

Review Article

Role of transanal decompression tubes in preventing anastomotic leakage after anterior resections for rectal cancer: a meta-analysis

Zhen-Hua Liu^{1,2}, Jie Ding¹, Qi Dong¹, Rui Mi¹, Zhuan Jiang¹, Hang Liu¹, Ning Wang³

¹Department of Gastrointestinal Surgery, Guizhou Provincial People's Hospital, Guiyang, China; ²Medical College of Guizhou University, Guiyang, China; ³Department of Pharmacy, Guizhou Provincial Orthopedic Hospital, Guiyang, China

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Abstract: Postoperative AL in rectal cancer surgery is a serious complication and a heavy burden for patients. The aim of this meta-analysis was to determine the value of transanal decompression tubes (TDT) in preventing anastomotic leakage in patients with rectal cancer after anterior resections. Published studies comparing TDT with non-TDT after rectal cancer resections, from 2002 to 2017, were searched without language preferences. Extracted data, including anastomotic leakage, re-operation, anastomotic bleeding, and length of hospital stays, were compared by meta-analysis. Fourteen studies, involving 3,332, patients were included. Compared with the non-TDT group, anastomotic leakage and re-operations in the TDT group were significantly reduced (RR 0.586; 95% CI 0.43 to 0.79; $P < 0.0001$; RR 0.28, 95% CI 0.16 to 0.52, $P < 0.0001$). No significant differences in anastomotic bleeding and length of hospital stays were observed between the two groups (RR 1.55, 95% CI 0.89 to 2.68, $P = 0.21$; MD -0.93, 95% CI -3.34 to -1.48, $P = 0.45$). TDT placement is a simple, noninvasive, and economic alternative approach in the prevention of anastomotic leakage after anterior resections in patients with rectal cancer.

Keywords: Rectal cancer, rectal cancer anterior resection, transanal decompression tubes, meta-analysis

Introduction

With the development of surgical instruments and techniques, total mesorectal excision (TME) has become a standard surgical technique, widely used in patients with low rectal cancer, especially ultralow rectal cancer. Preserving sphincter function is possible with this technique [1]. In contrast to significant increases in sphincter preservation rates, anastomotic leakage (AL) has not decreased, but rather increased, drawing much attention from surgeons [2, 3]. AL remains one of the most serious complications after colorectal surgery, with an incidence rate of 8.58% [4]. AL affects long-term survival and leads to other complications, such as local recurrence, anastomotic bleeding, re-operations, and increased postoperative mortality in patients with rectal cancer [5].

Aiming to decrease the rate of AL after anterior resections for rectal cancer, some centers have

advocated protective proximal enterostomies to protect the anastomosis [6]. However, some scholars believe that not all patients with rectal cancer resection require such operations. Protective proximal enterostomies require a re-operation to close the stoma. Re-operations cause increased pain and psychological and economic burden for patients, leading to complications, such as skin infections, incisional hernia, and electrolyte disorders [7-9]. Given these disadvantages, clinicians have continued to explore the value of transanal decompression tubes (TDT) in protecting the anastomosis after rectal surgery. The use of TDT can reduce intestinal pressure, provide drainage, protect the anastomosis, and promote gastrointestinal peristalsis. TDT placement is simple, safe, and noninvasive. It can decrease incidence of postoperative AL [10-12]. However, one study reported that TDT placement does not diminish the risk of AL but increases incidence of AL,

anastomotic bleeding, and bowel perforation [13].

In recent years, several prospective and retrospective studies have been conducted concerning incidence of AL after colorectal surgery, but results have remained controversial. A study by Yang et al. [14] showed significantly lower AL rates and re-operation rates in the TDT group, compared to the non-TDT group, after low anterior resections for rectal cancer. Anastomotic bleeding rates were similar between the two groups. Therefore, they concluded that TDT may be an efficient and economic intervention in preventing AL after rectal cancer surgery.

Unfortunately, only seven studies with a small number of cases were included in the meta-analysis by Yang et al. [14], making objective evaluation of the advantages of TDT difficult. Furthermore, included studies consisted of randomized controlled trials (RCTs) and non-RCTs. Therefore, sensitivity analysis should be performed to determine the validity of the results and a meta-analysis of more studies with larger sample sizes and objective appraisal of complications is necessary to determine the exact roles of TDT in preventing AL after rectal cancer resections. This analysis could be used as a basis to investigate the safety, noninvasiveness, and effectiveness of TDT.

Material and methods

Candidate studies included prospective RCTs and retrospective nonrandomized trial (RNTs) comparing TDT and non-TDT groups and involving rates of AL, anastomotic bleeding, re-operations, and length of hospital stays.

