VOLUME 29 · NUMBER 32 · NOVEMBER 10 2011

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Long-Term Reactions to Genetic Testing for *BRCA1* and *BRCA2* Mutations: Does Time Heal Women's Concerns?

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Submitted October 7, 2010; accepted August 9, 2011; published online ahead of print at www.jco.org on October 11, 2011.

Supported by National Human Genome Research Institute Grants No. P50HG004487 and R01HG004346.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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0732-183X/11/2932-4302/$20.00

DOI: 10.1200/JCO.2010.33.1561

ABSTRACT

Purpose
Short-term reactions to *BRCA1* and *BRCA2* (*BRCA1/2*) genetic test results have been described in several reports, but the long-terms effects of testing have not been examined extensively.

Methods
We conducted an observational study to characterize the long-term impact of genetic testing for *BRCA1/2* mutations in 167 women who had received genetic test results at least 4 years ago. We also evaluated the relationship between genetic testing–specific reactions and breast and ovarian cancer screening to determine the behavioral significance of adverse reactions.

Results
Seventy-four percent of women were not experiencing any distress regarding their test result, 41% were not experiencing any uncertainty, and 51% had a score for positive experiences that was suggestive of low levels of adverse reactions in terms of family support and communication. Mutation carriers (odds ratio, 3.96; 95% CI, 1.44 to 10.89; $P = .01$) were most likely to experience distress. Only less time since disclosure was related significantly to experiencing uncertainty (odds ratio, 0.62; 95% CI, 0.44 to 0.88; $P = .008$). In terms of cancer screening, 81% of women had a mammogram during the year before study enrollment, 25% had magnetic resonance imaging (MRI), 20% had a transvaginal ultrasound, and 20% had a CA-125. Experiencing distress was associated significantly with having a CA-125 ($\chi^2 = 3.89$, $P = .05$), and uncertainty was associated with having an MRI ($\chi^2 = 8.90$, $P = .003$).

Conclusion
Our findings show that women are not likely to experience genetic testing concerns several years after receiving *BRCA1/2* test results; distress and uncertainty are not likely to have adverse effects on screening among women at risk for hereditary disease.

J Clin Oncol 29:4302-4306. © 2011 by American Society of Clinical Oncology

INTRODUCTION

One of the most significant advancements in cancer genetics is the discovery of susceptibility genes for breast cancer and the availability of genetic testing for *BRCA1* and *BRCA2* (*BRCA1/2*) mutations. Understanding the psychological consequences of genetic testing for *BRCA1/2* mutations has been a key clinical question since testing became available; early findings demonstrated that adverse reactions to receiving positive test results are short lived, if they are experienced at all, and receiving negative results may reduce anxiety and depression symptoms in some women.[1,2] More recent work has shown that receiving positive *BRCA1/2* results may generate specific concerns related to the clinical and psychological integration of genetic risk information.[3] Mutation carriers reported significantly greater distress (eg, anxiety, sadness) and uncertainty (eg, understanding options for cancer prevention and early detection, difficulty making decisions about screening and prevention) compared with women who received negative or uncertain results.[3] Because decisions about screening and uptake of prophylactic surgery may unfold over time,[4,5] it is possible that these concerns persist for years after test results disclosure. Despite this, most studies have evaluated psychological reactions for only approximately 1 year after test results disclosure,[6] and to our knowledge, only one international study has evaluated psychological functioning among mutation carriers for longer periods of time.[7]

To address this gap, we conducted an observational study to evaluate the long-term impact of genetic testing for *BRCA1/2* mutations. In contrast to previous research that focused on general psychological functioning,[7] our aim was to examine the presence of genetic testing–specific concerns in

women in whom it has been at least 4 years since results were disclosed. We were also interested in determining the extent to which these concerns varied among women based on their sociodemographic background, medical history, and clinical experiences. We also examined the behavioral significance of genetic testing–specific concerns by evaluating the relationship between utilization of screening tests for breast and ovarian cancer and these reactions.

