Combination of Oral Antibiotics and Mechanical () Bowel Preparation Reduces Surgical Site Infection in Colorectal Surgery

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BACKGROUND:	Surgical site infections (SSI) are a common complication after colorectal surgery. An infection prevention bundle (IPB) was implemented to improve outcomes.
STUDY DESIGN:	A standardized IPB that included the administration of oral antibiotics with a mechanical bowel preparation, preoperative shower with chlorhexidine, hair removal and skin preparation in holding, antibiotic wound irrigation, and a "clean-closure" protocol was implemented in January 2013. Data from the American College of Surgeons NSQIP were analyzed at a single academic institution to compare pre-IPB and post-IPB SSI rates. In January 2014, a prospective database was implemented to determine compliance with individual IPB elements and their effect on outcomes.
RESULTS:	For the 24 months pre-IPB, the overall SSI rate was 19.7%. During the 30 months after IPB implementation, the SSI rate decreased to 8.2% (p < 0.0001). A subset of 307 patients was identified in both NSQIP and our prospective compliance databases. Elements of IPB associated with decreased SSI rates included preoperative shower with chlorhexidine (4.6% vs 16.2%; p = 0.005), oral antibiotics (3.4% vs 15.4%; p < 0.001), and mechanical bowel preparation (4.4% vs 14.3%; p = 0.008). Patients who received a full bowel preparation of both oral antibiotics and a mechanical bowel preparation had a 2.7% SSI rate compared with 15.8% for all others (p < 0.001). On multivariate analysis, full bowel preparation was independently associated with significantly fewer SSI (adjusted odds ratio 0.2; 95% CI 0.1 to 0.9; p = 0.006).
CONCLUSIONS:	Implementation of an IPB was successful in decreasing SSI rates in colorectal surgery patients. The combination of oral antibiotics with a mechanical bowel preparation was the strongest predictor of decreased SSI. (J Am Coll Surg 2017;225:465–471. © 2017 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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Correspondence address: Matthew L Silviera, MD, Department of Surgery, Section of Colon and Rectal Surgery, Washington University School of Medicine, 660 S Euclid Ave, Box 8109, St Louis, MO 63110. email: silviera@wustl.edu Surgical site infections (SSI) are a major cause of morbidity after surgery and are associated with increased hospital length of stay, readmissions, costs, and mortality.¹⁻³ Surgical site infections are disproportionally high in colorectal surgery and are estimated to affect between 15% and 30% of patients.⁴ In addition to the morbidity and mortality associated with SSI, there has been a growing effort to link reimbursements with outcomes. Preventable complications such as SSI are a burden on the surgeon and the health care system. Therefore, there is an important need to evaluate practices in order to reduce the incidence of preventable complications to improve patient safety and clinical outcomes.

Multiple advances have been made in surgery to improve and track quality of care. To better evaluate

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surgeon and hospital performance, the American College of Surgeons (ACS) NSQIP provides risk-adjusted outcomes and models for comparison with the aim of identifying areas for improvement.⁵ The Enhanced Recovery After Surgery (ERAS) Society has produced colorectalspecific bundles to further standardize medical care based on evidence-based practice,^{6,7} and many institutions have implemented variations of infection prevention bundles (IPBs) with the aim of reducing SSI.^{4,8-13} Nationwide, numerous projects have been put in place in an effort to decrease preventable complications.

Although these infection prevention measures have become emphasized, protocols are inconsistent, and the role and use of oral antibiotics and mechanical bowel preparation remain varied.¹⁴ Some evidence suggests mechanical bowel preparation may be unnecessary or even harmful and should be omitted.¹⁵⁻¹⁹ There is consensus that intravenous antibiotics should be given before colorectal surgery, but the role of oral antibiotics remains controversial.²⁰ However, due to the high incidence of SSI in colorectal surgery, there has been renewed interest in evaluating the utility of mechanical bowel preparation in combination with oral antibiotics. Recent studies suggest that full bowel preparation, defined as the combination of both oral antibiotics and mechanical bowel preparation, is associated with decreased infectious complications in patients undergoing elective colectomies.²¹⁻²³ Here we report our experience with an IPB for nonemergent colorectal surgery patients at our highvolume, tertiary care academic institution.

