Original Article

Knowledge Regarding and Patterns of Genetic Testing in Patients Newly Diagnosed With Breast Cancer Participating in the iCanDecide Trial

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Background: The current study reports rates of knowledge regarding the probability of a *BRCA1* and/or *BRCA2* pathogenic variant and genetic testing in patients with breast cancer, collected as part of a randomized controlled trial of a tailored, comprehensive, and interactive decision tool (iCanDecide). **Methods:** A total of 537 patients newly diagnosed with early-stage breast cancer were enrolled at the time of their first visit in 22 surgical practices, and were surveyed 5 weeks (496 patients; Response Rate [RR], 92%) after enrollment after treatment decision making. Primary outcomes included knowledge regarding the probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant and genetic testing after diagnosis. **Results:** Overall knowledge regarding the probability of having a *BRCA1* and/or *BRCA2* pathogenic variant was low (29.8%). Significantly more patients in the intervention group compared with the control group had knowledge regarding the probability of a *BRCA1* and/or *BRCA2* pathogenic variant (35.8% vs 24.4%; $P < .006$). In multivariable logistic regression, the intervention arm remained significantly associated with knowledge regarding the probability of having a *BRCA1* and/or *BRCA2* pathogenic variant (odds ratio, 1.79; 95% confidence interval, 1.18-2.70). **Conclusions:** The results of the current study suggest that although knowledge concerning the probability of having a *BRCA1* and/or *BRCA2* pathogenic variant remains low in this patient population, the interactive decision tool improved rates compared with a static Web site. As interest in genetic testing continues to rise, so will the need to integrate tools into the treatment decision process to improve informed decision making. ***Cancer* 2018;124:000-000** © *2018 American Cancer Society*

KEYWORDS: BRCA1 and/or BRCA2, breast cancer patients, decision making, decision tool, diagnosis, genetic testing, knowledge, probability information

INTRODUCTION

Advances in genetic technology, particularly multigene panel testing, have increased the clinical diagnostic and therapeutic uses of genetic testing in patients with breast cancer. However, results from multigene panel testing add to already difficult decisions regarding next steps in clinical care soon after a breast cancer diagnosis. The addition of multigene panel testing to the decision-making process requires additional knowledge, consideration, and the application of genetic risk information for the various treatment options. Given the association between genetic testing outcomes and treatment use, knowledge is critical. Nevertheless, patient knowledge regarding breast cancer genetics and the implications of genetic test results for different treatment options is low,[1,2] further widening the gap between the availability of more expansive genetic testing and the usefulness of the results from genetic testing in treatment decision making.[3–6]

To the best of our knowledge, few tools have been developed for breast cancer–related decision making that address important aspects of genetic testing on the implications of test results for the treatment of individuals already diagnosed.[7] This is particularly concerning given that a previous study found that the most commonly reported immediate postdiagnosis concerns are treatment and prognosis, followed by the probability of developing a second cancer and the probability of family members developing cancer.[8] Knowledge regarding the probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant, as well as the uses and benefits of genetic testing, in individuals with a family history of breast and ovarian cancer have been well described.[9,10] However, to our knowledge, only 3 tools have been designed specifically for women

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DOI: 10.1002/cncr.31731, **Received:** March 26, 2018; **Revised:** June 22, 2018; **Accepted:** July 13, 2018, **Published online** Month XX, 2018 in Wiley Online Library (wileyonlinelibrary.com)

Additional supporting information may be found online in the Supporting Information section at the end of the article.

with a pathogenic variant, or those already diagnosed with breast cancer.[11–13] Furthermore, we also believe that knowledge regarding the probability of *BRCA1* and/or *BRCA2* pathogenic variants and concerning the benefits and purpose of genetic testing in relation to treatment has not yet been assessed in patients with breast cancer after diagnosis. Few studies have formally evaluated the role of genetic testing in breast cancer treatment decision tools after a diagnosis of breast cancer. Because to our knowledge there is no consensus regarding what should be covered across the various phases of the genetic testing process (eg, health-related decision making, dissemination of results to family members), many tools lack important themes relevant to different points in the process.[11,14,15]

The purpose of the current analysis, which was conducted after the successful completion of a large randomized controlled trial assessing the effect of a decision tool (iCanDecide) on decision making for the treatment of locoregional breast cancer, was 2-fold. First, we sought to determine whether patients with breast cancer who viewed the intervention version of iCanDecide would have higher rates of knowledge regarding *BRCA1* and/or *BRCA2* pathogenic variant probabilities, the benefits of breast cancer genetics, and the implications of test results for treatment compared with those who viewed the control version. Second, we aimed to describe patterns of genetic testing use among participants in the iCanDecide study, who were recruited from community-based surgical practices in several states.

