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ORIGINAL ARTICLE

What Is the Effect of Stoma Construction on Surgical Site Infection After Colorectal Surgery?

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Abstract
Introduction The aim of our study was to evaluate the effect of stoma creation on deep and superficial surgical site infections after an index colorectal surgical procedure.
Methods We designed a retrospective cohort study from the National Surgical Quality Improvement Program. We evaluated all patients who underwent colorectal surgery procedures from January 2005 to December 2009 with or without creation of a stoma and sought to identify the effect of stoma creation on deep and superficial surgical site infections.
Results A total of 79,775 patients underwent colorectal procedures (laparoscopic 30.7 %, open 69.3 %), while 8,113 patients developed a surgical site infection (10.2 %). The univariate analysis revealed that surgical site infections were much more common in patients with a stoma compared to those with no stoma (11.8 % vs. 9.5 %, $p<0.0001$). On multivariate analysis, stoma construction during the index colorectal procedure (OR 1.3, CI 1.2 to 1.4), ASA class ≥2, smoking, and abnormal body mass index were associated with surgical site infection.
Conclusions The construction of a stoma with colorectal procedures is associated with a higher risk of surgical site infection. Although the stoma effect on surgical site infection is attenuated with laparoscopic techniques, the association remained statistically significant.

Keywords Infection · Colorectal surgery · Adverse event · NSQIP · Stoma

Introduction

Surgical site infections are the second most common healthcare-associated infection and are estimated to occur in 300,000 patients a year.[1] These infections occur with the highest frequency after colorectal surgery, with rates in the range of 20 % and higher.[2] Considerable resources have been designated to reduce healthcare-associated infections. To tackle these infections, surveillance and reporting strategies have been implemented for infection control and quality improvement strategies. Similar to the American College of Surgeons National Surgical Quality Improvement Program, the improvement theory is based on outcome reporting, leading to national or local projects to reduce adverse events. One quality initiative, the Surgical Care Improvement Project has led the way in measuring, assessing, and developing guidelines to prevent surgical infections. In addition to the Surgical Care Improvement Project, recently, the National Healthcare Safety Network[3] from the Centers for Medicare and Medicaid Hospital Inpatient Quality Reporting Program has mandated public reporting of surgical site infections after colectomy and hysterectomy.

Despite substantial efforts to reduce surgical site infections and close adherence to process measures, there have been few successes in preventing surgical site infections.[4] For example, the goal of reducing surgical complications by 25 % before calendar year 2010 through the Surgical Care Improvement Project has been largely unrealized.[5,6] A lack of significant outcome change despite adherence to the process

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measures aimed at reducing surgical site infections has perplexed investigators.[7] Given the high rate of adherence to infection control process measures and minimal changes in outcome, it stands to reason that other unmeasured risk factors may be associated with the development of these infections. At this time, many patient factors have been associated with risk of surgical site infection; however, the role of stoma creation has not been evaluated. In this study, we sought to identify the relationship between stoma creation and surgical site infection after colorectal surgery.

Methods

Data Source

We obtained the participant user data file from the American College of Surgeons National Surgical Quality Improvement Program for the calendar years 2005 through 2009. The National Surgical Quality Improvement Program collects data on 135 variables, including preoperative risk factors, intraoperative variables, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient setting.[8] The data files contain deidentified data as defined by the Health Insurance Portability and Accountability Act Privacy Rule.[9] A data use agreement is held by the American College of Surgeons National Surgical Quality Improvement Program; our study was considered exempt by the Lahey Clinic Institutional Review Board.

A complete summary of the National Surgical Quality Improvement Program sampling methods, data collection, and outcomes has been detailed previously.[10] Prior to January 2011, the sampling strategy required hospitals to report their first 40 consecutive eligible cases on an 8-day cycle in order to capture a variety of cases and minimize bias in case selection.[11] The National Surgical Quality Improvement Program samples a list of index cases based on Current Procedural Terminology codes.[12] Outcomes recorded in the National Surgical Quality Improvement Program are risk-adjusted and based on selected variables, including patient demographic factors, comorbidities, indication for surgery, preoperative laboratory data, and other intraoperative variables.[10] The National Surgical Quality Improvement Program collects postoperative 30-day outcomes related to morbidity, mortality, and length of stay using standard definitions.[12] Data are collected by participating hospitals, and data abstraction is overseen at each hospital by surgical clinical nurse reviewers.[12]

Patient and Procedure Selection

Using the National Surgical Quality Improvement Program participant user data file, we selected all patients with a procedure code for colorectal surgery using Current Procedural Terminology codes. We used codes previously described in comparisons of hospital performance reports provided by Ingraham[13] but added two additional Current Procedural Terminology codes (44152, 44153) for ileoanal pouch procedures available prior to 2007.