Search strategy

Two authors (Z.H.L. and J.D.) searched and identified all relevant published studies independently, up through November 1, 2017, via computer-assisted search of PubMed, Cochrane Library databases, SAGE Journals, and trial registry databases (International Clinical Trials Registry Platform and National Clinical Trials Registry) without language preferences. The following keywords were used: “rectal cancer”, “transanal tube OR transanal stent OR transanal decompression tube”, and “anasto-

motric leakage”. Cited references in each retrieved article were also checked for relevance.

Inclusion and exclusion criteria

Inclusion criteria were as follows: (1) Patients with rectal cancer; (2) Study design that compared outcomes of TDT and non-TDT groups; (3) Anastomosis was performed using the single- or double-stapling technique; and (4) Presence of raw data, including one or more of the following: AL, anastomotic bleeding, re-operation, and length of hospital stays. Exclusion criteria were as follows: (1) Incomplete data; (2) Duplicate studies; (3) Studies that included diverting stomas; and (4) Hand-sewn anastomosis.

Quality of literature evaluation

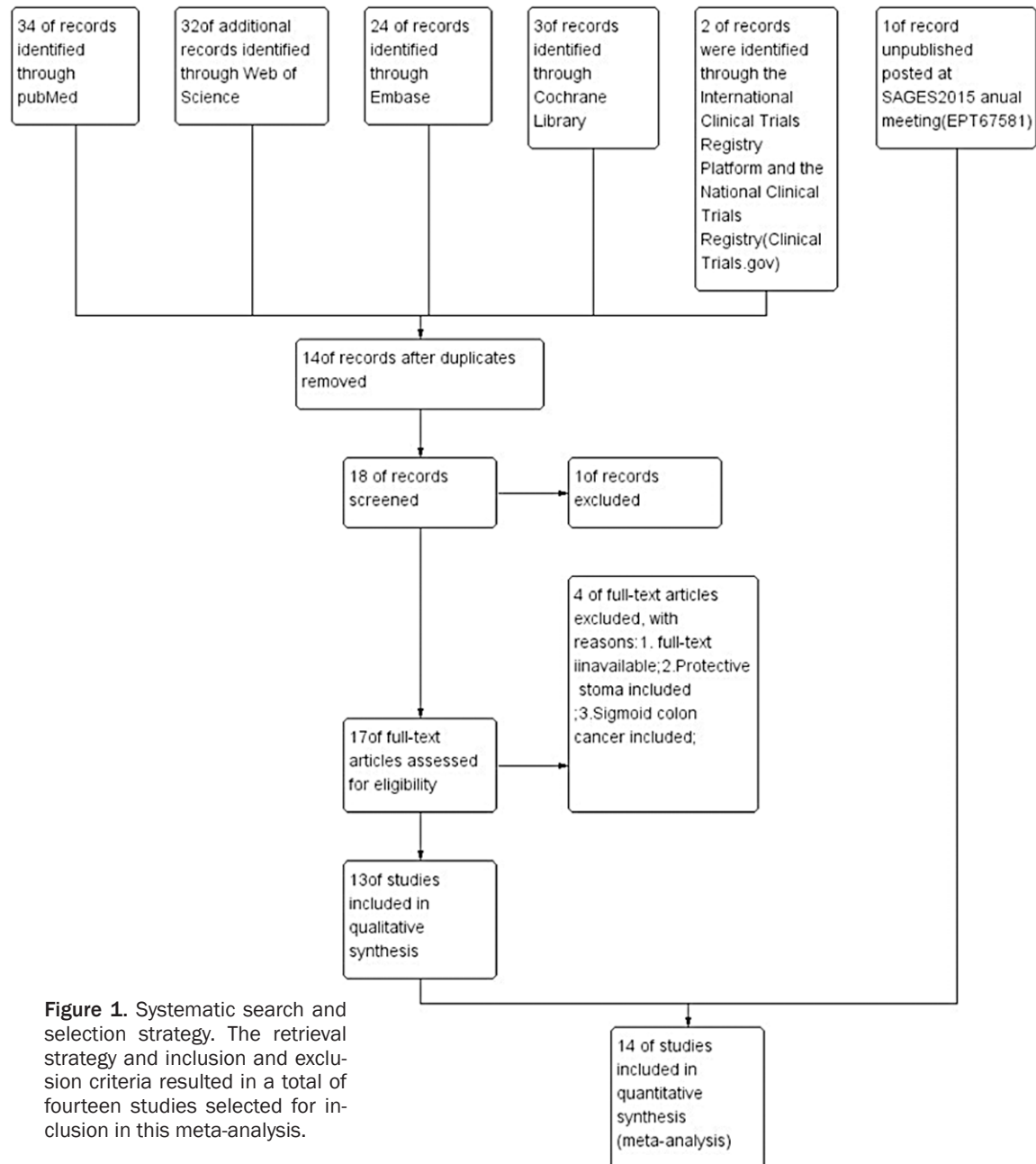
Two prospective RCTs were evaluated using the Cochrane Collaboration's tool for risk of bias assessment. Twelve RNTs were reviewed to determine the risk of bias and were scored 6-9, according to the Newcastle-Ottawa scale. These 14 studies were analyzed using a funnel plot.

