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ORIGINAL ARTICLE – BREAST ONCOLOGY

Frequency of Contralateral Prophylactic Mastectomy in Breast Cancer Patients with a Negative BRCA1 and BRCA2 Rapid Genetic Test Result

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ABSTRACT

Background. There is an increasing desire for contralateral prophylactic mastectomy (CPM) among patients with unilateral breast cancer. It is unknown if risk assessment and genetic testing at the time of diagnosis will aid women in their surgical choice. We report on the uptake and predictors of CPM in women receiving a negative genetic test result for *BRCA1* and *BRCA2* mutations before surgery.

Methods. Women diagnosed with breast cancer between June 2013 and May 2018 were recruited from four academic health sciences centers in Toronto, Canada. Genetic counseling (risk assessment) and genetic testing was performed prior to surgery. Women were asked about their surgical preference before surgery. At 1 year post-surgery we asked what surgery was completed. This study reports on women who received a negative *BRCA1/BRCA2* result.

Results. A total of 766 women with a mean age of 46 years (range 21–82) were included in the analysis. Before genetic counseling and testing, 37% of the women were undecided or leaning towards CPM; however, after receiving a negative *BRCA* test, 15% of the women opted for CPM. Thirty percent of women whose mother died of breast cancer elected for CPM, compared with 15% of women whose mother did not die of breast cancer ($p = 0.03$).

Conclusions. Women receiving a risk assessment and negative *BRCA1/BRCA2* genetic test result before surgery use this information to guide their surgical decision. Uptake of CPM for women who were planning on CPM before genetic testing decreases after receiving a negative *BRCA1/BRCA2* genetic test result.

For women diagnosed with unilateral breast cancer, the choice of contralateral prophylactic mastectomy (CPM) is a personal one. For breast cancer patients as a whole, a survival advantage has not been reported in association with CPM. National and international guidelines do not support the use of CPM in average-risk women;[1,2] nevertheless, the uptake of CPM has increased in recent years in many countries; in the United States, reported CPM rates have ranged between 4% and 25%.[3–6]

The 25-year lifetime risk of contralateral breast cancer is approximately 30% for women who have a *BRCA1* or *BRCA2* mutation and 10% for women without a mutation.[7] For women with a *BRCA1* or *BRCA2* mutation, CPM reduces the risk of a contralateral breast cancer[8] and may reduce long-term mortality.[9] However, most women are unaware of their *BRCA1/ BRCA2* mutation status at the time of breast cancer diagnosis. We have recently reported that among women with breast cancer who are aware that they carry a *BRCA1* or *BRCA2* mutation, the uptake of CPM is 78%.[10] These high-risk women reported that knowledge of the positive genetic test influenced their decision for contralateral mastectomy; however, it is

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unclear to what extent women who receive a negative *BRCA1* and *BRCA2* genetic test result use this information when making their decision.

Women often overestimate the risk of contralateral cancer and the survival advantage associated with CPM;[11] this highlights the need for presurgical education and counseling. Genetic counsellors have the opportunity to communicate the risk of contralateral breast cancer and to help women understand their risk in the context of the genetic test result, including those who test negative. Genetic counseling can lead to increased knowledge, perceived personal control, more accurate risk perception accuracy, and decreased anxiety and cancer-related distress.[12]

To better understand the motivation behind a woman's decision to undergo CPM, it is helpful to identify predictors of uptake of CPM. These factors may or may not relate to the actual risk of contralateral breast cancer. Younger age, higher education, insurance coverage, and White race have all been associated with higher rates of CPM.[3,4,13–15] Psychosocial factors that predict uptake of CPM include anxiety, distress, and concern about body image.[16,17]

The implications of having a positive genetic test result on CPM have been well-studied and, in general, most surgeons endorse CPM for *BRCA* mutation carriers. However, it is less common for physicians to recommend CPM for their patients with a positive family history but a negative genetic test result. In this case, the patient's wish to have the operation is the determining factor. It is unclear if women who are told that they do not carry a *BRCA* mutation use this information to make surgical choices, or if there are predictors of uptake of CPM in women who receive a negative genetic test result. In the current study, we report on the uptake of CPM in women who received a negative *BRCA1* and *BRCA2* genetic test result at the time of surgical decision making.

