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A meta-analysis of the use of a transanal drainage tube to prevent anastomotic leakage after anterior resection by double-stapling technique for rectal cancer

Kohei Shigeta[1,2] · Koji Okabayashi[1] · Hideo Baba[2] · Hirotoshi Hasegawa[1] · Masashi Tsuruta[1] · Kazuo Yamafuji[2] · Kiyoshi Kubochi[2] · Yuko Kitagawa[1]

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Abstract

Background The safety and efficacy of transanal drainage tube (TDT) placement to decrease the risk of postoperative anastomotic leakage after rectal cancer surgery has not been validated. The objective of this meta-analysis was to evaluate the usefulness of a TDT for the prevention of anastomotic leakage after an anterior resection for rectal cancer.

Methods The PubMed and Cochrane Library databases were searched for studies comparing TDT and non-TDT. The endpoint utilized in this study was defined as the rates of anastomotic leakage and re-operation. The relative effects of these variables were synthesized using Review Manager 5.1 software.

Results Four trials including 909 participants (401 TDT cases and 508 non-TDT cases) met our inclusion criteria. The weighted mean anastomotic leakage rate was 4 % [95 % confidence interval (CI) 1–6 %], and a significantly lower risk of anastomotic leakage was identified in the TDT group compared with the non-TDT group [odds ratio (OR) 0.30; 95 % CI 0.16–0.55; $p = 0.0001$]. Furthermore, there were significant differences between the TDT and non-TDT groups in terms of the re-operation rate (OR 0.18; 95 % CI 0.07–0.44; $p = 0.0002$). No significant covariates related to anastomotic leakage or re-operation were identified in meta-regression analysis. Both the anastomotic leakage and re-operation rates for all studies lay inside the 95 % confidence interval boundaries. No visible publication bias was found by visual assessment of the funnel plot (Egger's test; anastomotic leakage: $p = 0.056$, re-operation: $p = 0.681$).

Conclusions Placement of a TDT is an effective and safe procedure that can decrease the rate of anastomotic leakage and re-operation after an anterior resection.

Keywords Colorectal cancer · Anterior resection · Anastomotic leakage · Transanal tube

The advances in medical instrumentation and the development of the double-stapling technique have increased the sphincter preservation rate. However, anastomotic leakage is one of the most serious surgical complications of anterior resection for rectal cancer. The incidence rate of anastomotic leakage has been reported to range between 1.3 and 7.8 % [1–3]. Anastomotic leakage can cause serious morbidity, may lead to longer hospitalizations, and may affect the postoperative quality of life [4–6]. Furthermore, anastomotic leakage can increase the risk of local recurrence and may lead to poor survival rates [7, 8].

Several previous studies have reported the risk factors for anastomotic leakage after rectal cancer surgery [9–13]. Male gender, preoperative chemoradiotherapy, steroid use, longer duration of operation, and contamination of the operative field have been reported as significant risk factors for anastomotic leakage; however, the cause of and the steps for prevention of this anastomotic leakage remain unclear. Randomized multicenter trial has demonstrated a decreased rate of symptomatic anastomotic leakage by creation of diverting stoma in low anterior resection [14]. There are many other previous studies that demonstrate the effectiveness of diverting stoma

✉ Kohei Shigeta
ohlkoh@gmail.com

✉ Koji Okabayashi
okabayashikoji@gmail.com

[1] Department of Surgery, Keio University School of Medicine, 35 Shinano-machi, Shinjuku-ku, Tokyo 160-8582, Japan

[2] Department of Surgery, Saitama City Hospital, Saitama, Japan

to prevent anastomotic leakage [15, 16], and it is recommended in low anterior resection for rectal cancer. However, hospital stay was longer in patients with diverting stoma than in patients with no stoma, because they needed some time to learn how to handle the stoma appliance [14]. Moreover, diverting stoma also increases patient discomfort, overall cost, and the duration of hospitalization since the patient will need a second operation for closure of the stoma [17, 18]. Phatak et al. [19] reported that diverting ileostomies are associated with a significant risk for ileostomy-related morbidity including dehydration and perioperative complications of stoma closure. Although this morbidity may be balanced by the benefit of decreasing anastomosis leak, these disadvantages should be considered.

