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Randomized Trial of Proactive Rapid Genetic Counseling Vs. Usual Care for Newly Diagnosed Breast Cancer Patients

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Abstract

Purpose—Breast cancer patients who carry *BRCA1/BRCA2* gene mutations may consider bilateral mastectomy. Having bilateral mastectomy at the time of diagnosis not only reduces risk of a contralateral breast cancer, but can eliminate the need for radiation therapy and yield improved reconstruction options. However, most patients do not receive genetic counseling or testing at the time of their diagnosis. In this trial, we tested proactive rapid genetic counseling and testing (RGCT) in newly diagnosed breast cancer patients in order to facilitate pre-surgical genetic counseling and testing.

Methods—Newly diagnosed breast cancer patients at increased risk for carrying a *BRCA1/2* mutation were recruited. Of 379 eligible patients who completed a baseline survey, 330 agreed to randomization in a 2:1 ratio to RGCT (n=220) vs. UC (n=108). Primary outcomes were genetic counseling and testing uptake and breast cancer surgical decisions.

Results—RGCT led to higher overall (83.8% vs. 54.6%; $p<.0001$) and pre-surgical (57.8% vs. 38.7%; $p=.001$) genetic counseling uptake compared to UC. Despite higher rates of genetic counseling, RGCT did not differ from UC in overall (54.1% vs. 49.1%, $p>.10$) or pre-surgical

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Ethical Standards

This study was approved by the Institutional Review Boards of all participating sites. The study complies with all current laws of the United States of America.

Conflict of Interest

The authors declare that they have no conflicts of interest.

(30.6% vs. 27.4%, $p>.10$) receipt of genetic test results nor did they differ in uptake of bilateral mastectomy (26.6% vs. 21.8%, $P>.10$).

Conclusions—Although RGCT yielded increased genetic counseling participation, this did not result in increased rates of pre-surgical genetic testing or impact surgical decisions. These data suggest that those patients most likely to opt for genetic testing at the time of diagnosis are being effectively identified by their surgeons.

Keywords

BRCA1; BRCA2; Genetic Counseling; Contralateral Mastectomy

Introduction

About 10% of breast cancers are hereditary with most of these due to pathogenic variants in the *BRCA1* or *BRCA2* (*BRCA1/2*) genes [1]. Newly diagnosed breast cancer patients with a *BRCA1/2* mutation have a 17–37% risk of developing a contralateral breast cancer within ten years of their initial diagnosis [2–6]. Removal of the unaffected breast greatly reduces the likelihood of contralateral breast cancer [7–10] and may reduce breast cancer mortality [11]. In addition, opting for bilateral mastectomy rather than breast conservation as the initial breast cancer surgical treatment generally eliminates the need for radiation therapy and can yield improved reconstruction options and outcomes [12–13].

Clinic-based studies have established that when newly diagnosed breast cancer patients receive genetic testing results prior to their definitive breast cancer surgery, over 50% of mutation carriers opt for immediate bilateral mastectomy (BLM) [14–20]. However, identification and referral of newly diagnosed high-risk breast cancer patients is suboptimal. For example, a recent population-based study found that only 53% of high-risk newly diagnosed breast cancer patients received *BRCA1/2* testing [21]. The primary reason for this low rate of testing is lack of physician referral for genetic counseling [22]. When referral does take place, it is often made *after* definitive surgery or with insufficient time to receive test results prior to surgery. For example, many breast surgeons report that they would not delay surgery to wait for the results of a genetic test [23–24]. Thus, while appropriate referral to genetic counseling is critical, it is also critical to provide rapid access in order to maximize the value of testing without causing treatment delay.

Few studies have directly compared rapid (i.e., proactive delivery of genetic counseling prior to surgery) to standard (i.e., standard patient/physician referral to genetic counseling) delivery of genetic counseling and testing in newly diagnosed breast cancer patients. In a retrospective study comparing 1058 breast cancer patients who received genetic counseling and testing after breast cancer surgery to 110 who received counseling and testing pre-surgery, 41.7% of those who tested positive before surgery opted for BLM compared to 4.7% of those who tested positive after initial surgery [25]. In a Dutch trial of newly diagnosed breast cancer patients, compared to usual care, those randomized to rapid genetic counseling and testing (RGCT) were more likely to complete a genetic counseling session prior to surgery but were not more likely to opt for BLM [26].