METHODS

Study Population

Participants included women diagnosed with invasive breast cancer at one of four academic health sciences centers in Toronto, Canada (Women's College Hospital, Sunnybrook Health Sciences Centre, St. Michael's Hospital, and University Health Network) between June 2013 and May 2018. Inclusion criteria to be offered study participation and rapid genetic testing for *BRCA1* and *BRCA2* were first primary invasive breast cancer, no previous prophylactic breast surgery, age 18 years or older, able to read and understand English, and no previous testing for *BRCA1* or *BRCA2* mutations. In addition, women also had to meet at least one of the following criteria: Jewish ethnicity; triple-negative breast cancer; age of diagnosis $\leq$50 years; synchronous bilateral breast cancer or a family history of breast cancer. A positive family history was defined as a first- or second-degree relative with breast cancer diagnosed at age 50 years or younger, ovarian cancer at any age, or male breast cancer at any age.

Study Procedures

The study protocol received ethics approval from all participating institutions. At the time of breast cancer diagnosis, potentially eligible women were referred to the study by their breast surgeon and were contacted by telephone within 24 business hours. The genetic counsellor assessed eligibility. All participants provided written consent for participation in the study. Participants received standard pretest genetic counseling and were offered rapid genetic testing for *BRCA1* and *BRCA2* mutations. Genetic testing was performed at one of three laboratories (Mount Sinai Hospital, North York General Hospital, or Women's College Hospital). Genetic test results were disclosed by the genetic counsellor via telephone prior to surgery and results were faxed to the referring surgeon.

Measures

Participants completed baseline questionnaires prior to genetic counseling and a follow-up questionnaire at 1 week after receipt of the genetic test results.

Study-Specific Baseline Questionnaire: Sociodemographic variables included age, marital status, education, and parity. Women were also asked what surgery (lumpectomy, unilateral mastectomy, bilateral mastectomy, or unsure) they were leaning towards. The study personnel took a complete three-generation family history from each participant. Data collected included information on relatives' cancer diagnoses, including type of cancer, age at cancer diagnosis, and vital status.

Cancer-related distress was measured at baseline using the *Impact of Event Scale (IES)*,[18] a validated 15-item questionnaire that assesses subjective distress surrounding a stressful event (specified as 'having a breast cancer diagnosis'). Each item is rated on a 5-point scale from 0 ('not at all') to 5 ('often'). The sum of the ratings on each item is the total distress score. Higher total scores represent greater distress: 0–8, subclinical range; 9–25, mild; 26–43, moderate; and 44+ severe.

Anxiety was measured at baseline using the anxiety subscale of the *Hospital Anxiety and Depression Scale (HADS)*,[19,20] a validated, 14-item questionnaire that assesses anxiety (7 items) and depression (7 items), with subscale scores ranging from 0 to 21. Scores of 0–7

indicate normal symptoms, 8–10 indicate mild symptoms, 11–14 indicate moderate symptoms, and 15–21 indicate severe symptoms.[20]

A *Study-Specific One Week Follow-up Questionnaire* was completed by participants at 1 week following the disclosure of the genetic test result. Women were asked if the genetic test result changed their surgical decision.

Medical Chart Review

A medical chart review was completed at 1 year by the study genetic counsellor. Diagnostic, pathological, and treatment data were abstracted. Data were abstracted on tumor size, axillary nodal status, estrogen receptor (ER) status, progesterone receptor (PR) status, human epidermal growth factor receptor 2 (HER2) status, initial surgery (lumpectomy, unilateral mastectomy, bilateral mastectomy), hormonal therapy, chemotherapy (yes/no), and radiotherapy (yes/no).

Statistical Analysis

The Chi-square test was used to compare frequencies of categorical variables, and the *t*-test was used to compare the mean values of continuous variables. The *p*-values in Tables 1, 2, and 3 are the test of differences between subjects with or without contralateral mastectomy. In Tables 2 and 3, we also performed tests between the two groups by adjusting some variables. All statistical tests were performed using statistical software SAS version 9.4 (TS1M3; SAS Institute, Inc., Cary, NC, USA).

