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Original article

Post-mastectomy reconstruction: A risk-stratified comparative analysis of outcomes

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ABSTRACT

Introduction: Although breast reconstruction following mastectomy plays a role in the psychological impact of breast cancer, only one in three women undergo reconstruction. Few multi-institutional studies have compared complication profiles of reconstructive patients to non-reconstructive.
Methods: Using the National Surgical Quality Improvement database, all patients undergoing mastectomy from 2006 to 2010, with or without reconstruction, were identified and risk-stratified using propensity scored quintiles. The incidence of complications and comorbidities were compared.
Results: Of 37,723 mastectomies identified, 30% received immediate breast reconstruction. After quintile matching for comorbidities, complications rates between reconstructive and non-reconstructives were similar. This trend was echoed across all quintiles, except in the sub-group with highest comorbidities. Here, the reconstructive patients had significantly more complications than the non-reconstructive (22.8% versus 7.0%, $p < 0.001$).
Conclusion: Immediate breast reconstruction is a well-tolerated surgical procedure. However, in patients with high comorbidities, surgeons must carefully counterbalance surgical risks with psychosocial benefits to maximize patient outcomes.
Level of evidence: Level 3

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Introduction

In the last decade, significant changes have been made to reduce the morbidity of surgical treatment for breast cancer. Affecting 1 in 8 women in their lifetime, breast conservation therapies reduce the level of psychosocial impact of this devastating disease [1]. Total mastectomy remains standard care for approximately 37% of women with breast cancer [2]. However, less than a third of these women receive reconstructive surgery following mastectomy [3–5]. This does not seem to be purely based in economics; in 1998, the Women's Health and Cancer Rights Act required insurance companies to cover reconstructive surgery following mastectomy, with a number of states mandating that women who undergo mastectomy be referred to a reconstructive surgeon during initial evaluation [6]. Decades of research have shown women who undergo breast reconstruction have improved self-esteem, body image, and overall patient satisfaction [7–14]. However, opponents argue that reconstruction alone is not sufficient to improve psychological functioning above and beyond what psychosocial support and breast conservation therapies can provide [15,16]. Thus psychological benefits are heavily counterbalanced by the possibly of increased complications, since many patients perceive a lack of overall safety with reconstructive procedures [17].

Consequently, breast reconstruction rates have only risen by approximately 3.3% in the last decade, seemingly due to a lack of proper patient education on reconstructive options, data on safety, and proper referral to a reconstructive surgeon [4,18–20]. Most patients rely on their breast surgeon for treatment options, indicating a need for increased physician–patient communication regarding the risks and benefits of reconstruction [4]. Therefore, it is essential that both breast and reconstructive surgeons be knowledgeable of significant causes of post-reconstruction

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morbidity so that viable candidates for reconstruction can be identified and patients can be appropriately counseled about decisions regarding their care [17,18].

To date, few studies have provided a large-scale, multi-center, rigorous comparison of outcomes showing whether post-mastectomy reconstruction is a safe and viable choice for patients. The American College of Surgeon's (ACoS) National Surgical Quality Improvement Program (NSQIP) registry was instituted by the ACoS in 2004 to track multi-institutional outcomes of surgical procedures. The strength of the NSQIP database lies in the hundreds of tracked variables from 1.3 million de-identified patients, across 240 hospitals [21,22]. By employing the comprehensive nature of the NSQIP database, we aim to better characterize the risks and complications associated with breast reconstructive surgery, providing surgeons with the critical information needed to initiate the patient–doctor dialog about reconstructive options.

Materials and methods

Selection criteria

A retrospective review of the NSQIP database from 2006 to 2010 was performed for all patients undergoing total mastectomies. The details of the ACS-NSQIP data collection methods have previously been described and validated [23,24]. Patients were selected using concurrent *Current Procedural Terminology* (CPT) codes for total mastectomy; specifically defined as CPT codes 19180, 19182, 19200, 19220, 19240, and 19303 through 19307. Patients were further broken down into groups with or without immediate reconstruction, defined as CPT codes 19340, 19357, 19361, 19364, and 19367-19369. Patients who underwent partial mastectomies (CPT codes: 19301, 19302, 19160, 19162), delayed reconstruction, (CPT code: 19342) or those of male or unknown sex, were excluded. Concomitant axillary dissection and acellular dermal matrix codes were assessed by 19303-19307 and 15231-8, 15330-1, 15430-1, and 15777, respectively. The CPT codes and their corresponding definitions can be found in Table 1.

Patient demographics included age, race, and BMI. Clinical characteristics included smoking, alcohol, and/or steroid use, radiotherapy in the prior 90 days, chemotherapy in the prior 30 days, or a prior operation in the last 30 days. Additional comorbidities such as diabetes, dyspnea, hypertension, COPD, congestive heart failure, bleeding disorders, a history of percutaneous coronary intervention (PCI), cardiac surgery, stroke, transient ischemic attack (TIA), disseminated cancer, and ASA class were also assessed. Surgical case characteristics such as emergency case status, average work RVU, and average operative time were used in regression analysis.

Outcomes

The primary outcome of interest was overall complications, a sum of surgical, medical, and catastrophic complications. Surgical complications included surgical site infection (SSI), wound disruption, and flap/prosthesis failure. Surgical site infections (SSI) were defined according to NSQIP User Guide and included superficial, deep, and organ space SSIs. Reoperations were tabulated independently and were defined as a return to the operating room within 30 days of the primary procedure. Medical complications included pneumonia, unplanned intubation, ventilator dependence greater than 48 h, progressive renal insufficiency, acute renal failure (ARF), urinary tract infections (UTI), peripheral neurologic deficiency, and an intraoperative or immediate postoperative transfusion requirement. Catastrophic complications included pulmonary embolism (PE), stroke, coma, cardiac arrest, myocardial infarction, deep vein thrombosis (DVT), sepsis, septic shock, and/or death. Overall complications were defined as the total of one or more of the above events tracked by the NSQIP database.

Table 1
CPT codes and descriptions, detailing mastectomy and reconstructive procedures.

