Intervention Strategies to Reduce Surgical Site Infection Rates in Patients Undergoing Rectal Cancer Surgery

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Abstract. *Background/Aim:* This study aimed to determine the effectiveness of surgical site infection (SSI) prevention approaches in rectal cancer surgery. *Patients and Methods:* A total of 1,408 patients who underwent elective rectal cancer surgery between 1995 and 2017 were reviewed. Patients were divided into three groups: control group (group A, $n=245$), SSI prevention intervention group (group B, $n=516$), and laparoscopic or robotic surgery group (group C, $n=647$). The groups were compared in terms of SSI and anastomotic leakage (AL) incidences, and risk factors for SSI were investigated. *Results:* The overall SSI and AL rates were 19.4% and 3.6%, respectively. These rates were significantly lower in Group C (9.3%, 1.7%), compared to Groups A (40.0%, 6.1%) and B (22.5%, 3.5%). Abdominoperineal resection, open surgery, operation time, intraoperative bleeding, lack of absorbable sutures, lack of mechanical bowel preparation, and lack of oral antibiotics were independently associated with SSI. *Conclusion:* SSI reduction after rectal cancer surgery was achieved through various intervention strategies.

In colorectal surgery, surgical site infection (SSI) is one of the most frequent postoperative complications with a reported incidence ranging from 11 to 26% (1-3). SSI prolongs postoperative hospital stay, increases medical costs, and leads to mortality (4, 5). Anastomotic leakage (AL) is another major complication of colorectal surgeries, especially rectal surgery, which can lead to postoperative

intraoperative infections. Therefore, strategies to reduce SSI and AL are crucial to improve postoperative outcomes for colorectal cancer patients.

In 1999, the Centers for Disease Control and Prevention (CDC) published guidelines for SSI prevention, and specific interventions were recommended for colorectal surgery (6). One previous study suggested that SSI incidence and the associated risk factors might differ between colon and rectal surgeries (7), despite being grouped in clinical studies. Over 20 years ago at the present study site, the rates of SSI and AL after rectal surgery were high, often resulting in serious complications. Therefore, multidisciplinary stepwise interventions that aimed at reducing rates of SSI and AL were implemented.

The purpose of this study was to describe the outcomes associated with SSI reduction efforts over the past 22 years in patients who underwent rectal cancer surgery.

Patients and Methods

Study design and patients. A retrospective review of clinical data from 1408 consecutive patients who underwent elective surgery for rectal cancer at the University of Tokyo Hospital between January 1995 and December 2017 was performed. Patients were divided into three groups based on the timing of the implementation of SSI prevention strategy: patients treated between January 1995 and March 2001 received preoperative mechanical bowel preparation (MBP) only (group A, $n=245$), those treated between April 2001 and March 2012 underwent various SSI prevention strategies (group B, $n=516$), and the majority of patients treated between April 2012 and December 2017 underwent laparoscopic or robotic surgery (group C, $n=647$) (Table I).

Study protocol. Patients underwent preoperative MBP with sodium picosulfate and chloride or magnesium citrate the day before surgery except for those with severe bowel stenosis. Hair removal was performed the day before surgery. Povidone-iodine was used to disinfect the skin before the skin incision. In all groups, cefmetazole was administered intravenously 30 minutes preoperatively, and intraoperatively every 3 hours. For AL prevention, a transanal drainage tube was placed in the rectum after anastomosis.

The SSI prevention measures according to the three groups are summarized in Table I. In group A, no preventative measures except for MBP were performed. In group B, absorbable sutures were used

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Table I. Interventions implemented to reduce surgical site infection (SSI) in the three groups.

