

# Predictors of the major and minor ileostomy complications following ileostomy closure in rectal cancer patients: a retrospective cohort study

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## ABSTRACT

**Aim:** This study aimed to investigate the predictors associated with the ileostomy related complications after ileostomy closure among the patients with rectal cancer who underwent temporary diverting ileostomy following total mesorectal excision.

**Method:** A retrospective study included 151 patients who underwent total mesorectal excision for rectal cancer with ileostomy closure following temporary diverting ileostomy. Patients' demographic characteristics, clinical and laboratory findings, and the major and minor ileostomy complications were evaluated by univariate and multivariate analysis.

**Results:** The mean age was  $61.13 \pm 13.33$  years old. The population of data included 95 (62.9%) male patients. Adenocarcinoma was diagnosed in 149 (98.7%) patients. The duration of ileostomy was  $197.3 \pm 136.3$  days. The patients who received neoadjuvant therapy were 52.3%. The patients with major ileostomy surgical site complications were more likely to have colorectal anastomosis leakage and intraabdominal pelvic abscess (17.72% vs 0% and 25.32% vs 0%, respectively;  $p < 0.001$ ) whereas patients with minor complications were more likely to have colorectal anastomosis stenosis and intraabdominal pelvic abscess (18.67% vs 5.26% and 20.0% vs 6.58%, respectively;  $p < 0.05$ ). Deep incisional, organ space and superficial SSIs were significantly higher in patients with both major and minor ileostomy complications ( $p < 0.001$ ) comparing to those who had no complications. Higher duration of ileostomy significantly increased the risks of major (OR 1.015, 95% CI, 1.007-1.022,  $p < 0.001$ ) and minor complications (OR 1.006, 95% CI 1.002-1.011,  $p = 0.008$ ).

**Conclusion:** Ileostomy duration was analyzed as a continuous variable and demonstrated a significant association with SSI risk. While prior literature suggests a 3-month threshold, our data support a progressive increase in risk with longer duration, rather than a strict cutoff.

**Keywords:** ileostomy, colorectal surgery, surgical site infection

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## Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed form of cancer globally, with an increasing incidence in developing countries (1,2). Comprising 11% of all cancer diagnoses, CRC is the second most deadly cancer worldwide (1). Surgery remains the principal way of treatment in cases of early diagnosis, however, surgery may no longer be effective in the patients diagnosed with advanced and metastasized CRCs (3,4). In these patients, the effectiveness of neoadjuvant and adjuvant therapies has been applied regarding cancer recurrence, resulting in differences in disease-free survival and overall survival rates in patients with rectal tumors (5,6). Temporary diverting ileostomy is performed frequently in the treatment of numerous CRC cases, including rectal cancer. Patients who underwent temporary diverting ileostomy after total mesorectal excision for rectal cancer have shown reduced rates of morbidity and re-operation secondary to anastomotic leak than the patients without loop ileostomy (7-9). However, the main disadvantage of diverting ileostomy is that it implies some complications such as surgical site infection (SSI), ileostomy site infection, and anastomotic leak (10). The most known complication following an ileostomy closure is SSI, with a reported incidence between 2%–34% (11). Hence, SSI poses a considerable problem in the rectal cancer patients and a significant load to the health care system (10,11).

The overall predictors of post-closure complications for temporary loop ileostomies are likely underreported and poorly characterized among the rectal cancer cases. Improving our understanding of the SSI during the diverting ileostomy, as well as estimating the predictors for ileostomy-related SSI following the surgery may help us to identify the methods to reduce these complications before its closure (7,12). Therefore, this study aimed to investigate the predictors associated with the ileostomy-related SSI after closure among the patients with rectal cancer who underwent temporary diverting ileostomy following total mesorectal

excision. Despite its clinical relevance, predictors of SSI following ileostomy closure remain insufficiently defined. This study aims to evaluate risk factors associated with SSI after ileostomy closure and to clarify the impact of ileostomy duration on postoperative outcomes.