The use of a transanal drainage tube (TDT) has been reported to reduce the endoluminal pressure on the anastomotic portion and can prevent anastomotic leakage after rectal surgery [20, 21]. In theory, TDT causes drainage on the proximal side of the anastomosis, can provide protection from watery stool or gas, and can reduce bacterial contamination of the area. Since there have been few studies that have evaluated the efficacy of TDT placement following anterior resection for rectal cancer, it remains unclear whether this procedure can prevent anastomotic leakage after rectal surgery.

The objective of this meta-analysis was to evaluate the usefulness of a TDT for the prevention of anastomotic leakage after an anterior resection for rectal cancer. The findings of this analysis will help to improve surgical outcomes in rectal cancer and achieve better intraoperative safety.

Materials and methods

This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [22].

Search process

All relevant published studies were identified through a computer-assisted search of the PubMed and Cochrane Library databases from 1990 to 2014 without language limitations. References were retrieved using key words that included “Rectal cancer” AND “Transanal” OR “indwelling” AND “anterior resection” AND “leak” OR “leakage.” The cited references in each retrieved paper were also checked for relevance. All studies were individually assessed by two of the authors (KS and KO).

Inclusion and exclusion criteria

Inclusion criteria were as follows: (1) patients with rectal cancer, (2) a study design that compared the outcome of TDT and non-TDT, (3) an anastomosis performed using the single- or double-stapling technique, and (4) the assessment of therapeutic effects, including one or more of the parameters of anastomotic leakage and re-operation. Exclusion criteria were as follows: (1) incomplete data, (2) duplicate studies, (3) studies that included diverting stomas, and (4) hand-sewn anastomosis.

Data collection

The following data were extracted: author names, departments, institutes, year of publication, type of study (single center or multicenter), study period, total number of patients, patient age, patient sex, and the rates of anastomotic leakage and re-operation. We assessed the quality of the included studies according to the Newcastle–Ottawa scale, which was developed as a risk assessment tool for non-randomized studies in a meta-analysis [23].

Outcomes of interest and definition

The endpoints were the rates of anastomotic leakage and re-operation. Anastomotic leakage was defined as the discharge of feces, pus, or gas from the abdominal drain, peritonitis caused by leakage, the presence of a pelvic abscess, and the discharge of pus from the rectum or rectovaginal fistula. The diagnosis was verified by clinical and/or radiologic [computed tomography (CT) scan] investigations. The definition of re-operation was an operation caused by the presence of anastomotic leakage.

Data analysis

All analyses were conducted using a random effects model to reduce the influence of institutional heterogeneity in surgical skill and outcomes. We computed the weighted mean average, odds ratio (OR), and 95 % confidence interval (CI) for dichotomous data, including the rates for anastomotic leakage and re-operation. We also undertook a meta-regression analysis to assess the effects of study period, study design (RCT or non-RCT), female rate, rate of diabetes mellitus, distance from anal verge, location of the tumor (rate of below peritoneal reflection), and type of surgery (open or laparoscopic surgery). Publication bias was assessed using a funnel plot and the Egger’s test. Outcome variables were tested for homogeneity to calculate the Q statistics and associated p values. A two-tailed p value of <0.05 was considered statistically significant. The synthesized effect sizes were calculated using Review Manager 5.1 software (Cochrane Collaboration). Funnel plots were drawn using Stata Data Analysis and Statistical Software (version 11; StataCorp LP, College Station, TX, USA).

Results

Included studies

A total of 27 studies were identified that satisfied the inclusion criteria of comparing the outcomes between anterior resections with TDT and non-TDT for rectal cancer. However, after reading the titles and abstracts, 19 papers that did not conform to the entry criteria were excluded, as were four other papers after a review of the full text. After the exclusions, four studies were selected for inclusion in this meta-analysis [20, 21, 24, 25]. A Consolidated Standards of Reporting Trials flow diagram is shown in Fig. 1.