CPT	Description
Included	
Total mastectomy	
19180	Simple complete mastectomy
19182	Subcutaneous mastectomy
19200	Radical mastectomy
19220	Urban type mastectomy
19240	Modified radical mastectomy
19303	Simple mastectomy complete
19304	Subcutaneous mastectomy
19305	Radical mastectomy including pectoral muscles and axillary lymph nodes
19306	Radical mastectomy including pectoral muscles and axillary lymph nodes and internal mammary node
19307	Modified radical mastectomy including axillary lymph nodes
Immediate reconstruction	
19340	Immediate insertion of breast prosthesis
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19361	Breast reconstruction with latissimus dorsi flap, without prosthetic implant
19364	Breast reconstruction w free flap
19367	Breast reconstruction/tram single pedicle
19368	Breast reconstruction/tram 1 pedicle microvascular
19369	Breast reconstruction/tram double pedicle
Excluded	
Partial mastectomy	
19160	Partial mastectomy
19162	Partial mastectomy w axillary lymphadenectomy
19301	Partial mastectomy (Lumpectomy)
19302	Partial mastectomy (Lumpectomy) with axillary lymphadenectomy
Delayed reconstruction	
19342	Delayed insertion of breast prosthesis following mastoplexy, mastectomy, or in reconstruction
ADM	
15271-8	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15330-1	Acellular dermal allograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children
15430-1	Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children
15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (e.g., breast, trunk)

Statistical analysis

Patients were classified into two groups, those receiving immediate reconstruction, and those who received total mastectomy alone. Patient demographics, comorbidities, and outcomes were compared using chi-squared tests for categorical variables and one-way ANOVA tests for continuous variables. To control for selection bias and differences in demographics when exploring the association between surgical approach and outcome, patients were classified into risk-stratified quintiles using a propensity score [25–27]. The propensity score measured the likelihood to receive a reconstruction based on pre-operative patient characteristics. The pre-operative patient characteristics used to assign propensity score included gender, race, outpatient status, transfer status, age, year of operation, BMI, diabetes, smoking, alcohol use, resident presence concurrent chemotherapy/radiotherapy, dyspnea, chronic obstructive pulmonary disease, congestive heart failure, myocardial infarction, previous cardiac surgery or percutaneous intervention, hypertension, known PVD, hemiplegia, paraplegia, quadraplegia,

Table 2
Patient demographics and clinical characteristics between non-reconstructive and reconstructive patients.

Demographics and clinical characteristics	Non-recon (n = 26,405)		Reconstruction (n = 11,318)		p
Age > 50	20,530	77.8%	5977	52.8%	<0.001[a]
Race					
White	19,504	73.9%	9047	79.9%	<0.001[a]
Black/African American	3022	11.4%	803	7.1%	<0.001[a]
Other	3879	14.7%	1468	13.0%	<0.001[a]
BMI > 30	9419	35.7%	3055	27.0%	<0.001[a]
Resident presence	3494	13.2%	1838	16.3%	<0.001[a]
Clinical characteristics					
Smokers	3824	14.5%	1553	13.7%	0.053[a]
Alcohol use	342	1.3%	138	1.2%	0.547
Steroid use	456	1.7%	99	0.9%	<0.001[a]
Radiotherapy < 90 days	163	0.6%	50	0.4%	0.037[a]
Chemotherapy < 30 days	1738	6.6%	498	4.4%	<0.001[a]
Previous OP < 30 days	920	3.5%	325	2.9%	0.002[a]
Axillary dissection	10,256	38.8%	3244	28.7%	<0.001[a]
ADM	174	0.7%	1571	13.9%	<0.001[a]
Comorbidities					
Diabetes	3377	12.8%	531	4.7%	<0.001[a]
Dyspnea	2441	9.2%	442	3.9%	<0.001[a]
Hypertension	12,116	45.9%	2783	24.6%	<0.001[a]
COPD	863	3.3%	106	0.9%	<0.001[a]
Congestive heart failure	75	0.3%	9	0.1%	<0.001[a]
Bleeding disorders	608	2.3%	88	0.8%	<0.001[a]
Previous PCI	734	2.8%	88	0.8%	<0.001[a]
Previous cardiac surgery	571	2.2%	67	0.6%	<0.001[a]
Previous stroke w/ Neurological deficit	400	1.5%	46	0.4%	<0.001[a]
Previous stroke w/ out neurological deficit	428	1.6%	40	0.4%	<0.001[a]
Previous transient ischemic attack	564	2.1%	74	0.7%	<0.001[a]
Disseminated cancer	614	2.3%	113	1.0%	<0.001[a]
ASA level 1	1336	5.1%	1141	10.1%	<0.001[a]
ASA level 2	15,329	58.1%	8024	70.9%	<0.001[a]
ASA level 3	9218	34.9%	2126	18.8%	<0.001[a]
ASA level 4	499	1.9%	20	0.2%	<0.001[a]
Emergency case	119	0.5%	23	0.2%	<0.001[a]
Avg. work RVU sum	22.53 ± 0.12		56.21 ± 0.36		<0.001[a]
Avg. operative time (mean)	128.92 ± 0.99		236.50 ± 2.48		<0.001[a]

[a] Indicates statistical significance.

recent stroke or TIA, recent wound infection, disseminated cancer, known bleeding disorder, previous sepsis or septic shock, prior operation within 30 days, pregnancy, wound classification, and ASA classification. Hospital type was not tracked in the database. Quintile 1 has the highest odds of receiving reconstruction, while quintile 5 has the lowest odds. Outcomes and comorbidities were only considered significantly different between groups if an alpha value of 0.05 was reached in three out of the five quintiles.

