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ORIGINAL ARTICLE

The need for unique risk adjustment for surgical site infections at a high-volume, tertiary care center with inherent high-risk colorectal procedures

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Abstract
Background The aim of the present study was to create a unique risk adjustment model for surgical site infection (SSI) in patients who underwent colorectal surgery (CRS) at the Cleveland Clinic (CC) with inherent high risk factors by using a nationwide database.
Methods The American College of Surgeons National Surgical Quality Improvement Program database was queried to identify patients who underwent CRS between 2005 and 2010. Initially, CC cases were identified from all NSQIP data according to case identifier and separated from the other NSQIP centers. Demographics, comorbidities, and outcomes were compared. Logistic regression analyses were used to assess the association between SSI and center-related factors.
Results A total of 70,536 patients met the inclusion criteria and underwent CRS, 1090 patients (1.5%) at the CC and 69,446 patients (98.5%) at other centers. Male gender, work-relative value unit, diagnosis of inflammatory bowel disease, pouch formation, open surgery, steroid use, and preoperative radiotherapy rates were significantly higher in the CC cases. Overall morbidity and individual postoperative complication rates were found to be similar in the CC and other centers except for the following: organ-space SSI and sepsis rates (higher in the CC cases); and pneumonia and ventilator dependency rates (higher in the other centers). After covariate adjustment, the estimated degree of difference between the CC and other institutions with respect to organ-space SSI was reduced (OR 1.38, 95% CI 1.08–1.77).
Conclusions The unique risk adjustment strategy may provide center-specific comprehensive analysis, especially for hospitals that perform inherently high-risk procedures. Higher surgical complexity may be the reason for increased SSI rates in the NSQIP at tertiary care centers.

Keywords Risk adjustment · Surgical site infection · Tertiary care center · NSQIP

Introduction

Postoperative surgical site infection (SSI) is the most common nosocomial infection among surgical patients, and colorectal surgery (CRS) is a major contributor to institutional SSI rates due to its inherent risk factors [1, 2]. The delineation of both SSI incidence and associated risk factors is important because SSI increases the cost of surgical practice by prolonging hospital stay and reducing efficiency [3]. A number of studies have reported the incidence of SSI after CRS to range between 5 and 30% [4, 5]. This discrepancy may be related to differences in clinical practice between hospital centers, how SSI is defined, the nature of the different disease types, and differences in surgical complexity (tertiary referral centers tend to perform more complex procedures, which carry a higher risk of SSI even with standard prevention protocols) [6–8].

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) is a nationally validated, risk-adjusted, outcome-based database intended to measure and improve the quality of surgical care. With this nationwide platform, we can study SSI rates after colorectal procedures in a hospital setting by adjusting

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important preoperative and intraoperative factors. It is important to adjust risk for patient characteristics, case mix, and underlying diagnosis in order to make valid comparisons between hospitals and/or individuals surgeons [9].

No study to date has focused on the inherent risk factors for SSI after CRS in a tertiary care center. In this study, we aimed to evaluate independent risk factors associated with increased SSI rates after CRS in tertiary care settings and create a unique risk adjustment model for SSI in patients who underwent colorectal surgery at the Cleveland Clinic (CC) with inherent high risk factors.

Materials and methods

Data collection and variables

After obtaining institutional review board approval, we queried the ACS-NSQIP Participant Use Data File to identify all patients who underwent CRS according to their primary procedure Current Procedural Terminology (CPT) codes between 2005 and 2010. Patients with secondary procedures related to other specialties were excluded. Subsequently, CC cases were identified from all NSQIP data according to case identifier and separated from the other NSQIP centers. Patient demographics, characteristics, and preoperative comorbidities were analyzed by comparing the CC data with that from other NSQIP centers. Diagnosis was categorized as: colon cancer, rectal cancer, inflammatory bowel disease (IBD), and other benign diseases.

