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Editorial Board Member of *World Journal of Gastrointestinal Surgery*, Junichi Shindoh, MD, PhD, Chief Physician, Division of Hepatobiliary-pancreatic Surgery, Toranomon Hospital, Tokyo 105-8470, Japan. jshindoh@gmail.com

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ORIGINAL ARTICLE

Retrospective Study

Efficacy of staple line reinforcement by barbed suture for preventing anastomotic leakage in laparoscopic rectal cancer surgery

Bo Ban, An Shang, Jian Shi

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Bo Ban, An Shang, Jian Shi, Department of General Surgery, The Second Hospital of Jilin University, Changchun 130041, Jilin Province, China

Corresponding author: Jian Shi, MD, PhD, Associate Chief Physician, Associate Professor, Department of General Surgery, The Second Hospital of Jilin University, No. 218 Ziqiang Street, Nanguan District, Changchun 130041, Jilin Province, China. 383888697@qq.com

Abstract

BACKGROUND

Anastomotic leakage (AL) is a severe complication in rectal cancer surgery. Various methods, including intracorporeal reinforcing suturing, have been used to reduce the incidence of AL. However, little is known about the efficacy of staple-line reinforcement by barbed suture for preventing AL.

AIM

To evaluate the efficacy of staple-line reinforcement using barbed suture for preventing AL in laparoscopic surgery for rectal cancer.

METHODS

We retrospectively reviewed the clinical datum of 319 patients undergoing laparoscopic low anterior resection combined with double stapling technique between May 1, 2017 and January 31, 2021. All surgeries were performed by the same surgical team specializing in colorectal surgery. Patients were divided into two groups depending on whether they received reinforcing sutures. Patients' baseline characteristics did not show any significant difference between the two groups. We analyzed patient-, tumor-, as well as surgery-related variables using univariate and multivariate logistic analyses.

RESULTS

There were 168 patients in the reinforcing suture group and 151 patients in the non-reinforcing suture group. AL occurred in 25 cases (7.8%). Its incidence was significantly higher in the non-reinforcing suture group than in the reinforcing suture group (4.8% *vs* 11.3%, $P = 0.031$). The multivariate analyses demonstrated that the tumor site, tumor size and presence of staple-line reinforcement were independent risk factors for AL. We divided these patients into two risk groups based on the combination of tumor site and tumor size. Patients without any risk factor were assigned to the low-risk group ($n = 177$), whereas those having one or two risk factors were assigned to the high-risk group ($n = 142$). In the high-risk

group, the AL incidence considerably decreased in the reinforcing suture group compared with that in the non-reinforcing suture group (P = 0.038). Nonetheless, no significant difference was found in the low-risk group between the two groups.

CONCLUSION
Staple-line reinforcement by barbed suture may decrease the incidence of AL. A large-scale prospective randomized controlled trial is needed for evaluating the efficacy of staple-line reinforcement for preventing AL.

Key Words: Reinforcing suture; Anastomotic leakage; Laparoscope; Rectal cancer; Double-stapling technique; Barbed suture

Core Tip: Double stapling technique (DST) has been extensively applied in rectal surgery. However, the drawbacks of DST cannot be ignored, particularly because the linear cutter application as the distal rectum incision is not completely matched with a circular incision in the proximal intestinal tract. This leads to crossing at least two staple lines, which is referred as the "dog ear" structure. Some studies have reported that such intersection induced the vulnerable area causing anastomotic leakage (AL). This study was aimed to investigate the efficacy of reinforcing anastomosis with barbed suture in preventing AL after laparoscopic DST, and evaluate its feasibility and safety.

