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Identifying risk factors for surgical site infections in mastectomy patients using the National Surgical Quality Improvement Program database

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Surgical site infections;
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Abstract

BACKGROUND: The Centers for Disease Control and Prevention reported that surgical site infections (SSIs) create a significant hospital burden. To date, few multi-institutional studies have been performed to evaluate the risk factors for SSIs in mastectomy patients.

METHODS: By using the American College of Surgeons' National Surgical Quality Improvement Program database, all patients undergoing mastectomy from 2005 to 2009 were identified. The outcome was to determine the incidence rate and identify significant independent risk factors of SSIs.

RESULTS: The incidence of SSI was 2.3% (891 of 38,739; 95% confidence interval, 2.2%–2.5%) in patients undergoing mastectomy without reconstruction. Significant ($P < .05$) risk factors for SSI included a body mass index greater than 25, American Society of Anesthesiology classification of 3 or higher, diabetes mellitus, surgical time of 2 hours or longer (75th percentile), and current smoking status.

CONCLUSIONS: Before this study, there was wide variation in the incidence rate of surgical site infections in this patient population. This was a large-scale study to address these inconsistencies.
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Breast cancer is the most common cause of cancer among women in the United States, and the second leading cause of cancer mortality.[1] With the multimodality approach to cancer treatment today, it is estimated that more than 37% women will undergo mastectomy as part of their treatment plan.[2] Although breast cases are considered clean procedures, the rates of surgical site infections (SSIs) in this patient population are variable[3–6] and range from 1% to 26%.[7] In addition, recent studies have noted a trend away from the usual *Streptococci* and *Staphylococcus* isolates and to more severe infections including a higher incidence of gram-negative bacilli, anaerobes, and antibiotic-resistant staphylococcal infections.[7,8]

Surgical site infections are a significant cause of postoperative morbidity, prolonged hospital stay, and increased hospital costs.[6,9,10] A 2002 report, conducted by the National Nosocomial Infection Surveillance system (NNIS)

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and the Centers for Disease Control and Prevention, estimated that of the 1.7 million hospital-acquired infections reported annually, SSIs contributed up to 20% of cases and 8% of hospital-acquired infection–related mortality.[11] In addition, the increased expenditure related to surgical site infections has been estimated to be $166 to $345 million annually.[12] With recent focuses on health care reform, more scrutiny will be placed on preventable occurrences with emphasis on less hospital reimbursement and even implementation of financial penalties.[13,14]

The recent establishment of surveillance and prevention programs have shown a significant worldwide reduction in the rates of SSIs.[15–20] Nevertheless, even with these aggressive measures, the incidence rate of SSI after breast surgeries still is significant. To date, few large-scale, multi-institutional studies have been performed to evaluate risk factors in this patient population. By using the American College of Surgeon's National Surgical Quality Improvement Program (ACS NSQIP) registry, we evaluated this patient population with the primary objective to determine the incidence rate of SSI within 30 days of surgery in patients who underwent mastectomy without reconstruction. The secondary outcome was to identify significant independent risk factors that contributed to this rate.

Table 1 Procedures and corresponding CPT codes for mastectomy

CPT code	Procedure
19301 (19160)	Partial mastectomy (lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19302 (19162)	Partial mastectomy with lymph node removal (with axillary lymphadenectomy)
19303 (19180)	Mastectomy, simple, complete
19304 (19182)	Mastectomy, subcutaneous
19305 (19200)	Mastectomy, radical (including pectoral muscles, axillary lymph nodes)
19306 (19220)	Mastectomy, radical, urban type (including pectoral muscles, axillary and internal mammary lymph nodes)
19307 (19240)	Mastectomy, modified radical (including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle)

The procedures included in this study along with the CPT codes are listed. In 2007, CPT codes were changed, and codes used before 2007 are listed in parentheses.

Methods

Data source

The NSQIP database initially was developed within the Veterans Health Administration System in 1991 and subsequently was expanded by the ACS in 2004. It is a national database that provides validated, risk-adjusted surgical outcomes from 160 hospitals with the primary goal to improve the quality of care in surgical patients. Information is obtained through medical records and/or direct communication and includes demographics, laboratory values, and variables from the preoperative, perioperative, and postoperative settings. These data are used to generate risk-adjusted outcomes within 30 days of the index surgery, and they allow for the reviewers to conduct blinded, observational studies. On-site audit programs are used to standardize data collection to ensure data consistency and reliability.[21] The use of the database was approved by the NSQIP Participation Use Data Agreement, which implements the Health Insurance and Portability and Accountability Act of 1996 and the ACS NSQIP Hospital Participation Agreement.

