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Surgical Site Infection (SSI) After Breast Surgery: Impact of 2010 CDC Reporting Guidelines

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Abstract

Introduction—Reported surgical site infection (SSI) rates after breast operations range from 0.8–26% in the literature. Aims of the present study were to characterize SSI after breast/axillary operations and determine the impact on the SSI rate of the 2010 Centers for Disease Control and Prevention (CDC) reporting guidelines that now specifically exclude cellulitis.

Methods—Retrospective chart review identified 368 patients, with 449 operated sides, between 07/2004 and 6/2006. SSI was defined using CDC criteria: purulent drainage (CDC #1), positive aseptically collected culture (CDC #2), signs of inflammation with opening of incision and absence of negative culture (CDC#3), or physician diagnosis of infection (CDC #4). The impact of excluding cellulitis was assessed.

Results—Using prior CDC reporting guidelines, among 368 patients, 32 (8.7%) experienced SSI in 33/449 (7.3%) operated sides. Of these, 11 (33%) met CDC criteria 1–3, while 22 (67%) met CDC criterion 4. Excluding cellulitis cases per 2010 CDC SSI reporting guidelines eliminates 21 of the 22 infections previously meeting CDC criterion 4. Under the new reporting guidelines, the SSI rate is 12/449 (2.7%) operated sides. SSI rates varied by procedure but these differences were not statistically significant.

Conclusions—Cellulitis after breast and axillary surgery is much more common than other criteria for SSI, and SSI rates are reduced almost three-fold if cellulitis cases are excluded. Recently revised CDC reporting guidelines may result in underestimates of the clinical burden of SSI after breast/axillary surgery.

Keywords

surgical site; infection; breast surgery; case definition; CDC guidelines

Introduction

Surgical site infections (SSI) impact the oncologic care of breast cancer patients due to delays in additional therapy in some cases, increases in the cost of care, failed reconstructions, and potentially an increase in cancer recurrence rates.[1, 2] The reported rates

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of SSI after breast operations range dramatically from 0.8–26% in the literature.[3–8] One possible factor accounting for such wide-ranging SSI rates is the use of different definitions of SSI. Prior to 2010, cases of cellulitis could have been considered SSI cases according to the fourth CDC criterion - a physician diagnosis of infection.

In 2010, the Centers for Disease Control and Prevention (CDC) updated their 1999 reporting guidelines and specific criteria that must be met for the diagnosis of SSI [9, 10] As before, the timeframe specifies infections occurring within 30 days of the operation (if no implant was left in place or up to one year with an implant). To be classified as an SSI, the clinical scenario must meet one of the following criteria: purulent drainage, a positive aseptic culture, signs or symptoms of inflammation resulting in opening of the incision by a physician, or a physician's clinical diagnosis. However, this update specifically excludes "cellulitis" as a superficial incisional SSI, making the definition of SSI more stringent and restricting what constitutes an SSI in breast and axillary surgery.

The aims of this study were to investigate SSI rates after breast/axillary operations according to CDC criteria and to determine how excluding cases of cellulitis impacts the SSI rates.

Methods

An IRB-approved retrospective review was undertaken of patients undergoing breast and/or axillary procedures at Mayo Clinic, Rochester, MN. This patient dataset had previously been assembled to evaluate complications of postoperative antibiotic prophylaxis and methylene blue dye [11, 12] This dataset includes all patients of three surgeons (one full-time breast surgical oncologist, one general surgical oncologist, and one part-time general surgeon) who had undergone lymphatic mapping with methylene blue dye between July 2004 and June 2006. The dataset was expanded to include a detailed characterization of SSI cases at all surgical sites in these patients, including surgical sites with non-malignant indications (i.e. contralateral procedures for benign breast disease or risk reduction).

The study cohort initially included 389 patients with 471 operated sides. Twenty-one patients (22 operated sides) were excluded from the analysis due to inadequate follow-up (< 7 days postop), leaving an analysis sample of 368 patients with 449 operated sides. As per the CDC guidelines, we considered bilateral procedures as two separate observations [9] Patients undergoing more than one ipsilateral operation within the 30 days (n =18) were counted only in the most extensive operative category. All hospital and outpatient clinic records were reviewed for patient demographics, type of procedure, presence of SSI, and details related to the diagnosis and treatment of SSI from the immediate preoperative period through the last chart entry.