MATERIALS AND METHODS

Study Design and Patient Recruitment

The current study reports a secondary analysis of data collected as part of a randomized controlled trial of a tailored, comprehensive, and interactive decision tool (iCanDecide) compared with static online information.[16] The iCanDecide protocol and primary outcomes analyses have been published previously.[16,17] A total of 537 newly diagnosed patients with early-stage (AJCC stage 0-II) breast cancer who were aged 21 to 84 years were enrolled at the time of their first visit in 22 surgical practices in 4 states (California, Georgia, Michigan, and Tennessee). After receiving an introduction packet from the surgical practices, participants consented online; completed a short survey; and were allocated to a study arm using randomization stratified by site, age, race, educational level, and timing of the surgical consult. Eligible and consenting patients within each practice were randomized to the intervention (tailored and interactive) or control (static information) version of the iCanDecide Web site. The primary outcome was a high-quality locoregional treatment decision (defined as an informed decision that was concordant with the patient's values), with knowledge regarding genetic testing serving as a secondary outcome. Both were assessed from the time of the first follow-up survey, which was mailed 4 to 5 weeks (496 patients; RR, 92%) after enrollment. A rigorous posttest design comparing the intervention with the control group with regard to primary and secondary outcomes was used to increase engagement with the Web site and reduce the burden on the respondents associated with required baseline questions (iCanDecide intervention Web site available at: https://cansort.med.umich.edu/research/tools-and-resources/).[18]

Measuring Genetic Testing Knowledge

For the first objective of this analysis, the primary patient-reported outcomes measured included accurate knowledge regarding aspects of genetic testing: 1) the probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant (correct/incorrect/did not know); and 2) the benefits and purposes of genetic testing after a diagnosis of breast cancer.

Knowledge regarding the probability of carrying a BRCA1 and/or BRCA2 pathogenic variant

Knowledge regarding the probability of carrying a pathogenic variant was measured using an item designed by the study team. Participants were asked: "Out of 100 women diagnosed with breast cancer, how many have a pathogenic variant in the breast cancer genes *BRCA1* and/or *BRCA2*?" Response options included: "few (0-10 women)," "some (11-25 women)," "quite a few (26-50 women)," "many (51-75 women)," "most (76-100 woman)," or "don't know." Responses were categorized as "correct" for participants who selected "few (0-10 women)" and "incorrect" or "don't know" for all other endorsed response options.

Knowledge regarding the benefits and purposes of genetic testing after a diagnosis of breast cancer

Knowledge regarding the benefits and purposes of genetic testing was measured using 3 questions developed and pilot tested by our clinical team to be consistent with the existing knowledge scales for locoregional and systemic treatment also being used in this randomized controlled trial.[16,19]

Participants were asked if the purposes of genetic testing included deciding how to treat, determining the probability of a new breast cancer, the prevention of future cancers, and informing family members of their risk

TABLE 1. Description of Participant Characteristics

Characteristic	Control Arm (n=270) N (%) or mean (SD)	Intervention Arm (n=267) N (%) or mean (SD)	*p*-value
Age	57.03 +/- 10.88 (270)	56.52 +/- 10.72 (267)	0.59
Race			0.89
White	212 (79%)	210 (79%)	
Black	45 (17%)	42 (16%)	.
Other	13 (5%)	15 (6%)	.
Education			0.89
High school graduate or less	58 (21%)	57 (21%)	
Some college/ college graduate	145 (54%)	148 (55%)	.
Some/completed graduate school	67 (25%)	62 (23%)	.
Married/Partnered			0.08
No	83 (31%)	64 (24%)	
Yes	187 (69%)	203 (76%)	.

of breast cancer. Details regarding the survey questions are provided in Supporting Information Table 1.

