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Transanal drainage tube reduces rate and severity of anastomotic leakage in patients with colorectal anastomosis: A case controlled study

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HIGHLIGHTS

- A transanal drainage tube as a mechanism to reduce anastomotic leakage is proposed.
- Transanal drainage tube reduces anastomotic leakage 3.6% vs. 13.6% ($p = 0.007$).
- Transanal drainage reduced the grade of complication (e.g., Dindo ≧ 3b: 20.0% vs. 92.9%; $p = 0.006$).

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ABSTRACT

Background and aims: The aim of this study was to investigate the clinical usefulness of the placement of a transanal drainage tube to prevent anastomotic leakage in colorectal anastomoses.
Material and methods: This single-center retrospective trial included all patients treated with surgery for benign or malign colorectal disease between January 2009 and December 2012. The transanal drainage tube was immediately placed after colorectal anastomosis until day five and was routinely used since 2010. Patients treated with a transanal drainage tube were compared with the control group. Statistical analysis was performed using Fisher's exact or Chi-square tests for group comparison and a linear regression model for multivariate analysis.
Results: This study included 242 patients (46% female; median age 63 years; range 18–93); 34% of the patients underwent a laparoscopic procedure, and 57% of the patients received a placement of a transanal drainage tube. Anastomotic leakage occurred in 19 patients (7.9%). Univariate analysis showed a higher rate of anastomotic leakage in patients with an ASA score 4 ($p = 0.02$) and a lower rate in patients with transanal drainage placement (3.6% vs. 13.6%; $p = 0.007$). The grading of the complication of anastomotic leakage was reduced with transanal drainage (e.g., Dindo ≧ 3b: 20.0% vs. 92.9%; $p = 0.006$), and the hospital stay was shortened (17.6 ± 12.5 vs. 22.1 ± 17.6 days; $p = 0.02$). Multivariate analysis revealed that transanal drainage was the only significant factor (HR = −2.90; −0.168 to −0.032; $p = 0.007$) affecting anastomotic leakage.
Conclusions: Placement of a transanal drainage tube in patients with colorectal anastomoses is a safe and simple technique to perform and reduces anastomotic leakage, the severity of the complication and hospital stay.

1. Introduction

Anastomotic leakage (AL) after colectomy is one of the major complications in colorectal surgery. The incidence of AL ranges from 2% to 4% with proximal anastomosis to 6%–12% with distal extraperitoneal anastomosis [1] and is associated with mortality

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rates of approximately 10% [2,3]. However, incidence and mortality up of to 30% [4,5] have been reported in rectal surgery. A combination of anatomical inaccessibility, less than optimal blood supply, tightly closed anal sphincter below an ultralow anastomosis and an infected pelvic hematoma are likely to be contributory factors. In addition, leakage after low anterior resection in patients with cancer may be associated with a higher local recurrence rate and a worse outcome [6,7]. Consequently, several preliminary studies have been designed to investigate the role of transanal devices in the prevention of leakage. This technique has been proven to be comparable in the prevention of anastomotic failure, together with benefits of less surgical injury, avoidance of a second surgery, and finally, lower morbidity [8–10].

The potential role of a transanal drainage tube (TDT) is supposed to be beneficial for the reduction of endoluminal pressure as well as fecal diversion, resulting in a protective effect on anastomotic healing. However, the majority of previous studies have been limited by a small sample size and use of a nonrandomized control group. In addition, the nonstandardized use of the technique, including the material used in the construction of the TDT, the shape of the tube, and the duration of its placement, has been reported. Moreover, inconsistent results were obtained in a retrospective study, which failed to prove the efficacy of the device [11]. There has only been one prospective randomized controlled study, which demonstrated a benefit for the TDT with regard to the reduction of anastomotic bleeding and AL [12]. Thus far, no study had shown an effect of a TDT on the severity of anastomotic leakage.

To further clarify the question of whether a TDT reduces the rate and severity of AL after colorectal anastomosis, we performed this retrospective study of prospectively collected data.