Outcomes

Intraoperative and postoperative outcomes were compared between the two groups (CC vs Other). The primary outcomes of this study were rates of SSI among the centers, which were categorized separately as superficial SSI, deep SSI, organ-space SSI, and wound disruption in the ACS-NSQIP database. Postoperative complications included superficial SSI, deep SSI, organ-space SSI, wound disruption, bleeding requiring transfusion, reoperation, pulmonary embolism, unplanned intubation, progressive renal insufficiency, pneumonia, acute renal failure, urinary tract infection, coma longer than 24 h, ventilator support for more than 48 h (ventilator dependency), cerebrovascular accident, cardiac arrest, deep venous thrombosis, sepsis, septic shock, and myocardial infarction.

Definitions for SSI in the NSQIP are as follows: Superficial incisional SSI is an infection that occurs within 30 days of surgery, and the infection involves only skin or subcutaneous tissue of the surgical incision. Deep incisional SSI is an infection that occurs within 30 days of surgery, involves deep soft tissues (e.g., fascial and muscle layers) of the surgical incision, and appears related to the operation. Organ-space SSI is an infection that occurs within 30 days of surgery and involves any part of the anatomy (e.g., organs or spaces) other than the incision site. Wound disruption describes the separation of the wound layers created by the operation, which could be partial or complete, with disruption of the fascia.

Statistical analysis

Categorical variables are reported as frequency (%) and quantitative variables are reported as mean ± standard deviation (SD) except where noted. Categorical variables were analyzed with the Chi-square or Fisher's exact test and the quantitative variables were analyzed with a Wilcoxon rank-sum test. $p < 0.05$ was considered statistically significant. Univariate analysis was done to define the risk factors for each SSI among all patients. Subsequently, further multivariate logistic regression analysis was conducted to assess the associations between SSI and center-related factors with further covariate adjustments for the variables that were significantly associated with SSI. In the current study, the odds ratio (OR) with 95% confidence interval (CI) was also calculated after univariate analysis for each related outcome based on the ratio between the groups.

Results

A total of 70,536 patients met the inclusion criteria and underwent CRS. In particular, 1090 patients (1.5%) underwent surgery at the CC and 69,446 (98.5%) were treated at the other NSQIP centers. Table 1 compares patient demographics and comorbidities between CC and other NSQIP centers. Male gender, work-relative value unit (RVU), diagnosis of IBD, ileal pouch formation, open surgery, steroid use, and preoperative radiotherapy (RT) rates were significantly higher in the CC cases.

Overall morbidity and specific postoperative complication rates were similar in the CC and other NSQIP centers except for the following: organ-space SSI and sepsis rates were higher in CC cases, and pneumonia and ventilator dependency rates were higher in the other NSQIP centers. Mean operative times were significantly longer in the CC cases (Table 2). Table 3 shows the results of multivariate logistic regression analysis for SSI outcomes for the CC patients compared to the patients from the other NSQIP centers. Adjustment for the covariates reduced the OR between the CC and other NSQIP centers with respect to

Table 1 Patient demographics and comorbidities at the Cleveland Clinic and other NSQIP centers

Variables	CC ($N = 1090$)	Others ($N = 69{,}446$)	p value
Age (years)	52.3 ± 17.2	63.4 ± 64.2	<0.001
Gender (Male)	582 (53.4)	34,181 (49.2)	0.006
BMI (kg/m^2)	27.3 ± 6.4	27.9 ± 6.6	<0.001
ASA classification			0.002
I–II	589 (54.8)	37,723 (50)	
III–IV	501 (45.2)	37,723 (50)	
Diagnosis			
Colon cancer	142 (13.1)	18,750 (27)	
Rectal cancer	164 (15)	9028 (12.7)	
IBD	403 (37)	5556 (8.3)	
Other benign diseases[b]	381 (34.9)	36,112 (52)	
Open surgery	722 (66.2)	42,386 (61.0)	<0.001
Work RVU	26.8 ± 5.8	25.9 ± 4.7	<0.001
COPD	28 (2.6)	4305 (6.2)	<0.001
Pouch formation	151 (13.9)	2498 (3.6)	<0.001
Diabetes mellitus	117 (10.7)	10,068 (14.5)	<0.001
Bleeding disorders	48 (4.4)	4074 (5.9)	0.042
Dyspnea	51 (4.7)	8119 (11.7)	<0.001
Pneumonia	2 (0.2)	560 (0.8)	0.036
Congestive heart failure	10 (0.9)	965 (1.4)	0.19
MI (within the last 6 months)	7 (0.6)	635 (0.9)	0.35
Acute renal failure	8 (0.7)	568 (0.8)	0.76
Dialysis	15 (1.4)	861 (1.2)	0.69
Cerebrovascular accident	19 (1.7)	1762 (2.5)	0.1
Steroid usage[a]	220 (20.2)	5168 (7.4)	<0.001
Smoking history	178 (16.3)	12,672 (18.2)	0.1
Radiotherapy (within the last 3 months)	58 (5.3)	2823 (4.1)	0.038
Emergency	80 (7.3)	9944 (14.3)	<0.001