Outcome

The National Surgical Quality Improvement Program identifies occurrences of interest defined as intraoperative or postoperative.[12] We abstracted the data for superficial and deep surgical site infections and aggregated them where appropriate into a category of surgical site infections. Superficial surgical site infections are classified as infections of the skin or subcutaneous tissues of the incision with at least purulent drainage and/or isolated organisms and with incisional pain, swelling, redness or heat, and opening of the incision. Deep incision surgical site infections involve the deep fascial and muscular layers, and the deep tissues are opened spontaneously or by a surgeon.[12] We did not include patients with organ space infections as the risk of organ space infections is likely to be diminished with stoma creation.

Stoma Creation

We used Current Procedural Terminology codes to identify patients with creation of an ileostomy or colostomy. A stoma was coded as present when the current procedural terminology code was 44141, 44143, 44144, 44206, 45113, 45397, 45111, 44208, 44146, 44210, 44150, 44151, 44152, 44153, 44155, 44156, 45121, 44211, 44212, 44157, 44158, 44310, 45126, 45395, or 45110.

Covariates

We used the risk factors for surgical site infections previously described for past National Surgical Quality Improvement Program Semi-Annual Reports. Predictor variables included patient age, sex, race, body mass index, wound classification, American Society of Anesthesiologists class, preoperative functional status, preoperative sepsis, smoking, disseminated cancer, work relative value units, creatinine, white blood count, sodium, ventilator dependence, dialysis, congestive heart failure, emergency procedure, and transfusion.[14] Categories of laboratory values were constructed using the American College of Surgeons National Surgical Quality Improvement Program definitions of normal and abnormal.[7,14] In addition, we used the National Surgical Quality Improvement Program definition for emergency or nonemergency operation based on the status of the operation as designated by the surgeon or anesthesiologist.

An emergency case is usually performed as soon as possible and no later than 12 h after the patient has been admitted to the hospital or after the onset of related preoperative symptomatology.[7] Any missing data were classified into an additional category and labeled "null." We did use standard laparoscopy codes when adjusting for use of laparoscopy in the analysis.

Statistical Analysis

Data were analyzed with SAS version 9.2 (SAS Institute, Cary, NC, USA). In our initial analyses of factors associated with surgical site infections, we used chi-square tests for categorical variables and two-tailed Student's t tests for continuous variables. Statistical significance was designated at the level in which $p<0.05$.

Logistic regression models were constructed to identify those factors associated with surgical site infections. Risk adjustment with preoperative patient characteristics, comorbidities, laboratory values, and procedural factors was performed as described by the National Surgical Quality Improvement Program.[14] All covariates were entered into the multivariate model for analyses regardless of univariate associations.

Results

From January 2005 to December 2009, a total of 971,455 patients were identified in the National Surgical Quality Improvement Program; 79,775 patients met the inclusion criteria. A superficial surgical site infection occurred in 27,588 (2.8 %) patients and in 6,788 (8.5 %) of the colorectal surgery patients. Deep surgical site infections occurred in 7,479 of all patients (0.8 %) and in 1,402 (1.8 %) of all colorectal surgery patients. A total of 8,113 patients had 8,190 superficial and deep surgical site infections for an aggregate rate of surgical site infections of 10.2 %.

