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META-ANALYSIS

Efficacy of transanal drainage tube in preventing anastomotic leakage after surgery for rectal cancer: A meta-analysis

Shiki Fujino, Masayoshi Yasui, Masayuki Ohue, Norikatsu Miyoshi

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Abstract

BACKGROUND

Anastomotic leakage (AL) following rectal cancer surgery is an important cause of mortality and recurrence. Although transanal drainage tubes (TDTs) are expected to reduce the rate of AL, their preventive effects are controversial.

AIM

To reveal the effect of TDT in patients with symptomatic AL after rectal cancer surgery.

METHODS

A systematic literature search was performed using the PubMed, Embase, and Cochrane Library databases. We included randomized controlled trials (RCTs) and prospective cohort studies (PCSs) in which patients were assigned to two groups depending on the use or non-use of TDT and in which AL was evaluated. The results of the studies were synthesized using the Mantel-Haenszel random-effects model, and a two-tailed *P* value > 0.05 was considered statistically significant.

RESULTS

Three RCTs and two PCSs were included in this study. Symptomatic AL was examined in all 1417 patients (712 with TDT), and TDTs did not reduce the symptomatic AL rate. In a subgroup analysis of 955 patients without a diverting stoma, TDT reduced the symptomatic AL rate (odds ratio = 0.50, 95% confidence interval: 0.29–0.86, *P* = 0.012).

CONCLUSION

TDT may not reduce AL overall among patients undergoing rectal cancer surgery.

However, patients without a diverting stoma may benefit from TDT placement.

Key Words: Meta-analysis; Drainage; Transanal; Anastomotic leakage; Surgical stomas; Rectal cancer

Core Tip: Anastomotic leakage (AL) following rectal cancer surgery is a serious problem, and a transanal drainage tube (TDT) is expected to reduce AL. However, the preventive effects of TDT placement are controversial. Thus, we performed a meta-analysis of three randomized controlled trials and two prospective cohort studies. A systematic literature search was performed, and the results of the meta-analysis were synthesized using the Mantel-Haenszel random-effects model. Overall, TDT did not significantly reduce the symptomatic AL rate, but it did among patients without a diverting stoma.

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INTRODUCTION

Colorectal cancer (CRC) is a major cause of death in many countries and regions[1], and surgical resection of primary tumors is an important treatment for CRC[2]. With the development of surgical devices and procedures, from open to laparoscopic to robot-assisted surgeries, surgical outcomes have improved[3,4]. However, anastomotic leakage (AL) following surgery remains a serious complication related to mortality and recurrence, and the rate of AL is higher for rectal cancer surgery than that for colon cancer surgery[5,6].

To avoid AL, a combination of prophylactic procedures has been used, such as bowel preparation before surgery, anastomosis blood flow evaluation[7,8], and especially transanal drainage tubes (TDTs) and diverting stomas[8,9]. In recent years, preoperative therapies, such as chemoradiotherapy (CRT) or radiotherapy followed by chemotherapy, have been aggressively performed for advanced rectal cancer, and higher-risk patients are undergoing surgery after radiotherapy[10,11]. A diverting stoma is recommended for patients at high risk for AL[12], but stoma-related complications, such as high-output syndrome, skin irritation, stoma necrosis, and parastomal hernia, decrease the patient's quality of life and may lead to rehospitalization[13]. Therefore, many clinical studies have been performed to determine whether TDT can prevent AL; however, the results are controversial and most studies were retrospective[14-17]. Recently, the two most randomized controlled trials (RCTs) on the role of TDT in the prevention of AL were reported by Zhao *et al*[18] and Tamura *et al*[19]. The only related RCT published before these studies was reported by Bülow *et al*[20], but surgical procedures and pre-operative treatments have changed since then, as did the shape of the most commonly used TDT and the placement location. Thus, we performed an updated meta-analysis to incorporate the two new RCTs and new prospective cohort studies (PCSs), aiming to reveal the role of TDTs in preventing AL after rectal cancer surgery.

