for appropriate patients, a high proportion are likely to opt for such testing. In particular, patients who have not yet reached a decision about definitive local treatment may benefit from a genetic referral. (Cancer Epidemiol Biomarkers Prev 2005;14(4): 1003-7)

Introduction

Approximately 5% to 10% of all breast cancer is associated with hereditary predisposition (1), and the majority of hereditary breast cancer is attributable to mutations in either the BRCA1 or BRCA2 gene (2, 3). Unaffected women who carry a BRCA1/BRCA2 mutation have a 55% to 85% cumulative risk of developing breast cancer (4, 5). Moreover, breast cancer patients who carry a BRCA1/BRCA2 mutation have up to a 65% risk of developing a second breast cancer in the contralateral breast (6-8). Given the high rate of second cancers among BRCA1/BRCA2 carriers, bilateral mastectomy has emerged as a treatment option for newly diagnosed breast cancer patients who carry a BRCA1/BRCA2 mutation (9). Thus, high-risk patients may increasingly be asked to consider genetic testing at the time of their initial breast cancer diagnosis (10).

Among newly diagnosed breast cancer patients who receive a positive BRCA1/BRCA2 test result before their definitive local breast cancer treatment, over 50% opt for immediate bilateral mastectomy (9, 11). Advantages of immediate bilateral mastectomy for BRCA1/BRCA2 mutation carriers include the avoidance of radiation treatment and the possibility of enhanced reconstruction options (9, 11). Despite these

advantages, there are several reasons that patients may decide against genetic testing at the time of diagnosis. First, breast-conserving treatment is an effective local treatment even for BRCA1/BRCA2 mutation carriers (12). Thus, decisions about genetic testing and bilateral mastectomy need not be made at the time of initial diagnosis (13). Second, the process of obtaining genetic counseling and testing immediately post-diagnosis could lead to treatment delay and may not be feasible in many settings (9, 13, 14). Finally, for some patients, BRCA1/BRCA2 testing may represent an added psychological burden during the already stressful period following a breast cancer diagnosis (9, 13, 15).

Given these benefits and risks, we sought to identify factors that are associated with the decision to undergo BRCA1/BRCA2 testing at diagnosis. In addition to basic demographic, disease- and treatment-related variables, we were interested in the roles of physician recommendation and psychological distress. These variables have been shown to be important predictors of medical decisions in general (16, 17) and genetic testing decisions in particular (18-20).

Materials and Methods

This study was approved by the Institutional Review Board at Georgetown University. Newly diagnosed breast cancer patients referred to the study by contacting the program directly or by indicating their interest on a family history screening form that was completed in the waiting room of participating physicians at Lombardi Comprehensive Cancer Center or collaborating community practices. Eligible participants were women who were newly diagnosed with ductal

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carcinoma *in situ* to stage IIIa breast cancer, had ~10% or higher prior probability of carrying a BRCA1/BRCA2 mutation (21-23) and had not received definitive local breast cancer treatment. As in previous reports (9), we defined definitive local treatment as either mastectomy (unilateral or bilateral) or lumpectomy plus the initiation of radiation treatment. Thus, patients who had received a lumpectomy were not deemed to have received definitive local treatment until they initiated radiation or obtained a completion mastectomy.

Overall, 231 eligible patients referred to the study. Of these, 20 (8.7%) declined the baseline interview. Thus, our final sample consisted of 211 patients.

Procedures. Interested patients were contacted by study staff to assess eligibility. After completing a structured telephone interview that assessed sociodemographics, family history of cancer, disease characteristics, psychological distress, quality of life, and physician genetic testing and surgical recommendations, eligible participants were invited to a pretest genetic counseling session with a trained oncology nurse educator or genetic counselor. The content of this session has been described previously (24). Briefly, this session was comparable with traditional genetic counseling for hereditary breast cancer but with an added focus on risks for second breast cancers, risks and benefits of genetic testing at the time of initial diagnosis, and efficacy of breast conservation and bilateral mastectomy for BRCA1/BRCA2 mutation carriers. Following counseling, participants were given the option of providing a blood sample for BRCA1/BRCA2 testing. When test results were available (usually within 2-3 weeks) a disclosure session was scheduled. Genetic counseling and testing were provided free of charge.