Bivariate analysis was performed to assess the association between complications and pre-operative risk factors. Risk factors which met a cutoff alpha value of less than 0.2 in bivariate analysis were considered for multivariate logistic regression. The previous calculated propensity scores were included in the logistic regression model to decrease bias [25–27]. Furthermore, regression models were refined based on previously reported significant variables in the relevant plastic and reconstructive surgery literature; specifically, age, race, and smoking status were forced into regression models in addition to already significant variables including hypertension, diabetes, obesity, heart disease, vascular disease, and steroid use. Hosmer–Lemmeshow and c-statistics were then computed to assess model calibration and discrimination [28,29]. An alpha value of less than 0.05 was considered statistically significant for all multivariate analyses. All analyses were performed using SPSS, version 20 (Chicago, IL).

Results

Of the 1.3 million patients captured in the NSQIP database, 37,723 patients underwent total mastectomy and met inclusion criteria. Within this group, 11,318 patients (30%) underwent mastectomy with immediate reconstruction and 26,405 patients (70%) had mastectomy without immediate reconstruction. Demographically, reconstructive and non-reconstructive groups were significantly different. Compared to patients undergoing mastectomy alone, patients undergoing reconstructive surgery were significantly more likely to be white (79.9% versus 73.9%, $p < 0.001$), more likely to be younger than 50 (52.8% versus 77.8%, $p < 0.001$), and less likely to smoke (13.7% versus 14.5%, $p = 0.053$), and have significant pre-operative comorbidities (Table 1). Due to these significant differences in the patient population, propensity scoring was performed and patients were risk-stratified into quintiles (Table 2). Following quintile matching, many significant differences in patient demographics and clinical characteristics were eliminated. However, the differences in race were unable to be matched within quintiles and remained significant in all quintile groups.

In general, the crude incidence of overall complications was 6.7% in patients undergoing immediate reconstruction and 5.8% in patients undergoing mastectomy alone ($p = 0.001$), with a majority (73.2%) of complications related to surgical complications (Table 3). However, after correcting for differences in demographics and pre-operative comorbidities between groups, many of the complications that seemed significant in the crude comparison were shown not to be. The complications shown to be significant over a majority of the quintiles were superficial surgical infections, reoperation, and graft/flap/prosthesis failure. No other complications were found to be significant in a majority of the quintiles, including surgical and catastrophic complications (Table 4, Fig. 1).

Variables that passed the bivariate analysis and were found significant in the multivariate logistic regression are reported in Tables 6–8 There were many significant patient risk factors for overall complications, most notable for advanced age, (OR = 1.70; 95% CI = 1.31–2.21), obesity (OR = 2.00; 95% CI = 1.69–2.37), diabetes (OR = 1.75; 95% CI = 1.33–2.32), smoking (OR = 1.72; 95% CI = 1.41–2.11), COPD (OR = 3.44; 95% CI = 2.12–5.56), and hypertension (OR = 1.92; 95% CI = 1.54–2.40). Additionally, there was a 5% (95% CI = 1%–9%) increase in odds of complication for every 10 work RVUs and a 3% (95% CI = 3%–4%) increase in odds for every additional 10 min in the operative room. Additional risk factors are described in Table 5. Similar risk factors were identified for wound infections since they contributed most to the total rate of overall complications (Table 6).

Patient risk factors for reoperation include diabetes (OR = 1.60; 95% CI = 1.20–2.12), smoking (OR = 1.31; 95% CI = 1.08–1.59), history of stroke (OR = 2.02; 95% CI = 1.28–3.19), bleeding disorders (OR = 2.56; 95% CI = 1.49–4.40), and prior operation within 30 days (OR = 1.68; 95% CI = 1.18–2.39). Operative time also increased the odds of reoperation by 2% (95% CI = 2%–3%) for every additional 10 min in the operative room.

Discussion

The number of incident breast cancer cases continues to rise worldwide, with an increasing number of women opting to undergo mastectomy. Therefore, the importance of educating patients of all the treatment options available to them has never been greater [1]. Given the supposed benefits of reconstruction, it is concerning that the rate of women opting for breast reconstruction is so low. A 2010 study by Hershman et al., showed the rate of reconstruction has only risen in the last decade by 3.3% [29]. This indicates a need for increased discussion among patients and

Table 3
Preoperative patient characteristics between non-reconstructive and reconstructive patients after propensity score stratification.