Patterns of Testing in the iCanDecide Sample

At the follow-up survey, participants were asked to provide information regarding genetic tests that they might have undergone as part of the diagnosis or treatment of breast cancer or for cancer risk. Participants were provided a brief description of the purpose of genetic testing. Next, respondents were asked, "Did a doctor or other health professional talk with you about having a genetic test for breast cancer risk?" (yes/no/do not know), "Did you have a counseling session with a genetic counseling expert–that is, an appointment where the whole or most of the discussion is about genetic risk for breast cancer?" (yes/no/do not know), and "How much did you want to have a genetic test to tell you the risk of you or your family developing new cancers in the future?" (5-point scale from "not at all" to "very much"). Participants then were asked, "Have you ever had a blood or saliva genetic test for breast cancer risk that was ordered by a doctor?" If the participant endorsed that they undergone a doctor-ordered blood or saliva genetic test for breast cancer, they were asked about their perception regarding why the test was ordered, if they had the testing before or after their diagnosis, and the result of the genetic testing. However, the exact timing of testing or counseling relative to the intervention was not known because participants could have been tested before or after viewing the Web site. Participants who did not have a physician order a multigene panel test were asked to select why they did not undergo genetic testing for breast cancer.

Patient Factors

Patient characteristics were obtained from patient report at the time of log in and included age, race, educational level, and partnership status. The initial survey also assessed whether the patient had seen her surgeon yet (yes/no).

Statistical Analysis

To assess genetic testing knowledge, we followed a prespecified analytic plan[17] to assess whether rates of knowledge regarding both knowledge measures (probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant and knowledge regarding the benefits and purposes of genetic testing after being diagnosed with breast cancer) were higher among the intervention compared with the control participants. Preliminary analyses to explore combining all items into one knowledge scale did not indicate that one scale was appropriate. Internal consistency (Cronbach alpha, .65) suggested that internal reliability was not ideal, even after removing items with consistently low correlations (correlation coefficient [*r*] <3).

We used chi-square tests and testing was 2-sided, with a *P* value <.05 considered to be statistically significant. Participants with missing values regarding the outcome measures or covariates (<5%) were excluded from the analysis. In post hoc analyses, we used logistic regression to model the association between study condition and both dichotomous knowledge outcomes adjusting for patient factors that were significant in bivariate analyses as well as study site.

To describe patterns of genetic testing in this clinical sample, we generated descriptive statistics regarding

patterns of genetic testing and discussion, reasons for the provider-ordered genetic test, and participant-reported result of the testing.

The current study is registered at ClinicalTrials.gov (ClinicalTrials.gov identifier NCT01840163).

RESULTS

Participant Characteristics

Study packets were distributed to a total of 1084 patients, 567 of whom (52.3%) visited the Web site, nearly all of whom (537 patients; 94.7%) were eligible, created an account, and completed an enrollment survey (Fig. 1).[16] The response rate to the first follow-up survey was 92% (496 patients) in the both intervention and control arms (245 patients in the intervention arm and 251 in the control arm). The study arms were balanced with regard to demographic factors (Table 1).

Genetic Testing Knowledge

Knowledge about the probability of carrying a BRCA1 and/or BRCA2 pathogenic variant

Overall, the rate of knowledge regarding the probability of having a *BRCA1* and/or *BRCA2* pathogenic variant among women diagnosed with breast cancer was low (29.8%) when measured 5 weeks after the first surgical visit and after treatment decision making had occurred. In bivariate analyses, significantly more patients in the intervention group compared with the control group had knowledge regarding their *BRCA1* and/or *BRCA2* probability (35.8% vs 24.4%; P = .006). In an adjusted multivariable model, patients who viewed

