Oncologic Safety of Nipple-Sparing Mastectomy in Women with Breast Cancer



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BACKGROUND: Nipple-sparing mastectomy (NSM) has gained popularity for breast cancer treatment and

prevention. There are limited data about long-term oncologic safety of this procedure.

STUDY DESIGN: We reviewed oncologic outcomes of consecutive therapeutic NSM at a single institution.

Nipple-sparing mastectomy was offered to patients with no radiologic or clinical evidence of nipple involvement.

RESULTS: There were 2,182 NSM performed from 2007 to 2016. Long-term outcomes were assessed in the

311 NSM performed in 2007 to 2012 for Stages 0 to 3 breast cancer; 240 (77%) NSM were for invasive cancer and 71 (23%) were for ductal carcinoma in situ. At 51 months median follow-up, 17 patients developed a recurrence of their cancer. Estimated disease-free survival was 95.7% at 3 years and 92.3% at 5 years. There were 11 (3.7%) locoregional recurrences and 8 (2.7%) distant recurrences; 2 patients had simultaneous locoregional and distant recurrences. There were 2 breast cancer-related deaths in patients with isolated distant recurrences. No patient in the entire

2,182 NSM cohort has had a recurrence in the retained nipple-areola complex.

CONCLUSIONS: Rates of locoregional and distant recurrence are acceptably low after nipple-sparing mas-

tectomy in patients with breast cancer. No patient in our series has had a recurrence involving the retained nipple areola complex. (J Am Coll Surg 2017;225:361–365. © 2017 by the

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Nipple-sparing mastectomies (NSM) improve cosmetic outcomes for cancer and high-risk patients, and an increasing proportion of patients are now considered eligible for nipple sparing. ^{1,2} In many institutions, the majority of women undergoing mastectomy for breast cancer are candidates for NSM, including those with larger, node-positive cancers receiving neoadjuvant chemotherapy and/or postmastectomy radiation therapy. ^{3,4} Patients and surgeons are pleased with the superior cosmetic results achieved by

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retention of the nipple-areola complex (NAC), and more women are requesting preservation of their nipple(s).^{5,6}

Despite enthusiasm for NSM among many breast surgeons, plastic surgeons, and patients, some still have reservations about the oncologic safety of nipple preservation due to a lack of long-term follow-up. Local recurrence after NSM could occur in 2 ways. First, breast ductal tissue could be left behind the retained NAC and lead to a recurrence at the nipple. Second, breast tissue could remain on the skin flaps or at the periphery of the breast mound due to poor exposure when more esthetically pleasing, but technically challenging, incisions, such as the inferolateral or inframammary incisions, are used. 8

Our study aimed to evaluate the oncologic safety of NSM by looking at rates and patterns of recurrence in a large single institution series of NSM, with detailed analysis of long-term outcomes in consecutive breast cancer patients treated with NSM from 2007 to 2012.

METHODS

We used our prospectively maintained NSM database, which contained 2,182 NSM performed in 1,258 patients

Abbreviations and Acronyms

DCIS = ductal carcinoma in situ DFS = disease-free survival NAC = nipple-areola complex NSM = nipple-sparing mastectomy

for cancer treatment or risk reduction, at the Massachusetts General Hospital from June 2007 to December 2016. After IRB approval, we retrospectively reviewed consecutive therapeutic NSM performed for stages 0 to 3 breast cancer, from June 2007 to December 2012. We selected this time frame to allow a sufficient period of oncologic follow-up.

