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Impact of surgical complications on patient reported outcomes (PROs) following nipple sparing mastectomy

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ABSTRACT

Introduction: Nipple sparing mastectomy (NSM) is oncologically safe and provides excellent cosmetic outcomes. Complications after surgery may impact patient reported outcomes (PROs). We assessed the impact of complications on PROs after NSM.
Methods: We enrolled 63 patients (pts) who met eligibility criteria for NSM from September 2011 until August 2014. PROs were administered before surgery and at 1 year. Clinical data were collected from the electronic health record. Analyses were performed in SPSS Statistics for Windows (version 21.0). Pts with and without complications were compared using a one-way ANOVA.
Data: Sixty-three women were enrolled with a median age of 46. Postoperative complications requiring surgical treatment were seen in 10 patients (15.9%). Two patients required nipple excision due to necrosis (3.1%). No statistically significant differences in BREAST-Q scores were seen between pts with and without complications.
Conclusion: Experiencing a complication after initial NSM surgery is not associated with decrease in PROs.

Introduction

In the last decade, nipple sparing mastectomy (NSM) has evolved from a technique mostly used in prophylactic breast surgery to a more accepted offering for treatment for many breast cancer patients.[1] Recent studies describing NSM in breast cancer patients report low recurrence rates comparable to those undergoing skin-sparing mastectomy ranging from 4.0 to 5.3% with no evidence of increased risk for local recurrence at the nipple areolar complex (NAC) site at follow up of up to 168 months.[2,3,4] As confidence in oncologic safety of this procedure grew, international consensus guidelines reflect the expansion of oncologic indications for the procedure.,[5] and there has also been broadening of the indications from an aesthetic standpoint, with patients who may have previously been deemed suboptimal candidates, being offered the procedure. Data has suggested that patient factors such as smoking, higher body mass index, larger breast size or prior radiation may increase risk of complications in patients undergoing NSM.[6,7] However, desire to maximize patient satisfaction with outcome and cosmesis as well as increased demand from patients, has resulted in increasing numbers of women being offered NSM.

As the criteria for NSM continues to broaden, there is critical need for Patient Reported Outcomes (PROs) to evaluate outcomes after NSM. Some literature suggests that NSM results in superior PROs compared to skin sparing mastectomy (SSM).[8,9,10] There are also studies that do not demonstrate a significant difference in outcome for patients having NSM or SSM with reconstruction.[11,12,13] Available studies are limited by patient numbers or the lack of preoperative PROs.[8,10,13,14] We feel it is important to understand the impact of complications on outcome from the patient perspective, as increasing numbers of women are being offered NSM with

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expanded aesthetic criteria, potentially resulting in more perioperative complications.

This study aims to evaluate both baseline and postoperative PROs following the introduction of NSM into routine surgical practice at the Dana-Farber/Brigham and Women's Cancer Center, when rates of early postoperative complications would be expected to be higher. We examine the impact of early postoperative complications on PROs and correlate PROs to aesthetic outcome evaluation by plastic surgeons through photographs.

Methods

Study population

Between September 2011 and August 2014, consecutive patients meeting inclusion criteria above the age of 18 years scheduled to undergo upfront NSM at Dana-Farber/Brigham and Women's Cancer Center were prospectively included after written informed consent was obtained. Inclusion criteria were as follows: patients with clinical Stage 0, I, II breast cancer or undergoing prophylactic surgery eligible for immediate reconstruction, no clinical involvement of the nipple areolar complex, no suspicious findings on imaging <2.5 cm from the nipple, BMI <40, no macromastia or significant ptosis per plastic surgery notes and no active smoking reported at initial consult. The Dana Farber Cancer Institute institutional review board (IRB) approved this study.

Procedures

Patient, tumor and treatment characteristics were obtained from the electronic health record. Surgical variables were additionally collected in the postoperative period. For breast weight, we used the larger measurement in bilateral cases. Tumor topography and morphology were coded according to the 3rd edition of the International Classification of Diseases for Oncology (ICD-9).[15] Staging was coded according to the tumor, node and metastasis (TNM) classification system (International Union Against Cancer 7th (2010–2012) edition).[16] Estrogen Receptor (ER) or Progesterone Receptor (PR) was considered positive in case of $\geq$1% nuclear staining. Human epidermal growth factor 2 (HER2) was considered positive if 3+ on immunohistochemistry or amplified by fluorescence in situ hybridization testing.