Period		SSI prevention strategies
Group A	January 1995 to March 2001	Mechanical bowel preparation
Group B	April 2001 to March 2012	Absorbable suture closure of the fascia (from April 2001)
		Use of closing tray (from April 2003)
		Change of surgeons' gloves after anastomosis (from April 2003)
		Change of surgical instruments and drape after anastomosis (from April 2003)
		Wound lavage by saline before skin closure (from April 2003)
Group C	April 2012 to December 2017	Oral antibiotic preparation (from July 2003)
		Use of wound protectors (from April 2012)

to close the fascia starting in 2001. In 2003, additional sterile trays for abdominal closure were introduced, there were new protocols for changing gloves, surgical instruments, and drapes after anastomosis, and wounds were lavaged with saline prior to skin closure. Furthermore, an oral antibiotic preparation of 1 g of kanamycin and 750 mg of metronidazole twice a day preoperatively was initiated. In 2012, the majority of surgical approaches were changed from open to laparoscopic or robotic surgery and a wound protector was introduced.

Outcomes. The diagnosis of incisional or organ/space SSI was based on definitions in the CDC guidelines for infection control practices (6). Incisional SSI involved superficial and deep incisional SSIs. Wound surveillance was performed by surgeons and nurses daily during hospitalization. After hospital discharge, surgeons examined the wound and assessed the presence of SSI at the outpatient clinic around 30 days postoperatively. In the case of fecal discharge from the pelvic drain or suspicious symptoms such as peritonitis postoperatively, patients underwent an abdominal CT scan and/or fistulography to diagnose the AL or organ/space SSI (8).

Statistical analysis. All data are expressed as a median (interquartile range) or numbers (%). Differences in categorical variables were compared using the χ^2 test or Fisher's exact test, and continuous variables were compared using the parametric *t*-test or Mann-Whitney *U*-test. The independent risk factors for SSI were analyzed by logistic regression analysis. All analyses were performed with JMP Pro v. 14.0 software (SAS Institute, Inc., Cary, NC, USA), and a *p*-value <0.05 was considered statistically significant.

Results

Surgical site infection rate and timeline for interventions. The SSI and AL rates after rectal surgery and timeline for specific interventions implemented over 22 years are shown in Figure 1. The interventions were associated with a 90% relative decrease in the overall SSI rates over 22 years, from 34% in 1995 to 3.4% in 2017, and specific rates went down from 18% to 2.5% for incisional SSIs and from 14% to 0% for organ/space SSIs. Regarding anal preservation, abdominoperineal resection (APR) and Hartmann's procedure decreased from 21% in 1995 to 7.6% in 2017. AL incidence decreased from 9.7% in 1995 to 0.9% in 2017.

Patient characteristics. Patient characteristics and surgical outcomes are summarized according to the three groups in Table II. There were significant differences in age, distance from the anal verge (AV), serum albumin level, history of laparotomy, tumor size, neoadjuvant therapy, operation type, approach, and time and intraoperative blood loss between the groups. In group C, 92% of patients underwent laparoscopic or robotic surgery. Moreover, group C had significantly less intraoperative bleeding but longer operative times compared to other groups. The APR rate decreased and the intersphincteric resection (ISR) rate increased for anal preservation.

Incidence of surgical site infection. The incidence rate of overall, incisional, and organ/space SSIs in the three groups are shown in Table III. The overall SSI rate in this study was 19.5% (274/1408). It decreased to about half between groups A and B. The rate of overall SSI in group C was significantly lower than the other groups, as well as the rates of incisional SSI and organ/space SSI. The rate of AL in this study was 3.6% (43/1196, excluding APR and Hartmann's procedure), 8.3% (15/181) in group A, 4.1% (17/412) in group B, and 1.8% (11/603) in group C.

Risk factors for surgical site infection. The results from the analysis of the risk factors for overall SSI are presented in Table IV. Hypoalbuminemia, tumor size ≥ 35 mm, stage IV cancer, neoadjuvant therapy, APR, open surgery, operation time ≥ 240 min, intraoperative bleeding ≥ 200 ml, and lack of absorbable suture, closing trays, MBP, and oral antibiotics were significantly associated with overall SSI occurrence after rectal cancer surgery. A multivariate analysis showed that APR, open surgery, operation time ≥ 240 min, intraoperative bleeding ≥ 200 ml, and lack of absorbable suture, MBP, and oral antibiotics were independent risk factors for overall SSIs.