## Materials and Methods

The study protocol was approved by the Clinical Research Ethics Committee of Bagcilar Training and Research Hospital of Health Science University (date: 12.06.2020, number: 2020.06.1.10.081). All procedures performed in this study involving human participants were following the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

### *Study population*

The medical records of 151 patients who applied to Bagcilar Training and Research Hospital of Health Science University between February 2013 and January 2019 were evaluated retrospectively. The rectal cancer patients who were treated with or without neoadjuvant therapy, the clinical examination, radiological imaging, and histopathological findings were included and analyzed in the study. Patients older than 18 years of age, who underwent elective ileostomy closure following total mesorectal excision for a primary diagnosis of rectal cancer with a temporary diverting ileostomy were included. Patients younger than 18 years and those who underwent emergency colorectal excision or elective total mesorectal excision without diverting ileostomy or colon resection with or without a diagnosis of Inflammatory bowel diseases, diverticulitis or benign and malignant colon diseases and patients without the procedure of ileostomy closure were excluded from the study.

All patients received perioperative antibiotic prophylaxis according to institutional protocols. This consisted of a second-generation cephalosporin (e.g., cefuroxime

1.5 g intravenously) administered within 30–60 minutes prior to skin incision. In cases with anaerobic risk, metronidazole (500 mg intravenously) was added. No routine postoperative antibiotic continuation was applied unless clinically indicated.

Ileostomy closure was performed using standard surgical techniques, including either hand-sewn or stapled anastomosis, based on surgeon preference and intraoperative findings. Although general surgical principles were consistent across cases, the specific technique was not fully standardized and depended on the operating surgeon.

Surgical site infection (SSI) surveillance was conducted in accordance with Centers for Disease Control and Prevention (CDC) criteria. Patients were followed for a minimum of 30 days postoperatively. SSI assessment was performed through a combination of inpatient monitoring and outpatient follow-up visits.

SSI diagnosis was determined by the treating surgical team based on clinical evaluation, supported by medical record documentation. No independent blinded adjudication was performed.

### *Variables and outcomes*

Demographic, perioperative clinical findings, and laboratory parameters were recorded retrospectively. These included age, sex, comorbidities (hypertension, diabetes mellitus, coronary artery disease), neoadjuvant/adjuvant therapy, ASA score, surgical approach, and tumor characteristics. Complications related to the initial colorectal surgery, including anastomotic leakage, stenosis, and intraabdominal abscess, were defined as events occurring after total mesorectal excision and prior to ileostomy closure. These variables were considered pre-existing clinical factors and were analyzed as potential risk factors for post-closure complications, rather than as outcomes of ileostomy closure.

The primary outcome was the occurrence of surgical site infection (SSI) following ileostomy

closure, defined according to the Centers for Disease Control and Prevention (CDC) classification as:

- Superficial incisional SSI
- Deep incisional SSI
- Organ/space SSI

To facilitate clinical interpretation, complications were further categorized into:

- Major complications: conditions requiring invasive intervention, prolonged hospitalization, or associated with significant morbidity (e.g., deep incisional SSI, organ/space SSI, anastomotic leakage, intraabdominal abscess, bowel obstruction, acute renal failure).
- Minor complications: self-limiting or conservatively managed conditions (e.g., superficial SSI, skin irritation, electrolyte imbalance, minor wound infection).

This classification was based on clinical severity and management requirements, rather than infection type alone, to better reflect real-world surgical decision-making.

Importantly, SSI subtypes (superficial, deep, organ-space) were considered components of the outcome definition and were not treated as independent predictors in multivariate models.

### *Statistical analysis*

Statistical analyses were performed using SPSS (version 19.0). Continuous variables were expressed as mean  $\pm$  standard deviation, and categorical variables as frequencies and percentages.

Univariate analyses were conducted using Chi-square, Fisher's exact test, Student's t-test, or Mann-Whitney U test, as appropriate.

To identify independent predictors of SSI, multivariate logistic regression models were constructed separately for:

- Major complications
- Minor complications

Variables with  $p < 0.10$  in univariate analysis and clinically relevant factors (e.g., age, comorbidities, ileostomy duration, neoadjuvant therapy) were included in the multivariate model to control for confounding.

Variables representing components of the outcome (e.g., SSI subtypes) were excluded from regression models to avoid collinearity and misinterpretation. To avoid overlap between predictors and outcomes, variables such as deep incisional SSI and organ-space SSI were not included as independent predictors in multivariate analysis, as they are components of the SSI outcome.

Statistical significance was set at  $p < 0.05$ . No formal model validation (e.g., ROC curve, calibration) was performed; therefore, findings should be interpreted as exploratory rather than a validated prediction model.