Surgical site infection was defined using CDC criteria: purulent drainage (CDC #1), a positive aseptically collected culture (CDC #2), at least one sign of inflammation with opening of the incision and absence of a negative culture (CDC#3), or physician diagnosis of infection (CDC #4). For CDC category #4, we carefully noted details of these cases in order to discriminate situations of: 1) definite cellulitis that was treated with antibiotics (previously included but now excluded per 2010 reporting instructions), or 2) other scenarios that would fit the 2010 criteria for CDC#4 SSI (e.g., wound was opened, culture was negative and there was also cellulitis). Cases of minimal erythema treated with a course of outpatient antibiotics were not considered SSI by either old or new criteria unless the documentation of the treating physician indicated a clinical judgment of definite cellulitis; e.g. cases with comments of "probably not cellulitis" or "possible breast lymphedema" that were treated with antibiotics were not considered to be SSI nor to be cases of definite cellulitis. The CDC time period restrictions were observed for SSI identification: infections

occurring within 30 days of operation, or within one year of operation for those patients undergoing non-autologous reconstruction.

Data analysis was primarily descriptive. SSI proportions were estimated using the number of operated sides as the denominator. We classified each SSI according to the most definitive CDC criterion met for summary purposes, assuming the criteria are ordered from most definitive (#1 - purulent drainage) to least definitive (#4 – physician diagnosis). The association of operation type with SSI was assessed using Fisher's exact test. P-values < 0.05 were considered statistically significant. Analysis was performed using SAS (Version 9.2, SAS Institute Inc., Cary, NC).

Results

Patient Characteristics

Descriptive statistics for the 368 study patients are summarized in Table 1. The mean age was 60 years with a range from 23 to 90 years. American Society of Anesthesiologists' (ASA) physical status classification was 3 or 4 in 15% of patients, and 37% of patients were obese with BMI ≥ 30. In 72 patients with concurrent bilateral procedures, both sides were operated for cancer in 10 patients, while the contralateral side was operated for benign causes (risk reduction, benign breast disease) in the remaining 62. Preoperative prophylactic antibiotics were administered to 331 patients (90%); among these a cephalosporin was utilized in the majority (83%).

Inclusive SSI rates

Including cases of definite cellulitis, 33 infections were identified in 449 operated sides among 368 unique patients, with one patient with bilateral surgery having SSI on both sides (Table 2). Thus the SSI rate inclusive of cellulitis was 7.3% per operated sides. Among the 11 cases meeting at least one of the CDC criterion #1–3, 7 patients had purulent drainage (CDC #1), 2 patients had positive cultures (CDC #2), and 2 infections on different sides in one patient met CDC criterion #3.

Impact of excluding cellulitis on defined SSI rates

Of the 33 SSIs, 22 (67%) were classified as CDC category #4 (physician diagnosis of infection) per the "old" reporting methods (Table 2). Of these 22, 21 (95%) patients had cellulitis without purulent drainage or opening of the wound and resolved with antibiotic treatment, albeit hospital admission with intravenous antibiotics was required in 4 patients. The remaining one patient had cellulitis with opening of the wound, and cultures obtained were negative but had been preceded by antibiotic treatment. This patient was categorized as a physician diagnosis of SSI (CDC #4) by both old and new criteria. Overall, the SSI rate decreases almost 3-fold from 7.3% to 2.7% if patients treated for a physician diagnosis of definite cellulitis are excluded (Table 2).

Procedure-specific SSI rates

The SSI rate varied across procedure types (Table 3) with rates ranging from 0% for sentinel lymph node biopsy (SLNB) alone or wide local excision (WLE) alone to either 14.3% (old criteria) or 7.1% (new criteria) for modified radical mastectomy (MRM). Differences across procedure type did not reach the level of statistical significance ($p = 0.22$ or $p = 0.11$ for old and new criteria, respectively), but statistical power for this comparison was low due to the small number of events and small group sizes for some procedures. Among the 33 SSIs (inclusive definition), 6 (18%) were considered to be at an axillary site and the remaining 27 (82%) were considered to be at a breast or mastectomy site. Among the 41 patients with implant reconstruction, there were 70 operated sides with reconstruction, and 4/70 (5.7%)

operated sides developed SSI by both old and new criteria using the 1 year timeframe. Comparing this to mastectomy patients without implant reconstruction, in whom the rates were 18/186 (9.7%) by old criteria or 7/186 (3.8%) by new criteria, there was no statistically significant difference (p=0.45 and p=0.50, respectively).