Eligible patients were recruited at the outpatient clinic. Following written informed consent the first (baseline) BREAST-Q preoperative module was administered prior to the patient's scheduled mastectomy surgery. Postoperative BREAST-Q surveys were administered at a clinic visit, via mail or by telephone at about 1 year following surgery. If no response was received patients were asked to complete the survey via mail 2 additional times. The BREAST-Q is a validated patient reported outcome measure that is surgery-specific.[17]

The BREAST-Q includes separate modules for BCT, mastectomy without reconstruction and mastectomy with reconstruction and evaluates the following six domains: satisfaction with breasts (breast appearance in terms of size, texture and appearance in and out of clothes), psychosocial well-being (body image, confidence in social settings, emotional health and self-esteem), physical well-being (pain or tightness in the breast area, difficulty with mobility or activities), sexual well-being (feelings of attractiveness and confidence as relates to breasts, comfort during sexual activity), satisfaction with overall outcome and satisfaction with care (information, medical team, surgeon, office staff). We elected not to include satisfaction with care in this study, as it did not inform our outcome of interest. BREAST-Q scores were handled according to the scoring manual. Modules were considered missing if less than 50% of the questions of the module were completed as according to the developers' guidance.

Objective cosmetic outcome evaluation was performed using standard medical photographs taken at the preoperative visit and at one year following initial surgery. Two independent plastic surgeons were asked to rate the cosmetic outcome based on 5 categories (volume/contour/placement/fold/scars) using a 3-point Likert scale (0/1/2), see Supplementary Table S1.

We recorded complications as noted in clinical documentation in the first several months following initial surgery. We confined the scope of complications examined in this manuscript to those that would be expected to impact satisfaction with breast following the procedure. We defined minor complications as those that did not require treatment other than local wound care (partial thickness necrosis of flap and/or nipple) and major complications as those likely to require surgical intervention (full thickness flap and/or nipple necrosis, hematoma, implant loss). Patients may have undergone procedures unrelated to complications during the study period, but detailed information on this as related to timing of photographs or survey completion was not available.

The primary focus of this study was to evaluate PROs following the initiation of NSM within our center. Second, PROs were compared between baseline and follow-up and for patients with and without complications. Objective scores for cosmetic outcome (obtained through panel evaluation) were compared with postoperative PRO satisfaction with breast scores.

Statistical analysis

Analyses were performed in SPSS Statistics for Windows (version 24.0). Patient, tumor and treatment characteristics were compared for the two groups using a Chi square test or Fisher's exact (were indicated) for categorized data and the Mann-Whitney *U* test for continuous variables. BREAST-Q scores were presented as median with interquartile ranges (IQR) for both preoperative and postoperative scores. Related samples (pre- and postoperative BREAST-Q scores were compared using the Wilcoxon signed rank test. Postoperative scores for patients with and without complications and patients with complications needing surgery versus those with complications not needing surgery, were compared using the Mann-Whitney *U* test. The score of the objective cosmetic outcome evaluation was considered the sum of all category-scores. The interobserver agreement for the objective cosmetic outcome evaluation done by two plastic and reconstructive surgeons was evaluated by calculating the relatedness using the Interclass Correlation Coefficient (ICC) with corresponding 95% confidence interval. An ICC of <0.40 was considered as an 'poor' association, 0.40–0.59 as 'fair', 0.60–0.74 as 'good' and 0.75–1.00 as 'excellent '.[18] The relationship between the postoperative 'Satisfaction with breast'-score and the objective cosmetic outcome evaluation were evaluated using the R-square (R^2) and corresponding p-value.

Results

Study population

A total of 63 patients were included. Median age was 46 (range 21–66). Most patients (73%) had BMI of 18.5–24.9. Forty-seven (75%) of the enrolled patients underwent bilateral mastectomy and 44 (70%) had tissue expanders as initial reconstruction. A total of 18 patients (28.5%) underwent risk-reducing mastectomy due to BRCA mutation carrier status, and 45 (71.5%) had surgery for early stage breast cancer (although one patient was found to have pathologic Stage III disease on final pathology). Seven patients (11%) received postmastectomy radiation. Four patients (6%) were

found to have been actively smoking at time of surgery although this was not recorded at time of enrollment, and two patients had previous chest radiation. The nipples of three patients (4.8%) were removed due to close/positive nipple margin. Baseline characteristics of all 63 patients undergoing NSM are shown in Table 1.

Complications

Thirty-four (54%) of the 63 NSM patients had some complication (Table 2). None of the patients with minor complications required surgery. All patients with full thickness necrosis, which was considered a major complication, underwent surgery, and two patients had the NAC removed related to necrosis. One patient underwent surgery for a postoperative hematoma.

