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Colon and rectal surgery surgical site infection reduction bundle: To improve is to change

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A B S T R A C T

Background: Despite the introduction of the Surgical Care Improvement Project, surgical site infections remain a source of morbidity. The aim of this study was to determine the value of implementing a colorectal bundle on SSI rates.
Methods: Between 2011 and 2016 a total of 1351 patients underwent colorectal operations. Patients were grouped into pre-implementation (Group A, January 1, 2011–December 31, 2012), implementation (Group B, January 1, 2013–December 31, 2014) and post-implementation (Group C, January 1, 2015–December 31, 2016). Primary endpoints were superficial SSI, deep SSI, wound separation and total SSI.
Results: After the bundle was implemented, there was a significant reduction in superficial (6.6%–4%, $p < 0.05$), deep (3.7%–1.1%, $p < 0.05$), and total SSI rates (10.9%–4.7%, $p < 0.05$). Comparing Group A to Group C there was a decrease in total SSI (9.4%–4.7%, $p < 0.05$).
Conclusion: Implementation of the bundle resulted in a reduction in overall SSI rates particularly as compliance increased. This study offers evidence that small changes can lead to significant decreases in surgical site infections.

Introduction

Surgical site infections are a major cause of morbidity and mortality after surgery. Colon and Rectal Surgery is associated with higher surgical site infection rates with a range of 2%–45%[1,2]. Surgical site infections can result in prolonged hospital course, increased need for resources such as home nursing visits or need for a skilled post hospital facility, need for reoperation, as well as psychological and social stress for the patient. This results in significant overall healthcare cost.[1]

Due to this increase burden to the health care system, surgical site infections have become a focus of many institutions as well as the surgical care improvement project (SCIP)[3,4]. SCIP was introduced in 2002 as a collaboration between the Centers for Medicare and Medicaid Services and US Centers for Disease Control and Prevention in hopes of standardizing processes that reduce surgical site infections.[5] These include the use of perioperative hair clipping, perioperative antibiotics, and normothermia in colon and rectal surgery patients.[6] However, despite its introduction and implementation at numerous hospitals across the country, surgical site infections remain a source of morbidity.[1] Consequently, due to the large number of elective colorectal operations performed annually, there remains increased scrutiny on various best-practice methods to reduce surgical site infections and their associated morbidity[7,8]. Individual elements of these efforts vary across institutions, however the overall results are promising in reduction of overall infection rates.

In 2013, our institution implemented a surgical site infection reduction bundle in efforts to reduce surgical site infections among our colon and rectal surgery cohort of patients. Utilizing measures from the SCIP guidelines and institutional practices, a bundle of 11 elements were created. The objective of this study is to evaluate the effects of a surgical site infection reduction bundle on surgical site infection rates. Additionally, we seek to evaluate compliance with the bundle elements and the ease at which a new process can be implemented and adopted within an institution. We utilized both NSQIP data as well as a prospectively maintained database to assess surgical site infection rates before, during and after the

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implementation of the surgical site infection reduction bundle.

Methods

Study design

The patient sample for this study was drawn from an institutional database at the Miriam Hospital, a tertiary care affiliated university hospital. This database was used to capture NSQIP outcomes for the 30-day postoperative period. ACS-NSQIP data was used to identify all patients who underwent colon and rectal surgery at our institution between January 1, 2011–December 31, 2016. These procedures included CPT targeted codes for colectomy 44140–44147, 44150–44151, 44160, 44204, 44205, 44206, 44207, 44208, 44210, and CPT targeted codes for proctectomy 44155–44158, 44211–44212, 45110–45121, 45123,45126, 45130, 45135, 45160, 45395, 45397, 45402, 45550. Institutional data was also prospectively collected during the study period, and integrated with the NSQIP variables to include outcomes of interest related to the Bundle pathway.