A total of 56,984 patients had no stoma, while 22,791 patients underwent stoma creation. Surgical site infections occurred in 5,429 (9.5±0.3 %) of patients with no stoma and in 2,684 (11.8±0.4 %) of patients ($p<0.0001$) with a newly constructed stoma. Analysis of procedure type revealed that surgical site infections occurred most commonly in patients following abdominoperineal resection and least frequently following subtotal colectomy (Fig. 1). In partial colectomy patients ($n=52,672$), a surgical site infection occurred in 9.4±0.3 % of patients with no stoma compared to 11.2±0.7 % of all patients with a stoma ($p<0.0001$). In patients who underwent proctectomy with anastomosis and not abdominoperineal resection ($n=17,721$), a surgical site infection occurred in 10.0+0.5 % of patients with no stoma but in 11.8+1.0 % of all patients with a diverting stoma ($p=0.002$) (Fig. 2).

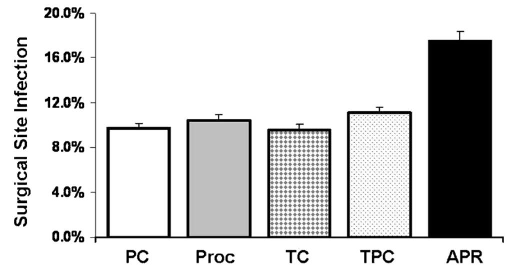

Fig. 1 Risk of surgical site infections for partial colectomy (*PC*), proctectomy (*Proc*), total colectomy (*TC*), total proctocolectomy (*TPC*), and abdominoperineal resection (*APR*) procedures

Characteristics

Patients with a stoma were younger in age but much more likely to be of male sex proportionately (Table 1). In addition, patients who underwent stoma creation were more likely to have a dirty wound, preoperative septic shock, and history of heart failure, require dialysis, and exhibit disseminated cancer. Table 1 lists characteristics of the patients with and without a stoma.

Multivariate Analysis

Logistic regression revealed that the creation of a stoma was associated with increased risk of surgical site infection (odds ratio (OR) 1.3, confidence interval (CI) 1.2–1.4, $p<0.0001$) (Table 2). The other factors associated with increased risk of surgical site infection included contaminated or dirty wounds, sepsis or septic shock, and higher body mass index. A full analysis using NSQIP recommended covariates is included in Table S2.

The multivariate analysis was re-performed with the addition of a laparoscopy variable. We noted that the use of laparoscopy was associated with a significant reduction in the risk of surgical site infection (OR 0.6, CI 0.5–0.6, $p<0.0001$). Inclusion of the laparoscopy code did attenuate the risk of surgical site infection, but a direct association was still noted (OR 1.1, CI 1.1–1.2, $p<0.03$).

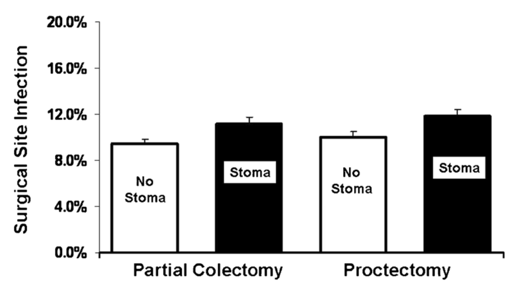

Fig. 2 Risk of surgical site infections for partial colectomy patients and proctectomy patients excluding abdominoperineal resections with (*black*) or without stoma (*white*)