2. Material and methods

This retrospective study of prospectively collected data included all consecutive patients who were treated by surgery for benign or malign colorectal disease with colorectal anastomosis between January 2009 and December 2012 in our operative department. The study was performed according to the guidelines of the local ethic committee.

The following variables were analyzed: gender, age, mortality, ASA-score, hospital stay, surgical complications, medical complications, placement of TDT, malignancy, urgency of the procedure (emergency vs. semi-elective vs. elective), bowel preparation, operation technique (laparoscopic vs. open), abdominal drainage, endoscopic control of the anastomosis, diverting ileostomy, type of resection (anterior, low anterior, extended low anterior rectum resection), anastomotic technique (E/E vs. E/S vs. S/E vs. S/S), delayed anastomosis and anastomotic procedure (hand-sewn vs. stapled).

The following are criteria for the inclusion of patients in our study: colorectal anastomosis after resection of the sigmoid or rectum for benign or malign underlying disease >18 years. Exclusion criteria were underlying gynecological disease as a reason for colorectal resection, Hartmann reversal operation, left-sided hemicolectomy and abdominoperineal resection.

For the purpose of this study, 242 patients were divided into two groups: the transanal drainage group (TD) and non-transanal drainage group (NTD), and we investigated whether a TDT was or was not used during the operation.

2.1. Surgical technique

The TDT was established as a routine clinical practice in December 2009 at our department. A 28 Charrière natural rubber latex foley catheter (Telefex Medical™) was inserted transanally immediately after the air leak test of the performed colorectostomy. It was placed between five and ten centimeters proximal to the anastomosis with visual or palpatory control and fixed using a 2-0 Vicryl™ perineal suture.

Every anastomosis, which was performed during a second-look operation after initial damage control surgery, was defined as delayed anastomosis. Loop ileostomy was selected for nearly all lower colorectal anastomosis below the peritoneal reflection in oncological surgery and routinely after neoadjuvant radiotherapy for rectal cancer.

2.2. Anastomotic leakage

In the TD group, AL was defined as an extravasation observed by the radiologist in the routinely performed radiography on POD five with a contrast clyster. In the control group, AL was mostly (75%) confirmed using a CT scan, in cases where clinical signs, such as fever, severe abdominal pain, elevation of leukocytes and CRP or fecal delivery of the abdominal drain, occurred. In the CT scan, AL was proven in cases of air bubbles or edema with inflammatory reactions in the perianastomotic area.

We established a dehiscence score related to the size of the AL as the following: 1 = small dehiscence <10 mm; 2 = medium dehiscence >10 mm <semi-circular; and 3 ≥ semi-circular.

Surgical and medical postoperative complications were classified as grade one to five according to Dindo et al. [13].

The urgency of the procedure was categorized as an emergency (which indicated an immediate operation due to, e.g., free perforation with peritonitis), semi-elective (within seven days after admission due to, e.g., ineffective antibiotic treatment in diverticulitis) and elective surgery.

Oral bowel preparation with CleanPrep™ was performed when a loop ileostomy or intraoperative colonoscopy was planned. Rectal clysters were applied at the surgical ward before the patient was moved to the operation room in all other elective cases. No preparation was performed in the emergency procedures.

2.3. Statistical tests

All statistical analysis was performed using SPSS Version 22.0 (International Business Machines Corporation, Armonk, NY). Continuous data are provided as the mean and standard deviation or the median and range. Dichotomous variables are represented as percentages. For group comparisons, either Fisher's exact or Chi-square tests were performed. All statistical tests were performed two-sided, and p-values <0.05 were considered statistically significant. For the multivariate analysis, a linear regression analysis was performed using the backwards method.

3. Results

In this study, 242 patients (103 (42.6%) female with a mean age of 63.5 (SD 14.3) years) were analyzed for the development of anastomotic leakage with a median hospital stay of 15 days. The hospital mortality rate was 1.2% (n = 3, myocardial infarction, AL, large bowel perforation).

The comparative demographic data, performed surgical techniques, underlying disease and complications between the interventional TD and the NTD groups are illustrated in Table 1.

The TDT was removed after a mean of 4.9 (SD 1.2) days. In 3 patients (2.2%), it was removed before postoperative day four, which caused the patients discomfort or perianal pain.