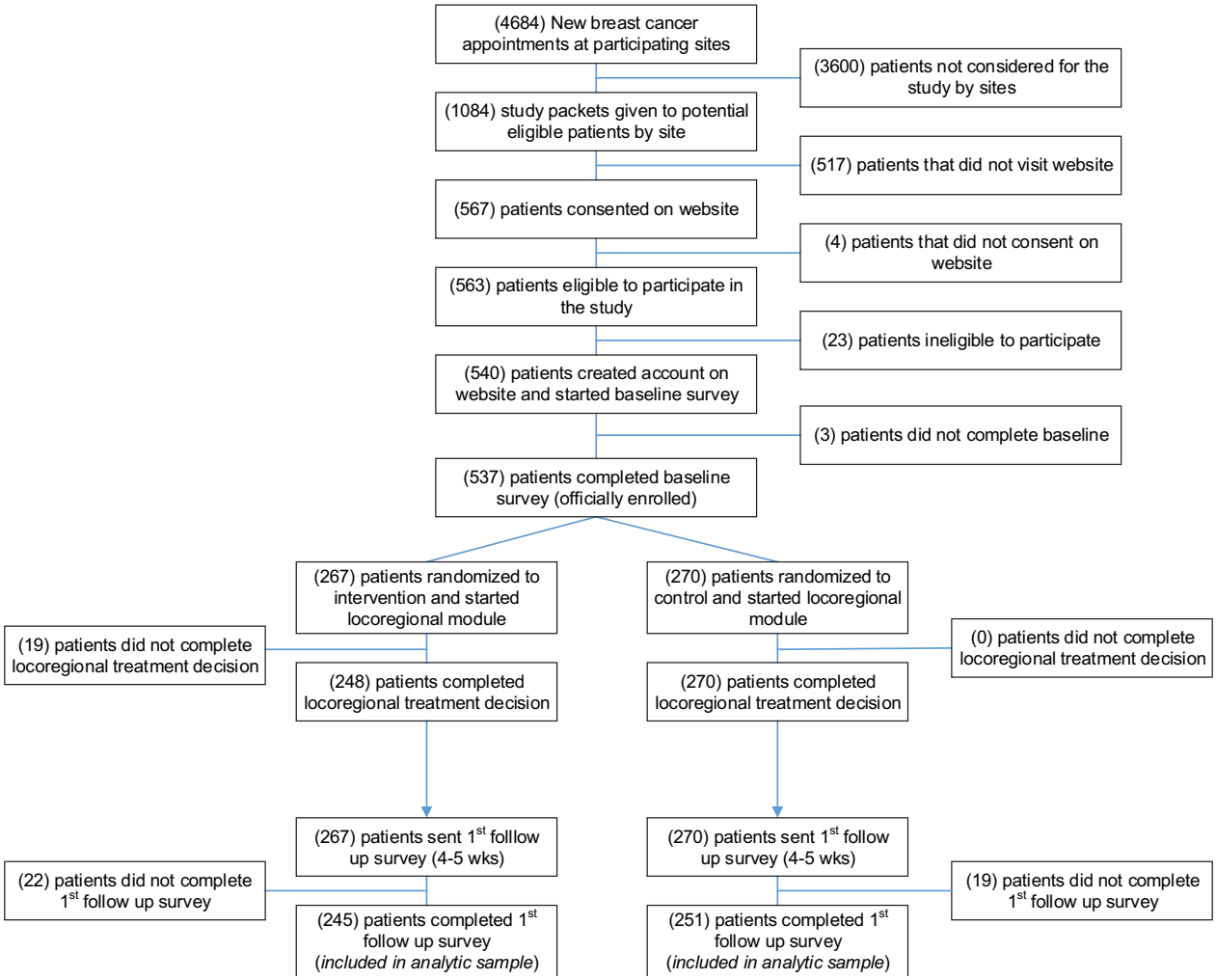

Figure 1. Patient participant recruitment diagram for the iCanDecide study.