The SSI reduction bundle

The bundle was implemented in 2013. A task force of members including a dedicated group of perioperative nurses, anesthesiologists and staff, and surgeons was created to both implement and enforce the utilization and compliance with the bundle elements. Measures were divided into the preoperative, intraoperative, and postoperative phases totaling the eleven bundle elements (Table 1, Fig. 1). Prior to surgery, patients were provided standardized oral antibiotic bowel preparation (neomycin and metronidazole). Mechanical bowel preparation was performed according to the surgeon's preference, but not mandatory. In the preoperative area, patients underwent hair removal with clippers. Blood glucose levels were maintained to <200 mg/dL. Standard preoperative intravenous antibiotics (cefazolin and metronidazole) were given within 60 min of skin incision. Re-dosing of cefazolin was performed every 3 h. Ciprofloxacin and metronidazole was employed if the patient had a penicillin allergy as per the most recent Infectious Diseases Society of America guidelines.[9] Intraoperative FiO2 was maintained at >60% and patient temperature kept at >36.5 degrees Celsius. At wound closure, all staff associated with the operative field changed into new gowns and gloves. New drapes were applied and clean instruments used. In the recovery unit, the patient was maintained on 100% FiO2 by nonrebreather face mask.

To follow compliance, each patient who met the criteria for the bundle protocol was tagged with a sign on the stretcher “Colorectal Bundle”. Each patient was assigned a check-sheet (Fig. 1) that followed the patient from the preoperative area to the operating room and post anesthesia care unit. Each element of the bundle was checked off by the responsible staff. We collected and monitored the bundle data in a prospective fashion which allowed for compliance for each element to be continuously measured and results shared with the entire task force monthly.

#	Bundle Data Element – ExpertScan	Respons e
1	Hair removal in Pre-Op with clippers?	Y/N
2	Glucose checked in Pre-Op holding?	Y/N
3	Glucose reading. Note: If glucose < 200, no further checks; if glucose>200, glucoses should be treated.	
4	Oral antibiotic prep taken by patient the day before surgery -Neomycin/Erythromycin (3 doses) or Neomycin/Metroinidazole (2 doses).	Y/N
5	Ancef/Flagyl dose within 60 minutes prior to incision?	Y/N N/A
6	Ancef re-dosed (if ≥ 3 hour case):	Y/N N/A
7	Fi02 > 0.6 intra-operatively?	Y/N
8	Patient temperature was ≥ 36.0° C from incision to wound closure. (T obtained: via foley/esophageal probe/nasal pharyngeal tube.)	Y/N N/A
9	Did the scrub team change gown / gloves before closing?	Y/N N/A
10	Were clean instruments used for closing?	Y/N N/A
11	100% FM non-rebreather while in PACU.	Y/N N/A

Fig. 1. Colon and rectal surgery bundle sheet.

Analysis

The primary outcome measure for our analysis were superficial surgical site infection (SSI), deep surgical site infection, wound separation, and total infection. The secondary outcome measure was compliance with individual bundle elements. In order to compare the primary outcomes, patients were grouped into: the pre implementation group (group A, January 1, 2011–December 31, 2012), before the Bundle was introduced; the implementation group (group B, January 1, 2013–December 31, 2014), during which the Bundle was rolled out and increasingly embraced; and the post implementation group (Group C, January 1, 2015–December 31, 2016), when the Bundle was well established in our institutional practice. Compliance with the individual bundle elements were compared between Group B and Group C. Continuous variables were described as means and standard deviation. Categorical variables were described as frequencies. Groups were compared using the Pearson Chi square test or the Fisher exact test for categorical variables and the student *t*-test or ANOVA test for continuous variables. Statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC) (Fig. 2).

Table 1
Bundle elements divided into the preoperative, intraoperative, and postoperative phases.

