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ORIGINAL RESEARCH ARTICLE

Defunctioning loop ileostomy with restorative proctocolectomy for rectal cancer: Friend or foe?

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Abstract:

Objectives: Temporary ileostomy is used to decrease morbidity from anastomotic leakages (ALs). However, ileostomies are associated with complications (i.e., stoma-related complications; SRCs), ileus due to stenosis, dehydration, and the need for a second operation. Here we retrospectively evaluated the impact of SRCs on the treatment of rectal cancer. Methods: We identified 180 consecutive patients who underwent curative resection for rectal cancer at Juntendo University Hospital between January 2006 and December 2014. We divided the patients into groups with and without defunctioning stoma (DS), and we compared the patient age and gender, tumor location, approach (laparotomy/laparoscopy), surgical procedure, distance of the tumor from the margin of the anus, T factor, stage, duration of postoperative hospital stay, and postoperative complications between these groups. Univariate and multivariate analyses were performed to determine the risk factors for postoperative hospital stay. Results: The symptomatic leakage rate in the DS group (n = 92) was not significantly different from that of the non-DS group (n = 88; p = 0.29). However, Grade ≥ 4 AL occurred significantly less frequently in the DS group (0%) than in the non-DS group (5.7%; p = 0.02). SRCs occurred in 14 DS-group patients (15.2%). The multivariate analysis demonstrated that both AL (odds ratio [OR] 9.24; confidence interval [CI] 4.91-19.4) and SRC (OR 1.84; CI 1.03-3.54) were independently predictive of short-term outcomes. Conclusions: The benefit of a DS is balanced against the risk of leakage and SRCs at rectal resection. Surgeons should focus on not only the consequences of AL, but also SRC risk.

Keywords:

defunctioning stoma, stoma-related complication, anastomotic leakage, rectal cancer, stoma stenosis

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Introduction

The creation of a defunctioning stoma (DS) has long been recommended as a method to reduce the rate of clinically relevant anastomotic leakages (ALs)[1,2]. The fecal diversion provided by a DS protects, for as long as possible, a low pelvic anastomosis from the septic effects of leaks, which can cause pelvic abscess formation and peritonitis. The impact of a DS on the long-term outcome is driven primarily by the potential development of infectious complications, particularly severe postoperative infections[3].

In 1995, Bokey et al.[4] indicated that a diverting stoma dampened the consequences of leakage and lessened the necessity of urgent abdominal reoperation for peritonitis. They showed there was no significant difference in the frequency of clinically relevant leaks in patients with or without a proximal stoma, but there was a significantly higher incidence of localized leaks in patients with a stoma[4]. The efficacy and utility of DS have thus been controversial for many years.

Although one of the most important potential surgical complications after a low rectal resection is an AL, which can result in morbidity and/or mortality, stoma-related complications (SRCs) such as stoma infection, parastomal hernias, prolapse, obstructive complications, and electrolyte imbalance can also lead to severe problems. In addition, patients with a DS may experience skin excoriation, odor, day and night-time leakage, day and night-time soiling, and

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night-time emptying[5]. It has also been contended that SRCs will improve with time and that "the patients get used to their stoma." Research has prospectively focused on surgeon-related complications (i.e., stenosis, hernia, prolapse), leaving patient-related complications (e.g., leakage, soiling, odor, night-time emptying) aside. Little is known about whether these SRCs are additional artificial complications, similar to those accompanying ALs. Our present retrospective analysis revealed that the potential for SRCs must be monitored as closely as that for ALs.

Methods

We reviewed cases of 180 consecutive patients who underwent curative resection for the treatment of their rectal cancer at Juntendo University Hospital between January 2006 and December 2014. All cases of emergency operations and double cancers were excluded from the analysis. We divided the patients into two groups: the patients with and without DS. We compared the following factors between the DS group and the non-DS group: the patient's age, gender, body mass index, performance status and American Society of Anesthesiologists score, the tumor location, the surgical approach (open/laparoscopic assisted colectomy, or LAC), surgical procedure, distance of the tumor from the margin of the anus, T factor, stage, duration of postoperative hospital stay, and postoperative complications.

Operative mortality was defined as death that occurred within 30 days after the primary operation. This retrospective study was approved by our hospital's Institutional Review Board, and the requirement for patient consent was waived.