Table 1
Demographic parameters comparing the NTD vs. TD group, significance ($p < 0.05$) is indicated by an *.

	NTD		TD		
	n	%	n	%	p-value
Patients	103	42.6	139	57.4	
Male gender	58	56.3	81	58.3	0.79
Age [years]	63.9 (SD 15.5)		63.2 (SD 13.4)		0.71
Neoplasm	51	49.5	74	53.2	0.60
Indication					0.49
Elective	72	69.9	105	75.5	
Semi-elective	19	18.4	18	12.9	
Emergency	12	11.7	16	11.5	
Bowel preparation					0.90
Oral	52	50.5	72	51.8	
Rectal	51	49.5	67	48.2	
ASA					0.11
1	9	8.7	17	12.2	
2	45	43.7	75	54.0	
3	41	39.8	43	30.9	
4	8	7.8	4	2.9	
Laparoscopic procedure	30	29.1	53	38.1	0.17
Abdominal drain	82	79.6	115	82.7	0.62
Endoscopic control	59	57.3	109	78.4	**0.001***
Loop ileostomy	22	21.4	41	29.5	0.18
Resection					0.24
Anterior	56	54.4	67	48.2	
Low anterior	31	30.1	38	27.3	
Extended low anterior	16	15.5	34	24.5	
Reconstruction					0.14
E/E	62	60.2	75	54.0	
S/E	35	34.0	61	43.9	
S/S	6	5.8	3	2.2	
Stapled anastomosis	81	78.6	128	92.1	**0.004***
Delayed anastomosis	13	12.6	16	11.5	0.84
Anastomotic leakage	14	13.6	5	3.6	**0.007***
Non surgical complications	23	22.3	31	22.3	1.0
Hospital stay [days]	22.1 (SD 17.6)		17.6 (SD 12.5)		**0.02***
Hospital mortality	3	2.9	0	0	0.08

3.1. Anastomotic leakage rate

In this study, 19 (7.9%) of the 242 patients developed an anastomotic leakage after a mean of 7.3 (SD 4.0) days (Table 2). The diagnostic tool was observed in the CT scan of 79% of the patients, in the contrast clyster in 11% of the patients and in only the clinical examination in 11% of the patients. The contrast clyster performed at postoperative day five detected three out of five (60%) ALs in the TD group. Two of the ALs were minor without any clinical sign and could be treated using antibiotics only. There was no difference in the time of detection of the AL for the TD (8.4 days) compared to the NTD group (6.9 days; $p = 0.91$). In the TD group, one (1/5) patient developing AL required surgical re-intervention compared to 14 (14/15) patients in the NTD group ($p = 0.006$). This patient in the TD group was not treated with open abdomen therapy compared to six (6/14) in the NTD group ($p = 0.008$) (Table 3).

An identified risk factor in univariate analysis for a higher leakage rate was ASA 4 ($p = 0.02$), whereas TDT was identified as a protective factor for AL ($p = 0.007$) (Table 1).

In the linear regression model of all potential risk factors, the only significant factor was TDT ($p = 0.004$) (Table 4).

3.2. Severity of anastomotic leakage

The mean deficiency score of AL was 1.2 in TD compared to 1.7 in the NTD group ($p = 0.24$). The grade of complication of anastomotic leakage was significantly reduced in the TD group (e.g., Dindo ≧ 3b: 20.0% vs. 92.9%; $p = 0.006$), as shown in Table 3.

Table 2
Clinical parameters and risk factors for anastomotic leakage, significance ($p < 0.05$) is indicated by an *.