The study design, study period, and demographic characteristics are summarized in Table 1. The patients who underwent hand-sewn anastomosis were excluded from this meta-analysis [24]. The analysis involved 909 patients, 401 (44.1 %) of whom had undergone anterior resection with TDT placement. The overall rate of anastomotic leakage was 8.3 % (75/909). Of the included studies, three were nonrandomized, two of which were retrospective and one was a prospective trial. The one remaining study was a randomized control study. All included studies had a publication year of 2011 or later and an overall sample size of 100 patients or more. Two studies included a laparoscopic group that comprised 50 % or more of the total sample size. One study included one patient with preoperative chemotherapy; however, patients who underwent preoperative radiation or chemotherapy were excluded in other three studies. The Newcastle–Ottawa score for all included studies ranged from 2 to 5, indicating a relatively low overall study quality. Finally, all the included studies were the report from far eastern countries, and there may be some difference in the

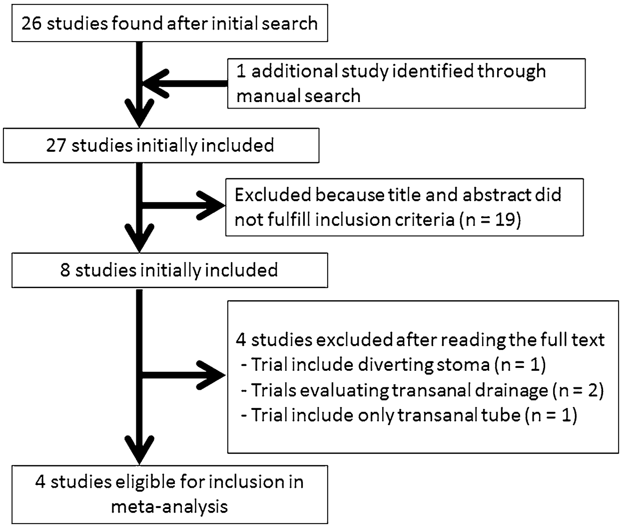

Fig. 1 Flow chart illustrating the inclusion process

Table 1 Characteristics of included studies

Author	Publication year	Study type	Study period	Gender (male/female)	Sample size		Lap/open	Below peritoneal reflection		Distance of tumor or anastomosis from anal verge		Tumor stage I or II		Preoperative radiation	Quality score
					TDT	Non-TDT		TDT	Non-TDT	TDT	Non-TDT	TDT	Non-TDT		
Xiao	2011	RCT	2003–2009	Not stated	188	182	Open	Not stated		7 (3.5–11)	8 (3.5–11)	101 (50.5 %)	114 (57.6 %)	0	5
Zhao	2013	Prospective	2007–2011	90/68	81	77	Open	47 (58.0 %)	42 (54.5 %)	≤10 cm 59 >10 cm 18	≤10 cm 68 >10 cm 13	39 (50.7 %)	42 (51.8 %)	0	2
Nishigori	2013	Retrospective	2007–2011	111/65	36	140	Lap/open	15 (41.7 %)	46 (32.9 %)	7.0 (4.0–10.0)	8.0 (4.5–12.0)	22 (61.1 %)	89 (63.6 %)	0	2
Hidaka	2014	Retrospective	2008–2013	129/76	96	109	Lap	42 (43.8 %)	22 (20.2 %)	45.0 ± 17.8	50.9 ± 15.9	59 (61.5 %)	76 (69.7 %)	0	3

postoperative management between far eastern country and the other world.

