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ORIGINAL ARTICLE – BREAST ONCOLOGY

How Protective are Nipple-Sparing Prophylactic Mastectomies in BRCA1 and BRCA2 Mutation Carriers?

Meghan Garstka, MD, MS, Anthony Henriquez, AB, Bridget N. Kelly, BA, Alexandra Webster, BS, Jasmine A. Khubchandani, MD, Kevin Hughes, MD, Anvy Nguyen, MD, Tawakalitu Oseni, MD, Michelle Specht, MD, Suzanne B. Coopey, MD, Michele A. Gadd, MD, and Barbara L. Smith, MD, PhD

Breast Program, Division of Surgical Oncology, Massachusetts General Hospital, MGH Center for Breast Cancer, Boston, MA

ABSTRACT

Background. Nipple-sparing mastectomy (NSM) is now routinely offered to BRCA mutation carriers for risk reduction. We assessed the rates of ipsilateral cancer events after prophylactic and therapeutic NSM in BRCA1 and BRCA2 mutation carriers.

Methods. BRCA1 and BRCA2 mutation carriers undergoing NSM from October 2007 to June 2019 were identified in a single-institution prospective database, with variants of unknown significance being excluded. Patient, tumor, and outcomes data were collected. Follow-up analysis was by cumulative breast-years (total years of follow-up of each breast) and woman-years (total years of follow-up of each woman).

Results. Overall, 307 BRCA1 and BRCA2 mutation carriers (160 BRCA1, mean age 41.4 years [range 21–65]; and 147 BRCA2, mean age 43.8 years [range 23–65]) underwent 607 NSMs, with a median follow-up of 42 months (range 1–143). 388 bilateral prophylactic NSMs had 744 cumulative woman-years of follow-up, with no new cancers seen (< 0.0013 new cancers per woman-years); 251 BRCA1 prophylactic NSMs had 1034 cumulative breast-years of follow-up, with no new ipsilateral cancers seen (< 0.0010 per breast-year); 66 BRCA1 therapeutic NSMs had 328 cumulative breast-years of follow-up, with one ipsilateral cancer recurrence not directly involving the nipple or areola (0.0030 per breast-year); 237 BRCA2 prophylactic NSMs had 926 cumulative breast-years of follow-up, with no new ipsilateral cancers seen (< 0.0011 per breast-year); and 53 BRCA2 therapeutic NSMs had 239 cumulative breast-years of follow-up, with two ipsilateral recurrent cancers, neither of which directly involved the nipple or areola (0.0084 per breast-year).

Conclusions. The risk of new ipsilateral breast cancers is extremely low after NSM in BRCA1 and BRCA2 mutation carriers. NSM is an effective risk-reducing strategy for BRCA gene mutations.

The cumulative risk of breast cancer by age 80 years is estimated to be 72% for BRCA1 mutation carriers and 69% for BRCA2 mutation carriers.[1] Furthermore, the risk of a second, contralateral breast cancer within 20 years of initial breast cancer diagnosis remains high—40% for BRCA1 carriers and 26% for BRCA2 carriers.[1]

Bilateral prophylactic mastectomy is highly effective in preventing breast cancer in high-risk women, reducing the risk by approximately 90% in women with increased risk from family history or biopsy-proven atypia,[2] and specifically in women with BRCA1 and BRCA2 mutations.[3] Many of these prophylactic mastectomies were subcutaneous mastectomies,[2] in which the nipple and areola were retained, along with 5–10 mm of subareolar breast tissue, thought necessary to maintain nipple viability.

Anatomical studies of the nipple have shown that it is possible to remove ductal tissue from within the nipple while maintaining reliable nipple perfusion.[4–6] Modern nipple-sparing mastectomy (NSM) techniques now include thorough removal of ductal tissue from within and under the nipple. NSM has gained increasing acceptance for

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B. L. Smith, MD, PhD
e-mail: blsmith1@mgh.harvard.edu

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breast cancer treatment and risk reduction[7] with low rates of tumor recurrence in the nipple after NSM for breast cancer.[8–10]

Current nipple-sparing techniques have improved cosmetic outcomes, which may be particularly appealing to young, risk gene mutation carriers considering prophylactic mastectomy. Data on the long-term risk of new ipsilateral cancer after modern NSM in BRCA gene mutation carriers is limited, with series to-date being small and/or with limited follow-up.[11–15] We evaluated the rates of ipsilateral cancer events after modern NSM for treatment or risk reduction in a large series of BRCA1 and BRCA2 mutation carriers.