MATERIALS AND METHODS

This meta-analysis was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines[21]. The inclusion criteria were as follows: (1) An RCT or PCS for patients with a TDT; (2) Patients assigned to two groups depending on the use or non-use of TDT; and (3) The primary endpoint was the AL rate. Studies were excluded if one of the following occurred: (1) It was retrospective; (2) It was a review or case report; (3) Data were duplicated; (4) No comparisons were performed with a non-TDT group; (5) Full text could not be obtained; or (6) The TDT was not located at least several centimeters above the anastomosis. This study was not registered to public database.

Patients and study outcomes

We targeted patients with rectal cancer who underwent surgery for resection of the primary tumor with anastomosis. This is because the outcome is difficult to understand if the patient population is expanded, for instance, including those with inflammatory bowel disease. The outcome was the incidence of symptomatic AL after TDT.

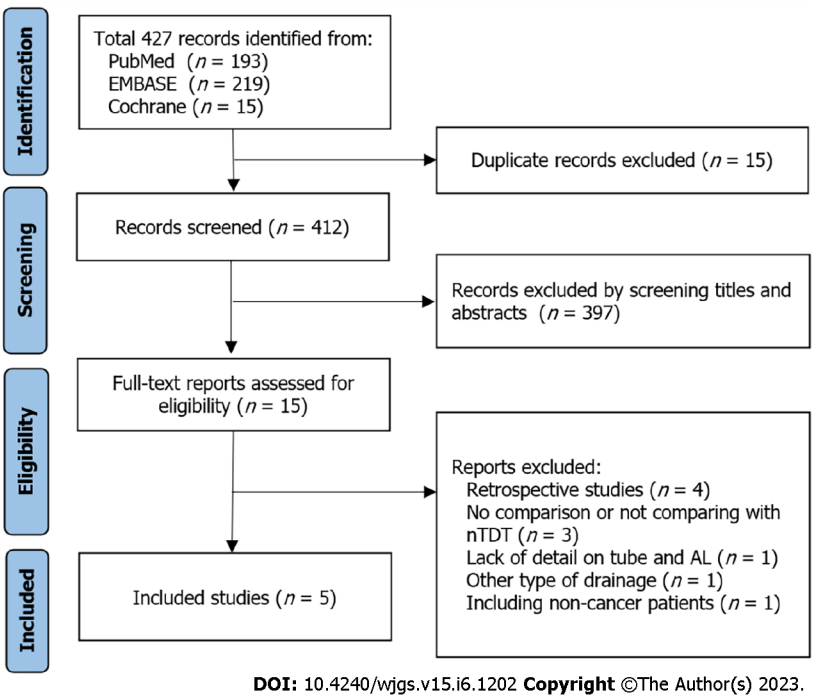

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Figure 1 Identification of studies *via* databases and registers. nTDT: Non-transanal drainage; AL: Anastomotic leakage.

Data sources and extraction

A systematic literature search for this study was performed using the advanced search of MEDLINE/PubMed, Embase, and Cochrane Library databases from inception until December 12, 2022, without language restrictions. The following search terms were used in all database searches: "transanal OR trans anal" AND "drainage OR tube OR stent" AND "rectal cancer". The titles and abstracts of all the retrieved records were reviewed independently by two investigators (Fujino S and Miyoshi N). All disagreements were resolved by consensus with a third investigator (Yasui M). The information extracted included the name of the first authors, year of publication, study design, study setting, types of operation, randomization procedure, TDT-related information (material, diameter, placement, duration), number of cases of AL, and grades of AL.

Meta-analysis

The results were synthesized using the Mantel-Haenszel random-effects model. Data were expressed as odds ratios (ORs) and 95% confidence intervals (CIs). A funnel plot was used to evaluate potential publication bias and other possible biases. A two-tailed P value > 0.05 was considered statistically significant. A sensitivity analysis detected the influence of individual studies on the pooled OR by omitting one study at a time and recalculating the pooled OR. Subgroup analyses determined the effect of TDT in patients without a diverting stoma. Data were analyzed using R software (CRAN, R 3.6.2; cran.r-project.org) and the meta package (v4.17-0)[22]. The statistical methods of this study were reviewed by Miyoshi N.

