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Utility of Transanal Tube for Preventing Severe Anastomotic Leakage Following Low Anterior Resection for Patients With Diverting Stoma

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Purpose: The incidence of anastomotic leakage (AL) associated with sphincter-preserving surgery has increased. Diverting stoma (DS) and transanal tube (TT) placement have been reported to reduce the rate of AL. This multicenter study examined the efficacy of TT and DS for preventing AL in rectal cancer patients.

Methods: We reviewed 126 patients who underwent low anterior resection with double-stapling reconstruction between April 2016 and March 2020. Patients were divided into 2 groups according to presence (n = 90) or absence (n = 36) of a TT. Clinicopathologic features were compared between groups.

Results: Twenty-one patients (16.7%) experienced AL. Frequency of severe AL was significantly lower in the TT group (7.7%) than in the non-TT group (19.4%, $P < 0.001$). Performance status, operation time, blood loss, and hospital stay were similar between groups. Patients who experienced AL showed significantly longer hospital stays (29 days

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versus 15 days, $P < 0.001$). Multivariate analysis revealed placement of a TT as an independent predictor of no AL (odds ratio, 0.306; 95% confidence interval, 0.108–0.870; $P = 0.026$). Twenty-one patients received both DS construction and TT placement; none of them experienced severe AL.

Conclusion: The present multicenter study confirmed the efficacy of TT for preventing AL. Transanal tube may have synergistic effects against AL in selected patients with DS.

Key words: Transanal tube – Anastomotic leakage – Diverting stoma

Low anterior resection (LAR) with double-stapling technique reconstruction is commonly performed for low rectal cancer.[1,2] Recent advances in surgical technique and surgical devices have led to an increase in the proportion of sphincter-preserving surgeries.[3,4] However, anastomotic leakage (AL) in association with this procedure has increased, and the incidence of AL has been reported 3%–19%.[5–9] AL has serious consequences in terms of morbidity, mortality, decreased bowel function, and high risk of permanent stoma, which may lead to decreased quality of life.[10] Several randomized studies have reported that a diverting stoma (DS) can reduce the rate of AL after LAR.[11–13] However, about 20% of patients who undergo LAR experience various degrees of AL even after DS construction.[13]

Transanal tube (TT) placement can reduce pressure on the anastomotic site and is considered another potential device for preventing AL.[14] A recent systemic review showed that patients with TT had a lower AL rate, a lower reoperation rate, and a shorter hospital stay.[15] However, while many colorectal surgeons believe in the efficacy of TT in clinical practice, only about 16% of surgeons apply a TT after LAR according to a nationwide study.[16]

The present multicenter study examined the efficacy of TT for preventing AL in patients with LAR. We also examined whether TT has synergistic effects in patients with a DS.

Patients and Methods

This multicenter, retrospective study was designed by the Nagasaki Colorectal Oncology Group. We retrospectively reviewed consecutive rectal cancer patients who had undergone LAR with reconstruction using a double-stapling technique, at 6 participating hospitals, between April 2016 and March 2020. Patients with incomplete laboratory data, synchronous colon cancer, preoperative treatment, emergency surgery, or only stoma construction were excluded. A total of 126 patients were eligible for this study. The study protocol was reviewed and approved by the clinical research review boards of all participating hospitals, and informed consent was obtained in the form of opt-out on the institutional web sites.