	Quintile 1			Quintile 2			Quintile 3			Quintile 4			Quintile 5		
	No recon ($n = 3254$) %	Recon ($n = 4226$) %	p	No recon ($n = 4532$) %	Recon ($n = 2948$) %	p	No recon ($n = 5391$) %	Recon ($n = 2088$) %	p	No recon ($n = 6131$) %	Recon ($n = 1348$) %	p	No recon ($n = 6855$) %	Recon ($n = 624$) %	p
Age>50 (1[a])	5.5%	4.7%	<0.001[a]	63.0%	63.3%	0.755	87.8%	85.3%	0.005[a]	94.6%	93.5%	0.103	98.2%	98.1%	0.796
Race (1,2,3,4[a])															
White	75.9%	75.6%	<0.001[a]	76.1%	80.8%	<0.001[a]	76.0%	82.6%	<0.001[a]	73.7%	100.0%	<0.001[a]	72.2%	77.4%	0.008[a]
Black/African American	9.5%	6.1%	<0.001[a]	7.8%	6.2%	<0.001[a]	9.7%	6.6%	<0.001[a]	12.7%	8.8%	<0.001[a]	15.4%	13.9%	0.008[a]
Other	19.6%	14.7%	<0.001[a]	16.1%	13.0%	<0.001[a]	14.3%	10.8%	<0.001[a]	13.6%	10.0%	<0.001[a]	12.4%	8.7%	0.008[a]
BMI > 30	22.5%	19.1%	0.083	23.3%	21.7%	0.116	32.6%	31.5%	0.251	41.1%	44.6%	0.019	49.4%	52.2%	0.180
Resident presence (1,2[a])	15.4%	17.2%	0.042[a]	13.6%	16.9%	<0.001[a]	13.5%	10.1%	0.112	13.7%	15.5%	0.079	55.1%	51.8%	0.115
Clinical characteristics															
Smokers (1[a])	16.1%	12.6%	0.004[a]	13.1%	13.2%	0.900	14.2%	14.0%	0.819	13.6%	15.4%	0.089	16.1%	16.5%	0.816
Alcohol use	1.2%	0.9%	0.430	1.3%	1.6%	0.353	1.3%	1.3%	0.885	1.3%	1.3%	0.861	1.3%	1.1%	0.686
Steroid use	0.5%	0.3%	0.206	0.7%	0.7%	0.320	1.0%	1.1%	0.727	1.6%	1.6%	0.914	3.7%	3.4%	0.653
Radiotherapy < 90 days	0.5%	0.3%	0.144	0.5%	0.4%	0.399	0.4%	0.7%	0.219	0.4%	0.5%	0.570	1.0%	1.1%	0.839
Chemotherapy < 30 days	3.0%	2.2%	0.109	5.3%	4.2%	0.042[a]	4.8%	5.6%	0.146	6.7%	7.4%	0.346	10.6%	9.3%	0.307
Previous OP < 30 days	2.3%	1.7%	0.274	3.0%	3.4%	0.360	3.7%	3.4%	0.545	3.9%	3.9%	0.967	3.9%	4.0%	0.919
Axillary dissect ion (1[a])	25.9%	19.5%	<0.001[a]	21.1%	22.8%	0.072	34.7%	36.5%	0.134	44.9%	47.5%	0.086	11.4%	12.7%	0.351
ADM (1,2,3,4,5[a])	1.7%	15.1%	<0.001[a]	1.2%	12.4%	<0.001[a]	0.7%	13.6%	<0.001[a]	0.3%	12.6%	<0.001[a]	0.2%	16.0%	<0.001[a]
Comorbidities															
Diabetes	0.9%	0.8%	0.917	1.6%	1.6%	0.865	3.4%	3.4%	0.958	14.4%	13.9%	0.688	31.8%	29.8%	0.316
Dyspnea	1.4%	1.5%	0.486	1.7%	2.2%	0.156	4.1%	4.0%	0.852	8.6%	7.0%	0.055	22.6%	20.2%	0.173
Hypertension	7.0%	7.1%	0.248	12.5%	11.1%	0.058	38.7%	40.0%	0.306	60.8%	59.4%	0.341	78.9%	78.0%	0.602
COPD	0.1%	0.1%	0.732	0.2%	0.3%	0.367	0.5%	0.7%	0.317	2.4%	2.7%	0.607	9.8%	6.6%	0.008
Congestive heart failure	0.0%	0.0%	0.853	0.0%	0.1%	0.665	0.1%	0.1%	0.547	0.2%	0.1%	0.441	0.9%	0.5%	0.316
Bleeding disorders	0.3%	0.2%	0.578	0.4%	0.4%	0.989	0.7%	0.8%	0.913	1.6%	1.3%	0.322	6.4%	5.3%	0.273
Previous PCI	0.1%	0.1%	0.294	0.2%	0.2%	0.873	0.5%	0.4%	0.771	1.9%	2.2%	0.498	8.3%	5.9%	0.035
Previous cardiac surgery	0.1%	0.1%	0.955	0.2%	0.1%	0.666	0.2%	0.3%	0.480	1.5%	1.3%	0.534	6.5%	5.3%	0.219
Prev. stroke w/ neuro. deficit	0.1%	0.1%	0.748	0.1%	0.1%	0.852	0.2%	0.2%	0.794	0.9%	0.7%	0.471	4.7%	4.0%	0.405
Prev. stroke w/out neuro. deficit	0.0%	0.0%	0.215	0.1%	0.0%	0.048	0.1%	0.0%	0.539	0.8%	0.5%	0.268	5.4%	4.8%	0.550
Previous TIA	0.1%	0.1%	0.615	0.2%	0.3%	0.101	0.7%	0.6%	0.535	1.7%	1.3%	0.387	6.0%	5.0%	0.304
Disseminated cancer	0.2%	0.3%	0.442	0.8%	0.6%	0.320	1.0%	1.3%	0.309	2.1%	1.7%	0.320	5.6%	5.0%	0.536
ASA level 1 (5[a])	17.0%	16.7%	0.221	9.6%	9.5%	0.892	3.6%	3.8%	0.955	1.9%	2.3%	0.609	0.7%	1.6%	<0.001[a]
ASA level 2 (5[a])	81.9%	73.2%	0.221	75.7%	75.3%	0.892	72.6%	72.7%	0.955	56.1%	57.9%	0.609	27.6%	38.6%	<0.001[a]
ASA Level 3 (5[a])	6.0%	6.4%	0.221	14.7%	15.2%	0.892	23.7%	23.4%	0.955	41.8%	39.7%	0.609	64.4%	57.1%	<0.001[a]
ASA level 4 (5[a])	0.0%	0.0%	0.221	0.0%	0.0%	0.892	0.0%	0.0%	0.955	0.1%	0.1%	0.609	7.1%	2.7%	<0.001[a]
Emergency case (1[a])	0.7%	0.2%	0.001[a]	0.4%	0.3%	0.297	0.4%	0.2%	0.260	0.4%	0.2%	0.313	0.5%	0.0%	0.082
Avg. work RVU sum	172.8 ± 3.9	246.6 ± 4.0	<0.001[a]	142.3 ± 2.6	237.3 ± 5.0	<0.001[a]	127.5 ± 2.1	226.3 ± 5.7	<0.001[a]	118.4 ± 1.7	221.8 ± 6.9	<0.001[a]	110.7 ± 1.5	229.5 ± 10.6	<0.001[a]
Avg. operative time (mean)	26.3 ± 0.5	57.7 ± 0.6	<0.001[a]	23.6 ± 0.3	56.7 ± 0.7	<0.001[a]	22.5 ± 0.3	54.6 ± 0.8	<0.001[a]	21.6 ± 0.2	27.5 ± 1.0	<0.001[a]	21.0 ± 0.2	53.9 ± 1.5	<0.001[a]

[a] Indicates statistical significance.

Table 4
Crude complication rates between non-reconstructive and reconstructive patients.