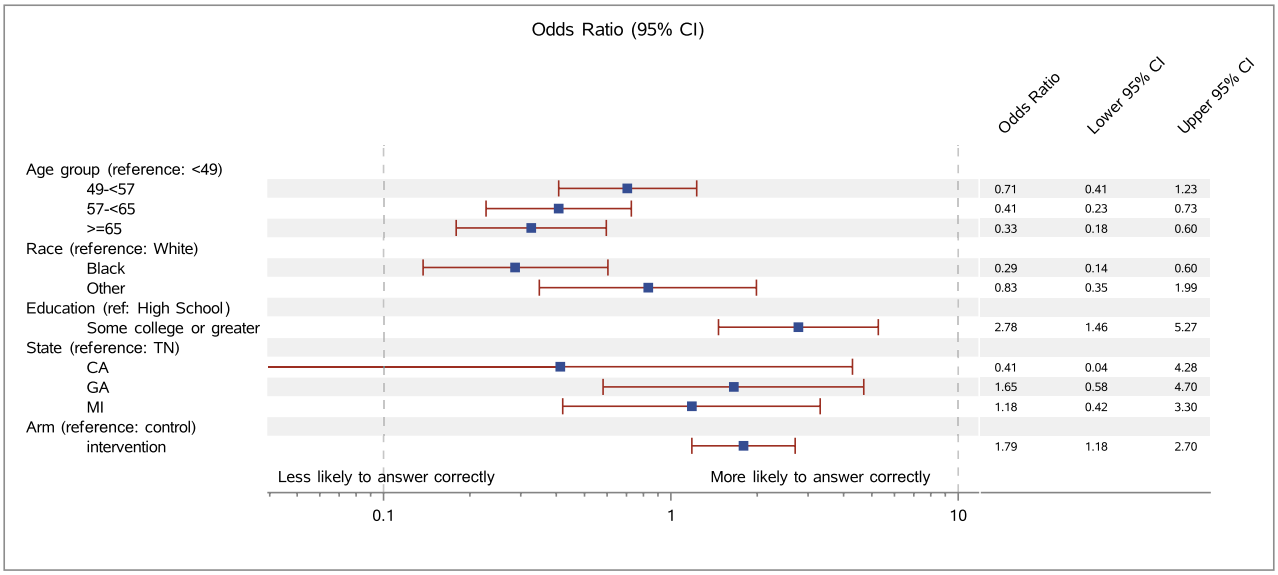

Figure 2. Results from the logistic regression model regarding the likelihood of a correct response to the knowledge question regarding the frequency of women with a pathogenic variant in *BRCA1* and/or *BRCA2* who already were diagnosed with breast cancer. 95% CI indicates 95% confidence interval; CA, California; GA, Georgia; MI, Michigan; TN, Tennessee.

the intervention had higher odds than those of the control group of correctly answering the question regarding the probability of having a *BRCA1* and/or *BRCA2* pathogenic variant (odds ratio [OR], 1.79; 95% confidence interval [95% CI], 1.18-2.70) (Fig. 2). Other factors found to be significantly associated with odds of high knowledge included higher educational levels (OR, 2.78; 95% CI, 1.46-5.27). Compared with participants who self-reported as white, black patients were less likely answer the question regarding the probability of having a *BRCA1* and/or *BRCA2* pathogenic variant correctly (OR, 0.29; 95% CI, 0.14-0.60). Older individuals were less likely than patients aged <49 years to answer this question correctly (aged 57-65 years: OR, 0.44 [95% CI, 0.23-0.73]; and aged >65 years: OR, 0.33 [95% CI, 0.18-0.60]).

Knowledge regarding the benefits and purposes of testing after being diagnosed with breast cancer

Patient knowledge regarding the benefits and purposes of genetic testing for treatment decision making generally was high (percentage correct for each question [range, 72.49%-89.20%]). In bivariate analyses, the only item for which there was a significant difference in the correct response noted between the intervention and control subjects was the question regarding whether the purpose of undergoing *BRCA1* and/or *BRCA2* genetic testing after a diagnosis of breast cancer is to help a woman know whether her family members may be at risk of developing breast cancer (95.51% vs 89.21%, respectively; *P*=.023).

This association held in multivariable logistic regression (OR, 2.75; 95% CI, 1.18-6.43) (Fig. 3). The only other factor found to be significantly associated with higher odds of knowledge of the benefits and purposes of genetic testing included higher educational level (OR, 2.78; 95% CI, 1.22-6.34). There were no differences regarding the percentage of patients answering the other knowledge questions correctly noted by study arm.

Patterns of Testing in the iCanDecide Sample

The majority of survey respondents (71%) stated that a health care professional spoke with them about undergoing a genetic test for breast cancer risk. However, fewer than one-half of respondents (42%) reported having a counseling session with a genetic counseling expert. Approximately 56% of respondents endorsed that they wanted to undergo genetic testing to learn about the risk of future cancers either "quite a bit" or "very much." The percentage of respondents who spoke with a health care professional regarding undergoing a genetic test and the percentage of respondents who endorsed that they wanted to undergo a genetic test did not appear to vary by the state in which the surgical practice was located. However, a chi-square test of goodness-of-fit determined that the frequencies of

