ASTR

ORIGINAL ARTICLE
pISSN 2288-6575 • eISSN 2288-6796
http://dx.doi.org/10.4174/astr.2015.88.5.260
Annals of Surgical Treatment and Research

Comparative study between transanal tube and loop ileostomy in low anterior resection for mid rectal cancer: a retrospective single center trial

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Purpose: To investigate the efficacy and safety of the transanal tube (TAT) in preventing anastomotic leak (AL) in rectal cancer surgery.
Methods: Clinical data of the patients who underwent curative surgery for mid rectal cancer from February 2010 to February 2014 were reviewed retrospectively. Rectal cancers arising 5 to 10 cm above the anal verge were selected. Patients were divided into the ileostomy, TAT, or no-protection groups. Postoperative complications including AL and postoperative course were compared.
Results: We included 137 patients: 67, 35, and 35 patients were included in the ileostomy, TAT, and no-protection groups, respectively. Operation time was longer in the ileostomy group (P = 0.029), and more estimated blood loss was observed (P = 0.018). AL occurred in 5 patients (7.5%) in the ileostomy group, 1 patients (2.9%) in the TAT group, and 6 patients (17.1%) in the no-protection group (P = 0.125). Patients in the ileostomy group resumed diet more than 1 day earlier than those in the other groups (P = 0.000). Patients in the no-protection group had about 1 or 2 days longer postoperative hospital stay (P = 0.048). The ileostomy group showed higher late complication rates than the other groups as complications associated with the stoma itself or repair operation developed (P = 0.019).
Conclusion: For mid rectal cancer surgery, the TAT supports anastomotic site protection and diverts ileostomy-related complications. Further large scale randomized controlled studies are needed to gain more evidence and expand the range of TAT usage.
[Ann Surg Treat Res 2015;88(5):260-268]

Key Words: Surgical stomas, Drainage, Ileostomy, Anastomotic leak, Rectal neoplasms

INTRODUCTION

Despite several development in operative methods and instruments for colorectal patients, the incidence of anastomotic leak (AL) has not decreased [1]. Furthermore, although total mesorectal excision in rectal cancer surgery has improved the oncologic outcome, it has raised the risk of AL [2].

AL shows a 20%–30% morbidity rate and 7%–12% mortality rate in colorectal surgery [3-5]. Regarding oncologic outcomes, AL raises locoregional recurrence [5,6], and reduces long-term survival rate [3,7].

A diverting stoma is known to mitigate life threatening complications of AL, such as fecal peritonitis or sepsis, though it does not reduce clinical leak rate [8,9].

However, a diverting stoma does have its own complications. A previous study reported a morbidity rate of 34% for loop colostomy and 19% for loop ileostomy [10]. Moreover, stoma repair still requires additional operation, which is accompanied

Received September 17, 2014, **Revised** November 3, 2014,
Accepted November 26, 2014

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by the risk of operative complications.

The transanal tube (TAT) is known to protect the anastomotic site, but few studies have reported the efficacy and safety of the TAT for preventing AL in rectal cancer surgery. Here, we report our experiences of TAT usage. Clinical results of the TAT group are reviewed in comparison to the ileostomy and control (no other protection for anastomosis) groups.

METHODS

Patients

Data were collected retrospectively from patients who had undergone curative rectal cancer surgery for lesions located 5 to 10 cm above the anal verge in Seoul St. Mary's Hospital, Seoul, Republic of Korea, between February 2010 and February 2014. The TAT was introduced to our hospital in February 2012. The ileostomy, TAT, and no-protection groups were designated for the study. The no-protection group included patients without any protective methods for the anastomosis. The no-protection group underwent operations between February 2010 and January 2012 (before TAT introduction). Patients who received neoadjuvant chemotherapy- and/or radiation therapy, had synchronous cancer, transanal local excisions, robot-assisted surgery, and had undergone colonoscopic stent insertion before surgery were excluded.

Preoperative and operative management

The bowel was prepared preoperatively with 4 litters of polyethylene glycol (Colyte powder, Taejoon Pharm Co., Seoul, Korea) and 2 times of enema (Yal solution, Bukwang Pharm., Co., Seoul, Korea). Intravenous and oral antibiotics were administered to the patients. Two surgeons who are specialized in colorectal surgery in our hospital operated on all patients enrolled in this study. Patients received laparoscopic operation in most cases. Laparotomy or conversion to open surgery was decided based on the operator's clinical decision. Whether performing loop ileostomy formation or not was decided by the operator in the operating room considering operative difficulty and clinical status of the patient. The surgical principle was to secure high vascular ligation. Splenic mobilization was carried out when excessive anastomotic site tension was suspected. Anastomosis was performed with the double stapling technique in an end-to-end or side-to-end fashion. A closed drain was placed in the presacral space at the end of the surgery. Anesthesiologists decided whether to provide blood transfusion according to the intra-operative status of the patients.