Discussion

This study aimed to determine the factors associated with reduced rates of SSI and AL in patients who underwent rectal

Figure 1. Surgical site infection (SSI) and anastomosis leakage (AL) rates after rectal surgery and infection prevention implementation strategies over time. APR: Abdominoperineal resection.

cancer surgery. The results show a significant reduction in overall SSI rates over a 22-year period when various infection control procedures were introduced. Independent risk factors for SSI included abdominoperineal resections, open surgery, operation time, intraoperative bleeding, and lack of absorbable sutures, MBP, and oral antibiotics. Our results show that when interventions to address these factors were implemented, patient outcomes improved.

There is a lack of long-term evidence to verify SSI prevention strategies according to various surgical outcomes. Currently, there are many “SSI bundles” and guidelines available to assist with SSI prevention and treatment (4, 9). However, these guidelines were not widely implemented 20 years ago, and a standard protocol to reduce SSI was not in place. As such, the first group of patients (group A) that underwent treatment prior to the prevention strategies received only preoperative MBP. Not surprisingly, SSI incidence in group A patients was extremely high. In the present study, we demonstrated a significant reduction in overall postoperative SSI rates after rectal surgery over the 22-year period.

Patients in group B underwent treatment during a period when various SSI prevention strategies were being introduced. The first intervention associated with a decrease in SSIs was the introduction of absorbable sutures. In the 1970s, a clinical randomized controlled study to compare absorbable with nonabsorbable sutures found that silk sutures promoted granulation and caused infection (10). In our institution, absorbable sutures were introduced in 2001, resulting in a significant improvement in overall SSIs, especially incisional SSIs.

Moreover, the benefits of sterile closing trays and pre-closure glove changes were noted in a recent meta-analysis of colorectal bundles (11). According to the study, the interventions with the most significant impact on SSI reduction were sterile closing trays (58.6% vs. 33.1%), pre-closure glove changes (56.9% vs. 28.5%), and MBP with oral antibiotics (55.4% vs. 31.8%). Conventionally, MBP alone does not reduce SSI after colorectal surgery (12); however, there are several reports in which the use of MBP along with oral antibiotics was associated with a significant decrease in SSI incidence (13, 14). Our institution

Table II. Patient and procedural characteristics over time.

		Group A (n=245)	Group B (n=516)	Group C (n=647)	p-Value
Gender	Male	168 (68.6%)	337 (65.3%)	393 (60.7%)	0.062
	Female	77 (31.4%)	179 (34.7%)	254 (39.3%)	
Age, years ^a		62 (55-68)	64 (58-72)	64 (56-72)	0.022
BMI ^a		21.6 (19.8-24.5)	22.5 (20.8-24.3)	22.3 (19.9-24.7)	0.180
Distance from AV, cm ^a		7 (4-12)	8 (6-15)	8 (3-7)	0.002
Diabetes	Present	20 (8.2%)	64 (12.4%)	88 (13.6%)	0.070
	Absent	225 (91.8%)	452 (87.6%)	559 (86.4%)	
Smoking	Never or Ex-	177 (72.2%)	389 (75.4%)	511 (79.0%)	0.082
	Current	68 (27.8%)	127 (24.6%)	136 (21.0%)	
Alb, g/dl ^a		3.8 (3.5-4.0)	3.9 (3.6-4.2)	4.0 (3.5-4.2)	<0.001
Previous laparotomy	Present	37 (15.1%)	85 (16.5%)	141 (21.8%)	0.020
	Absent	208 (84.9%)	431 (83.5%)	506 (78.2%)	
Tumor size, mm ^a		40 (28-55)	36 (26-56)	35 (23-46)	<0.001
Stage	0-III	209 (85.3%)	442 (85.7%)	571 (88.3%)	0.322
	IV	36 (14.7%)	74 (14.3%)	76 (11.7%)	
Neoadjuvant therapy	None	153 (62.4%)	339 (65.7%)	468 (72.3%)	<0.001
	RT/CRT or CTx	92 (37.6%)	174 (34.3%)	179 (27.7%)	
Operation	AR	181 (73.9%)	404 (78.3%)	528 (81.6%)	<0.001
	ISR	0 (0.0%)	11 (2.1%)	72 (11.1%)	
	Hartmann	8 (3.3%)	19 (3.7%)	12 (1.9%)	
	APR	56 (22.8%)	82 (15.9%)	35 (5.4%)	
Stoma	Present	74 (30.2%)	133 (25.8%)	262 (40.5%)	<0.001
	Absent	171 (69.8%)	383 (74.2%)	385 (59.5%)	
Approach	Open	244 (99.6%)	490 (95.0%)	52 (8.0%)	<0.001
	Laparoscopic	1 (0.4%)	26 (5.0%)	464 (71.7%)	
	Robotic	0 (0.0%)	0 (0.0%)	131 (20.3%)	
Operation time, min ^a		245 (195-335)	262 (218-390)	300 (295-488)	<0.001
Blood loss, ml ^a		525 (280-900)	495 (290-1057)	30 (20-206)	<0.001