METHODS

Study Population

This research was approved by the institutional review board at the University of Pennsylvania (Philadelphia, PA). Participants were women who were evaluated through one of two clinical and research programs at the University of Pennsylvania. These programs included the Cancer Risk Evaluation Program (CREP) and a genetic counseling research program that was developed specifically for African American women (With Our Voices).[8,9] All women received individual pretest counseling, test result disclosure, and immediate postdisclosure follow-up by board-certified genetics counselors. In addition, women met with physicians with training in cancer genetics to discuss medical management options and were given a written summary of their family history, test results, and recommendations for medical management. Some women had continued follow-up with CREP; these women included *BRCA1/2* mutation carriers and those at high risk for breast or ovarian cancer without mutations who wished to have a CREP physician coordinate their surveillance. With the exception of a brief intervention that examined the utility of a decision support system in 32 *BRCA1/2* mutation carriers enrolled onto the CREP program,[10] women did not receive ancillary interventions as part of the clinical or research programs. Women were also offered psychological counseling from mental health professionals when clinically indicated. The sample consisted of 167 women who were age 25 years and older and had received their *BRCA1/2* test results between 1995 and 2005.

Procedures

Women who were at least 4 years after disclosure of results were identified from the databases of the programs described earlier. After identification, women were mailed an introductory letter that described the purpose of the study and procedures involved in participation. The introductory letter included a response card for women to return if they were not interested in being contacted about the study. Women who did not opt out of enrollment were contacted by telephone by a research assistant from the University of Pennsylvania. During this contact, the purpose of the study was reviewed, and verbal consent for enrollment was obtained using a standardized script. After obtaining verbal consent, a 40-minute telephone interview was completed to evaluate screening behaviors and genetic testing–specific concerns. Among women who had a working telephone number (n = 360), 53 declined participation, 51 could not be reached after multiple attempts, 41 were pending contact, and 215 (60%) were enrolled. Our study included 167 enrolled women who received *BRCA1/2* test results.

Measures

Sociodemographics. Age, race, marital status, education, employment, and income were obtained by self-report during the telephone interview.

Medical history and clinical experiences. Information on personal history of cancer was obtained by self-report using items from our previous research.[9] Specifically, women were asked if they had a personal history of cancer, and we categorized them as having a history of breast cancer, a history of other types of cancer, or no cancer history. Women were also asked if they had their breasts or ovaries removed (yes or no).

Genetic testing variables. Women were asked if they had received their *BRCA1/2* test results (yes or no) and if their results were positive or negative or had uncertain clinical significance. There was 100% agreement between self-reported test results and the results recorded in clinic records. We calculated the amount of time between test result disclosure and completion of the interview using disclosure dates from clinic records. For the small number of women (n = 11) who had additional testing (eg, BRACAnalysis Rearrangement Test; Myriad Genetics, Salt Lake City, UT) after their first disclosure, we used the original disclosure date to calculate the amount of time between enrollment and disclosure because their results did not change.

Cancer screening. We evaluated utilization of breast and ovarian cancer screening by asking women to report the date of their last mammogram, CA-125, and transvaginal ultrasound (TVU). Because breast magnetic resonance imaging (MRI) was not routinely covered by insurance before 2005, data on MRI use were obtained from clinic records and were available for 122 women (73%). As in previous research,[11,12] women who had a mammogram during the year before study enrollment were categorized as being adherent, and women who did not have this screening at all or whose last screening was more than 1 year ago were categorized as being nonadherent. We used this same procedure to characterize utilization of CA-125, TVU, and MRI. Because clinic data on MRI were collected more recently, some women (n = 22) reported having an MRI within 1 to 1.5 years after study enrollment. We categorized women who had an MRI $\leq$ 1 year after study enrollment as being adherent, and women whose MRI was obtained more than 1 year after study enrollment were categorized as being nonadherent.

Genetic testing–specific concerns. We used the Multidimensional Impact of Cancer Risk Assessment (MICRA)[3] to evaluate genetic testing–specific concerns. The MICRA is a validated instrument that evaluates genetic testing–specific concerns. Previous research has shown that the MICRA is superior to other scales (eg, Impact of Events Scale) in terms of distinguishing *BRCA1/2* mutation carriers from noncarriers in terms of adverse psychological responses to genetic test results.[3] The instrument consists of three subscales that measure concerns related to the psychological, behavioral, and clinical integration of *BRCA1/2* test results. The distress scale evaluated adverse psychological reactions (eg, sadness, anxiety, nervousness) about one's *BRCA1/2* test result, and the uncertainty scale measured the extent to which women were experiencing difficulty making decisions about cancer screening, uncertainty about their cancer risk, and whether or not options for risk management and prevention were understood. Items for the positive experiences scale are recoded so that scores reflect adverse reactions in terms of lack of family support during counseling and testing, dissatisfaction with family communication, and not being relieved or happy about one's *BRCA1/2* test result. All scales had good internal consistency in our sample (Cronbach's α = .87 for distress, .84 for uncertainty, and .82 for positive experiences).

