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Risk of Outlet Obstruction Associated With Defunctioning Loop Ileostomy in Rectal Cancer Surgery

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Abstract. *Background: The outlet obstruction (OO) rate is 5.4-18.4% after defunctioning ileostomy (DI) following rectal cancer resection to reduce the incidence and severity of anastomotic leakage; OO affects a patient's quality of life and prolongs hospitalization. Patients and Methods: A retrospective analysis was performed of patients who underwent anterior rectal resection and DI for rectal cancer. Results: Among 100 patients undergoing anterior rectal resection with DI for rectal cancer, 28 (28%) developed OO. Anastomotic leakage and a rectus abdominis muscle thickness ≥10 mm on preoperative computed tomography were significantly associated with the risk of OO in univariate analysis. Multivariate analysis also demonstrated that anastomotic leakage (odds ratio=4.320, 95% confidence interval=1.280-14.60, p=0.019) and rectus abdominis muscle thickness ≥10 mm (odds ratio=3.710, 95% confidence intervaI=1.280-10.70, p=0.016) were significantly risk factors for OO. Conclusion: When OO is observed, an anastomotic leakage should be suspected, especially if there is a high rectus abdominis muscle thickness.*

More patients are now undergoing sphincter-preserving surgery for rectal cancer to avoid the need for a permanent stoma. However, this surgery is more difficult when the cancer is close to the anal verge (1-3), with an anastomotic leakage rate of 6-14% (4-7). When anastomotic leakage does occur, it is extremely serious and can worsen not only short-term outcomes, such as reoperation and duration of hospitalization, but also the long-term outcomes, such as local recurrence and concurrently, cancer-specific survival (6-9). Defunctioning ileostomy (DI) reduces the rate of symptomatic anastomotic leakage and the need for urgent reoperation by reducing the severity of anastomotic leakage (10-13). In recent years, with the increase in sphincter-preserving surgery for rectal cancer, DI has become a frequent procedure. However, stoma-related complications occur in 20-70% of all stoma cases (14), affect quality of life, and increase the financial burden (15-18). Among stoma-related complications, outlet obstruction (OO) is particularly problematic after loop ileostomy. OO, defined as a bowel obstruction at the stoma opening, occurs in 5.4-18.4% of cases (19-22). It leads to distress and prolonged hospital stay for the patient. Risk factors for OO have not been sufficiently investigated. Thus, the aim of this study was to identify the risk factors for OO.

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Key Words: Outlet obstruction, rectal cancer, defunctioning ileostomy, loop ileostomy.

Patients and Methods

A retrospective single-center study was conducted to examine patients who underwent anterior rectal resection and DI for rectal cancer between January 2014 and December 2020 at Jikei University Daisan Hospital in Japan. Data were obtained from a prospectively collected database and electronic medical records.

The stoma site was marked preoperatively by wound ostomy care nurses. Rectal cancer surgery was performed with total mesorectal excision and rectal reconstruction with a double-stapled colorectal or a handsewn coloanal anastomosis. Loop ileostomy was created in patients who required very low anastomoses or for whom there were technical difficulties (bulky tumor, narrow pelvis, positive air leak test, or incomplete anastomotic ring). A loop ileostomy was constructed using the distal ileum (approximately 30-40 cm from Bauhin's valve), which was lifted through a divided incision of the *rectus abdominis* at the planned stoma site without torsion. The proximal limb of the ileum was oriented according to the surgeon's preference. To prevent stenosis, the ileostomy aperture was sized to easily allow for the passage of two fingers. The limbs were not sutured to the *rectus abdominis* fascia.