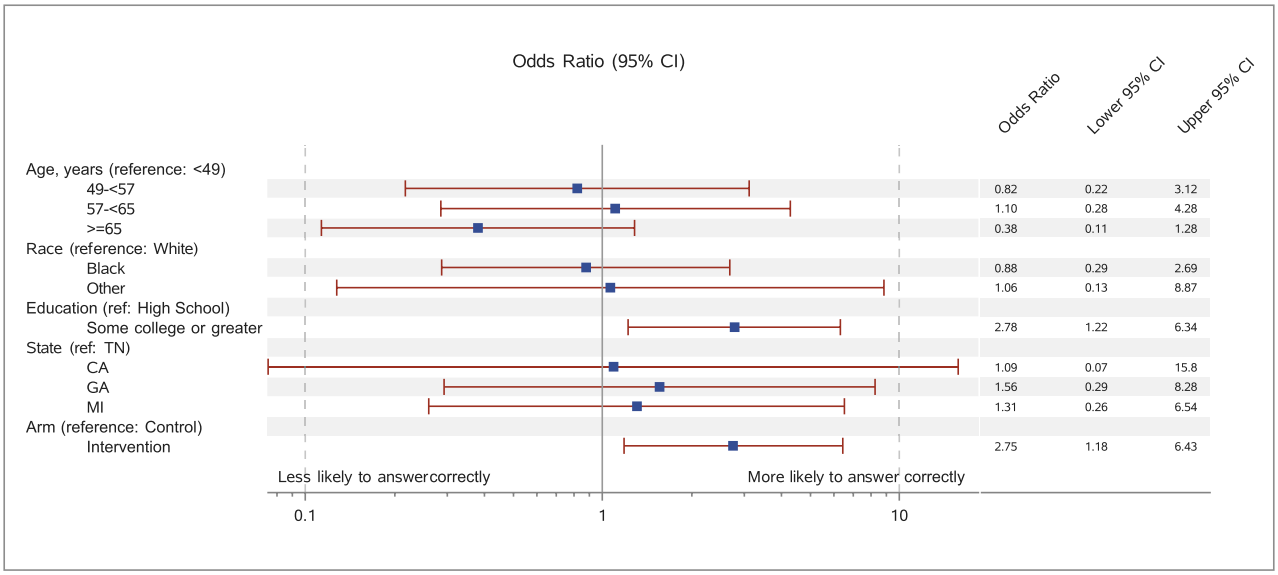

Figure 3. Results from a logistic regression model regarding the likelihood of a correct response to whether undergoing BRCA genetic testing after a diagnosis of breast cancer helps a woman know whether her family is at risk of developing breast cancer. 95% CI indicates 95% confidence interval; CA, California; GA, Georgia; MI, Michigan; TN, Tennessee.

respondents reporting having a counseling session with a genetic counseling expert was higher if the surgical practice was located within the state of Georgia compared with the other 3 states (χ^2 (9 [496 patients] = 21.14; P <.04). Among the 196 tested patients, 95.41% underwent testing after being diagnosed with breast cancer. Approximately 73% said that no pathogenic variant was detected, 3.57% stated that they had a pathogenic variant in *BRCA1* and/or *BRCA2* or another gene associated with breast cancer risk, 7.56% reported a genetic variant of uncertain significance was detected, and 8.67% did not know the results of genetic testing.

Untested participants (254 patients) who were randomized to the intervention group had higher knowledge than control subjects. However, the sample size was too small to detect an interaction between testing and assigned group in the multivariable logistic regression model.

The most commonly selected reasons for getting tested were: "My doctor thought I should" (78.57%), "I wanted to get more information about my own health" (70.41%), and "I wanted to get more information for my family member" (68.88%). Among those participants who did not undergo testing (278 patients), the most frequently endorsed reason for not having genetic testing performed was that "my doctor did not recommend it" (59.71%), a finding that was similar to previous reports (Table 2).[5]

DISCUSSION

The results of the current randomized controlled trial, which was conducted in a large clinical sample of women with a new diagnosis of breast cancer, suggest that a decision tool can improve components of knowledge regarding genetic testing. Patterns of testing in this sample were similar to those in larger population-based samples,[5] and many women reported that they had not received formal genetic counseling. Although we did not know the timing of counseling relative to study participation, this result confirms findings from population-based studies suggesting that there may be opportunities for tools to be integrated into the clinical workflow to educate patients regarding the availability and information that can result from undergoing genetic testing.[5,20] Prior studies have suggested that patients' recollection and interpretation of complex information (eg, pedigree-based hereditary likelihood) may differ from what was discussed during a genetic counseling session.[21–25] Given that verbal information during counseling alone may be inadequate, interactive decision tools are one possible way with which to enhance and improve patients' knowledge, and interpretation of information regarding *BRCA1* and/or *BRCA2* genetic testing. Therefore, the potential for online decision tools to help address patient information needs in this complex area is particularly compelling. Although not a replacement for professional advice, the findings