Data collection

Two investigators (Z.H.L. and J.D.) independently extracted data from eligible studies by reviewing abstracts and full texts of retrieved articles. Disagreements were resolved by discussion. The following data were extracted from each study: author names, publication year, type of study, study period, sample size, patient age, gender, BMI, anastomosis location, rate of AL, bleeding, re-operation, and length of hospital stays.

Outcomes of interest and definition

Outcomes of interest included rates of AL, bleeding, re-operations, and length of hospital stays. AL diagnosis was verified by peritoneal drainage of excrement, pus, or gas, indicating peritonitis, and the presence of pelvic abscesses and pus discharge from the rectovaginal or rectovaginal fistula. Clinical and/or radiological (radiographic or computed tomography scans) examinations were also performed. Re-operations were required for anastomotic fistula or bleeding.



Data analysis

Risk ratios (RRs) between dichotomous outcomes of AL, anastomotic bleeding, re-operation rates, and length of hospital stays were calculated for each study. Statistical heterogeneity was assessed using I^2 and χ^2 statistics with 95% confidence intervals (CIs). Outcome variables were tested for homogeneity to calculate Q statistics and associated P values. Two-tailed $P < 0.05$ is considered statistically significant. Synthesized effect sizes were calculated

using Review Manager 5.3 software (Cochrane Community, London, United Kingdom).

Results

Data included

The retrieval strategy and inclusion and exclusion criteria resulted in a total of two RCTs [13, 15] and 12 RNTs for analysis [6, 11, 12, 16-24]. Search and exclusion strategies are shown in **Figure 1**. The 14 case studies included 3,332

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Table 1. General characteristics of included studies

Author	Stud type	Study period	Publication year	Distance of tumor or anastomosis from anal verge		Surgical type	Stapling technique	Type of tube	Diameter of tube	Tube position	Duration of TDT (day)	Follow-up (day)
				TDT	Non-TDT							
Bülow <i>et al.</i> [13] 2006	PRCT	September 2000-September 2003	2006	1/18/35 (lower/middle/upper)	1/9/40/1 (lower/middle/upper/unknown)	NA	Staple	Silicone stent	NA	NA	4	NA
Cong <i>et al.</i> [6] 2009	RNT	2005-2008	2009	NA	NA	TME	NA	NA	NA	NA	NA	NA
Xiao <i>et al.</i> [14] 2011	PRCT	June 2003-December 2009	2011	7 (3.5-11)	8 (3.5-11)	TME	188/182 (double-staple/control) 12/16 (hand-sewn/control)	Soft silicone tube	NA	NA	5-7	30
Zhao <i>et al.</i> [15] 2013	RNT	January 2007-May 2011	2013	22/46/13 (lower/middle/upper)	21/38/18 (lower/middle/upper)	TME	Single or double-staple technique	Ordinary rubber drainage tube	26Fr (9.4 mm)	Tip 3-5 cm proximal to the anastomosis	5-6	NA
Nishigori <i>et al.</i> [23] 2014	RNT	January 2007-August 2011	2014	4.5 (2.0-6.5)	4.5 (1.0-7.5)	TME	Double-staple technique	Ficon (silicone) drain	24Fr (8 mm)	Tip 3-5 cm proximal to the anastomosis	5	30
Adamova <i>et al.</i> [16] 2014	RNT	January 2008-June 2013	2014	Within 10 cm of the anal verge	Within 10 cm of the anal verge	NA	Stapler	Soft silicone tube	NA	NA	5-6	NA
Lee <i>et al.</i> [18] 2015	RNT	January 2005-December 2014	2015	70/84 (lower/middle/upper)	68/86 (lower/middle/upper)	TME	Double-staple technique	Rubber catheter	10Fr (3.3 mm)	Tip 5-10 cm proximal to the anastomosis	3	30
Yang <i>et al.</i> [22] 2015	RNT	September 2009-June 2013	2015	67/136/21 (lower/middle/upper)	64/139/23 (lower/middle/upper)	TME	Double-staple technique	PVC	25.5Fr (8.5 mm)	Tip 3-5 cm proximal to the anastomosis	7	30
Hidaka <i>et al.</i> [19] 2015	RNT	September 2008-August 2013	2015	45.0 ± 17.8 (mm)	50.9 ± 15.9 (mm)	TME CMCC	Double-staple technique	Marecot Catheter or Pleats drain	28Fr (9.4 mm) or 30Fr (10 mm)	Tip 3 cm proximal to the anastomosis	7	NA
Tanaka <i>et al.</i> [21] 2015	RNT	January 2008-October 2013	2015	NA	NA	NA	NA	NA	NA	NA	NA	NA
Kim <i>et al.</i> [17] 2015	RNT	February 2010-February 2014	2015	8.8 (median)	8.9 (median)	NA	Double-stapling technique	Silicone tube	7 mm	NA	5 (4-7)	30
Yang <i>et al.</i> [12] 2016	RNT	April 2012-October 2014	2016	4.0	4.5	TME	Stapler	Ordinary rubber tube	24Fr (8 mm) OR 28-Fr (9.4 mm)	Tip 4-6 cm proximal to the anastomosis	4-6	NA
Tanaka <i>et al.</i> [11] 2017	RNT	February 2008-August 2010	2017	57/46 (lower/upper)	163/129 (lower/upper)	NA	Stapler	NA	NA	NA	NA	NA
Goto <i>et al.</i> [20] 2017	RNT	April 2009-March 2014	2017	8 (6-10)	10 (8-15)	TME or TSME	Double stapling technique	Silicone or rubber tube	30Fr (10 mm)	Tip 3-5cm proximal to the anastomosis	4-6	30