Patients were divided into 2 groups according to the presence (n = 90) or absence (n = 36) of a TT. Clinicopathologic and surgical features were compared between the 2 groups. The following data were collected: sex, age, body mass index (BMI), American Society of Anesthesiologists–performance status (ASA-PS), comorbidities, tumor location, surgical approach, presence or absence of a DS, clinical T/N/M status, operation time, estimated blood loss, histologic type, pathologic T/N status, lymph-vascular invasion, tumor size, postoperative complications, and postoperative hospital stay. Postoperative complications were defined as Clavien-Dindo (CD) grade 2 or higher that occurred within 30 days after the primary surgery. AL was defined as "any defect of the intestinal wall integrity at the colorectal or coloanal anastomotic site leading to a communication between the intra- and extraluminal components."[17] Selection of either a 24-Fr MIT drain (CREATE MEDIC CO, Yokohama, Japan) or 24-Fr Silascon duple drain (Kaneka Medix Corp, Osaka, Japan) as a TT was left to the discretion of the surgeon. The TT was inserted after reconstruction using a double-stapling technique, fixed on the perianal skin, and positioned with the tip 50 mm above the anastomotic site. After anastomosis, an air leak test was performed using the TT. If the leak test yielded a positive result, we repaired the anastomotic site by suture until a negative result was obtained. Usually, the TT was removed on postoperative day 5 (range, days 3–7). Indications for TT insertion or selection of TT type, and timing of TT removal were made according to the choice of the surgeon. The constructed DS was ileostomy, and no cases of diverting colostomy were observed. We subdivided groups according to the presence (n = 21) or absence

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(n = 105) of AL, and clinicopathologic and surgical features were compared between groups.

Statistical analysis was performed using Bell Curve for Excel software (Version 2.02, Social Survey Research Information Co, Ltd, Tokyo, Japan). Data are presented as the median value and range. Differences in continuous variables were analyzed with the Mann-Whitney *U* test. Differences in categorical variables were compared using Fisher's exact test or the χ^2 test. Multivariate analysis using a Cox proportional hazards model was used to identify independent risk factors for postoperative complications. All values of $P < 0.05$ were considered significant.

Results

Table 1 lists the clinicopathologic characteristics of the 126 patients. The study population comprised 82 men and 44 women, with a median age of 69 years (range, 37–90 years). Median BMI was 22 kg/m^2 (range, 15–38 kg/m^2), with 71 patients (56.4%) showing poor PS (ASA-PS $\geq$ 2), and 81 (64.3%) displaying comorbidities. Low rectal cancer was diagnosed in 41 patients (32.5%). Laparoscopic surgery was performed for 115 patients (91.3%). A DS was constructed in 35 patients (27.8%). Fourteen patients (11.1%) were clinically diagnosed as T4 preoperatively. Fifty-two patients (41.3%) were diagnosed as clinically node positive, and 8 patients (6.3%) showed distant metastasis. Thirty-two patients (25.4%) had postoperative complications, and 21 patients (16.7%) experienced AL.

Table 2 lists the clinicopathologic characteristics of patients with or without a TT. Postoperative complications (17.8% versus 44.4%, $P = 0.003$) and severe AL (7.7% versus 19.4%, $P < 0.001$) were significantly lower in the TT group. Sex, age, BMI, ASA-PS, comorbidities, tumor location, surgical approach, presence of DS, clinical T/N/M status, operation time, estimated blood loss, histologic type, pathologic T/N status, lymph-vascular invasion, tumor size, and hospital stay were similar between groups.

Table 3 lists details of postoperative complications among patients with or without DS and TT. Twenty-one patients received both DS construction and TT placement. None of these 21 patients experienced severe AL (CD $\geq$3). Fourteen patients received DS construction only; of them, 2 patients (14.2%) experienced severe AL. Among the 22 patients without either DS or TT, 5 patients (22.7%) experienced severe AL.