Definitions

The level of the lower edge of the tumor from the anal verge was measured by colonoscopy in every case. Each patient's barium enema examination-based tumor assessment was reviewed retrospectively in a rectal cancer evaluation. The rectum was divided into three regions according to the Japanese Classification of Colorectal Carcinoma: the upper rectum (Ra), the lower rectum (Rb), and Rab. The Ra is located between the lower border of the second sacral vertebra and the peritoneal reflection. The Rb is from the peritoneal reflection to the upper border of the anal canal. Tumors abutting the line were denoted as Rab.

Most of the total and tumor-specific mesorectal excisions were performed by the same team of staff colorectal surgeons. DS was created selectively based on the surgeon's opinion according to the situation, which included consideration of the lower anastomosis and neoadjuvant therapy.

For the investigation of the feasibility of DS, intersphincteric resection, ultra-lower anterior resection, lower anterior resection and anterior resection were registered in this study. Rectal anastomoses were performed with a double stapling technique. Reconstructions consisted of a hand-sewn coloanal anastomosis. Patients operated on by the authors were given the option of open/laparoscopic surgery, and the final decision depended on the surgeon's discretion. The staging of all cancers is described according to the Classification of Malignant Tumors, seventh edition (TNM 7th). The criteria for the indications for a loop ileostomy were anastomosis <5 cm from the anal verge, obstruction, intraoperative technical problems, severe diabetes mellitus, and severe kidney disease. The exclusion criteria for this study were the placement of a transanal drain for the prevention of AL, and previous pelvic radiotherapy.

AL was defined by clinical criteria: pelvic abscess, fecal discharge from the wound and drain, septicemia, and peritonitis, sometimes with or without radiologically confirmed leakage[6]. Postoperative ileus is defined as the inability to tolerate food together with the presence of abdominal distention, the absence of bowel sounds, and the need to delay enteral feeding[7].

Complications of ileostomy such as parastomal hernia, stenosis, prolapse, and electrolyte imbalance were recorded by our stoma care nurses and surgeons and were described in detail in prior studies[5,8]. Surgical site infections were defined using the U.S. Centers for Disease Control definitions[9]. These complications were based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE v4.0).

Statistical Analysis

The comparison of categorical variables was performed using the chi-square test or Fisher's exact test where appropriate. Continuous variables are presented as median values and were compared using the Mann-Whitney U-test. Clinicopathological factors for which there were significant differences in the univariate analysis were used as covariables for the multivariate analysis. For the multivariate analysis, the Cox proportional-hazard regression model was used with the hazard ratio.

Results

Patient characteristics

Table 1 summarizes the clinicopathologic characteristics of the 180 patients who underwent surgical resection for rectal cancer. The study group comprised 115 males and 65 females aged 25-86 years (median 63 years). The most frequently encountered tumor location was the upper rectum (Ra) in 99 patients (55.0%), followed by the lower rectum (Rb) in 74 patients (41.1%), and Rab in seven patients (3.9%). The TNM 7th T categories were T1 in 60 patients (33.3%), T2 in 41 patients (22.7%), T3 in 72 patients (40.0%), and T4 in seven patients (3.9%).

Regarding TNM staging, 78 patients (43.3%) were stage I, 42 patients (23.3%) were stage II, 53 patients (29.4%) were stage III, and seven patients (3.9%) were stage IV. The

Table 1. Baseline Characteristics of the 180 Patients who Underwent Surgical Resection for Rectal Cancer.

Variable	n=180
Sex (M/F)	115/65
Age (median)	63
BMI	23
PS	0.08
ASA	1.03
Ra/Rab/Rb	99/7/74
Distance of the tumor from the anal verge (cm) (median)	8
Operation AR/LAR/uLAR/ISR	5/134/15/26
T1/T2/T3/T4	60/41/72/7
Stage I/II/III/IV	78/42/53/7
AL	20 (11.1%)
SRC	14 (7.7%)
Ileus	15 (8.3%)
Posthospital stay (days) (median)	14
Mortality	1 (0.5%)

BMI: body mass index, PS: performance status, ASA: American Society of Anesthesiologists score
AR: anterior resection, LAR: lower anterior resection, uLAR: ultra-lower anterior resection
ISR: intersphincteric resection, AL: anastomotic leakage, SRC: stoma-related complication

Table 2. Characteristics and Outcomes of the Patients with and without Ileostomy.