Transanal tube

The TAT (Sewoon Medical Co., Cheonan, Korea) used in this study was a custom-fitted 65-cm silicone tube, consisting of a long and wide drainage part (17.5 mm × 7 mm × 150 mm), a 30-Fr connecting tube, and a thin polyvinyl chloride bag (Fig. 1). After finishing the anastomosis, the surgeon inserted the TAT into the bowel lumen through the anus. The drainage part of the tube was placed above the anastomotic site (Fig. 2). The TAT was sutured to the perianal skin for fixation. It was removed on the 4th to 6th postoperative day according to the patient's general status and feeding process.

Fig. 1. (A) The custom-fitted transanal rectal tube used in this study. (B) Main drainage portion of the transanal tube (17.5 mm × 7 mm × 150 mm).

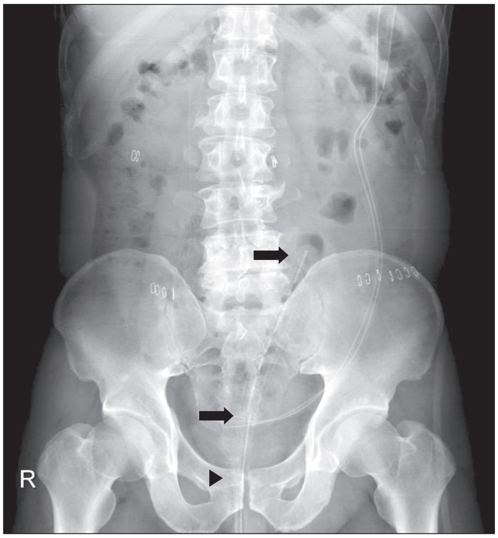

Fig. 2. Plain x-ray shows the transanal tube (TAT) remaining in the intraluminal space after installation. Main drainage portion of the TAT can be seen between the arrows. Arrowhead is indicating stapler line of anastomosis.

Postoperative management and follow-up

Patients visited the outpatient clinic for the first time, within a month after the surgery, and then follow-up was conducted every 3 months within 2 years of the surgery and biannually between 2 and 5 years after the surgery. Colonoscopy and abdomino-pelvic CT scans were checked at least annually. Adjuvant chemotherapy with or without radiation therapy was performed on patients with pathologically proven high risk stage II or stage III disease. Ileostomy repair was performed at least 2 months after surgery for the patients who had received adjuvant therapy, or at least 10 days after surgery for the patients who did not.

Clinicopathological characteristics and outcome

Age, gender, body mass index (BMI), tumor location, American Society of Anesthesiologists score, diabetes mellitus, history of previous abdominal surgery, preoperative serum hemoglobin and albumin levels, operator, anastomosis type (end-to-end or side-to-end), surgical procedure type (laparoscopic *vs.* open or conversion), other intra-abdominal organ resection, operation time, estimated blood loss, intraoperative transfusion, TNM stage, tumor size, distal resection margin, diet resumption, postoperative hospital stay, and early (within 30 days after surgery) and late postoperative complications including AL were identified. For the patients with ileostomies, the time between the primary operation and ileostomy repair, complications, and postoperative hospital stay ascribed to the repair surgery were additionallay checked.

Definition of AL

The definition of AL in this study is clinical: AL was considered present when suspicious symptoms or signs of AL such as abdominal pain with tenderness and/or muscle guarding, fever (body temperature > 38°C), rectovesical or rectovaginal fistula, pus or fecal discharge from the drain, discharge of abnormal material per rectum or chronic ileus (no improvement over 7 days) developed, and the diagnosis was confirmed by one or more of the following exams: CT scan, sigmoidoscopy, or laparotomy. For the CT scan, air bubble and/or fluid collection around the anastomotic site after the 7th postoperative day occurred in patients with suspected signs mentioned above was considered as AL.

