

# Diverting Stoma Complications in Rectal Cancer Surgery.

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## Research Article

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# Abstract

**Background:** A consensus regarding diverting stoma (DS) construction in rectal cancer surgery was reached to avoid reoperation related to anastomotic leakage. However, the incidence of stoma-related complications (SRCs) remains high. In this study, we aimed to examine the perioperative outcomes of DS construction in patients who underwent sphincter-preserving surgery for rectal cancer.

**Methods:** Between 2005 and 2017, we included 400 participants who underwent radical sphincter-preserving surgery for rectal cancer. These participants were divided into two groups: DS (+) and DS (-) groups, and the outcomes, including postoperative complications (POCs), were compared.

**Results and conclusion:** The incidence of ileus was higher in the DS (+) group ( $P < 0.01$ ); however, no patient showed anastomotic leakage of grade 3. Furthermore, early SRCs were observed in 33 patients (21.6%) and bowel obstruction-related stoma outlet syndrome occurred in 19 patients (12.4%). There was no intergroup difference in the incidence of grade 3b POCs. However, the most common reason for reoperation was different in the two groups: anastomotic leakage in 91.7% of patients with 3b POCs in the DS (-) group, and SRCs in 85.7% of patients with 3b POCs in the DS (+) group.

In patients with DS, there was an increase in the incidence of overall POCs, severe POCs (grade 3), and bowel obstruction, including stoma outlet syndrome, compared to patients without DS. Therefore, it is important to construct an appropriate DS to avoid SRCs and to be more selective in assigning patients for DS construction.

## Introduction

In recent years, the development of surgical instruments and operation techniques for lower rectal cancer surgery has led to sphincter preservation (1). Consequently, the number of cases requiring diverting stoma (DS) has increased. A consensus was reached regarding DS construction during rectal cancer surgery to prevent severe peritonitis related to anastomotic leakage (AL) (2-5). AL significantly reduces patient quality of life (QOL); therefore, the prevention of AL-related severe peritonitis is crucial. Moreover, stoma-related complications (SRCs) can reduce patient QOL. As reported in numerous studies, the incidence of SRCs is between 21% and 70% (6, 7). The onset rate of SRCs reported by different studies varies greatly, with a small number of reported cases. The benefits of DS construction over the effects of SRCs remain unelucidated.

We retrospectively compared the short-term outcomes of sphincter-preserving surgery for rectal cancer in patients managed with and without DS.

## Materials And Methods

We retrospectively enrolled 400 participants who underwent radical sphincter-preserving surgery for rectal cancer between 2005 and 2017. We excluded patients who underwent emergency surgery, transanal ileus

tube insertion, or colonic stent placement for obstructive colorectal cancer. DS construction was indicated in patients lower tumor margin was  $\leq 5$  cm from the anus, those receiving preoperative treatment (chemoradiotherapy (CRT) or neo-adjuvant chemotherapy (NAC)), those with malnutrition, those on steroid therapy, and those with AL on intraoperative examination. However, surgeons were responsible for the final decision of DS construction.

The case that there is possibility of the stoma construction in does a stoma site marking beforehand. A circular skin incision cut about 3cm in diameter in the part. Rectus abdominis anterior sheath is cut in lengthwise direction, and split rectus abdominis muscle. And we construct the tunnel where 2 fingers enter the intraperitoneal enough. Ileum end or transvers colon is selected as a stoma and construct loop stoma. As much as possible oral side is twisted to caudal. When ileum is selected as a stoma, we use ileum from the ileum end around 30-40cm.