RESULTS

Overall, 412 records were identified from the selected databases. We carefully evaluated each of them according to the inclusion and exclusion criteria. Finally, three RCTs[18,19,23] and two PCSs[24,25] were included in this study (Figure 1). The characteristics of the study population are summarized in Table 1. None of the studies revealed differences between the TDT and non-TDT groups in terms of sex, age, diverting stoma, or preoperative CRT. Patients undergoing preoperative CRT were excluded from three studies, and patients undergoing diverting stoma were excluded from two studies.

Symptomatic AL

Symptomatic AL was examined in all 1417 patients: 712 with TDT and 705 without TDT. Funnel plots based on AL grades are shown in Figure 2. Symptomatic AL was observed in 47 patients (6.6%) with TDT and 60 (8.5%) without TDT. TDT did not reduce the symptomatic AL rate (OR = 0.74, 95%CI: 0.39-1.40, P = 0.355) (Figure 3A). AL that required re-operation, *i.e.*, grade C, was observed in 13 patients (1.8%) with TDT and 34 (4.8%) without TDT. TDT did not reduce the grade C AL rate (OR = 0.43,

Table 1 Characteristics of the studies

		Zhao *et al* [18]	Tamura *et al* [19]	Xiao *et al*[23]	Challine *et al*[24]	Zhao *et al* [25]
Country		China	Japan	China	France	China
Published year		2021	2021	2011	2020	2013
Study design		RCT	RCT	RCT	PCS	PCS
Study setting		Multicenter	Multicenter	Single center	Single center	Singlecenter
Age	TDT	62 (54-69)[1]	69 (40-90)[1]	59 ± 11[2]	64 ± 12[2]	≥ 60/< 60, 30/51
	Non-TDT	62 (52-69)[1]	69 (39-91)[1]	58 ± 12[2]	60 ± 12[2]	≥ 60/< 60, 36/41
Sex (male/female)	TDT	177/103	51/28	115/85	51/21	47/34
	Non-TDT	169/111	50/28	121/77	51 / 21	43/34
Preoperative treatment (radiochemotherapy)	TDT	Excluded	10 (12.7%)	Excluded	41 (56.9%)	Excluded
	Non-TDT	Excluded	19 (24.3%)	Excluded	47 (65.3%)	Excluded
DS	TDT	72 (25.7%)	34 (43.0%)	Excluded	Unknown but equal rate by matching	Excluded
	Non-TDT	89 (31.8%)	37 (47.4%)	Excluded	Unknown but equal rate by matching	Excluded
Type of tube		Silicone tube, 28 Fr	Latex tube, 20-24 Fr	Silicone tube commonly used for abdominal drainage	Foley catheter, Ch 22	Rubber tube, 26 Fr
Duration		3-7 d	At least 5 d	5-7 d	At least 4 d	5-6 d
Significant side effects relating to anal tube		Anal pain	None	Perianastomotic bleeding	None	None
AL (A/B/C)	TDT	NA/14/4	2/5/1	NA/6/2	12/9/4	NA/0/2
	Non-TDT	NA/11/8	3/7/1	NA/3/16	9/5/2	NA/0/7
AL in the patients wihout a DS (A/B/C)	TDT	NA/8/4	NA	NA/6/2	NA	NA/0/2
	Non-TDT	NA/7/8	NA	NA/3/16	NA	NA/0/7

[1]Median (range).
[2]mean ± SD.
NA: Not available; TDT: Transanal drainage tube; RCT: Randomized controlled trial; PCS: Prospective cohort study; AL: Anastomotic leakage; DS: Diverting stoma.

95%CI: 0.16-1.17, P = 0.099) (Figure 3B). Sensitivity analysis showed that the pooled estimate of the effect of TDT for AL in all patients did not vary substantially (Figure 4).