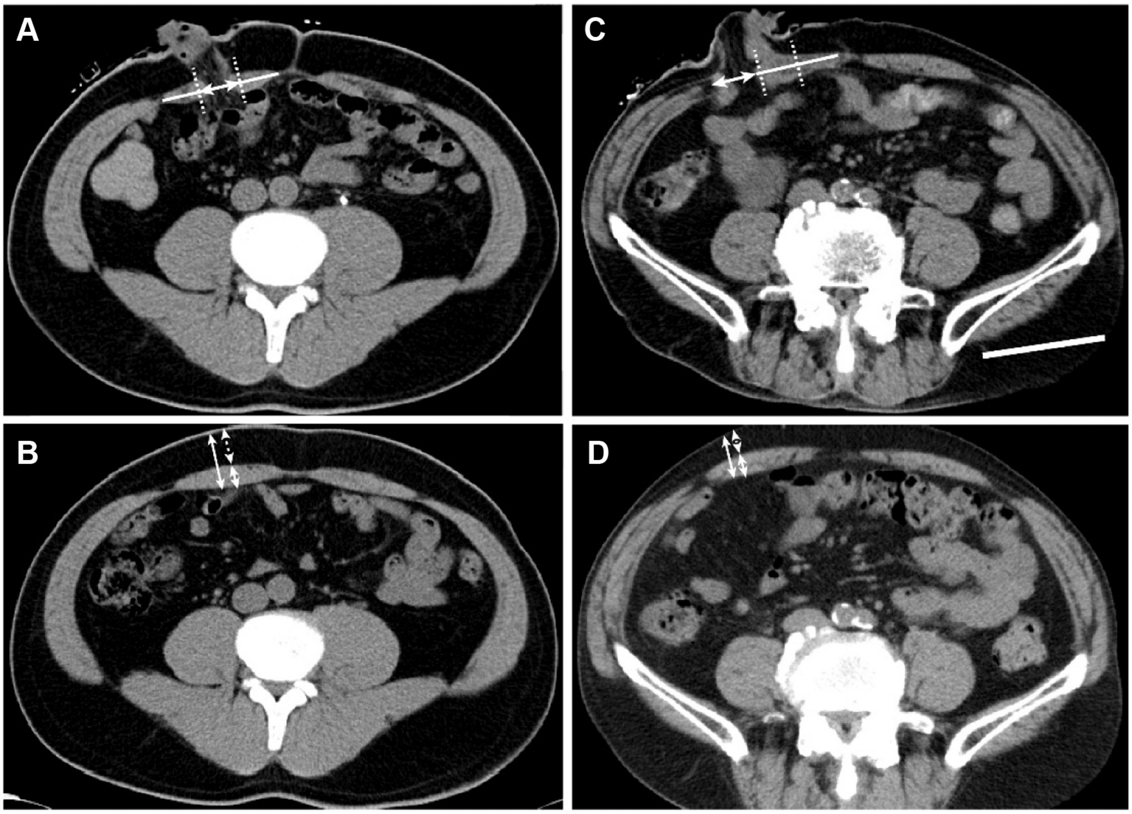

Figure 1. *Definition of the stoma position and method for measuring the thickness of the abdominal wall. A: In this patient, the stoma ran through the middle of the rectus abdominis muscle. B: Preoperative computed tomography of the patient in part A. The thickness of the abdominal wall was measured in the middle of the rectus abdominis muscle where the stoma was created. C: In this patient, the stoma ran through the lateral side of the rectus abdominis muscle. D: Preoperative computed tomography of the patient in part C. The thickness of the abdominal wall was measured on the lateral side of the rectus abdominis muscle where the stoma was created.*

OO following DI was diagnosed based on the following two criteria: (i) clinical symptoms of bowel obstruction such as nausea, vomiting and abdominal pain, and (ii) computed tomography (CT) or/and enema examinations of the ileostomy that showed dilatation of the small bowel just proximal to the ileostomy opening.

There is no consensus on the definition of high-output stoma (HOS). In this study, HOS was diagnosed based on an output of ≥2,000 ml/day. All patients with a clinical suspicion of anastomotic leakage underwent one or more of the following examinations: Gastrografin enema, injection of contrast through the drain, and CT.

The patients were classified into two groups, namely, the OO group and the non-OO group. The following data were collected to compare clinical and surgical outcomes between the two groups: Age at surgery, sex, body mass index, history of diabetes, treatment with neoadjuvant chemoradiotherapy, tumor location, TNM classification (23), type of surgery, anastomosis and approach, operation time, estimated blood loss, postoperative complications, location and direction of the stoma, site where the stoma passed through the *rectus abdominis* muscle, thickness of the abdominal wall, thickness of the subcutaneous fat, thickness of the *rectus abdominis* muscle, and postoperative hospital stay.

The thickness of the abdominal wall, the subcutaneous fat, and the *rectus abdominis* muscle at the stoma site was estimated on axial preoperative CT images. A vertical line was drawn from the skin to the dorsal surface of the *rectus abdominis*, and the distance from the anterior to the posterior margin of this muscle was measured at the level of the stoma (Figure 1). The thickness of the subcutaneous fat and abdominal wall was also measured at the same level. A receiver operating characteristic curve was constructed to determine the appropriate cut-off value for these measured thicknesses.