	All patients		Anastomotic leakage		
	n	%	n	%	p-value
All patients	242	100	19	7.9	
Male gender	139	57.4	8	5.8	0.23
ASA					
1	26	10.7	3	11.5	
2	120	49.6	9	7.5	
3	84	34.7	4	4.8	
4	12	5.0	3	25.0	**0.02***
Indication					0.83
Elective	177	73.1	13	7.3	
Semi-elective	37	15.3	3	8.1	
Emergency	28	11.6	3	10.7	
Neoplasm	125	51.7	12	9.6	0.35
Bowel preparation					0.48
Oral	124	51.2	8	6.5	
Rectal	118	48.8	11	9.3	
Laparoscopic procedure	83	34.3	7	8.4	0.81
Transanal drain	139	57.4	5	3.6	**0.007***
Abdominal drain	197	81.4	15	7.6	0.76
Endoscopic control	168	69.4	12	7.1	0.61
Loop ileostomy	63	26.0	4	6.3	0.79
Resection					0.39
Anterior	123	50.8	8	6.5	
Low anterior	69	28.5	8	11.6	
Extended low anterior	50	20.7	3	6.0	
Reconstruction					0.62
E/E	137	56.5	12	8.8	
S/E	96	39.7	7	7.3	
S/S	9	3.7	0	0	
Stapled anastomosis	209	86.4	17	8.1	1.0
Other complications	54	22.3	3	5.6	0.58

Table 3
Difference between patients with AL for the NTD and TD groups, significance ($p < 0.05$) is indicated by an *.

	NTD (n = 14)		TD (n = 5)		p-value
	Mean	SD	Mean	SD	
Occurrence [days]	6.86	3.28	8.40	6.03	0.91
Deficiency score	1.71	0.73	1.2	0.45	0.24
Dindo ≥ 3b [%]	92.9	26.7	20.0	44.7	**0.006***
Abdominal vacuum therapy [%]	42.9	51.4	0	0	0.008*

Table 4
Linear regression analysis using the backwards method for anastomotic leakage, significance ($p < 0.05$) is indicated by an *.

	Hazard ratio	95% confidence interval		p-value
Age	−0.61	−0.003	0.002	0.54
Gender	−1.37	0.171	−0.115	0.17
ASA	−0.20	−0.060	0.049	0.85
Indication	1.28	−0.19	0.088	0.20
Neoplasm	1.48	−0.017	0.120	0.14
Bowel preparation	−0.62	−0.096	0.050	0.54
Laparoscopic procedure	0.95	−0.040	0.115	0.34
Transanal drain	−2.90	−0.168	−0.032	**0.004***
Abdominal drain	−0.41	−0.102	0.067	0.68
Endoscopic control	−0.46	−0.103	0.064	0.65
Loop ileostomy	−0.54	−0.111	0.063	0.59
Resection	0.50	−0.51	0.086	0.62
Reconstruction	−0.36	−0.045	0.031	0.72
Stapled anastomosis	−1.15	−0.166	0.044	0.25
Delayed anastomosis	−0.61	−0.176	0.093	0.54

3.3. Medical complications

Other medical complications occurred in 63 (22.7%) patients and included mainly (90.5%) the urinary tract, wound infections or pneumonia and were treated locally or with antibiotics (Dindo-Clavien $\leq$2).

4. Discussion

AL after colorectal surgery is one of the major complications that has a great effect on mortality. Various risk factors contributing to AL after rectal cancer surgery have been reported in the literature [6,14–18], including old age, male gender, smoking, diabetes, cardiovascular disease, obesity, preoperative radiochemotherapy, air leak, prolonged operating time, and pelvic drainage.

The overall leak rate of 7.9% reported in our study is comparable to previously published studies, reporting leak rates ranging from 2.8 to 15% [14,19–21].

Our study showed one significant risk factor for AL in the univariate analysis, with ASA 4 ($p = 0.02$) presenting a higher rate of AL, while the TDT has been found to be a preventive factor for AL ($p = 0.007$).

Comorbidities and patient performance are known factors that influence anastomotic healing [22,23] and were confirmed in our study.

A comparison of patient demographics of the interventional TD group with the NTD group identified several significant differences:

The TD group showed higher rates in intraoperative endoscopic control of anastomosis ($p = 0.001$). Routinely used intraoperative colonoscopy to evaluate the anastomosis appears to have a beneficial effect in reducing the AL rates, although previously published data were only Level IV, and due to the small sample size, it was partially not significant and not very strong [24,25].