Statistical analysis

To compare the three groups, the Fisher exact test was performed for categorical data, and the analysis of variance test was performed for continuous data. When there was a significant difference, the Sceffe or Games-Howell method was adopted for inter-group analysis. Non-inferiority of the TAT in preventing AL compared to loop ileostomy was tested with the independent t test. Statistical significance was defined as $P < 0.05$. IBM PASW ver. 18.0 (IBM Co., Armonk, NY, USA) was used for the statistical program.

RESULTS

In total, 578 consecutive surgical patients were diagnosed with primary rectal cancer during the study period. According to the inclusion criteria, 137 patients were enrolled as follows: 67, 35, and 35 patients in the ileostomy, TAT, and no-protection groups, respectively (Table 1). The average level of tumor was 8.5 ± 1.5 cm (range, 5–10 cm) above the anal verge, and there were no significant differences in age, gender, tumor level, history of previous abdominal surgery, preoperative serum hemoglobin and albumin levels, operator, anastomosis type, and surgical procedure type among the groups. BMI of the no-protection group was statisctically lower than that of the ileostomy group or TAT group ($P = 0.028$), but intergroup analysis showed no statistical differences between the ileostomy and TAT groups.

Operative and pathologic outcomes (Table 2) showed no significant difference in concomitant resection of other intra-abdominal organs, intraoperative transfusion, TNM stage, tumor size and distal resection margin. Most patients (122/137, 89.1%) received laparoscopic operations. However, operation time was longer in the ileostomy group (286.8 ± 66.2 > 238.9 ± 71.6, 256.0 ± 61.5, $P = 0.029$), and more estimated blood loss was observed (418.0 ± 355.1 > 244.3 ± 178.5, 346.7 ± 225.7, $P = 0.018$).

Regarding the postoperative course, patients in the ileostomy group resumed their diets more than 1 day earlier than the

Table 1. Clinicopathological characteristics of 137 patients enrolled in this study

Characteristic	Ileostomy (n = 67)	TAT (n = 35)	No-protection (n =35)	P-value
Age (yr)	32.2 ± 12.5	62.2 ± 11.1	59.3 ± 10.7	0.462
Sex				0.469
Male	48 (71.6)	21 (60.0)	23 (65.7)	
Female	19 (28.4)	14 (40.0)	12 (34.3)	
Body mass index[a)] (kg/m^2)	24.3 ± 3.1	23.7 ± 2.5	22.7 ± 2.9	0.028
Tumor level (cm)	8.2 ± 1.7	8.8 ± 1.2	8.9 ± 1.4	0.069
ASA score				0.285
1	16 (23.9)	11 (31.4)	15 (42.9)	
2	48 (71.6)	23 (65.7)	20 (57.1)	
3	3 (4.5)	1 (2.9)	0 (0)	
Diabetes mellitus				0.232
Absent	53 (79.1)	27 (77.1)	32 (91.4)	
Present	14 (20.9)	8 (22.9)	3 (8.6)	
History of previous abdominal operation				0.446
No	56 (83.6)	26 (74.3)	30 (85.7)	
Yes	11 (16.4)	9 (25.7)	5 (14.3)	
Preoperative hemoglobin level (mg/dL)	13.3 ± 1.9	13.5 ± 1.5	13.4 ± 2.0	0.807
Preoperative albumin level (mg/dL)	4.1 ± 0.3	4.1 ± 0.3	4.1 ± 0.4	0.845
Operator				0.474
1	56 (83.6)	26 (74.3)	27 (77.1)	
2	11 (16.4)	9 (25.7)	8 (22.9)	
Types of anastomosis				0.128
End-to-end	67 (100)	35 (100)	33 (94.3)	
Side-to-end	0 (0)	0 (0)	2 (5.7)	
Types of surgical procedure				0.681
Laparoscopic	61 (91.0)	31 (88.6)	30 (85.7)	
Open, conversion	6 (9.0)	4 (11.4)	5 (14.3)	

Values are presented as mean ± standard deviation or number (%).
TAT, transanal tube; ASA, American Society of Anesthesiologists.
[a)]Intergroup analysis: Ileostomy, MRT > No protection.