TABLE 2. Participant Patterns of Testing for Breast Cancer

iCanDecide survey question	Overall % Endorsed	Intervention % Endorsed	Control % Endorsed
Did a doctor or other health professional talk with you about having a genetic test for breast cancer probability ?	335 (70.97)	164 (69.79)	171 (72.15)
Did you have a counseling session with a genetic counseling expert – that is, an appointment where the whole or most of the discussion is about genetic probability for breast cancer?	203 (42.12)	99 (41.08)	104 (43.15)
How much did you want to have a genetic test to tell you the risk of you or your family developing new cancers in the future? [quite a bit or very much]	281 (56.65)	142	139
Have you **ever** had a blood or saliva genetic test for breast cancer risk that was ordered by a doctor?			
Why did you get tested:			
My doctor thought I should	154 (78.57)	79 (79.00)	75 (78.13)
I wanted to get more information about my own health	138 (70.41)	72 (72.00)	66 (68.75)
I wanted to get more information for my family members	135 (68.88)	69 (69.00)	66 (68.75)
Because of my family history	104 (53.06)	55 (55.00)	49 (51.04)
My family wanted me to be tested	20 (10.20)	11 (11.00)	9 (9.38)
Other	15 (7.65)	5 (5.00)	10 (10.42)
When did you have the test?			
Before I was diagnosed	8 (4.08)	4 (4.00)	4 (4.17)
After I was diagnosed	187 (95.41)	96 (96.00)	91 (94.79)
What was the result			
I did not have any pathogenic variants in the gene tests	144 (73.47)	72 (72.00)	72 (75.00)
I had a pathogenic variant in a gene that increases probability of breast cancer (BRCA1 or BRCA2)	7 (3.57)	5 (5.00)	2 (2.08)
A gene pathogenic variant was found, but not one that has been shown to increase risk of BrCa	15 (7.56)	5 (5.00)	10 (10.42)
I don't know the results	17 (8.67)	10 (10.00)	7 (7.29)
Other	12 (6.12)	8 (8.00)	4 (4.17)

of the current study suggest that online tools can provide a useful complement.

Although the majority of patients newly diagnosed with breast cancer are unlikely to carry a high-risk cancer pathogenic variant, the growth of testing options and increases in the accessibility of testing underscore the importance of ensuring that all individuals have accurate knowledge regarding what the test(s) do, not just those who opt to receive genetic testing.[26,27] Although overall knowledge regarding the probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant was found to be low in this population, the interactive decision tool was associated with higher knowledge concerning this probability and some of the benefits and purposes of genetics testing after being diagnosed with breast cancer when compared with a static Web site. The improvement in aspects of knowledge noted after interaction with the iCanDecide intervention demonstrates that the integration of clinical decision support tools into the breast cancer treatment decision process can provide additional support to patients. The 11.4% increase in genetic testing knowledge observed in the current study is promising, particularly because genetic testing was not the primary focus of the iCanDecide Web site. Despite this positive finding, the overall rates of knowledge even in the intervention arm were relatively low (11.4%), suggesting an opportunity for further work to improve knowledge regarding genetic testing. It is important to note that prior work assessing improvements in knowledge concerning locoregional treatment in this population similarly found the need for improvements in knowledge.[16] This work and other reports[28–30] have demonstrated that low knowledge exists in patients with breast cancer, even after treatment. Persistent low knowledge along with the

fact that it remains unclear what is clinically significant in this context underscores the need for interventions focused on enhancing knowledge using novel and engaging methods. Tools that offer the ability to link with clinicians, or the clinical system, could be useful in providing clinicians with additional opportunities to close the loop with patients, even after interacting with a decision tool.

Results from the current study indicate that patients generally have high knowledge regarding the probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant after being diagnosed with breast cancer, and we did not observe an intervention effect on this type of knowledge, with the exception of the need to test in family members. Although overall knowledge of these items may be high in patients with a new breast cancer diagnosis, the potential to influence knowledge regarding the need to test family members suggests an area in which tools may be particularly useful. However as noted above, the results of the current study suggest that there still is considerable room to improve the knowledge regarding the probability of carrying a *BRCA1* and/or *BRCA2* pathogenic variant, particularly in older individuals and patients with less education. This also is important given the implications of having a *BRCA1* and/or *BRCA2* pathogenic mutation for testing in family members, and cascade testing to identify individuals who may be at risk of developing breast cancer. Future work should address other factors that contribute to lingering knowledge deficits. These areas of enhancement include addressing emotional issues (anxiety and worry), which can contribute to the ability to truly comprehend cognitively, and providing educational materials to the provider that highlight remaining knowledge deficits.