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INTRODUCTION

Colorectal cancer ranks 4th among global cancers in terms of mortality, it causes nearly 900000 deaths every year, and surgery is still the cornerstone of curative intent treatment[1]. Laparoscopic surgery exhibited better clinical and oncologic outcomes and demonstrated its noninferiority in comparison with open surgery in numerous trials, including Colorectal Cancer Laparoscopic or Open Resection II and Comparison of Open Versus Laparoscopic Surgery for Mid or Low Rectal Cancer After Neo-adjuvant Chemoradiotherapy (COREA), and has been extensively applied in rectal cancer surgery[2,3]. Recently, with the constant and intensive investigation of the anatomy, pathology, biological characteristics, and lymph node metastasis mechanisms of rectal cancer, as well as the introduction and popularization of the total mesorectal excision (TME) concept, specification of surgical procedures and innovation of surgical instruments, the sphincter preservation rate in the middle and low rectal cancer surgery has been increased[4,5]. With an increase in sphincter-preserving operations, anastomotic leakage (AL) has become an unavoidable problem. AL is related to a high short-/long-term morbidity, increased local recurrence and impaired quality of life[5-7], with rates varying between 1% and 30%[8-10]. AL is possibly induced by the combination of local, systemic, and technical factors, as well as certain risk factors. It is associated with a male sex, obesity, old age, diabetes, intraoperative blood loss, longer operation duration, lower tumor location and larger tumor size[11,12]. The double stapling technique (DST), originally proposed by Griffen and Knight[13], has been extensively used in colorectal surgery because anastomosis can be made at a low pelvic location during this procedure while preserving the anal sphincter. Nonetheless, the safety of DST has attracted wide concern, particularly because the linear cutter application as the distal rectum incision is not completely matched with a circular incision in the proximal digestive tract. This leads to crossing at least two staple lines, which is referred as the "dog ear" structure (Figure 1)[14,15]. Some studies have reported that such intersection induces the vulnerable area causing AL[16,17]. Therefore, we conducted a retrospective evaluation to determine whether reinforced circular-stapled anastomosis using barbed suture can reduce the incidence of AL after laparoscopic DST, and investigate whether this surgical approach is feasible and safe.

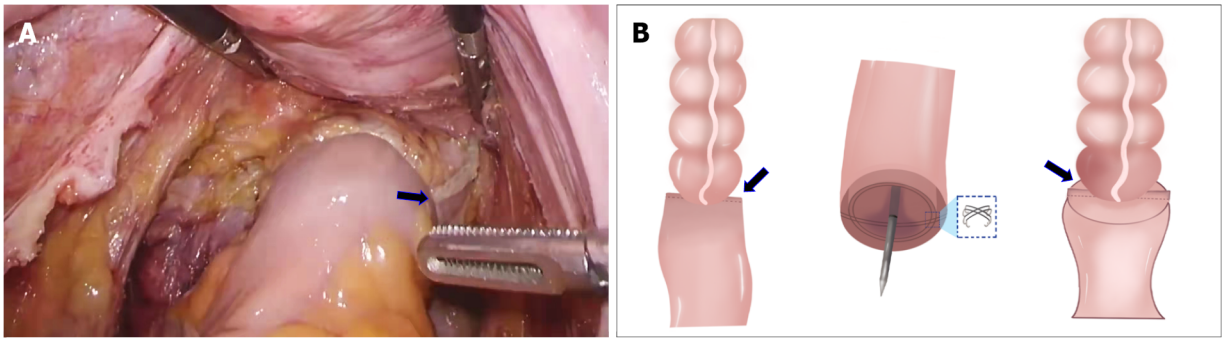

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Figure 1 "Dog ear" structure. A: The intersection of the staple lines (arrow); B: schematic diagram of the intersection of the staple lines (arrow).

MATERIALS AND METHODS

Patients

The study protocol was approved by the Ethics Committee of the Second Hospital of Jilin University. This work was carried out in line with the Helsinki Declaration of the World Medical Association. Patients were carefully selected, and finally, 319 patients undergoing laparoscopic low anterior resection (LAR) with DST between May 1, 2017 and January 31, 2021, at colorectal center of Jilin University were included in the study. All patients were divided into two groups: Those who received reinforcing sutures (n = 168) as experimental group and those who did not receive reinforcing sutures (n = 151) as control group. The tumor was located within 10 cm from the anal verge. The inclusion criteria were: Primary rectal cancer confirmed by colonoscopy and biopsy, American Society of Anesthesiologists (ASA) Grades I-III, and clinical TNM stage of cT1-4aN0-2M0 based on imaging examinations. The exclusion criteria were: Patients with terminal ileal protective stoma or patients receiving colostomy, emergency surgery, intersphincteric resection, preoperative chemotherapy or radiotherapy, and patients with incomplete follow-up data. All surgeries were performed by the same surgical team specializing in colorectal surgery. We have routinely reinforced anastomotic structure using barbed sutures since January 2019; therefore, most of the patients with reinforcing sutures received surgical treatment between 2019 and 2021.