Values are reported as mean ± SD or absolute values (%)

CC Cleveland Clinic, *NSQIP* National Surgical Quality Improvement Program, *BMI* body mass index, *ASA* American Society of Anesthesiologists classification, *IBD* inflammatory bowel disease, *RVU* relative value unit, *COPD* chronic obstructive pulmonary disease, *MI* myocardial infarction

[a]Steroid usage for a chronic medical condition within 30 days before surgery

[b]Non-adenomatous polyp, volvulus, motility disorders, unspecified noninfectious gastroenteritis and colitis

organ-space SSI from 1.80 (CI 1.41–2.30; $p < 0.001$) to 1.45 (CI 1.12–1.84; $p = 0.004$).

Results of univariate analysis of patient characteristics and operative factors associated with organ-space SSI among all patients are shown in Table 4. The factors, which were significantly higher in the CC cases, including male gender, higher work RVU, diagnoses of rectal cancer and IBD, pouch formation, open surgery, steroid use, and preoperative RT, were significantly higher in the patients with organ-space SSI.

Univariate analysis of patient characteristics and operative factors for patients who had organ-space SSI comparing the CC and other NSQIP centers is shown in Table 5. Pouch formation, diagnosis of IBD and rectal cancer, and preoperative steroid use were significantly higher in the CC cases. Subsequently, multivariate risk adjustment was performed with those factors, which were different between the groups (Table 6). The OR between the CC and other institutions with respect to organ-space SSI decreased from 1.80 (CI 1.41–2.30; $p < 0.001$) to 1.36 (CI 1.05–1.73; $p = 0.016$).

Table 2 Perioperative outcomes comparing the Cleveland Clinic (CC) and other NSQIP centers

Outcomes	CC ($N = 1090$)	Others ($N = 69{,}446$)	p value
Operative time (min)	168 ± 83	155 ± 79	<0.001
Length of hospital stay (days)	8.9 ± 9.4	9.2 ± 10.2	0.86
Morbidity	286 (26.2)	18,918 (27.2)	0.46
Any SSI	168 (15.4)	9292 (13.4)	0.51
Superficial SSI	84 (7.7)	5501 (7.9)	0.79
Deep SSI	17 (1.6)	982 (1.4)	0.69
Organ-space SSI	71 (6.5)	2588 (3.7)	<0.001
Wound disruption	19 (1.7)	1088 (1.6)	0.64
Bleeding requiring transfusion	22 (2.0)	1944 (2.8)	0.23
Return to operating room	68 (6.2)	4584 (6.6)	0.63
Pulmonary emboli	9 (0.8)	493 (0.7)	0.65
Myocardial infarction	1 (0.1)	420 (0.6)	0.06
Pneumonia	19 (1.7)	2301 (3.3)	0.005
Cardiac arrest	5 (0.5)	549 (0.8)	0.22
Cerebrovascular accident	1 (0.1)	265 (0.4)	0.15
Coma > 24 h	1 (0.1)	102 (0.2)	0.76
Sepsis	86 (7.9)	3093 (4.5)	<0.001
Unplanned intubation	25 (2.3)	2042 (2.9)	0.21
Septic shock	27 (2.5)	2037 (2.9)	0.38
Ventilator dependency[a]	35 (3.2)	3327 (4.8)	0.01
Urinary tract infection	36 (3.3)	2528 (3.6)	0.55