METHODS

Patients with deleterious BRCA1 and BRCA2 mutations undergoing NSM at the Massachusetts General Hospital from October 2007 to June 2019 were identified in a prospective database of consecutive NSMs. Patient, tumor, and outcomes data were collected and analyzed. Patients with variants of unknown significance (VUS) or metastatic disease diagnosed within 4 months of a breast cancer diagnosis were excluded. Institutional Review Board (IRB) approval was obtained for this study.

Patients were offered the option of NSM using previously described eligibility criteria[7] and were only excluded as a result of direct involvement of the nipple areola complex (NAC) by tumor on examination or imaging, inflammatory cancer, or if the final nipple position was expected to be poor. Eligibility criteria were similar throughout the study period. Details of the surgical technique have been previously published.[16] Nipple/subareolar margin status was determined on permanent pathology without frozen section. All bilateral prophylactic NSMs had both mastectomies performed the same day, and all patients had immediate reconstruction, with reconstruction type determined by the plastic surgeon.

Length of follow-up was defined from date of surgery to date of the last clinical breast examination documented in the medical record. To estimate the annual risk of a new ipsilateral breast cancer after bilateral prophylactic mastectomy in BRCA mutation carriers, we calculated years of follow-up for each breast and for each woman and combined them as cumulative breast-years and cumulative woman-years of follow-up. For patients undergoing bilateral NSM with a unilateral cancer, we calculated the years of follow-up for the contralateral prophylactic breast alone and combined them as cumulative breast-years of follow-up. Outcomes for cancer-bearing breasts were calculated and analyzed separately. Information on ipsilateral new or recurrent cancers within the follow-up period was recorded and analyzed.

RESULTS

A total of 307 women with BRCA1 or BRCA2 mutations underwent 607 NSMs during the study period, including 160 BRCA1 mutation carriers [mean age 41.4 years (range 21–65)] and 147 BRCA2 mutation carriers [mean age 43.8 years (range 23–65)]. One woman with deleterious mutations in both BRCA1 and BRCA2 genes was included with the BRCA1 mutation carriers for analysis. Patient and follow-up details are shown in Table 1.

Among the 607 NSMs performed in BRCA1 and BRCA2 mutation carriers, 388 were performed for risk reduction in women without cancer. An additional 100 unilateral prophylactic NSMs were performed in women who underwent a contralateral therapeutic mastectomy for breast cancer. Among the patients with cancer, 62% received chemotherapy, 45% received endocrine therapy, and, overall, 76% received some systemic therapy.

At a median follow-up of 42 months (range 1–143), with a total of 1960 breast-years of follow-up, there were no new ipsilateral breast cancers after prophylactic mastectomy in any BRCA mutation carrier in this cohort. The annual risk of new breast cancer in BRCA1 and BRCA2 mutation carriers undergoing follow-up alone was 2–3%.[1] In contrast, the annual rate of new breast cancers was $<$ 0.13% after bilateral prophylactic NSMs (Table 2).

Among BRCA1 and BRCA2 mutation carriers who underwent *bilateral* prophylactic NSM, there were 744 woman-years of follow-up without a new breast cancer, an annual rate of $<$ 0.0013 new cancers per woman-year of follow-up (Table 2). Among all therapeutic NSMs performed in BRCA1 and BRCA2 mutation carriers, at a median follow-up of 57 months (range 1–141) there were three ipsilateral cancer recurrences (0.0053/year), all on the cancer-bearing side. Patients undergoing an NSM for cancer have more frequent and longer follow-up in our practice, resulting in a longer median follow-up for therapeutic NSM in this study.

BRCA1 mutation carriers underwent 251 prophylactic NSMs, including 198 during bilateral prophylactic NSM procedures and 53 unilateral prophylactic NSMs in patients with contralateral breast cancer. Cumulative follow-up for all prophylactic NSM breasts in BRCA1 carriers was 1034 breast-years, with 48 months (range 1–141) of median follow-up. No new ipsilateral cancers were observed after prophylactic NSM in any BRCA1 carriers, a rate of $<$ 0.0010 ipsilateral cancers per breast-year of follow-up.

