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Surgical site infection reduction bundle in patients with gynecologic cancer undergoing colon surgery

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Abstract

Objective—Surgical site infections (SSIs) can lead to substantial morbidity, prolonged hospitalization, increased costs, and death in patients undergoing colorectal procedures. We sought to investigate the effect of using an SSI reduction bundle on the rate of SSIs in gynecologic cancer patients undergoing colon surgery.

Methods—We identified all gynecologic cancer patients who underwent colon resection at our institution from 2014–2016, during which time a service-wide SSI reduction bundle was introduced. The intervention included preoperative oral antibiotics with optional mechanical bowel preparation, skin preparation with antibacterial solution, and the use of a separate surgical closing tray. SSI rates were assessed within 30 days post-surgery.

Results—Of 233 identified patients, 115 had undergone colon surgery prior to (PRE) and 118 after (POST) the implementation of the intervention. A low anterior resection was the most common colon surgery in both cohorts. The incidence of SSI within 30 days of surgery was 43/115 (37%) in the PRE and 14/118 (12%) in the POST cohorts ($p = 0.001$). Wound dehiscence was noted in 30/115 (26%) and 2/118 (2%) patients, respectively ($p = 0.001$). In patients whose operation took longer than 360 minutes, 30-day SSI rates were 37% (28/76) and 12% (8/67),

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Conflict of Interest Statement

Unassociated to this work, Dr. Chi is on the Medical Advisory Board of Bovie Medical Corporation. The other authors have no disclosures.

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respectively (p 0.001). In patients with an estimated blood loss >500 cc, SSI rates were 44% (27/62) and 15% (10/67), respectively (p 0.001).

Conclusions—The implementation of an SSI reduction bundle was associated with a significant reduction in 30-day SSIs in these patients. The intervention remained effective in patients undergoing longer operations and in those with increased blood loss.

Background

The American College of Surgeons (ACS) recently reported that surgical site infections (SSIs) are the most common and costly of all hospital-acquired infections (HAIs), accounting for roughly 20% of documented HAIs [1]. For those undergoing inpatient surgery, the rate of SSIs is 2–5% [2]. SSIs are associated with an increased length of hospital stay, readmission rates, hospitalization costs, and overall mortality [3]. A 2015 ACS National Surgical Quality Improvement Program (NSQIP) analysis showed that the most common reason for unplanned postoperative readmission was general SSIs (19.5%) [4]. SSIs are associated with an increased length of hospital stay of approximately 10 days and increased hospital costs of approximately \$20,000 per admission [1]. The indirect costs of SSIs, such as loss of productivity for patients and families are more difficult to quantify [3]. Overall, the estimated cost of SSIs is \$3.5–10 billion per year in the United States [1].

It has been suggested that SSI rates can be improved with the use of evidence-based measures, and therefore, many institutions have implemented quality improvement efforts to reduce the incidence and prevalence of SSIs [1–6]. SSI reduction “bundling” recently has gained interest as a means of managing the complicated, multifactorial nature of SSIs [7–10]; however, results have been mixed across a range of subspecialties [11, 12]. Colorectal surgery, consistently associated with the highest SSI rates, has been particularly notable for equivocal results on SSI reduction bundling in various studies using a mixture of interventions [7, 9, 13–21]. In the field of gynecology, such studies are lacking, despite SSI rates of 2–4% in patients undergoing hysterectomy and an approximate 30% rate of hospital readmissions attributable to postoperative SSIs [4, 22, 23].

Given the known elevated rates of SSIs in patients undergoing colon surgery, as well as the importance of SSI reduction within our increasingly value-based reimbursement system, our institution implemented a service-wide SSI reduction bundle for patients with gynecologic cancer undergoing colorectal surgery. The aim of this study was to investigate the incidence of SSIs before and after the bundle was instituted, as well as to evaluate the intervention’s efficacy.

Methods

In February 2015, as part of a quality improvement project, Memorial Sloan Kettering Cancer Center (MSK) introduced a service-wide SSI reduction bundle for gynecologic patients undergoing a colorectal procedure. The initiative employed an interdepartmental team composed of physicians, nurses, presurgical testing and operating room personnel, inpatient and outpatient personnel, and staff from wound care and infection control

departments. Teams were divided into four sections focusing on preoperative care, intraoperative care, postoperative care, and data collection.

