Incidence and Risk Factors for and the Effect of a Program To Reduce the Incidence of Surgical Site Infection after Cardiac Surgery

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Abstract

Background: Surgical site infection (SSI) after cardiac surgery (CS) is a serious complication that increases hospital length of stay (LOS), has a substantial financial impact, and increases mortality. The study described here was done to evaluate the effect of a program to reduce SSI after CS.

Methods: In January 2007, a multi-disciplinary CS infection-prevention team developed guidelines and implemented bundled tactics for reducing SSI. Data for all patients who underwent CS from 2006–2008 were used to determine whether there was: 1) A difference in the incidence of SSI in white patients and those belonging to minority groups; 2) a reduction in SSI after intervention; and 3) a statistically significant difference in the incidence of SSI in the third quarter of each year as compared with the other quarters of the year.

Results: Of 3,418 patients who underwent CS; 1,125 (32.9%) were members of minority groups and 2,293 (67.1%) were white. Eighty (2.3%) patients developed SSI. There was no significant difference in the incidence of SSI in non-Hispanic white patients and all others (2.1% vs. 2.8%, $p=0.42$). The incidence of SSI decreased significantly from 2006 (3.0%) to 2007 (2.5%) and 2008 (1.4%), ($p=0.03$). Surgical site infection occurred more often in the third quarter of each of the years of the study than in other quarters of each year (3.3 vs. 2.0%, $p=0.038$).

Conclusions: Implementation of a program to reduce SSI after CS was associated with a lower incidence of SSI across all racial and ethnic groups and over time, but was not associated with a lower incidence of SSI in the third quarter of each year than in the other quarters.

APPROXIMATELY 275,000 PATIENTS in the United States have cardiac surgery (CS) annually [1], and as many as 30% of these patients experience a severe complication of this surgery [1]. The annual cost of CS in the United States is more than \$41 billion [1], and the cost of caring for post-operative complications of CS is a substantial portion of that cost [2]. Data of the New York State Department of Health (NYSDOH) from 2007 (the most recent data available) show that the incidence of complications after CS has varied from 12.3% for coronary artery bypass graft (CABG) surgery to 31.2% for the combination of valve surgery and CABG. A reduction in the incidence of post-operative complications of CS could reduce the overall cost of CS.

Many complications of CS are potentially preventable, including surgical site infection (SSI). Such surgical infections are among the four most common healthcare-associated infections, which affect nearly two million hospitalized patients

each year [3]. Although a number of individual tactics to reduce the risk of SSI have been described, we had the opportunity in the present study to assess the effect of a bundled, multi-modal intervention for reducing the incidence of SSI.

The objectives of the study were to determine the incidence and factors associated with SSI in a population of patients who underwent CS in a large academic medical center, and to assess the effect of a focused effort to reduce the incidence of SSI in this population. In addition to assessing the effect on SSI of our incremental interventions, we also examined specifically the association between SSI and race/ethnicity and the frequency of SSI in relation to the time of year when new surgical fellows begin their training. We tested the following hypotheses: 1) The incidence of SSI after CS is higher for minority populations than for non-Hispanic white persons; 2) the incidence of SSI after CS is decreased significantly after the implementation of a program to reduce

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the incidence of SSI; and 3) the incidence of SSI after CS is higher in the third quarter of the year than in the other three quarters of the year.

Methods

After obtaining institutional review board approval for our study, we retrieved demographic and clinical data retrospectively for a population of patients who underwent CS. We obtained these data from a large data set developed previously to study the costs of health-care-associated infections [4]. The creation of the data set, which included information for all patients discharged from a large academic health center in New York City during the years 2006–2008, has been described previously [5].

To test our hypotheses, we included in the data set all patients who underwent CS (International Classification of Diseases-Ninth Revision [ICD-9] procedure codes 35–37). We extracted the following data elements for all included patients: admission date, discharge date, whether or not the patient was admitted through the emergency department, type of surgical procedure (CABG, cardiac valve surgery, other), age, gender, race/ethnicity, principal and secondary diagnoses, history of diabetes mellitus, history of renal insufficiency, blood culture results, results of surgical site culture, and score on the Charlson Comorbidity Index. We used previously described algorithms to identify SSI [6] (Table 1).