RESULTS

Study Sample

Overall, a total of 1007 women underwent rapid genetic testing for *BRCA1* and *BRCA2* at the time of breast cancer diagnosis. For the current analysis, we included the 850 women with a negative genetic test result. Of these 850 women with a negative *BRCA* result, we excluded 28 women with stage IV breast cancer and 56 women with bilateral breast cancer. A total of 766 women were included in the current analysis.

The mean age of participants was 46.2 years (range 21–82). The majority (90.8%) had a college education or higher; 71.5% were married or cohabitating; 70.5% had children; 11.2% had triple-negative breast cancer; 46.4% had positive lymph nodes; and 32% had stage I, 50.0% had stage II, and 18.0% had stage III breast cancer. The demographic and clinical characteristics of the sample are presented in Table 1. Overall, 378 women (49.3%) had breast-conserving therapy, 274 (35.8%) had unilateral mastectomy, and 114 women (14.9%) had CPM.

Demographic and Clinical Predictors

Women with CPM were significantly younger than those who did not elect for CPM (mean age 42.9 years vs. 46.8 years; $p = 0.0002$). Forty-three (20.9%) women aged 40 years or younger at diagnosis elected for CPM compared with 71 (12.7%) women over the age of 40 years. There were no significant differences in education ($p = 0.90$), marital status ($p = 0.35$), or having children ($p = 0.66$) between those with and without CPM.

Women with ER-positive tumors were more likely to have CPM compared with women with ER-negative tumors (16% vs. 8%; $p = 0.01$). Women with triple-negative tumors were significantly less likely to have CPM compared with women without triple-negative tumors (5.9% vs. 16.0%; $p = 0.01$). There were no significant differences in the uptake of CPM by stage ($p = 0.94$).

Psychosocial Predictors

There were no significant differences in mean scores for any of the psychosocial predictors in women who elected for or against CPM (Table 2).

Family History Predictors

Overall, 24.4% of women reported having one or more first-degree relative with breast cancer; 16.6% of women had a mother with breast cancer and 8.9% had at least one sister with breast cancer. Women who had a mother with breast cancer were significantly more likely to have a CPM compared with women without a mother with breast cancer (23.2% vs. 13.5%; $p = 0.006$); 29.6% of women with a mother who died of breast cancer elected for CPM, compared with 14.6% of women with a mother who had not died of breast cancer ($p = 0.03$). There were no significant differences in the uptake of CPM in relation to having a sister diagnosed with ($p = 0.96$) or dying of ($p = 0.10$) breast cancer.

Surgical Choices

Of the 638 women who responded to the question about surgical preference prior to surgery and genetic testing, 405 women (63.5%) were leaning against having a CPM, 70 (11.0%) were leaning towards CPM, and 163 women (25.5%) were unsure. Of the 70 women who were leaning towards CPM prior to genetic testing, 42 (60.1%) had CPM after learning of their negative BRCA genetic test. Of the

TABLE 1 Demographic and clinical characteristics of participants with and without contralateral prophylactic mastectomy

Variable	All	CPM		*p* value
		No [*n* = 652]	Yes [*n* = 114]	
Demographics				
Age, years				0.01
< 40	206 (26.9)	163 (79.1)	43 (20.9)	
40–50	365 (47.7)	312 (85.5)	53 (14.5)	
50–60	117 (15.3)	106 (90.6)	11 (9.4)	
60+	78 (10.2)	71 (91.0)	7 (9.0)	
Education				0.90
High school or below	70 (9.2)	60 (85.7)	10 (14.3)	
College or above	693 (90.8)	590 (85.1)	103 (14.9)	
Unknown	3	2	1	
Marital status				0.35
Single, divorced, widowed	211 (27.7)	183 (86.7)	28 (13.3)	
Married, cohabitating	545 (71.5)	462 (84.8)	83 (15.2)	
Unknown	10	7	3	
Children				0.66
No (0)	225 (29.5)	190 (84.4)	35 (15.6)	
Yes (1)	538 (70.5)	461 (85.7)	77 (14.3)	
Unknown	3	1	2	
Clinical characteristics				
ER status				0.01
Positive	624 (81.7)	522 (83.7)	102 (16.4)	
Negative	140 (18.3)	129 (92.1)	11 (7.9)	
Unknown	2	1	1	
PR status				0.0002
Positive	567 (74.3)	467 (82.4)	100 (17.6)	
Negative	196 (25.7)	183 (93.4)	13 (6.6)	
Unknown	3	2	1	
HER2/neu status				0.78
Positive	170 (22.4)	142 (83.5)	28 (16.5)	
Negative	571 (75.2)	489 (85.6)	82 (14.4)	
Equivocal	18 (2.4)	15 (83.3)	3 (16.7)	
Unknown	7	6	1	
Triple negative				0.01
Yes	85 (11.2)	80 (94.1)	5 (5.9)	
No	676 (88.8)	568 (84.0)	108 (16.0)	
Unknown	5	4	1	
Size, cm [mean (range)]	3.0 (0.0–13.4)	3.0 (0.0–13.4)	3.2 (0.2–13.0)	0.30
Stage				0.94
I	245 (32.0)	207 (84.5)	38 (15.5)	
II	383 (50.0)	227 (85.4)	56 (14.6)	
III	138 (18.0)	118 (85.1)	20 (14.5)	
Nodal status				0.40
Negative	410 (53.6)	353 (86.1)	57 (13.9)	
Positive	355 (46.4)	298 (83.9)	57 (16.1)	
Unknown	1	1	0	