Patient outcomes	Non-recon		Reconstruction		*p*
	(*n* = 26,405)		(*n* = 11,318)		
Overall complications	1531	5.8%	757	6.70%	0.001[a]
Surgical complications	1096	4.2%	579	5.10%	<0.001[a]
Wound infection	960	3.6%	421	3.70%	0.690
Superficial SSI	679	2.6%	209	1.80%	0.894
Deep SSI	198	0.7%	139	1.20%	<0.001[a]
Organ/space SSI	92	0.3%	78	0.70%	<0.001[a]
Graft/flap necrosis, prosthesis failure	78	0.3%	148	1.30%	<0.001[a]
Wound disruption	109	0.4%	62	0.50%	0.074[a]
Reoperations	1346	5.1%	840	7.40%	<0.001[a]
Medical complications	237	0.9%	71	0.63%	0.008[a]
Pneumonia	48	0.2%	16	0.10%	0.384
Unplanned intubation	45	0.2%	6	0.10%	0.004[a]
Ventilator > 48 h	24	0.1%	2	0.00%	0.013[a]
Renal insufficiency	16	0.1%	1	0.00%	0.032[a]
Acute renal failure	12	0.0%	3	0.00%	0.575
UTI	137	0.5%	38	0.30%	0.016[a]
Peripheral neurologic deficit	6	0.0%	8	0.10%	0.027[a]
Catastrophic complications	294	1.1%	129	1.10%	0.824
PE	34	0.1%	28	0.20%	0.009[a]
Stroke	28	0.1%	3	0.00%	0.011[a]
Coma	1	0.0%	0	0.00%	0.513
Cardiac arrest	17	0.1%	0	0.00%	0.003[a]
MI	17	0.1%	3	0.00%	0.143
DVT	56	0.2%	39	0.30%	0.019[a]
Sepsis/septic shock	27	0.1%	7	0.10%	0.231
Mortality	53	0.2%	1	0.00%	<0.001[a]

[a] Indicates statistical significance.

surgeons regarding all the options available to women post-mastectomy.

As previously mentioned, the strengths of the NSQIP database lie in its 1.3 million patient population spanning hundreds of hospitals [21–23]. Previously published reports comparing complication rates in this type of patient population have been smaller, or focused on cosmesis alone [30–34]. One of the largest multi-center data sets, the Michigan Breast Reconstruction Outcome Study (MROC) out of University of Michigan, although population-based, contained only 326 patients, limiting the strength of any regression analysis [35].

The need for a large sample size is illustrated by the significant differences between the demographics of our two study groups (mastectomy alone and mastectomy with reconstruction), which required propensity scoring and risk-stratification for statistical analysis. Specifically, patients undergoing reconstructive surgery were younger, Caucasian, non-smokers, and had fewer overall pre-operative comorbidities. These comorbidities included diabetes, hypertension, and peripheral vascular disease, which have been widely recognized to predispose to poor outcomes in immediate breast reconstruction [36–38]. The low percentage of patients with these factors in the reconstructive group is suggestive of careful pre-operative patient selection by surgeons [36–41]. In spite of propensity scoring and quintile matching however, this study could not entirely eliminate the possibility of selection bias, with race remaining significant in all quintiles after matching. Variance in race between reconstructive and non-reconstructive cohorts is not uncommon and has been demonstrated in nearly every other study of breast reconstruction utilization, certainly a direction for future breast reconstruction research [17,34,35].

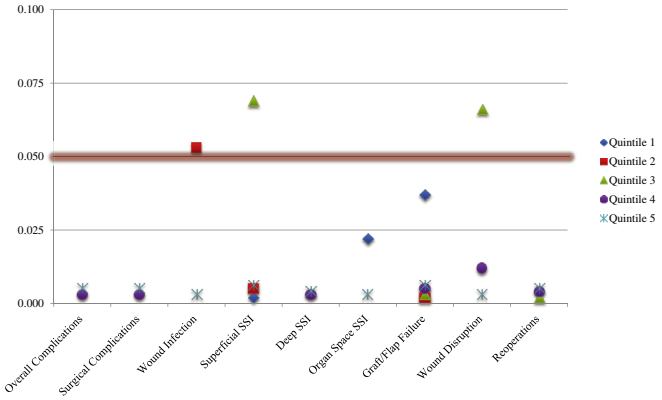

Fig. 1. Plotted significance values of complications in non-reconstructive and reconstructive patients after quintile scoring.

Prior to propensity scoring, the incidence of overall complications was elevated in the reconstructive group; the majority of these complications attributed to SSIs. In previous studies, one of the most significant causes of postoperative morbidity following mastectomy was SSIs, with Alderman et al. reporting an 18.8% infection rate [20,35,42–48]. After quintile matching, SSIs were no longer more common in the reconstructive group, leading to non-significance of differences in overall complications. Given that non-reconstructive patients were more comorbid, this reversal of significance demonstrates the exponential increase in complications in more risky quintiles of the reconstructive group. This effect was corroborated in the regression analysis, which demonstrated that age, diabetes, hypertension, and BMI were all risk factors for overall complications. Propensity scoring matched patients who most frequently had these aforementioned risk factors were in quintile 1, with the likelihood of comorbidities increasing as quintiles moved from 1 to 5. When looking at the resulting complication profiles, quintiles 4 and 5 were much more likely to exhibit SSIs and a subsequent increase in overall complications, than groups 1 through 3. Ultimately, while healthier quintiles tolerated reconstruction better, with a range of complications from 3.6% in quintile 2–18.5% in quintile 5, the summative result demonstrated no statistical difference between the non-reconstructive and reconstructive groups.

These results emphasize the importance of patient selection and counseling when carefully assessing the "counterbalance" between the psychosocial benefits of reconstruction and the possibility of complications. The psychological impact of breast cancer, mastectomy, and reconstructive surgery has been well studied over the last two decades. Many of these studies have demonstrated improved quality of life, psychosocial functioning, body image, and self-esteem in reconstructive patients [7–14]. Nevertheless, these positive results can vary significantly among patients and the benefits of reconstruction should not be taken as implicit. In fact, some studies have argued that reconstruction alone is not sufficient, and that appropriate psychotherapy and counseling can be just as effective as reconstruction [15,16].