All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (R Foundation for Statistical Computing, Vienna, Austria) (24).

Demographic data, clinical variables and operative measures were collected for all patients. Depending on the distribution of the data, continuous data are reported as medians with ranges. Categorical data are reported as counts and percentages. Univariate analyses were performed using Fisher's exact test or the Mann–Whitney U-test to compare the OO and non-OO groups. Univariate logistic regression was performed to identify risk factors for OO. Potential risk factors detected by univariate analysis were then entered into a multivariate logistic model to identify independent risk factors for OO. Statistical significance was defined as $p<0.05$. The severity of anastomotic leakage and OO were classified according to the Clavien–Dindo classification system (25).

Table I. *Clinical data of the 100 included patients.*

Variable	Value
Age (years), median (range)	
Median (range)	60.5 (50-89)
Gender, n	
Male	73
Female	27
Body mass index, kg/m^2	
Median (range)	22.1 (19.0-39.4)
Diabetes, n	
Yes	24
Preoperative CRT, n	
Yes	14
Lower rectum	22
Tumor location, n	
Middle rectum	69
Upper rectum	9
≥cT3, n	
Yes	57
cN+, n	
Yes	29
TNM stage	
I	37
II	32
III	25
IV	6
Type of resection, n	
Low anterior	90
Intersphincteric	8
Total proctocolectomy	1
Total pelvic dissection	1
Approach, n	
Open	19
Laparoscopic	81
Double stapling technique, n	
Stapled anastomosis	92
Hand-sewn anastomosis	8
Lateral lymph node dissection, n	
Yes	12
Operation time, min	
Median (range)	290 (166-601)
Blood loss, ml	
Median (range)	5 (0-2726)

CRT: Chemoradiotherapy.

The study protocol was approved by the Ethics Committee of the Jikei University Hospital [registration no. 30-249 (9270)]. The requirement for informed consent was waived owing to the retrospective nature of this study.

Results

During the study period, 100 patients underwent anterior rectal resection and cDI for rectal cancer. Table I outlines the clinical data of the patients in this study. Seventy-three patients (73.0%) were male, with a median age of 60.5 (range=50-89) years and a median body mass index of 22.1 (range=19.0-39.4) kg/m^2. A laparoscopic approach was used in 81 patients (81.0%). Double-stapling anastomosis was performed in 92 patients (92.0%), and hand-sewn coloanal anastomosis was performed in eight patients (8.0%).

Table II. *Stoma-related factors and findings from computed tomography.*

Variable	Value
Stoma site, n	
Lower right side	92
Upper right side	5
Lower left side	3
Stoma direction, n	
Oral-cranial	97
Oral-caudal	3
Site of stoma through *rectus abdominis*, n	
Middle	58
Lateral	42
Median thickness (range), mm	
Abdominal wall	25.05 (10.29-49.31)
Subcutaneous fat	16.05 (4.06-41.86)
Rectus abdominis	8.56 (2.35-14.98)

Table III. *Postoperative complications.*

Variable	Frequency
Outlet obstruction (n=28)	
Clavien–Dindo grade II	6
Clavien–Dindo grade IIIa	18
Clavien–Dindo grade ≥IIIb	4
Anastomotic leakage (n=16)	
Clavien–Dindo grade II or IIIa	16
Clavien–Dindo grade ≥IIIb	0
High-output stoma	
Yes	34

Table II outlines the stoma-related factors and findings from CT scans. The stoma was created on the lower right side in ninety-two patients (92.0%) and in the oral-cranial direction in ninety-seven patients (97.0%). The stoma passed through the middle of the *rectus abdominis* muscle in fifty-eight patients (58.0%). The exact thicknesses of the subcutaneous fat and the *rectus abdominis* muscle at the marked stoma site that were 10 mm or more were 16.1 (range=4.1-41.9) mm and 8.6 (range=2.4-15.0) mm, respectively.

Table III outlines the postoperative complications. OO was observed in 28.0% of patients, with four patients undergoing stoma closure during hospitalization. Eighteen patients had either a stoma or a nasogastric decompression tube placed. Anastomotic leakage was observed in sixteen patients (16.0%). None of the patients required emergency surgery. An HOS was observed in thirty-four patients (34.0%), and 50% of OO cases were combined with an HOS.

