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Nipple-Sparing Mastectomy and Infection Risk after Immediate Breast Reconstruction

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Abstract

Background: Wound complications are known to occur after nipple-sparing mastectomy (NSM), especially in procedures involving a periareolar incision. We sought to determine the independent risk of infection and overall wound complications associated with NSM vs. skin-sparing mastectomy (SSM) in a contemporary cohort of women undergoing immediate implant reconstruction.

Study Design: We identified 352 women ≥ 21 years of age undergoing mastectomy plus immediate implant reconstruction from 09/2021–12/2022 using electronic health records from two hospitals. The relative risk of surgical site infection (SSI) and of serious wound complication (infection or noninfectious wound complication (NIWC; dehiscence or tissue necrosis) requiring surgical treatment in the operating room) within 180 days after surgery associated with NSM vs. SSM was determined using a modified Poisson regression model, controlling for established risk factors for SSI.

Results: NSM was performed in 128 women (36.4%), most commonly via an inframammary fold incision (73.4%). Surgical site infection occurred in 49 (13.9%) women within 180 days after surgery, while 70 (19.9%) women developed an SSI and/or noninfectious wound complication. Although the incidence of SSI and the composite SSI/NIWC outcome were similar after NSM vs. SSM (14.8% vs. 13.4% and 21.1% vs. 19.2%, respectively), in multivariable analysis NSM was associated with increased risk of both SSI (RR 2.13, 95% CI 1.26–3.59) and SSI/NIWC (RR 2.19, 95% CI 1.40–3.43).

Conclusions: Nipple-sparing mastectomy was associated with increased risk of both SSI and noninfectious wound complications requiring surgical treatment after controlling for other

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established risk factors, despite uncommon use in this cohort of a periaerolar incision. This information should be communicated to women at the time of pre-surgical counseling to facilitate shared decision making.

Precis

In a contemporary cohort of women undergoing mastectomy plus immediate implant reconstruction, nipple-sparing mastectomy was independently associated with a 2-fold increased risk of surgical site infection. Risk of infectious wound complication persists with nipple-sparing mastectomy, despite infrequent use of a periareolar incision.

INTRODUCTION

Approximately 38% of women undergoing mastectomy for breast cancer in the United States underwent immediate breast reconstruction in 2017, most commonly with insertion of a breast implant.¹ A skin-sparing mastectomy (SSM) is the most commonly performed procedure, with the goal of obtaining sufficient skin flaps to facilitate immediate breast implant or autologous flap reconstruction. To improve cosmetic outcomes, a more recent trend has been increasing use of nipple-sparing techniques in eligible women.

Although oncologic safety with low locoregional breast cancer recurrence rates has been demonstrated in numerous studies, nipple-sparing mastectomy (NSM) is associated with increased risk of implant reconstruction failure² and of necrosis, primarily of the skin flaps but also the nipple areolar complex (NAC) in women undergoing NSM via a periareolar incision.^{3,4} In studies of women undergoing immediate breast reconstruction with NSM, increased risk of NAC necrosis has been associated with prior irradiation, and increased risk of skin flap necrosis was associated with higher body mass index (BMI).⁵ Overall wound complications, including acute NAC or skin flap necrosis, and infection, have been associated with prior irradiation, recent/current smoking, and increased BMI, while longer term reconstruction failure was associated with adjuvant radiotherapy.⁶

The psychosocial benefits of nipple-sparing mastectomy and immediate reconstruction should be balanced with the increased risks of wound complications associated with these procedures, which may result in delayed onset and completion of chemo- and radiotherapy,⁷⁻⁹ in addition to increased healthcare costs.^{10,11} We performed a retrospective review of a contemporary cohort of women undergoing therapeutic or prophylactic mastectomy with immediate implant reconstruction at two urban medical centers to determine whether NSM was associated with significantly increased risk of surgical site infection (SSI), using a strict definition of infection. We also assessed whether NSM was associated with a composite outcome of surgical site infection (SSI) or noninfectious wound complications (NIWC) requiring surgical intervention. These results can provide important information to women considering NSM to help make an informed decision regarding their personal risk of complications after mastectomy with immediate reconstruction.