Figure 2. Quality of literature evaluation. Two prospective RCTs were evaluated according to the Cochrane Collaboration standards on risk of bias assessment and were graded 4 and 5 points. Author judgements were reviewed regarding each risk of bias item for each included study according to the Newcastle-Ottawa scale. Twelve OCTs were scored 6 or 8 stars in the Newcastle-Ottawa scale.

patients. Of these patients, 1,486 were in the TDT group and 1,846 were in the non-TDT group. General characteristics of these cases are shown in **Table 1**. Quality assessment of the reported studies is displayed in **Figure 2**.

Anastomotic leakage

All 14 clinical studies provided data on AL. AL rates in TDT (1,486 cases) and non-TDT (1,846

cases) groups in these 14 studies were calculated. The heterogeneity test showed an acceptable but relatively high heterogeneity ($I^2 = 48\%$; $P = 0.02$) for AL in the 14 clinical studies. Mantel-Haenszel fixed-effects model was used to combine the data. A total of 248 cases had AL, resulting in an AL rate of 7.44%. AL rates were significantly lower in the TDT group (5.11%) than the non-TDT group (9.31%) (RR 0.586; 95% CI 0.43-0.79; $P < 0.0001$) (**Figure 3**).

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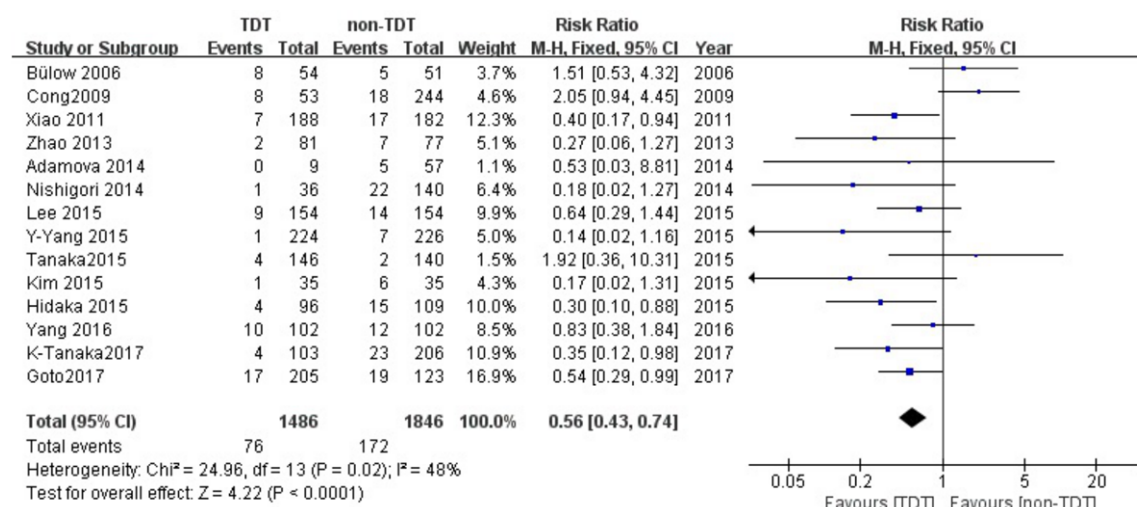