Preoperative interventions included an emphasis on preoperative glucose control, oral antibiotics with optional mechanical bowel preparation (MBP), skin preparation with a 4% chlorhexidine antibacterial solution, and procedure-based patient education (Figure 1). Improvement in glucose control was achieved through a process involving the use of standard presurgical testing orders to include measurements of glucose and hemoglobin A1C levels. Random glucose levels >200 and hemoglobin A1C levels >7 prompted additional consultation by internal medicine physicians. The need for additional testing and/or the need to delay the surgical procedure was based on the individualized recommendations of the consultant physicians. Patients were given two doses of neomycin and metronidazole the night before surgery and a chlorhexidine-based skin wash the night before and the morning of surgery. Given the conflicting literature on the utility of mechanical bowel preparation in colorectal procedures, attending gynecologic surgeons at our institution preferred that this component of the SSI reduction bundle remain optional.[24, 25] All but one surgeon in our department chose to routinely perform preoperative MBP for all patients. Patients were also given information regarding the prevention of SSIs. Intraoperative interventions included intravenous (IV) antibiotics per standard institutional guidelines and repeat dosing as needed, strict glycemic control, the use of separate sterile wound “closing trays”, and re-gloving at the time of fascial closure. Standard institutional guidelines for the administration of intraoperative IV antibiotics were devised with the input of the infectious disease department and included the administration of the first dose of prophylactic antibiotics within 60 minutes before the initial surgical incision to ensure adequate serum and tissue levels [26, 27]. Re-dosing was required if the duration of the procedure exceeded two half-lives of the antimicrobial agent or if there was excessive blood loss during the procedure (defined as >1500 mL). Standard prophylaxis was with one dose of 2 gm cefotetan IV. Patients with a severe penicillin allergy were alternatively given one dose of 900 mg clindamycin IV plus one dose of 1.5 mg/kg gentamicin IV. Closure technique, type of suture utilized, and the placement of intraperitoneal or subcutaneous drains were left to the discretion of the attending gynecologic surgeon and were not specified within the SSI reduction bundle. Intraoperative glycemic control was obtained through the use of IV insulin infusions to achieve maintenance goal glucose levels between 140 and 170 mg/dL throughout surgery [28]. Postoperative interventions included the removal of all dressings 48 hours after surgery and daily showering with a 4% chlorhexidine antibacterial solution beginning on postoperative day 2. Emphasis on hand hygiene for both patients and staff was reinforced and audited. Patients were provided with hand sanitizer and chlorhexidine wash during their inpatient stay and upon discharge home. Postoperative glucose monitoring was not a component of our institutional SSI reduction bundle.

Our study retrospectively evaluated all patients who were diagnosed with a gynecologic malignancy and underwent a colorectal procedure at our institution between 2014 and 2016. Patients were grouped into PRE and POST cohorts, respectively, based on whether their surgery preceded or followed the date the SSI reduction bundle was implemented. Colon operations included in our analysis were categorized as low anterior resections, colostomies, other types of colectomy, or a combination of any of the three. The incidence of SSIs and

wound dehiscence were analyzed within 30 days of surgery. SSIs were defined as per Centers for Disease Control and Prevention (CDC) guidelines and categorized by depth and tissue space involvement [29]. Superficial incisional SSIs were defined as those involving only the skin and subcutaneous tissue of the incision. Deep incisional SSIs were defined as those involving the fascial and muscle layers of the incision. Organ space SSIs were defined as those involving any part of the body deeper than fascia or muscle that was opened or manipulated during the operative procedure.

SSIs were diagnosed through a combination of daily inpatient assessments, outpatient visits, evaluations performed in our urgent care center, and routine phone calls conducted by nursing staff. SSIs diagnosed at MSK are reported to the New York State Department of Infection Control, as well as the ACS NSQIP. Our institutional division of quality and safety began collecting compliance data on the SSI reduction bundle starting in March 2015. Compliance with the SSI reduction bundle from an institutional level was reported to the Centers for Medicaid and Medicare Surgical Care Improvement Project (SCIP). Association tests between variables were performed using the Wilcoxon rank-sum test for continuous variables and Fisher's exact test for categorical variables.