The participants in the current study were unique in the sense that this was a clinical sample of newly diagnosed patients with breast cancer who were recruited at the time they were making their surgical treatment decision, and most likely reflects what is happening in the current clinical context. The majority of participants in the current study reported that a health care professional spoke with them about undergoing a genetic test for breast cancer risk. Our patterns of testing are similar to those in our prior recent report in a population-based sample of patients with breast cancer.[6] Nevertheless, similar to population-based data, we found that fewer than one-half of participants reported having a counseling session with a genetic counseling expert. Although sufficient pretest counseling could have occurred by other means, this finding suggests that the majority of patients did not receive optimal pretest discussions regarding genetic testing. This also could be the result of an insufficient genetic counseling workforce nationwide,[14] providing further support for tools that address key aspects of genetic testing such as ours.

The findings of the current study are consistent with the broader literature concerning the potential positive impact of interactive online decision aids. Trials have demonstrated improvements in the understanding of prognosis, treatment options, decisional conflict, and satisfaction with the use of decision aids in patients with breast cancer as well as other cancers such as colorectal cancer and thoracic oncology.[31–34] Furthermore, decision aids have been shown to weigh the absolute magnitude of benefit against competing risks and ideally align choices more closely with the individual patient's personal preferences, particularly within the context of genetic testing.[13,35]

The strengths of the current study included a large, diverse sample; detailed information regarding patterns of genetic testing; and a high participation rate. Limitations included self-report of genetic test results, which may be subject to recall bias. Although we achieved good representation of patients across subgroups, there remain limits to the generalizability of these results to all racial and socioeconomic groups, and nonresponse might have biased results. Given the importance of genetic testing in treatment decision making for patients and family members, further work is needed to understand what clinically meaningful differences in knowledge regarding genetic testing would be from the perspective of clinicians who care for patients with breast cancer. Finally, it is important to note that the current study was conducted prior to the widespread adoption of multiplex testing, and therefore was focused on individual gene testing. However, we suspect that limitations in knowledge will only be exacerbated by multiplex testing.

As the scope of and interest in genetic testing continues to rise, an already scarce genetic counseling workforce is increasingly taxed.[3,5,6,14] Offering patients decision support tools that educate them regarding genetic testing and its relevance to the breast cancer treatment decision-making process may be a promising method for supplementing and supporting genetic counselors. Tools can be used to deliver key information to patients, tailored to their risk and interest in genetic testing, that can be useful in directing the clinical resources for counseling and testing. Moreover, tools can be used to inform patients regarding the need for family involvement and education concerning genetic testing. In addition, tools that can help to calculate

the probability of an individual carrying a pathogenic variant and interest in testing prior to meeting with genetic counselors may help to tailor discussions appropriately. Nevertheless, the existence of knowledge gaps even after tool viewing underscores the importance of continued work to engage clinicians in the process of educating patients through the integration of tools into the clinical and genetic counseling workflow to support the growing complexity of breast cancer treatment decision making.

FUNDING SUPPORT

Supported by grant P01 CA163233 from the National Cancer Institute to the University of Michigan. Work conducted to develop iCanDecide was performed using the University of Michigan Cancer Center Health Communication Shared Resource (grant P30CA46592).

CONFLICT OF INTEREST DISCLOSURES

Allison W. Kurian reports a grant from Myriad Genetics for research funding to her institution for work performed outside of the current study. Reshma Jagsi was supported by a grant from the National Cancer Institute for work performed as part of the current study. In addition, Dr. Jagsi was supported by grants from the National Cancer Institute, the Doris Duke Charitable Foundation, and Blue Cross Blue Shield of Michigan and has acted as a paid consultant for Amgen for work performed outside of the current study.

AUTHOR CONTRIBUTIONS

All authors have contributed toward the article in the following ways: 1) substantial contributions to the conception and design or analysis and interpretation of the data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) agreement to be accountable for all aspects of the work.

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