Figure 3. Forest plot of anastomotic leakage rates in the TDT group compared with the non-TDT group. All 14 clinical studies provided data on AL. AL rate was significantly lower in the TDT group (5.11%) than in the non-TDT group (9.31%) (RR 0.586; 95% CI 0.43 to 0.79; $P < 0.0001$). The heterogeneity test showed an acceptable, but relatively high heterogeneity ($I^2 = 48\%$; $P = 0.02$) in AL in the 14 clinical studies.

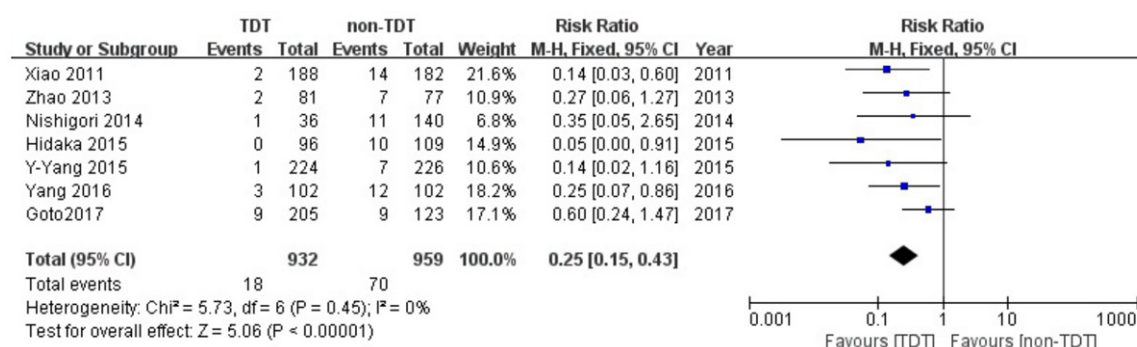


Figure 4. Forest plot of re-operations in the TDT group compared with the non-TDT group. Seven studies included data on re-operation rates. Results indicated that TDT contributed to a significantly lower re-operation rate than non-TDT (RR 0.25; 95% CI 0.15 to 0.43; $P < 0.0001$). A fixed-effects model was used to combine the data, as heterogeneity was not evident ($I^2 = 0\%$; $P = 0.45$).

Re-operations

Seven studies [12, 15, 16, 20, 21, 23, 24] included data on re-operation rates. A fixed-effects model was used to combine the data, as heterogeneity was not evident ($I^2 = 0\%$; $P = 0.45$). Results indicated that TDT contributed to significantly lower re-operation rates than non-TDT (RR 0.25; 95% CI 0.15-0.43; $P < 0.0001$) (Figure 4).

Anastomotic bleeding

Data concerning anastomotic bleeding were obtained. A total of 1,580 cases from six studies [12, 15, 16, 18, 21, 23] were included in

this meta-analysis. Anastomotic bleeding in the TDT group increased, compared to the non-TDT group. A fixed-effects model was used to combine the data, as heterogeneity was not evident ($I^2 = 30\%$; $P = 0.21$). Rates of anastomotic bleeding were not significantly different between TDT and non-TDT groups (RR 1.55; 95% CI 0.89-2.68; $P = 0.12$) (Figure 5).

Length of hospital stays

Three clinical studies [15, 23, 24] presented data on the length of hospital stays. The heterogeneity test showed heterogeneity in hospitalization lengths in all three clinical studies ($I^2 = 87\%$; $P = 0.0005$). Therefore, a random-