Results

Two hundred thirty-three patients with gynecologic cancer who had undergone a colorectal procedure between 2014 and 2016 were identified. One hundred fifteen had undergone colon surgery before (the PRE cohort) and 118 after (the POST cohort) implementation of the SSI reduction bundle. Demographic characteristics of each cohort are listed in Table 1. The median age of both cohorts was 63 (PRE range, 31–87; POST range, 22–84; $p=0.8$). The median BMIs were 25.6 kg/m² (range, 14.7–43 kg/m²) and 25.5 kg/m² (range, 18.3–45 kg/m²), respectively ($p=0.4$). Seven (6%) of 115 patients in the PRE cohort compared with 12 (10%) of 118 patients in the POST cohort had a past medical history of diabetes mellitus ($p=0.3$). Two (2%) of 115 and 4 (3%) of 118 patients, respectively, had a history of smoking ($p=0.7$). Eighty-four percent of PRE and 79% of POST patients had an American Society of Anesthesiologists (ASA) score of 3; and 4% and 9%, respectively, had an ASA score of 4 ($p=0.3$). The most common diagnosis in both cohorts was ovarian cancer (88 patients [77%] and 92 patients [78%] in the PRE and POST groups, respectively; $p=0.5$). Patients with a primary uterine cancer accounted for 19% ($n=22$) and 15% ($n=18$) of the PRE and POST groups, respectively. Other gynecologic malignancies accounted for 4% ($n=5$) and 7% ($n=8$) of the PRE and POST groups, respectively.

Surgical procedures were recorded as scheduled operations in 92 (80%) of 115 PRE and 103 (87%) of 118 POST patients ($p=0.2$; Table 2). Emergent or “add-on” cases were noted in 23 (20%) of the PRE and 15 (13%) of the POST patients. Of these 23 cases in the PRE cohort, 9 (39%) were for small bowel obstructions, 10 (43%) were for large bowel obstructions, and 4 (17%) were for bowel perforations. Of the 15 cases in the POST cohort, 2 (13%) were for small bowel obstructions, 9 (60%) were for large bowel obstructions, 3 (20%) were for bowel perforations, and 1 (7%) was for other indications. Of the 195 scheduled cases, 183 patients (94%) underwent an MBP prior to their surgical procedure and 12 (6%) did not. All 12 cases were performed by one surgeon, who did not perform an MBP on any patient in

this analysis. Forty-six patients who did undergo an MBP (25%) were subsequently diagnosed with an SSI. Of the 12 patients who did not undergo a preoperative MBP, 3 (25%) were diagnosed with an SSI ($p=1.0$). All 3 of these patients were in the PRE cohort. All 3 of these patients were in the PRE cohort. The most frequent type of colon surgery performed was a low anterior resection (59 patients [51%] in the PRE and 53 patients [45%] in the POST cohorts; $p=0.1$). Other types of colon resection were performed in 27% ($n=31$) and 20% (23) of the PRE and POST patients, respectively. Colostomy creation alone was documented in 9% ($n=10$) and 10% ($n=12$) of patients, respectively. A combination of these three procedures was noted in 13% and 25%, respectively. Creation of any stoma (colostomy or ileostomy) was noted in 30 (26%) and 35 (30%) patients, respectively ($p=0.6$). Concomitant hysterectomy was performed in 59 (51%) and 57 (48%) patients, respectively ($p=0.7$).

One hundred one (88%) of the 115 PRE patients and 94 (80%) of the 118 POST patients had clean contaminated wounds, as classified by the CDC ($p=0.1$). Fourteen (12%) and 24 (20%), respectively, had contaminated or grossly dirty wounds. The median estimated blood loss (EBL) was 650 cc (range, 15–5000 cc) in the PRE group and 600 cc (range, 10–3850 cc) in the POST group ($p=0.9$). Patients whose skin was intentionally left open postoperatively accounted for 9% ($n=10$) of the PRE cohort and 14% ($n=16$) of the POST cohort ($p=0.3$). Median operative time was 444 minutes (range, 35–1033 minutes) and 388 minutes (range, 38–835 minutes), respectively ($p=0.005$).