In the current study, we identified breast cancer patients at their first clinic visit following their diagnosis in order to compare RGCT to usual care (UC). For those randomized to RGCT, we proactively scheduled and rapidly delivered an initial genetic counseling session in order to facilitate pre-surgical genetic testing. In this report, we present analyses comparing the impact of RGCT on uptake of genetic counseling, genetic testing and BLM. We predicted that the proactive offer and rapid delivery of genetic counseling would yield higher genetic counseling participation, increased receipt of genetic test results prior to definitive surgery and increased uptake of BLM.

Methods

Participants

From 2006–2012, we recruited participants for a two-armed, randomized controlled trial comparing rapid genetic counseling (RGCT) to usual care (UC). Participants were recruited from breast surgery clinics at Georgetown University Medical Center (Washington, DC), The Icahn School of Medicine at Mount Sinai (New York, NY), and Hackensack University Medical Center (Hackensack, NJ) as well as an affiliated private practice in Washington DC. Eligible women were aged 18–75, diagnosed with TNM stage 0 to IIIa breast cancer within the previous 6-weeks and had not undergone definitive breast cancer surgical treatment. In addition, they had to be at increased risk for carrying a *BRCA1/2* mutation as defined as being diagnosed at <50 years of age or a family history of one or more first- or second-degree relatives diagnosed with breast cancer at < 50, ovarian cancer at any age or male breast cancer at any age. Women with a prior history of cancer (except non-melanoma skin cancer), bilateral, inflammatory, or metastatic breast cancer, or who had previously received *BRCA1/2* counseling or testing were ineligible. Women who were pregnant, lacked the cognitive capacity to provide informed consent or could not communicate in English were also excluded.

Randomization

Participants were randomized to RGCT or UC in a 2:1 ratio using a computer-generated random number and stratified by study site.

Procedure

The institutional review boards at all study sites approved this study. All new patients were asked to complete a family history form and provide consent for study contact. Research assistants (RA) reviewed appointment and pathology records to identify newly diagnosed patients. If a patient had not completed the family history form, we contacted the patient's surgeon to obtain permission to approach the patient. Potentially eligible patients were approached by an RA in clinic or by telephone shortly after the clinic visit. At this initial contact, the RA introduced the study and obtained permission to contact her by telephone to complete the baseline interview.

An RA then called interested patients to confirm eligibility, explain the study, obtain verbal consent and complete the baseline survey to collect demographic, cancer history and psychosocial information. If the baseline survey was not completed within 6-weeks of

diagnosis, the participant was considered a study decliner. Immediately following the baseline survey, participants were randomized to RGCT or UC in a 2:1 ratio. After randomization, participants were sent (via priority mail) informed consent and medical records release forms. Participants were asked to mail back the consent and release forms in pre-stamped envelopes.

RGCT participants were proactively contacted by telephone within 24–72 hours of randomization to schedule a genetic counseling session. To further expedite genetic counseling, RGCT participants had the option to schedule an in-person or telephone genetic counseling session. Ninety-three (49.5%) RGCT participants who received genetic counseling chose telephone counseling and 95 (50.5%) chose in-person counseling. UC participants were not proactively contacted but could contact the genetic counseling program for an appointment. All study-related genetic counseling was provided at no cost. *BRCA1/2* testing costs were billed to patients or insurers directly by the testing laboratory. All participants who opted for genetic testing had an in-person disclosure session when test results were available. We conducted follow-up surveys 1-, 6-, and 12-months post-randomization.

Measures

Sociodemographics and Family History—We assessed sociodemographics, family and personal cancer history. We used personal and family cancer history to calculate a priori risk with the BRCAPRO model[27].

Clinical Variables—From participants' medical records we abstracted date of diagnosis, cancer stage and receptor status.

Outcome Variables—Genetic Counseling. We assessed completion of a pre-test genetic counseling session and timing of genetic counseling relative to definitive breast cancer surgery. **Genetic Testing.** We assessed whether the participant obtained genetic testing and whether test results were received before or after definitive surgery. **Breast Cancer Surgery.** We assessed breast cancer surgery and whether the surgery was obtained before or after the receipt of genetic test results.