Preoperative	Hair removal with clippers
	Maintain Glucose <200
Intraoperative	Dosing antibiotics within 60 min of skin incision
	Maintain intraoperative FiO2 >60%
	Hourly temperature monitoring; temperature below 36.5 to be discussed between Anesthesiologist and Surgeon
	At closing, all workers associated with operative field to change gown and gloves; use of closing tray
Postoperative	100% face mask for 2 h postoperatively

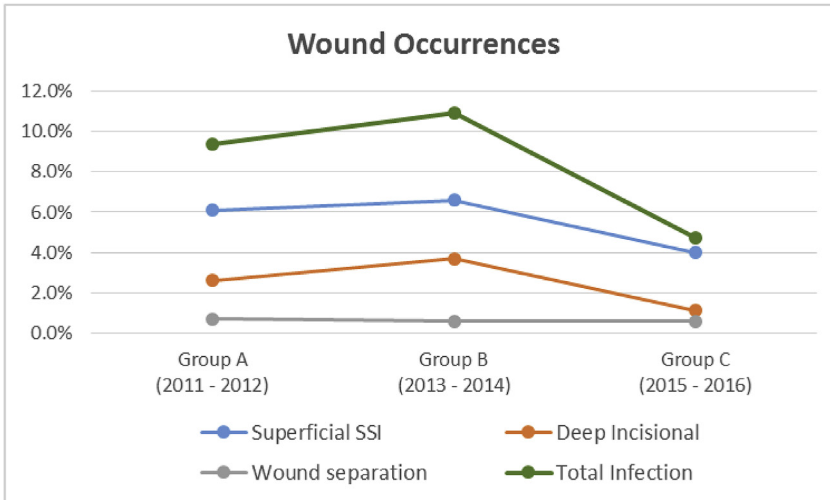

Fig. 2. Superficial, deep incisional, total and wound separation infection by bundle group.

Results

Patient characteristics

During the study period a total of 1351 patients underwent colon and rectal surgery at our institution (Table 2). The vast majority of cases were performed by five Board-certified colorectal surgeons. There were 436 patients in group A, 456 patients in group B, and 459 patients in Group C. All three groups were similar in mean age, sex, BMI, use of immunosuppression preoperatively, and smoking status. In keeping with the increase in laparoscopic colorectal surgery seen nationally, there was a greater number of patients undergoing laparoscopic surgery in Group C compared to the earlier Group A (75% v 59%, $P < 0.001$). There was a greater number of patients undergoing surgery for colon cancer in Group C compared to Group A (27% v 18%, $P = 0.002$) but fewer number of patients undergoing rectal cancer surgery (8% v 9.5%, $P = 0.013$). Although there was no difference in number of emergency cases between the three groups, there was a greater proportion of patients undergoing contaminated surgery in Group C (25% v 7%,

Table 2
Patient characteristics.

	Group A	Group B	Group C	P value
Inclusion Dates	1/1/2011- 12/31/2012	1/1/2013-12/31/2014	1/1/2015–12/31/2016	
Number of patients	436	456	459	ns
Mean Age (y,SD)	60, 16.7	61.2, 15.6	61.4, 14.9	ns
Male (n,%)	182, 42.5	175, 38.4	202, 45.1	ns
Mean BMI (n,SD)	27.8, 6.2	27.9, 5.4	28.4, 6.6	ns
Length of stay (mean,SD)	8, 7.3	8.2, 7.8	6.9, 6.7	ns
ASA (n, %)				<0.001
Class 1	7, 1.6	22, 4.8	18, 4	
Class 2	327, 76.2	290, 63.6	281, 62.7	
Class 3	87, 20.3	128, 28.1	136, 30.3	
Class 4	8, 1.9	15 3.3	13, 2.9	
Diabetes (n,%)				ns
IDDM	10, 2.3	22, 4.8	21, 4.7	
NIDDM	419, 97,7	434, 95.2	427, 95.3	
Smoker (%)	84, 19.6	92, 20.2	73, 16.3	ns
Steroids/immunosuppressant use (n,%)	24, 5.6	37, 8.1	39, 8.71	ns
Albumin (mean, SD)	3.4, 0.7	3.7, 0.6	3.8, 0.6	ns
Emergency Case (n,%)	36, 8.4	26, 5.9	40, 8.9	ns
Wound Class (n, %)				
Clean	2, 0.5	2, 0.4	1, 0.2	ns
Clean contaminated	352, 82	342, 75	269, 60.6	<0.001
Contaminated	30, 7	62, 13.6	112, 25	<0.001
Dirty/Infected	45, 10.5	50, 11	66, 14.5	ns
Diagnosis (n, %)				
Diverticulitis	96, 22.4	101, 22.1	118, 25.8	ns
Colon Cancer	79, 18.5	113, 24.7	124, 27.1	0.002
Rectal Cancer	41, 9.5	49, 10.7	36, 8.0	0.013
Benign neoplasm	51, 11.9	47, 10.3	46, 10.5	ns
Regional enteritis	25, 5.8	24, 5.2	36, 8.2	ns
Ulcerative Colitis	13, 3	20, 4.4	17, 3.8	ns
Emergent Case, n (%)	36, 8.4	30, 5.9	40, 8.8	ns
Laparoscopy, n (%)	254, 59.3	294, 64	344, 75	<0.001