The participants were divided into two groups: DS (-) and DS (+) groups. Intergroup comparisons were made for patient background (age, gender, body mass index (BMI), tumor location, CRT or NAC use, and p Stage), perioperative factors (procedure type, use of lateral lymph node dissection, surgical approach, operative time, volume of intraoperative blood loss, and ano-anastomotic distance (measured intraoperatively using an endoscope)), and postoperative course (interval until the start of oral ingestion, postoperative hospitalization period, postoperative complications, and reoperation). With respect to tumor location, the rectum was classified into rectosigmoid (RS), upper rectum (Ra), and lower rectum (Rb) (8). Cancer staging was undertaken using the 8<sup>th</sup> edition of the American Joint Committee on Cancer, tumor-node-metastasis staging system, and the 2017 World Health Organization classification (9). Postoperative complications (POCs) were examined using CTCAE v4.0 (National Cancer Institute, Bethesda, MD, U.S.A.) (10). Furthermore, patients with intestinal obstruction related to the stenosis of DS excretory pore were considered to have stoma outlet syndrome. Among POCs, this syndrome was analyzed as a type of bowel obstruction, and infection-related stoma separation was analyzed as a type of surgical site infection (SSI).

Furthermore, SRCs were investigated in DS (+) group patients, and the SRCs that developed within 30 days post-surgery were defined as early complications. SRCs were also examined in patients who underwent reoperation, those with a prolonged time to DS reversal, and those in whom DS reversal was impossible.

This retrospective study was approved by Juntendo University Institutional Review Board, and the requirement for patient consent was waived. And all methods were performed in accordance with the relevant guidelines and regulations

For statistical analysis, the chi-square test and Fisher's exact test were used to compare categorical variables, whereas the Student's t-test was used to compare continuous variables. A p-value of 0.05 was considered significant. We used JMP version 10 software (SAS Institute Inc. Cary, NC) for statistical analyses.

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

## Results

Table 1 shows the patient background. The median patient age was 64 years (range, 25–86 years). The participants consisted of 267 men and 133 women. The median BMI of the patients was 23.0 kg/m<sup>2</sup> (14.3 to 34.4 kg/m<sup>2</sup>). The tumors were located in the RS, Ra, and Rb in 115, 172, and 112 patients, respectively. The laparoscopic approach was adopted in 272 patients (68%). Concerning the surgical procedure, low anterior resection, high anterior resection, and intersphincteric resection were performed in 308 (77.0%), 55 (13.8%), and 37 (9.3%) patients, respectively. Furthermore, DS was constructed in 153 (38.3%) patients. Overall, POCs were identified in 120 (30%) patients, leading to reoperation in 19 (4.8%) patients. One case of patient death was recorded due to cerebral hemorrhage.

The characteristics of patients in the DS (-) and DS (+) groups are shown in Table 2. There were no significant intergroup differences in age, gender, or BMI. Regarding the distribution of tumor location, the proportion of patients with Rb tumors was significantly higher in the DS (+) group ( $p < 0.01$ ). The choice of preoperative treatment, including CRT and NAC, was significantly different in the two groups ( $p < 0.01$ ). The p Stage was I, II, III, and IV in 67, 65, 85, and 18 patients in the DS (-) group, and 62, 39, 45, and 7 patients in the DS (+) group, respectively ( $p = 0.03$ ).

The surgical outcomes of patients in the DS (-) and DS (+) groups are shown in Table 3. There were intergroup differences in the distribution of surgical procedure type, performance rate of lateral lymph node dissection, and laparoscopic approach rate. The operative time was significantly longer in patients in the DS (+) group (268 min vs. 405 min,  $p < 0.01$ ); nonetheless, the volume of blood loss was not significantly different (30 mL vs. 50 mL,  $p = 0.84$ ). Furthermore, the ano-anastomotic distance was significantly smaller in patients in the DS (+) group (8 cm vs. 4 cm,  $p < 0.01$ ).

Short-term outcomes of DS construction are shown in Table 4. Oral ingestion was started on postoperative day 6 (4 to 41) in the DS (-) group and on postoperative day 4 (2 to 18) in the DS (+) group. This demonstrated that the time to oral ingestion was significantly shorter in the DS (+) group ( $p = 0.01$ ).

POCs with grade >4 was detected in 1 patient in the DS (+) group. Moreover, the number of patients with grade 1-3 POCs was significantly higher in the DS (+) group. However, there was no significant intergroup difference in the number of patients with POCs grade 3b (12 vs. 7,  $p = 0.90$ ). There was no significant intergroup difference in the proportion of patients with AL of all grades (10.9% vs. 15.0%,  $p = 0.31$ ); the proportion of patients with AL grade 3b was significantly higher in the DS (-) group (4.5% vs. 0%,  $p = 0.01$ ). On the other hand, to patients occurring bowel obstruction, not only the incidence of all grade but also the incidence of grade 3, were significantly higher in the DS (+) group (4.0% vs. 25.5%,  $p < 0.01$ , 2.4% vs. 17.0%,  $p < 0.01$ , respectively).