METHODS

This study was approved by the Human Research Protection Offices of Washington University with a waiver of informed consent.

Mastectomy Patient Population:

We conducted a retrospective cohort study using electronic health record and billing data from one academic and one community hospital in a midwestern city. We initially identified women aged 21 years and older undergoing either a unilateral or bilateral mastectomy surgical procedure from 09/01/2021 to 12/31/2022 using Current Procedural Terminology (CPT) and International Classification of Diseases 10th Revision Clinical Procedure System (ICD-10-PCS) codes. The population was then restricted to women undergoing same day breast implant reconstruction (direct-to-implant (DTI) or tissue expander) by a plastic surgeon, using CPT and ICD-10-PCS codes (list of ICD-10 codes in Supplement Table 1). Potential discrepancies in mastectomy and reconstruction (e.g., plastic surgeon involved but no breast reconstruction procedure codes listed, no oncologic surgeon listed for mastectomy) were verified by medical record review. Outcomes after a small subset of the procedures performed by two surgeons from 9/2021–12/2021 were previously reported in two publications.^{2,12} In this current study 4 oncologic and 7 plastic surgeons performed surgery at site A, and 2 breast and 5 plastic surgeons at site B (one oncologic and 3 plastic surgeons operated at both sites).

Bilateral procedures were identified via the surgeon description in the operating log available from the BJC Clinical Data Repository or with the ICD-10-PCS code 0HTV0ZZ, with review of the medical record as needed to resolve discrepancies. Procedures were identified as either nipple- or skin-sparing mastectomy using the surgeon's description in the operating log, with verification by review of the medical record.

Surgical Site infection and Noninfectious Wound Complications:

An indicator of a potential infectious or noninfectious wound complication was created using a comprehensive set of ICD-10-CM diagnosis, ICD-10-PCS, and HCPCS/CPT codes, and/or the performance of a microbiologic breast culture during all inpatient and ambulatory encounters within 180 days after mastectomy (Supplement Table 2). Medical records were reviewed for all women flagged with a potential wound complication indicator for signs/symptoms of infection, documentation of wound dehiscence, tissue or fat necrosis by the surgeon, and microbiology results. We defined SSI based on the presence of signs/symptoms suggestive of infection (i.e., erythema, swelling, pus, fever) noted in the medical record plus other objective evidence of infection (e.g., growth in culture from an aseptically collected specimen of a pathogen or skin microorganism known to cause wound infections (e.g., *Staphylococcus epidermidis*), abundant polymorphonuclear leukocytes in an aseptically collected specimen) or documented physician diagnosis of infection.¹³ NIWCs were verified by surgeon description of tissue necrosis, wound dehiscence, or fat necrosis. SSIs and NIWCs were further restricted to more serious complications, defined as those requiring surgical treatment in the operating room, including implant removal, debridement, and/or incision and drainage. SSI and NIWC that occurred after second stage reconstruction were

excluded. We prioritized SSI such that women with both SSI and NIWC were classified as an SSI.

Confounding Risk Factors:

Risk factors for wound complications assessed for inclusion in the risk models included age, BMI (based on weight and height at the time of mastectomy, with review to confirm heights and weights <1st or >99th percentile in the cohort), breast weight (using the larger breast weight for those with bilateral mastectomy), bilateral mastectomy, and tissue expander vs. DTI reconstruction. Comorbidities known to be associated with infection and/or poor wound healing and smoking were defined by ICD-10 diagnosis codes at the time of mastectomy (Supplement Table 3). Neoadjuvant chemotherapy was based on diagnosis codes and drug codes for chemotherapy in the 180 days before mastectomy; a port insertion code in the 270 days before the mastectomy admission was also included in the definition of neoadjuvant chemotherapy due to frequent receipt of chemotherapy at other institutions (Supplement Table 3). Breast weight, prior chest, and adjuvant radiotherapy were identified via medical record review. Prior radiotherapy was recorded if it was performed on the mastectomy surgical side. For women with complications, the radiotherapy was required to be on the same side as the complication. Adjuvant radiotherapy was restricted to therapy initiated within 180 days after mastectomy and before SSI/NIWC, if applicable. For the SSI outcome, prior surgically treated NIWC was included as a potential risk factor. Since breast weight was highly correlated with BMI (see Appendix Figure), we focused on BMI as a risk factor for complications due to the extensive literature documenting increased risk of SSI with higher BMI,¹⁴ including in breast reconstruction.¹⁵

Statistical Analysis:

We assessed factors associated with the outcomes of SSI and a composite variable of SSI or NIWC in bivariate analyses using relative risks (RR) and chi-square and Fisher's exact tests, as appropriate. We used a Poisson regression model with a robust error variance to estimate adjusted relative risks of the binary outcomes of SSI and composite SSI/NIWC and 95th percentile confidence intervals (CI), excluding variables from entry with small cell sizes ($n < 5$).¹⁶ Relative risks were calculated since odds ratios are often inflated when the outcome is not rare.^{17,18} After assessing for collinearity, by examining tolerance values to ensure independence of independent variables (with values < 0.1 indicating a high degree of collinearity), we used clinical judgement to determine the additional variables to be entered into the model and backward selection with $p < 0.1$ for retention in the final model. NSM was included in all models as the primary variable of interest. A REDCap electronic database and SAS v9.4 (SAS Institute Inc., Cary, NC) were used for all data management and analyses.

RESULTS

A total of 352 women underwent mastectomy with immediate implant-only reconstruction and had available data during the 16-month study period. The median age of women was 45 years for those with NSM vs. 51 years for women undergoing SSM (Table 1). Two hundred ninety-five (84%) procedures included bilateral mastectomy, and 267 (76%) involved tissue

expander reconstruction. Nipple-sparing mastectomy occurred in 128 (36%) of procedures. Compared to SSM, NSM was significantly more common in younger women and in those with lower BMI (both $p < 0.001$), in women undergoing DTI reconstruction ($p < 0.001$), and with nonsmoking status compared to women with documented history of recent/current smoking ($p = 0.049$, Table 1). Among women undergoing NSM, an inframammary fold incision was used in 73% of patients while only 6% involved a perioareolar incision (Table 1).

Forty-nine (13.9%) procedures were complicated by a surgically treated SSI within 180 days after surgery, while 70 (19.9%) procedures resulted in a surgically-treated SSI and/or NIWC (Table 1). Twenty two of the 49 patients with SSI had an ipsilateral NIWC that was treated in the OR prior to or at the time of SSI treatment. Of the 21 patients with only an operatively treated NIWC, 1 had a prior SSI that was treated conservatively. The incidence of SSI was similar after NSM vs. SSM (14.8% vs. 13.4% respectively, $p = 0.71$), as was the incidence of the composite SSI/NIWC outcome (21.1% vs. 19.2% respectively, $p = 0.67$).

In bivariable analysis, increasing BMI, diabetes, hypertension, and prior chest radiotherapy were associated with significantly increased risk of SSI, while increasing BMI, diabetes, hypertension, prior radiotherapy, and age 60 years or older were associated with significantly increased risk of the composite SSI/NIWC outcome (Supplement Tables 4 and 5). Three of the 19 women (15.8%) who developed SSI after a NSM procedure had a surgically treated NIWC before development of the SSI, compared to 4 of the 30 women (13.3%) who subsequently developed an SSI after a SSM procedure ($p = 1.00$).