Table 1 Background characteristics of patients

	All patients, n (%), N = 126
Sex	
Male	82 (65.1)
Female	44 (34.9)
Age, median (range), y	69 (37–90)
BMI, median (range), kg/m^2	22 (15–38)
ASA-PS	
1	55 (43.7)
2	64 (50.8)
3	7 (5.6)
Comorbidity	
None	45 (35.7)
Yes	81 (64.3)
Distance of tumor from the anal verge (mm)	
>80	85 (67.5)
≤80	41 (32.5)
Laparoscopic surgery, yes	115 (91.3)
CS, yes	35 (27.8)
Clinical T status	
1	24 (19.0)
2	21 (16.7)
3	67 (53.2)
4	14 (11.1)
Clinical N status	
Negative	74 (58.7)
Positive	52 (41.3)
Distant metastasis	
No	118 (93.7)
Yes	8 (6.3)
Operation time, min (range)	260 (134–627)
Blood loss, mL (range)	40 (0–1533)
Histologic type	
Well/mod	121 (96.0)
Poor/muc	5 (4.0)
Pathologic T status	
1	27 (21.4)
2	25 (19.8)
3	66 (52.4)
4	8 (6.3)
Pathologic N status	
Negative	82 (65.1)
Positive	44 (34.9)
Lymphovascular invasion	
Negative	30 (23.8)
Positive	96 (76.2)
Tumor size, mm (range)	31 (3–100)
Postoperative complications, CD >2	32 (25.4)
AL, CD >2	21 (16.7)
Hospital stay, d (range)	18 (7–162)

Data are presented as number of patients or median (range).

Table 4 lists the clinicopathologic characteristics of patients with or without AL. Patients with TT experienced a lower frequency of AL ($P < 0.001$). Hospital stay was longer in patients with AL (29 days) than in those without AL (15 days, $P < 0.001$). Sex, age, BMI, ASA-PS, comorbidities,

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Table 2 Comparison of clinical characteristics with or without transanal tube

	TT present, n (%), n = 90	TT absent, n (%), n = 36	*P* value
Sex			0.839
Male	58 (64.4)	24 (66.7)	
Female	32 (35.6)	12 (33.3)	
Age, median (range), y	68 (37–90)	70 (38–88)	0.798
BMI, median (range), kg/m^2	22 (15–38)	22 (15–27)	0.266
ASA-PS			0.686
1	40 (44.4)	15 (41.7)	
2	46 (51.1)	18 (50.0)	
3	4 (4.4)	3 (8.3)	
Comorbidity			0.837
None	33 (36.7)	12 (33.3)	
Yes	57 (63.3)	24 (66.7)	
Distance of tumor from the anal verge (mm)			1.000
>80	61 (67.8)	24 (66.7)	
≤80	29 (32.2)	12 (33.3)	
Laparoscopic surgery, yes	84 (93.3)	31 (86.1)	0.292
CS, yes	21 (23.3)	14 (38.9)	0.122
Clinical T status			0.419
1	17 (18.9)	7 (19.4)	
2	12 (13.3)	9 (25.0)	
3	51 (56.7)	16 (44.4)	
4	10 (11.1)	4 (11.1)	
Clinical N status			0.071
Negative	48 (53.3)	26 (72.2)	
Positive	42 (46.7)	10 (27.8)	
Distant metastasis			0.437
No	83 (92.2)	35 (97.2)	
Yes	7 (7.8)	1 (2.8)	
Operation time, median (range), min	276 (134–627)	240 (167–548)	0.089
Blood loss, median (range), mL	31 (0–1533)	47 (0–500)	0.620
Histologic type			0.623
Well/mod	87 (96.7)	34 (94.4)	
Poor/muc	3 (3.3)	2 (5.6)	
Pathologic T status			0.859
1	20 (22.2)	7 (19.4)	
2	19 (21.1)	6 (16.7)	
3	46 (51.1)	20 (55.6)	
4	5 (5.6)	3 (8.3)	
Pathologic N status			1.000
Negative	59 (65.6)	23 (63.9)	
Positive	31 (34.4)	13 (36.1)	
Lymphovascular invasion			1.000
Negative	22 (24.4)	9 (25.0)	
Positive	68 (75.6)	27 (75.0)	
Tumor size, median (range), mm	31 (8–100)	30 (3–98)	0.215
Postoperative complications, CD ≥2	16 (17.8)	16 (44.4)	0.003
AL, CD ≥3	7 (7.7)	7 (19.4)	<0.001
Hospital stay, median (range), d	15 (7–162)	20 (10–137)	0.450

Data are presented as number of patients or medians (range).

Differences in categorical variables were compared using Fisher's exact test or the χ^2 test, as appropriate. Differences in continuous variables were analyzed with the Mann-Whitney *U* test.

tumor location, surgical approach, presence of DS, clinical T/N/M status, operation time, estimated blood loss, histologic type, pathologic T/N status, and lymph-vascular invasion were similar between groups.