Values are reported as mean ± SD or absolute values (%)

CC Cleveland Clinic, *NSQIP* National Surgical Quality Improvement Program, *SSI* surgical site infection

[a]Ventilator support for more than 48 h

Table 3 Odds ratios (95% CI) for SSI outcomes for Cleveland Clinic patients relative to patients from other NSQIP centers based on logistic regression models

Model	Type of SSI			
	Any SSI	Superficial SSI	Deep SSI	Organ-space SSI
OR (95% CI)	1.18 (1.00–1.39)	0.97 (0.78–1.21)	1.10 (0.68–1.79)	1.80 (1.41–2.30)
(Univariate)	$p = 0.051$	$p = 0.79$	$p = 0.69$	$p < 0.001$
OR (95% CI)	1.04 (0.88–1.23)	0.92 (0.73–1.15)	0.99 (0.58–1.56)	1.45 (1.12–1.84)
(Multivariate)	$p = 0.62$	$p = 0.47$	$p = 0.97$	$p = 0.004$

NSQIP National Surgical Quality Improvement Program, *SSI* surgical site infection *CI* confidence interval, *OR* odds ratios (multivariate analyses adjusted for diabetes mellitus, bleeding disorder, preoperative transfusion, sepsis, dialysis, work RVU, disseminated cancer, and wound classification)

Discussion

The current study demonstrates the impact hospital settings have on SSI rates and identifies independent risk factors associated with organ-space SSI after CRS using a nationwide cohort. Our findings confirmed that a large proportion of the CC patient population were IBD and pouch cases. Our patients who had IBD and pouch surgery used steroids preoperatively and had more organ-space SSI than patients from other centers.

Since 2005, our institution has been an active participant of the NSQIP, and our SSI rates have been compared with NSQIP data. In 2006, we were found to be a high outlier institution for SSI, with an observed-to-expected ratio of 1.27 [7]. This was due to the high proportion of colorectal procedures we perform compared to other centers, which carries an inherent risk of SSI [10]. Colorectal procedures represented 17% of all surgical cases at our institution compared to a nationally reported average of 9% in 2006. Indeed, for colorectal procedures, the reported SSI rate was 14.3%—higher than the SSI rate of 9.4% for general and vascular procedures. This previously published report [7] from our institution comparing SSIs in our department and all other NSQIP centers motivated us to perform further

Table 4 Univariate analysis of patient characteristics and operative factors associated with organ-space SSI among all patients

Variables	Organ-space SSI (−) ($N = 67,877$)	Organ-space SSI (+) ($N = 2659$)	p value
Hospital			
Cleveland Clinic	1019 (93.5)	71 (6.5)	<0.001
Other	66,858 (96.3)	2588 (3.7)	
Gender (Male)	34,563 (50.9)	1210 (45.5)	<0.001
Diagnosis			
Colon cancer	474 (18.3)	9 (12.7)	<0.001
Rectal cancer	451 (17.4)	6 (8.5)	
IBD	392 (15.1)	28 (39.4)	
Other benign diseases[a]	1271 (49.1)	28 (39.4)	
Surgical approach			
Open	41,225 (95.6)	1883 (4.4)	<0.001
Laparoscopic	26,652 (97.2)	776 (2.8)	
Pouch formation	2449 (3.6)	200 (7.5)	<0.001
Work RVU	25.9 ± 4.7	26.9 ± 5.1	<0.001
Age (years)	63.4 ± 64.9	58.2 ± 16.5	<0.001
BMI (kg/m^2)	27.9 ± 6.6	28.3 ± 7.1	0.002
Smoking	12,224 (18.0)	626 (23.5)	<0.001
Ventilation	984 (1.4)	66 (6.3)	<0.001
COPD	4144 (6.1)	189 (7.1)	0.03
Ascites	1201 (1.7)	72 (2.7)	<0.001
MI (within the last 6 months)	600 (0.01)	42 (1.5)	<0.001
Renal failure	537 (0.7)	39 (1.4)	<0.001
Dialysis	811 (1.1)	65 (2.4)	
Steroid usage	5028 (7.4)	360 (13.5)	<0.001
Weight loss	3580 (5.2)	196 (7.3)	<0.001
Bleeding disorder	3912 (5.8)	210 (7.8)	<0.001
Transfusion	885 (1.3)	62 (2.3)	<0.001
Radiotherapy (within the last 3 months)	2710 (3.9)	171 (5.9)	<0.001
Emergency	9492 (13.9)	532 (20%)	<0.001