In January 2007, our institution employed a peri-operative infection-prevention specialist who was hired to develop a program to reduce the incidence of SSI. The specialist documented current practice and provided recommendations designed to improve outcomes in CS and other types of surgery. A multi-disciplinary CS infection-prevention team was formed, guidelines for reducing SSI were developed, and the following strategies were implemented for this purpose:

1. Limit traffic into and out of the operating room (OR), restrict visitors, and limit entry to the OR from the semi-restricted area when a patient's surgical site is open

2. Mandate the use of a 70% isopropyl alcohol and 2% chlorhexidine gluconate skin preparation for the site of surgery
3. Develop and implement use of an equipment cleaning resource book
4. Implement education about environmental cleaning, enhance environmental cleaning, and reduce clutter to facilitate improved cleaning
5. Develop and implement an algorithm to facilitate improved intra-operative serum glucose control
6. Reduce or eliminate the use of immediate "flash" steam sterilization
7. Create a performance-improvement team to monitor staff performance and provide real-time analysis of any patient complications
8. Identify a surgeon who will act as an infection-prevention "champion"
9. Restrict work in ORs in which CS is done to designated physician assistants

To enhance the implementation of these strategies, a grand rounds led by a cardiac surgeon was conducted to discuss them. All OR staff were empowered to address any non-compliance with the guidelines by any member of the infection-prevention team or to refer concerns to the surgical champion or infection-prevention specialist for follow up. Additionally, mandatory education was implemented for all OR staff and all incoming CS fellows. Specific education modules included:

1. Hand preparation for surgery
2. Preparation of the patient's skin
3. Gowning and gloving, changing gowns following changes in level of sterility (e.g., after harvesting of the internal mammary artery for CABG)
4. Maintaining a sterile operating field
5. Wearing of proper attire for surgery, including disposable hats, and wearing masks in semi-restricted and restricted areas
6. Recognizing the importance of traffic control into and out of the OR

To document compliance with these guidelines and to provide the opportunity to address any non-compliance, the peri-operative infection-prevention specialist made random direct observations during two or more cases per week and reported the results to the infection-prevention team. The team addressed occurrences of non-compliance as well as instances of complications of CS.

Statistical analysis

Differences in patient characteristics and incidence of SSI by race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, or other/unknown), year (2006, 2007, or 2008), and fiscal quarter of the year (quarter three vs. all other quarters) were assessed with χ^2 tests for independence or with one-way analysis of variance (ANOVA). Three separate multivariable logistic regression models were used to calculate adjusted odds ratios (OR) and 95% confidence intervals (CI) to evaluate the effects on the incidence of SSI of race/ethnicity, year (2006 vs. 2008), and fiscal quarter on SSI incidence, with control for factors that were significant predictors of SSI in the univariate analyses.

TABLE 1. DEFINITION OF INFECTION

<i>Case</i>	<i>Control</i>
Any NHSN operative procedure (as per ICD-9-CM procedure code) performed AND positive wound culture within 30 d of NHSN procedure	Any NHSN operative procedure (as per ICD-9-CM procedure code) performed Negative wound culture within 30 d of NHSN* procedure OR Positive wound culture OR No wound culture performed BUT Encounter has an ICD-9-CM code for post-operative infection

ICD-9=International Classification of Diseases, Revision 9; NHSN=National Healthcare Safety Network.

TABLE 2. PATIENT CHARACTERISTICS AND INCIDENCE OF SURGICAL SITE INFECTION BY RACE AND ETHNICITY

	<i>Non-Hispanic white</i>	<i>Hispanic</i>	<i>Non-Hispanic black</i>	<i>Other or unknown</i>	<i>Total</i>	<i>p value*</i>
% (N) of total	67.1 (2,293)	11.0 (375)	7.1 (243)	14.8 (507)	100 (3,418)	
% (N) Female	34.2 (785)	42.4 (159)	47.3 (115)	37.1 (188)	36.5 (1,247)	<0.001
% (N) With history of diabetes	22.7 (521)	42.4 (159)	34.2 (83)	30.0 (147)	26.6 (910)	<0.001
% (N) With history of renal failure	21.2 (487)	31.7 (119)	39.9 (97)	30.4 (154)	25.1 (857)	<0.001
% (N) Admitted through emergency department	3.8 (83)	44.3 (166)	35.0 (85)	10.1 (51)	11.4 (388)	<0.001
Procedure type						<0.001
% (N) CABG	28.2 (646)	42.7 (160)	40.7 (99)	37.9 (192)	32.1 (1,097)	
% (N) Valve	64.9 (1,488)	51.7 (194)	51.4 (125)	57.2 (290)	61.4 (2,097)	
% (N) Other	6.9 (159)	5.6 (21)	7.8 (19)	4.9 (25)	6.6 (224)	
Mean (SD) age	66.3 (17.8)	61.7 (14.3)	60.0 (13.3)	65.6 (15.9)	65.2 (14.9)	<0.001
Mean (SD) Charlson Comorbidity Index score	1.2 (1.4)	1.8 (1.6)	1.9 (1.7)	1.6 (1.5)	1.4 (1.5)	<0.001
% (N) Patients developing SSI	2.1 (48)	3.5 (13)	2.5 (6)	2.6 (13)	2.3 (80)	0.420