SSIs were diagnosed within 30 days postoperatively in 43 (37%) of 115 PRE patients and 14 (12%) of 118 POST patients ($p=0.001$; Table 3). Of patients diagnosed with SSIs, 20 (17%) and 5 (4%), respectively, had a superficial incisional infection; 7 (6%) and 3 (3%), respectively, had a deep incisional infection; 6 (5%) and 5 (4%), respectively, had an organ space infection; and 10 (9%) and 1 (1%), respectively, had various combinations of SSIs. In a subset analysis of the 57 total patients who developed an SSI within 30 days, no significant difference was noted between type of SSI in the PRE versus POST cohorts ($p=0.2$). Thirty patients (26%) in the PRE cohort and 2 (2%) in the POST cohort had wound dehiscence ($p=0.001$).

Table 4 provides data on a subset analysis of PRE and POST SSI rates based on various demographic and procedure-based variables. Age greater than 65 years, stoma creation, concomitant hysterectomy, operative time longer than 360 minutes, and blood loss of more than 500 cc were significantly different between the PRE and POST cohorts. Twenty-two (42%) of the 53 patients in the PRE cohort and 8 (16%) of the 49 in the POST cohort who were older than 65 years of age developed an SSI within 30 days of surgery ($p=0.008$). Eleven (37%) of the 30 patients in the PRE cohort and 3 (9%) of the 35 in the POST cohort who had a stoma created at the time of surgery developed a postoperative SSI ($p=0.008$). Twenty-one (36%) of 59 patients in the PRE group and 6 (11%) of 57 in the POST group who underwent a concomitant hysterectomy developed an SSI ($p=0.002$). Twenty-eight (37%) of the 76 patients in the PRE group and 8 (12%) of the 67 in the POST group who had operative times of more than 360 minutes developed a postoperative SSI ($p=0.001$). Finally, 27 (44%) of the 62 patients in the PRE group and 10 (15%) of the 67 in the POST

group with an EBL of more than 500 cc developed an SSI within 30 days of surgery (p 0.001).

Of the 118 patients in the POST cohort, preoperative compliance data were available for 49 patients (42%). Of these, 37 (76%) of 49 were compliant with all preoperative aspects of the SSI reduction bundle. Intraoperative antibiotic re-dosing compliance information for the PRE bundle cohort was available for 96 (83%) of 115 patients. Of these 96 patients, 85 (89%) were compliant with antibiotic re-dosing, as per institutional guidelines. In the POST cohort, 106 (90%) of 118 patients had re-dosing compliance information available and 94 (89%) were noted to be in compliance.

Discussion

In our study, the implementation of a surgical site reduction bundle was associated with a significant reduction in 30-day SSI rates in patients with gynecologic cancer undergoing colon surgery. Our findings are akin to those of a number of studies in the colorectal literature. In a 2013 study by Cima et al, the implementation of a colorectal SSI reduction bundle at a tertiary care medical center yielded an absolute SSI reduction rate from 9.8% to 4% (p 0.05) [13]. Their intervention included preoperative patient cleansing with a 4% chlorhexidine solution, SCIP-compliant intraoperative antibiotic administration, the use of a fascial closure tray, and greater emphasis on postoperative hand hygiene for patient and staff. Notably, the authors reported significant reductions in SSIs in the overall and superficial incisional wound class categories, but a non-significant reduction in organ space infections (2.6%, P=0.10). In another study of 559 patients undergoing major elective colorectal surgery, a comparison of matched pre- and post-implementation cohorts demonstrated a reduction in superficial incisional SSI rates from 19.3% to 5.7% (p 0.001) [30]. In that study, all patients were required to undergo a preoperative MBP, and novel aspects of care included limiting operating room traffic during the surgical procedure. A more recent study published by Hewitt and colleagues evaluated SSI rates in more than 700 colorectal surgical patients at the Thomas Jefferson University Hospital [15]. The authors reported a drop in the SSI rate from 13.9% before the implementation of a reduction bundle to 4.7% after. Bundle components noted in that study included the use of preoperative oral antibiotics, as well as an intraoperative gentamicin/clindamycin-based antibiotic peritoneal lavage.