By using the ACS NSQIP database, all female patients who underwent mastectomy without reconstruction from 2005 to 2009 were identified using the Current Procedural Terminology (CPT) codes indicated in Table 1. Only clean procedures were analyzed, and clean-contaminated, contaminated, and dirty-infected procedures were excluded. Surgical site infections were defined according to the Centers for Disease Control and Prevention guidelines.[22] Superficial, deep, and organ space surgical site infections were included in the analysis. Further exclusion criteria included male sex or sex unknown, clinical variables in which more 20% of data of interest were missing, mastectomy for gynecomastia, mortality within 30 days of surgery, more than 2 mastectomy procedures recorded in the NSQIP database, and confounding procedures (ie, appendectomy) where the location of surgical site infection could not be clearly confined to the site of mastectomy. In addition, bilateral mastectomies were included as 2 separate procedures.

The variable of age was dichotomized into 2 groups, younger than age 50 years and 50 years and older, because age of 50 years has been cited in the literature as the age when there is an increased surgical site infection risk in this patient population.[7,23,24] Body mass index (BMI) was calculated from the following formula: BMI = mass (kg)/height (cm^2), and was categorized based on clinical criteria for normal weight ($>$25 to $<$30), obese ($\geq$30 to $<$35), and morbidly obese ($\geq$35). The American Society of Anesthesiology (ASA) Physical Status classification was defined as follows: 1 = normal healthy patient; 2 = mild systemic disease; 3 = patient with severe systemic disease; 4 = severe systemic disease with constant threat to life; and 5 = moribund patient not expected to survive without surgery. The patients were grouped into categories of ASA classification of 1 and 2 or ASA classification of 3 or higher, which is an NNIS index risk category for SSI.[25] Patients were considered to have diabetes mellitus only if they were taking oral hypoglycemic agents and/or insulin.[26] Intraoperative time greater than the 75th percentile is a significant risk

Table 2 Procedures and corresponding CPT codes for axillary lymph node dissection

CPT code	Procedure
19302	Mastectomy, partial with axillary lymphadenectomy (including lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19305	Mastectomy, radical, including pectoral muscles, axillary lymph nodes
19306	Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (urban-type surgery)
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle
38740	Axillary lymphadenectomy; superficial
38745	Axillary lymphadenectomy; complete

The procedures included in this study along with the Current Procedural Terminology codes are listed.

factor described by the NNIS risk index,[25] which in our study was 2 or more hours. The patient was considered a smoker if he/she had smoked cigarettes in the year before admission for surgery.[26] Patients who had axillary lymph node dissections were extracted from the database by the CPT codes listed in Table 2. The CPT codes commonly used for sentinel lymph node biopsy, 38525 (open, deep axillary node), 38530 (open internal mammary node), 38500, 38510, 38520, 38525, 38530, and 39542, were not included in the database. Preoperative renal failure included patients with the following: (1) acute renal failure, defined as rapid increasing azotemia and increasing creatinine level greater than 3 mg/dL within 24 hours before surgery; or (2) peritoneal dialysis, hemodialysis, hemofiltration, or ultrafiltration within 2 weeks before surgery. Chemotherapy treatment was defined as administration of chemotherapeutic agents for cancer within 30 days before surgery (as defined in the NSQIP database). Radiotherapy included patients who had treatment within 90 days before surgery.[26]

Statistical analysis

Univariate analysis was performed to assess the association of each risk factor with the presence or absence of SSI. The Student *t* test was used to assess the difference of the means, and the 2-sided Fisher exact test was used for proportions. Risk factors with *P* values less than .20 from the univariate analysis were included in the stepwise logistic regression analysis. Adjusted odds ratios and 95% confidence intervals (CI) were derived for each risk factor included in the stepwise logistic regression analysis. SAS statistical software (version 9.2) (SAS Institute Inc, Cary, NC) was used for all statistical analyses. A *P* value of less than .05 was considered statistically significant.

Results

A total of 38,739 patients were identified who met the inclusion criteria of having mastectomies without reconstruction during this time period. A total of 891 patients developed an SSI (incidence rate, 2.3%; 95% CI, 2.2%–2.5%). A comparison of the demographic and clinical characteristics between the SSI and no-SSI groups is presented in Table 3. Age and preoperative chemotherapy were not significantly different between the SSI and no-SSI groups in this patient population and therefore were not included in subsequent analyses. In addition, preoperative renal failure and radiotherapy were not included because less than 10% of patients included in the study had these risk factors. The results of the univariate and multivariate analyses with the odds ratios and 95% confidence intervals for each risk factor are presented in Table 4.

From the univariate analysis, the variables of age (<50 vs ≥50 y), BMI groups, ASA classifications, diabetes mellitus, intraoperative time (≥2 vs <2 h), smoking status, axillary lymph node dissection, and chemotherapy were included in the stepwise logistic regression analysis. Statistically significant independent risk factors identified by the stepwise logistic regression analysis were BMI greater than 25, ASA classification of 3 or higher, diabetes mellitus, intraoperative time of 2 or more hours, and current smoker status (Table 4).