Time frame of infections

The 33 SSIs included 30 that occurred within 30 days and 3 infections that developed after 30 days (at 32, 48 and 52 days) in patients with implant-based breast reconstruction (in whom the SSI reporting period extends to one year per CDC guidelines). The median time to SSI diagnosis was 9 days (range 2–52), with 25/33 (76%) of SSI occurring within the first 14 days after surgery. There was no significant difference in time to infection for cellulitis only cases versus all other SSI.

Management of SSIs

Of the 33 SSIs (inclusive of cellulitis), all were treated with antibiotics - 19 oral only, 13 both oral and intravenous, and 1 intravenous only. Ten of 33 SSIs (30.3%) underwent drainage in the operating room or in the clinic. Of the three patients (4 operated sides) who developed SSI after immediate implant reconstruction, three tissue expanders in two patients were removed due to infection.

Discussion

Breast and axillary surgical wounds are classified as “clean” and are expected to have an SSI rate of <2%. However, SSI rates after breast operations have varied widely in the published literature. Several recent prospective studies have reported rates between 8 and 17%,[13–15] in keeping with the SSI rate demonstrated in this study when cellulitis cases are included (7.3% per operated side or 8.7% per patient).

The ACOSOG Z0011 trial prospectively examined postoperative complications in patients undergoing SLNB versus SLNB followed by completion axillary dissection. In that study, the overall SSI rate was 5.6% for all patients, while the rate was higher (8%) among patients who underwent completion dissection. Infection rates were examined at 30 days and included cases of cellulitis treated with antibiotics.[13] The ALMANAC trial similarly compared patients undergoing SLNB to those undergoing axillary dissection. The reported SSI rate was 11% in the SLNB group and 15% in the axillary dissection group, although criteria and timeframe for SSI diagnosis were not described in the report.[14] A group at the University of California San Francisco reviewed two cohorts of patients undergoing total skin-sparing mastectomy with preservation of the skin of the nipple and areola followed by immediate reconstruction. Although our patient population is different and included only a minority of patients who underwent immediate reconstruction, their report is notable as an example of a recent publication in which patients treated for cellulitis on an outpatient basis were not included as SSI. The group reported rates of “serious” infections, with 9% and 17% of patients readmitted for intravenous antibiotics or emergency care, respectively.[15]

In our study, the SSI rate was 7.3% using the 30-day CDC timeframe and including cases of cellulitis. If cases of cellulitis are excluded per the 2010 CDC reporting guidelines, then the SSI rate is dramatically reduced to 2.7%. With current emphasis on post-surgical quality outcomes assessment programs, the manner in which cases of SSI are defined has garnered increasing importance. A weakness of the CDC category #4 – SSI diagnosis by the surgeon or attending physician - is the significant subjectivity that likely exists among providers when judging milder cases of skin inflammation, which some providers might elect to observe without treatment while others would treat with antibiotics. Breast lymphedema, for

example, could be confused with cellulitis, as it often presents with erythema and edema of the breast skin.[16] Furthermore, cases of inflammatory skin changes that resolve with outpatient oral antibiotics may not be judged consistently as infections. This subjectivity may have provided impetus for the recent change in CDC SSI reporting guidelines to exclude cases of cellulitis. An approach that restricts defined cases of SSI to those with "hard" evidence (CDC criteria 1–3) should result in more reliable assessment of SSI rates that can be compared across providers and institutions. However, that approach will not be able to capture the majority of wound complications after breast and axillary surgery, where cellulitis predominates over frankly purulent or dehisced wounds.

Excluding cases of cellulitis may make SSI rates more reliable because this approach eliminates the subjectivity inherent in CDC category #4. However, excluding cellulitis cases falsely lowers SSI rates after breast and axillary surgery and underestimates the true burden of SSI in this patient population. We found that cellulitis is the most common scenario encountered with wound healing concerns after breast/axillary surgery, and it generates additional physician visits, antibiotic treatments, cost, concern, and inconvenience to the patient. Of 22 cases of cellulitis, only one required opening of the wound, but four patients were admitted to the hospital for intravenous antibiotics, and all 22 were treated with antibiotics and subjected to its associated risks.[11] Excluding cases of cellulitis also may underestimate the impact of infection because the use of antibiotic treatment in a patient with cellulitis may prevent progression to a more serious complication that would meet the 2010 CDC criteria. It also could result in cases of infection that remain ambiguous for classification in CDC category 4 due to antibiotic treatment for cellulitis, with subsequent negative cultures but ongoing wound problems. We had one such case of cellulitis treated with antibiotics, subsequent negative cultures but ongoing wound problems that required debridement and packing. Perhaps the antibiotic treatment compromised the culture, or perhaps this was a sterile seroma with significant inflammatory changes. Although we elected to classify that case as an infection, other providers might not.