Table 1 Characteristics of colorectal surgery patients with and without stoma

	Stoma	No stoma	All	*p* value
n	22,791	56,984	79,775	
Age (years)	59.7±16.7	62.3±15.1	61.6±15.7	0.01
Male sex	11,533 (50.6 %)	26,367 (46.3 %)	37,900 (47.5 %)	0.0001
Missing	7 (0.1 %)	1 (0.1 %)	8 (0.1 %)	
BMI				0.0001
0–18.4	1,689 (7.4 %)	2,497 (4.4 %)	4,186 (5.3 %)	
18.5–24.9	7,410 (32.5 %)	17,841 (31.3 %)	25,251 (31.7 %)	
25.0–29.9	6,924 (30.4 %)	18,821 (33.0 %)	25,745 (32.3 %)	
30.0–34.9	3,681 (16.1 %)	10,361 (18.2 %)	14,042 (17.6 %)	
≥35.0	2,748 (12.1 %)	7,031 (12.3 %)	9,779 (12.3 %)	
Missing	339 (1.5 %)	433 (0.8 %)	772 (1.0 %)	
Wound class				0.001
Clean	6 (0.1 %)	7 (0.1 %)	13 (0.1 %)	
Clean/contaminated	13,821 (60.6 %)	46,085 (80.8 %)	59,906 (75.1 %)	
Contaminated	3,262 (14.3 %)	6,356 (11.2 %)	9,618 (12.1 %)	
Dirty	5,702 (25.0 %)	4,536 (8.0 %)	10,238 (12.8 %)	
ASA classification				0.0001
No disturbance	405 (1.8 %)	2,074 (3.6 %)	2,749 (3.1 %)	
Mild disturbance	8,399 (36.9 %)	27,837 (48.9 %)	36,236 (45.4 %)	
Severe disturbance	9,828 (43.1 %)	23,433 (41.1 %)	33,261 (41.7 %)	
Life threatening	3,714 (16.3 %)	3,421 (6.0 %)	7,135 (8.9 %)	
Moribund	419 (1.8 %)	178 (0.3 %)	597 (0.8 %)	
Missing	26 (0.1 %)	41 (0.1 %)	67 (0.1 %)	
Preoperative sepsis				0.0001
None	16,218 (71.2 %)	52,292 (91.8 %)	68,510 (85.9 %)	
SIRS	3,077 (13.5 %)	2,963 (5.2 %)	6,040 (7.6 %)	
Sepsis	1,910 (8.4 %)	1,113 (1.9 %)	3,023 (3.8 %)	
Septic shock	1,586 (6.9 %)	616 (1.1 %)	2,202 (2.8 %)	
Current smoker	4,670 (20.5 %)	10,329 (18.1 %)	14,999 (18.8 %)	0.0001
Disseminated cancer	1,406 (6.2 %)	2,276 (4.0 %)	3,682 (4.6 %)	0.0001
Work RVU	29.6±4.4	24.3±4.0	25.8±4.8	0.0001
Functional status				0.0001
Independent	20,542 (90.1 %)	54,620 (95.8 %)	75,162 (94.2 %)	
Partially dependent	1,631 (7.2 %)	1,909 (3.4 %)	3,540 (4.4 %)	
Totally dependent	417 (1.8 %)	301 (0.5 %)	718 (0.9 %)	
Missing	201 (0.9 %)	154 (0.3 %)	355 (0.5 %)	
Creatinine >1.2	4,455 (19.6 %)	7,327 (12.9 %)	11,782 (14.8 %)	0.0001
Missing	1,050 (4.6 %)	4,341 (7.6 %)	5,391 (6.8 %)	
White blood count				0.0001
≤4.5	2,185 (9.6 %)	4,506 (7.9 %)	6,691 (8.4 %)	
Normal	13,102 (57.5 %)	42,165 (74.0 %)	55,267 (69.3 %)	
>11	6,572 (28.8 %)	7,079 (12.4 %)	13,651 (17.1 %)	
Missing	932 (4.1 %)	3,234 (5.7 %)	4,166 (5.2 %)	
Sodium <135 meq	3,180 (13.9 %)	3,895 (6.9 %)	7,075 (8.9 %)	0.0001
Hispanic	918 (4.0 %)	2,416 (4.2 %)	3,334 (4.2 %)	0.4
Ventilator dependence	1,120 (4.9 %)	483 (0.9 %)	1,603 (2.0 %)	0.0001
Dialysis	591 (2.6 %)	534 (0.9 %)	1,125 (1.4 %)	0.0001
Heart failure	553 (2.4 %)	684 (1.2 %)	1,237 (1.6 %)	0.0001
Transfusion >4 units preoperatively	386 (1.7 %)	424 (0.7 %)	810 (1.0 %)	0.0001

Values include mean ± standard deviation or proportion with 95 % confidence interval. *p* value represents comparison between stoma and no stoma patients

Table 2 Multivariate analysis evaluating risk of developing a surgical site infection for patients having colorectal surgery