However, there were no significant intergroup differences in the incidences of SSI and micturition disorders. The postoperative hospitalization period was significantly shorter in the DS (-) group (12 days vs. 15 days,  $p=0.02$ ).

Reoperation was required in 12 (4.9%) and 7 (4.6%) patients in the DS (-) and DS (+) groups, respectively, which was not significantly different between the groups ( $p=0.90$ ). Reoperation factors in the DS (-) group included AL (11 cases) and adhesive bowel obstruction (1 case). In the DS (+) group, reoperation factors included stoma outlet syndrome (4 cases), electrolyte imbalance (1 case), mucocutaneous stoma separation (1 case), and intraperitoneal hematoma (1 case); moreover, reoperation was required for SRCs in 6 of the 7 patients (Table 5).

Early complications were observed in 33 patients (21.6%): stoma outlet syndrome (19 cases, 12.4%), electrolyte imbalance (7 cases, 4.6%), peristomal dermatitis (6 cases, 3.9%), and infection-related stoma separation (1 case, 0.7%). Neither hemorrhage nor necrosis was reported in these patients (Table 5). As a late complication, parastomal hernia was noted in 3 patients (2.0%). Neither prolapse nor fistula formation was noted.

The median follow-up time after DS construction was 229 (range, 10–2,331) days. In 145 (94.8%) of the 153 patients, DS reversal was achieved. In 8 patients (5.2%), a DS was left due to death cause by other disease (3 cases), refractory fistulae (2 cases), stage IV cancer (2 cases), and the patient's request (1 case).

## Discussion

Sphincter-preserving surgery is selected for patients with lower rectal cancer due to recent advances in the use of automatic staplers and the widespread indications for laparoscopic or robotic surgery. Consequently, DS construction is being performed in an increasing number of patients. Furthermore, advances in preoperative treatment (CRT and NAC) might also have accelerated the increase in the number of DS construction procedures, considering an adverse-reaction-related delay in wound healing. The incidence of SRCs was previously reported to be between 21% and 70% (6, 7, 11).

In this study, DS construction was also frequently selected for patients with advanced lower rectal tumors who underwent preoperative treatment or in whom lateral lymph node dissection was simultaneously scheduled. This might have depended on the tumor location and oncological factors.

In previous studies, DS construction in sphincter-preserving surgery for rectal cancer reduced the risk of severe peritonitis related to AL (7, 12, 13). However, there is no precise means to identify which patients will benefit from a dysfunctional stoma. In our study, although the incidence of overall AL was similar in patients with and without DS, the incidence of severe AL (grade3) was significantly higher in patients without DS.

Conversely, patients with DS were more likely to develop POCs, which were categorized in the overall grade. Furthermore, the incidence of patients with ileus, which was categorized in both grade 2 and 3, was significantly higher in patients with DS. It was considered that these factors were related to the additional procedure of stoma construction. Furthermore, diverting loop ileostomy construction (96.7%) was more frequently performed than loop colostomy, and stoma outlet syndrome occurred in 19 of 33 patients (57.6%) with SRCs. Fujii et al. (14) reported that adhesions and twisting of the ileostomy were the causes of stoma outlet obstruction, and loop ileostomy was reported as an independent risk factor for stoma outlet syndrome (15).

The postoperative hospitalization period was significantly longer in patients in the DS (+) group. First, it was initially considered that patients with all grades of bowel obstruction, including stoma outlet syndrome, were more common in the DS (+) group. Once bowel obstruction occurred, hospitalization might have been prolonged by intestinal peristalsis and interruption of oral intake, even though the patients were conservatively treated with ileus tube insertion or tubing of the DS afferent loop. Second, patients and families take time to learn about stoma management during hospitalization. Cirocchi et al. (16) also reported similar results. However, Hignett et al. noted no prolongation of the admission period (17). These differences might have also been associated with the patient's background or region.

