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Increased Risk of Surgical Site Infection Among Breast-Conserving Surgery Re-Excisions

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Abstract

Purpose—To determine the risk of surgical site infection (SSI) after primary breast-conserving surgery (BCS) versus re-excision among women with carcinoma *in situ* or invasive breast cancer.

Methods—We established a retrospective cohort of women aged 18–64 years with ICD-9-CM procedure or CPT-4 codes for BCS from 6/29/2004–12/31/2010. Prior insurance plan enrollment of at least 180 days was required to establish the index BCS; subsequent re-excisions within 180 days were identified. SSIs occurring 2–90 days after BCS were identified by ICD-9-CM diagnosis codes. The attributable surgery was defined based on SSI onset compared to the BCS date(s). A chi-square test and generalized estimating equations model were used to compare the incidence of SSI after index and re-excision BCS procedures.

Results—23,001 women with 28,827 BCS were identified; 23.2% of women had >1 BCS. The incidence of SSI was 1.82% (418/23,001) for the index BCS and 2.44% (142/5,826) for re-excision BCS (p=0.002). The risk of SSI after re-excision remained significantly higher after accounting for multiple procedures within a woman (odds ratio 1.34, 95% confidence interval, 1.07–1.68).

Conclusions—Surgeons need to be aware of the increased risk of SSI after re-excision BCS compared to the initial procedure. Our results suggest that risk adjustment of SSI rates for re-excision would allow for better comparison of BCS SSI rates between institutions.

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INTRODUCTION

Breast-conserving surgery (BCS) is the most common operative treatment for early stage breast cancer. A clear pathological margin is not always obtained after initial surgery, and re-excision is required in 10–40% of women with breast cancer.[1–5] Re-excision rates vary by age,[1;2] number of comorbidities,[1] carcinoma *in situ* (CIS) component,[1;2] non-palpable or multifocal lesions,[2] tumor size,[3] lobular histology,[5] lack of preoperative malignant diagnosis,[3] smaller breast size,[5] prior surgical biopsy,[5] adjuvant chemotherapy,[5] and hospital- and surgeon-factors.[3;4]

Revision operations are generally thought to be associated with increased risk of surgical site infection (SSI) compared with primary procedures. Increased risk of SSI following re-operation has been described after hip and knee arthroplasty,[6–8] instrumented lumbar spine fusion,[9] and open-heart surgery.[10] The reoperation SSI rate may not be higher for a simpler procedure such as BCS, which involves excision of soft tissue, does not usually result in appreciable fibrosis, and does not involve an implanted device. Three studies reported increased risk of SSI associated with breast reoperation, but these studies included both BCS and mastectomy reoperations and did not specifically report the SSI rates after primary versus revision BCS.[11–13] The goal of our study was to compare SSI rates following primary and re-excision BCS procedures in a large population of younger women with carcinoma *in situ* or invasive breast cancer.

METHODS

Data Source

We conducted a retrospective cohort study using the HealthCore Integrated Research Database (HIRD^{SM}) of individuals from 13 WellPoint-affiliated plans. Data in the HIRD^{SM} include all fully-adjudicated paid claims submitted for reimbursement from providers, facilities, and outpatient pharmacies linked to health plan enrollment information. Members with an International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis code or prescription claim consistent with HIV infection were excluded due to privacy considerations.

Fully insured women with enrollment in a fee-for-service plan that included coverage of hospital and physician services were eligible for study inclusion. Women were excluded if they were enrolled in multiple plans at the time of the surgery, if their insurance coverage ended on the day of BCS, or if they did not have 180 days of medical coverage prior to the index BCS.

BCS Population

We identified BCS operations among eligible women aged 18–64 years from 6/29/2004–12/31/2010 using ICD-9-CM and/or Current Procedural Terminology, 4th edition (CPT-4) procedure codes from inpatient and outpatient facility (other than home health agencies) and provider claims (Table 1).

Operation Exclusions

We excluded claims containing CPT-4, Healthcare Common Procedure Coding System, or Uniform Billing (UB-04) revenue codes truncated to 4 digits and populated in the fields reserved for ICD-9-CM procedure codes, as described previously.[14] Operations defined by a BCS code on only one line of a single claim with no other claims on the same date were also excluded.