Table 5 shows the results of uni- and multivariate analyses of risk factors for AL. Presence of a TT ($P = 0.002$) or DS ($P = 0.048$) was significantly associated with AL on univariate analysis. Multivariate analysis revealed only presence of TT (odds ratio, 0.306;

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Table 3 Comparison of postoperative complication with or without CS

	CS, present (n = 35)		CS, absent (n = 91)	
	TT (+), n (%), n = 21	TT (−), n (%), n = 14	TT (+), n (%), n = 69	TT (−), n (%), n = 22
CD2	1 (4.8)	2 (14.3)	7 (10.1)	3 (13.6)
AL	1 (4.8)	1 (7.1)	1 (1.4)	3 (13.6)
Urinary tract infection	–	1 (7.1)	–	–
Ileus	–	–	2 (2.9)	–
Colitis	–	–	1 (1.4)	–
Pneumonia	–	–	3 (4.3)	–
CD3a	0 (0)	1 (7.1)	6 (8.7)	5 (22.7)
AL	0 (0)	1 (7.1)	4 (5.8)	2 (9.1)
Ileus	–	–	1 (1.4)	2 (9.1)
Anastomotic hemorrhage	–	–	1 (1.4)	–
Pneumonia	–	–	–	1 (4.5)
CD ≥3b	0 (0)	1 (7.1)	3 (4.3)	3 (13.6)
AL	0 (0)	1 (7.1)	3 (4.3)	3 (13.6)

95% confidence interval [CI], 0.108–0.870; $P = 0.026$) as an independent predictor of AL.

Discussion

In the present study, insertion of a TT was associated with a lower frequency of postoperative AL in both uni- and multivariate analyses. Severe postoperative AL (CD ≥3) developed in 14.3% of patients (2/14) with only DS and 10.1% of patients (7/69) with only TT. On the other hand, patients who received both DS and TT experienced no severe AL. This is the first multicenter study to examine the safety and efficacy of DS and TT.

Several factors could be associated with AL. Operative factors reportedly associated with AL include surgical skill of the operator, operation time, blood loss, blood transfusion, and bowel preparation.[18–20] Patient factors associated with AL include male sex, high age, low ASA-PS, and preoperative treatment.[18–20] Despite recent advances in surgical techniques and perioperative care, the frequency of AL has been reported as 3%–19%.[18,21] AL causes serious morbidities and mortality, leading to longer hospital stays. AL has also been reported as a cause of postoperative recurrence in patients with colorectal cancer[22–24] and is considered to contribute to poor postoperative quality of life such as poor postoperative function and risk of permanent stoma.[25,26] In the present study, the rate of AL in all participants was 16.6% (21 of 126). Recently, diagnoses of colorectal cancer have been increasing, and prevention of AL represents a crucial problem for improving both prognosis and quality of life.

TT placement has been recognized as a promising method for preventing AL. In general, complete rest of the anastomotic site for a certain period of time is ideally required to prevent AL. Several factors can increase endoluminal pressure in the postoperative period, including passage of stool or diarrhea from the oral side and tight contraction of the anal sphincter because of pain and inflammation.[27] The mechanism by which TT prevents AL is considered to be reduction of endoluminal pressure in the rectum by draining fecal flow or gas.[28] In addition, TT could drain old blood or bowel contents, reducing the bacterial load and protecting against direct damage to the anastomotic site.[27] A recent meta-analysis showed that the TT group had a lower rate of AL than the non-TT group, as well as a lower reoperation rate and shorter hospital stay.[15] In the present multicenter study, the severe AL rate was significantly lower in the TT group (7.7%) than in the non-TT group (19.4%, $P < 0.001$), as was the reoperation rate (6.6% versus 25%, $P < 0.001$), supporting previous studies.[15] However, placement of the TT risks serious complication such as perforation or bowel injury.[29] In the present study, we usually left a soft-type tube in place for no longer than 7 days (range, 3–7 days) to prevent injury from the tube itself. No patients developed serious complications from the TT, but future studies should examine optimal types of tube and appropriate durations of tube placement.