Statistical Analyses

We confirmed the comparability of RGCT and UC at baseline using chi-square and t-tests. In intention-to-treat analyses, we compared RGCT to UC on overall and pre-surgical genetic counseling uptake using chi-square tests. Among participants who participated in genetic counseling, we compared RGCT to UC on pre-surgical completion of counseling chi-square analyses. We also compared the groups on time from randomization to genetic counseling using a Wilcoxon Rank Sum Test. We conducted identical analyses for receipt of genetic test results. For surgery decisions, we compared uptake of BLM in RGCT vs. UC with chi-square analysis. We repeated this analysis stratified by test result using chi-square and Fisher Exact tests.

Results

As displayed in Figure 1, of 717 *potentially* eligible women, 61 did not complete a family history screener in clinic, 38 were missed by our staff in clinic, 73 declined the baseline, 44 had surgery prior to their baseline and 108 could not be reached to complete the baseline despite repeated attempts. Of 393 women who completed a baseline survey, 14 were ineligible for randomization. Of the 379 eligible participants, 49 (12.9%) declined to be randomized and 330 (87.1%) were randomized in a 2:1 ratio to RGCT (n=222) vs. UC (n=108). The only variable on which participants and decliners differed was education with participants being more likely to have graduated from college (75.5% vs. 61.2%; X^2 (n=379, df=1)=4.45, p=.03). Baseline group comparisons indicated that participants in both groups were highly similar with no statistically significant differences between the groups (Table 1). Overall, 296 (89.7%), 286 (86.7%) and 283 (85.8%) participants completed the 1-, 6-, and 12-month assessments respectively. The groups did not differ on attrition at any of the follow-up assessments.

Uptake of Genetic Counseling

As displayed in Figure 2, in intention-to-treat analyses, 83.8% of the RGCT group completed a genetic counseling session within 12-months of study enrollment compared to 54.6% of the UC group (X^2 (n=330, df=1)=32.3, p<.0001) and 57.8% of the RGCT group completed a genetic counseling session prior to definitive breast cancer surgery compared to 38.7% of the UC group (X^2 (n=322, df=1)=10.5, p=.001).

In analyses limited to those who completed a genetic counseling session, the groups did not differ in the likelihood of completing that session before surgery (RGCT = 69.4%; UC = 71.9%; X^2 (n=237, df=1)=0.13, p=0.72). The mean time from randomization to completion of the initial genetic counseling session was 14.6 (SD=26.7) days for RGCT participants vs. 40.4 (SD=73.4) days for UC participants. Since these distributions were highly positively skewed, we used the nonparametric Wilcoxon Rank Sum test which revealed that the groups did not differ in time from randomization to genetic counseling (RGCT Median=7 days; UC Median=8 days; z=0.11, p=.91).

The Wilcoxon Rank Sum test also revealed that RGCT participants who opted for telephone genetic counseling took longer to complete their initial genetic counseling session (Median=10 days) compared RGCT participants who chose in-person counseling (Median=5 days; z=4.42, p<.0001).

Uptake of Genetic Testing

As displayed in Figure 3, in intention-to-treat analyses, 54.1% of RGCT participants opted for *BRCA1/2* gene testing compared to 49.1% of UC participants (X^2 (n=330, df=1)=0.72, p=.40) and 30.6% of RGCT participants received a test result pre-surgery compared to 27.4% of UC participants (X^2 (n=325, df=1)=0.36, p=.55). The distribution of test results did not differ between the two groups. Among those who were tested, 6.7% of RGCT and 7.5% of UC participants received a positive test result (χ^2 (n=173, df=1)=0.04, p=.83).

In analyses limited to those who participated in genetic counseling (n=245), test uptake was higher for UC vs. RGCT (89.8% vs. 64.5%; χ^2 (n=245, df=1)=13.8, $p=0.0002$). The mean time from randomization to receipt of test result was 45.3 (SD=50.4) days in RGCT vs. 64.6 (SD=76.8) days in UC. A Wilcoxon Rank Sum test revealed that the time from randomization to result disclosure did not differ between the two groups (RGCT Median=27 days, UC Median=29 days; $z=0.93$, $p=.35$).