	DS group 92	non-DS group 88	P
Sex	64/28	51/37	0.18
Age (median)	64	64	0.68
BMI	21.6	22.9	0.32
PS	0.06	0.09	0.76
ASA	1.05	1.08	0.52
Location (Ra/Rab/Rb)	20/7/65	79/0/9	＜0.0001
Distance of the tumor from the anal verge (cm) (median)	6	10	＜0.0001
Operation AR/LAR/uLAR/ISR	0/51/15/26	5/83/0/0	＜0.0001
OPEN/LAC	17/75	19/69	0.60
T1/T2/T3/T4	29/28/35/0	31/13/37/7	0.006
Stage I/II/III/IV	42/22/25/3	36/20/28/4	0.88
AL≥Grade 1-4	8	12	0.29
AL≥Grade 4	0	5	0.02
SRC	14	0	＜0.0001
Ileus	7	3	0.22
Posthospital stay (days) (median)	19	12	＜0.0001
Reoperation	3	6	0.27

BMI: body mass index, PS: performance status, ASA: American society of Anesthesiologists score
LAC: laparoscopic assisted colectomy, AL: anastomotic leakage, SRC: stoma-related complication

median distance of the tumor from the anal verge was 8 cm. As for complications, 20 patients (11.1%) suffered ALs. Fourteen patients (7.7%) presented with SRCs, and 15 patients (8.3%) developed postoperative ileus.

The median number of post-hospital stay days was 14 (1-114 days). One patient died of severe thrombosis on postoperative day 1.

Defunctioning stoma prevented severe anastomotic leakages

Loop ileostomy was performed in 92 patients (the DS group), and tumor resection without ileostomy was performed in 88 patients (the non-DS group). Short-term outcomes are shown in Table 2. Postsurgery, AL complications (i.e., CTCAE v4.0 ≥ Grade 4) occurred significantly less frequently in the DS group (0%) than in the non-DS group (5.7%; p = 0.02). However, there was no significant between-group difference in the rate of AL at CTCAE v4.0 ≥ Grade 1-4 containing symptomatic leakage (p = 0.29), as in a previous study[10].

Postoperative ileus occurred in seven patients (7.6%) in the DS group and three patients in the non-DS group (3.4%;

p = 0.22). SRCs occurred in 14 patients (15.2%) of the DS group. As for reoperation, two DS patients underwent a stoma closure for stoma stenosis and one DS patient underwent a stoma closure for dehydration. In the non-DS group, in contrast, five patients underwent an ileostomy because of AL and one patient in the non-DS group underwent an ileostomy because of an ileus. Thus, there were no significant differences regarding reoperation between the DS and non-DS groups (p = 0.27).

Stoma-related complications

The SRCs recorded are generally classified as early and late complications. Early complications include inappropriate location, skin excoriation, leakage, stoma retraction, dehydration, and stoma necrosis. The late complications include parastomal hernia, stomal prolapse, stenosis, and stoma site infection[11]. As shown in Table 3, the causes of SRCs were stenosis (n = 8), electrolyte imbalance (n = 5), and stoma site infection (n = 1).

Of note, two of the patients with stenosis showed repeated and worsening intestinal obstruction. The etiology of outlet stenosis can be temporal twisting/wrong orientation, adhesive kinking of a proximal limb, subcutaneous kink of a proximal limb, and tight abdominal wall fascia[12]. For two patients in our series, it was necessary to perform an operation for a new DS. In another case, a stoma closure was performed in advance. The single patient with an electrolyte imbalance underwent the same operation due to the repeated occurrence of dehydration.

Risk factors for prolonged postoperative hospital stay

Table 4 presents the results of the univariate analyses of the long hospital stay factors. This analysis demonstrated that the operation method (p = 0.01), operation with or without ileostomy (p < 0.0001), AL (p < 0.0001), SRC (p = 0.008), and ileus (p = 0.0004) were significant factors.