It is worth noting that the colorectal literature includes a number of studies that do not support intervention bundling to decrease SSI rates. In a 2015 Canadian study, 205 patients undergoing elective colon resection were separated into pre and post cohorts. The SSI reduction bundle in that study included MBP, intraoperative warming blankets, and a fascial closure tray. [31] Overall SSI rates were 25.2% during the pre-intervention and 26.6% during the post-intervention time periods (p=0.82). Similarly, Tanner et al reported a non-statistically significant difference between rates before and after bundle implementation (24% baseline vs 28% bundled group, p 0.05) [16].

In the gynecologic literature, there are only a few studies evaluating the efficacy of SSI reduction bundling [8, 32]. The most noteworthy data were reported in a 2016 publication by

Johnson and colleagues from the Mayo Clinic [8]. In that study, baseline SSI rates were retrospectively compared to those prospectively documented after the implementation of an SSI reduction bundle for all patients undergoing major gynecologic cancer surgery. The intervention included a 4% chlorhexidine preoperative wash, fascial closure trays, and postoperative daily showering with the chlorhexidine solution. Overall 30-day SSI rates were 6% for the pre-intervention cohort and 1.1% for the post-intervention cohort, constituting a relative risk reduction of 82.4% for this patient population. SSI reduction was greatest in patients who did not undergo a bowel resection at the time of their gynecologic surgical procedure. Post-implementation SSI rates for patients who did undergo intestinal surgery was 2.4% ($p=0.19$), with a relative risk reduction of 77.6%.

Cost is an important consideration with SSI reduction bundle interventions. The annual cost of SSIs in the United States is estimated at up to \$10 billion [1]. Furthermore, the ability to accurately quantify such costs is limited by the far reaching consequences of an SSI diagnosis. The implementations of surgical site reduction bundles, however, are also not without a financial impact on participating institutions. In a 2017 Australian meta-analysis of more than 1,200 studies on cost effectiveness of SSI reduction interventions, a mere 5 articles were considered suitable for review, and of these, only 2 were categorized as “high quality” studies [3]. All 5, notably, did find some measure of cost effectiveness in the use of various SSI reduction interventions (specifically in wound dressings). Given the much broader, and frequently variable, interventions involved in SSI reduction bundles, however, it becomes much more complicated to analyze the potential benefit of these bundles in the context of their not insignificant costs to institutions.

The success of bundling interventions requires significant involvement, cooperation, and “buy in” from relevant personnel across patient care specialties. A key component of our initial quality improvement prospectus was the creation of interdepartmental teams to review the literature and collectively decide upon bundled interventions and their implementation. This aspect of reduction bundling is similarly supported and emphasized throughout the literature [1, 2, 11, 15]. Furthermore, the ongoing issues of compliance and monitoring are integral to the creation and success of an SSI reduction bundle program. The centralization of event reporting and frequent evaluations are important mechanisms for success [6].

The strengths of this study include the reporting of SSI rates in a patient population for which such data are lacking, as well as the relatively large number of gynecologic cancer patients who underwent colorectal surgery within the study period. Our study shares the limitations inherent in all reduction bundle studies, particularly the inability to identify which specific elements of the bundle truly contribute to infection reduction [13]. An analysis of more than 8,500 patients in the US and UK highlights that despite the use of core interventions such as antibiotic administration and glycemic control, SSI reduction bundles are highly variable between institutions [9]. Furthermore, studies on singular interventions frequently fail to demonstrate any significant decline in SSI rates [33–35].

Our study demonstrated a significant decline in SSI rates after the implementation of a service-wide reduction bundle in patients with gynecologic cancer undergoing colorectal surgery. The rate of SSI reduction was most pronounced with superficial incisional SSIs,

which is consistent with a number of other studies in the literature [13, 30]. Although this was not found to be statistically significant, this could be an effect of small numbers within this subset analysis. Patients in our POST cohort were also noted to have statistically significant increased operative time; however, it is questionable as to whether a median increase of less than 1 hour is clinically significant. With continued emphasis on quality improvement in surgical outcomes, SSI reduction bundling provides an attractive means of infection control and cost reduction in a high-risk patient population [36]. As more institutions adopt bundling as a way of reducing SSI rates, however, we must continue to evaluate for efficacy, risk stratification, and cost effectiveness in order to confirm these promising early results.