Data Analysis

First, we generated descriptive statistics to characterize women in terms of sociodemographics, medical history, clinical experiences, *BRCA1/2* test results, and genetic testing concerns. Next, we conducted bivariate analyses to evaluate the association between genetic testing concerns and these variables. We used this same approach to evaluate the relationship between test-specific concerns and cancer screening. Finally, we used regression analyses with generalized estimating equations to identify factors having significant independent associations with genetic testing concerns while controlling for potential familial clustering. Variables that had a bivariate association of $P < .10$ with each outcome were included in the regression model for that variable.

RESULTS

Sample Characteristics

Table 1 lists the characteristics of the women in our sample. Forty percent of women were mutation carriers, and 60% were *BRCA1/2* negative. Overall, levels of genetic testing–specific concerns were low. Distress scores ranged from 0 to 26, and 74% of women reported no distress (eg, distress score was 0). Uncertainty scores ranged from 0 to 38, and 41% of women reported no uncertainty (eg, uncertainty score was 0). Scores for positive experiences ranged from 0 to 20, and 51% of women reported a score that was suggestive of low levels of adverse reactions in terms of lack of family support, dissatisfaction with family communication, and no positive reactions to their *BRCA1/2* test result

Table 1. Demographics and Clinical Characteristics of the Women in the Sample

Demographic or Clinical Characteristic	No. of Women (N = 167)	%
Time since test result disclosure, years*		
Mean	7.2	
Standard deviation	2.2	
Median	7.0	
BRCA1/2 test result		
Positive	67	40
Negative/ambiguous	100	60
Race		
White	159	95
African American	8	5
Marital status		
Married	140	84
Not married	27	16
Education level		
College graduate	144	86
≤ Some college	23	14
Employment status		
Employed	104	62
Not employed	63	38
Income level†		
≥ $75,000	119	80
< $75,000	30	20
Cancer history		
Breast cancer	84	50
Other cancer	17	10
No cancer	66	40
Breast removed		
Yes	77	46
No	90	54
Ovaries removed		
Yes	90	54
No	77	46
Age, years		
Mean	54.2	
Standard deviation	9.8	

NOTE. There were 12 cases in which women were from the same family, and the average family size was 1.0.
*Test result disclosure occurred between 1995 and 2005.
†Eighteen women were missing data for income.

Table 2. Bivariate Analysis of Genetic Testing Concerns

Variable	Distress		Uncertainty	
	% Distress	χ^2	% Uncertain	χ^2
Sociodemographic factors				
Race				
White	26	0.01	58	0.05
African American	25		62	
Marital status				
Married	26	0.18	58	0.24
Not married	30		63	
Education level				
College graduate	25	0.98	59	0.05
≤ Some college	35		56	
Employment status				
Employed	26	0.02	60	0.41
Not employed	27		56	
Income level				
≥ $75,000	23	1.45	59	0.01
< $75,000	33		60	
Age, years†				
Yes				
Mean	50.8	2.72†‡	52.6	2.43†§
SD	9.6		9.3	
No				
Mean	55.4		56.3	
SD	9.6		9.9	
Genetic testing and clinical variables				
BRCA1/2 test result‖				
Positive	45	19.58¶	64	1.39
Negative/ambiguous	14		55	
Cancer history				
Breast cancer	23	4.92#	56	2.34
Other cancer	12		47	
No cancer	35		65	
Breast removed				
Yes	26	0.01	57	0.14
No	27		60	
Ovaries removed				
Yes	34	6.59‡	61	0.47
No	17		56	

Abbreviation: SD, standard deviation.
*Yes indicates experiencing distress or uncertainty; no indicates not experiencing distress or uncertainty.
†*t* value.
‡$P < .01$.
§$P < .05$.
‖The mean level of distress was 3.9 (SD, 6.6) in mutation carriers and 0.74 (SD, 2.4) in women negative for mutations. The mean level of uncertainty was 6.8 (SD, 8.4) in mutation carriers and 4.3 (SD, 6.0) in women negative for mutations. The mean level for positive experiences was 14.8 (SD, 5.7) in mutation carriers and 14.3 (SD, 7.1) in women negative for mutations.
¶$P < .001$.
#$P < .10$.

(eg, positive experiences scores ranged from 0 to 19). Because more than half of the sample did not report experiencing any distress and 43% reported no uncertainty, we created a dichotomous variable (yes or no) for experiencing distress and uncertainty for subsequent analyses. We used this same approach to create a dichotomous variable for positive experiences because 51% of women reported a score of 0 to 19 and 49% reported a score of 20, which suggested the most difficulty with family communication and support.

