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Concise Communication

Clinical implications of restrictions in criteria for defining surgical site infections after mastectomy

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Abstract

More than 50% of women with clinically apparent infection after mastectomy did not meet the 2020 National Healthcare Safety Network (NHSN) definition for surgical site infection (SSI). Implant loss was similar whether the 2020 NHSN SSI definition was met or not, suggesting equivalent adverse outcomes regardless of restriction to the surveillance definition.

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Surgical site infections (SSIs) are the most common healthcare-associated infection in the United States.[1] Accurate SSI surveillance and feedback to surgeons is essential to devise and implement strategies to prevent postoperative infections. The Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) definitions for deep-incisional and organ-space SSIs have changed over time. For example, in 2013 the surveillance period for deep and organ space infections was reduced from 1 year to 90 days for procedures including implants.[2,3] We sought to determine the impact of underreporting infections after mastectomy using the 2020 NHSN SSI definition.

Methods

We conducted a retrospective cohort study using electronic health record and billing data from 1 academic hospital and 1 community hospital. We identified mastectomy admissions among women aged ≥18 years from July 1, 2010 to June 30, 2015, using the *International Classification of Diseases, 9th Revision* (ICD-9) procedure codes (Supplementary Table 1 online) and verified mastectomy by surgeon description.

Potential SSIs were identified by selecting records to review based on performance of a microbiology culture or diagnosis or procedure code suggestive of a wound complication within 180 days after mastectomy (Supplementary Table 1 online). Infections were verified by review of outpatient and hospital records for signs and symptoms of infection, intervening procedures, expansion history, and microbiology data.

We defined clinically apparent infections as infections that met the pre-2013 NHSN definition or documented signs consistent with SSI (eg, cellulitis necessitating implant removal). The 180-day SSI rates were calculated using the pre-2013, 2020 NHSN, and clinical definitions (Supplementary Table 2 online). The Fisher's exact test was used to compare implant removal rates and physician documentation of infection using SAS version 9.4 software (SAS Institute, Cary, NC). The study was approved by the Washington University Human Research Protection Office with a waiver of informed consent.

Results

In total, 1,902 women underwent mastectomy, of whom 148 developed clinically apparent infection at the surgical site within 180 days after operation. Infections in 69 women (46.6%) met the 2020 NHSN SSI criteria. Infections in 102 women (68.9%) met the pre-2013 NHSN criteria, due to 33 infections after implant reconstruction meeting the earlier SSI criteria (Table 1).

Of the 148 women with clinically apparent infections, 23 (15.5%) underwent mastectomy only and 125 (84.5%) underwent immediate reconstruction. Moreover, 100 women (67.6%) had placement of tissue expander(s), 10 (6.8%) had permanent implant(s), and 15 (10.1%) underwent autologous flap reconstruction.

The reasons for exclusion of clinically apparent infections based on 2020 NHSN criteria (not mutually exclusive) included diagnosis of a superficial incisional SSI >30 days after mastectomy (n = 22), diagnosis of a deep incisional or organ-space SSI >90 days after mastectomy (n = 19; 2 deep incisional, 17 organ-space), manipulation of the surgical site after mastectomy in the absence of signs/symptoms of infection [ie, surgical debridement (n = 18), needle aspiration of seroma (n = 9), tissue expander access (n = 40)], and negative intraoperative cultures (n = 14) (Table 2). Methicillin-sensitive *Staphylococcus aureus* was the most commonly isolated etiologic organism, regardless of the onset timing of infection (Supplementary Table 3 online).

Tissue expanders were accessed in 40 women before the onset of clinically apparent infection, a median of 2 times (range, 1–7), resulting in exclusion of 13 infections (32.5%) using the 2020

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Table 1. Impact of Changes in the National Healthcare Safety Network Surgical Site Infection (SSI) Definitions on the Number and Rate of Infections After Mastectomy

Procedure	Total Surgeries	Total No. of Clinically Apparent Infections (n=148)[a]	No. of SSI Meeting the Pre-2013 NHSN Definition (n=103)	No. of SSI meeting the 2020 NHSN definition, (n=69), No. (No. Identified By Surgeons)	Total No. of Clinically Apparent Infections Excluded by 2020 NHSN Definition (n=79), No. (No. identified by surgeons)	SSI Rate by Clinically Apparent Infections	SSI Rate by Pre-2013 NHSN Definition	SSI Rate by 2020 NHSN Definition
Mastectomy only	683	23	12	12 (11)	11 (9)	3.37	1.76	1.76
Mastectomy + implant reconstruction	1,122	110	86	53 (46)	57 (48)	9.80	7.66	4.72
Mastectomy + flap reconstruction	97	15	4	4 (3)	11 (7)	15.46	4.12	4.12

[a]Clinically apparent infections at the surgical site includes infections that met the pre-2013 NHSN definition, plus any of the following within 180 d after surgery: infections with onset after a prior diagnostic/therapeutic procedure, superficial infections >30 d, deep-incisional and organ-space infections >90 d with no implant, physician opened the deep wound in the presence of signs/symptoms of infection (eg, erythema, warmth), or the physician described the wound as infected, despite negative culture results.