Surgical procedure

Surgical procedures of each included studies are summarized in Table 2. TME was performed in all included studies, and TDT was inserted gently into the anus after anastomosis. Xiao et al. [24] used a soft silicone tube that was 12 cm in length and with several lateral apertures. Zhao et al. [25] used a rubber drainage tube (26 Fr) and positioned it with the tip 3–5 cm proximal to the anastomotic site. Nishigori et al. [21] used a Ficon tube (24 Fr) and placed the tip of a transanal tube approximately 3–5 cm from the oral side of the anastomosis. Finally, Hidaka et al. [20] used a Malecot catheter (28 Fr) or pleats drain (10 mm), and the tube was positioned with the tip 30 mm proximal to the anastomotic site. Zaho et al. placed the tube using oval forceps thorough the anoscope; however, other three studies do not state how the tubes are placed. TDT was removed on postoperative 5–7 days in all four included studies. Thus, there were slight differences in material and in the diameters of the tubes in each study, but the procedures for all four studies were almost equivalent.

Meta-analysis of surgical outcomes

Anastomotic leakage

Among the included studies, the anastomotic leakage rate ranged from 2.5 to 4.2 %. The weighted mean anastomotic leakage rate was 4 % (95 % CI 1–6 %) and the OR was 0.30 (95 % CI 0.16–0.55; $p = 0.0001$) (Fig. 2A), indicating that anterior resection with TDT had a significantly lower rate of anastomotic leakage compared with non-TDT procedures. No significant covariates related to anastomotic leakage were identified in meta-regression analysis (Table 2).

Re-operation

Among the included studies, the re-operation rate ranged from 0 to 2.8 %. The weighted mean overall complication rate was 2 % (95 % CI −0.01 to 4). Random effects model was utilized and the OR was 0.18 (95 % CI 0.07–0.44; $p = 0.0002$) (Fig. 2B), indicating that the TDT group had a significantly lower rate of re-operation because of anastomotic leakage than the non-TDT group. No significant covariates related to re-operation were identified in meta-regression analysis (Table 3).

Publication bias

Publication bias of the anastomotic leakage rates and re-operation rates was evaluated in the meta-analysis using a funnel plot as shown in Fig. 3. Both the anastomotic leakage and re-operation rates for all studies lay inside the 95 % confidence interval boundaries. No visible publication bias was found by visual assessment of the funnel plot (Egger's test; anastomotic leakage: $p = 0.056$, re-operation: $p = 0.681$).

Discussion

Anastomotic leakage is a very severe complication of rectal cancer surgery and is associated with considerable morbidity and mortality. The present study results suggested that anterior resection with TDT placement for rectal cancer had significantly lower anastomotic leakage and re-operation rates than anterior resection without TDT. Each study included a small number of patients; therefore, some of the studies did not reach statistical significance. However, the benefits of TDT placement to prevent anastomotic leakage and re-operation following leakage were revealed according to this meta-analysis.

Various risk factors have been reported from previous studies. Gender, tumor location, the presence of diabetes mellitus, distance of anastomosis from the anal verge, the presence of preoperative chemoradiation, and advanced cancer stage have been identified as risk factors [9–11, 26, 27]. Furthermore, the preservation of the left colonic artery in anterior resection for middle and low rectal cancer has also been reported to be associated with lower risk of anastomotic leakage [28]. These clinicopathological factors

Table 2 Surgical procedure of included studies

Author	Surgical type	Type of tube	Diameter of tube	Position	Tube removal
Xiao	TME	Silicone tube	12 cm	Not stated	5–7 days after operation
Zhao	TME	Rubber drainage tube	26 Fr	Tip 3–5 cm proximal to the anastomotic site	5–6 days after operation
Nishigori	TME	Ficon tube	24 Fr	Tip 3–5 cm proximal from the oral side of the anastomosis	5 days after operation
Hidaka	TME	Malecot catheter Pleats drain	28 Fr 10 mm	Tip 30 mm proximal to the anastomotic site	7 days after operation

