

Multicenter analysis of transanal tube placement for prevention of anastomotic leak after low anterior resection

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Transanal tube for prevention of leak

Conflicts of interest:

The authors have no conflicts of interest to declare.

Synopsis: (<1-3 sentences)

We retrospectively analyzed a multicenter cohort of 328 consecutive patients and demonstrated that transanal tube placement is effective for decreasing the incidence of symptomatic anastomotic leakage after low anterior resection. This is the first multicenter study to assess the effectiveness of transanal tube placement.

Abstract

Background

Anastomotic leak (AL) is a serious complication of low anterior resection (LAR). This study aimed to evaluate the effect of transanal tube placement for prevention of AL.

Methods

This multicenter retrospective cohort study enrolled 328 consecutive patients who underwent LAR for rectal cancer at participating hospitals from 2009 to 2014. Multivariate logistic regression was used to adjust for confounding factors.

Results

A transanal tube was placed in 205 patients (TA group) and not placed in 123 patients (non-TA group). Symptomatic AL occurred in 36 cases (11%), with significantly higher incidence of symptomatic AL in the non-TA group than in the TA group (15% vs 8.3%, odds ratio [OR] 2.02, 95% confidence interval [CI] 1.01–4.06). After adjusting for confounding factors, multivariate analysis revealed that placement of a transanal tube could decrease the incidence of symptomatic AL (adjusted OR 0.37, 95% CI 0.15–0.91). There was no significant difference in postoperative morbidity, mortality, length of hospital stay, or local recurrence rate between the two groups. Local recurrence rate tended to be higher in patients with symptomatic AL (3/36) than in those without it (10/292).

Conclusions

Transanal tube placement is effective for decreasing the incidence of symptomatic AL after LAR.

[197 words] < 200 words

Keywords:

Anastomotic leak, transanal tube, transanal drainage, low anterior resection, rectal cancer

Introduction

Colorectal cancer is the third most common malignancy and the fourth leading cause of cancer-related deaths worldwide, accounting for about 1.4 million new cases and almost 700,000 deaths annually.[1] Rectal cancer presently accounts for 30%–40% of all colorectal cancers.[2, 3]

Anastomotic leak (AL) is a serious complication after low anterior resection (LAR) for rectal cancer. It increases short-term morbidity and medical costs, prolongs hospital stay, and can be fatal.[4] The incidence of AL after LAR varies from 5% to 16%, [5-9] and a meta-analysis revealed that AL has a negative prognostic impact on local recurrence and long-term survival in rectal cancer.[10]

Since the 1980s, total mesorectal excision (TME) and tumor-specific mesorectal excision (TSME) have been standard techniques for rectal surgery because they decrease the risk of local recurrence.[11] With improvements in surgical techniques and operative instruments, sphincter-preserving surgery is also increasingly being performed[12] with improved oncological and functional outcomes.[13, 14] However, despite these advances, the number of high-risk cases of AL has also increased.[9]

Meta-analyses have reported that a diverting stoma (DS) decreases the incidence of symptomatic AL and/or the need for reoperation after LAR.[15, 16] However, in clinical practice, we construct a DS only for high-risk patients, given the risks of stoma-related complications and worsened quality of life, as well as the need for an additional operation for stoma closure.[17, 18]

Recent reports showed that placement of a transanal tube after LAR could decrease the incidence of AL.[19-21] We previously reported that lack of transanal tube placement may be a risk factor for AL after laparoscopic LAR.[22] Transanal tube placement is

both time- and cost-effective, and compared with a DS, is much less invasive. However, as few studies have investigated the effectiveness of transanal tube placement, this study sought to evaluate its effectiveness for prevention of AL after LAR.

Methods

Data for this multicenter, retrospective cohort study were collected from Kyoto University Hospital and two affiliated hospitals (Nishi-Kobe Medical Center and Saiseikai Noe Hospital). The study was approved by the ethics committees of all three participating hospitals. The primary endpoint was the incidence of symptomatic AL. We also investigated the prognostic impact of symptomatic AL.

Patients

We collected surgical and prognostic data along with clinicopathologic and demographic characteristics for all 359 enrolled consecutive patients who underwent LAR (defined as an anastomotic level located below the peritoneal reflection) for rectal cancer between April 2009 and March 2014. Patients with a DS were included. Patients with a transanal hand-sewn anastomosis or need for emergency surgery were excluded, as were patients who underwent conversion to abdominoperineal resection or Hartmann's procedure. In principle, the transanal tube placement procedure was established as routine clinical practice in 2011 at our hospitals.