Data are expressed as *n* (%) unless otherwise specified

CPM Contralateral prophylactic mastectomy, *ER* Estrogen receptor, *PR* Progesterone receptor, *HER2* Human epidermal growth factor receptor 2

TABLE 2 Univariable and multivariable models for associations between psychosocial variables and contralateral prophylactic mastectomy

	CPM		Adjusted[a] *p*-value
	No [mean (range)]	Yes [mean (range)]	
Psychosocial			
IES (total score)	36.1 (0–75)	38.4 (0–67)	0.31
Anxiety	9.9 (0–21)	10.5 (0–21)	0.42
Depression	5.6 (0–20)	5.5 (0–18)	0.77

[a]Adjusted for age, estrogen receptor status, progesterone receptor status, stage

CPM Contralateral prophylactic mastectomy, *IES* Impact of event scale

TABLE 3 Univariate and multivariable models for association between family history of breast cancer and contralateral prophylactic mastectomy (missing data not included)

	CPM		*p* value
	No [n = 652]	Yes [n = 114]	
Family history			
Number of first-degree relatives with breast cancer			0.17
0	489 (86.4)	77 (13.6)	
1	129 (79.6)	33 (20.4)	
2	19 (82.6)	4 (17.4)	
3	2 (100)	0	
Mother had breast cancer			0.006
No	543 (86.5)	85 (13.5)	
Yes	96 (76.8)	29 (23.2)	
Mother died of breast cancer			0.03
No	618 (85.3)	106 (14.6)	
Yes	19 (70.4)	8 (29.6)	
Sister had breast cancer			0.96
No	582 (84.8)	104 (15.2)	
Yes	57 (85.1)	10 (14.9)	
Sister died of breast cancer			0.10
No	624 (84.6)	114 (15.5)	
Yes	15 (100)	0	

Data are expressed as n (%) unless otherwise specified

CPM Contralateral prophylactic mastectomy

163 women who were unsure about CPM, 24 (14.7%) elected for CPM. Of the 405 women leaning against having a CPM, 29 (7.2%) elected for a CPM.

Overall, 34.0% of the women reported that their surgical decision changed after receipt of a negative genetic test result.

DISCUSSION

In the current study, we have reported on surgical decision making in women who received genetic counseling and a negative *BRCA1* and *BRCA2* genetic test result at the time of breast cancer diagnosis and before surgery. Prior to genetic counseling and testing, 37% of women were unsure of or leaning towards having a CPM. However, after receipt of pre- and post-test genetic counseling, 15% of high-risk women without a *BRCA1* or *BRCA2* mutation elected for CPM. Forty percent of women who were planning on CPM prior to genetic testing did not have a CPM after receiving negative genetic test results. Seven percent of women who initially preferred not to have CPM did have CPM despite receiving a negative genetic test result.