For reconstructive surgeons, the responsibility lies in weighing the perceived risks of the reconstructive procedure with all the potential treatment options available to the patient in the multi-disciplinary approach to breast cancer. Specifically, studies have generally demonstrated a range of 3–11% improvement in overall psychosocial functioning following reconstruction [12–16]. Since our study suggests that rates of complications can occur in up to one of every five patients when significant comorbidities are present, it is evident these individuals may not derive sufficient benefit from reconstruction to outweigh the overall risks, and alternative treatment to improve psychosocial function should be pursued. Conversely, younger and healthier patients who have significant declines in psychological outcomes following breast cancer

Table 5
Complication profiles compared between non-reconstructive and reconstructive patients after propensity score stratification.[b]

	Quintile 1			Quintile 2			Quintile 3			Quintile 4			Quintile 5		
	No recon ($n = 3254$) %	Recon ($n = 4226$) %	p	No recon ($n = 4532$) %	Recon ($n = 2948$) %	p	No Recon ($n = 5391$) %	Recon ($n = 2088$) %	p	No Recon ($n = 6131$) %	Recon ($n = 1348$) %	p	No Recon ($n = 6855$) %	Recon ($n = 624$) %	p
Overall complications (4,5[a])	5.6%	5.1%	0.328	5.3%	4.6%	0.201	5.2%	5.9%	0.244	5.6%	9.8%	<0.001[a]	7.0%	22.8%	<0.001[a]
Surgical complications (4,5[a])	4.1%	4.1%	0.970	3.9%	3.6%	0.505	3.6%	4.3%	0.172	4.2%	6.8%	<0.001[a]	4.8%	18.3%	<0.001[a]
Wound infection (5[a])	3.4%	2.9%	0.153	3.4%	2.6%	0.053	3.2%	2.6%	0.181	3.6%	4.5%	0.115	4.3%	16.0%	<0.001[a]
Superficial SSI (1,2,5[a])	2.3%	1.4%	0.002[a]	2.5%	1.4%	0.002[a]	2.1%	1.5%	0.069	2.7%	2.7%	0.980	3.1%	100.0%	<0.001[a]
Deep SSI (4,5[a])	0.8%	0.8%	0.956	0.6%	0.9%	0.231	0.9%	0.8%	0.808	0.6%	1.5%	0.001[a]	0.9%	6.7%	<0.001[a]
Organ/space SSI (1,5[a])	0.4%	0.8%	0.022[a]	0.4%	0.3%	0.921	0.3%	0.3%	0.580	0.4%	0.4%	0.639	0.4%	3.5%	<0.001[a]
Wound disruption (4,5[a])	0.3%	0.4%	0.652	0.5%	0.3%	0.344	0.2%	0.5%	0.066	0.4%	0.9%	0.012[a]	0.6%	2.1%	<0.001[a]
Reoperations (3,4,5[a])	6.4%	7.3%	0.133	5.8%	6.2%	0.561	5.4%	7.2%	0.003[a]	4.5%	7.9%	<0.001[a]	4.3%	14.3%	<0.001[a]
Graft/Flap necrosis (1,2,3,4,5[a])	0.5%	0.9%	0.037[a]	0.2%	0.8%	<0.001[a]	0.3%	1.4%	<0.001[a]	0.2%	1.9%	<0.001[a]	0.4%	4.3%	<0.001[a]
Medical complications (1,4[a])	0.9%	0.4%	0.002[a]	0.6%	0.4%	0.151	0.7%	0.7%	0.807	0.8%	1.3%	0.050[a]	1.3%	2.1%	0.149
Pneumonia	0.1%	0.1%	0.135	0.1%	0.2%	0.452	0.1%	0.1%	0.703	0.1%	0.1%	0.669	0.4%	0.0%	0.258
Unplanned intubation	0.1%	0.0%	0.583	0.0%	0.0%	0.522	0.1%	0.0%	0.164	0.1%	0.2%	0.161	0.5%	0.3%	1.000
Ventilator > 48h	0.1%	0.0%	0.107	0.0%	0.0%	1.000	0.0%	0.0%	0.534	0.0%	0.0%	1.000	0.2%	0.3%	0.669
Acute renal failure	0.0%	0.0%	0.435	0.0%	0.0%	1.000	0.0%	0.0%	0.379	0.0%	0.1%	0.180	0.1%	0.3%	0.232
UTI (1,5[a])	0.6%	0.1%	<0.001[a]	0.4%	0.2%	0.062	0.5%	0.5%	0.724	0.6%	0.7%	0.619	0.5%	1.3%	0.022[a]
Periph. Neuro. deficit (4,5[a])	0.1%	0.1%	1.000	0.0%	0.0%	1.000	0.0%	0.0%	0.834	0.0%	0.2%	0.044[a]	0.0%	0.2%	0.001[a]
Catastrophic complications (5[a])	0.7%	0.7%	0.699	0.7%	0.7%	0.668	0.7%	0.7%	0.881	1.0%	1.3%	0.219	2.1%	7.2%	<0.001[a]
PE (3,4[a])	0.1%	0.1%	0.711	0.1%	0.3%	0.102	0.1%	0.3%	0.037[a]	0.0%	0.4%	0.001[a]	0.2%	0.5%	0.201
Stroke	0.1%	0.0%	0.659	0.0%	0.0%	0.522	0.0%	0.0%	1.000	0.2%	0.0%	0.138	0.2%	0.0%	0.317
Cardiac arrest	0.0%	0.0%	1.000	0.0%	0.0%	1.000	0.0%	0.0%	1.000	0.0%	0.0%	1.000	0.2%	0.0%	0.296
MI	0.0%	0.0%	1.000	0.0%	0.0%	0.394	0.1%	0.0%	0.565	0.1%	0.0%	1.000	0.1%	0.2%	0.582
DVT (5[a])	0.2%	0.3%	0.223	0.3%	0.3%	0.978	0.2%	0.2%	0.766	0.1%	0.1%	1.000	0.2%	1.3%	<0.001[a]
Sepsis/septic shock (4,5[a])	0.4%	0.2%	0.207	0.2%	0.1%	0.430	0.2%	0.2%	1.000	0.4%	0.9%	0.022[a]	1.2%	6.1%	<0.001[a]
Mortality	0.0%	0.0%	1.000	0.0%	0.0%	1.000	0.1%	0.0%	0.693	0.1%	0.0%	0.365	0.6%	0.0%	0.076

[a] Indicates statistical significance.