Table 2. Reasons for Not Meeting the 2020 National Healthcare Safety Network Definition of Surgical Site Infection (SSI)

Reason for Not Meeting Criteria[a]	Mastectomy Only (n=11)	Mastectomy + Implant Reconstruction (n=57)	Mastectomy + Flap Reconstruction (n=11)	Total No. Of Patients With Signs Suggesting Surgical Site Infection[a] (n=79)
Superficial incisional SSI diagnosed >30 d postoperatively	10	5	7	22
Deep incisional or organ space SSI diagnosed > 90 d postoperatively	0	18	1	19
Prior procedure in the absence of signs/symptoms of infection				
Debridement of surgical site	1	12	5	18
Needle aspiration of breast	2	7	0	9
Accession of breast expanders	N/A	40	N/A	40
Culture negative microbiology from surgical site	0	14	0	14

[a]An infection may have been excluded for >1 of these reasons.

NSHN criteria. Expanders were last accessed a median 16 days (range, 5–132) before infection onset. Overall, 9 women had 1–3 documented needle aspirations of a seroma, with the last aspiration a median of 11 days (range, 1–48) before infection onset. Also, 18 women had debridement of necrotic skin flaps a median of 13.5 days (range, 3–111) before infection onset.

Of the 14 women who failed to meet the NHSN criteria for SSI due to a negative intraoperative culture, all had been treated with antibiotics (median, 3 days) in the 2 weeks prior to implant removal. Prior antibiotics before the negative intraoperative cultures included intravenous vancomycin, piperacillin/tazobactam, and/or clindamycin (n = 8 women), or oral clindamycin, doxycycline, cephalexin, and/or sulfamethoxazole-trimethoprim (n = 6).

Of the 33 women with infection after implant reconstruction that met the pre-2013 but not the 2020 NHSN SSI definition, 13 had an organ-space SSI >90 days after mastectomy, and 7 met the pre-2013 definition of deep-incisional or organ-space SSI (3 deep incisional and 4 organ space) solely due to surgeon diagnosis at the time of implant removal.

Of the 110 women who had expander or permanent implant reconstruction, 94 (85.5%) had an infection at the surgical site diagnosed by a surgeon and/or infectious diseases physician. The percentage of women with physician-documented infection was the same in women whose infection met the 2020 NHSN SSI criteria (86.8%, 46 of 53) or whose infection did not meet 2020 criteria (84.2%, 48 of 57) ($P = .790$).

Overall, 102 of 110 women (92.7%) who developed clinically apparent infection following immediate implant reconstruction had their implants removed. These rates were 92.5% (49 of 53) versus 93.0% (53 of 57) among those who met versus did not meet the 2020 NHSN SSI criteria ($P = 1.0$).

Discussion

We reviewed records of women after mastectomy with or without reconstruction and found that 53% of women with clinical infection did not meet the 2020 NHSN SSI definition. The number of infections after implant reconstruction that met NHSN criteria

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decreased substantially after the criteria changes, which restricted the surveillance period in 2013 and definitions of deep-incisional and organ-space SSIs in 2014 and excluded infections after access of tissue expanders in 2017. The differential impact of the definition changes on implant reconstruction SSIs is important because immediate reconstruction has steadily increased during the past 20 years and tissue expanders account for the majority of reconstruction procedures.[4] The SSI rate after mastectomy is typically at least twice as high with versus without reconstruction,[5] which is obfuscated by changes to the surveillance definition that have differential impact on postimplant infections.

Manipulation of the surgical site post-mastectomy may contribute to the risk of infection, depending on the frequency and adherence to asepsis during manipulation. This is especially true for breast tissue expander reconstruction, since the port is accessed frequently for saline injection during expansion. Surveillance with feedback of all infections involving the surgical site post-mastectomy may alert surgeons and infection prevention specialists of suboptimal practices, particularly regarding tissue expansion, which could be targeted for infection prevention.[6,7]

In our cohort, systemic antibiotic therapy was administered in women with implant reconstruction who presented with cellulitis, in hopes of salvaging the implant.[8] This likely led to negative intraoperative cultures at the time of implant removal in the 14 women who met the clinical but not 2020 NHSN SSI definition. Most of these infections met the pre-2013 NHSN definition due to physician diagnosis. Re-evaluation of physician diagnosis to define SSI may need to be considered given the frequent empiric antibiotic treatment in this population.

We have demonstrated that implant loss was virtually the same in women with clinically diagnosed SSIs, regardless of whether the 2020 NHSN definition was met or not. Implant loss is important from a patient perspective because it results in additional morbidity, procedures, hospital costs, and delays in completion of adjuvant therapy.[9]

Our study of 2 academically affiliated hospitals may not reflect all community practices. The substantial changes in the NHSN SSI definitions in the past decade[2,3,10] have resulted in underreporting of potentially preventable infections and underestimation of infectious morbidity after mastectomy. Comprehensive infection surveillance, particularly after breast implant reconstruction, is essential to provide women with accurate information about complication risks and to determine the need for additional infection prevention strategies.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/ice.2020.1288

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