Surgical procedures

Each patient lay in the modified lithotomy position following general anesthesia. In the laparoscopic surgery, a 5-port technique was used. Surgeons evaluated whether the left colonic artery should be preserved on the basis of the condition of the patient and their experiences. The standard surgical technique was used according to the principle of TME, which was sharp mesorectal dissection with nerve preservation. If necessary, splenic flexure was mobilized. After the rectal division using a linear cutter stapler, the circular stapler was used for end-to-end anastomosis. Routine evaluation of the blood supply of the anastomotic stoma was completed by intraoperative indocyanine green (ICG) fluorescence angiography. After anastomosis, each patient underwent an air leakage test. Patients showing risk factors, such as uncertain blood perfusion, insufficient circular stapling donut, and positive results in the air leakage test, underwent temporary diverting stoma. In the reinforcing group, running full-layer stitches were adopted using the unidirectional absorbable 3–0 V-Loc 180 sutures (Covidien, Mansfield, MA, United States) to reinforce the intersection of the cutting lines and anterior anastomosis wall (Figure 2). Pelvic drainage was used in all cases in this study.

Definition of AL

AL is defined as the defect of the intestinal wall at the anastomotic site causing the communication between the intra-and extraluminal compartments[18]. In our colorectal surgery center, all patients routinely received contrast enema radiography 5–7 d after surgery to evaluate asymptomatic AL. Symptomatic AL was confirmed based on the following symptoms: Discharge of feces, pus, or gas from the pelvic drainage, peritonitis, fever, sepsis with pelvic abscess and abdominal pain. We performed computed tomography, digital rectal examination, and surgical to confirm the suspicious cases. AL severity was graded according to the guidelines given by the international study group on rectal cancer [18].

Variables related to AL

The following 24 factors were identified as potential risk factors for AL: Gender, age at the time of operation, body mass index (BMI ≥ 25 or < 25 kg/m^2), diabetes mellitus, hypertension, heart disease, chronic obstructive pulmonary disease, tumor site (≥ 5 or < 5 cm from anal verge), tumor size (≥ 4 or < 4

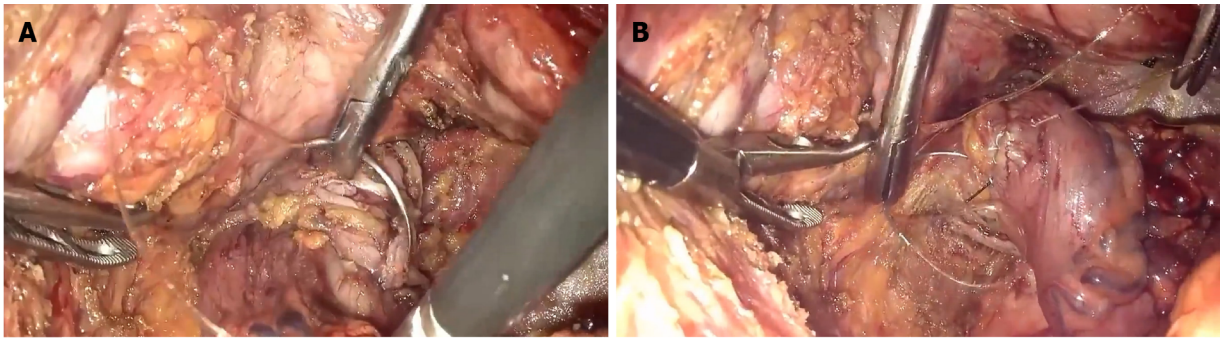

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Figure 2 Continuous suture reinforcement. A: Use of a 3-0 barbed suture at the intersection of the staple lines; B: Completion of the suture on the other side of staple line intersection.

cm), tumor infiltration depth, lymph node metastasis, previous abdominal surgery, preoperative carcinoma embryonic antigen (≥ 5 or < 5 ng/mL), preoperative albumin level (≥ 35 or < 35 g/L), preoperative hemoglobin levels (≥ 90 or < 90 g/L), preoperative serum C-reactive protein level (≥ 10 or < 10 mg/L), ASA scores, ligation of left colic artery (LCA), operation time (≥ 150 or < 150 min), number of staple firings (≥ 3 or < 3), intraoperative blood transfusion, intraoperative blood loss (≥ 60 or < 60 mL), the placement of reinforcing sutures and postoperative intestinal obstruction. All blood samples were collected 3-5 d preoperatively. Thresholds of tumor size, operation time, intraoperative blood loss, and anal exhaust time were determined by average value. The cutoff level for BMI was 25 kg/m^2 as a BMI of ≥ 25 is considered obesity in Chinese people.