Because our goal was to determine SSI rates in uncomplicated procedures based on the number of excisions, we excluded operations in women with end stage renal disease (ICD-9-CM diagnosis codes 585.6, V45.1–V45.12, V56.0–V56.2, V56.8), since this complex population has a higher risk of infection. We excluded BCS performed at the time of/after another operation during the same hospital admission; other surgical procedures were identified using the National Healthcare Safety Network (NHSN) list of CPT-4 and ICD-9-CM procedure codes for SSI surveillance.[15] We also excluded BCSs coded for mastectomy or breast reconstruction within +/− 5 days to ensure that BCS was the only breast procedure performed. Finally, we excluded BCSs performed ≥ day 3 of an inpatient hospital stay since these were likely complex patients.

BCS Date(s) and Supporting Evidence for Surgery

BCS dates within 5 days were collapsed into a single surgery date because of the potential inaccuracy in dates.[16] When there was >1 date within 5 days coded for BCS, we compared facility and provider surgery dates and incorporated supplemental evidence from other provider claims coding for anesthesia, pathology, or needle localization to determine the most likely date of surgery. BCSs coded by a provider- or facility-only without supplemental evidence that an operation took place were excluded (Table 1).

We defined the index BCS as the first procedure for a woman with at least 180 days prior coverage with no previous BCS claims. Re-excision operations were identified within 180 days after the index BCS. We excluded re-excision BCSs that followed an excluded BCS (defined above) and any re-excision BCS that followed a procedure with an attributable SSI.

Indication for BCS

We used ICD-9-CM diagnosis codes for invasive breast cancer and CIS from provider and facility sources to determine the indication for BCS (Table 1). With the exception of patients who received neoadjuvant chemotherapy, we prioritized the diagnosis on provider pathology claims (CPT-4 codes 88173, 88182, 88304–88309, 88321, 88323, 88325, 88342, 88360, 88361, 88365, 88367, 88368) when available from 30 days before through 90 days after surgery. ICD-9-CM diagnosis codes on provider pathologist claims most accurately report pathology findings.[17] If they were not available we used facility pathology claim(s) to determine the diagnosis of breast cancer.

In the absence of pathology claims for cancer, we used other claims from 365 days before through 30 days after surgery to define the indication for BCS. We categorized the diagnosis as invasive cancer or CIS if it was coded on ≥ 1 inpatient facility claims or ≥2 provider or outpatient claims. The provider or outpatient cancer claims had to have ≥ 1 of the following

revenue or procedure codes: any ICD-9-CM procedure code; UB-04 codes for therapeutic radiology, operating room, respiratory services, emergency department, clinic; or any CPT-4 codes other than those for diagnostic radiology, laboratory, and phlebotomy. The highest overall diagnosis through 30 days after surgery was defined as the indication for BCS (through 90 days for women with multiple BCSs or mastectomy). Women without evidence for invasive breast cancer or CIS were excluded.

Concurrent Procedures

We used ICD-9-CM and CPT-4 codes to identify needle localization, axillary and sentinel lymph node dissection, and brachytherapy catheter placement procedures performed at the time of BCS.

Identification of SSI

SSIs first recorded from 2–90 days after eligible surgeries were identified using ICD-9-CM diagnosis codes from inpatient and outpatient facility and provider claims (excluding laboratory claims with CPT-4 codes 88104–88399) (Table 2). We also defined SSI using a code for *Staphylococcus aureus* +/− 7 days of a procedure code for incision/drainage or diagnosis of cellulitis, or cellulitis on the same claim as an incision/drainage code, to be consistent with the NHSN SSI definition.[15] We previously validated these diagnosis codes in breast surgery compared to microbiology data.[18]

We excluded non-breast specific SSI codes (e.g., 998.59) if the SSI code occurred within 7 days of a device-associated infection (ICD-9-CM 996.61–996.68, 999.31). Non-breast specific SSI codes were not classified as SSI attributable to BCS if they were first coded after a subsequent NHSN operation. Because the ICD-9-CM diagnosis code 611.0 could be used to indicate inflammatory breast cancer, we did not use this code to identify SSI if it was coded in the month prior to BCS. Finally, we excluded SSIs based on coding for cellulitis after the start of radiotherapy since our goal was to identify SSIs attributable to surgery.