CABG=coronary artery bypass graft; SD=standard deviation; SSI=surgical site infection.

* χ^2 test for independence (categorical variables) or one-way analysis of variance (continuous variables).

All analyses were done with SAS version 9.2 (SAS Institute, Cary, NC).

Results

A total of 3,418 patients underwent CS with midline sternotomy during the study period and 80 (2.3%) subsequently developed an SSI (Table 2). Non-Hispanic whites had lower average scores on the Charlson Comorbidity Index than did patients belonging to minority groups (1.2 vs. 1.4, respectively), and were less likely to have a history of diabetes (22.7% vs. 26.6%, respectively) or renal failure (21.2% vs. 25.1%, respectively) or to have been admitted through the emergency department (3.8% vs. 11.4%, respectively). Non-Hispanic white patients were also slightly older on average

than those belonging to minority groups (66.3 vs. 65.2 y, respectively) and included a smaller proportion of women (34.2% vs. 36.5%, respectively). The incidence of SSI was similar across racial/ethnic groups in the univariate analysis, ranging from 21 per 1,000 for non-Hispanic white patients to 35 per 1,000 for Hispanic patients ($p=0.42$). In the multi-variable analyses there was no significant difference in the incidence of infection by race/ethnicity after control for age, gender, history of diabetes, history of renal failure, admission source, or score on the Charlson Comorbidity Index (OR and 95% CI: 1.14 [0.56–2.3], 0.78 [0.31–1.95], and 1.04 [0.55–1.95] for Hispanic, non-Hispanic black, and other/unknown vs. non-Hispanic white patients, respectively).

Table 3 compares the incidence of SSI and patient characteristics in the years before (2006), during (2007), and after

TABLE 3. DIFFERENCES IN PATIENT CHARACTERISTICS AND SURGICAL SITE INFECTION IN YEARS BEFORE, DURING, AND AFTER IMPLEMENTATION OF INFECTION-REDUCTION PROGRAM FOR SURGICAL SITE INFECTION

	<i>Year 1 (2006)</i>	<i>Year 2 (2007)</i>	<i>Year 3 (2008)</i>	<i>p value*</i>	<i>OR (95% CI) 2006 vs. 2008**</i>
N	1,185	1,107	1,126		
Procedure type				0.045	
% (N) CABG	31.5 (373)	33.5 (371)	31.3 (353)		0.89 (0.35–2.25)
% (N) Valve	61.4 (728)	58.9 (652)	63.7 (717)		1.48 (0.59–3.72)
% (N) Other	7.1 (84)	7.6 (84)	5.0 (56)		
% (N) Female	37.4 (443)	36.0 (399)	36.0 (405)	0.728	
% (N) Admitted through emergency department	10.7 (127)	12.5 (138)	10.9 (123)	0.360	
% (N) With history of diabetes	25.4 (301)	27.1 (300)	27.4 (309)	0.491	
% (N) With history of chronic kidney disease	22.6 (268)	25.5 (282)	27.3 (307)	0.034	0.43 (0.25–0.75)
Race/ethnicity				0.165	
% (N) Non-Hispanic white	67.5 (800)	67.3 (745)	66.4 (748)		
% (N) Hispanic	10.6 (126)	11.7 (130)	10.6 (119)		
% (N) Non-Hispanic black	5.8 (69)	8.0 (88)	7.6 (86)		
% (N) Other/unknown	16.0 (190)	13.0 (144)	15.4 (173)		
Mean (SD) age	64.5 (15.1)	64.7 (15.2)	66.5 (14.4)	0.003	0.99 (0.98–1.02)
Mean (SD) Charlson Comorbidity Index score	1.2 (1.4)	1.5 (1.5)	1.5 (1.5)	<0.001	1.12 (0.96–1.31)
% (N) Patients developing SSI	3.0 (36)	2.5 (28)	1.4 (16)	0.032	2.35 (1.29–4.29)

OR=odds ratio; CI=confidence interval; CABG=coronary artery bypass graft; SD=standard deviation; SSI=surgical site infection.