	Odds ratio	CI	*p* value
Stoma	1.3	1.2–1.4	0.001
Male sex (vs. female)	1.1	1.1–1.2	
Age			
Under 80	Referent	Referent	
Over 80	0.7	0.5–0.9	0.05
BMI			
0–18.4	1.0	0.9–1.1	0.7
18.5–24.9	Referent	Referent	
25.0–29.9	1.3	1.2–1.4	0.0001
30.0–34.9	1.5	1.4–1.7	0.0001
≥35.0	2.3	2.1–2.5	0.0001
Missing	1.3	1.1–1.7	0.05
Wound class			
Clean	0.7	0.1–5.7	0.7
Clean/contaminated	Referent	Referent	
Contaminated	1.3	1.2–1.4	0.0001
Dirty	1.3	1.2–1.4	0.0001
ASA classification			
No disturbance	Referent	Referent	
Mild disturbance	1.4	1.2–1.6	0.0002
Severe disturbance	1.9	1.6–2.2	0.0001
Life threatening	1.7	1.4–2.1	0.0001
Moribund	1.7	1.1–2.4	0.01
Missing	2.2	1.0–4.5	0.05
Preoperative sepsis			
None	Referent	Referent	
SIRS	1.1	0.9–1.2	0.3
Sepsis	0.7	0.6–0.8	0.0001
Septic shock	0.6	0.5–0.8	0.0001
Current smoker	1.2	1.1–1.2	0.0001
Disseminated cancer	1.1	1.0–1.2	0.1
Increasing work RVU	1.1	1.1–1.1	0.01
Functional status			
Independent	Referent	Referent	
Partially dependent	1.1	1.0–1.3	0.1
Totally dependent	1.0	0.8–1.3	0.8
Missing	1.0	0.7–1.4	0.9
Creatinine >1.2 (vs. normal)	0.8	0.8–0.9	0.001
Missing	0.8	0.7–0.9	0.03
White blood count			
≤4.5	1.0	0.9–1.1	0.8
Normal	Referent	Referent	
>11	0.9	0.9–1.0	0.02
Missing	1.1	1.0–1.1	0.1
Sodium <135 meq (vs. normal)	1.0	1.1–1.1	0.3
Not Hispanic	0.8	0.8–0.9	0.002
Ventilator dependent	0.7	0.6–0.9	0.005
Dialysis	0.7	0.6–1.0	0.03
Heart failure	1.0	0.8–1.2	0.7
Transfusion >4 units preoperatively	1.3	1.0–1.6	0.04

The table includes odds ratios, confidence intervals, and *p* values. The analysis was performed with all recommended National Surgical Quality Improvement Program covariates

Discussion

In the National Surgical Quality Improvement Program cohort that underwent colorectal surgery procedures, over 10 % of the patients developed a superficial or deep surgical site infection. Thus, deep and superficial surgical site infections occurred almost three times more commonly in colorectal surgery patients as compared to the remainder of the surgical population. When a stoma was created during a colorectal surgery procedure, we noted a substantially higher risk of surgical site infection. At the individual procedural level, surgical site infections were much more common in patients who underwent abdominoperineal resection as compared to those who underwent segmental resection. Although a laparoscopic technique attenuated the increased risk of surgical site infection from stoma creation, the direct association between stoma creation and surgical site infection remained statistically significant despite adjustment for laparoscopic technique.

Surgical site infections are a challenging problem to substantively reduce as there are many portals of entry for pathogens to contaminate wounds. It is thought that the source of most surgical site infections is the patient's own skin or other mucosal membranes and viscera.[15] However, in addition to this direct source, there are a number of potential sources for bacteria to enter a wound, including ambient air, surgical instruments, and the operating room team itself. There may also be the potential for introduction of bacteria into the wound after incision closure such as with maturation of a stoma or in the immediate postoperative period. Given the numerous potential portals of wound entry for bacteria in a patient with a stoma, we hypothesized that surgical site infections were much more common following stoma creation after colorectal surgery.

We found that surgical site infections occur much more commonly after stoma creation, particularly after abdominoperineal resection. Despite this direct association, it is unclear at which time bacteria actually entered the wound of the patient with a stoma. We cannot identify whether or not the construction of the stoma was the "source" of the infection. In order to implicate the stoma itself as the source of infection, an investigator could culture all surgical site infections in patients with a stoma and compare that bacteriology with patients who had no stoma. Yet, the source could still include the patient's own gastrointestinal viscera or contamination during surgery. The absolute source of surgical site infections is obviously academic, but our data might be used to assess the timing and direction at which new techniques should be developed to prevent these adverse events.