Surgical method

All patients received standard bowel preparation and antibiotic prophylaxis. All operations were performed by or with the assistance of skilled colorectal surgeons and were based on guidelines approved by the Japanese Society for Cancer of the Colon and Rectum.[23] The standard surgical technique performed was TME or TSME, the main principle of which is sharp mesorectal dissection with nerve preservation. All anastomoses were performed with an end-to-end double stapling technique using a circular stapler. Cases requiring conversion to open surgery were regarded as laparoscopic. The decision to create a DS was made by the operating surgeon.

For transanal tube placement, a silicone or rubber tube (10 mm in diameter) was positioned such that the top of the tube was located 3–5 cm above the anastomotic site with visual or palpatory control in order to avoid injury to the anastomotic site or intestinal wall. The tube was anchored to the buttocks with sutures and hooked to a drainage bag and usually kept in place for 4–6 days. We removed the tube at the bedside after watery stool came out of the tube.

Definition of symptomatic anastomotic leak

Clinical symptoms caused by AL were defined as emission of gas, pus, or feces from the abdominal drain or wound or from the vagina. All clinically suspicious symptoms,

including fever, peritonitis, or turbid discharge from an abdominal drain, were confirmed on digital rectal examination, sigmoidoscopy, computed tomography, and/or contrast enema. We defined AL as AL diagnosed within 30 days of surgery.

Severity of AL was classified according to the system proposed by the International Study Group of Rectal Cancer in 2010: grade A, no change in patient management needed; grade B, active therapeutic intervention required but manageable without reoperation; or grade C, reoperation required.[24] Symptomatic AL was defined as grade B or C.

Statistical analysis

Patient demographic and surgical data are summarized as numbers or medians with interquartile range (IQR) or as prevalence, as appropriate. The primary outcome (incidence of symptomatic AL) was analyzed with Pearson's χ^2 test. We performed multivariable logistic regression to adjust for confounding factors. Imbalanced variables between the two groups and variables that were considered clinically relevant were included in the multivariable analyses. Other comparisons between the two groups were analyzed with Pearson's χ^2 test or Fisher's Exact test (categorical variables) and the Mann-Whitney U test (continuous variables). For long-term outcomes, Kaplan-Meier curves were plotted and the log-rank test was used for analysis.

All analyses were two-sided and considered statistically significant at $P < 0.05$. Data analysis was performed using JMP® 11 software (SAS Institute Inc., Cary, NC).

Results

Patient characteristics

Of 359 patients considered for inclusion, 328 were eligible; the 31 patients excluded had either undergone transanal hand-sewn anastomosis (n=25) or high anterior resection (n=6). The incidence of symptomatic AL was 11% (36/328). There were 205 patients in the TA group and 123 patients in the non-TA group.

Table 1 shows the patient characteristics. The TA group contained more patients who had undergone neoadjuvant therapy and had a lower anastomotic level. The non-TA group contained more patients who underwent open surgery and creation of a DS, and the volume of intraoperative blood loss tended to be higher.

Anastomotic leak

Table 2 shows the incidence of AL in the two groups. The incidence of symptomatic AL (grade B or C) was significantly higher in the non-TA group (15%, 19/123) than in the TA group (8.3%, 17/205; odds ratio [OR] 2.02, 95% confidence interval [CI] 1.01–4.06).

Timing of AL onset was on postoperative day (POD) 3 (median; IQR 2–6) in the non-TA group and POD 4 (IQR 3–11) in the TA group. Symptomatic AL requiring reoperation (grade C) occurred in 3.4% (7/205) of the TA group and 6.5% (8/123) of the

non-TA group ($P = 0.195$), and median time to reoperation was 13 days (IQR 4–35) and 3.5 days (IQR 2–26), respectively ($P = 0.244$).

In multivariable analysis, transanal tube placement significantly decreased symptomatic AL (adjusted OR 0.37, 95% CI 0.15–0.91). Presence of diabetes and long operation time (≥ 5 h) were identified as statistically significant covariates (Table 3).

After stratification of the independent risk factors for AL, we performed a subgroup analysis of the effectiveness of transanal tube placement. Figure 1 shows the ORs with 95% CIs for the effect of no transanal tube placement on AL. A transanal tube was significantly effective for preventing AL in the following subgroups: male, diabetes, low body mass index ($\text{BMI} < 25$), no neoadjuvant therapy, longer operation time (≥ 5 h), and no lateral lymph node dissection. Moreover, transanal tube placement tended to be effective in the laparoscopic surgery and no DS subgroups. There was a significant difference in effectiveness between patients with high BMI (≥ 25) and those with low BMI (P value for interaction = 0.027). Transanal tube placement significantly decreased symptomatic AL in the low BMI subgroup in both univariate and multivariate analyses (adjusted OR 0.22, 95% CI 0.07–0.61).