Bivariate Analysis of Genetic Testing–Specific Reactions

The results of the bivariate analysis of genetic testing concerns are listed in Table 2. Receiving positive *BRCA1/2* test results, having had one's ovaries removed, and younger age were significantly associated with experiencing distress. There were also differences in experiencing distress between women who had different types of negative *BRCA1/2* test results (n = 100). Women from a family with a known *BRCA1/2* mutation were significantly more likely to experience distress (30%) compared with women who were not from a family with a known mutation (10%; $\chi^2 = 5.32$, $P = .02$). There was also a nonsignificant association between distress and cancer history ($\chi^2 = 4.92$, $P = .08$). Time from disclosure was not associated significantly with experiencing distress ($t = 1.12$, $P = .27$).

None of the clinical variables or *BRCA1/2* test results were associated significantly with experiencing uncertainty. There were also no

differences in uncertainty between women with informative or uninformative negative results ($P = 1.00$). However, women who were experiencing uncertainty had received their results more recently (mean, 6.7 years; standard deviation, 2.1 years) compared with women who were not experiencing uncertainty (mean, 7.8 years; standard deviation, 2.3 years; $t = 3.23$, $P = .002$). Younger age also had a significant association with experiencing uncertainty. None of the other sociodemographic characteristics were significantly associated with experiencing uncertainty or distress.

With the exception of age, none of the sociodemographic variables, genetic testing variables, or clinical experiences had a significant association with scores for positive experiences (data not shown). Women who were older were most likely to experience these reactions ($t = -2.48$, $P = .01$).

Multivariate Regression Analysis of Genetic Testing–Specific Concerns

The results of the final multivariate regression models for distress and uncertainty are listed in Table 3. We did not generate a model for positive experiences. Because unaffected women were more likely to experience distress compared with women who had a personal history of cancer, we created a dichotomous variable for cancer history (no cancer history *v* personal history of disease) for the regression analysis. We also recoded age into a binary variable to facilitate interpretation. We tested the interaction between *BRCA1/2* test results and cancer history, but it was not significant ($P = .09$). Therefore, we removed it from the final model. Only the effect for *BRCA1/2* test results was significant; mutation carriers were most likely to experience distress. We reran the distress model controlling for the amount of time between test result disclosure and completion of the interview, and the results were unchanged (data not shown). Only less time since test result disclosure had a significant effect on uncertainty.

Table 3. Final Multivariate Regression Model of Experiencing Genetic Testing–Specific Distress and Uncertainty

Variable	Odds Ratio	95% CI	*P*
Distress			
BRCA1/2 test result			
Positive	3.96	1.44 to 10.89	.01
Negative			
Cancer history			
Unaffected	1.84	0.82 to 4.12	.14
Personal history			
Ovaries removed			
Yes	1.21	0.40 to 3.61	.73
No			
Age, years			
≤ 50	1.89	0.82 to 4.37	.14
> 50			
Uncertainty			
Age, years			
≤ 50	1.69	0.79 to 3.61	.17
> 50			
Time since disclosure*			
Continuous	0.62	0.44 to 0.88	.008

*Odds ratio reflects the increase in the odds associated with a 1 standard deviation increase in the continuous measure of time since test results disclosure.

Analysis of Screening Outcomes

To determine the behavioral significance of experiencing adverse reactions to *BRCA1/2* results, we evaluated the relationship between these concerns and breast and ovarian cancer screening. These analyses were limited to women who had at least one intact breast (n = 110) or ovary (n = 78); the sample size was 79 women for MRI and 77 women for TVU. Eighty-one percent of women had a mammogram, and 25% had an MRI. In terms of ovarian cancer screening, 20% had a CA-125, and 21% had a TVU. Distress was not associated with having a mammogram ($\chi^2 = 0.20$, $P = .65$), MRI ($\chi^2 = 0.97$, $P = .32$), or TVU ($\chi^2 = 1.36$, $P = .24$). However, women who were experiencing distress were more likely to have had a CA-125 (42%) compared with women who were not experiencing distress (17%; $\chi^2 = 3.89$, $P = .05$). Uncertainty was also not associated significantly with having a mammogram ($\chi^2 = 0.23$, $P = .63$), TVU ($\chi^2 = 1.36$, $P = .24$), or CA-125 ($\chi^2 = 0.01$, $P = .92$), but women who were experiencing uncertainty (37%) were significantly more likely to have an MRI compared with women who were not experiencing this reaction (7%; $\chi^2 = 8.90$, $P = .003$). Positive experiences were not associated with any of the screening variables. In addition, with the exception of mammography, mutation carriers were significantly more likely than women with negative results to have breast and ovarian cancer screening (data not shown).