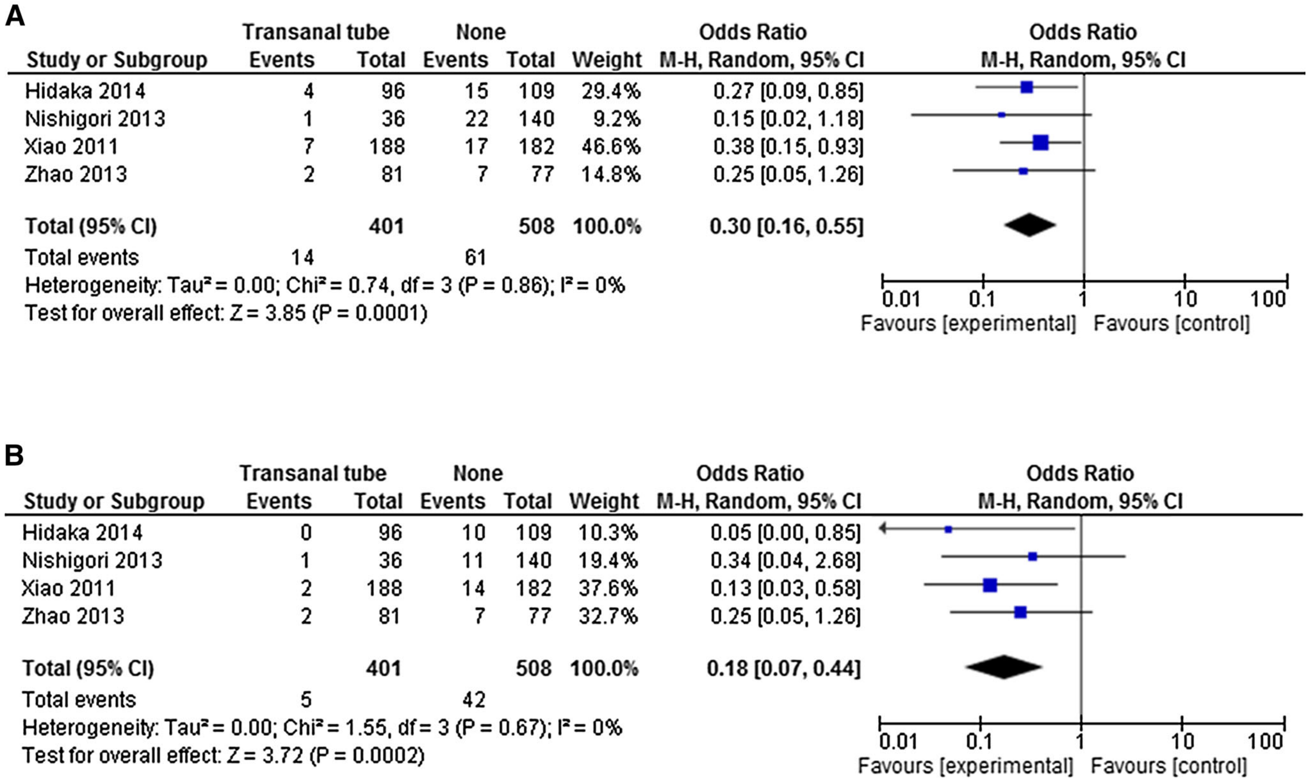

Fig. 2 Outcome of meta-analysis. **A** Forest plot illustrating the meta-analysis of the anastomotic leakage rate. **B** Forest plot illustrating the meta-analysis of the re-operation rate