TABLE 1 Patient characteristics and ipsilateral cancer outcomes in BRCA1 and BRCA2 mutation carriers undergoing prophylactic and therapeutic NSM

	BRCA1 carriers [$n = 160$]	BRCA2 carriers [$n = 147$]	All BRCA1 and BRCA2 carriers [$N = 307$]
Age, years [median (range)]	42 (21–65)	42 (23–65)	42 (21–65)
Race [*n* (%)]			
White	149 (93)	140 (95)	289 (94)
Asian	3 (1.9)	3 (2.0)	6 (2.0)
Black	4 (2.5)	1 (0.7)	5 (1.6)
Not reported/other	4 (2.5)	3 (2.0)	7 (2.3)
Total NSMs (breasts)	317	290	607
Prophylactic NSMs (total breasts)	251	237	488
Follow-up, months [median (range)]	48 (1–141)	38 (1–143)	42 (1–143)
Bilateral NSM (no. of breasts)	198	190	388
Unilateral NSM, contralateral cancer (no. of breasts)	53	47	100
Cumulative breast-years of follow-up (prophylactic)	1034	926	1960
Ipsilateral cancers after prophylactic NSM	0	0	0
Annual rate of new cancers (prophylactic, per breast)	< 0.0010/year	< 0.0011/year	< 0.0005/year
Therapeutic NSMs (total breasts)	66	53	119
Follow-up, months [median (range)]	57.5 (3–141)	55 (1–113)	57 (1–141)
Cumulative breast-years of follow-up (therapeutic)	328	239	567
Ipsilateral cancers after therapeutic NSM [*n* (%)]	1 (1.5)	2 (3.8)	3 (2.5)
Annual rate of new cancers (therapeutic, per breast)	0.0030/year	0.0084/year	0.0053/year

NSMs nipple-sparing mastectomies

TABLE 2 Risk of developing breast cancer after bilateral prophylactic NSM in BRCA1 and BRCA2 mutation carriers, by woman-years of follow-up

	BRCA1 carriers [$n = 160$]	BRCA2 carriers [$n = 147$]	All BRCA1 and BRCA2 carriers [$N = 307$]
Bilateral NSMs (no. of breasts)	198	190	388
Follow-up, months [median (range)]	48 (1–118)	34 (1–143)	38 (1–143)
Cumulative woman-years of follow-up	383	361	744
Annual rate of new cancers (prophylactic, per breast)	< 0.0026/year	< 0.0028/year	< 0.0013/year

NSMs nipple-sparing mastectomies

Sixty-seven therapeutic NSMs were performed in BRCA1 carriers with breast cancer. Cumulative follow-up for all therapeutic NSM breasts in BRCA1 carriers was 328 breast-years, with 57.5 months (range 3–141) of median follow-up. One ipsilateral cancer recurrence did not directly involve the nipple-areolar complex. The risk of ipsilateral breast cancer recurrence after therapeutic NSM in BRCA1 carriers was 0.0030 ipsilateral cancers per breast-year of follow-up.

BRCA2 mutation carriers underwent 237 prophylactic NSMs, including 190 during bilateral prophylactic NSM procedures and 47 unilateral prophylactic NSMs in patients with contralateral breast cancer. Cumulative follow-up for all prophylactic NSM breasts in BRCA2 carriers was 926 cumulative breast-years, with 38 months (range 1–143) of median follow-up. No new ipsilateral cancers were observed after prophylactic NSMs performed in any BRCA2 carriers, a rate of < 0.0011 ipsilateral cancers per breast-year of follow-up.

Fifty-three therapeutic NSMs were performed in BRCA2 carriers with breast cancer. Cumulative follow-up for all therapeutic NSM breasts in BRCA2 carriers was 239 breast-years, with 55 months (range 1–113) of median follow-up. Two new ipsilateral cancers occurred after

therapeutic NSM in BRCA2 carriers, neither directly involving the nipple-areolar complex. One of these patients underwent nipple excision for a subareolar chest wall recurrence, with no tumor identified in the resected nipple or areola. The resulting risk of ipsilateral breast cancer recurrence after therapeutic NSM in BRCA2 carriers was 0.0084 ipsilateral cancers per breast-year.

DISCUSSION

Women with BRCA1 and BRCA2 mutations have an approximately 70% lifetime risk of developing breast cancer.[1,17,18] The annual risk of breast cancer is estimated to be as high as 2–3% per year, beginning in their 30s for BRCA1 carriers and in their 40s for BRCA2 carriers, with the annual risk remaining constant until at least age 80 years.[1]

Many women with BRCA gene mutations seek options for reducing their risk. Five years of tamoxifen[19–21] or aromatase inhibitor therapy[22] reduces the risk of estrogen receptor-positive breast cancers by 50% or more during treatment and for several additional years. However, endocrine chemoprevention is of limited value for BRCA1 mutation carriers,[23] as up to 75% of their cancers will be estrogen receptor-negative.[24,25] In addition, although BRCA2 carriers are likely to have some benefit from endocrine chemoprevention, endocrine therapy has not been used as a lifelong protection strategy in healthy women and adverse effects often limit prolonged use.