Timing of SSI—For SSI newly coded by an inpatient facility during the original operative admission, we assigned the date of SSI to the discharge date if the length of stay was ≥ 2 days. For SSI diagnosed during an inpatient readmission, the date of SSI onset was assumed to be the readmission date. For SSI diagnosed initially by a provider or in an outpatient setting, the onset date was defined as the first service date coded for SSI.

We censored the observation period for SSI at the end of insurance enrollment, a subsequent BCS, or at the time of another breast operation (e.g., mastectomy). We censored the day after a subsequent operation since an infection coded at the time of a subsequent surgery was most likely attributed to the previous BCS.

Preexisting Infections—BCS procedures with claims containing ICD-9-CM diagnosis codes for SSI or cellulitis from 30 days before to 1 day after BCS were excluded. Operations in women coded for septicemia (038.0–0.38.9, 790.7) between 7 days before to 1 day after the BCS date were also excluded due to preexisting systemic infection.

Statistical Analyses

We used a chi-square test and generalized estimating equations (GEE) model accounting for clustering of observations by person to compare SSI incidence after the index versus re-excision BCS. Data management and statistical analyses were performed using SAS v9.3 (SAS Institute Inc., Cary, NC). This study was approved by the Washington University Human Research Protection Office.

RESULTS

A total of 81,256 BCS procedures met the initial inclusion criteria. The number of distinct procedures was reduced to 28,827 in 23,001 women after removing procedures with no supporting evidence for BCS (n=2,665), operations in women with ESRD (n=82), complicated BCS operations (n=3,863), operations with preexisting SSI/septicemia (n=297), operations without a 180 day BCS-free period (n=456) or >180 days after the index BCS (n=2,558), re-excision BCS following a complicated BCS operation (n=19), re-excision BCS following BCS complicated by SSI (n=19), and operations in women without CIS or invasive breast cancer (n=42,470).

The average age of the women at the time of surgery was 52.3 years (standard deviation 7.8). Nineteen percent of procedures were performed in women with CIS and 81% were performed due to invasive breast cancer. Needle localization was used in 53.3% (n=15,357) of procedures, 23.4% (n=6,755) had a sentinel lymph node procedure, 24.6% (n=7,081) had axillary lymph node dissection, and brachytherapy catheters were placed in 1.3% (n=367) of procedures. Almost 77% of women had one BCS (76.8%, n=17,659), 4,892 (21.3%) women had two procedures, and 450 (2.0%) women had three or more total BCS procedures within 180 days of the index BCS.

SSIs were identified after 560 procedures (1.94%, Table 3). Almost 58% of SSI were identified within 30 days after BCS (n=324), 115 (20.5%) were identified 31–45 days, 53 (9.5%) were identified 46–60 days, and 68 (12.1%) were identified 61–90 days after surgery. The incidence of SSI was 1.82% for the index BCS, 2.43% for the second, and 2.48% for the third or greater procedure (p=0.009, Table 3).

Since the SSI incidence for a second, third, or higher number of BCS excisions was similar, further comparisons were done comparing the index BCS to any re-excision (i.e., ≥ 2 BCS). In the GEE model accounting for clustering and including operative factors, the risk of SSI associated with re-excision was higher than the index BCS (OR 1.34, 95% CI 1.07–1.68; Table 4). Axillary and sentinel lymph node dissection were also independent risk factors for SSI. Sensitivity analyses were performed restricting SSIs to those first coded within 30, 45, and 60 days after BCS. Re-excision was statistically significant in the 60-day model (OR 1.29, 95% CI 1.02–1.64), and trended towards significance when SSIs were restricted to 45 days (OR 1.28, 95% CI 0.99–1.65) and 30 days after BCS (OR 1.17, 95% CI 0.87–1.56).