Table 3 Meta-regression analysis

	Anastomotic leakage		Re-operation	
	Coefficient (95 % CI)	*p*	Coefficient (95 % CI)	*p*
Publication year	−0.16 (−1.13 to 0.81)	0.561	0.16 (−1.43 to 1.76)	0.701
Study design (RCT)	0.44 (−2.28 to 3.16)	0.559	−0.53 (−4.69 to 3.63)	0.638
Sex (female)	3.66 (−29.03 to 36.36)	0.677	1.86 (−58.45 to 62.16)	0.907
Prevalence of diabetes militias	−6.20 (−107.8 to 95.41)	0.580	6.09 (−106.8 to 118.9)	0.617
Distance from anal verge (mm)	0.01 (−0.36 to 0.37)	0.850	0.05 (−0.75 to 0.85)	0.581
Location of the tumor (below peritoneal reflection)	1.49 (−25.99 to 28.98)	0.837	1.69 (−30.56 to 33.94)	0.842
Tumor stage (stage I/II)	−2.25 (−30.73 to 26.2)	0.766	−2.15 (−41.04 to 36.75)	0.834
Type of surgery (laparoscopy)	−0.36 (−3.15 to 2.42)	0.632	0.06 (−4.34 to 4.46)	0.959

should be considered in evaluating the effectiveness of TDT placement. Two retrospective studies had a significantly greater number of patients with diabetes mellitus and lower tumor locations in the TDT group, suggesting that more patients with a high risk background were included in the TDT group [20, 21]. Only one study included a patient who received preoperative chemotherapy [21]; therefore, further investigation should be performed to clarify the influence of chemoradiotherapy. Preoperative chemoradiotherapy is preferably applied in patients with advanced rectal cancer, and these patients potentially have a risk of anastomotic leakage. Taking these facts into consideration, the benefit of TDT placement should also be evaluated in these patients. Other risk factors were also analyzed, and no significant risk factors were detected in this meta-analysis. Furthermore, meta-regression analysis demonstrated that there were no significant covariates associated with either anastomotic leakage or re-operation rate. These analyses suggested that the results of this meta-analysis may have high validity.

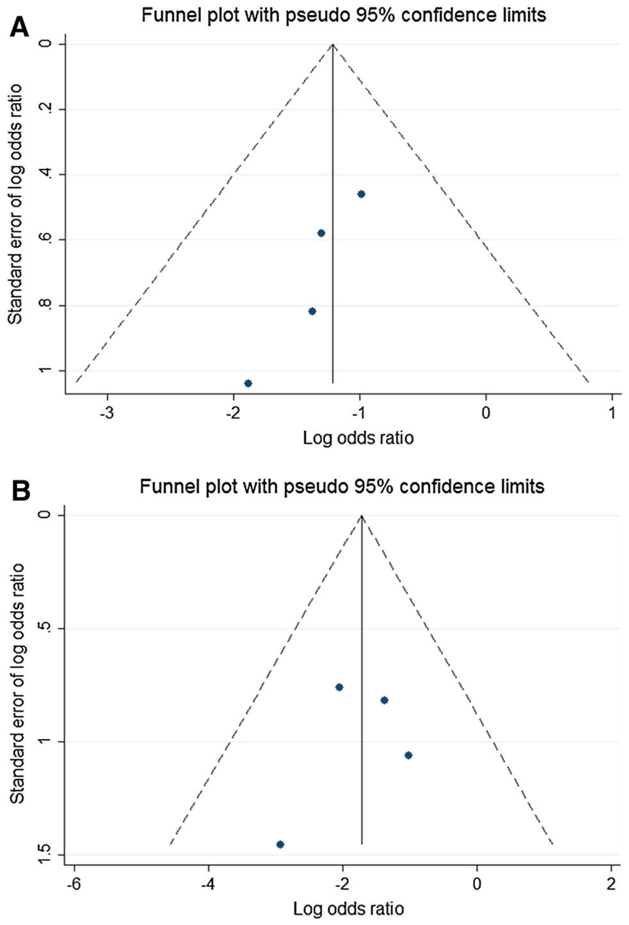

Fig. 3 Outcome of publication bias. **A** Funnel plot to detect publication bias regarding the anastomotic leakage rate. **B** Funnel plot to detect publication bias regarding the re-operation rate

TDT placement has been useful in the prevention of anastomotic leakage in previous studies [29, 30]. However, Cong et al. reported that the leakage risk with TDT placement was significantly higher than in the non-TDT group. The reason of this discrepancy is not clear; however, we think that this result may be closely associated with the selection bias because most of the patients in the TDT group had low rectal cancers than those in the non-TDT group. Furthermore, no significant difference was detected in the distance of the tumor and anastomosis from the anal verge between the two groups. There are slight differences in each study such as material and diameter of TDT, length of TDT insertion, and length of TDT placement. Moreover, the difference in management of TDT might also be attributed to postoperative outcomes (leakages and re-operation). Standardized procedure of insertion of TDT should be validated, and further investigation is required to elucidate the usefulness of TDT.