ns = not significant ($p > 0.05$).

$P < 0.001$) and a greater proportion of patients undergoing clean contaminated surgery in Group A (82% v 60%, $P < 0.001$).

Surgical site infections

Superficial surgical site infections, deep surgical infection, wound separation and total infection were compared across the three groups (Table 3). There were no significant decrease in superficial, deep, wound separation or total infections when comparing Group A to Group B. However when comparing Group B to Group C, there was a significant decrease in superficial SSI (6.6% v 4%, $P = 0.017$), deep incisional SSI (3.7% v 1.1%, $P = 0.002$) and total infection (10.9% v 4.7%, $P = 0.0001$). Additionally, when comparing Group A with Group C again there was a significant decrease in superficial SSI (6.1% v 4%, $P = 0.02$), deep incisional SSI (2.6% v 1.1%, $P = 0.04$), and total infection (9.4% v 4.7%, $p = 0.003$) (Fig. 1).

To account for the possible confounding effects of laparoscopic surgery on surgical site infections rates in Group C, a subgroup analysis was performed. Comparing laparoscopic to non laparoscopic surgeries, we did not find any significant difference in superficial SSI (3.6% v 5.4%, $p = 0.45$), deep SSI (1.4% v 0%, $p = 0.19$) and wound separation (0% v 1.8%, $p = 0.13$) rates in Group C.

Compliance

Compliance with the Bundle Elements was also evaluated. There were a total of 335 audits in Group B and 459 audits in Group C (Table 4). Comparing the two groups, there was an increase in compliance in re-dosing of intraoperative antibiotics (38% v 75%, $P < 0.05$), utilization of closing tray (95% v 99.4%, $P = 0.00012$), and changing of gowns and gloves at closing (95% v 99.4%, $P = 0.00012$). There was no difference in maintenance of intraoperative FiO_2 >60%, and use of postoperative non rebreather. Notably there was a decrease in compliance with preoperative hair removal (100% v 98%), and maintenance of intraoperative temperature > 36.5 (98% v 88%).

Discussion

Surgical site infections are one of the most common healthcare-associated infections.[10] They occur at a higher rate after colorectal surgery than other types of operations and can result in significant patient morbidity, longer hospital stays and a substantial impact on health care costs[11,12]. In this study, we demonstrated that a surgical site reduction bundle can be successfully implemented with good outcomes in surgical site infection rates.

The surgical site infection reduction bundle was implemented at our institution in 2013. In selecting members for the bundle task force, it was important to include representative members from all perioperative staff. We felt that these representatives then became accountable to encourage compliance amongst the other staff members that were involved with colon and rectal surgical patients. Having the involvement of infection control personnel provided a way to follow these patients in the postoperative setting. We had a designated infection control nurse who maintained a prospective database of the patients and tracked patients who were subsequently readmitted for surgical site infections. We had a total of 5 colon and rectal surgeons who contributed to the vast majority of these cases however, as the bundle was applied and increasingly embraced, general surgeons started utilizing it as well.