Measures

Sociodemographics. We assessed sociodemographics at the baseline interview. We dichotomized these variables as follows: age (≤ 40 versus > 40), race (Caucasian versus other), marital status (married/living with partner versus other), education (college graduate versus $<$ college graduate), employment (employed full time versus other), and religion (Jewish versus other).

Family History. We assessed the number of first- and second-degree relatives affected with breast or ovarian cancer. For analysis, we dichotomized this variable to compare patients with ≤ 2 affected relatives versus those with > 2 affected relatives.

Cancer Stage. Tumor-node-metastasis stage was abstracted from medical records and dichotomized to compare patients with ductal carcinoma *in situ*/stage I versus stage II/IIIa. Staging data was missing for 38 (18%) participants.

Psychological Distress. We measured baseline cancer-specific distress with the total score on the 15-item Impact of Events Scale (Cronbach's Alpha, this study = 0.82; refs. 25, 26). We measured baseline anxiety with the 20-item State Anxiety Scale of the State Trait Anxiety Inventory (Cronbach's Alpha, this study = 0.92; refs. 27, 28).

Quality of Life. We measured baseline quality of life with the total score on the 27-item Functional Assessment of Cancer Therapy-General (Cronbach's Alpha this study = 0.87; refs. 29, 30).

Genetic Testing Recommendation. We categorized patients into those who reported (on the baseline interview) receiving a genetic testing recommendation from their surgeon, medical or radiation oncologist ($n = 117$) versus those who did not ($n = 94$).

Surgical Recommendation. We categorized patients into those who reported receiving a surgical recommendation to consider bilateral mastectomy ($n = 43$) versus those who received no recommendation ($n = 168$).

Rapid versus Delayed Local Treatment Decision. We categorized patients into those who could delay their definitive local treatment decision until completing adjuvant chemotherapy (i.e., had received a lumpectomy, were eligible for breast conservation and required adjuvant chemotherapy; $n = 74$) versus those who could not (i.e., ineligible for lumpectomy or did not require adjuvant chemotherapy; $n = 128$). Ten (5%) patients were missing data on this variable.

Definitive Local Treatment Intentions. We classified patients as to whether they reported having made a definite local treatment decision ($n = 167$) or not ($n = 44$) at baseline.

Time Until Availability of Test Results. Patients who were tested ($n = 177$), were further classified into those whose test result was available for disclosure within 14 days ($n = 95$) versus those whose test result was not available within 14 days ($n = 82$).

Genetic Testing Decision. Participants were classified into those who received test results ($n = 177$) versus declined testing ($n = 34$). Participants who received test results were further classified into those who received their results before their definitive local treatment ($n = 139$) versus those who received their results after proceeding with definitive local treatment ($n = 38$).

Data Analysis. After generating descriptive statistics to characterize the sample, we conducted bivariate analyses (χ^2 , t tests) to determine the association between genetic testing decision and baseline predictors. Next, we entered significant ($P \leq 0.05$) bivariate predictors of testing decision into a backward logistic regression to identify independent predictors of testing decision. In analyses limited to patients who underwent BRCA1/BRCA2 testing, we conducted bivariate analyses (χ^2 , t tests) to identify predictors of the decision to proceed with definitive local treatment before the receipt of test results. Next, we employed logistic regression to identify independent predictors of this decision.

Results

Sample Characteristics. The mean age of participants was 43 years (SD = 9), 85% were Caucasian, 67% were married, 60% were employed full time, 81% were college educated, 31% were of Ashkenazi Jewish descent, 25% had at least two first-degree relatives with breast or ovarian cancer, and 61% were diagnosed with ductal carcinoma *in situ* or stage I breast cancer.

Bivariate Predictors of Genetic Testing Decisions. Of 231 eligible patients, 20 (9%) declined study participation, 34 (15%) agreed to participate in the study but declined BRCA1/BRCA2 testing, and 177 (76%) chose to undergo BRCA1/BRCA2 testing. Among study participants, three variables distinguished those who received test results from those who declined testing (Table 1). Those who received test results had poorer baseline quality of life, were less likely to have reached a definitive local treatment decision, and were more likely to have received a physician recommendation for BRCA1/BRCA2 testing.