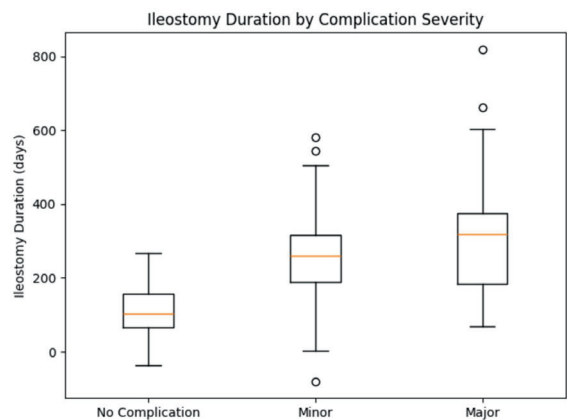
**Results**

The patients who were diagnosed with rectal cancer (151), 56 (37.1%) were female and 95 (62.9%) were male. The major ileostomy-related surgical site complications were showed in 57.1% of female patients and 49.5% of male patients, while 42.9% of female and 53.7% of male patients showed minor complications without any significant difference (Table 1-4). The mean age of all patients was  $61.13 \pm 13.33$  years old, the patients with major ileostomy-related surgical site complications were  $63.32 \pm 12.6$  and with minor complications was  $61.45 \pm 13.1$ . (Figure 1 and Figure 2) The duration of ileostomy was  $197.3 \pm 136.3$  days. The duration of ileostomy closure with major complications was  $272.1 \pm 135.5$  days and with minor complications was  $260.55 \pm 142.3$  days.

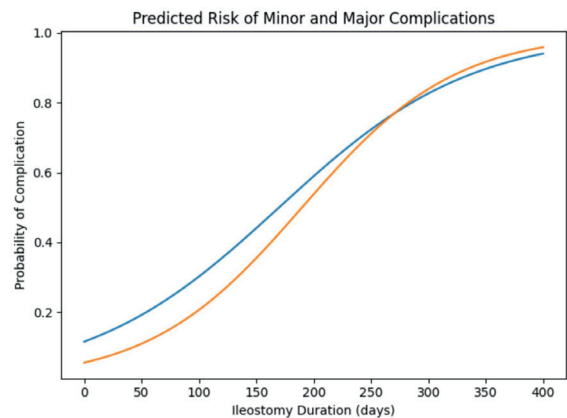
Regarding the demographic characteristics of patients, older patients, patients with CAD or HT, the patients with radiological stage III rectum cancer and T3 or N0 stage, and patients having neoadjuvant or adjuvant therapy were more likely to have major ileostomy surgical site complications ( $p < 0.05$ ). It was also determined

that the mean age, the distribution of sex, number of patients with DM or HT, ASA scores, any of laboratory findings, histological type of tumor, and M stage did not differ among the patients according to the presence of minor complications (Table 1). However, the patients with CAD, the patients with radiological stage III rectum cancer and T3 or N0 stage, and patients having neoadjuvant or adjuvant therapy were more likely to have minor complications ( $p < 0.05$ ).

Clinical findings of the patients showed that both hospitalization and ileostomy durations were significantly longer among patients with major or minor complications ( $p < 0.001$ ) (Table 2 and Table 3, Figure 1 and Figure 2). Among



**Figure 1.** Relationship between ileostomy duration and probability of minor and major complications. The risk increases progressively with longer duration.