Endoluminal pressure at the anastomotic site has been reported to be associated with anastomotic leakage [31] and can be an important factor in the prevention of anastomotic leakage after rectal surgery. The proximal diversion, by means of either a colostomy or an ileostomy, minimizes the consequences of anastomotic leakage by preventing fecal flow through the anastomosis [32–34]. TDT can be another effective method that can reduce the endoluminal pressure as TDT is known to be effective in obstructive colorectal cancer and has been suggested as good method to reduce endoluminal pressure [35, 36]. Animal model indicates that endoluminal pressure is associated with leakage [37]. TDT placement may be more cost-effective because TDT placement does not require another operation for stoma closure. Therefore, TDT placement is considered an effective and low-invasive treatment, linking with the reduction in psychological stress of patients due to the creation of diverting stoma. Since there has been no study which compared TDT against diverting stoma, a large randomized study is needed to evaluate safety and improvement of quality of life.

The rate of re-operation caused by anastomotic leakage was also reduced in the TDT group than in the non-TDT group. Recent studies have reported that TDT was effective for localizing leakage, controlling sepsis, and reducing the diverting stoma rate after a low anterior resection of the rectum [38, 39]. From these results, we hypothesized that TDT placement can drain stool and gas from the rectum; therefore, the stool cannot spread out from the anastomotic fistula to the pelvic space and result in a localized peritonitis. Localization of inflammation by TDT placement might reduce the incidence of re-operation, and localized inflammation can be cured conservatively. Moreover, TDT placement may lead to reduce the length of hospitalization and the cost in total treatment.

Preoperative chemoradiotherapy is performed for patients with local advanced rectal cancer followed by high-quality mesorectal excision (TME) surgery, and it is reported that this method can reduce the local recurrence rate [40–42]. However, there are many previous studies that report the relationship between preoperative radiation and anastomotic leak, and it is known that radiotherapy is one of the most important risk factor of anastomotic leak [9–13]. Although the included studies do not enroll the patients who underwent preoperative radiotherapy, TDT placement may be one of the methods to avoid diverting stoma from the result of this current study. Further investigation is needed to assess the efficacy and feasibility of TDT placement by comparing with diverting stoma for the patient with preoperative chemoradiotherapy.

The present study had several limitations. First, despite the inclusion of the outcomes from 909 patients in four studies, a lack of high-quality evidence was evident. Three studies were derived from non-randomized prospective and retrospective studies, and only one randomized controlled trial met the inclusion criteria for this meta-analysis. Although most of the included studies demonstrated homogeneity, the background of this meta-analysis may lead to less powerful results than data based purely on randomized patients. Second, two studies were open surgery only, whereas two studies also included laparoscopic surgery. Although recent comparative studies have demonstrated equivalent short-outcome and patient survival for open versus laparoscopic curative resection for colorectal cancer, the differences in surgical procedures may affect the results. Moreover, TDT placement may be more difficult in laparoscopic surgery than open surgery because the surgeon cannot check the TDT placement by tactile sense. This fact may be another considerable bias and should be considered in further investigation. Finally, all the included studies were published from far eastern countries so there may be some regional differences in the postoperative management. The findings of this study therefore have to be read with some cautions.

In conclusion, the results of the present meta-analysis have suggested that anterior resection with TDT placement for rectal cancer appeared to prevent anastomotic leakage. However, further confirmation and evaluation will be required to assess the advantage of TDT placement against diverting stoma.

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