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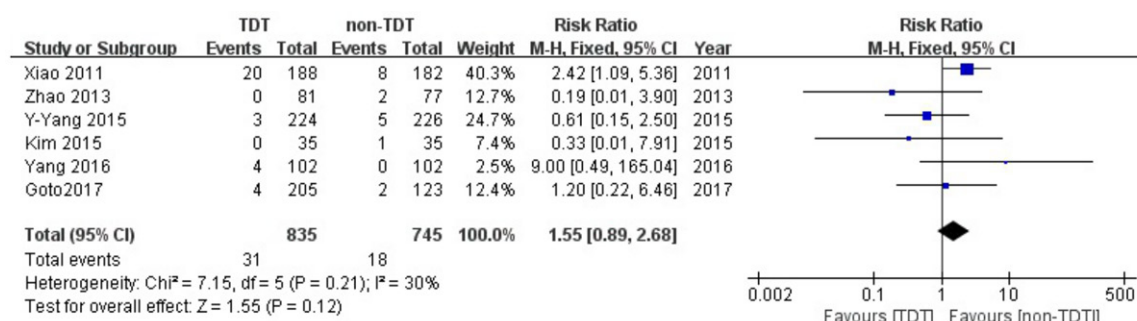


Figure 5. Forest plot of anastomotic bleeding in the TDT group compared with the non-TDT group. A total of 1,580 cases from six studies were included in this meta-analysis. Rate of anastomotic bleeding was not significantly different between the TDT and non-TDT groups (RR 1.55; 95% CI 0.89 to 2.68; $P = 0.12$).

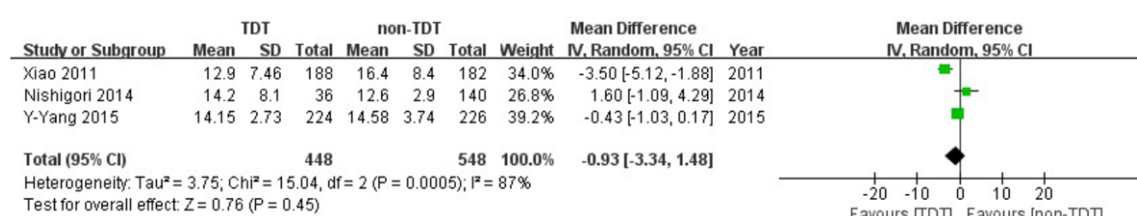


Figure 6. Forest plot of length of hospital stays in the TDT group compared with the non-TDT group. Three clinical studies presented data on the length of hospital stays. Length of hospital stays in the TDT and non-TDT groups in all three studies was analyzed and compared. No significant difference was observed (MD -0.93; 95% CI -3.34 to 1.48; $P = 0.45$).

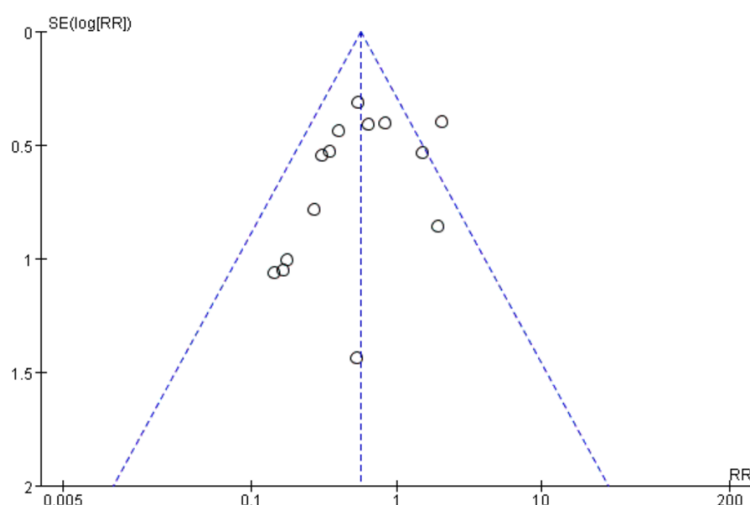


Figure 7. Funnel plot of comparison of anastomotic leakage rates between TDT group and the non-TDT group, including both prospective RCTs and RNTs. There was no visible publication bias in the funnel plot of anastomotic leakage rates.

effects model was used to combine the data. Length of hospital stays in TDT and non-TDT groups in all three studies was analyzed and compared. No significant differences were ob-

served, however (MD -0.93; 95% CI -3.34 to 1.48; $P = 0.45$) (Figure 6).

Assessment of publication bias

A funnel plot of standard error by effect size for measurements of AL, re-operations, and anastomotic bleeding was carried out. Scatter points in the plot were distributed around the middle line, indicating that publication bias was not evident (Figures 7-9).