**Figure 2.** Comparison of ileostomy duration between patients with minor and major complications.

**Table 1.** Demographic characteristics of patients compared with the presence major and minor ileostomy complications

Variable	Major Complications			Minor Complications		
	None (N=72)	Yes (N=79)	p value	None (N=76)	Yes (N=75)	p value
Age (±SD)	58.74 ± 13.8	63.32 ± 12.6	<b>0.034</b>	60.82 ± 13.6	61.45 ± 13.1	0.770
Sex (n, %)						
Female	24 (42.9)	32 (57.1)	0.362	32 (57.1)	24 (42.9)	0.199
Male	48 (50.5)	47 (49.5)		44 (46.3)	51 (53.7)	
Comorbidities (n, %)						
DM	18 (42.9)	24 (57.1)	0.461	20 (47.6)	22 (52.4)	0.679
CAD	13 (28.3)	33 (71.7)	<b>0.002</b>	17 (36.9)	29 (63)	<b>0.030</b>
HT	30 (37.97)	49 (62.03)	<b>0.012</b>	36 (45.6)	43 (54.4)	0.220
ASA (n, %)						
1	41 (56.94)	39 (49.37)		44 (57.89)	36 (48)	
2	24 (33.33)	21 (26.58)	0.078	19 (25)	26 (34.67)	0.571
3	7 (9.72)	15 (18.99)		11 (14.47)	11 (14.67)	
4	0 (0)	4 (5.06)		2 (2.63)	2 (2.67)	
Laboratory Findings						
HGB (±SD)	12.45 ± 2.9	12.77 ± 2.9	0.501	12.27 ± 3.1	12.97 ± 2.7	0.130
ALB (±SD)	4.15 ± 0.9	4.05 ± 0.9	0.324	4.12 ± 0.9	4.08 ± 0.8	0.711
Histology (n, %)						
Adenocarcinoma	68 (49.3)	70 (50.7)		71 (51.5)	67 (48.6)	
Mucinous adenocarcinoma	3 (27.3)	8 (72.7)	0.263	4 (36.4)	7 (63.6)	0.366
Signet-ring cell carcinoma	1 (100)	0 (0)		1 (100)	0 (0)	
Neuroendocrine tumor	0 (0)	1 (100)		0 (0)	1 (100)	
Stage (MRI) (n, %)						
1	52 (72.2)	20 (27.8)		52 (72.2)	20 (27.8)	
2	6 (27.3)	16 (72.7)	<b>0.001</b>	9 (40.9)	13 (59.1)	<b>&lt;0.001</b>
3	13 (26.0)	37 (74.0)		13 (26.0)	37 (74.0)	
4	1 (14.3)	6 (85.7)		2 (28.6)	5 (71.4)	
Histopathological Stage (n, %)						
T stage						
1	17 (68.0)	8 (32.0)		18 (72.0)	7 (28)	
2	38 (61.3)	24 (38.7)	<b>0.001</b>	37 (59.7)	25 (40.3)	<b>0.001</b>
3	15 (25.4)	44 (74.6)		19 (32.2)	40 (67.8)	
4	2 (40.0)	3 (60.0)		2 (40.0)	3 (60)	
N stage						
0	58 (61.1)	37 (38.9)	<b>0.001</b>	61 (64.2)	34 (35.8)	<b>&lt;0.001</b>
1	12 (30.0)	28 (70.0)		14 (35)	26 (65)	
2	2 (12.5)	14 (87.5)		1 (6.3)	15 (93.8)	
M stage						
0	71 (49.3)	73 (50.7)	0.070	74 (51.4)	70 (48.6)	0.276
1	1 (14.3)	6 (85.7)		2 (28.6)	5 (71.4)	
Neoadjuvant (n, %)	20 (25.3)	59 (74.7)	<b>0.001</b>	24 (30.4)	55 (69.6)	<b>&lt;0.001</b>
Adjuvant (n, %)	23 (28.4)	58 (71.6)	<b>0.001</b>	25 (30.9)	56 (69.1)	<b>&lt;0.001</b>

±SD: Standard deviation; DM: Diabetes Mellitus; CAD: Coronary artery disease; HT: Hypertension; HGB: Hemoglobin; ALB: Albumi; ASA: American Society of Anesthesiologists; MRI: Magnetic resonance imaging.