Multivariate Model of Genetic Testing Decisions. To identify independent predictors of BRCA1/BRCA2 testing decisions, we entered baseline quality of life, physician recommendation for genetic testing, and indecision regarding definitive local treatment into a logistic regression model

Table 1. Bivariate associations between baseline variables and genetic testing decision

Variable	Level	% Receiving test results	χ^2 (1 <i>df</i>)
Age	<40	89	1.64
	>40	82	
Race	Caucasian	85	0.90
	Other	78	
Education	<College	75	2.88
	>College	86	
Marital status	Unmarried	83	0.08
	Married	84	
Employment status	<Full time	87	0.87
	Full time	82	
Religion	Jewish	85	0.08
	Non-Jewish	83	
First-degree relatives with breast cancer	<2	82	1.14
	>2	88	
Required to make a rapid treatment decision	No	92	3.24
	Yes	83	
TNM stage	0/I	91	0.08
	II/IIIa	93	
Physician recommendation for BRCA1/BRCA2 testing	No	76	8.75*
	Yes	91	
Surgical recommendation	UM/BCT/BLM	82	3.33
	No record	93	
Patient definitive surgery decision	Undecided	97	6.23*
	Decided	81	

Continuous variables

Variable	Received results, mean (SD)	Declined testing, mean (SD)	<i>t</i> (209 <i>df</i>)
Quality of life (FACT-G)	79.7 (13.9)	84.7 (8.5) [†]	2.0 [†]
Cancer distress (IES)	25.7 (14.0)	23.9 (13.8)	0.7
State anxiety (STAI-S)	47.8 (12.5)	44.7 (12.3)	1.4

Abbreviations: *df*, degrees of freedom; TNM, tumor-node-metastasis stage; IES, Impact of Events Scale; STAI-S, State Anxiety Scale of the State Trait Anxiety Inventory; FACT-G, Functional Assessment of Cancer Therapy-General.

**P* = 0.01.

[†]*P* < 0.05.

with backward elimination of nonsignificant variables. After eliminating nonsignificant variables [Functional Assessment of Cancer Therapy-General: χ^2 (1) = 2.5, *P* = 0.11], the final model included physician recommendation for genetic testing and indecision about definitive local treatment. Compared with patients who did not receive a physician recommendation, those who reported receiving such a recommendation were three times more likely to undergo genetic testing (odds ratio, 3.2; 95% confidence interval, 1.5-7.1). Furthermore, compared with patients who had reached a definitive local treatment decision at baseline, those who were undecided about their definitive local treatment were five times more likely to undergo genetic testing (odds ratio, 5.3; 95% confidence interval, 1.2-23.3). The wide confidence interval for the effect of indecision about definitive local treatment reflects the fact that only 2 of 38 undecided participants declined testing.

Bivariate Predictors of Receiving Test Results before Definitive Treatment. Of the 177 patients who were tested, 38 (21%) chose to proceed with definitive local treatment before receiving the results of their BRCA1/BRCA2 test. In bivariate analyses (Table 2), patients who were less anxious and those for whom test results were not available within 14 days were more likely to proceed with definitive local treatment before receiving test results.

Multivariate Model of the Receipt of Test Results before Definitive Local Treatment. In multivariate modeling, both time until the availability of test result and baseline anxiety independently predicted the decision to proceed with definitive local treatment before the receipt of test results. Compared with patients for whom test results were available within 14 days, patients whose test results took longer to become available were over three times more likely to proceed with testing before receiving test results (odds ratio, 3.4; 95% confidence interval, 1.5-7.6). In contrast, compared with less anxious patients, those patients who reported higher levels of baseline anxiety, were 23% less likely to proceed with definitive local treatment before receiving test results (odds ratio, 0.77; 95% confidence interval, 0.59-0.91).

Table 2. Bivariate associations between baseline variables and decision to proceed with definitive local treatment before the receipt of test results

Variable	Level	% Received results before definitive local treatment	χ^2 (1 <i>df</i>)
Age	<40	89	1.64
	>40	82	
Race	Caucasian	85	0.90
	Other	78	
Education	<College	75	2.88
	>College	86	
Marital status	Unmarried	83	0.08
	Married	84	
Employment status	<Full time	87	0.87
	Full time	82	
Religion	Jewish	85	0.08
	Non-Jewish	83	
First-degree relatives with breast cancer	<2	82	1.14
	>2	88	
Required to make a rapid treatment decision	No	92	3.24
	Yes	83	
TNM stage	0/I	91	0.08
	II/IIIa	93	
Physician recommendation for BRCA1/BRCA2 testing	No	76	8.75*
	Yes	91	
Surgical recommendation	UM/BCT/BLM	82	3.33
	no record	93	
Patient definitive surgery decision	Undecided	97	6.23*
	Decided	81	
Time until BRCA1/2 test results were available for disclosure (d)	<14	88	11.9*
	>14	67	