This effort led to a significant reduction in overall SSI rates after colorectal surgery (9.4% pre-bundle to 4.7% post-bundle). This improvement was related to an increase in compliance rates. We believe the prospective nature of the study allowed more careful monitoring of compliance, thus providing better and earlier ways to analyze any deficiencies and strategies for improvement. Specifically, during the transition Group B phase when compliance levels were lower, no discernible change in SSI rates were noted. This finding is similar to that found from the Michigan Surgical Collaborative where there was direct correlation between compliance of bundle implementation and colorectal SSI rate.[13] To account for the time it takes for buy-in from the staff, and for the bundle process to be run smoothly, the data was intentionally grouped. When compliance rates increased during the group C phase, SSI rates decreased (10.9% group B v. 4.7% group C). This improvement was particularly notable with regards to re-dosing of antibiotics intraoperatively as well as a ‘clean’ wound closure set-up, suggesting that these constituents of the bundle may have played a significant role in SSI reduction. The antibiotic regimen of cefazolin and metronidazole was chosen due to several recent reports suggesting its superiority in reduction of SSI rates compared to second generation cepholosporins with anaerobe activity, such as cefotetan or cefoxitin, which we had used commonly in the past[14,15]. The benefit of sterile closure trays and pre-closure glove changes were also noted in a recent meta-analysis of colorectal bundles. In that report, interventions resulting in the most significant impact on SSI reduction were clean trays (58.6% vs 33.1%), pre-closure glove changes (56.9% vs 28.5%) as well as mechanical bowel preparation with oral antibiotics (55.4% vs 31.8%).[16] Our findings are similar to several previous reports on the benefits of bundling multiple interventions to reduce SSI rates in this setting[17,8]. These findings were reiterated by two recent meta-analyses[15,18]. Zywot et al., in a review of 23 bundle studies involving 17,557 patients, found an overall SSI risk reduction of 40% with 44% for superficial SSI and 34% for organ-space SSI.[16] In addition, Tanner in a review of 8515 patients noted that the SSI rate decreased from 15.1% with standard care to 7.0% in the bundle group.[18]

Maintenance of normothermia and blood glucose monitoring has long been emphasized by SCIP as an effort to reduce surgical site infections. Emphasis on blood glucose monitoring was historically studied in cardiac surgery patients, however, there is emerging data on the importance of strict glucose control in colon and rectal surgery patients as well.[19] Previous studies have shown hypothermia to be detrimental at a cellular level as it affects the function of the innate immune response.[20] However, these effects are reversible with active rewarming. In this study, we saw a decline in compliance with maintenance of intraoperative temperature >36.5 degrees Celsius. In order to achieve normothermia, we utilize warming blankets, Bair hugger (3 M, Maplewood, MN), and warming the operating room prior to the patient entering the room. Patient's temperature is measured using a urinary catheter probe, esophageal probe or via the nasopharyngeal tube. During

Table 3
Superficial SSI, deep SSI, wound separation and total infection across the three groups.

Wound Occurrences n %	Group A (n = 436)	Group B (n = 456)	Group C (n = 459)
Superficial SSI	26 (6.1)	30 (6.6)	18 (4)
Deep SSI	11 (2.6)	17 (3.7)	5 (1.1)
Wound Separation	3 (0.7)	3 (0.6)	3 (0.6)
Total Infection	39 (9.4)	49 (10.9)	22 (4.7)

Table 4
Compliance with Bundle Elements comparing Group B (implementation phase) to Group C (post implementation phase).