METHODS

Infection prevention bundle

A collaborative team consisting of colorectal surgeons, anesthesiologists, surgical residents, clinical nurses, patient education nurses, and performance improvement specialists was formed at our institution to evaluate SSI and patient outcomes. An IPB consisting of preoperative and perioperative interventions was implemented in January 2013 (Table 1). Patients were instructed to take oral antibiotics (neomycin 1 g po and Flagyl [Pfizer] 500 mg po at 1:00 PM, 2:00 PM, and 10:00 PM) and a mechanical bowel preparation (Dulcolax [Sanofi] 10 mg po at 10:00 AM and 12:00 PM and MiraLAX [Bayer] 238 g po beginning at 11:00 AM) on the day before surgery. Patients were also instructed to bathe with 4% chlorhexidine gluconate body wash the evening before and morning of surgery. In the preoperative holding area, hair was clipped and skin wiped with a 2% chlorhexidine gluconate cloth. Intraoperative measures included intra-abdominal antibiotic irrigation (240 mg gentamicin and 600 mg clindamycin in 1 L of normal saline) and clean closure protocol, which included surgeons and scrub staff changing gowns and gloves and repreparing and draping the surgical field. Sterile and dedicated wound closure instruments were also used. The subcutaneous tissues were also irrigated with the antibiotic solution before closure.

Data collection and study design

The Washington University School of Medicine Institutional Review Board approved this project. Bundle effectiveness was evaluated by examining trends in SSI rates for nonemergent colorectal procedures based on ACS NSQIP data from January 2011 to June 2015 (n = 1,152). Historical (pre-implementation) ACS NSQIP SSI rates were compared with post-implementation SSI rates. The ACS NSQIP maintains a prospective database of patient demographics, comorbidities, intraoperative factors, and 30day outcomes in order to provide risk-adjusted outcomes measures, with the goal of providing institutional feedback for improvement in quality of care.⁵

Prospective compliance data of IPB measures were obtained by preoperative nursing staff patient interviews as well as intraoperatively on the day of surgery, beginning in January 2014, for all patients undergoing colorectal surgery by a colorectal surgeon at Barnes-Jewish Hospital. Institutional ACS NSQIP data files were then used to identify patients from January 2014 to June 2015. There were 404 patients who underwent a colorectal procedure by the following CPT codes: 44140 to 44141, 44143 to 44147, 44150 to 44151, 44155 to 44158, 44160, 44204 to 44208, 44210 to 44212, 45110 to 45114, 45116, 45119 to 45121, 45123, 45126, 45130, 45135, 45160, 45395, 45397, 45402, and 45550. Both open and laparoscopic procedures were included. Emergent cases were excluded because the standard IPB intervention cannot be commonly applied. Only board certified colorectal surgeons from the

Table 1. Infection Prevention Bundle Interventions

Preoperative (at home)	Preoperative (in hospital)	Intraoperative
Oral antibiotics (neomycin and Flagyl)	Hair clipping in holding	Antibiotic irrigation (gentamicin and clindamycin)
Mechanical bowel preparation (Dulcolax and MiraLAX)	Skin preparation (2% chlorhexidine gluconate, 70% isopropyl alcohol solution)	Clean closure protocol
Preoperative shower (4% chlorhexidine cleanser)	_	_

Section of Colon and Rectal Surgery at our institution were included to avoid biases and effects from other surgical services that did not participate in the IPB. The prospective compliance database was then merged with the ACS NSQIP data in order to pair our database of patient demographics and bundle compliance with objectively obtained clinical outcomes of interest (SSI), which resulted in the identification of 307 common patients.

Statistical analysis

RESULTS

Two-sample t-test and chi-square test or Fisher's exact test were used to evaluate the association between independent variables and SSI. Univariate and multivariate binary logistic regression tests were performed to assess the IPB variables in reducing SSI rate. The association of each key bundle element with SSI rate reduction was evaluated, and a bowel preparation composite was formed based on oral antibiotics and mechanical bowel preparation to evaluate the crude and adjusted odds ratios. Covariates with a value of p < 0.2 in the bivariate analysis were first selected, and after adding selected covariates one by one into the model, variables that did not change the -2log likelihood value significantly or change the composite adjusted odds ratios by 10% were eliminated. A value of p < 0.05 was considered statistically significant. All statistical tests were conducted using SAS (version 9.3, SAS Institute).

An IPB was implemented in January 2013 with the aim of

reducing SSI among colorectal surgery patients. To

determine whether there was a decrease in the rate of after IPB implementation, institutional ACS SSI NSQIP files were queried, and it was observed that the rate of SSI significantly decreased after intervention from 21.2% in 2011 to 6.0% in 2015 (Fig. 1; p = 0.0002).