Values are reported as mean ± SD or absolute values (%)

SSI surgical site infection, *IBD* inflammatory bowel disease, *RVU* relative value unit, *BMI* Body Mass Index, *COPD* chronic obstructive pulmonary disease, *MI* myocardial infarction

[a]Non-adenomatous polyp, volvulus, motility disorders, unspecified noninfectious gastroenteritis and colitis

analysis to develop a unique risk-adjusted SSI model that is specific to CRS in a tertiary care center.

Our study showed that pouch creation, diagnosis of IBD, and preoperative steroid use were significantly higher in the CC cases. In fact, these findings clearly demonstrate that our surgical patient population is derived mainly from our referral center for IBD and pouch surgery. Patients who had IBD and pouch surgery used steroids preoperatively and had more organ-space SSI in our institution [11] than such patients at other centers. It is also important to consider that not all IBD and pouch patients have the same surgical complexity. Due to our referral pattern, a substantial proportion of patients had redo surgery at our institution having had the primary procedure elsewhere, which further increased the complexity of their cases [12].

Surgical infections are the major factors that increase hospital expenses; SSI rates are commonly used for quality parameters [13]. SSI varies widely among different hospitals in the NSQIP [14]. Higher rates may be due to increased surgical complexity, especially in tertiary referral centers. It has been suggested that the current quality improvement programs do not accurately reflect risks associated with CRS. Rather, they tend to focus on risk factors associated with patient comorbidities. Less focus has been placed on variables within the surgical procedure and underlying diagnosis itself. A novel approach is needed

Table 5 Univariate analysis of patient characteristics and operative factors for patients who had organ-space surgical site infection comparing Cleveland Clinic and other NSQIP centers

Variables	CC ($N = 71$)	Others ($N = 2588$)	p value
Age (years)	49.3 ± 16.3	58.4 ± 16.4	<0.001
Gender (Male)	46 (64.8)	1403 (54.2)	0.08
BMI (kg/m^2)	29.1 ± 8.8	28.3 ± 6.9	0.79
ASA classification			0.09
I–II	39 (54.9)	1158 (44.7)	
III–IV	32 (45.1)	1430 (55.3)	
Diagnosis			<0.001
Colon cancer	474 (18.3)	9 (12.7)	
Rectal cancer	451 (17.4)	6 (8.5)	
IBD	392 (15.1)	28 (39.4)	
Other benign diseases[b]	1271 (49.1)	28 (39.4)	
Open surgery	47 (66.2)	1836 (70.9)	0.39
Work RVU	27.8 ± 6.5	26.9 ± 5.1	0.053
COPD	1 (1.4)	188 (7.3)	0.09
Pouch formation	17 (23.9)	183 (7.1)	<0.001
Diabetes mellitus	11 (15.5)	370 (14.3)	0.78
Dyspnea	1 (1.4)	336 (13.0)	0.02
Bleeding disorders	8 (11.3)	202 (7.8)	0.29
Hypertension	23 (32.4)	1276 (49.3)	0.006
Sepsis	12 (16.9)	529 (20.4)	0.47
Steroid usage[a]	18 (25.4)	342 (13.2)	0.004
Radiotherapy (within the last 3 months)	5 (7.0)	166 (6.4)	0.80
Emergency	10 (14.1)	522 (20.2)	0.21

Values are reported as mean ± SD or absolute values (%)

CC Cleveland Clinic, *BMI* Body Mass Index, *ASA* American Society of Anesthesiologists classification, *IBD* inflammatory bowel disease, *RVU* relative value unit, *COPD* chronic obstructive pulmonary disease, *MI* myocardial infarction

[a]Steroid usage for a chronic medical condition within 30 days before surgery

[b]Non-adenomatous polyp, volvulus, motility disorders, unspecified noninfectious gastroenteritis and colitis

to calculate risk-adjusted quality assessments using the current NSQIP dataset variables to predict outcomes specifically in colorectal surgery [15].