**Table 2.** Clinical findings of patients with major ileostomy complications

	None (N=72)	Yes (N=79)	p value
<b>Post-closure hospitalization duration (day, ±SD)</b>	4.9 ± 1.3	8.9 ± 4.8	<0.001
<b>Ileostomy duration (day, ±SD)</b>	115.1 ± 77.3	272.1 ± 135.5	<0.001
<b>Surgery type (n, %)</b>			
Laparotomy	32 (44.4)	29 (36.7)	
Laparoscopy	35 (48.6)	43 (54.4)	0.613
Lap to Open Conversion	5 (6.9)	7 (8.9)	
<b>Hypokalemia / Hyponatremia (n, %)</b>	3 (4.17)	12 (15.19)	0.024
<b>Anastomosis related complications (n, %)</b>			
Colorectal anastomosis stenosis	6 (8.33)	12 (15.19)	0.194
Colorectal anastomosis leakage	0 (0)	14 (17.72)	<0.001
Intraabdominal pelvic abscess	0 (0)	20 (25.32)	<0.001
<b>Ileostomy related complications (n, %)</b>			
Skin Irritation	10 (13.89)	21 (26.58)	0.054
Retraction	0 (0)	12 (15.19)	0.001
Parastomal Infection	0 (0)	24 (30.38)	<0.001
Post-closure Ileostomy Site Infection	7 (9.72)	19 (24.05)	0.020
<b>Reoperation (n, %)</b>	2 (2.78)	9 (11.39)	0.042
<b>Post-Closure Diarrhea (n, %)</b>	11 (15.28)	9 (11.39)	0.482
<b>Deep Incisional SSI (n, %)</b>	0 (0)	39 (49.37)	<0.001
<b>Organ Space SSI (n, %)</b>	0 (0)	28 (35.44)	<0.001
<b>Superficial SSI (n, %)</b>	16 (22.22)	38 (48.1)	0.001

±SD: Standard deviation, SSI: Surgical site infection.

the patients with major ileostomy surgical site complications, the incidence of hypokalemia/hyponatremia and the rate of reoperation was observed significantly higher (15.19% vs 4.17% and 11.39% vs 2.78%, respectively;  $p < 0.05$ ) while the surgery type and the incidence of post-closure diarrhea did not differ (Table 2). Among the patients with minor complications, the incidence of acute renal failure, postoperative ileus, the surgery type, and post-closure diarrhea also did not differ according to the minor complications (Table 3-4). Patients who had experienced colorectal anastomosis leakage prior to ileostomy closure were more likely to develop major complications after closure and intraabdominal pelvic abscess (17.72% vs

0% and 25.32% vs 0%, respectively;  $p < 0.001$ ) whereas patients with minor complications were more likely to have colorectal anastomosis stenosis and intraabdominal pelvic abscess (18.67% vs 5.26% and 20.0% vs 6.58%, respectively;  $p < 0.05$ ). The patients with major complications were more likely to have prior to closure; retraction, parastomal infection and ileostomy site infection (15.19% vs 0%,  $p < 0.01$ ; 30.38% vs 0%,  $p < 0.001$  and 24.05% vs 9.72%,  $p < 0.05$ , respectively) whereas patients with minor complications were more likely to have post-closure ileostomy stenosis, ischemia and ileostomy leakage (14.67% vs 1.32%,  $p < 0.01$ ; 25.33% vs 3.95%,  $p < 0.001$  and 12.0% vs 0%,  $p < 0.01$ , respectively).

**Table 3.** Clinical findings of patients with minor ileostomy complications

	None (N=76)	Yes (N=75)	p value
<b>Hospitalization</b> (day, ±SD)	5.62 ± 2.2	8.39 ± 5.0	<0.001
<b>Ileostomy duration</b> (day, ±SD)	134.83 ± 95.9	260.55 ± 142.3	<0.001
<b>Surgery type (n, %)</b>			
Laparotomy	35 (57.38)	26 (42.62)	
Laparoscopy	37 (47.44)	41 (52.56)	0.239
Lap to Open Conversion	4 (33.33)	8 (66.67)	
<b>Anastomosis related complications (n, %)</b>			
Colorectal anastomosis stenosis	4 (5.26)	14 (18.67)	<b>0.011</b>
Colorectal anastomosis leakage	5 (6.58)	9 (12)	0.211
Intraabdominal pelvic abscess	5 (6.58)	15 (20)	<b>0.015</b>
<b>Ileostomy related complications (n, %)</b>			
Ileostomy Stenosis	1 (1.32)	11 (14.67)	<b>0.002</b>
Ischemia	3 (3.95)	19 (25.33)	<0.001
Parastomal Hernia Prolapses	5 (6.58)	2 (2.67)	0.442
Post-Closure Leakage	0 (0)	9 (12)	<b>0.006</b>
<b>Reoperation (n, %)</b>	2 (2.63)	9 (12)	<b>0.027</b>
<b>Post-Closure Diarrhea (n, %)</b>	12 (15.79)	8 (10.67)	0.353
<b>Acute Renal Failure (n, %)</b>	2 (2.22)	7 (7.78)	0.051
<b>Post-closure Obstruction (Ileus) (n, %)</b>	12 (15.79)	14 (18.67)	0.640
<b>Deep Incisional SSI (n, %)</b>	3 (3.95)	36 (48)	<0.001
<b>Organ Space SSI (n, %)</b>	6 (7.89)	22 (29.33)	<0.001
<b>Superficial SSI (n, %)</b>	0 (0)	54 (72)	<0.001

SSI: Surgical site infection.