To evaluate the effectiveness of the bundle, a prospective compliance database was established. This prospective database was merged with institutional ACS NSQIP files, resulting in the identification of 307 common patients who underwent nonemergent colorectal surgery by a colorectal surgeon at our institution between January 2014 and June 2015. The overall rate of SSI was 6.2% (n = 19), and characteristics of patients who did and did not develop an SSI are presented in Table 2. The groups were balanced with respect to many characteristics such as age, BMI, race, operative approach, elective procedure, diabetes, severe COPD, smoking status, and American Society of Anesthesiologists (ASA) classification. However, significant differences existed in regard to wound classification (p < 0.001), whether an ostomy was present at the beginning of surgery (p = 0.028), and sex (p = 0.016).

Compliance of bundle elements was first assessed. Preoperative interventions such as mechanical bowel preparation, oral antibiotics, and preoperative shower with chlorhexidine closure resulted in compliance rates of 83.6%, 78.5%, and 87.6%, respectively. In preoperative holding, skin preparation was successful (94.0%), but hair clipping had the lowest compliance rate of all bundle elements (68.9%). Antibiotic irrigation and clean closure

6.0%

25.0% Pre-intervention 21.2% Post-intervention 20.0% 18.6% **SSI Rate** 10.0% 9.7% 7.7% 5.0%

0.0% 2011 2012 2013 2014 2015* 8 **Events** 40 45 27 24 Cases 189 242 278 310 133

Figure 1. Surgical site infection (SSI) rate decreased significantly after implementation of the infection prevention bundle (IPB) (p < 0.0001). Rates decreased from 19.7% in the 24 months before IPB implementation to 8.2% in the 30 months post-implementation. The annual incidence of SSI is displayed; asterisk denotes that cases only through June 2015 were included.

Characteristic	SSI (n = 19)	No SSI (n = 288)	p Value
Age, y, mean \pm SD	57.6 ± 12.3	59.2 ± 16.1	0.666
\overline{BMI} , kg/m ² , mean \pm SD	30.2 ± 7.4	29.1 ± 7.6	0.551
Female sex, n (%)	5 (26)	163 (57)	0.016
Race, n (%)			0.619
White	15 (79)	232 (81)	
African American	4 (21)	41 (14)	,
Other	0 (0)	15 (5)	
Operative approach, n (%)			0.095
Open	11 (58)	111 (39)	
Laparoscopic	8 (42)	177 (61)	
Elective surgery, n (%)	14 (74)	245 (85)	0.193
Wound classification, n (%)			< 0.001
Dirty/infected	3 (16)	9 (3)	,
Contaminated	6 (32)	27 (9)	
Clean/contaminated	10 (53)	252 (88)	
Clean	0 (0)	0 (0)	
Ostomy present at time of surgery, n (%)	5 (26)	25 (9)	0.028
Diabetes, n (%)	5 (26)	41 (14)	0.179
Severe COPD, n (%)	3 (16)	26 (9)	0.405
Current smoker within past year, n (%)	6 (32)	67 (23)	0.410
ASA class, n (%)			0.532
1—No disturbance	0 (0)	2 (1)	
2-Mild disturbance	8 (42)	151 (52)	
3–Severe disturbance	11 (58)	132 (46)	
4-Life threatening	0 (0)	3 (1)	

 Table 2.
 Patient Demographics and Surgical Site Infection Risk Factors of Interest Stratified by Development or Absence of a Surgical Site Infection

ASA, American Society of Anesthesiologists; SSI, surgical site infection.

protocol were also successfully implemented at rates of 81.1% and 76.2%, respectively.

Infection prevention bundle elements were independently examined to determine association with SSI. On univariate analysis, mechanical bowel preparation (4.4%) vs 14.3%; p = 0.008), oral antibiotics (3.4% vs 15.4%; p < 0.001), and preoperative shower with chlorhexidine cleanser (4.6% vs 16.2%; p = 0.005) were associated with decreased risk of SSI (Table 3). Chlorhexidine skin preparation and clean closure protocol had a trend toward decreased risk of SSI, but this did not reach statistical significance. Hair removal in holding and antibiotic irrigation were not associated with decreased risk of SSI. The specific role of oral antibiotics and mechanical bowel preparation was then examined. Patients who received both oral antibiotics and a mechanical bowel preparation had a 2.7% SSI rate compared with a 15.8% SSI rate for all others (Table 4; p < 0.001). Multivariate regression analysis revealed that only the full bowel preparation, consisting of both oral antibiotics and a mechanical bowel preparation, was associated with a decreased rate of SSI (adjusted odds ratio 0.2; 95% CI 0.1 to 0.9; p = 0.006), even after adjusting for sex, wound classification, ostomy status, elective surgery, and operative approach. Single preparation with either oral antibiotics or mechanical bowel preparation was not associated with a decreased rate of SSI on multivariate regression analysis.