Risk adjustment is the key component of the NSQIP dataset [16]. Most variables included in risk adjustment models focus on patient-related factors and comorbidities [17]. Less attention has been given to surgical complexity and center-related inherent risk factors [18]. The role of the underlying disease process and its impact on SSI rates has been evaluated, and it was shown that diagnosis is a confounding factor for different types of SSI and that it is also important for comparisons of SSI rates in institutions that perform CRS [19, 20].

Different risk adjustment models should be considered for superficial, deep and organ-space SSI based on different pathologies [6, 21]. This is because some operative factors may affect organ-space SSI rates with more complex mechanisms [11, 22]. For example, anastomotic leak, an unavoidable cause of organ-space SSI, can be influenced by tissue perfusion, apposition, tension and local spillage and may mask the potential effects of preventative measures on all SSI types, particularly organ-space. In addition, the method of conflating different SSIs weakens the significance of SSI assessment by combining distinct forms of infectious complications which have quite different potential effects on care.

On the other hand, the ACS-NSQIP helped us to better understand why our organ-space SSI rates were higher than the national average as well as the patient profile that is associated with high postoperative risk and how we can make improvements. By understanding our targeted patient population, our department initiated an SSI reduction strategy program called the "CORS SSI Prevention Bundle Project" in 2014. ACS-NSQIP posts semiannual reports for all participating hospitals in 6-month intervals. Using this information, we were able to monitor our success and change our CORS SSI status to "low outlier–exemplary performance."

Table 6 Full details of the model for organ-space SSI versus site, with covariates selected as those variables significantly different between sites among patients with organ-space SSI

Variable	Odds ratio (95% CI)	*p* value
Pouch formation	1.42 (1.21–1.68)	<0.001
Dyspnea	1.22 (1.08–1.37)	0.001
Hypertension	1.15 (1.06–1.26)	0.001
Steroid use	1.52 (1.33–1.73)	<0.001
Diagnosis		
Benign disease (non-IBD)	1	
IBD	1.45 (1.26–1.67)	
Colon cancer	0.75 (0.67–0.83)	
Rectal cancer	1.45 (1.30–1.62)	
Age > 62	0.76 (0.70–0.83)	<0.001
CC (vs Other NSQIP centers)	1.36 (1.05–1.73)	0.016

SSI surgical site infection, *CI* confidence interval, *IBD* inflammatory bowel disease, *CC* Cleveland Clinic, *NSQIP* National Surgical Quality Improvement Program

The present study has some limitations, most of which arise from the nature of the NSQIP database. Unfortunately, the ACS-NSQIP does not allow users to separate the centers specifically. Also, the NSQIP does not provide information by subspecialty, including CRS, and level of care center (primary, secondary and tertiary). Additionally, the retrospective nature of the study did not allow us to perform a comprehensive analysis of other evidence-based interventions that can be used to target SSI rates after CRS. Previously described independent risk factors associated with SSI by single institution studies of CRS could not be investigated because the NSQIP does not provide them. However, the high case volume, our strict selection criteria, and unique adjustment analysis strengthen the clinical value of this study.

Conclusions

The unique risk adjustment strategy may provide center-specific comprehensive analysis, especially for hospitals that perform inherently high-risk procedures. Greater surgical complexity may be the reason for increased SSI rates in the NSQIP at the tertiary care centers.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The Cleveland Clinic Institutional Review Board, Cleveland, OH approved this study (IRB#14-094).

Informed consent As this is a study based on data from nationwide dataset, informed consent statements for patient enrollment is not applicable.

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