DISCUSSION

To our knowledge, this is the first US study to evaluate the long-term impact of genetic testing for *BRCA1/2* mutations in women more than 1 year after test results disclosure. Overall, distress and uncertainty were low; 74% of women did not experience any distress, and 41% of women did not experience any uncertainty. In addition, 51% of women reported low levels of adverse reactions in terms of no family support, dissatisfaction with family communication, and positive reactions to their *BRCA1/2* test result. Although mutation carriers were most likely to report distress, our findings demonstrate that women who experience these reactions are not likely to be adversely affected in terms of cancer screening. There were no differences in mammography or TVU based on genetic testing concerns. However, women who were experiencing distress were significantly more likely to have a CA-125 compared with women who were not experiencing distress, and women who were experiencing uncertainty were most likely to have an MRI. *BRCA1/2* test results were also important to screening; with the exception of mammography, mutation carriers were significantly more likely than women with negative results to have breast and ovarian cancer screening.

Recent reports have described the effects of adjunctive psychosocial and decision-making support programs for *BRCA1/2* mutation carriers,[13,14] but our findings raise questions about the need for these interventions. Although mutation carriers were most likely to experience distress, the level reported by carriers in our sample was 3.9 compared with 6.7 in a sample of carriers who had received their test results during the past month.[3] A recent meta-analysis found that distress among carriers and noncarriers decreased over time during a 1-year period. It could be that not only are women unlikely to experience adverse reactions such as distress several years after receiving *BRCA1/2* test results, but also these concerns may dissipate over time after pretest counseling, test results disclosure, and postdisclosure follow-up.[15] In light of our findings, it is important to ask whether

postdisclosure programs are needed to reduce distress and minimize uncertainty about risk and management options. Because we did not evaluate utilization of psychological or psychiatric services among women in our study, it is not possible to rule this out as an explanation for the low levels of adverse reactions in our sample. Women may be referred to mental health services when indicated as part of genetic counseling; it could be that these services are used as the need arises after disclosure. However, the prevalence of psychiatric symptoms and clinical distress is low among high-risk women,[16] and other work has shown that mutation carriers are not likely to use counseling services after disclosure.[17] Thus, it is not likely that use of mental health services explains the low levels of adverse reactions to *BRCA1/2* test results in our sample. In settings where appropriate pre- and post-test counseling is provided and medical recommendations are given by a qualified physician with expertise in cancer genetics, these resources may be sufficient to help women cope with and integrate genetic risk information effectively. However, recent research has shown that some carriers benefit from postdisclosure interventions that address concerns such as making medical decisions and managing psychological reactions.[13,14] Our findings suggest that it may be useful to evaluate reactions to *BRCA1/2* test results several years after disclosure and to offer postdisclosure interventions to women who carry *BRCA1/2* mutations.

Our findings should be considered within the context of some limitations, which include a modest response rate (60%) and a homogeneous sample in terms of racial background and other sociodemographic characteristics. This may explain the lack of variation in genetic testing concerns. However, our sample is similar to those included in other research that evaluated uptake of *BRCA1/2* test results.[18] An additional limitation may be that all of the participants in this study were evaluated for genetic counseling and testing through comprehensive programs that provided ongoing follow-up care and, in some instances, coordinated medical services to all interested women found to carry *BRCA1/2* mutation and those at high risk due to strong family history. Further, when clinically indicated, individuals were offered psychological services from mental health professionals. Future studies should evaluate genetic testing concerns in diverse populations who have had testing in different settings. As part of this research, it is important to determine the extent to which scores for adverse reactions in terms of positive experiences are associated with family communication and relationships after genetic testing.

Despite these potential limitations, our study demonstrates that women are unlikely to experience genetic testing concerns several years after receiving *BRCA1/2* test results. However, mutation carriers may still experience distress, and identifying women who could benefit from further psychosocial support remains an important goal. Future research is needed to determine the level and types of support that may be most useful several years after genetic counseling and testing and to develop a model of care within which it can be provided. It will also be important to evaluate receptivity to support programs that are offered to women several years after *BRCA1/2* test results are disclosed.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design: Chanita Hughes Halbert, Susan Domchek
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