Procedures with a stoma, either as a temporary diversion or for a more permanent fecal stream diversion, tend to be more technically challenging, which may ultimately lead to a significant risk of surgical site infection. In addition, these procedures may have additional wounds (as with abdominoperineal resection), increasing the wound area that might be subject to contamination. However, a wound size hypothesis is unlikely as our data reveal that a patient with a stoma and anastomosis is at a substantially higher risk of surgical site infection as compared to those patients with an anastomosis and no stoma. Patients with an anastomosis are unlikely to have a perineal wound, and thus, a substantial risk of wound infection is related to the technical details of the actual procedure of stoma creation. Alternatively, during the postoperative period, contamination may occur into the wound.

Laparoscopic procedures are associated with reduced blood loss, smaller wounds, and improved outcomes such as fewer wound infections.[16,17] In our study, we noted that when a stoma is created laparoscopically, the risk of surgical site infection is attenuated. Yet, the association between surgical site infection and stoma is not negated when a laparoscope is used as a persistent direct association between wound infections and stoma creation was identified. These results imply that even in the setting of smaller wounds and less tissue trauma or blood loss (as seen with laparoscopy), the risk of surgical site infections remains substantial when a stoma is created. Thus, we can infer that stoma creation led to an appreciable increase in the risk of surgical site infection regardless of the size of the incision.

Given the high risk of surgical site infections in patients with stoma, novel methods to prevent infection will need to be developed and tested. Evidence-based practices such as prophylactic antibiotic use, hair removal with clippers, and postoperative normothermia are critical elements in preventing surgical site infections.[18] However, the dataset does not record the use of these evidence-based practices, and consequently, it is unclear if much of the difference in outcome is related to selective use of these techniques in the setting of a stoma. Differential application of evidence-based practices is, however, unlikely based on stoma creation. In addition, there is also increasing evidence that wound protectors reduce surgical infections after gastrointestinal and biliary tract surgery.[19] No other techniques or methods have been developed in patients with a stoma, however. The controversial role of mechanical bowel preparation has been largely avoided in our manuscript. Recent data from the Michigan Surgical Quality Collaborative-Colectomy Best Practices Project do reveal a reduction in surgical site infections with mechanical bowel preparation in elective colectomy.[20] We might hypothesize that a targeted benefit exists for bowel preparation in high-risk patients with a stoma, removing the potential for wound contamination.[20] However, in the most recently published meta-analysis on bowel preparation, no subgroup analysis has been performed comparing stoma patients to nonstoma patients.[21]

Our study has limitations based on secondary analysis of prospectively collected data which might lead to concerns of confounding as well as biases related to selection, information retrieval, and misclassification. There is also the potential that stoma creation is a confounder for another risk factor for wound infections. The use of radiation and other adjuvant therapies was not recorded and may similarly be associated with stoma creation and thus confound the results. Yet, we also demonstrate high rates of surgical site infections in patients with a stoma and more proximal resections with low likelihood of radiation use. We have no direct evidence from the literature that radiation is associated with wound infection once the other variables are properly adjusted. In addition, because of the associations between many of the surgical infection risk factors, there is potential for collinearity of data points and thus inaccurate results. Other risks such as glycemic control and normothermia are not recorded in the dataset but would be of substantial value in understanding the results. We can only speculate as to whether patients with a new stoma are more likely to experience hypothermia or hyperglycemia. Despite these limitations, this study was able to identify technical considerations of colorectal surgery associated with surgical site infections. The data used in these analyses are the most complete multi-institutional clinical data available with the advantage of an impartial nurse reviewer reducing the possibility of measurement error and other bias. Thus, our study provides an assessment of surgical site infections after colorectal surgery across a wide variety of hospitals interested in quality improvement.

In conclusion, our data reveal the substantial increased risk associated with stoma creation during colorectal surgery procedures. This added risk may be secondary to more difficult procedural issues, different indications for surgery, or potentially additional risk from contamination from the open gastrointestinal tract. Therefore, patients who undergo stoma creation after colorectal procedures represent a high-risk group that may benefit from alternative wound management options. In addition, adjustment for procedures with stoma would provide for better risk-stratified outcome reporting.

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