DISCUSSION

Complications such as SSI are associated with significant morbidity, in addition to being increasingly tied to reimbursements from insurance companies. Therefore, there is an important need to reduce preventable complications and improve quality of care. Our institution was identified by ACS NSQIP as having a higher than expected rate of SSI among colorectal surgery patients, and in an effort to improve quality of care, we developed a set of standard practices and implemented an IPB. After changing our practices, we successfully reduced the rate of SSI for patients undergoing nonemergent colorectal surgery

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Bundle element	Patients, n	SSI, n (%)	p Value
Mechanical bowel	preparation		0.008
Yes	250	11 (4.4)	
No	49	7 (14.3)	
Oral antibiotics			< 0.001
Yes	237	8 (3.4)	
No	65	10 (15.4)	
Preoperative showe	0.005		
Yes	262	12 (4.6)	
No	37	6 (16.2)	
Hair removed in he	1.000		
Yes	210	13 (6.2)	
No	95	6 (6.3)	
Chlorhexidine skin	preparation in ho	lding	0.295
Yes	282	16 (5.7)	
No	18	2 (11.1)	
Antibiotic irrigation	1		0.541
Yes	245	16 (6.5)	
No	57	2 (3.5)	
Clean closure proto	0.564		
Yes	224	12 (5.4)	
No	70	5 (7.1)	

by surgeons in our division, from 19.7% to 8.2%. Independent examination of the interventions revealed a high compliance rate among all bundle elements, and further assessment by using our prospective compliance database in combination with institutional ACS NSQIP data found that patients who received both oral antibiotics and mechanical bowel preparation had a significantly lower rate of SSI compared with no preparation at all. Furthermore, single agent preparation with either oral antibiotics or mechanical bowel preparation alone was not sufficient to reduce SSI.

The role of oral antibiotics and mechanical bowel preparation has long been a subject of debate and has been

both supported and criticized over the past few decades. Although oral antibiotics serve to reduce the bacterial concentration of the colonic mucosa, it is thought that mechanical bowel preparation would improve antibiotic efficacy by reducing fecal bulk. In the 1970s, the Nichols-Condon bowel preparation of neomycin and erythromycin in combination with mechanical bowel preparation became standard of care due to evidence that the mechanical cleansing improved mucosal delivery and local concentration of the intraluminal antibiotic.²⁴ However, practice patterns evolved over time, and mechanical bowel preparation eventually fell out of favor. Hughes²⁵ concluded early that a laxative rather than vigorous mechanical preparation before surgery would suffice. Another trial again questioned the necessity of mechanical bowel preparation, arguing that the preparation was time-consuming and expensive, in addition to being unnecessary.²⁶ Over time, the role of each component was increasingly evaluated and scrutinized. With preventable complications such as SSI being increasingly examined, it is important to re-evaluate our standard of care.

Mechanical bowel preparation itself is not benign and has been associated with electrolyte abnormalities and renal impairment.¹⁶ One study demonstrated that elective left-sided colectomy without mechanical bowel preparation was safe and associated with decreased postoperative morbidity,¹⁵ and multiple meta-analyses did not find any evidence that mechanical bowel preparation improves outcomes.¹⁷⁻¹⁹ Furthermore, current Enhanced Recovery After Surgery (ERAS) guidelines for elective colonic and rectal/pelvic operations also recommend against routine use of mechanical bowel preparation,^{6,7} concluding that it may be necessary only if intraoperative colonoscopy or a diverting ileostomy is to be performed.⁷ However, the studies on which these recommendations are based have only compared mechanical bowel preparation to no preparation at all, failing to compare the combination of both oral antibiotics and a mechanical bowel preparation.