Table IV. *Comparison of the groups with and without outlet obstruction (OO).*

Variable		OO group	Non-OO group	*p*-Value
Age, years	Median (range)	69.5 (50-89)	71.0 (43-87)	0.591
Gender, n (%)	Male	22 (78.6)	51 (70.8)	0.616
Body mass index, kg/m^2	Median (range)	21.4 (15.9-32.2)	21.8 (15.5-39.4)	0.721
Diabetes, n (%)	Yes	4 (14.3)	20 (27.8)	0.198
Preoperative CRT, n (%)	Yes	4 (14.3)	10 (13.9)	>0.99
Lower rectum, n (%)	Yes	4 (14.3)	18 (25.0)	0.294
Laparoscopic surgery, n (%)	Yes	23 (82.1)	58 (80.6)	>0.99
Stapled anastomosis, n (%)	Yes	26 (92.9)	66 (91.7)	>0.99
Lateral lymph node dissection, n (%)	Yes	3 (10.7)	9 (12.5)	>0.99
Operative time, min	Median (range)	292 (190-601)	290 (166-547)	0.512
Blood loss, ml	Median (range)	5 (0-2726)	5 (0-2572)	0.956
Anastomotic leakage, n (%)	Yes	9 (32.1)	7 (9.7)	**0.012**
High-output stoma, n (%)	Yes	14 (50.0)	20 (27.8)	0.059
Postoperative hospitalization, days	Median (range)	28 (17-94)	21 (10-60)	**<0.001**
Site of stoma through *rectus abdominis*, n (%)	Middle	15 (53.6)	43 (59.7)	0.654
Median thickness (range), mm	Abdominal wall	24.6 (11.0-45.4)	25.1 (10.3-49.3)	0.997
	Subcutaneous fat	15.0 (4.1-36.7)	16.1 (4.9-41.9)	0.420
	Rectus abdominis	9.5 (4.1-14.6)	8.1 (2.4-15.0)	**0.018**

CRT: Chemoradiotherapy. Statistically significant *p*-values are shown in bold.

Table V. *Univariate and multivariate analyses of risk factors for outlet obstruction.*

Variable		Univariate analysis			Multivariate analysis		
	Event rate %	OR	95% CI	*p*-Value	OR	95% CI	*p*-Value
Age ≥75 years	6 (21.4)	0.486	0.143-1.446	0.232			
Male gender	22 (78.6)	1.504	0.495-5.193	0.616			
BMI ≥25 kg/m^2	5 (17.9)	0.828	0.210-2.767	>0.99			
Diabetes	4 (14.3)	0.437	0.098-1.507	0.198	0.301	0.079-1.150	0.080
Anastomotic leakage	9 (32.1)	4.320	1.247-15.69	**0.012**	4.160	1.270-13.60	**0.018**
Abdominal wall thickness ≥32.5 mm	5 (17.9)	0.706	0.182-2.314	0.602			
Subcutaneous fat thickness ≥25.6 mm	2 (7.1)	0.352	0.036-1.732	0.223			
Rectus abdominis thickness ≥10 mm	14 (50)	4.074	1.448-11.78	**0.005**	4.350	1.580-12.00	**0.005**

BMI: Body mass index; CI: confidence intervaI; OR: odds ratio. Statistically significant *p*-values are shown in bold.

Table IV shows a comparison of the OO and non-OO groups. Anastomotic leakage was observed in significantly more patients in the OO group (32.1% *vs.* 9.7%, *p*=0.012). The duration of postoperative hospitalization was 21 (range=10-60) days for the non-OO group and 28 (range=21-94) days for the OO group, with a significantly longer hospital stay in the OO group (*p*<0.001). The *rectus abdominis* muscle was significantly thicker in the OO group (*p*=0.018).

Table V shows the risk factors for OO in rectal cancer surgery. In the univariate analysis, a *rectus abdominis* muscle thickness of 10 mm or more (*p*=0.003) and anastomotic leakage (*p*=0.009) were significantly associated with the occurrence of OO. Both of these factors were independent risk factors for OO in the multivariate analysis (odds ratio=3.710, 95% CI=1.280-10.70, *p*=0.016; and odds ratio=4.320, 95% confidence intervaI=1.280-14.60, *p*=0.019, respectively). No significant associations were found for the other factors.