Postoperative outcome

Table 4 and Figure 2 show postoperative outcome in the two groups. Overall operative

morbidity (grade $\geq$ II, grade $\geq$ IIIa) occurred in 106 patients (32%) and 37 patients (11%), respectively. Ninety-day mortality was 0.61% (2/328), and both deaths were in patients without AL. There was no significant difference in postoperative morbidity, mortality, or length of hospital stay between both groups. Furthermore, transanal tube placement did not affect local recurrence rate (Figure 2A), but the rate tended to be higher in patients with symptomatic AL than in those without symptoms (3/36 and 10/292, respectively; log-rank test, $P = 0.087$; Figure 2B).

Discussion

Our results demonstrate that transanal tube placement contributes to a decreased risk of symptomatic AL after LAR. To our knowledge, this is the first multicenter study to evaluate the impact of transanal tube placement on prevention of AL after LAR.

AL is presumably associated with increased intraluminal pressure.[20] In the early postoperative period, the anal sphincter is in a state of spasm, leading to high intraluminal pressure, and therefore transanal decompression and drainage may help prevent AL. A transanal tube can decrease intraluminal pressure by providing effective drainage on the proximal side of the anastomosis. A DS is thought to work via a similar mechanism.

Several single-center studies have suggested that transanal tube placement is effective in

reducing AL.[20, 21, 25, 26] The reported incidence of AL in patients with a transanal tube is 2.7%–4.1% versus 7.8%–16% in those without one. The incidence of AL in our TA group (8.3%) was higher than in previous studies because we included patients at high-risk for AL including male sex and lower anastomosis level.[25, 27] In clinical practice, surgeons tend to place a transanal tube in a patient with more risk factors for AL; however, the data reported previously were subjected to univariable and not multivariable analysis.[21, 25, 26] Furthermore, most previous studies involved small numbers of patients with a transanal tube and excluded patients with a DS,[19, 21, 25] so there was no adjustment for confounding factors. Using both univariable and multivariable analyses, we showed that transanal tube placement can decrease the incidence of symptomatic AL after LAR.

We found a tendency, albeit not significant, for the transanal tube to decrease grade C AL. However, due to the limited number of events, our study might have lacked the power needed to detect a true effect. Considering only patients with grade C AL, the median time to reoperation was longer in the TA group than in the non-TA group (13 days versus 3.5 days, $P = 0.24$). This could be because of a reduction in the severity of AL as a result of the transanal tube and therefore a decreased number of patients requiring emergency reoperation. However, emergency reoperation was performed in 3

cases each in the TA group (1.5%) and non-TA group (2.4%; $P = 0.68$). Possible reasons for the lack of a significant difference in the reoperation rate include the limited number of events and the fact that reoperation may have been delayed due to the presence of the transanal tube. This may also account for the longer time to reoperation in the TA group. All patients with grade C AL required ileostomy. We believe that a DS should be created for high-risk patients in whom AL cannot be prevented by placing a transanal tube. Several risk factors for AL have been reported, including male sex, obesity, neoadjuvant therapy, a lower level of anastomosis, larger tumor size, and absence of a DS.[9, 20, 22, 27, 28] Our study indicates that diabetes, longer operation time (≥ 5 h), and no transanal tube placement were risk factors for AL, which is consistent with previous reports.[21, 25, 27, 29] When the operation time is longer than expected, a DS needs to be created because the OR was particularly high for this risk factor (9.31 [95% CI 3.25–32.5]) in our study. The effectiveness of a transanal tube was poor in our subgroup of patients with a DS, so it may not be necessary to combine the two procedures.

Transanal tube placement did not affect postoperative morbidity, mortality, length of hospital stay, or local recurrence rate (Table 4 and Figure 2A). However, there were 2 cases of thrombosis and 1 perforation in the TA group. A transanal tube might cause thrombosis by making postoperative ambulation more difficult so early ambulation is

recommended for these patients, as is the case without a transanal tube. The patient who had perforation had multiple diverticula in the sigmoid colon, and there are some reports of bowel perforation in association with a transanal tube.[21] Therefore, care should be taken to ensure that the transanal tube does not perforate the colon, especially in patients with multiple diverticula.

Consistent with previous studies,[10] we found that AL tended to increase the local recurrence rate (Figure 2B). Therefore, transanal tube placement might reduce the risk of local recurrence indirectly.