We recently reported on the uptake of CPM in a large Canadian prospective cohort of women with no documented *BRCA1* or *BRCA2* mutation.[17] The mean age of the women at breast cancer diagnosis was 55 years, and 22% of the women elected for CPM. Previous research has shown that young age is a predictor of CPM.[3–5] The average age of women in the current study was relatively young, at 46 years. We therefore would have expected the uptake of CPM in this cohort to be higher that what has been reported

in previous studies with older participants. However, in the current study where women had genetic counseling and testing and received a negative *BRCA* genetic test result, only 15% of the women elected for CPM despite this being a relatively young cohort.

Having a mother with breast cancer or a mother dying of breast cancer were among the most significant predictors of uptake of CPM. Thirty percent of women who had a mother who died of breast cancer elected for CPM. In most previous research, family history has been defined as yes or no, and there has not been an examination of family history with regard to specific relatives and mortality associated with the cancer in the relative.

Women who have experienced the death of a mother from breast cancer experience elevated levels of cancer-related distress and high cancer risk perception.[21] For women without breast cancer, this often translates into high rates of cancer screening adherence, including mammography.[22,23] Interestingly, although family history of cancer is associated with higher screening adherence, the death of a relative due to breast cancer may be a more significant predictor than a cancer diagnosis alone.[24] It has been hypothesized that women with a mother who survived breast cancer may be more optimistic than women who have a mother who died of breast cancer.[24] Less is known about how the death of mother from breast cancer may impact on breast cancer treatment decisions. Previous research has shown that uptake of CPM is associated with greater worry about recurrence.[25] For women who witnessed a breast cancer recurrence and death in a mother, they may have greater worry about recurrence, which could explain the high uptake of CPM in this group of women.

Family history of breast cancer also impacts on women's decision making related to preventive surgery. We have previously reported on uptake of prophylactic surgery in 517 Canadian women with a *BRCA1* or *BRCA2* mutation.[26] Women with a first-degree relative with breast cancer were significantly more likely to elect for prophylactic mastectomy, and women with a first-degree relative with ovarian cancer were more likely to elect for prophylactic oophorectomy. Although all women with a *BRCA1* or *BRCA2* mutation are at a high risk of both breast and ovarian cancers, those who have not experienced a cancer diagnosis in a relative are less likely to elect for preventive surgery.

Unlike previous research, we did not observe that psychosocial functioning predicted uptake of CPM. We and others have previously reported that women who elected for CPM had higher levels of cancer worry and cancer-related distress, and lower levels of body satisfaction and optimism.[16,17,27] However, in the previous studies, the women did not have genetic counseling and testing at the time of surgical decision making. There may be a role for genetic counseling at the time of breast cancer diagnosis, specifically in using genetic testing to assist women to understand their risk of a contralateral breast cancer, and also to provide psychosocial support during the treatment decision period. Christie and collegues reported that genetic counseling is associated with a decrease in distress for women with breast cancer,[28] and also reported that women who had genetic counseling at the time of treatment decision making had the largest decline in distress compared with women who had genetic counseling after treatments were completed. Future research is needed to evaluate the impact of genetic counseling on psychosocial and decision outcomes in women at the time of breast cancer diagnosis.

There are limitations to the current study. Women in the current study were all recruited from academic health science centers, which may not be representative of the Canadian population, which limits the generalizability of the findings to women who are being treated in non-academic centers. In addition, all Canadian women have access to universal healthcare, therefore access to surgery is not limited as it may be in other countries, and insurance status does not have an impact on surgical choices. We did not collect data on surgeon recommendations. Furthermore, we did not have a control group and relied on historical cohorts. Studies with a control group that does not receive rapid genetic testing are needed. Furthermore, testing was limited to the analysis of the *BRCA1* and *BRCA2* genes. There is less evidence of the effectiveness of various treatments for women with mutations in genes other than *BRCA1* and *BRCA2*.

CONCLUSION

Women who receive genetic counseling and a negative *BRCA1* and *BRCA2* genetic test result at the time when breast cancer treatment choices are being made use this information to inform surgical decisions. The uptake rate of 15% for CPM is lower than what has been reported previously, despite this being a young group of breast cancer patients. The American Society of Breast Surgeons has recently recommended that all women with breast cancer receive genetic testing.[29] The results of this study support this recommendation, in that negative genetic test results can also be informative when making treatment decisions.

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