Discussion

In the present study, a *rectus abdominis* muscle thickness at the marked stoma site of 10 mm or more was found to be a risk factor for OO. There are two other studies that have investigated the thickness of abdominal wall structures on CT scans. One stated that thick subcutaneous fat at the stoma site (vertical distance ≥20 mm) was a risk factor for OO (19). However, that study did not evaluate the thickness of the *rectus abdominis* muscle. Another found that a *rectus abdominis* muscle thicker than 10 mm at the umbilicus level is a risk factor (22). In that study, the thickness of the *rectus abdominis* muscle was measured at the stoma site; thus, the measurement was obtained from a different site. However, a thick *rectus abdominis* muscle was a risk factor in both studies. The tightening and narrowing of the stoma outlet by the *rectus abdominis* muscle may be associated with the cause of OO.

Suwa *et al*. suggested that anatomically, there is a strong posterior sheath at the level of or just caudal to the umbilicus, which predisposes patients to OO (26). In our study, the stoma was placed in these positions in many cases, which may be the reason for the high incidence of OO. If the stoma is created in the area of the strong posterior sheath or if the *rectus abdominis* muscle is thicker than 10 mm, a larger *rectus abdominis* separation may be a better approach. Further research is needed to confirm this theory.

Anastomotic leakage was found to be another risk factor for OO. Hara *et al*. reported that intraperitoneal infection was associated with the cause of OO, and the reason for this is that inflammation of the small intestine due to anastomotic leakage or pelvic abscess can increase mucosal edema (21). After stoma creation, mucosal edema is usually most severe on the third or fourth postoperative day and decreases from approximately the seventh postoperative day, taking one to several months for the edema to disappear (27). Anastomotic leakage is often evident within 7 days postoperatively, and inflammation of the small bowel at this time may lead to more mucosal edema and trigger the development of OO. When OO develops, a temporary decompression tube is effective (21, 22), and if the tube is removed later, the stoma can be tube-free without recurrence of OO. This clearly shows that mucosal edema is a factor in the development of OO.

HOS occurs early in the postoperative period and usually improves with time. In our study, half of the patients had both OO and HOS. OO can also trigger an HOS. In other words, OO may cause mucosal edema, which may lead to the development of an HOS. Reports suggest that the output of ileostomy peaks on the fourth day after surgery and then decreases on the ninth or tenth day (28). In this study, there was a median output peaked on day 3, and the median maximum drainage volume was 2,970 (2,100-5,900) ml in patients with an HOS. In the period of increased intestinal fluid production and mucosal edema, OO may occur due to an intolerance to the high fluid volume, even if the narrowing of the stoma due to mucosal edema is mild. It can be assumed that HOS and OO are interrelated.

Another interesting feature of HOS and OO should be noted. Overall, four out of 16 (25%) patients with anastomotic leakage had a combination of OO and HOS, and 13/16 (81.3%) had an OO or HOS in this study. Therefore, HOS and OO may be useful as early signs of anastomotic leakage. In other words, it is better to perform an examination if an anastomotic leakage is suspected.

Our study has several limitations worth mentioning. Firstly, this was a retrospective study conducted at a single center. Secondly, the sample size was a relatively small. Thirdly, factors predicted to be related to the development of OO, such as the surgeon's experience, presence of stoma torsion, length of the *rectus abdominis* sheath incision and degree of *rectus abdominis* muscle separation, and degree of mucosal edema, were not evaluated.

In conclusion, the results of this study suggest that thickness of the *rectus abdominis* muscle contributes to the prediction of OO. If an OO is observed, an anastomotic leakage should be suspected. OO prolongs the length of hospitalization and affects patient quality of life. Furthermore, OO delays the start of adjuvant chemotherapy and might worsen the patient's prognosis. Methods to prevent OO will hopefully be identified in the future.

Conflicts of Interest

No potential conflicts of interest are reported by the Authors.

Authors' Contributions

H. Enomoto and K. Suwa contributed equally to the article. Hiroya Enomoto and Katsuhito Suwa collected and interpreted the data and wrote the article. Nana Takeuchi, Yoshito Hannya, Yuhei Tsukazaki, Takuro Ushigome, Tomoyoshi Okamoto and Ken Eto made substantial contributions to the conception and design of the study, and they were involved in drafting the article and revising it critically for important intellectual content. All Authors declare that they contributed to this article and that they approve the final submitted version.

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