^aData were expressed as median (interquartile range). BMI: Body mass index; AV: anal verge; Alb: albumin; RT: radiotherapy; CRT: chemoradiotherapy; CTx: Chemotherapy; AR: anterior resection; ISR: intersphincteric resection; APR: abdominoperineal resection.

Table III. Risk comparison of surgical site infection (SSI) in the three groups.

	Group A (n=245)	Group B (n=516)	Group C (n=647)	p-Value
Overall SSI	98 (40.0%)	116 (22.5%)	60 (9.3%)	<0.001
Incisional SSI	74 (30.2%)	80 (15.5%)	31 (4.8%)	<0.001
Organ/Space SSI	49 (20.0%)	58 (11.2%)	32 (4.9%)	<0.001
Without anastomotic leakage	34 (13.9%)	40 (7.7%)	21 (3.2%)	<0.001
With anastomotic leakage	15 (6.1%)	18 (3.5%)	11 (1.7%)	<0.001

introduced oral antibiotics in addition to MBP in 2003, around the same time closing trays and glove changes after anastomosis were introduced. The multivariate analysis in the present study showed that the absence of MBP and oral antibiotics were both independent risk factors for SSI, although the lack of sterile closing trays was not. This result may be due to other SSI prevention measures, such as the administration of oral antibiotics being introduced at the same time.

In the present study, APR was an independent risk factor for SSI; however, stoma construction excluding APR was not

associated with SSI incidence. Previous reports showed that APR and stoma construction were predictive of the development of SSI (2, 7, 15, 16). Perineal wound complications after APR remain a serious clinical problem because of the intensive treatment for distal rectal cancer such as neoadjuvant chemoradiotherapy (17, 18). These results suggest that the reason why APR was associated with a higher risk of SSI was not stoma construction but perineal wound complications. Corresponding to the trend toward anal preservation, the APR rate gradually decreased in group A (22.8%) compared to group B (15.9%) and C (5.4%),

Table IV. Association between surgical site infection (SSI) and clinical factors.