BREAST-Q scores

For satisfaction with breasts, patients had median preoperative scores of 68.5 (interquartile range (IQR) 58–79) and median postoperative scores of 72 (IQR 57–81), p-value 0.48. Patients had median preoperative physical well-being scores of 57 (IQR 52–63) and median postoperative scores were 77 (IQR 66–85), p-value <0.01. Median psychosocial well-being scores were 81 (IQR 71.8–100) preoperatively and 79 (IQR 60–100) postoperatively, p-value 0.13. For sexual well-being, patients had median preoperative scores of 100 (IQR 83–100) and median postoperative scores of 60 (IQR 44.5–77), p-value <0.01. Preoperative satisfaction with outcome was median 70 (IQR 63–86) and postoperatively this was median 80 (IQR 61–100), p-value 0.79. Only 16 patients (25.3%) completed the satisfaction with nipples questions postoperatively

Table 2
Complications following initial NSM.

COMPLICATIONS[a]	All (N = 63)
Complication requiring surgery	10 (15.9)
Minor Complication	
Partial thickness necrosis nipple	18 (28.6)
Partial thickness necrosis skin flap	3 (4.8)
Partial thickness necrosis nipple and skin flap	2 (3.2)
Major Complication	
Full thickness necrosis nipple	4 (6.3)
Full thickness necrosis skin flap	3 (4.8)
Full thickness necrosis nipple and skin flap	2 (3.2)
Hematoma	2 (3.2)
Loss of implant	2 (3.2)
Loss of nipple areola complex due to necrosis	2 (3.2)

[a] Some patients may have had more than one complication.

Table 1
Patient, tumor and treatment characteristics of 63 NSM patients, n (%).

Demographic information		All (n = 63)
Age at diagnosis	Median (min-max)	46 (21–66)
BMI	<18.5	3 (4.8)
	18.5–24.9	46 (73.0)
	>24.9	14 (22.2)
BRCA mutation		22 (34.9)
Diagnosis	Prophylactic	18 (28.5)
	DCIS	11 (17.5)
	IDC	28 (44.5)
	ILC	6 (9.5)
Active smoker		4 (6.3)
Prior radiation therapy		2 (3.2)
Tumor and surgery information		
Initial reconstruction	Tissue expander	44 (69.8)
	Single Stage Implant	15 (23.8)
	DIEP	2 (3.2)
	LD with SSI	1 (1.6)
	PAP/TUG/Other autologous	1 (1.6)
Surgery laterality	Unilateral	16 (25.4)
	Bilateral	47 (74.6)
Axillary surgery	None	20 (31.7)
	SLNB	36 (57.1)
	ALND	7 (11.1)
Pathologic stage	Not applicable	16 (25.4)
	Stage 0	14 (22.2)
	Stage 1	17 (27.0)
	Stage 2	15 (23.8)
	Stage 3a	1 (1.6)
ER/PR status	Not applicable	19 (30.2)
	Positive	36 (57.1)
	Negative	8 (12.7)
HER2 status	Not applicable	19 (30.2)
	Negative	41 (65.1)
	Positive	3 (4.8)
Specimen weight		
	<400 gm	45 (71.5)
	400-800 gm	18 (28.5)
	>800 gm	0
NAC margin	Negative	45 (71.4)
	ADH/LCIS/ALH	8 (12.7)
	DCIS	3 (4.8)
	IDC/ILC	1 (1.6)
	Not available	6 (9.5)

LD = latissimus dorsi, SSI = single stage implant, SLNB = sentinel lymph node biopsy, ALND = axillary lymph node dissection, ER = estrogen receptor, PR = progesterone receptor, HER2 = Human epithelial growth factor receptor 2, NAC = nipple-areolar-complex.

and scores were 85 (IQR 67–100). Both the baseline and postoperative BREAST-Q scores are presented in Table 3.

No statistically significant differences were seen between patients with or without complications. Postoperative satisfaction with breast median scores were 78 (IQR 64–85) and 69 (IQR 54–76.5), p-value 0.10 in patients without and with complications respectively. Postoperative physical well-being was scored at a median of 81 (IQR 68–85) and 77 (IQR 61–91), p-value 0.71 for patients without and with complications respectively. Postoperative satisfaction with outcome was median 86 (IQR 75–100) and 75 (IQR 55–100), p-value 0.21 in patients without and with complications respectively. The postoperative BREAST-Q scores are presented in (Table 3). When comparing postoperative BREAST-Q scores for patients with a complication needing surgery versus those with a complication not needing additional surgery, no statistical differences were found (data not shown).

Objective cosmetic outcome evaluation

The median time between the photos taken preoperatively and postoperatively was 13 months (IQR 8–16.8). Interobserver agreement between the two plastic surgeons for the cosmetic outcome evaluation was 'excellent' with ICC 0.77 (0.62–0.86), $p < 0.001$. The goodness of fit of the postoperative 'Satisfaction with breast'-scores and the objective cosmetic outcome evaluation was 'poor' with R^2 0.04 ($p = 0.21$) and R^2 0.12 ($p = 0.03$) for plastic surgeon 1 and 2 respectively.