DISCUSSION

To our knowledge, this is the first study to report higher SSI rates following BCS re-excision compared to the index BCS among women with breast cancer. Ashraf reported an overall SSI rate of 18.2% following reoperation for breast cancer from 1990 to 2008, including an SSI rate of 11% when the primary operation was open biopsy and 19.4% after re-excision BCS when the primary operation was BCS plus axillary dissection.[11] Teija-Kaisa *et al.* found that reoperation was an independent risk factor for SSI after BCS, however the type of previous operation was not described.[12] Using data from the National Surgical Quality Improvement Program, de Blacam reported that wound complications (SSI or wound disruption) after BCS were nearly twice as likely when there was a prior (unspecified) operation within 30 days.[19]

In our study, 23.2% of women had one or more re-excision BCS operations within 180 days, which is within reported re-excision rates of 10–40%.[1–5] Recently the Society of Surgical Oncology and the American Society for Radiation Oncology developed a consensus guideline encouraging adoption of “no tumor on ink” as the standard definition of a negative margin for early stage breast cancer.[20] Our findings suggest that this recommendation to restrict re-excisions to women with tumor present at the margin may have an additional benefit of lower SSI rates after BCS.

Our study has several limitations. By definition, the use of claims data involves secondary analysis of data collected for billing purposes. Since there is no distinction in coding of index vs. re-excision BCS, we developed an algorithm to distinguish index and re-excision procedures. There is the potential for misclassification if a BCS was performed > 180 days before the “index” BCS and “re-excision” procedures could have been performed on the contralateral breast. There is also potential for misclassification of cancer diagnoses, axillary versus sentinel lymph node dissection, and likely undercoding of SSIs, particularly minor infections during the 90-day global surgical reimbursement period.[21] Given the potential for misclassification of index vs. re-excision procedures and undercoding of infections, the net result is likely bias towards the null, and thus our finding of increased SSI risk associated with re-excision BCS is probably a conservative estimate of the true effect.

An additional limitation involves the timing of SSI. While the onset of SSI symptoms can often be captured in clinical data, in claims data SSIs cannot be detected until the date of the first paid claim coded for infection. Because of delays in seeking care, awaiting laboratory results to confirm the diagnosis, undercoding of minor infections, and potential rejection of claims in the 90-day global surgical reimbursement period, there is likely a delay between the onset of clinical infection and presence of paid claims for SSI. This may explain why we only captured 58% of the total SSIs within 30 versus 90 days after BCS, resulting in reduced power to detect a difference in SSI rates between index and re-excision BCSs in our sensitivity analyses.

Our study strengths include a large number of procedures performed in multiple, geographically diverse surgical facilities. We applied a rigorous algorithm to identify SSIs attributable to BCS and censored at the time of subsequent operations, including

mastectomy. This is extremely important given the higher rate of SSI after mastectomy.[19;22;23] The use of claims data allowed identification of SSIs across the spectrum of care, including infections treated in outpatient facilities which are often missed by hospital-based infection prevention surveillance programs.

We found a higher risk of SSI after re-excision compared with the index BCS in a large cohort of younger, privately-insured women with breast cancer. This finding is particularly important due to the current high rates of re-excision BCS and the variation in re-excision rates among individual surgeons and facilities. Physicians should be aware of the increased risk of SSI after re-excision and counsel patients regarding the signs and symptoms of infection. It may also be important to risk adjust SSI rates by re-excision status to facilitate more accurate comparisons of SSI rates after BCS between institutions.