Variables	Univariate analysis		Multivariate analysis	
	OR (95%CI)	p-Value	OR (95%CI)	p-Value
Gender, male	0.88 (0.67-1.15)	0.344		
Age, ≥65 years	1.08 (0.83-1.40)	0.585		
BMI, ≥25	0.99 (0.72-1.38)	0.972		
Diabetes	1.07 (0.71-1.60)	0.762		
Smoking	1.32 (0.98-1.78)	0.066		
Alb, <3.5 g/dl	1.66 (1.18-2.32)	0.003	1.03 (0.70-1.51)	0.881
Previous laparotomy	1.29 (0.90-1.85)	0.158		
Tumor size, ≥35 mm	1.46 (1.11-1.91)	0.006	1.14 (0.82-1.58)	0.425
Stage, IV	1.86 (1.31-2.64)	<0.001	1.15 (0.77-1.75)	0.489
Neoadjuvant therapy	1.64 (1.25-2.16)	<0.001	1.11 (0.78-1.59)	0.562
Operation, APR	5.67 (4.05-7.94)	<0.001	3.71 (2.47-5.59)	<0.001
Stoma excluding APR	1.30 (0.92-1.84)	0.136		
Approach, Open	4.69 (3.37-6.52)	<0.001	2.14 (1.32-3.45)	0.002
Operation time, ≥240 min	2.08 (1.54-2.80)	<0.001	1.80 (1.25-2.59)	0.002
Blood loss, ≥200 ml	4.52 (3.29-6.21)	<0.001	1.72 (1.10-2.69)	0.017
Absorbable suture	0.27 (0.20-0.36)	<0.001	0.53 (0.29-0.96)	0.037
Closing tray	0.28 (0.21-0.37)	<0.001	0.76 (0.32-1.83)	0.540
Mechanical bowel preparation	0.32 (0.20-0.50)	<0.001	0.48 (0.28-0.83)	0.008
Oral antibiotics	0.27 (0.20-0.35)	<0.001	0.49 (0.28-0.85)	0.011
Intraoperative colonoscopy	0.31 (0.24-0.41)	<0.001	0.81 (0.43-1.54)	0.525

BMI: Body mass index; Alb: albumin; APR: abdominoperineal resection.

whereas the ISR rate and the stoma construction rate increased. We hypothesize that colorectal reconstruction prevents serious perineal wound complications because it fills the dead space within the pelvis.

Another important cause of organ/space SSIs is AL. Previous reports showed that the incidence of AL was approximately 10% in rectal surgery (8), and Poon *et al.* (19) reported that AL was the only factor that predicted organ/space SSIs in colorectal surgery. In the present study, the AL rate was significantly lower than that in previous studies. As preventive measures for AL in rectal surgery, our institution performed transanal tube placement. It is evident that the use of transanal tubes is effective in preventing AL after rectal cancer surgery (20).

We changed our surgical approaches mainly from open to laparoscopic or robotic surgery in 2012, along with the introduction of a wound protector. Consequently, SSI incidence was further improved in group C. Currently, laparoscopic surgery is the standard treatment for colorectal cancer, and previous studies indicated that laparoscopic surgery for colorectal cancer lowers SSI incidence compared with open surgery (19, 21). In addition, robotic surgery has been recognized as an alternative to standard laparoscopic surgery especially in complex dissections such as the rectum, and several studies have reported that there was no significant difference in the SSI rate between laparoscopic and robotic rectal surgery (22-24). SSI incidence after

laparoscopic rectal surgery has been reported at 12-14% (25, 26), and SSI incidence in group C in the present study was lower. In the present study, we posit that the use of wound protectors for laparoscopic or robotic surgery may have an additional effect on SSI prevention.

There are several limitations to consider in this study. First, we conducted a retrospective control study, which did not allow us to identify causal factors for improved outcomes. Second, other known risk factors for SSI in colorectal surgery were not assessed, such as blood transfusion, intraoperative hypothermia, and intraoperative hyperglycemia (9). Despite these defects, we consider that our results will be valuable for developing strategies to prevent SSIs.

The measures taken at our institution over the past 22 years to reduce SSIs, including preoperative MBP with oral antibiotics, intraoperative use of absorbable sutures and closing trays, intraoperative changes of gloves and instruments, and performing anal preservation procedures in laparoscopic and robotic surgery with wound protectors, can be adopted by other medical institutions focused on improving SSI rates after rectal cancer surgery.

Conflicts of Interest

The Authors have no conflicts of interest to declare in relation to this study.

Authors' Contributions

KK and SI conceived the study and contributed to its design. MO acquired the data and drafted the manuscript. KK and KS contributed to the interpretation of the results and revised the manuscript. KK, KS, HN, MK, KM, SE, YI, HI, YY, HA, HS and SI managed the literature search and revised the manuscript critically. All Authors read and approved the final manuscript.

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