Discussion

Multiple studies have shown low recurrence rates following NSM.[1–4] Although the number of NSM being performed are increasing,[1,4,19] data on PROs obtained both preoperatively and postoperatively in patients undergoing NSM is still limited.[8,10] Recent consensus recommendations note that NSM outcomes should be evaluated through oncologic data but also by evaluating quality of life and cosmetic outcomes.[5] This is of particular concern with the broadening of oncologic and aesthetic criteria for NSM, as risk for complications may increase and impact outcomes.

To our knowledge this is the first study comparing PROs for patients with and without complications following NSM, including preoperative and postoperative PRO data. The rate of complications reported was comparable to other cohorts describing their initial experiences.[4,20] We did not find significant differences in PROs among patients with or without complications. The scores obtained with the BREAST-Q were comparable to other cohorts evaluating NSM pre- and postoperatively, except for the preoperative physical well-being which was lower in the current cohort then in previous cohorts evaluated.[8,10,12] It is possible that this is due to proximity of the administration of the questionnaire to the patients' breast biopsies, such that patients had significant discomfort related to that. Preoperative scores for sexual and psychosocial well-being were higher than those seen in normative data sets,[22] which raises the question as to whether baseline characteristics of patients seeking NSM may differ from the overall cohort of women having breast cancer surgery.

In this study NSM was also evaluated through photographs taken following NSM. Comparing patient reported breast satisfaction to objective aesthetic outcome evaluation by two independent plastic and reconstructive surgeons, 'poor' correlation was found. This poor correlation implies that the judgment of professionals did not align with patients' perceptions of outcome within this cohort. Comparable results have been published when comparing objective evaluation to PROs in breast cancer patients following breast conserving therapy.[21,22] This emphasizes the need to evaluate PROs to understand the outcomes that are important to patients.

Strengths of this study are the use of preoperative and postoperative PROs compared to photographs and the detailed postoperative clinical information on complications.

Patient number and the total number of completed questionnaires limited this study. The low preoperative physical well-being-scores are not well understood. Previous reports have shown higher preoperative physical well-being scores.[8,10,12] The postoperative scores are however comparable to previous studies.[8,10,12,23,24] In this study, postoperative BREAST-Q was obtained at 1 year, and PROs may be different at longer periods of follow up. However, we chose to look at early complications after initial NSM surgery, which would likely be captured at the 1-year interval. In our study, we also noted that most patients filling out the BREAST-Q did not answer the questions that related to satisfaction about the nipple as the module refers to "nipple reconstruction" which is a limitation of the current study. A module looking specifically at PROs in NSM is in development, and this will enable evaluation of satisfaction with native nipples after NSM.[25]

Current knowledge on PROs following NSM is still limited. Studies evaluating NSM or other emerging techniques in breast surgery should therefore include validated PRO tools. It is reassuring that this early cohort of patients with ideal habitus for NSM, in which rate of complications was as expected with initiation of a new procedure, did not differ with respect to PROs by presence of a complication after surgery. This supports expansion of criteria for NSM in order to offer this procedure to more women,[1,19] but

Table 3
Median (interquartile range (IQR)) and mean (standard deviation) BREAST-Q scores for all NSM patients and those without complications and with complications following NSM.

BREAST-Q modules	All (n = 63)			No complications (n = 29)	Complications (n = 34)
	Baseline	Postoperative	p-value	Postoperative	Postoperative
Satisfaction with breast	68.5 (58–79) N = 54	72 (57–81) N = 52	0.48	78 (64–85) N = 23	69 (54–76.5) N = 29
Satisfaction with outcome	70 (63–86) N = 55	80 (61–100) N = 50	0.79	86 (75–100) N = 23	75 (55–100) N = 27
Psychosocial well-being	81 (71.8–100) N = 56	79 (60–100) N = 51	0.13	86 (65–100) N = 23	73 (54.25–100) N = 28
Sexual well-being	100 (83–100) N = 55	60 (44.5–77) N = 50	<0.01	60 (47–77) N = 23	60 (41–77) N = 27
Physical well-being chest	57 (52–63) N = 55	77 (66–85) N = 51	<0.01	81 (68–85) N = 23	77 (61–91) N = 28
Satisfaction with abdomen	NA	94.5 (84.3–100) N = 6	NA		
Satisfaction with nipples	NA	85 (67–100) N = 16	NA		

continued assessment of PROs to evaluate outcomes is essential. Future studies with broader inclusion criteria and advanced experiences in NSM should provide additional insight in PROs.

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Declaration of competing interest

The authors of this study declare no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2020.06.066.

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