Subgroup analysis of patients without a diverting stoma

In two studies, incidence of AL in patients without a diverting stoma was not mentioned. Therefore, a total of 955 patients without a diverting stoma were identified in three studies[18,23,25]: 489 with TDT and 466 without TDT. Symptomatic AL was observed in 22 patients (4.5%) with TDT and 41 (8.8%) without TDT. TDT reduced the symptomatic AL rate (OR = 0.50, 95%CI: 0.29-0.86, P = 0.012) (Figure 5A). Grade C AL was observed in eight patients (1.6%) with TDT and 31 (6.7%) without TDT. TDT also reduced the grade C AL rate (OR = 0.26, 95%CI: 0.11-0.59, P = 0.001) (Figure 5B). Sensitivity analysis revealed that the pooled estimate of the effect of TDT for AL in patients without a diverting stoma did not vary substantially (Figure 6).

DISCUSSION

The development of surgical methods and the intensification of combination therapies with radiation

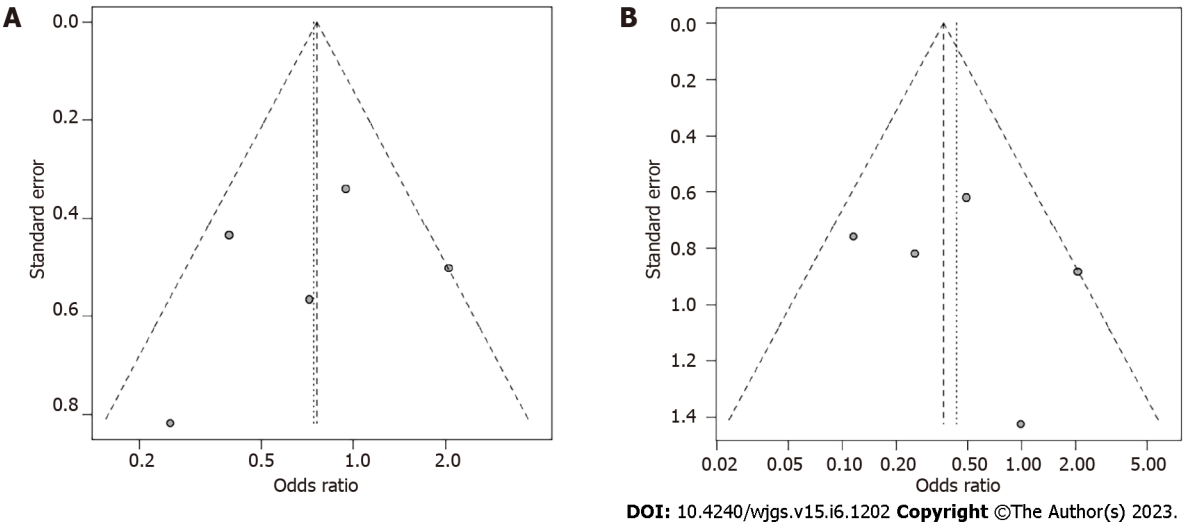

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Figure 2 Funnel plots based on symptomatic anastomotic leakage grades. A: Symptomatic leakage of grades; B: Leakage that required re-operation (grade C).