Within the group of patients who underwent NSM and implant reconstruction, the risk of SSI was lower for women who had DTI vs. use of a tissue expander (5/56 (8.9%) vs. 14/72 (19.4%), $p = 0.097$). For patients who underwent SSM plus implant reconstruction, the risk of SSI was similar in the two groups (3/29 (10.3%) for DTI vs. 27/195 (13.8%) for tissue expander, $p = 0.77$). Although not significant, the risk of the composite outcome was also lower in women undergoing NSM with DTI reconstruction vs. a tissue expander (9/56 (16.1%) vs. 18/72 (25.0%), respectively, $p = 0.22$) and in those undergoing SSM depending on type of implant reconstruction (3/29 (10.3%) for DTI vs. 40/195 (20.5%) for tissue expander, $p = 0.19$).

After selection of clinically meaningful variables with sufficient numbers, in multivariable analysis, diabetes, increasing BMI, and prior radiotherapy were associated with significantly increased risk of SSI and with the composite SSI/NIWC outcome (Table 2). Smoking was associated with significantly increased risk of SSI/NIWC but not SSI alone ($p = .09$). Despite lack of a significant association in bivariable analysis, NSM was associated with increased risk of both SSI (RR 2.13, 95% CI 1.26–3.59) and the composite SSI and/or NIWC outcome (RR 2.19, 95% CI 1.40–3.43) in the final multivariable models.

DISCUSSION

Using a contemporary cohort of women from 9/2021–12/2022 undergoing mastectomy with immediate reconstruction, we found that a nipple-sparing approach for mastectomy was

associated with increased risk of surgically-treated wound complications within 180 days of surgery after controlling for other known risk factors. After controlling for diabetes, increasing BMI, smoking, and prior radiotherapy, NSM was associated with increased risk of SSI. Additionally, after controlling for those four factors, NSM was associated with SSI and/or tissue necrosis or dehiscence requiring surgical intervention. The increased risk of wound complications is notable, given that NSM was primarily performed in lower risk women (e.g., younger, with lower BMI and less likely to have current/recent tobacco use).

Standard oncologic criteria used to determine eligibility for NSM include tumor size < 2 cm, tumor distance > 2 cm from the nipple, and tumor-free lymph node status.³ Obesity, large or ptotic breasts, and prior irradiation are considered relative contraindications for NSM, although more recently techniques for performance of NSM in women with obesity, ptotic breasts, or prior breast surgery or irradiation have been described.³ NSM is more frequently performed in women undergoing risk reducing prophylactic mastectomy,³ which coincides with the younger age of women undergoing the procedure compared to SSM in our study. Some of the factors associated with a relative contraindication for NSM are also risk factors for SSI and NIWC, particularly obesity and prior breast irradiation.^{6,15} Thus, although women who meet criteria for NSM tend to have lower risk for both infectious and noninfectious wound complications, the incidence of SSI and our composite wound complications outcome were slightly higher in women who underwent NSM vs. SSM (14.8% vs. 13.4% for SSI, respectively and 21.1% vs. 19.2%% for SSI/NIWC, respectively).

Despite inherently lower risk in women selected for the procedure, NSM was associated with 2-fold increased risk of SSI and the composite SSI/NIWC after controlling for other risk factors for wound complications. In this contemporary cohort use of a periareolar NSM incision was uncommon, due to the well described risk of NAC necrosis,¹⁹ while an inframammary fold incision was used in almost three quarters of patients. In NSM procedures involving an inframammary fold incision, the necrosis tends to occur along the leading edge of the mastectomy flap just superior to the incision, possibly from upward retraction resulting in some ischemia.²⁰ For procedures performed through a lateral radial or a vertical incision, most of the ischemia occurs along the incision margin. In contrast, in SSM procedures ischemia generally presents at the wound margin. Because the impact of trimming the skin in a NSM may have greater impact of cosmesis (due to areolar distortion and potentially malposition of the NAC), plastic surgeons may be hesitant to aggressively trim poorer quality skin than in SSM, in which the cosmetic impact is lessened due to the loss of the NAC.