There was no significant intergroup difference in the number of reoperations. In the DS (+) group, no patient required reoperation due to AL, and this corroborated with the findings of Shiomi et al. (12). However, reoperation related to SRCs was required in our study. In addition, AL was a reoperation factor in 11 of 12 patients (91.7%) in the DS (-) group, whereas reoperation related to SRCs accounted for 85.7% (n=6) of the 7 patients in the DS (+) group. In patients with SRCs, the anastomosis was confirmed prior to reoperation. Four cases with AL necessitated DS reconstruction. Three patients without AL underwent DS closure.

In our study, stoma outlet syndrome improved in 80% of patients after conservative treatment such as tube placement, and this was the most common SRCs. However, four patients required reoperation. The use of an operation technique that does not cause stoma outlet syndrome is crucial. We had a case wherein a patient was reoperated using several devices for DS construction (this was one of the limitations of our study). Furthermore, we introduce other articles of devices used for DS creation. It was reported that stoma outlet syndrome could be prevented by avoiding twists during intestinal elevation; ameliorating stoma construction procedures, such as the angle of approaching the abdominal wall, handling subcutaneous fat thickness; or applying a DS for cases concerning the colon (11, 14). Furthermore, it may be important to perform DS involving a change of the elevated intestinal tract while considering methods other than the use of a DS and patient background such as age (18-20).

DS reversal was impossible in 8 patients (5.2%) in this study. Gadan reported a reversal impossibility rate of 18% (20/110 cases) (21). The DS reversal rate in our study was higher than that reported in their study; however, DS reversal was achieved within 6 months after surgery in 55 patients (35.9%) and  $\geq 2$  years after surgery in many patients. This was possibly due to the follow-up period and because the opinions of

the attending physicians regarding DS reversal were not standardized in the initial follow-up phase. DS reversal after treatment was expected in patients who underwent adjuvant chemotherapy.

This study has some limitations. First, we included a small number of cases and the deflection of the race. Moreover, we conducted a retrospective and single-center study. The DS procedure gradually changed over time. For example, DS was created ileum of the distal part from ileocecal valve (about 40-50 cm), and oral side of intestinal tract lifted more naturally position without being concerned with caudalis. Finally, after re-observation, we confirmed that there was no torsion of the DS. Therefore, it is necessary to conduct a prospective study with a large number of cases wherein a standardized DS indication and procedure is used.

## **Conclusion**

In rectal cancer surgery, the use of a DS helped prevent severe peritonitis related to AL and led to an early start of oral ingestion; nonetheless, it did not reduce the postoperative hospitalization period. Furthermore, postoperative complications included an increase in the incidence of bowel obstruction, including stoma outlet syndrome, in patients in the DS (+) group and SRCs-related reoperation was required in some patients. Therefore, it is important to construct an appropriate DS to avoid SRCs and to select patients for whom a DS should be constructed.

## **Declarations**

### **Disclosure**

The authors declare no conflicts of interest associated with this manuscript. And all authors have no funding.

### **Consent for publication:**

All study participants provided informed consent.

### **Availability of data and materials:**

The datasets during and/or analysed during the current study available from the corresponding author on reasonable request.

### **Competing interests:**

All author report no conflict of interest related to our manuscript.

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### **Author Contributions:**

M.K: Conceptualization, Methodology, Formal analysis, Investigation, Data Curation and Writing – Original Draft. K.S: Writing – Review & Editing. K.H: Investigation. Y.O: Investigation. R.T: Investigation. S.K: Methodology. S.M: Methodology. K.S: Methodology. S.I: Methodology. M.T: Writing – Review & Editing. Y.K: Writing – Review & Editing. Y.T: Writing – Review & Editing.

### **Ethics approval and consent to participate:**

The study design was approved by an ethics review board.

Ethics Review Board of Juntendo University Medical School Hospital: 14-172

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## Tables

Due to technical limitations, table 1 to 5 is only available as a download in the Supplemental Files section.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table15.xlsx](#)