Sensitivity analysis

The following three outcomes were selected for sensitivity analysis (Table 2): (1) Two randomized controlled trials; (2) Twelve studies with a quality score ≥ 12 ; and (3) Thirteen studies with ≥ 30 cases per group. Outcomes that could not be analyzed due to insufficient

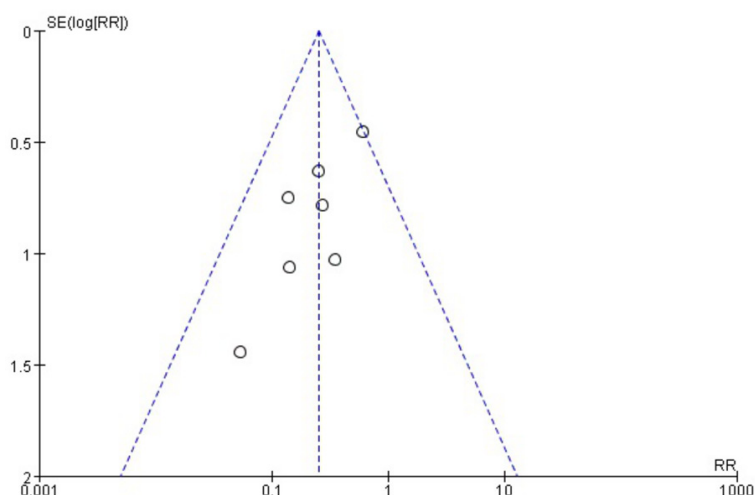


Figure 8. Funnel plot of comparison of re-operations between TDT group and the non-TDT group. There was no visible publication bias in re-operation.

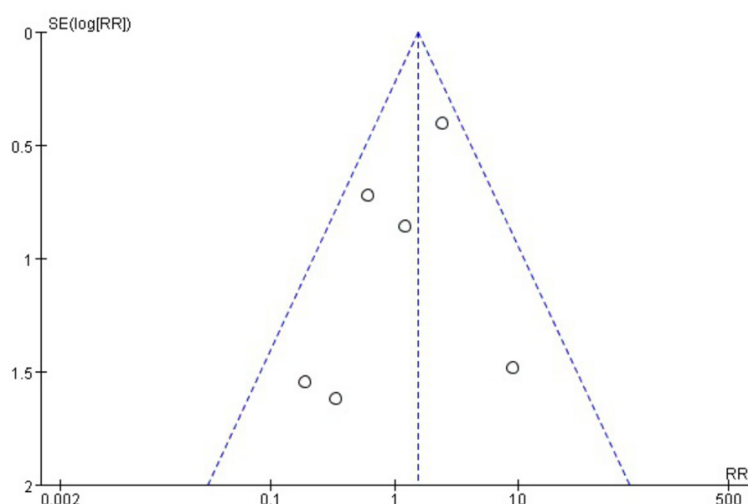


Figure 9. Funnel plot of comparison of anastomotic bleeding between TDT group and non-TDT group. There was no visible publication bias in the funnel plot of anastomotic bleeding.

data (< 2 studies) were excluded from analysis.

Randomized controlled trials

Incidence of AL was not significantly different between TDT and non-TDT groups (RR 0.75; 95% CI = 0.20 to 2.76; $P = 0.66$). However, three variables, including re-operations, anastomotic bleeding, and length of hospital stays, were not estimated due to insufficient data.

Studies with a quality score > 6

All four variables were similar to variables in the original analysis.

Studies with ≥ 30 cases per group

Four variables, including AL, re-operations, anastomotic bleeding, and length of hospital stays, were similar to original TDT vs non-TDT analysis.

Discussion

Postoperative AL in rectal cancer surgery is a serious complication with a heavy burden for patients [5, 25]. Patients with rectal cancer that require radical tumor resections desire to retain the physiological function of the anus. However, both surgeons and patients face the risks and challenges of AL. Proximal enterostomy is a reliable and effective surgical intervention in preventing AL [26], but causes complications, such as hernias, electrolyte imbalances, and fistula reclosures [8, 27, 28]. Hence, the use of TDT is a potentially simple method for the prevention of anastomotic leakage in patients with rectal cancer surgery. However, its validity remains controversial.

The present meta-analysis was conducted to evaluate existing data, aiming to clarify the roles of TDT in rectal cancer complications, such as AL, anastomotic bleeding, re-operations, and increased length of hospital stays. In several medical centers, TDT is an alternative intervention that can achieve similar efficiency and avoid stomal complications [18]. Previous studies have shown that TDT reduces intraluminal pressure in obstructive colorectal cancer [18]. Current results were in accord with previously published meta-analyses [10, 30, 31]. AL occurring within 4-7 postoperative days is considered early AL [32, 33]. Various risk factors have been associated with occurrence of AL. Cong et al. [6] retrospectively collected data of 738 patients with rectal cancer, aiming to analyze factors associated with AL after anterior resections. They found that low rectal cancer, a