Prophylactic mastectomies remain the most effective approach for reducing breast cancer risk, with a 90% reduction in breast cancer incidence after bilateral mastectomy in women with and without risk gene mutations.[2,3] This reduction in risk comes at the high price of losing both breasts. It is therefore essential to fully characterize the degree of protection conferred by current prophylactic NSM, to better enable BRCA mutation carriers to make informed decisions about risk-reducing surgery.

Ninety percent of mastectomies in the landmark Mayo Clinic prophylactic mastectomy series were subcutaneous mastectomies in which "the majority of breast tissue (> 90%) is removed, leaving residual tissue immediately beneath the nipple and areola."[2] The modern NSM surgical techniques used in current practice and in this study strive for more complete removal of breast tissue, with resection extending to the underside of the nipple and areola dermis.[6,26] Prophylactic NSMs now also include thorough removal of all visible breast tissue, with creation of the same thin mastectomy flaps used in mastectomies for cancer.[27] It is hoped that this thorough removal of breast tissue will improve the protection of prophylactic mastectomies beyond the 90% reduction in risk of new cancers seen in early series, even for BRCA mutation carriers.

Prophylactic NSM was extremely effective in reducing breast cancer risk in our study. We observed no new breast cancers after bilateral prophylactic NSM in any BRCA gene mutation carrier in our cohort with 744 cumulative woman-years of follow-up. This translated to a $< 0.13\%$ per year rate of new breast cancers after bilateral prophylactic NSM, in contrast to the 2–3% annual risk with follow-up alone.[1] We considered that the risk of cancer after prophylactic NSM might be higher in a BRCA mutation carrier with a contralateral cancer compared with an unaffected BRCA mutation carrier. However, there were no new breast cancers in any of the 100 contralateral prophylactic mastectomies. The risk of locally recurrent breast cancer was also low in the therapeutic NSM in this series.

Our study, which is among the largest to date, adds to other data on the oncologic safety of NSM for risk reduction in BRCA mutation carriers. None of the 26 women in the Mayo Clinic prophylactic mastectomies series who subsequently tested positive for a BRCA gene mutation had developed breast cancer at 14 years of median follow-up.[12] In larger series with shorter follow-up, Jakub et al.[14] reported no new ipsilateral cancers in 346 BRCA mutation carriers who underwent 548 prophylactic NSMs at nine institutions between 1968 and 2013, with 34 months of median follow-up. Manning et al.[15] saw no new ipsilateral cancers at 28 months of median follow-up after 177 NSMs in 89 women with deleterious BRCA gene mutations or VUS, and Yao et al.[13] reported four cancer events in 397 NSMs in BRCA mutation carriers at a mean follow-up of 32.6 months—one in an NSM for risk-reduction and three in NSMs for cancer diagnoses; none of these occurred at the nipple-areola complex. Valero et al.[10] found no new breast cancers after prophylactic NSM in 117 BRCA mutation carriers at 36.8 months of median follow-up. A small series of prophylactic NSMs in 30 BRCA mutation carriers reported an axillary recurrence 18 months after prophylactic NSM in a BRCA2 carrier, with no other new cancers at 50 months of mean follow-up.[28]

Additional studies are underway to address the limitations of our work to date. Longer follow-up is planned to confirm the long-term outcomes after prophylactic NSM in BRCA gene mutation carriers. The efficacy of prophylactic NSM is also being assessed in carriers of other risk gene mutations.[29] Studies of patient satisfaction after NSM and reconstruction are underway to better address the needs of high-risk women choosing prophylactic mastectomy.[30]

Until other risk-reducing options become available, prophylactic mastectomy is a difficult but highly effective risk-reducing option for BRCA mutation carriers.

CONCLUSIONS

The risk of new ipsilateral breast cancers is extremely low after prophylactic NSM in BRCA1 and BRCA2 mutation carriers, including those with a contralateral breast cancer diagnosis. Prophylactic NSM is an effective risk-reducing strategy for BRCA1 and BRCA2 mutation carriers.

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