[b] Propensity score assigned using the following preoperative variables: gender, race, outpatient status, transfer status, age, year of operation, BMI, diabetes, smoking, alcohol use, resident presence concurrent chemotherapy/radiotherapy, dyspnea, chronic obstructive pulmonary disease, congestive heart failure, myocardial infarction, previous cardiac surgery or percutaneous intervention, hypertension, known PVD, hemiplegia, paraplegia, quadraplegia, recent stroke or TIA, recent wound infection, disseminated cancer, known bleeding disorder, previous sepsis or septic shock, prior operation within 30 days, pregnancy, wound classification, and ASA classification.

Table 6
Multivariate regression of preoperative risk factors contributing to overall complications in patients receiving reconstruction.[b]

Overall complications		
Preoperative variable	Odds ratio [95% CI]	*p*
Outpatient	1.504 [1.173, 1.929]	0.001[a]
Age > 50	1.705 [1.314, 2.212]	<0.001[a]
Obesity (BMI > 30)	2.000 [1.689, 2.368]	<0.001[a]
Diabetes	1.753 [1.325, 2.318]	<0.001[a]
Smoking	1.724 [1.405, 2.114]	<0.001[a]
COPD	3.436 [2.123, 5.563]	<0.001[a]
Previous PCI or cardiac surgery	1.952 [1.250, 3.048]	0.003[a]
Hypertension with medication	1.924 [1.540, 2.404]	<0.001[a]
Stroke or TIA	4.880 [3.313, 7.189]	<0.001[a]
Disseminated cancer	4.215 [2.555, 6.954]	<0.001[a]
Steroids	2.333 [1.256, 4.333]	0.007[a]
Bleeding disorders	4.175 [2.481, 7.026]	<0.001[a]
Chemotherapy	2.070 [1.462, 2.933]	<0.001[a]
Radiotherapy	1.679 [0.691, 4.080]	0.253
Prior operation within 30 days	1.830 [1.255, 2.667]	0.002[a]
Work RVUs	1.005 [1.001, 1.009]	0.011[a]
Operative time	1.003 [1.003, 1.004]	<0.001[a]

[a] Denotes statistical significance; HL: 0.494; C-statistic: 0.737.
[b] Adjusted for quintile scoring.

diagnosis appear to have no additional conferred risk when reconstruction is performed according to our study. This suggests that reconstruction should be aggressively pursued in this population.

When presenting these risks and benefits to the patient during consultation, it is clear not all reconstructive procedures are made equal. Almost universally, patients who receive autogenous reconstruction using abdominal donor sites report a statistically significant improvement in cosmesis and body image [14–16]. However, given the inherent difficulty in autogenous reconstruction, many studies have demonstrated increased complications compared to the use of prostheses [35,36,38–42]. In this study, the rate of overall flap/prosthesis loss was four times as great in the most comorbid 5th quintile versus the 1st (4.3% versus 0.9%). These percentages are similar to those reported by the MROC study, with an overall implant/flap loss of 1.8% [35]. However, it must be noted that the NSQIP variable "graft/prosthesis/flap failure" is a combined variable including mastectomy flap necrosis. Mastectomy flap necrosis may occur before or after reconstruction, explaining the 78

Table 7
Multivariate regression of preoperative risk factors contributing to surgical site infections in patients receiving reconstruction.[b]

Surgical site infections		
Preoperative variable	Odds ratio [95% CI]	*p*
Outpatient	1.340 [0.976, 1.840]	0.070
Age > 50	1.532 [1.098, 2.136]	0.012[a]
Obesity (BMI > 30)	1.813 [1.456, 2.256]	<0.001[a]
Diabetes	2.094 [1.509, 2.905]	<0.001[a]
Smoking	1.597 [1.225, 2.083]	0.001[a]
COPD	3.526 [2.054, 6.054]	<0.001[a]
Previous PCI or cardiac surgery	2.230 [1.356, 3.668]	0.002[a]
Hypertension with medication	1.897 [1.428, 2.520]	<0.001[a]
Stroke or TIA	4.791 [3.118, 7.363]	<0.001[a]
Disseminated cancer	3.332 [1.795, 6.185]	<0.001[a]
Steroids	2.669 [1.306, 5.455]	0.007[a]
Bleeding disorders	3.307 [1.822, 6.004]	<0.001[a]
Chemotherapy	2.154 [1.400, 3.316]	<0.001[a]
Radiotherapy	1.861 [0.664, 5.212]	0.237
Work RVUs	1.006 [1.001, 1.011]	0.027[a]
Operative time	1.001 [1.001, 1.002]	<0.001[a]

[a] Denotes statistical significance; HL: 0.735; C-statistic: 0.718.
[b] Adjusted for quintile scoring.