The univariate regression analysis of all variables showed that older age (OR: 1.027; 95% CI: 1.002-1.053; P = 0.037) and longer ileostomy duration (OR: 1.015; 95% CI: 1.011-1.020; P < 0.001) and the presence of ileostomy site infection (OR: 2.940; 95% CI: 1.154-7.489; P = 0.024) primarily affected the risk of major complications (Table 5).

The univariate regression analysis of all variables showed that the presence of comorbidity such as CAD (OR: 2.188; 95% CI: 1.073-4.460; P = 0.031), longer ileostomy duration (OR: 1.01; 95% CI: 1.006-1.013; P < 0.001) and ileostomy stenosis (OR: 12.891; 95% CI: 1.6200-102.58; P = 0.016) initially affected the risk of minor complications (Table 6).

**Table 4.** Frequencies of ileostomy related complications

	N (%)
<b>Major complications</b>	
Ileostomy Stenosis	12 (7.95)
Ischemia	22 (14.57)
Parastomal Hernia Prolapses	7 (4.64)
Acute Renal Failure	9 (5.96)
Post-closure Obstruction	26 (17.22)
Ileostomy Leakage	9 (5.96)
Deep Incisional SSI	39 (25.83)
Organ Space SSI	28 (18.54)
<b>Minor complications</b>	
Skin Irritation	31 (20.53)
Retraction	12 (7.95)
Parastomal Infection	24 (15.89)
Hypokalemia / Hyponatremia	15 (9.93)
Ileostomy Site Infection	26 (17.22)
Superficial Space SSI	54 (35.76)

SSI: Surgical site infection.

**Table 5.** Unadjusted covariates for major ileostomy complications

Characteristics	Odds Ratio	95% CI	p value
Age	1.027	1.002-1.053	<b>0.037</b>
<b>Comorbidities</b>			
CAD	3.256	1.540-6.884	<b>0.002</b>
HT	2.287	1.191-4.392	<b>0.013</b>
Ileostomy duration	1.015	1.011-1.020	<b>&lt;0.001</b>
Stage (MR)	2.747	1.867-4.041	<b>&lt;0.001</b>
<b>Histopathological Stage</b>			
T stage	2.479	1.555-3.952	<b>&lt;0.001</b>
N stage	3.479	1.915-6.322	<b>&lt;0.001</b>
Adjuvant	12.38	0.534-286.77	0.117
Neoadjuvant	7.670	3.721-15.81	<b>&lt;0.001</b>
Reoperation	4.500	0.938-21.58	0.060
Hypokalemia / Hyponatremia	4.119	1.113-15.25	<b>0.034</b>
Ileostomy Site Infection	2.940	1.154-7.489	<b>0.024</b>

CAD: Coronary artery disease; HT: Hypertension, SSI: Surgical site infection.

**Table 6.** Unadjusted covariates for minor ileostomy complications

Characteristics	Odds Ratio	95% CI	p value
<b>Comorbidities</b>			
CAD	2.188	1.073-4.460	<b>0.031</b>
Ileostomy duration	1.010	1.006-1.013	<b>&lt;0.001</b>
Stage (MR)	2.496	1.722-3.619	<b>&lt;0.001</b>
<b>Histopathological Stage</b>			
T	2.241	1.421-3.535	<b>0.001</b>
N	3.991	2.171-7.336	<b>&lt;0.001</b>
Adjuvant	6.013	2.965-12.192	<b>&lt;0.001</b>
Neoadjuvant	5.958	2.947-12.049	<b>&lt;0.001</b>
Reoperation	5.045	1.052-24.196	<b>0.043</b>
Colorectal Anastomosis Stenosis	4.131	1.292-13.209	<b>0.017</b>
Intraabdominal Pelvic Abscess	3.550	1.219-10.338	<b>0.020</b>
Ileostomy Stenosis	12.891	1.6200-102.58	<b>0.016</b>
Ischemia	8.256	2.327-29.294	<b>0.001</b>

CAD: Coronary artery disease; SSI: Surgical site infection.