Surgical Decisions

In intention-to-treat analyses (among patients with final surgery data), 26.6% of RGCT participants opted for BLM vs. 21.8% of UC participants (χ^2 (n=304, df=1)=1.37, $p=.50$). When stratified by genetic test result, 7 of 8 (87.5%) mutation carriers in the RGCT group opted for BLM compared to 2 of 4 (50%) in the UC arm (Fisher Exact Test: $p=0.24$). Among those who received negative/uninformative results, 28.4% of RGCT participants opted for BLM compared to 31.9% of UC participants (χ^2 (n=156, df=1)=0.19, $p=0.66$). Among those who were not tested, 18.6% of RGCT participants opted for BLM compared to 10.0% of UC participants (χ^2 (n=136, df=1)=1.90, $p=0.39$).

In analyses limited to participants who received genetic test results prior to their definitive surgery, 30.2% of RGCT participants opted for BLM compared to 33.3% of UC participants (χ^2 (n=116, df=1)=0.17, $p=0.92$).

Discussion

We compared the uptake of genetic counseling, *BRCA1/2* testing and BLM among newly diagnosed breast cancer patients who were randomized to RGCT vs. UC. Despite significantly increased genetic counseling participation in the RGCT arm, the groups did not differ in the uptake or timing of genetic testing or surgery decisions.

The higher participation in genetic counseling in the RGCT group suggests high interest in genetic counseling among newly diagnosed high-risk breast cancer patients. Compared to UC, proactive contact, rapid scheduling and the option of telephone delivery led to about a 50% increase in overall genetic counseling participation and a nearly 80% increase in pre-surgical genetic counseling. The lower rate of counseling participation in UC may indicate that potentially interested patients were not referred or did not pursue genetic counseling. UC patients who had already made a definitive surgery decision or whose surgeon did not recommend consideration of BLM may have been less likely to participate in genetic counseling. This is consistent with previous evidence indicating that surgeon's referral for genetic counseling and recommendation for BLM are associated with pre-surgical genetic counseling and testing [28 29].

RGCT participants completed their initial genetic counseling session an average of nearly three-weeks sooner than UC participants suggesting that proactive contact and rapid delivery can reduce the time to completion of genetic counseling. However, this difference was primarily due to a subset of UC participants who sought genetic counseling well after their initial diagnosis as the median time from randomization to genetic counseling was comparable in both arms (7 days vs. 8 days). The higher rate of pre-surgical genetic

counseling in RGCT was primarily a function of higher overall participation rather than more rapid completion of counseling. This interpretation is supported by per-protocol analyses demonstrating that among those who completed a genetic counseling session, about 70% of participants in both groups completed that session before surgery.

RGCT participants were no more likely than UC participants to undergo genetic testing overall or receive their results before surgery. The higher than anticipated rate of testing in UC and the clinical availability of pre-surgical genetic counseling at our study sites certainly contributed to this finding. It is possible that awareness of this trial sensitized surgeons to the availability and potential benefits of pre-surgical genetic testing. It is also likely that proactive contact, facilitation of scheduling and the option of telephone delivery motivated some RGCT participants to complete genetic counseling despite having already decided on their surgical treatment or having low interest in genetic testing. In contrast, UC participants who pursued counseling likely did so at the recommendation of their surgeon in order to inform surgical decision making. This explains our finding that among those who completed a genetic counseling session, 90% of those in UC were tested compared to only 64% of RGCT participants. The fact that the two groups did not differ in uptake of BLM further supports this interpretation. This is also consistent with the previously published Dutch trial in which RGCT and UC did not differ in overall rate of BLM [26].

Study Limitations

The study had few mutation carriers, limiting our ability to reach conclusions about the impact of RGCT vs. UC among carriers. We also had considerable missing data on stage and receptor status due to lack of consent to access pathology records for some participants. However, the groups did not differ on the distribution of these variables among participants with complete clinical data. This study was conducted in highly resourced metropolitan medical centers and only about one-third of our sample was comprised of minority participants limiting our ability to reach conclusions about the impact of RGCT in community settings and among minority breast cancer patients. We also provided all genetic counseling free of charge in both groups. These factors may have led to higher rates of genetic counseling uptake compared to other settings. Finally, this study was conducted prior to the widespread use of multi-gene panel testing for cancer predisposition, thus it is not known whether our findings would apply in the multiplex testing setting.