Table 2. Operative and pathologic outcomes

Variable	Ileostomy (n = 67)	TAT (n = 35)	No-protection (n =35)	P-value
Operation time[a)] (min)	286.8 ± 66.2	238.9 ± 71.6	256.0 ± 61.5	0.002
Concomittant resection of other intra-abdominal organ				0.056
No	61 (91.0)	35 (100)	30 (85.7)	
Yes	6 (9.0)	0 (0.0)	5 (14.3)	
Estimated blood loss[b)] (mL)	418.0 ± 355.1	244.3 ± 178.5	346.7 ± 225.7	0.018
Intraoperative transfusion (mL)	87.6 ± 262.3	0.0 ± 0.0	80.0 ± 228.6	0.140
Stage				0.993
0	3 (4.5)	2 (5.7)	2 (5.7)	
1	24 (35.8)	12 (34.3)	11 (31.4)	
2	12 (17.9)	7 (20.0)	6 (17.1)	
3	25 (37.3)	13 (37.1)	13 (37.1)	
4	3 (4.5)	1 (2.9)	3 (8.6)	
Tumor size (cm)				0.635
<3	27 (40.3)	16 (45.7)	12 (34.3)	
≥3	40 (59.7)	19 (54.3)	23 (65.7)	
DRM (cm)	2.9 ± 2.1	3.5 ± 1.8	3.6 ± 1.5	0.115

Values are presented as mean ± standard deviation or number (%).
TAT, transanal tube; DRM, distal resection margin.
Intergroup analysis: [a)]Ileostomy > MRT, No protection; [b)]Ileostomy > MRT, No protection.

other groups (P <0.001) (Table 3). Postoperative hospital stay was about 1 to 2 days longer for the no-protection group (P = 0.048), and no difference was observed between the ileostomy and TAT groups. Stoma closure was performed in 63 of 67 patients (94.0%) in the ileostomy group. One case of cancer recurrence with hepatic confusion, and one case of anastomotic site stricture prevented the ileostomy repair procedure from taking place. Two patients had permanent stoma after undergoing abdominoperineal resection because of AL and severe ischemic colitis respectively (The later patient was in the ileostomy group with the preoperative diagnosis of systemic lupus erythematosus. Ischemic colitis was detected in the sigmoid colon by sigmoidoscopy on 50th postoperative day, and the intact anastomotic site was identified below 10 cm from the lesion). A 4 months interval (range, 0–13) was observed from the primary operation to the ileostomy repair. About 4 additional days of postoperative stay were needed for the ileostomy repair.

AL occurred in 5 patients (7.5%) in the ileostomy group, 1 patient (2.9%) in the TAT group, and 6 patients (17.1%) in the no-protection group. The difference was not statistically significant

Table 3. Postoperative course

Postoperative course	Ileostomy (n = 67)	TAT (n = 35)	No-protection (n = 35)	P-value
Diet (day)	2.2 ± 1.6	3.3 ± 0.8	3.7 ± 1.0	<0.001
Postoperative hospital stay (day)	7.7 ± 3.9	7.3 ± 1.7	9.2 ± 4.0	0.048
Ileostomy repair				
Interval months from first surgery	4 (0–13)	-	-	
Postoperative day	4 (2–13)	-	-	
Duration of remained TAT (day)	-	5 (4–7)	-	
Anastomotic leak	5 (7.5)	1 (2.9)	6 (17.1)	0.125

TAT, transanal tube.

Table 4. Postoperative complications

Postoperative complication	Ileostomy (n = 67)	TAT (n = 35)	No-protection (n = 35)	P-value
Early complications				0.204
Ileus	6	1	1	
Atelectasis	4	1		
Acute renal failure	2			
Urinary retention	2	1	1	
Postop bleeding	2		1	
Wound infection	1	1		
Chyle leak	1	1		
Pneumonia	1			
Delirium	1			
Ureter obstruction	1			
Prostatitis			1	
Pleural effusion			1	
Late complications				0.016
Ileus	4 (operation for 3)		1	
Parastomal hernia	2			
Parastomal ulcer	1			
Incisional hernia after repair of ileostomy	1			
Anastomotic site stenosis	1 (APR)		1 (bougination)	
Pulmonary edema	1			
Ischemic colitis c pelvic abscess	1			
Method-specific complications (7.5%)				0.033
ARF	2			
Parastomal hernia	1			
Parastomal ulcer	1			
Incisional hernia	1			

TAT, transanal tube; ARF, acute renal failure; APR, abdominoperineal resection.

among groups (P = 0.125). The TAT presented noninferiority in preventing AL compared to ileostomy with a –5% noninferiority margin (limit of 95% confidence interval for difference between preventing rates: –2.9% to 15.1%). Among the 5 AL patients in the ileostomy group, 1 patient underwent reoperation (abdominoperineal resection) because of AL. One AL patients in the TAT group and 5 of 6 AL patients in the no-protection group underwent reoperation, and temporary ileostomies were created. Other AL patients were treated successfully with conservative methods such as fasting, fluid resuscitation, antibiotics, and/or pigtail insertion.