Comments

Our data revealed an SSI incidence rate of 2.3% in patients having mastectomies alone without immediate reconstruction. This rate was slightly higher than the NNIS rate reported in 2004 for patients having mastectomies in low-risk categories.[3] The strongest influence on SSI in this patient population was morbid obesity (BMI ≥ 35). These patients were more than 2 times more likely to develop SSI (adjusted odds ratio, 2.60; 95% CI, 2.13–3.27; $P < .0001$) than normal-weight individuals. In addition, patients who were considered obese (BMI, ≥30 but <35) were 1.77 times more likely to develop an SSI, which is consistent with other published studies for a wide range of surgical procedures.[4,27–30] Current smoking status also was determined to be an independent risk factor. The Centers for Disease Control and Prevention guidelines describe cigarette smoking being linked to an increased risk for SSI.[28] There have been conflicting reports on diabetic status as a risk factor for SSI in breast literature.[4,6,7,20,23,28,30,31] Our study showed that diabetic patients were more than 1.3 more times likely to develop an SSI than nondiabetic patients (95% CI, 1.10–1.59; $P = .0036$). This was not surprising because diabetes is associated with impaired wound healing because of poor microcirculation, tissue hypoxia,[32] and impaired wound-healing cascade.[33] Unfortunately, because of limitations of the NSQIP database, we were not able to determine the level of diabetic control before the surgery. Numerous studies have indicated that prolonged surgical

Table 3 Comparison of risk factors for surgical site infection in mastectomy without immediate reconstruction

	All patients (n = 38,739)	Presence of SSI (n = 891)	Absence of SSI (n = 37,848)	*P* value
Age, y				
<50	8,745 (22.6%)	186 (20.9%)	8,559 (22.6%)	.220
≥50	29,994 (77.4%)	705 (79.1%)	29,289 (77.4%)	
BMI				
<25	12,891 (33.7%)	183 (20.9%)	12,708 (34.0%)	
>25 to <30	11,647 (30.4%)	217 (24.8%)	11,430 (30.6%)	.006
>30 to <35	7,337 (19.2%)	200 (22.8%)	7,137 (19.1%)	<.0001
≥35	6,393 (16.7%)	276 (31.5%)	6,117 (16.3%)	<.0001
ASA				
<3	26,711 (69.1%)	493 (55.5%)	26,218 (69.4%)	<.0001
≥3	11,955 (30.9%)	395 (44.5%)	11,560 (30.6%)	
Diabetes mellitus				
No	34,344 (88.6%)	722 (81.0%)	33,622 (88.8%)	<.0001
Yes	4,395 (11.4%)	169 (19.0%)	4,226 (11.2%)	
Intraoperative time, h				
<2	28,971 (74.8%)	565 (63.4%)	28,406 (75.0%)	<.0001
≥2	9768 (25.2%)	326 (36.6%)	9,442 (25.0%)	
Current smoker				
No	33,205 (85.7%)	695 (78.0%)	32,510 (85.9%)	<.0001
Yes	5,534 (14.3%)	196 (22.0%)	5,338 (14.1%)	
Axillary lymph node dissection				
No	25,679 (66.3%)	538 (60.4%)	25,141 (66.4%)	<.0001
Yes	13,060 (33.7%)	353 (39.6%)	12,707 (33.6%)	
Preoperative renal failure				
No	38,639 (99.7%)	885 (99.3%)	37,754 (99.7%)	.028
Yes	100 (.3%)	6 (.7%)	94 (.3%)	
Chemotherapy				
No	37,116 (95.8%)	855 (96.0%)	36,261 (95.8%)	.932
Yes	1,623 (4.2%)	36 (4.0%)	1,587 (4.2%)	
Radiotherapy				
No	38,591 (99.6%)	884 (99.2%)	37,707 (99.6%)	.087
Yes	148 (.4%)	7 (.8%)	141 (.4%)	

time, more than the 75th percentile, is a risk factor for SSI.[25,30,34,35] This was concordant with our study, which showed that patients with procedures lasting longer than the 75th percentile were 1.61 times more likely to develop an SSI (95% CI, 1.40–1.85; $P < .0001$). With advancements in breast cancer treatment options, more women are undergoing neoadjuvant chemotherapy before surgical resection. Plentiful studies in the breast cancer literature have proven that neoadjuvant chemotherapy, in the absence of concomitant radiation therapy, was not a significant risk factor for SSI.[4,7,30,36,37] Our data also supported the premise that preoperative chemotherapy is not a significant risk factor. However, we were unable to assess the role of neoadjuvant chemoradiation therapy because of the low number of patients who received preoperative radiation treatment. In addition, axillary lymph node dissection was not shown to be a significant risk factor, which is supported by the literature.[6,37,38] The role of sentinel lymph node biopsy could not be assessed because it was a variable not obtained by the NSQIP database.