The TD group showed a significant higher rate of stapled colorectal anastomosis ($p = 0.004$). In a Cochrane analysis 2012 [26], Neutzling et al. demonstrated no difference in the AL between hand sewn and stapled anastomosis and confirmed previously published reviews [27,28].

Considering the fact that AL was significantly reduced in the TD group compared to the NTD group ($p = 0.007$), the reduced hospital stay for patients with TDT could be easily explained.

The first report regarding the use of a TDT was published 17 years ago [29] and showed a benefit for protective use in colorectal anastomosis [9]. Following two published studies [12,30], we confirmed the protective effect of the TDT, resulting in improved clinical outcomes of colorectal anastomosis in a more diverse study population, which included patients with preoperative radiotherapy, loop ileostomy and rectal resection for gynecological neoplasm.

In 2011, Xiao et al. published a single center prospective randomized trial of 398 patients with rectal cancer. Patients with TDT presented a lower incidence of AL and a lower rate of reoperation for symptomatic AL. TDT placement decreased the rectal resting pressure and was associated with an accelerated restoration of gastrointestinal peristalsis function, both of which might play a potential role in better outcomes. Nevertheless, this study excluded preoperative radiotherapy and, as stated by the authors, it appears to be biased on the basis of surgical skills.

Zhao et al. published in 2013 a single center prospective nonrandomized trial of 158 patients with rectal cancer. Patients who underwent a protective stoma procedure, emergency or palliative operation as well as patients who received preoperative chemo- or radiotherapy were excluded. This study also reported a lower anastomotic leakage and bleeding rate in patients where a TDT was placed, but failed to achieve significance due to the small sample size.

The results of these two studies are confirmed in our study. Multivariate analysis of potential risk factors for AL revealed TDT as the only significant factor. Furthermore, we demonstrated an advantage in the reduction of the severity of AL in patients with TDT. Patients suffering from AL with TDT developed significantly less severe complications. A potential explanation could be the earlier detection of AL by the routinely performed radiography with a contrast clyster on POD five in patients with a TDT only, although the difference between 7.0 days in the TD group compared to 9.1 days for the NTD group did not reach a level of significance. Furthermore, the routinely used contrast clyster identifies clinically silent AL and might contribute to a lower severity rate of AL, but is in contrast theoretic to the higher rate of AL by detecting silent AL. Moreover, the benefit of the TDT derives from its effect on the anal sphincter, resulting in partial incontinence for gas and liquids, which avoids the elevation of intraluminal pressure and therefore supports a better blood supply in the colon wall. Despite this benefit, the TDT cannot circumvent known risk factors of anastomotic healing, such as tension, on the anastomosis or limited blood supply. In cases of AL, the TDT appears to function as a target drainage, reducing the propagation of sepsis into the intrabdominal space. This effect results in a reduction of both reoperation and open abdomen treatment rates in cases of AL similarly to the observed results of Xiao et al.

Three patients (2.2%) mentioned discomfort or perianal pain and asked for drain removal before POD five. It seems obvious, that the TDT generates discomfort, but there is actually no data about this topic. Indeed, discomfort was not regularly measured in patients with TDT, but this question will be answered by an ongoing prospective clinical study at our department.

Our retrospective study demonstrates a significant reduction in the AL rate in colorectal anastomoses using a TDT for five days. In contrast to two recently published studies, this study does not exclude patients who received radiotherapy before the operation or patients with a loop ileostomy ($n = 67$; 24.2%). In addition, it is the first study to demonstrate a significant beneficial effect of this technique on the severity of AL and hospital stay. To investigate this effect, further prospective randomized trials are needed to confirm these.

Ethical approval

The study was performed according to the guidelines of the local ethic committee.

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Author contribution

Study design: Andreas Brandl, Reinhard Mittermair, Reinhold Kafka-Ritsch.

Data collection: Andreas Brandl, Sascha Czipin, Sascha Weiss.

Data analysis: Andreas Brandl, Johann Pratschke, Reinhold Kafka-Ritsch.

Writing: Andreas Brandl.

Conflicts of interest

No conflicts of interest to declare.

Guarantor

Andreas Brandl M.D.

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