Eligibility for NSM at our institution is very inclusive.¹ Patients are excluded only for clinical or imaging evidence of NAC involvement, locally advanced breast cancer with skin involvement, inflammatory breast cancer, bloody nipple discharge, or if breast size and/or ptosis would result in an unacceptable nipple location. Preoperative breast MRI is at the discretion of the surgeon; in our initial 2013 eligibility study, we found that 112 of 315 (35.5%) cancer-containing breasts undergoing NSM had a preoperative MRI at our institution.¹

Incision placement is at the discretion of the breast surgeon and plastic surgeon, with the majority using inferolateral incisions.9 Skin flaps are raised in the Cooper's ligaments plane, usually with electrocautery, identical to our procedures for skin-sparing mastectomy. At the level of the nipple, areola skin flaps are raised, leaving the nipple duct bundle intact. The duct bundle within the nipple is then grasped with a curved clamp and sharply divided immediately below the NAC dermis and on the deep side of the clamp. The contents of the clamp are sent for permanent pathology as the nipple margin specimen. We use frozen sections only rarely because previous work found frozen section analysis less accurate than permanent pathology review, with difficulty distinguishing benign atypia from ductal carcinoma in situ (DCIS).¹⁰ Our technique leaves only nipple and areola dermis, with little or no breast or ductal tissue left beneath the NAC. If the nipple margin specimen contains invasive cancer or DCIS, it is considered positive, and the nipple is excised, often with retention of most of the areola.11

Data on patient and tumor characteristics, local and systemic treatments, and local, regional, and distant recurrences were collected from the electronic medical record. Tumor stage was based on pathologic staging by the American Joint Committee on Cancer 7th edition criteria, and neoadjuvant chemotherapy cases were excluded from staging determination. For bilateral cases, recurrence

information was considered per patient (not per breast). Duration of follow-up was from the time of surgery to the time of last follow-up by any physician who documented a complete review of systems and physical examination including breast and lymph nodes. If a patient experienced a recurrence, her follow-up was censored at the time of recurrence. Kaplan-Meier analysis was performed to estimate disease-free survival in our cohort using MedCalc Software, version 17.2.

RESULTS

There were 2,182 NSM performed in 1,258 patients for breast cancer treatment or for risk reduction between June 2007 and December 2016. Oncologic outcomes were determined for the 311 NSM performed in 297 patients for stages 0 to 3 breast cancer, from June 2007 through December 2012. Within this cohort, 14 patients had bilateral breast cancers. One patient was excluded for stage 4 disease diagnosed before NSM. Two-hundred forty (77%) NSM were for invasive cancer and 71 (23%) were for DCIS. The distribution of tumor stages among the 284 patients who did not receive neoadjuvant chemotherapy was 25.0% stage 0, 50.7% stage 1, 17.6% stage 2, and 6.7% stage 3. Germline risk gene mutations were documented in 33 (11%) of 297 patients (20 BRCA1, 10 BRCA2, 2 p53, 1 PTEN). Additional patient and tumor characteristics are described in Table 1.

The nipple margin contained tumor in 20 (6.4%) breasts. Of these 20 positive nipple margins, 10 were managed with excision of the nipple papilla and 9 with excision of the entire NAC; 1 patient with tumor 2 mm from the closest inked margin had no additional surgical treatment. As previously reported, the rate of nipple loss due to necrosis in this NSM cohort was 1.7%.

Many patients received systemic therapy. Twenty-seven (9%) patients had received neoadjuvant chemotherapy and 92 (31%) received adjuvant chemotherapy. Adjuvant endocrine therapy was given to 181 of 202 (90%) patients with estrogen receptor (ER)+ invasive cancer and 41 (60%) patients with DCIS. Post-mastectomy radiation was administered to 56 (18%) breasts.

Median follow-up was 51 months (range 4 to 101 months). Sixty-seven (23%) patients had less than 3 years of follow-up, 167 (56%) patients had 3 to 5 years of follow-up, and 63 (21%) patients had more than 5 years of follow-up. During the follow-up period, 17 patients developed a recurrence of their cancer (Table 2). Estimated disease-free survival (DFS) was 95.7% at 3 years and 92.3% at 5 years (Fig. 1). There were 11 (3.7%) locoregional recurrences and 8 (2.7%) distant recurrences; 2 patients had simultaneous locoregional and distant

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