In women undergoing NSM, the SSI rate was about 2-fold lower in women who had DTI reconstruction compared to those who underwent tissue expander placement. In contrast the rates of SSI were similar after skin-sparing mastectomy in those with DTI vs. tissue expander reconstruction, although DTI placement was only performed in 12.7% of the skin-sparing population. Similar findings were reported previously by Chiang et al. with rates of any complication and of implant loss (premature TE removal or any DTI removal) lower for DTI vs tissue expander in bivariate analysis, which did not remain significant in multivariate analysis.¹² Likewise, Lin et al. reported higher rates of infection, nipple, and skin flap necrosis in women undergoing tissue expander vs. DTI reconstruction over a 13-year period,

although implant type did not remain significantly associated with overall complications in multivariate analysis.²¹ The correspondence of results in these studies suggests that patients selected for DTI placement in nipple-sparing mastectomy are at inherently lower risk for complications, due to patient selection, similar to what we found with NSM vs SSM.

Our study has several strengths. We included SSI using a rigorous definition of infection, and NIWC documented by the surgeon up to 180 days post-mastectomy. We used a 180-day follow-up period, since we and others have reported late-onset SSIs associated with immediate breast implant reconstruction, particularly involving tissue expanders.^{22–25} We censored outcomes before 180 days at the time of second stage reconstruction, in order to restrict identification of complications to those associated with the mastectomy procedure. We restricted both SSI and NIWC to those requiring surgical treatment in the operating room, to focus on more serious complications, rather than those treated solely with conservative therapy and minimal impact on reconstruction outcomes. Extensive review of the medical record for some important risk factors (e.g., bilateral surgery, BMI, radiotherapy) and the primary exposure (NSM vs. SSM) were done to ensure accurate characterization of these conditions.

Limitations of our study include the restriction to patients treated at two urban hospitals in the same healthcare system, potentially limiting generalizability of our results. Use of a retrospective study design with some comorbidities defined by ICD-10 diagnosis codes may have resulted in incomplete identification, in particular current/recent smoking. The referral nature of the two hospitals staffed largely by academic surgeons may have resulted in incomplete identification of neoadjuvant chemotherapy, due to receipt at other institutions closer to the patients' homes.

CONCLUSIONS

Decision aids and other techniques to assist patients in making a truly informed decision regarding surgical procedures have become available, including decision aids regarding breast reconstruction after mastectomy. We recently reported results from a randomized trial of a decision aid that incorporated patient risk factors with calculation of wound complication risk, in order to provide personalized risk information to patients regarding the type and timing of breast reconstruction.²⁶ The risk prediction tool used in the BREASTChoice decision aid did not include use of NSM vs. SSM as a predictor of wound complications.²⁷ Our finding of 2-fold increased risk of SSI and SSI/noninfectious wound complications after adjustment for other risk factors for complications suggests that incorporation of NSM into a risk prediction tool with presentation of this information is important to allow women to make a truly informed decision regarding use of surgical technique for mastectomy with immediate reconstruction.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.
 Characteristics of 352 Women Undergoing Mastectomy with Immediate Breast Implant Reconstruction