Table 4. Bowel Preparation Composite Comparing Surgical Site Infection Incidence and Crude and Adjusted Odds Ratios

 Between Bowel Preparation Groups

Bowel preparation	Patients, n	SSI, n (%)*	Crude OR (95% CI)	Adjusted OR † (95% CI)
No preparation	37	5 (13.5)	Reference	Reference
Oral antibiotics only	12	2 (16.7)	1.3 (0.2-7.6)	0.9 (0.1-6.7)
Mechanical bowel preparation only	27	5 (18.5)	1.5 (0.4-5.6)	1.5 (0.3-6.8)
Full preparation (oral antibiotics plus				
mechanical bowel preparation)	223	6 (2.7)	$0.2 (0.1 - 0.6)^{\ddagger}$	$0.2 (0.1 - 0.9)^{\$}$

*p value for Fisher's exact test is < 0.001.

 † Ådjusted for sex, wound classification, ostomy present at the beginning of the surgery, elective surgery, and operative approach. ‡ p = 0.031.

 ${}^{\$}p = 0.006.$

ÔR, odds ratio; SSI, surgical site infection.

The utility of oral antibiotics has also been recently investigated. A retrospective study of the Veterans Affairs Surgical Quality Improvement Program identified 9,940 patients who underwent elective colorectal resection at Veterans Affairs hospitals between 2005 and 2009; it found that oral antibiotics alone were associated with a 67% decrease in SSI rate.²⁷ Additionally, oral antibiotics were favorably associated with decreased hospital length of stay and hospital readmissions.²⁸ Further analysis from Veterans Affairs Surgical Quality Improvement Program also determined that addition of a mechanical bowel preparation did not further improve SSI rate for patients undergoing elective colorectal resections.²⁷ These findings, while supportive of the use of oral antibiotics, are imperfect because the study methods relied on prescription and were not able to track or assess compliance.

Recent studies have demonstrated the utility of a full bowel preparation using both oral antibiotics and mechanical bowel preparation. The Michigan Surgical Quality Collaborative compared 1,363 patients who received a full bowel preparation with 1,112 patients who received no bowel preparation; it found that full bowel preparation was associated with decreased infectious complications in patients undergoing elective colectomies.²¹ Analyses of the 2012 Colectomy-Targeted ACS NSQIP database have also demonstrated that a full bowel preparation is associated with decreased rate of SSI as well as other favorable outcomes such as decreased anastomotic leak, ileus, and hospital readmission.^{22,23} Further analysis of the 2012 and 2013 ACS NSQIP data also validated the findings that full bowel preparation was associated with decreased rate of SSI as well as decreased anastomotic leak, dehiscence, readmission, reoperation, and other non-SSIrelated infectious complications.²⁹ Our work agrees with these recent publications, and we now favor a full bowel preparation, with both oral antibiotics and a mechanical bowel preparation, before nonemergent colorectal surgery at our institution.

There were several limitations to our study. The IPB was implemented uniformly across the colorectal surgery service rather than through a randomized controlled trial, which resulted in a very high compliance rate of all bundle elements and correlated with a low SSI rate, limiting the analysis of individual bundle components. Although this suggests the ease with which the bundle can be implemented, it also suggests that the study was underpowered to assess the role of mechanical bowel preparation or oral antibiotics alone. Furthermore, our multivariate analysis controlled for several variables such as laparoscopic or open approach, presence of a stoma, wound classification, sex, and elective surgery, but there remains the potential for unmeasured confounders that may also contribute to

the rate of SSI in our patient population. There was also a variable use of interventions before bundle implementation, and we were unable to assess the preintervention group for compliance or association of specific elements with SSI because we only have complete data for evaluation after the prospective database was implemented. However, our objective was to evaluate the effect of each bundle component on SSI in the post-implementation period to determine which factors were most essential. Despite these limitations, we recommend oral antibiotics combined with a mechanical bowel preparation for patients undergoing nonemergent colorectal surgical procedures in order to reduce the incidence of SSI.

CONCLUSIONS

Implementation of an IPB was successful in reducing SSI among nonemergent colorectal surgery patients. The combination of oral antibiotics and mechanical bowel preparation was the strongest predictor of decreased rate of SSI; single preparation was insufficient in reducing SSI.

Author Contributions

- Study conception and design: Ohman, Wan, Guthrie, Johnston, Glasgow, Hunt, Mutch, Wise, Silviera
- Acquisition of data: Ohman, Wan, Guthrie, Johnston, Silviera
- Analysis and interpretation of data: Ohman, Wan, Guthrie, Leinicke, Silviera
- Drafting of manuscript: Ohman, Wan, Silviera
- Critical revision: Ohman, Guthrie, Johnston, Leinicke, Glasgow, Hunt, Mutch, Wise, Silviera

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