Early and late postoperative complications except AL were compared (Table 4). Early complications that occurred within 30 days after surgery showed no significant difference among the groups. However, the ileostomy group had a higher late complication rate than the other two groups as complications associated with the stoma itself or repair operation occurred (P = 0.016). Anastomotic site stricture was observed in 1 patient in the ileostomy group and 1 patient in the no-protection group. The patient with stricture in the ileostomy group was treated with abdominoperineal resection, and the patient with stricture in the no-protection group received intermittent endoscopic bougination. No stricture was observed in the TAT group during the follow-up period. The median (range) follow-up period was 27 months (3–49 months) for the ileostomy group, 17 months (3–29 months) for the TAT group, and 42 months (21–51 months) for the no-protection group. No surgical mortality was observed.

DISCUSSION

The International Study Group of Rectal Cancer defined AL as communication between the intraluminal and extraluminal compartments caused by a defect in the intestinal wall integrity at the anastomosis [11]. AL is one of the most serious complications related to colorectal surgery. It not only increases morbidity, mortality, and postoperative hospital stay but also impairs the long-term oncologic and functional outcomes after rectal cancer surgery.

The mechanism of AL is still uncertain, but it seems that increased intraluminal pressure is a significant risk factor. Hallbook and Sjodahl [12] reported that "neo-rectal" volume, which is sustainable to distension or straining pressure, is significantly decreased in AL patients. Nesbakken et al. [13] reported decreased "neo-rectal capacity" in patients who experienced AL despite proximal diversion after rectal resection. Accordingly, proximal decompression is an important point in preventing AL. Clinically, proximal decompression can be achieved with diverting stomas, transanal decompression devices, or intraluminal devices.

Among these methods, temporary loop ileostomy is the most commonly used method. It is known to diminish the catastrophic complication of AL, and reduce the risk of surgical reintervention [9,10,14]. On the other hand, some researchers have insisted that ileostomy does not actually decrease the leak rate [1,8,15]. Ileostomy itself can induce many complications such as wound infection, prolapse, retraction, stenosis, necrosis, parastomal hernia, ileus, obstruction, and so on. In this study, no differences in early postoperative complications were observed among the groups, but the late complication rate was significantly higher in the ileostomy group.

Additional surgery under general anesthesia is necessary for an ileostomy repair and this exposes the patients to additional operative risks. Pulmonary edema took place in a patient who received ileostomy repair (the patient underwent laparoscopic cholecystectomy simultaneously), and an incisional hernia at the repair site developed in another patient.

Transanal decompression devices may protect the anastomotic site and prevent the shortcomings of diverting stomas. The TAT in this study was devised from the existing rectal tube to maximize the decompressive effect. Many wide holes in our TAT make sufficient drainage or decompression possible. The TAT can be inserted and removed easily. The TAT has a low risk of bowel wall injury because of its curvelinear shape and soft silicone texture.

Compared to the ileostomy group, AL was not significantly different in the TAT group. The two groups had equivalent clinicopathological characterisitcs including tumor location and BMI. However, the ileostomy group showed longer operation times and, larger amounts of intraoperative blood loss. Increased intraoperative blood loss or blood transfusion is mentioned as a risk factor for AL in some studies [16-18]. From this point of view, the AL rate of the TAT group in this study may show significantly higher leak rates if intraoperative blood loss increases. However, other results suggest that they are not significant factors [19-21]; therefore, more evidence in this regard should be accumulated. Effectiveness of indwelling TAT can be estimated with adjustment of these factors by comparing the TAT group with the no-protection group, since there are no significant differences in these variables between the two groups. Although no statistical significance (P = 0.106) was observed, the leak rate tended to decrease in the TAT group with 2.9% versus 17.1%.