Continuous variables

Variable	Results before treatment, mean (SD)	Results after treatment, mean (SD)	<i>t</i> (175 <i>df</i>)
Quality of life (FACT-G)	78.8 (14.3)	82.9 (12.2)	1.6
Cancer distress (IES)	26.3 (14.1)	23.5 (13.4)	1.1
State anxiety (STAI-S)	49.2 (12.6)	42.5 (10.8)	3.0 [†]

Abbreviations: *df*, degrees of freedom; TNM, tumor-node-metastasis stage; IES, Impact of Events Scale; STAI-S, State Anxiety Scale of the State Trait Anxiety Inventory; FACT-G, Functional Assessment of Cancer Therapy-General.

**P* = 0.01.

[†]*P* < 0.05.

Discussion

This is the first report to examine factors associated with BRCA1/BRCA2 testing among newly diagnosed breast cancer patients. Within this sample of self-referred patients, 77% chose to receive BRCA1/BRCA2 test results. Consistent with research on a variety of medical decisions (16, 17, 31), physician recommendation was a strong predictor of patients' testing decisions. This underscores the need for physicians to accurately identify patients who are candidates for genetic testing and discuss options and implications of genetic referral. We also found that patients who were undecided about their definitive local treatment were more likely to choose testing. This reflects a key benefit of offering genetic testing at the time of diagnosis. Such testing can provide undecided patients with the opportunity to incorporate genetic information into their local treatment decision making to reach a more fully informed decision. In contrast, patients who have already reached a definitive local treatment decision would benefit little from immediate genetic testing.

Among patients who chose to be tested, 21% proceeded with definitive local treatment before receiving test results. It is possible that these patients chose to be tested for reasons other than treatment decision making. The fact that testing was provided free of charge might have been a motivator to pursue testing at this time even for patients who had already made a definitive local treatment decision. However, our data also indicate that delay in the availability of test results may have led some patients to proceed with definitive local treatment rather than wait further for their test results to become available. This highlights the need to provide test results as quickly as possible in this setting. However, it is also important to consider the possibility that this finding may be partially artifactual. It is logistically difficult to proceed with definitive local treatment within 2 to 3 weeks of diagnosis. Thus, regardless of whether a patient intended to wait for test results or not, the more quickly those test results became available, the more likely it is that that patient would have received the results before having an opportunity to proceed with definitive local treatment. This situation was likely the case for some participants. However, the strong effect of genetic test result on definitive local treatment decisions (11) suggests that many participants did indeed wait for their test results to guide their final local treatment choice.

We also found that participants who were most anxious were also most likely to wait for genetic test results before proceeding with definitive local treatment. This is consistent with previous research suggesting that anxiety may motivate participation in genetic testing (18-20). However, it is also plausible that anxiety may be a consequence of genetic testing rather than a cause. For example, patients who chose to await test results before proceeding with their treatment may have experienced anxiety in anticipation of their test result and the uncertainty associated with their treatment status (32). This is consistent with conceptual models that emphasize the role of uncertainty in the adjustment to genetic testing (33). Regardless of whether anxiety is a cause or consequence of genetic testing decisions, anxiety can serve as barrier to informed medical decision making (34) and risk comprehension (35). Thus, future research must further evaluate the role of anxiety in this context.

Generalizability of this study is limited by participant self-selection, the provision of genetic counseling/testing free of charge, and the lack of diversity of our sample. The most important limitation is that we do not know how many eligible patients chose not to refer to the study. Without this true denominator, any conclusions regarding level of interest or characteristics of patients who seek pretreatment BRCA1/BRCA2 counseling and testing must be considered preliminary. Clinically, it would be premature to recommend genetic

testing at the time of initial diagnosis before there are data evaluating the effect of testing on subsequent patient quality of life. Although evidence suggests few adverse effects of BRCA1/BRCA2 testing among breast cancer survivors (36, 37), the unique concerns and stresses of newly diagnosed breast cancer patients make it difficult to extrapolate from previous studies. Future research can address these limitations by replicating these results in a clinical setting in which a true denominator of eligible patients can be characterized.

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