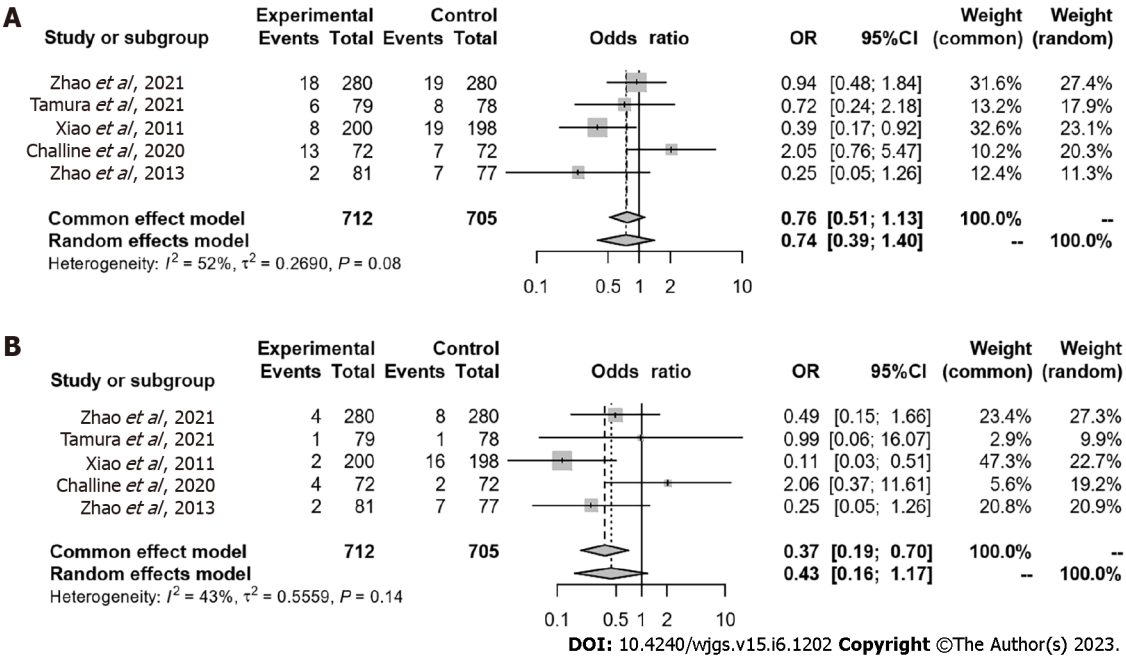

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Figure 3 Comparison of anastomotic leakage rates between transanal drainage tube group and non-transanal drainage tube group in all patients. A: Analysis based on symptomatic leakage (grades B and C); B: Analysis based on leakage that required re-operation (grade C). OR: Odds ratio; CI: Confidence interval.

therapy, chemotherapy, *etc*., constantly changes the background of the patients that physicians encounter. However, we must continue efforts to improve surgical outcomes because they are directly related to patient outcomes[5,6]. Regarding the background of the five trials included in this meta-analysis, patients who had received preoperative treatment were excluded in three. as the stated reason was that radiotherapy is a risk factor for AL[18]. In addition, patients with diverting stomas were excluded from two studies and allowed in three studies. The decision to use a diverting stoma depended on the surgeon, that is, diverting stomas were used in patients whom surgeons considered at a high risk for AL. Thus, the results of these studies should be interpreted carefully, recognizing the limitations inherent in the patient samples. In this meta-analysis, TDT did not reduce the rate of AL in any of the patients. Therefore, we attempted to clarify the role of TDT by subgroup analysis. Accordingly, we revealed that TDT significantly reduced the incidence of AL among patients without a diverting stoma.

Thus, based on patients' background and the analysis results, a diverting stoma should be used in high-risk patients, but TDT is sufficient in patients who are not at a high risk of AL, without the use of a

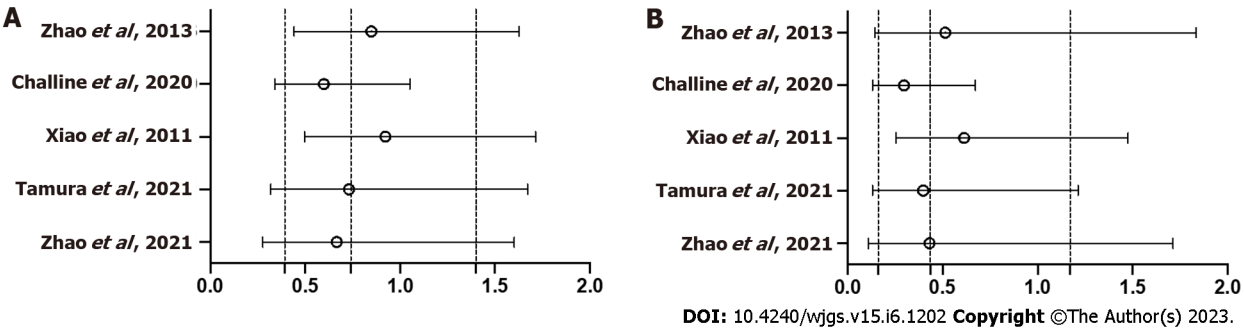

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Figure 4 Sensitivity analysis of anastomotic leakage rates between transanal drainage tube group and non-transanal drainage tube group in the meta-analysis. A: Analysis based on symptomatic leakage (grades B and C); B: Analysis based on leakage that required re-operation (grade C). Odds ratios (ORs) and 95% confidence intervals (CIs) are shown as circles and bars when each noted study is omitted. The dash lines show the pooled ORs and 95%CIs for all included studies.