This study has several limitations. First is its retrospective cohort design. Although we included recent data generated in the last 5 years, better outcomes may simply reflect improvements over time rather than changes related to a specific intervention when a historical control is used. There was an expected increase in the number of laparoscopic procedures and neoadjuvant therapy. The operative approach (open or laparoscopic) and administration of neoadjuvant therapy were therefore included in the adjusted multivariable analysis. Although confounding factors were controlled for in multivariate analysis, we could adjust only for the covariates measured. Further large, multicenter, randomized controlled studies are required in the future. Second, some studies have suggested that the variability among individual surgeons may be a risk factor for AL,[30,

31] and we did not investigate this possibility. It is difficult to evaluate the skill of individual surgeons, especially in a multicenter setting. However, in this study, all participating hospitals were affiliated with Kyoto University, so the surgical techniques and skills used were considered similar, which could have minimized the impact of the individual surgeon.

In conclusion, transanal tube placement may decrease the incidence of symptomatic AL after LAR, and is a less invasive method than creation of a DS for prevention of AL.

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Figure Legends

Fig. 1 Odds ratios for the effect of no transanal tube placement on the occurrence of anastomotic leak according to each risk subgroup. Abbreviations: AV, anal verge; BMI, body mass index; DS, diverting stoma

Fig. 2 Kaplan-Meier plots showing the cumulative incidence of local recurrence in patients after LAR. (A) Dashed line: TA group, solid line: non-TA group. (B) Dashed line: patients with AL, solid line: patients without AL. Abbreviations: AL, anastomotic leak; LAR, low anterior resection; TA, transanal tube placement

Table 1. Patient characteristics					
	Transanal tube group		Non-transanal tube group		
Variable	(n=205)		(n=123)		
Sex					
Female	62	30%	46	37%	
Male	143	70%	77	63%	
Age (y)					
Median (IQR)	67	(60-74)	70	(62-77)	
Body mass index					
Median (IQR)	22	(20.2-24.1)	22.7	(20.2-25.2)	
ASA score					
1-2	196	96%	118	97%	
3-4	9	4%	4	3%	
Diabetes					
Yes	38	19%	20	16%	
No	167	81%	103	84%	
Heart disease					
Yes	27	13%	15	12%	
No	178	87%	108	88%	
Hemoglobin (g/dl)					
Median (IQR)	13.6	(12.4-14.7)	13.2	(11.9-14.3)	
Albumin (g/dl)					
Median (IQR)	4.1	(3.8-4.4)	4.0	(3.7-4.3)	
Tumor stage					
0-II	165	80%	94	76%	
III-IV	40	20%	29	24%	
Neoadjuvant therapy					
Yes	30	15%	6	5%	
No	175	85%	116	95%	
Approach					
Open	15	7%	24	19%	
Laparoscopic	179	87%	98	80%	
Robotic	11	5%	1	1%	
Operation time (min)					
Median (IQR)	301	(250-361)	295	(243-353)	
Intraoperative bleeding (ml)					
Median (IQR)	32	(5-99)	90	(20-235)	
Tumor location from AV (cm)					
Median (IQR)	8	(6-10)	10	(8-15)	
Anastomotic level from AV (cm)					
Median (IQR)	5	(3-7)	7	(5-10)	
Tumor size (mm)					
Median (IQR)	38	(26-50)	42	(25-54)	
Combined resection					
Yes	22	11%	15	12%	
No	183	89%	108	88%	
Lateral lymph node dissection					
Yes	9	4%	3	2%	
No	196	96%	120	98%	
Diverting stoma					
Yes	8	4%	19	16%	
No	197	96%	104	84%	

ASA, American Society of Anesthesiologists; AV: anal verge; IQR, interquartile range

Table 2. Incidence of anastomotic leak			
	Transanal tube group n=205	No transanal tube group n=123	P value
Anastomotic leak			
Grade B+C	17 (8.3%)	19 (15%)	0.044
Grade C	7 (3.4%)	8 (6.5%)	0.195

Table 3. Multivariable analysis for anastomotic leak

Variables		Adjusted odds ratio	95% CI	P value
Transanal tube	Yes	0.37	0.15-0.91	0.029
	No	ref		
Sex,	male	1.14	0.45-3.10	0.790
Age	≥75 years	1.28	0.52-3.30	0.598
BMI	≥25	1.36	0.53-3.73	0.530
Diabetes (+)		2.78	1.07-7.00	0.036
Neoadjuvant therapy		0.86	0.17-3.16	0.826
Approach	Laparoscopic	0.35	0.09-1.42	0.138
	Open	ref		
Tumor location from AV	<7 cm	1.13	0.47-2.84	0.791
Diverting stoma		0.39	0.07-1.55	0.191
Lateral lymph node dissection		3.96	0.89-15.8	0.069
Intraoperative bleeding	≥100 m	0.82	0.31-2.10	0.690
Operating time	≥5 h	9.79	3.38-34.7	<0.001