Table 8
Multivariate regression of preoperative risk factors contributing to reoperation in patients receiving reconstruction.[b]

Reoperation		
Preoperative variable	Odds ratio [95% CI]	*p*
Obesity (BMI > 30)	1.127 [0.959, 1.325]	0.147
Diabetes	1.597 [1.200, 2.124]	0.001[a]
Smoking	1.314 [1.084, 1.592]	0.005[a]
COPD	1.702 [0.981, 2.951]	0.058
Previous PCI or cardiac surgery	1.249 [0.749, 2.081]	0.394
Hypertension with medication	1.175 [0.963, 1.433]	0.113
Stroke or TIA	2.017 [1.276, 3.188]	0.003[a]
Disseminated cancer	1.667 [0.922, 3.014]	0.091
Steroids	1.887 [1.036, 3.437]	0.038[a]
Bleeding disorders	2.556 [1.485, 4.401]	0.001[a]
Prior operation within 30 days	1.684 [1.184, 2.393]	0.004[a]
Work RVUs	1.000 [0.997, 1.004]	0.853
Operative time	1.002 [1.002, 1.003]	<0.001[a]

[a] Denotes statistical significance; HL: 0.785; C-statistic: 0.607.
[b] Adjusted for quintile scoring.

patients in the non-reconstructive cohort who were positive for the flap loss variable. In reoperation, similar trends are visible across quintiles, and reoperation was necessary in reconstructive quintiles 4 and 5 more often than in quintiles 1–3, as well as statistically more common compared to the non-reconstructive group. Since reconstructive failure directly affects psychological and cosmetic outcomes, it seems autogenous procedures, with increased complexity, should be reserved for the most ideal reconstructive candidates.

In this study, the incidence of complications directly follows suit with the increased complexity of the reconstructive procedure [42–44,49]. Overall, reconstruction of any type was reflected by the nearly 0.75 additional hours needed compared to mastectomy alone. This increased complexity also corroborated by the average 31% increase in total RVUs for reconstructive procedures. Prolonged operative time has historically correlated with prolonged anesthesia time, increased incisional contamination secondary to desiccation and exposure, and increased blood requirements [42,44,49]. More specifically, this study demonstrated that for every hour of additional operative time, there was increased overall complications by 18%, SSI by 6%, and reoperation by 12%. Thus when deciding between autogenous and prosthetic reconstruction, choosing a simpler and more efficient procedure is particularly important in the patient with more comorbidities in order to maximize the psychosocial benefit, minimize the risk of complications, and optimize the cost/time investment to overall outcome ratio.

Although ACS-NSQIP is a useful database to conduct large observational studies, it has several limitations in its applicability to plastic and reconstructive surgery. The nature of the database limits the specific risk factors that can be evaluated. For example, the duration of postoperative drain has been shown to be a significant risk factor for SSI in breast surgeries, but is a variable that is not collected by the NSQIP database [50]. Similarly, the use of pre- and postoperative antibiotics is not accurately tracked, an important variable given that compliance with SCIP recommendations of withholding postoperative antibiotics has been shown to increase implant infection rates [51]. Furthermore, the NSQIP database does not include information on previous breast conservation therapy failure, disease stage, tumor burden, or remote radiation therapy, all of which may play a role in the development of complications.

One critical factor influencing surgical outcomes is surgeon experience. NSQIP does not track this data, and thus is a significant limitation to our study. As a surrogate, we have utilized the presence of a resident as a proxy for hospital setting, an analysis that

has precedence in the literature [52]. After matching with propensity scoring, only one significant difference in residence presence between reconstructive and non-reconstructive groups was found across all 5 groups (Table 3).

Additionally, the role of ADM in increasing complications in the setting of breast reconstruction is controversial [53,54]. In our study, we found a much higher utilization of ADM in the reconstruction cohort. This is expected, given ADM's use in breast reconstruction surgery, shown in Table 2, (0.7% versus 13.9%). Given the extreme differences in utilization of ADM in the reconstruction versus non-reconstruction cohorts, we were unable to control for its utilization using propensity scoring. However, in spite of this, we did not observe any statistical difference in outcomes between the reconstruction and non-reconstruction cohorts. It should be noted that the present study was not designed to evaluate the relationship between ADM and breast reconstruction outcomes. Thus our findings should not be interpreted as contributing to this discussion.

There are several limitations regarding the lack of information regarding mastectomy-specific procedures in NSQIP. Factors that have been shown to predispose to complications such as breast size, acellular dermal matrix usage, skin-sparing and nipple-sparing mastectomy are not captured. These, along with concurrent axillary dissection, are known to be predictors of mastectomy complications. However, certain breast specific complications such as mastectomy skin necrosis and seroma occurrence are also not captured. Although many of these breast specific prognostic factors and complications are indiscernable, concurrent axillary dissections were determined using CPT codes 19305-7. Similar to most variables in the crude demographics table (Table 2), there was a significant difference in axillary dissection in patients with and without reconstruction (28.7% versus 38.8%). However, after controlling for axillary dissection through quintile matching, the variable was not significantly higher across a majority of quintiles.

The database also does not follow patients for more than 30 days postoperatively, eliminating potential evaluation of long term complications [22]. Lastly, the patient populations extracted from the database had known differences in demographics and preoperative comorbidities even after quintile matching. While propensity scoring attenuated the impact of such differences, only randomized cohorts could have provided a more unbiased outcome.

Conclusion

Data from the NSQIP database suggests that reconstruction following total mastectomy is overall a safe and well-tolerated procedure. Patients who have significant comorbidities are at increased risk of surgical site infections, prosthesis loss, and reoperation. Thus, reconstruction is not a panacea for global improvement in health-related quality of life, and many patients may be better served through alternative methods such as counseling. These risks must be carefully counterbalanced with the psychosocial benefits of reconstruction to select candidates appropriate for reconstruction. Increased operative time required to perform the reconstruction, was a highly significant risk factor in all cases. As such, proper patient selection and counseling is essential to develop appropriate expectations and maximize patient satisfaction following reconstruction. Future research aimed at controlling identified risk factors, identifying potential "protective" surgical factors, and determining interventions to equalize racial disparities in breast reconstruction will help further minimize the perceived negative effects of breast reconstruction.

List of products used

No products, devices, or drugs were used in this article.

Ethical approval

De-identified patient information is freely available to all institutional members who comply with the ACS-NSQIP Data Use Agreement. The Data Use Agreement implements the protections afforded by the Health Insurance Portability and Accountability Act of 1996 and the ACS-NSQIP Hospital Participation Agreement.

Disclaimer

The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Conflict of interest statement

The authors have no financial disclosures relevant to this paper.

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