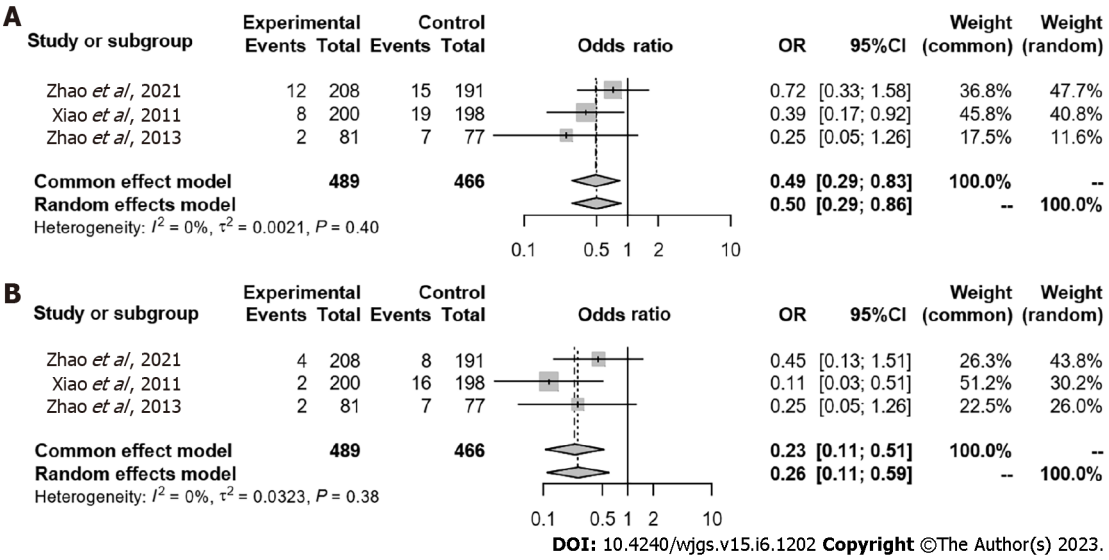

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Figure 5 Comparison of anastomotic leakage rates between transanal drainage tube group and non-transanal drainage tube group among patients without diverting stoma. A: Analysis based on symptomatic leakage (grades B and C); B: Analysis based on leakage that required re-operation (grade C). OR: Odds ratio; CI: Confidence interval.

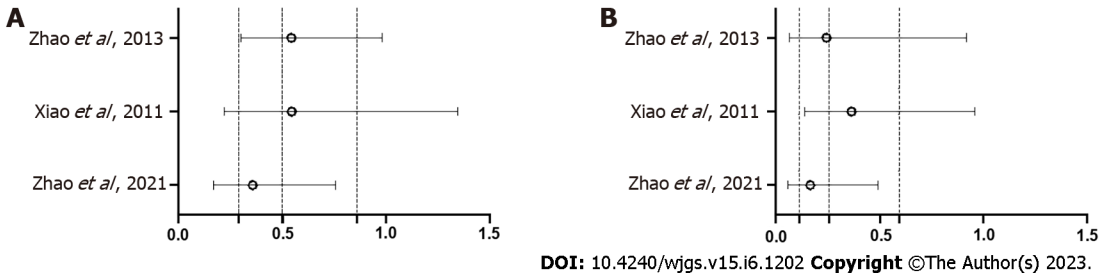

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Figure 6 Sensitivity analysis of anastomotic leakage rates between transanal drainage tube group and non-transanal drainage tube group in the sub-group meta-analysis. A: Analysis based on symptomatic leakage (grades B and C); B: Analysis based on leakage that required re-operation (grade C). Odds ratios (ORs) and 95% confidence intervals (CIs) are shown as circles and bars when each noted study is omitted. The dash lines show the pooled ORs and 95%CIs for all included studies.