A previous study revealed that TT had no promising effects on theincidence of AL among patients showing high-risk factors such as male sex, lower rectal cancer, and preoperative treatment.[30] Another study showed that AL occurred after TT removal in high-risk patients.[28] Considering previous investigations, TT may have a strong benefit on local pressure control within a certain of period, but

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Table 4 Comparison of clinical characteristics between patients with or without AL

	AL (+), n (%), n = 21	AL (−), n (%), n = 105	*P* value
Sex			0.319
Male	16 (76.2)	66 (62.9)	
Female	5 (23.8)	39 (37.1)	
Age, median (range), y	68 (38–83)	68 (37–90)	0.353
BMI, median (range), kg/m^2	19 (15–26)	22 (15–38)	0.013
ASA-PS			0.113
1	10 (47.6)	45 (42.9)	
2	8 (38.1)	56 (53.3)	
3	3 (14.3)	4 (3.8)	
Comorbidity			0.807
None	8 (38.1)	37 (35.2)	
Yes	13 (61.9)	68 (64.8)	
Distance of tumor from the anal verge (mm)			0.311
>80	12 (57.1)	73 (69.5)	
≤80	9 (42.9)	32 (30.5)	
Laparoscopic surgery, yes	19 (90.5)	96 (91.4)	1.000
CS, yes	4 (19.0)	31 (29.5)	0.428
Clinical T status			0.892
1	3 (14.3)	21 (20.0)	
2	4 (19.0)	17 (16.2)	
3	11 (52.4)	56 (53.3)	
4	3 (14.3)	11 (10.5)	
Clinical N status			0.332
Negative	10 (47.6)	64 (61.0)	
Positive	11 (52.4)	41 (39.0)	
Distant metastasis			0.619
No	19 (90.5)	99 (94.3)	
Yes	2 (9.5)	6 (5.7)	
Operation time, median (range), min	240 (138–473)	274 (134–627)	0.217
Blood loss, median (range), mL	50 (0–233)	30 (0–1533)	0.561
TT, present	8 (38.1)	82 (78.1)	<0.001
Histologic type			1.000
Well/mod	20 (95.2)	100 (95.2)	
Poor/muc	1 (4.8)	5 (4.8)	
Pathologic T status			0.809
1	4 (19.0)	23 (21.9)	
2	3 (14.3)	22 (21.0)	
3	12 (57.1)	54 (51.4)	
4	2 (9.5)	6 (5.7)	
Pathologic N status			0.213
Negative	11 (52.4)	71 (67.6)	
Positive	10 (47.6)	34 (32.4)	
Lymphovascular invasion			0.581
Negative	6 (28.6)	24 (22.9)	
Positive	15 (71.4)	81 (77.1)	
Hospital stay, d (range)	29 (12–162)	15 (7–137)	<0.001

Data are presented as number of patients or median (range).

Differences in categorical variables were compared using Fisher's exact test or the χ^2 test, as appropriate. Differences in continuous variables were analyzed with the Mann-Whitney *U* test.

the effect is limited for patients with high risk of AL who require long-term rest of the anastomotic site.

The DS is the most commonly created proximal fecal diversion to protect anastomotic sites.[31,32] A previous meta-analysis examined the efficacy of DS for preventing AL and showed that a DS significantly reduced the rate of AL (range, 1.7%–15.2%) and reoperation rate (range, 0%–10.3%).[33] In this study, rates of AL and reoperation in patients with DS were 11.4% (4 of 35) and 5.7% (2 of 35), respectively, similar to previous reports.[33] However, DS does not actually decrease the rate of occult AL needing emergent reoperation.[34,35] In a Japanese multicenter study, only 1% of rectal cancer patients

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Table 5 Clinical factors predicting AL in colorectal cancer patients