Table 4 also presents the results of the multivariate analysis of risk factors for a prolonged postoperative hospital stay. The analysis demonstrated that the presence or absence of ileostomy (p = 0.0002, OR 1.85; CI 1.34-2.57), Grade ≥ 1 AL (p < 0.0001, OR 9.24; CI 4.91-19.4), and SRC (p = 0.03, OR 1.84; CI 1.03-3.54) were independently predictive of short-term outcomes. In addition, postoperative ileus was also revealed to be a high-risk factor (p = 0.0006, OR 2.41; CI 1.43-4.35).

Table 3. Frequency (%) of Stoma-related Complications.

Stoma-related complication type	n=14
stoma stenosis	8
electrolyte imbalance	5
stoma site infection	1

Discussion

The use of defunctioning ileostomy is a common practice to reduce the risk of severe ALs in colorectal surgery[13]. However, the results of the present study remind us that SRCs also extend the short-term outcomes afforded by DS. With the use of laparoscopic methods to operate at an early stage of rectal cancer (even advanced cancer), obstructive complications of laparoscopically created ileostomy have been reported. Ng et al. noted that the frequency of these outlet obstructions is 5% and that it may be difficult to differentiate these complications from those of postoperative paralytic ileus. As they suggested, we also think that preventive laparoscopic procedures are important; for example, in order to take care of a large stoma tunnel, the use of a blind procedure with possible rotation during this maneuver and checking the orientation of the rest of the proximal small bowel after delivering the terminal ileum under the pneumoperitoneum are helpful. It is not until these operative procedures are performed that we can prevent ileostomy problems[12]. In the future, after sufficient data are obtained regarding long-term outcomes for advanced rectal cancer patients in several randomized clinical trials, including the COLOR II, ACOSOG-Z6051, and COREAN trials[14,15], the use of laparoscopic surgery will continue to increase, highlighting the need to pay greater attention to the risk of ALs and SRCs.

Mortality after AL is often high, ranging from 7.5% to 36%[16]. However, improvements in surgical techniques and devices have lessened the impact of ALs as a cause of death

Table 4. Association between Postoperative Hospital Stay and the Patient and Tumor Characteristics.

	Univariate	Multivariate	HR (CI)
With/without ileostomy	<0.0001	0.0002	1.85 (1.34-2.57)
T factor	0.32		
Stage	0.13		
AL	<0.0001	<0.0001	9.24 (4.91-19.4)
SRC	0.008	0.03	1.84 (1.03-3.54)
Ileus	0.0004	0.0006	2.41 (1.43-4.35)
Reoperation	0.0003	0.60	

AL: anastomotic leakage, SRC: stoma-related complication, HR: hazard ratio, CI: confidence interval

after rectal surgery. We note that Grade ≥ 4 AL was not selected by our multivariate analysis as a significant factor. The reason why a Grade ≥ 4 AL leads to a relatively shorter hospital stay may be that the salvage operation is performed as soon as possible to treat the AL before fatal peritonitis develops. These data suggest that the occurrence and management of AL are widely known by surgeons, because several studies showed that anastomotic dehiscence is the most serious complication of rectal resection[1,10]. However, little has been published discussing AL and SRCs at the same time.

Chude et al. noted that ileostomy-related problems were minor from the standpoint of morbidity and mortality[17]. Our present findings indicate that SRCs are occasionally major problems that prolong the patient's hospitalization. Moreover, the routine creation of a stoma will reduce the quality of life even in patients in whom no complications occur. Despite the non-routine use of fecal diversion, stoma placement itself remains a source of morbidity. In addition, the closure of a DS requires a second hospital stay, and additional surgery and is accompanied by considerable patient management costs[1].

Chow et al. demonstrated in their systematic review that 17.3% of patients with temporary ileostomies are also at risk for complications associated with a second operation for ileostomy closure[18]. In a study by Platell et al., among their cohort of patients undergoing colorectal surgery, more than 90% derived no benefit from their DS[19]. We speculate that colorectal surgeons should perhaps adopt a more selective approach to the use of a DS to protect an anastomosis.

Based on the data obtained here in our retrospective study, we recognized that DS is a 'friend' that helps prevent severe ALs, but on the other hand DS may be a 'foe' causing complications. The use of a defunctioning loop ileostomy in patients undergoing rectal surgery with anastomosis prevents severe AL and has low morbidity. However, the consequences of stoma reversal should not be underestimated.

Conflicts of Interest

There are no conflicts of interest.

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