Nasal colonization of *Staphylococcus aureus* has been shown to be an independent risk factor for *S aureus* surgical site infections in orthopedic procedures[39] and cardiac sternal wound infections.[40,41] Recent studies, including prospective, randomized, controlled trials,[42] have revealed that effective eradication of nasal carriage of *S aureus* significantly decreases the rate of subsequent postoperative wound infections in elective cardiac, vascular, orthopedic, and gynecologic surgery.[39,40,43–48] Intranasal mupirocin is an ideal treatment for eradication of nasal carriage of *S aureus* and, more importantly, methicillin-resistant *S aureus*, because it is easy to administer as a 2% ointment with minimal side effects and is cost effective in comparison with the SSI-attributable costs.[49] Interestingly, Portigliatti Barbos et al[50] showed through a preliminary study that decolonization of surgical team members decreased the overall rate of postoperative SSIs in orthopedic procedures at a single institution. This compelling evidence supports the implementation of universal screening and treatment protocols at major surgical centers.

Although the ACS NSQIP is a useful database to conduct large, observational studies, it does have several limitations that must be addressed. Pertaining to our study, the database limits one to evaluate risk factors that are obtained in the database. For example, the duration of a postoperative drain has been shown to be a significant risk factor for SSIs in breast procedures.[7,24,30,31] However, this variable is not collected in

Table 4 Odds ratio of surgical site infection by risk factors in mastectomy without immediate reconstruction: univariate and multivariate analysis

	Univariate analysis			Multivariate analysis	
	SSI cases (%)	Unadjusted odds ratio (95% CI)	Unadjusted *P* value	Adjusted odds ratio (95% CI)	Adjusted *P* value
Age, y					
<50	186 (20.9%)	1.00	.220	—	—
≥50	705 (79.1%)	1.11 (.94–1.30)			
BMI					
<25	183 (20.9%)	1.00		1.00	
>25 to <30	217 (24.8%)	1.31 (1.08–1.60)	.006	1.25 (1.02–1.53)	.0277
>30 to <35	200 (22.8%)	1.95 (1.59–2.38)	<.0001	1.76 (1.44–2.16)	<.0001
≥35	276 (31.5%)	3.13 (2.59–3.79)	<.0001	2.56 (2.10–3.13)	<.0001
ASA					
<3	493 (55.5%)	1.00	<.0001	1.00	<.0001
≥3	395 (44.5%)	1.82 (1.59–2.08)		1.43 (1.24–1.66)	
Diabetes mellitus					
No	81.0% (722/891)	1.00	<.0001	1.00	.008
Yes	19.0% (169/891)	1.86 (1.57–2.20)		1.28 (1.06–1.54)	
Intraoperative time, h					
<2	565 (63.4%)	1.00	<.0001	1.00	<.0001
≥2	326 (36.6%)	1.73 (1.51–1.99)		1.60 (1.39–1.84)	
Current smoker					
No	695 (78.0%)	1.00	<.0001	1.00	<.0001
Yes	196 (22.0%)	1.72 (1.46–2.02)		1.73 (1.46–2.03)	
Axillary lymph node dissection					
No	538 (60.4%)	1.00	<.0001	1.00	.390
Yes	353 (39.6%)	1.30 (1.13–1.49)		1.06 (.93–1.22)	
Chemotherapy					
No	855 (96.0%)	1.00	.822		—
Yes	36 (4.0%)	.96 (.69–1.35)		—	

the database, which limits investigation into this particular risk factor. Furthermore, the NSQIP database does not include information of previous breast-conservation therapy failure, disease stage/tumor burden, or history of remote radiation therapy, which may play a role in the development of SSIs in this patient population. In addition, the database does not allow one to determine compliance with SCIP guidelines; thus, information on perioperative antibiotics and the time in which they were given is not known. Finally, in our particular study, variables that were found to have greater than 20% missing data in the database were excluded from the study. Exclusion of these variables potentially could eliminate the evaluation of other potential risk factors of interest.

In conclusion, by using the ACS NSQIP database, we identified that the incidence rate of SSIs was 2.3% in mastectomy patients. Independent risk factors for SSIs in this patient population were increased BMI, current smoking status, surgical time of 2 or more hours, ASA classification of 3 or higher, and diabetes mellitus. Before our study, there was wide variability in SSI incidence rates in the literature for this patient population. Despite the limitations of the ACS NSQIP database, our analysis of risk factors was consistent with previous published studies, validating the utility of the database in retrospective cohort studies.

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