	Univariate analysis	Multivariate analysis		
	P value	Odds ratio	95% CI	*P* value
Sex	0.314			
Female				
Male				
Age, y	0.286			
<75				
≥75				
ASA-PS	0.533			
1				
2, 3				
BMI, kg/m^2	0.142			0.218
<25		1		
≥25		0.268	0.033–2.180	
Distance of tumor from the anal verge (mm)	0.199			
<80				
≤80				
Comorbidities	0.633			
No				
Yes				
TT	0.002			0.026
Absent		1		
Present		0.306	0.108–0.870	
Operative procedure	0.788			
Laparoscopic surgery				
Open surgery				
CS	0.048			0.196
Absent		1		
Present		0.437	0.125–1.532	
Lymph nodes	0.128			0.116
Negative		1		
Positive		2.294	0.816–6.199	
Distant metastasis	0.687			
No				
Yes				

A Cox proportional hazards model was used to identify independent risk factors for postoperative complications.

with DS experienced AL requiring reoperation, but 20.1% of rectal cancer patients had asymptomatic or occult AL.[13] One explanation is that patients who required DS originally had high-risk features for AL. Fecal fluid accumulating between the DS and anastomosis and passing through the anastomotic site might then cause minor leakage. Even in cases of minor leakage, prolonged leakage may delay stoma closure and thus lead to various stoma-associated complications, and local inflammation around the anastomotic site may lead to poor defecation after stoma closure.[13] Prevention of any grade of AL, even in patients with DS, is required for better quality of life after stoma closure.

Several reports have compared the efficacy of AL prevention by TT and DS, and TT could offer an alternative to DS.[16,36–38] Rondeli *et al* revealed that the rate of AL in patients with DS (1.3%) was similar to that in patients with TT (2.6%).[38]

The concept of placing a TT is quite similar to that of DS. TT could control local endoluminal pressure for a few postoperative days but cannot control fecal flow from the oral side. However, DS can control the stool and gas from the oral side over a long period of time but cannot control local pressure from fecal fluid remaining past the stoma to the anastomotic site in the early postoperative period.[36]

In the present study, AL and severe AL (CD ≥2 and CD ≥3, respectively) were observed in 11.4% (4 of 35) and 5.7% (2 of 35) of patients with DS compared with 10% (9 of 90) and 7.8% (7 of 90) of patients with TT, respectively. However, patients

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who received both DS and TT showed AL with covering stoma (CS) $\geq$2 in 4.8% (1 of 21) and CD $\geq$3 in 0% (0 of 21). These results suggest that TT may not only prevent AL by itself but also have synergistic effects for AL prevention by controlling local endoluminal pressure in patients with a DS. Rectal cancer patients with bulky tumor, constipation, and incomplete bowel preparation are at risk of high endoluminal pressure because of fecal liquid even in cases with DS construction. The use of both a TT and DS could reduce the risk of AL in such patients and thus improve quality of life. A recent randomized controlled trial showed that a TT may not confer any benefit for AL prevention, regardless of whether a CS was present.[39] This finding obviously differs from our results. One possible explanation is that the present study contained open surgeries, and the type of TT and duration of TT insertion differed from those in the previous study. Another explanation is that the AL rate in our study was relatively high compared with the rate in the previous study. In the present study, participating hospitals were located in a rural area in Japan, and not all hospitals were experienced, high-volume centers. Previous studies have revealed that rural hospitals experienced poor short-term outcomes in various surgeries compared with urban hospitals.[40,41] TT might be useful in selected areas or hospitals.

Several limitations to this study should be considered. First, the study design was retrospective, with a limited number of patients. Second, indications for insertion of a TT, length of TT insertion, and duration of TT placement depended on the choices of the surgeon and influenced the results. Third, all constructed diverting stomas were ileostomy, and the distance from the DS to the anastomotic site was relatively long compared with colostomy. TT may show different results in cases of DS using the colon.

Even taking these limitations into consideration, the results of the present multicenter study indicate the efficacy of TT for preventing AL, and potential synergistic effects against AL in selected patients with DS.

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