Patient and oncologic characteristic	Nipple-sparing mastectomy, N = 128	Skin-sparing mastectomy, N = 224
Age, y, median (IQR)	45 (39, 52)	51 (41, 62)
Age category, n (%)		
< 40 y	38 (29.7)	35 (15.6)
40–49 y	47 (36.7)	70 (31.3)
50–59 y	24 (18.8)	55 (24.6)
≥ 60 y	19 (14.8)	64 (28.6)
Race, n (%)		
Black	6 (4.7)	37 (16.5)
Other	3 (2.3)	5 (2.2)
White	119 (93.0)	182 (81.3)
Reason for mastectomy, n (%)		
Ductal carcinoma <i>in situ</i>	18 (14.1)	36 (16.1)
Invasive breast cancer	77 (60.2)	157 (70.1)
Prophylactic mastectomy or benign breast disease	33 (25.8)	31 (13.8)
Prior chest radiotherapy, n (%)	7 (5.5)	18 (8.0)
Adjuvant radiotherapy, n (%)	10 (7.8)	42 (18.8)
Neoadjuvant chemotherapy, n (%)	17 (13.3)	29 (12.9)
Comorbidity		
BMI category, n (%)		
BMI <25: normal or underweight	78 (60.9)	47 (21.0)
BMI 25 to <30: overweight	34 (26.6)	83 (37.1)
BMI 30 to <35: obese class 1	12 (9.4)	43 (19.2)
BMI 35 to <40: obese class 2	3 (2.3)	31 (13.8)
BMI ≥ 40: obese class 3	1 (0.8)	20 (8.9)
Congestive heart failure, n (%)	1 (0.8)	5 (2.2)
Depression, n (%)	27 (21.1)	43 (19.2)
Diabetes, n (%)	4 (3.1)	20 (8.9)
Hypertension, n (%)	18 (14.1)	75 (33.5)
Liver disease, n (%)	2 (1.6)	4 (1.8)
Rheumatologic disease, n (%)	2 (1.6)	3 (1.3)
Smoking, n (%)	28 (21.9)	71 (31.7)
Operative characteristic		
Bilateral mastectomy, n (%)	119 (93.0)	176 (78.6)
Tissue expander (vs direct-to-implant) reconstruction	72 (56.3)	195 (87.1)
Nipple-sparing mastectomy incision type, n (%)		
Inferior vertical	4 (3.1)	NA
Inframammary	94 (73.4)	NA

Patient and oncologic characteristic	Nipple-sparing mastectomy, N = 128	Skin-sparing mastectomy, N = 224
Periareolar	8 (6.3)	NA
Radial lateral or lateral	22 (17.2)	NA
Breast weight, g, median (IQR) *	395 (266, 529)	805 (571, 1164)
Outcomes †, n (%)		
SSI	19 (14.8)	30 (13.4)
SSI and/or NIWC	27 (21.1)	43 (19.2)

* Breast weight among procedures among those with available data (n= 126 nipple-sparing mastectomy and n= 213 skin-sparing mastectomy). For patients with bilateral mastectomy the maximum weight was used.

† SSI and NIWC restricted to those requiring surgical treatment in the operating room.

NA, not applicable; NIWC, noninfectious wound complication; SSI, surgical site infection.

Table 2.

Models of Factors Associated with Surgical Site Infection and Composite Wound Complications (Surgical Site Infection and/or Noninfectious Wound Complication) after Mastectomy with Immediate Breast Reconstruction

Risk factor	Surgical site infection RR (95% CI)	Composite wound complication RR (95% CI)
Nipple-sparing mastectomy	2.13 (1.26, 3.59)	2.19 (1.40, 3.43)
Diabetes	2.46 (1.33, 4.53)	2.34 (1.41, 3.88)
Smoking	1.59 (0.92, 2.75)	1.86 (1.21, 2.88)
BMI <25 kg/m ²	1.00	1.00
BMI 25 to <30 kg/m ²	2.31 (1.10, 4.84)	2.13 (1.16, 3.92)
BMI 30 to <35 kg/m ²	2.58 (1.09, 6.10)	2.86 (1.41, 5.76)
BMI 35 to <40 kg/m ²	3.79 (1.56, 9.24)	3.78 (1.78, 8.04)
BMI ≥ 40 kg/m ²	6.29 (2.69, 14.73)	7.22 (3.76, 13.89)
Prior radiotherapy kg/m ²	2.38 (1.24, 4.53)	2.54 (1.52, 4.22)

SSI and NIWC restricted to those requiring surgical treatment in the operating room.

CI, confidence interval; RR, relative risk