Multivariate analysis by adjusted covariates showed that the patients with longer ileostomy duration were more likely to have major (OR: 1.015; 95% CI: 1.007-1.022; P <0.001) and minor (OR: 1.006; 95% CI: 1.002-1.011; P = 0.008)

complications. Eventually, the increase in ileostomy duration had an impact on the risks of major and minor complications (Table 7 and Table 8).

**Table 7.** Adjusted covariates for major ileostomy complications

Parameter	Odds Ratio	95% CI	p value
Age	0.997	0.948-1.049	0.915
Hypokalemia/ Hyponatremia	0.553	0.081-3.761	0.545
Stoma Site Infection	0.417	0.066-2.619	0.350
CAD	2.497	0.644-9.680	0.185
HT	1.268	0.349-4.604	0.718
Stage MR	0.952	0.198-4.587	0.951
T Stage	0.853	0.355-2.048	0.722
N stage	2.177	0.467-10.139	0.322
Neoadjuvant	0.946	0.048-18.693	0.971
Ileostomy duration	<b>1.015</b>	<b>1.007-1.022</b>	<b>&lt;0.001</b>

CAD: Coronary artery disease; HT: Hypertension, SSI: Surgical site infection.

**Table 8.** Adjusted covariates for minor ileostomy complications

Parameter	Odds Ratio	95% CI	p value
Colorectal Anastomosis Stenosis	2.460	0.530-11.422	0.251
Intraabdominal pelvic abscess	0.709	0.024-21.242	0.843
Stomal Stenosis-Obstruction	3.025	0.209-43.835	0.417
Ischemia	0.001	0.0001-1	0.998
Re-operation	2.844	0.320-25.26	0.348
Ileostomy duration	1.006	1.002-1.011	<b>0.008</b>
CAD	1.888	0.717-4.971	0.198
Stage MR	0.403	0.102-1.588	0.194
T Stage	0.982	0.422-2.282	0.966
N stage	4,879	0,90-26,24	0,065
Adjuvant	3.629	0.611-21.56	0.156

CAD: Coronary artery disease; SSI: Surgical site infection.

## Discussion

The incisional SSI and intestinal obstruction are the most frequent complications after a diverting ileostomy, both related to low morbidity rates of around 5%, but reported up to 43%, among which are mainly problems with the anastomotic dehiscence, the appearance of incisional hernias (8,13-18). These infectious complications lead to a significant economic burden with increased hospitalization and costs (19). Understanding of the SSI-related morbidities, as well as estimating the predictors for ileostomy-related SSI following the diverting ileostomy closure might be beneficial to reduce these complications, the hospitalization duration, and

costs (20). Therefore, we focused on specifically the predictors associated with the ileostomy-related SSI among the patients with rectal cancer who underwent temporary diverting ileostomy closure. Subsequently, we reported that the ileostomy site-related complications including retraction, parastomal, and ileostomy site infections were observed more likely in patients with major ileostomy-related SSI, and complications including ileostomy stenosis, ischemia, and leakage were more likely in patients with minor complications. Deep incisional, organ space and superficial SSIs were significantly higher in patients with both major and minor complications (Table 2 and Table 3).

There are numerous factors associated with a high risk of SSI including obesity, emergent surgery, an open operative approach, preoperative abscess, advanced age (>70 yr), and comorbidities (13,21). We compared these factors in terms of the presence of major complications including ileostomy stenosis, ischemia, parastomal hernia prolapses, post-closure obstruction, post-closure ileostomy leakage, deep incisional SSI, organ space SSI, and also the minor complications including skin irritation, retraction, parastomal infection, post-closure ileostomy site infection, superficial space SSI. We determined that older age and the presence of comorbidities such as CAD, and HT, and longer ileostomy duration primarily affected the risk of major complications. Moreover, the presence of comorbidity and longer ileostomy duration significantly affected the risk of minor complications. Considering the duration of ileostomy and its effects on ileostomy-related SSI, several studies focused on early and delayed ileostomy reversal time and examined the effect of the timing of closure on morbidity and mortality rates (7,18,22-24). In a recent study, the rates of complication variables were found to be more likely among the patients who had ileostomy duration longer than 3 months and also, ileostomy-site complications were observed in 61.1% of the patients who had delayed closure time, too (7). Consistent with these previous findings, we showed that increase duration of ileostomy significantly affected the risks of major and minor complications. The longer waiting period of ileostomy closure was primarily a predictor of post-closure ileostomy-related SSI for the patients who underwent temporary diverting ileostomy with total mesorectal excision.