These results also suggests that the operators preferred ileostomy rather than TAT in difficult operative cases. Similarly, in 2005, Gurjar et al. [22] reported that only about 16% of surgeon respondents in Britain and Ireland used indwelling tubes for low anterior resection. This is because the evidence regarding the safety and efficacy of indwelling TAT are yet insufficient for its general use [23]. A few studies on this issue [24-28] were reported recently. They compared the AL rate between a TAT group and control (without TAT) group after anterior resection

Table 5. Studies about transanal tube for preventing anastomotic leakage in rectal cancer surgery

Author	Year	Study design	Mean level of tumor (above the anal verge, cm)	No. of patients		AL, n (%)		P-value
				TAT	Control	TAT	Control	
Cong et al. [24]	2009	Retrospective	4.61	62	676[a)]	9 (14.5)	24 (3.6)	<0.010
Xiao et al. [25]	2011	Prospective, randomized	7 (TAT), 8 (Control)[b)]	200	198	8 (4.0)	19 (9.6)	0.026
Zhao et al. [26]	2013	Prospective, nonrandomized	Unknown	81	77	2 (2.5)	7 (7.8)	0.160
Nishigori et al. [27]	2014	Retrospective	7 (TAT), 8 (Control)[b)]	36	140	1 (2.7)	22 (15.7)	0.040
Hidaka et al. [28]	2015	Retrospective	Unknown	96	109	4 (4.2)	15 (13.8)	<0.050
Present study	2015	Retrospective	8.8 (TAT), 8.9 (Control)	35	35	1 (2.9)	6 (17.1)	0.106

TAT, transanal tube; AL, anastomotic leak.
[a)]Including diverting stoma patients. [b)]Median.

for rectal cancer. Most of them showed a lower AL rate in the TAT group compared to the control group, and the leak rates of each group were similar to our results (Table 5). Among these studies, this is the first report to compare a TAT group to an ileostomy group for investigating the efficacy and safety of TAT in preventing AL after rectal cancer surgery.

Deciding on the necessity of a diverting stoma in each individual patient is a challenging issue. Karliczek et al. [29] reported that intraoperative prediction of AL has low sensitivity and specificity. In surgical cases with a definite high risk of AL, diverting stoma is warranted. However, in some cases with moderate or indistinct risk of AL, when diverting stoma creation is not absolutely indicated, the TAT can be an alternative to the diverting stoma; this may spare patients possible complications of a stoma and still provide anastomosis protection. Moreover, the TAT can be used simultaneously with a diverting stoma. It can assist in the drainage and decompression of the remaining fecal material past the ileostomy site. This situation can be apparent in cases of incomplete bowel preparation or emergency operation.

The TAT group did not have longer hospital stay periods compared to the ileostomy group. Postoperative hospital stays in the no-protection group were more than 1 day longer than those in the other two groups. For the no-protection group, a tendency of slow postoperative diet resumption was observed, and this may have contributed to the longer hospital stay. Furthermore, in the ileostomy group, considering the additional hospital stay that would be needed for ileostomy repair, the actual total postoperative hospital stay was the shortest in the TAT group.

Insertion of the TAT is easy and requires less time than that of ileostomy. Operation time of the TAT group was more than 40 minutes shorter than that of the ileostomy group, and was not significantly different from that of the no-protection group. Performing ileostomy takes about 20–40 minutes in usual practice. Thus, we think the difference in operation time between the ileostomy group and the other groups was because of rather the operation time for performing the ileostomy than the operative difficulty. On the other hand, it takes only a few minutes to insert the TAT, and this short installation time can be a merit for some situations such as emergency operation.

Our data showed that the TAT provides a comparable protective effect on the anastomotic site and diverts the ileostomy-related complications. However, there are some limitations for these study results to be directly applied to common practice. First, this study enrolled a relatively small number of patients. An estimate of exact AL rate can be achieved only with large patient numbers, which will provide sufficient statistical power. Second, we chose which method of protection would be performed to each patient at the time of the operation, and decided the tumor level that would be included in our study retrospectively. Thus, selection bias might confound the results. A prospective randomized study is required to exclude bias, but disastrous effects and difficulty in predicting AL risk make the study design challenging. Finally, to expand the range of usage for TAT, additional studies on cases bearing high risks for AL such as low rectal cancer located below 5 cm above the anal verge and patients who underwent neoadjuvant chemoradiotherapy are needed in the future. With more evidence, expanded TAT use will bring benefit in AL protection and avoidance of stoma-related complications.

In conclusion, in mid rectal cancer surgery, the TAT showed no significant difference in AL compared to conventional loop ileostomy. While loop ileostomy possesses its own complications, the TAT didn't show any significant complications. Therefore, the TAT may serve as a safe and easy alternative to diverting stomas in mid or upper rectal cancer surgery. Further large-scale and/or prospective randomized studies are required to gain more evidence that can validate the expanded clinical use of TAT.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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