* χ^2 test for independence (categorical variables) or one-way analysis of variance (continuous variables).

**Multi-variable model adjusting for procedure type, renal failure, age, and Charlson Comorbidity Index score.

(2008) implementation of the SSI reduction program at the institution at which the study was conducted. The incidence of SSI decreased significantly, from 30 per 1,000 patients in 2006 to 25 and 14 per 1,000 patients in 2007 and 2008, respectively ($p=0.032$). The odds of SSI remained significantly higher in 2006 than in 2008 after control for changes in patient characteristics (procedure type, renal failure, age, and Charlson Comorbidity Index score) during the study period ($OR=2.35$, 95% CI 1.29–4.29). Notably, patient age, severity of illness, prevalence of renal failure, and prevalence of diabetes all increased slightly during the three-year study period.

Table 4 compares the incidence of SSI after CS operations done during the third quarter (July–September) of each year of the study with its incidence after operations done during the remainder of the year (October–June). In the univariate analysis, the incidence of SSI was significantly higher in the third quarter than in the remainder of the year (33 vs. 20 per 1,000 patients, respectively, $p=0.038$). Patient age and severity of illness were also slightly but significantly greater in the third quarter than in the remainder of the year (66.7 vs. 64.7 y, $p=0.001$, and 1.5 vs. 1.4, respectively, $p=0.03$). With control for age and severity of illness, the odds of SSI continued to be higher in the third quarter than in the remainder of the year, although this difference was no longer statistically significant at the $\alpha=0.05$ level ($OR=1.58$, 95% CI 0.99–2.53).

Discussion

Racial and ethnic disparities in surgical outcomes have been reported after surgery for many types of cancer, as well as for the treatment of such benign diseases as morbid obesity and diverticulitis [7–20]. Potential causes of these disparities include poor access to surgical care, lack of access to minimally invasive surgery [10,18,19], type of insurance [14], and a higher incidence of co-morbidities in some racial and

ethnic groups than in others. A review of the literature revealed no previous reports of racial or ethnic disparities in outcome after CS; however, because nearly one-third of the patients who underwent CS in the present study were members of minority groups, it was feasible to determine whether such a disparity existed in the outcomes of these patients and non-Hispanic white patients at our institution. Although the incidence of SSI in minority populations was higher than in non-Hispanic white patients, the difference was not statistically significant. Despite this lack of a difference, the black and Hispanic patients in the study population had a greater risk of SSI because of significantly higher scores on the Charlson Co-morbidity Index, higher incidences of diabetes mellitus and chronic kidney disease, and more frequent admission through the emergency department. Despite the increased risk of SSI among black and Hispanic patients, however, their rates of SSI were not significantly higher and for non-Hispanic white patients for reasons that are unclear. It is possible that the interventions taken to reduce SSI at our institution contributed to these results.

The higher percentage of cardiac valve operations than of CABG procedures in the present study is unusual. Most institutions have a much higher percentage of CABG than of cardiac valve procedures. However, a large majority of the patients at our institution who have coronary artery disease are treated with percutaneous coronary interventions. This aggressive treatment of coronary artery disease by the cardiologists at our institution not only diverts patients away from CABG, but also attracts a large number of patients with aortic valve disease who are then referred for surgical aortic valve replacement.

On the basis of our results, it appears that the intervention program introduced at our institution to reduce the incidence of SSI had a significant effect. The incidence of SSI decreased during each year in the study, and it appears reasonable to conclude that the implementation of the bundled strategy for infection prevention was associated with that decrease. The results in the study are comparable to those of