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Research Highlights

- Surgical site infections (SSIs) are the most common hospital-acquired infections
- Clinical data show that SSI reduction bundles can significantly reduce SSI rates
- This intervention is effective in gynecology patients undergoing colon resection

Figure 1.
Perioperative components of surgical site infection (SSI) reduction bundle

Table 1

Characteristics of all gynecologic cancer patients undergoing colorectal surgery, 2014–2016 (N=233)

Characteristic	PRE (n=115)	POST (n=118)	p
Age			0.797
Median	63	62.5	
Range	31 – 87	22 – 84	
BMI			0.396
Median	25.6	25.5	
Range	14.7 – 43	18.3 – 45	
ASA score 3/4	100 (87%)	103 (87%)	0.294
History of Diabetes	7 (6%)	12 (10%)	0.339
History of Smoking	2 (2%)	4 (3%)	0.684
Primary diagnosis			0.553
Ovarian cancer	88 (77%)	92 (78%)	
Uterine cancer	22 (19%)	18 (15%)	
Other	5 (4%)	8 (7%)	

Patients were grouped into PRE and POST cohorts, respectively, based on whether their surgery preceded or followed the date an SSI reduction bundle was implemented

BMI, body mass index; ASA, American Society of Anesthesiologists

Table 2

Operative characteristics

Characteristic	PRE (n=115)	POST (n=118)	p
Operation type			0.157
Scheduled	92 (80%)	103 (87%)	
Emergent	23 (20%)	15 (13%)	
MBP*	84 (91%)	99 (96%)	
Procedure			0.105
LAR	59 (51%)	53 (45%)	
Other colectomy	31 (27%)	23 (20%)	
Colostomy	10 (9%)	12 (10%)	
Combination	15 (13%)	29 (5%)	
Stoma	30 (26%)	35 (30%)	0.562
Hysterectomy	59 (51%)	57 (48%)	0.695
Wound class			0.111
Clean contaminated	101 (88%)	94 (80%)	
Contaminated	11 (10%)	23 (19%)	
Dirty	3 (3%)	1 (1%)	
EBL (mL)			0.901
Median	650	600	
Range	15–5000	10–3850	
Operative time (min)			0.005
	444	388	
	35–1033	38–835	
Skin open	10 (9%)	16 (14%)	0.3
Skin closed	105 (91%)	102 (86%)	

Patients were grouped into PRE and POST cohorts, respectively, based on whether their surgery preceded or followed the date an SSI reduction bundle was implemented

MBP, mechanical bowel preparation; LAR, low anterior resection; EBL, estimated blood loss

* scheduled procedures only

Table 3

Rates of surgical site infection and wound dehiscence in PRE and POST bundle cohorts

Postoperative Event	PRE (n=115)	POST (n=118)	p
SSI 30 days	43 (37%)	14 (12%)	<0.001
Superficial	20 (46.5%)	5 (35.7%)	
Deep	6 (14%)	5 (35.7%)	
Organ space	7 (16.3%)	3 (21.4%)	
Combination	10 (23.3%)	1 (7.1%)	
Wound Dehiscence	30 (26%)	2 (2%)	<0.001

Patients were grouped into PRE and POST cohorts, respectively, based on whether their surgery preceded or followed the date an SSI reduction bundle was implemented

SSI, surgical site infection

Table 4

Subset analysis of SSI rates between PRE and POST cohorts

Characteristic	PRE	POST	p
Age ≥ 65	n=53	n=49	
SSI rate	22 (42%)	8 (16%)	0.008
Stoma	n=30	n=35	
SSI rate	11 (37%)	3 (9%)	0.008
Hysterectomy	n=59	n=57	
SSI rate	21 (36%)	6 (11%)	0.002
OR time >360 min	n=76	n=67	
SSI rate	28 (37%)	8 (12%)	<0.001
EBL > 500 cc	n=62	n=67	
SSI rate	27 (44%)	10 (15%)	<0.001

Patients were grouped into PRE and POST cohorts, respectively, based on whether their surgery preceded or followed the date an SSI reduction bundle was implemented

SSI, surgical site infection; OR, operative time; EBL, estimated blood loss