Ileostomy complications especially encountered after the construction of the loop ileostomy are the retraction of loop ileostomy, ileostomy flux, stomal prolapse, parastomal herniation, parastomal abscess, and severe

skin excoriation (17-19,25). After reversal of the ileostomy, complications related to ileostomy are anastomotic leakage or around the site of ileostomy reversal resulting in small bowel fistula, small bowel obstruction, and stitch-related adverse outcomes after ileostomy closure. Furthermore, after the closure of ileostomy and preservation of intestinal stability, the fistulas such as recto-vaginal fistula, pouch-vaginal fistula, and pouch-anal fistula are hardly witnessed (17-21,25). In our data analysis, we evaluated that major complications was more likely affected by deep incisional SSI, organ space SSI, and post-closure obstruction while the minor complications were exaggerated by superficial space SSI, skin irritation, and ileostomy site infection, respectively. Our findings are consistent with previous studies demonstrating that delayed ileostomy closure is associated with increased postoperative morbidity. Similarly, prolonged ileostomy duration may increase local inflammation, bacterial colonization, and technical difficulty during closure. Clinically, these findings support consideration of earlier closure when feasible.

Regarding Aydin and Soyulu, the factors such as age, ASA score, presence of chronic lung disease, presence of hyperglycemia, hematocrit and albumin levels, location of disease (colon or rectum), surgery duration, colostomy or ileostomy during the operation, and surgeon volume were associated with the incidence rates of SSI among patients who underwent colorectal surgery (26). Al-Khamis et al. modified a five-item frailty index to use predictor of 30-day postoperative outcomes after colorectal surgery, and to proactively recognize frail patients to instigate interventions to optimize them preoperatively (15). Consistently, we performed a multivariate logistic regression analysis to identify factors associated with major and minor complications. This approach allows assessment of independent associations

but does not constitute a predictive or diagnostic model. As previously mentioned in various aspects of other complications of colorectal diseases, we first tried to build a new diagnostic model to perform clinically adjustable to measurements of ileostomy related complications by identifying the major and minor complications (13-16,20-28). We performed a new diagnostic approach to predict the specific ileostomy complications, other than a common well-known Clavien-Dindo grading system which reflects generally the post-surgical complications (27). Eventually, as we expected based on our clinical practice, deep incisional, organ space, and superficial SSIs were seen to be significantly higher in patients with both major and minor complications.

However, this study has several limitations. First, its retrospective design introduces potential selection and information bias. Second, it represents a single-center experience with a relatively small sample size, which may limit generalizability. Third, variability in surgical technique and perioperative management could not be fully controlled. Finally, no external validation or performance assessment (e.g., ROC analysis) was performed, limiting the predictive applicability of the findings. No model validation (e.g., discrimination or calibration) was performed; therefore, the findings should be interpreted as exploratory associations rather than a validated predictive model. SSI assessment was based on routine clinical evaluation without independent adjudication, which may introduce observer variability. Despite these limitations, this study provides clinically relevant insights into factors associated with postoperative complications that could measure the predictors of ileostomy-related SSI among rectal cancer patients, suggesting a multivariate risk factor analysis for the major and minor complications following total mesorectal excision.

## Conclusion

Prolonged ileostomy duration is independently associated with an increased risk of surgical site infection following ileostomy closure. Rather than a strict temporal cutoff, the risk appears to increase progressively over time. These findings highlight the importance of optimizing the timing of ileostomy closure to reduce postoperative complications. Further prospective, multicenter studies are needed to validate these results.

## Ethical approval

The Clinical Research Ethics Committee of Bagcilar Training and Research Hospital of Health Science University approved the study protocol (date:12.06.2020, number: 2020.06.1.10.081).

## Author contribution

Study conception and design: YA, EY; data collection/processing: YEA, MT, SM, HY; analysis and interpretation of results: YA, YEA, MT, SM, HY, EY; draft manuscript preparation: YA. All authors reviewed the results and approved the final version of the manuscript.

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## Conflict of interest

The authors declare that there is no conflict of interest.

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