TABLE 4. DIFFERENCES IN PATIENT CHARACTERISTICS AND INCIDENCE OF SURGICAL SITE INFECTION BY FISCAL QUARTER

	Third quarter	All other quarters	<i>p</i> value*	OR (95% CI) third quarter vs. all others**
% (N) of total	25.0 (856)	75.0 (2,562)		
Procedure type			0.982	
% (N) CABG	32.2 (276)	32.1 (821)		
% (N) Valve	61.3 (525)	61.4 (1,572)		
% (N) Other	6.4 (55)	6.6 (169)		
% (N) Female	37.7 (323)	36.1 (924)	0.380	
% (N) Admitted through emergency department	11.6 (99)	11.3 (289)	0.820	
% (N) With history of diabetes	26.8 (230)	26.5 (680)	0.851	
% (N) With history of chronic kidney disease	26.5 (227)	24.6 (630)	0.260	
Race/ethnicity			0.580	
% (N) non-Hispanic white	66.8 (572)	67.2 (1,721)		
% (N) Hispanic	10.3 (88)	11.2 (287)		
% (N) non-Hispanic black	6.8 (58)	7.2 (185)		
% (N) Other/unknown	16.1 (138)	14.4 (369)		
Mean (SD) age	66.7 (14.2)	64.7 (15.1)	0.001	1.00 (0.98–1.01)
Mean (SD) Charlson Comorbidity Index score	1.5 (1.5)	1.4 (1.5)	0.030	1.27 (1.12–1.44)
% (N) Patients developing SSI	3.3 (28)	2.0 (52)	0.038	1.58 (0.99–2.53)

OR=odds ratio; CI=confidence interval; CABG=coronary artery bypass graft; SD=standard deviation; SSI=surgical site infection.

* χ^2 test for independence (categorical variables) or one-way analysis of variance (continuous variables).

**Multi-variable model adjusting for age and Charlson Comorbidity Index score.

two European studies, in the first of which Graf et al. reported having successfully reduced the incidence of deep sternal SSI from 3.61% to 1.83% by implementing a “comprehensive infection control program” [21], and in the second of which Finkelstein, et al. reported a significant reduction in SSI caused by methicillin-resistant *Staphylococcus aureus* after implementing such a program over a six-year period [22]. It is not possible on the basis of the present study to determine which of the specific efforts undertaken to reduce SSI contributed to the reduction in its incidence, nor is it possible to determine whether the interventions that were implemented, either individually or collectively, were responsible for this reduction or whether the reduction in SSI was simply related to the increased focus on its prevention. Notwithstanding, it is gratifying to document that a quality improvement effort of the magnitude described here was strongly associated with improved patient outcomes.

The incidence of SSI in the present study was consistently higher in the third quarter of the calendar year than in the remainder of the year. One possible explanation for this is the “July Effect,” which is conceptually associated with the arrival of new members of the clinical staffs of teaching hospitals in July of each year. However, more detailed analysis of the data of the patient population in the present study revealed that the patient population in the third quarter of each of the years in the study was significantly older and sicker than in the remaining quarters of these years. When these two variables were controlled, the incidence of SSI was not significantly higher in the third quarter than in the remaining quarters of the study years. Although it is reassuring to think that the “July Effect” may not be a factor at our institution, it continues to provide education for all incoming CS fellows about the importance of preventing SSI and the methods for accomplishing this.

Our study has several limitations. The ability to ‘tease out’ the individual components of the interventions taken to reduce the incidence of SSI is a problem in any field trial, including the one described here. We undertook such a complex effort on the basis of evidence that single, simple interventions are unlikely to be successful in achieving such a goal. Hence, many efforts at infection prevention and control are now using (and recommending) a bundled approach with multi-modal strategies that have a greater potential for making a difference in outcomes and achieving a sustainable culture change [23–26]. Additionally, the data set used in the present study was limited in several ways. All of the data were gathered electronically from inpatient records, and there were no data from outpatient encounters after patients’ discharges. Beyond this, the racial/ethnic data used in the study were self-reported; the intervention taken to reduce the incidence of SSI was a quality-improvement project, and the follow-up methods were not tightly defined prospectively. It is always possible that other changes, occurring simultaneously with the improvement interventions, may have also influenced the rates of SSI found in the study, although to our knowledge no other major changes were made.

Complications of CS are a cause of human suffering and of significant cost to the health care system in the United States. This study shows that implementing a program focused on reducing the incidence of SSI after CS can effectively do so. Although we report no significant differences in the incidence of SSI in the subpopulations in the study, it is important to

systematically examine patient data so that decisions and policies are evidence-based. The significant difference in the incidence of SSI that we found in the third quarter of each year is a matter of concern, although it may have been to the result of older and sicker patients being treated during that period. Although the incidence of complications may vary by time of year without an explanation for why this should be so, it is important to continue to educate all care providers about the importance of sustaining efforts to reduce and eliminate the occurrence of SSI in patients who require CS.

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Author Disclosure Statement

The authors have no conflicts of interest to report.

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