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Table 1

Codes Used to Identify Breast-Conserving Surgery (BCS), Evidence for Surgery, and Indication For BCS

	ICD-9-CM Procedure	CPT-4 Procedure	UB-04 Revenue	ICD-9-CM Diagnosis
Codes to Identify Surgery				
Breast-conserving surgery	85.20–85.23	19120, 19125, 19160, 19162, 19301, 19302		
Codes to Provide Evidence for Surgery				
Anesthesia		00400–00406, 01610		
Needle localization		19290–19295, 19297, 19298, 76003, 76095, 76096, 76355, 76360, 76393, 76942, 7002, 77011, 77012, 77021, 77031, 77032		
Pathology		88305, 88307		
Surgery-related revenue codes			0201, 0360, 0361, 0369, 0370, 0379, 0490, 0499, 0963, 0964, 0975	
Codes to Identify Indication for BCS				
Carcinoma *in situ* of breast				233.0
Invasive breast cancer				174.0–174.9, 198.2, 196.3, 196.9
Codes to Identify Operative Procedures				
Needle localization		19290, 19291		
Sentinel lymph node dissection	40.11, 40.19, 40.23	38500, 38525, 38740, 38792		
Axillary lymph node dissection	40.3, 40.50, 40.51	19162, 19302, 38745		
Brachytherapy catheter placement	92.27	19297, 19298		

ICD-9-CM, International Classification of Diseases, 9th Revision, Clinical Modification; CPT-4, Current Procedural Terminology, 4th edition; UB, Uniform Billing.

Table 2

Codes Used to Identify Surgical Site Infection Following Breast-Conserving Surgery

	ICD-9-CM Diagnosis	CPT-4 or HCPCS Procedure	ICD-9-CM Procedure
Breast specific complication codes			
Infection	611.0		
Incision/drainage[a, b]		19020	85.0, 85.91
Non-breast specific complication codes			
Postoperative infection	998.5–998.59		
Cellulitis[b]	682.2, 682.9[c]		
Staphylococcus aureus[a]	041.1–041.19[d]		
Incision/drainage[a, b]		10060, 10061, 10140–10180, 11000, 11001, 11040–11044, 20000, 20005, A6550, A6551, E2402, K0538	83.44–83.49, 86.01, 86.04, 86.09, 86.22, 86.28

ICD-9-CM, International Classification of Diseases, 9th Revision, Clinical Modification; CPT-4, Current Procedural Terminology, 4th edition; HCPCS, Healthcare Common Procedure Coding System.

[a] Codes used in combination with a ICD-9-CM diagnosis code for cellulitis to indicate SSI

[b] Codes used in combination with a ICD-9-CM diagnosis code for *Staphylococcus aureus* to indicate SSI

[c] Diagnosis code 682.9 refers to cellulitis and abscess at an unspecified site; it was only used if on the same claim line as a breast-specific incision/drainage code or coded by the patient's breast surgeon.

[d] *S. aureus* code was only used if it was coded by the patient's breast surgeon or was associated with a cellulitis code or incision/drainage code that was breast-specific.

Table 3

Surgical Site Infection (SSI) Rates after Index and Re-excision Breast-Conserving Surgery (BCS)

	Number of Procedures	SSI n (%)	SSI Rate/100 Procedures
Index BCS	23,001	418	1.82
BCS 2	5,342	130	2.43
BCS 3^{+}	484	12	2.48

Table 4

Comparison of Breast-Conserving Surgery (BCS) Surgical Site Infection (SSI) Rates by Index Versus Re-Excision Procedure

	Total Procedures	SSI n (%)	*p*[a]	Adjusted Odds Ratio (95% CI)[b]
Index BCS procedure	23,001	418 (1.82)		1.00
BCS procedure 2^{+}	5,826	142 (2.44)	0.002	1.34 (1.07, 1.68)
No needle localization	13,470	296 (2.20)		1.00
Needle localization	15,357	264 (1.72)	0.003	0.86 (0.71, 1.05)
No sentinel lymph node dissection	22,072	416 (1.88)		1.00
Sentinel lymph node dissection	6,755	144 (2.13)	0.198	1.57 (1.27, 1.94)
No axillary lymph node dissection	21,746	360 (1.66)		1.00
Axillary lymph node dissection	7,081	200 (2.82)	<0.001	2.03 (1.67, 2.47)
No brachytherapy catheter placement	28,460	550 (1.93)		1.00
Brachytherapy catheter placement	367	10 (2.72)	0.275	1.28 (0.67, 2.42)

[a] Univariate chi-square test.

[b] Multivariable analysis of parameter estimates in generalized estimating equation (GEE) model, accounting for clustering of procedures within women.