Clinical Implications

Our study sites had sufficient clinical infrastructure to accommodate pre-surgical genetic counseling referrals and breast surgeons who routinely made such referrals, this may not be the case at many sites. Population-based research indicates that most breast cancer survivors at increased risk for a *BRCA1/2* mutation have not been tested [30] and among newly diagnosed breast cancer patients who were tested, many were tested after surgery and without receiving genetic counseling [31]. These low rates likely reflect lack of access, lack of capacity and suboptimal referral rates. Genetic counselor access remains a barrier to physician genetic counseling referral [32]. However, recent reports indicate improving access to cancer genetic counseling [33]. In settings where counselor access is an issue,

telegenetic counseling could be an option. Recent research strongly supports telephone-based genetic counseling as an approach to enhance access [34–41].

In the current study, the availability of telephone counseling in the RGCT arm may have led to increased genetic counseling participation but did not result in more rapid receipt of genetic testing results. In fact, those who opted for telephone counseling took longer to complete their initial genetic counseling session than those who opted for in-person counseling. Even with efforts to expedite testing, the median time from randomization to the receipt of test results in the

RGCT arm was nearly a month. To maximize the likelihood that test results can be used to inform treatment decisions, surgeons, trained nursing staff or nurse navigators providing genetic testing at the point of care may be warranted. Preliminary studies also suggest that targeted print education materials can be used in lieu of pre-test genetic counseling to provide information and foster informed testing decisions [42–43]. Although these studies have not yet addressed the complexities raised by the emergence of multiplex panel testing, these data certainly suggest that new approaches could be considered to expedite the delivery of pre-surgical genetic testing for patients whose surgical decision will be informed by the results. Patients who prefer to meet with a genetic counselor, who have more complicated histories or who may have challenges understanding or coping with their results could be triaged for more comprehensive genetic counseling[44].

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Figure 1.
Study Flow Chart

Figure 2.
Uptake of Genetic Counseling by Study Group

Figure 3.
Uptake of Genetic Testing by Study Group

Table 1

Sample Characteristics of Participants

	UC (N=108)		RGCT (N=222)	
Characteristic	N	%	N	%
Age, years				
Mean (SD)	47.0 (9.1)		45.8 (8.1)	
<i>BRCA1/2</i> carrier probability (%)				
Mean (SD)	12.7 (19.5)		14.0 (22.4)	
Education				
College Graduate	76	70.4	173	77.9
< College Graduate	32	29.6	49	22.1
Employment Status				
Full Time	82	75.9	155	69.8
< Full Time	26	24.1	67	30.2
Race				
White	67	62.0	159	71.6
Nonwhite	41	38.0	63	28.4
Marital Status				
Married/Partnered	64	59.3	149	67.1
Single/Widow/Divorced	44	40.7	73	32.9
Jewish Ethnicity				
Jewish	10	9.3	24	10.8
Non-Jewish	98	90.7	198	89.2
First Degree Relatives With Breast/Ovarian Ca				
1	76	70.4	150	67.6
2+	32	29.6	72	32.4
Candidate for Breast Conservation ^a				
Yes	71	66.4	154	70.3
No	33	30.8	58	26.5
Not Sure	3	2.8	7	3.2
Previous breast biopsies ^a				
Yes	32	30.2	58	26.7
No	74	69.8	159	73.3
Stage ^b				
0/1	43	53.8	106	64.6
2/3	37	46.2	58	35.4
ER/PR status ^c				
Positive	70	83.3	136	77.7
Negative	14	16.7	39	22.3

	UC (N=108)		RGCT (N=222)	
Characteristic	N	%	N	%
Recruitment Site				
Georgetown	93	86.1	188	84.7
Mount Sinai	9	8.3	23	10.4
Hackensack University Medical Center	6	5.6	11	4.9

^aMissing data = 4;

^bMissing data = 82;

^cMissing data = 67