Table 2. Sensitivity analysis of included studies

Outcomes	No. of patients		No. of studies	RR/WMD	95% CI	P
	TDT	non-TDT				
Randomized controlled trials						
AL	15	22	2 [13, 15]	0.75	0.20-2.76	0.66
Studies with quality score ≥ 6						
AL	61	150	12 [6, 11, 12, 16-24]	0.55	0.41 to 0.73	< 0.05
Reoperation	18	70	7 [12, 15, 16, 20, 21, 23, 24]	0.25	0.15 to 0.43	< 0.05
Anastomotic bleeding	31	18	6 [12, 15, 16, 18, 21, 23]	1.55	0.89 to 2.68	0.12
Hospitalization days	448	584	3 [15, 23, 24]	-0.93	-3.34 to 1.48	0.45
Studies with ≥ 30 cases per group						
AL	76	167	13 [6, 11, 12, 16, 18-24]	0.58	0.38 to 0.90	< 0.05
Reoperation	18	70	7 [12, 15, 16, 20, 21, 23, 24]	0.25	0.15 to 0.43	< 0.05
Anastomotic bleeding	31	18	6 [12, 15, 16, 18, 21, 23]	1.55	0.89 to 2.68	0.12
Hospitalization days	448	584	3 [15, 23, 24]	-0.93	-3.34 to 1.48	0.45

nonspecialized surgeon, and diabetes mellitus are risk factors for AL after anterior resections for rectal cancer with TME. Patients at high risk of different levels of AL include male patients and those with a low anastomosis site [21]. However, the impact of these factors has not been fully elucidated and remains controversial [34, 35]. The present meta-analysis revealed that the use of TDT in patients with rectal cancer undergoing laparoscopic anterior resections and stapler anastomosis reduced rates of postoperative AL and re-operations. TDT possibly decreased rectal resting pressure, provided effective drainage and promoting gastrointestinal motility. These mechanisms play a potential role in protecting the anastomosis [15] and treating localized peritonitis related to AL [36, 37].

Anastomotic bleeding is another feared complication of colorectal surgery. Incidence of anastomotic bleeding with the double-stapling technique is as high as 6.1% [38]. Anastomotic bleeding is highly likely to occur in middle and low rectal cancer. Rates of postoperative anastomotic bleeding were higher in the TDT group than the non-TDT group, but differences were not statistically significant. Xiao et al. [15] reported that 10.6% (20/188) of patients in the TDT group developed postoperative perianastomotic bleeding, compared with 4.4% (8/182) of patients in the non-TDT group ($P = 0.023$). These patients with anastomotic bleeding did not require surgery or other interventions. Observation of anastomotic bleeding may be easier after placement of a TDT.

No significant differences in lengths of hospital stay were observed in this study. Thus, TDT placement did not increase total length of hospital stays. Xiao et al. [15] found that the TDT group had an average reduced hospital stay of 3 days, compared with the non-TDT group. They speculated that transanal decompression may accelerate gastrointestinal function recovery, resulting in lower AL rates. In a retrospective analysis of 69 patients, Ito et al. [39] compared the length of hospital stay of 28 patients that underwent anal canal decompression (13.1 ± 4.1 days) with that of the control group (22.7 ± 12.3 days). They reported that lengths of hospital stays in the former group were significantly decreased. TDT placement may reduce the unfavorable consequences of early postoperative diarrhea and prevent AL.

The current meta-analysis had several limitations. First, the small sample size of prospective RCTs limited the statistical power. Second, these trials were not uniform in terms of anal canal size, materials used, location and time of study, and specific body parts involved, causing heterogeneity of the outcomes. Third, three trials explicitly mentioned that TDT was only used in the second half of their studies and not in the first half. To some extent, surgeon skills can also affect rates of AL, especially with an increased number of anastomoses [40]. Location of the tumor, comorbidity, and surgical approaches can all lead to differences in results.

In conclusion, the present meta-analysis revealed that the risk of AL and re-operations can

be decreased by TDT placement following anterior resections. However, the number of included studies was small and most of these studies were RNTs. Therefore, additional well-designed, multicenter, and prospective RCTs are necessary to provide more convincing results for evaluation.

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Disclosure of conflict of interest

None.

Address correspondence to: Dr. Jie Ding, Department of Gastrointestinal Surgery, Guizhou Provincial People's Hospital, Medical College of Guizhou University, Guiyang 550002, China. Tel: +86-851-5937710; Fax: +86-851-5937710; E-mail: dingjiesydoc@126.com

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