One limitation of our study is that it was retrospective in design and therefore may have underestimated SSI rates. As an academic tertiary care practice, it is possible that patients had infections treated by their local care givers, although it is unlikely that many infections were missed, with 95% follow-up at our institution. For optimal surveillance of SSI, prospective collection of data for this outcome should be undertaken as per the National Surgical Quality Improvement Program of the American College of Surgeons [17] and other quality improvement programs. Since cellulitis is the most likely scenario for possible wound infection after breast and axillary surgery, hospital readmission is unlikely and therefore outpatient surveillance would be needed to detect it. Indeed, one published study found an inpatient SSI rate of 0.4% and an outpatient SSI rate of 2.4% within 30 days after breast surgeries.[18] Another found that the rate of SSI after breast biopsy doubled when a post-discharge surveillance program was instituted.[19]

In today's outcome-focused environment, it is important to establish a reproducible and reliable definition of SSI, as well as standardized methods for surveillance and identification of cases of infection. Beginning in October 2008, the Centers for Medicare and Medicaid Services (CMS) no longer reimburses for care required to treat several types of hospital-acquired infections, including those related to use of central access catheters, urinary catheters, and mediastinitis.[20] Although this does not currently impact breast and axillary operations, having a clear, reproducible, and clinically meaningful definition of what is considered an SSI is critical considering the increasing importance of quality metrics and comparisons among physicians and institutions.

Conclusions

Historically, reported infection rates after breast and axillary surgery have been variable and often higher than expected from clean surgical wounds. The recent CDC recommendation to exclude cellulitis cases from SSI reporting reduces SSI rates after breast/axillary operations by approximately three-fold. Cellulitis constitutes the majority of SSI in breast surgery, and these cases should not be excluded. Although excluding cellulitis likely achieves a more objective and reproducible definition, it underestimates the overall burden of infection after breast and axillary surgery and may have untoward effects on research efforts to reduce infections.

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Synopsis

This retrospective study demonstrates that excluding cases of cellulitis after breast and axillary surgery per CDC 2010 reporting guidelines dramatically reduces surgical site infection rates.

Table 1

Clinical features of 368 study patients

	N = 368 patients
Age, years, mean (range)	60 (23, 90)
ASA status, N (%)	
I	39 (10.6%)
II	272 (73.9%)
III	55 (14.9%)
IV	2 (0.5%)
BMI, mean (range)	29 (18, 56)
BMI category, N (%)	
< 25	120 (32.7%)
25–29	110 (30.0%)
30–34	72 (19.6%)
≥ 35	65 (17.7%)
Missing	1
Immediate reconstruction, N (%)	44 (12.0%)
Implant	41
Tissue	3
Preoperative antibiotics, N (%)	331 (89.9%)
Concurrent bilateral procedures, N (%)	72 (19.6%)

Table 2

Proportions with SSI by CDC reporting criteria prior to and after 2010 , per 449 operated sides. Each SSI is categorized only once according to the lowest numerical criterion fulfilled.

	CDC Reporting Guidelines prior to 2010	CDC Reporting Guidelines as of 2010
CDC #1	7 (1.6%)	7 (1.6%)
CDC #2	2 (0.4%)	2 (0.4%)
CDC #3	2 (0.4%)	2 (0.4%)
CDC #4	22 (4.9%)	1 (0.2%)
Total	33 (7.3%)	12 (2.7%)

Table 3

Proportions with SSI by CDC reporting criteria prior to and after 2010, by procedure type (per 449 operated sides).

Procedure	N	CDC Reporting Guidelines prior to 2010	CDC Reporting Guidelines as of 2010
SLNB alone or WLE alone	14	0	0
WLE + SLNB	153	8 (5.2%)	1 (0.7%)
ALND alone or WLE + ALND	26	3 (11.5%)	0
TM ± SLNB	214	16 (7.5%)	8 (3.7%)
MRM	42	6 (14.3%)	3 (7.1%)