Abbreviations: BMI, body mass index; AV, anal verge; CI, confidence interval

Table 4. Postoperative outcomes					
	Transanal tube group		No transanal tube group		P value
	n=205		n=123		
Overall operative morbidity					
≥ Grade II	65	32%	41	33%	0.76
≥ Grade IIIa	25	12%	12	10%	0.58
Anastomotic leak	17	8%	19	15%	
Wound infection	6	3%	3	2%	
Intestinal obstruction	10	5%	7	6%	
Anastomotic bleeding	4	2%	2	2%	
Anastomotic stricture	3	1%	2	2%	
Transient urinary dysfunction	12	6%	5	4%	
Enteritis	2	1%	5	4%	
Pneumonitis	5	2%	1	1%	
Intraabdominal abscess	2	1%	4	3%	
Thrombosis	4	2%	0	0%	
Perforation	1	0.5%	0	0%	
Postoperative mortality	1	0.5%	1	0.8%	1.00
Reoperation rate	9	4.4%	9	7.3%	0.26
Anastomotic leakage	7	3.4%	8	6.5%	0.19
Intestinal obstruction	1		0		
Anastomotic bleeding	0		1		
Perforation	1		0		
Length of postoperative hospital stay (median [IQR])	14 (10-20)		14 (11-19)		0.24

Figure 1

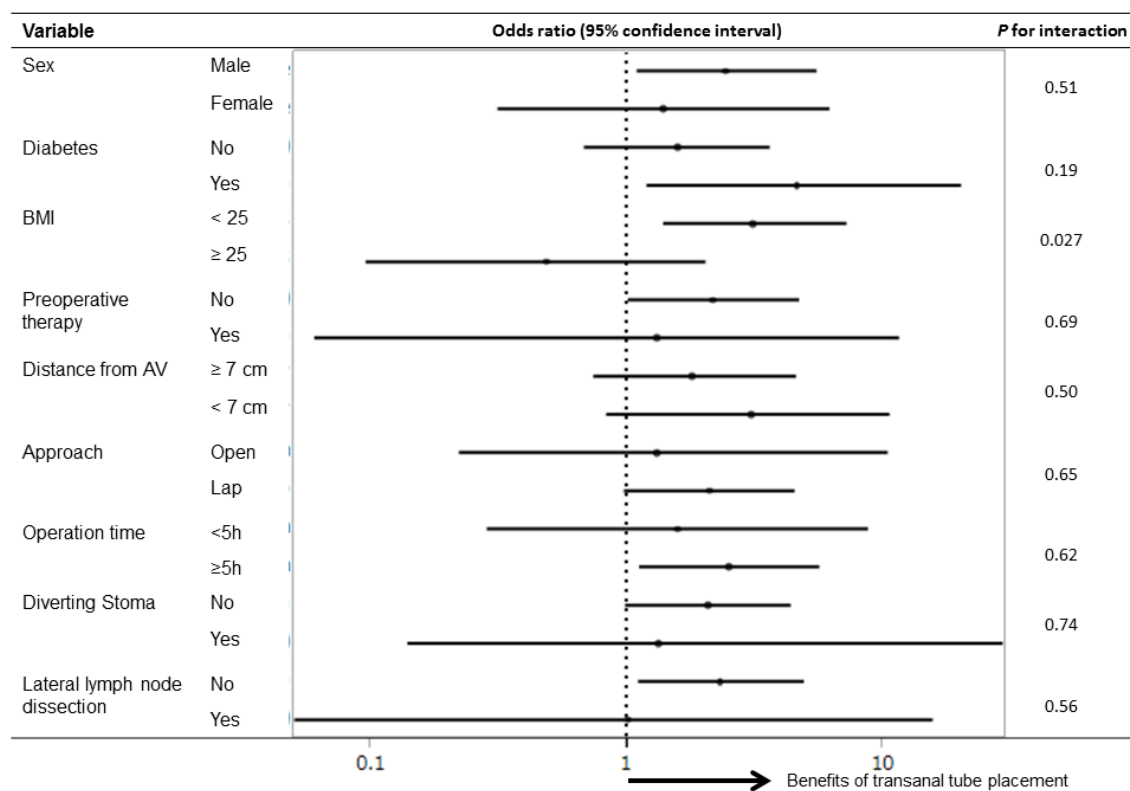


Figure 2