diverting stoma. We expect that further research will be conducted to determine which patients are at a high risk and are eligible for diverting stoma augmentation. The time from preoperative radiation therapy to surgery varies among patients[10], and other risk factors for AL, such as sex, age, tumor size, and tumor location have been reported[26,27]. The role of TDT may be to steadily reduce AL in patients for whom a stoma may be avoided, rather than to place a stoma in such high-risk patients.

Besides, there are also some meta-analyses including tow RCTs[18,19] reported in 2021. Zhao *et al*[18] analyzed only 3 RCTs[18,19,23] and concluded that TDTs do not reduce the incidence of AL, but may reduce the grade C AL[28]. Deng *et al*[29] analyzed 7 studies, including retrospective studies, and concluded that TDTs do not reduce the incidence of AL in all patients. They also performed subgroup analyses and the AL rate was significantly low in patients without neoadjuvant therapy and diverting stoma but mentioned that TDT may be useless for those in high-risk situations. Zhang *et al*[30] analyzed 13 studies including retrospective studies and concluded that TDT reduced the incidence of AL in the patients without diverting stoma. Although each study was conducted in a different, separately selected group, we can conclude, as we did, that the benefit of TDT for all patients is low, but the benefit of TDT for a limited number of patients is high. Therefore, we would like to reiterate that the role of TDT would not be to avoid diverting stoma, but to steadily decrease AL in low-risk patients who were thought to be able to avoid diverting stoma.

Finally, in the five included studies, complications of TDT were anal pain and anal bleeding, whereas no intestinal injuries due to the tube were observed. However, such injuries were previously reported [31], and patients should be carefully monitored to determine when and where to place a TDT and to confirm its position using radiography.

As the limitations of this study, the patients' background was different in studies, and the criteria for high-risk patients with a diverting stoma was not standardized. Additionally, the number of studies included in our review was small, and there may have been some bias. However, rather than viewing TDTs as substitutes for diverting stomas, one may need to identify high-risk patients, in whom a stoma should be used, and non-high-risk patients, in whom a TDT should be placed to prevent AL and improve surgical outcomes for patients with rectal cancer.

CONCLUSION

TDTs did not reduce AL in any of the patients with rectal cancer who underwent primary tumor resection with anastomosis. However, patients who do not undergo diverting stoma augmentation based on the surgeon's decision may benefit from TDT placement.

ARTICLE HIGHLIGHTS

Research background

Anastomotic leakage (AL) following rectal cancer surgery remains a serious problem, and transanal drainage tubes (TDTs) and diverting stomas have been performed to avoid AL. However, the efficiency of TDTs results is controversial.

Research motivation

Recently, the two randomized controlled trials (RCTs) on the role of TDT were reported. Therefore, we performed an updated meta-analysis to incorporate them.

Research objectives

We aimed to reveal the role of TDTs in preventing AL after rectal cancer surgery.

Research methods

A systematic literature search was performed using databases and meta-analyses were performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines.

Research results

TDT did not reduce the symptomatic AL rate in all patients, but TDT reduced the symptomatic AL rate in patients without a diverting stoma.

Research conclusions

TDT may not reduce AL in all patients undergoing rectal cancer surgery. However, patients without a diverting stoma may benefit from TDT placement.

Research perspectives

Rather than viewing TDTs as substitutes for diverting stomas, we must identify high-risk patients, in whom a stoma should be used, and non-high-risk patients, in whom a TDT should be placed to prevent AL.

FOOTNOTES

Author contributions: Fujino S, Yasui M, Ohue M, and Miyoshi N designed the research study; Fujino S, Yasui M, and Miyoshi N performed the research; Fujino S and Miyoshi N analyzed the data; Fujino S wrote the manuscript; and all authors have read and approve the final manuscript.

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