Bundle Element	Group B n (%)	Group C n (%)	p value
Total Audits (n)	335	459	
Preoperative Hair Removal	335 (100)	449 (98)	0.009
Preoperative Glucose < 200	335 (100)	454 (99)	0.0004
Preoperative antibiotics < 60 min	331 (99)	453 (99)	ns
Redosing of intraoperative antibiotics	127 (38)	344 (75)	<0.05
Intraoperative FiO2>60%	333 (99)	454 (99)	ns
Intraoperative temperature >36.5	329 (98)	403 (88)	<0.05
Closing Gowns/Gloves	321 (95)	456 (99.4)	0.00012
Closing Tray	321 (95)	456 (99.4)	0.00012
PostOp NonRebreather	277 (82)	397 (86.5)	ns

ns = not significant ($p > 0.05$).

the surgery, the patient's temperature is recorded hourly by the anesthesiology staff. If the patient's temperature drops below 36.5 degrees Celsius, the surgeon and operating room staff are made aware for the need to increase the room temperature or to turn on the Bair hugger. Temperature below 36.5 degrees Celsius is reported as "non-compliance" with the Bundle elements. SCIP reports normothermia as the first recovery room temperature and does not account for the patient's intraoperative temperature.[1] Therefore we believe that our approach sets a higher standard for achieving patient normothermia. Compliance rates of 98% in group B and 88% in group C is much higher than we originally anticipated prior to analyzing our data. In contrast to SCIP guidelines, two large studies have questioned the association of hypothermia to SSI. A multicenter study of 1008 patients undergoing major colorectal procedures failed to correlate SSI with temperature, while a recent report from the Vanderbilt group of almost 300 patients who underwent segmental colectomy noted that patients who sustained a period of intraoperative hypothermia were no more likely to develop an SSI than those who were normothermic[21],[22]. We are currently analyzing whether as the compliance in this area increases, our surgical site infections rates will continue to drop.

Our study has important limitations. Our study was performed at a 254 bed hospital affiliated with a tertiary care university hospital. We are fortunate to have committed staff members who worked closely with the surgical team to achieve compliance and improvements. Additionally, staff members who work with our colorectal surgeons tend to be consistent, making buy-in and compliance easier. This may not be representative of a larger institution whereby team members may change on a case by case basis.

In addition, the significant reduction in SSI rates observed may have been impacted by the greater use of laparoscopy in the post-implementation Group C phase as well as the lower percentage of rectal cancer cases performed during this time period. As mentioned above, there has been a national increase in the use of laparoscopic colon surgery over the last decade likely coinciding with the results of several randomized trials for colon cancer[23],[24],.[25] Although no significant difference in SSI was noted in this study, the benefits of laparoscopic surgery in reducing SSI have been demonstrated in other reports. In a prospective study from Hong Kong of over 1000 patients, the proportion of SSI was significantly higher following open surgery (5.7% open vs. 2.7% laparoscopic, $p < 0.05$).[26] This finding was recently confirmed on another examination of the NSQIP database, a benefit that was particularly observed in obese patients. The SSI proportions in obese (body mass index > 30) patients undergoing open colectomy, open proctectomy, laparoscopic colectomy and laparoscopic proctectomy were 18.7, 22.3, 10.7, and 13.3% respectively ($p < 0.001$), an effect that persisted on multivariate analysis.[27] Furthermore, a note should be made regarding elective rectal surgery. It has been well documented that the risk of anastomotic leak is greater in this setting compared to colon surgery, particularly when associated with low extra-peritoneal anastomoses.[28] A recent observational analysis involving patients undergoing resection surgery for colorectal cancer found that rectal resections were independently associated with an increased likelihood of both superficial as well as deep/organ space SSI.[29]

Conclusion

We believe that the surgical site infection reduction bundle made a difference in our surgical site infection rates and created increased awareness and stewardship among our staff, surgeons, residents and fellows. Although there is no clear consensus as to the most efficacious interventions in a colorectal bundle, we have demonstrated that rigorous implementation of a bundle consisting of several evidence-based approaches, with cooperation and buy in from all perioperative staff results in a significant reduction in surgical site infection rates.

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