Definition of postoperative defecation dysfunction and anastomotic stricture

Patients with a LAR syndrome score ≥ 21 were considered to have postoperative defecation dysfunction [19]. Follow-up was performed at 3, 6, and 12 mo postoperatively by specialized follow-up personnel *via* a telephonic interview. The anastomotic stricture was defined as tight stenosis of anastomosis associated with the inability to traverse a flexible endoscope[20-22]. In the present study, the anastomotic stricture was referred to as the tight stenosis of anastomosis narrower than the 12-mm diameter colonoscope. Colonoscopy was routinely performed for 6-9 mo postoperatively in our hospital.

Statistical analysis

IBM SPSS26.0 was used for data analysis. Continuous variables were represented as mean ± SD (range). Student's *t*-test was used for comparison. Ranked data were analyzed using Mann-Whitney U-test. Moreover, the categorical variables were shown by numbers (percentage). Fisher's exact test and $\chi 2$ test were used for comparison. Multivariate logistic regression was performed for identifying distinct factors that independently predicted the risk of AL. After univariate regression, variables satisfying $P < 0.05$ were enrolled in the multivariate regression. $P < 0.05$ was considered statistically significant.

RESULTS

Between May 2017 and January 2021, we recruited a total of 636 patients who underwent laparoscopic surgery for rectal cancer at the Second Affiliated Hospital of Jilin University. Among them, 498 meeting our pre-determined inclusion criteria were selected for further analysis, whereas 179 were excluded based on the exclusion criteria (34 undergoing colostomy, 43 with a terminal ileal protective stoma, 40 undergoing intersphincteric resection, 6 undergoing emergency surgery, 26 receiving preoperative chemotherapy or radiotherapy, and 30 patients with incomplete clinical data) (Figure 3). Finally, we enrolled 319 patients (153 male and166 female cases). Correlations between various clinicopathological factors in the two groups are presented in Table 1. There were 168 patients in the reinforcing suture group and 151 patients in the non-reinforcing suture group. Among them, 237 patients (74.3%) had middle rectal cancer, and the remaining 82 patients (25.7%) had low rectal cancer. Patients' features did not show any significant difference between the two groups. Surgery-related information is presented in Table 2. LCA preservation rate, number of staple firings, intraoperative transfusion, or intraoperative blood loss did not show any significant difference between the two groups. The experimental group had a longer operation time than the control group, with no significant difference. In terms of complications, the incidence of AL was 7.8% (25/319), with 8 patients from the reinforcing suture group and 17 patients from the control group. There was no significant difference in anastomotic stricture and postoperative defecation dysfunction. The incidence of postoperative defecation dysfunction decreased gradually with the increase in recovery time. Table 3 shows the AL-related information. The experi-

Table 1 Baseline characteristics of patients (*n* = 319)

Variables	Reinforcing sutures		*P* value
	Yes, *n* = 168	No, *n* = 151	
Age (yr)	61.8 ± 8.7	63.0 ± 9.7	0.229
Men/Women	80/88	73/78	0.897
BMI (kg/m^2)	23.2 ± 3.6	22.8 ± 3.8	0.378
ASA score, *n* (%)			0.948
1	60 (35.7)	54 (35.8)	
2	67 (39.9)	61 (40.4)	
3	41 (24.4)	36 (23.8)	
Tumor diameter (cm)	4.4 ± 1.7	4.1 ± 1.8	0.178
Tumor site (from anal verge, cm), *n* (%)			0.641
≥ 5	123 (73.2)	114(75.5)	
< 5	45 (26.8)	37(24.5)	
Depth of tumor invasion, *n* (%)			0.295
T1-T2	33 (19.6)	37 (24.5)	
T3-T4	135 (80.4)	114 (75.5)	
Lymph node metastases, *n* (%)			0.493
Yes	77 (45.8)	75 (49.7)	
No	91 (54.2)	76 (50.3)	
Diabetes mellitus, *n* (%)	31 (18.5)	22 (14.6)	0.352
Hypertension, *n* (%)	37 (22.0)	25 (16.6)	0.218
Heart disease, *n* (%)	18 (10.7)	11 (7.3)	0.287
COPD, *n* (%)	9 (5.4)	7 (4.6)	0.768
Previous abdominal surgery, *n* (%)	17 (10.1)	14 (9.3)	0.799
Preoperative CEA (ng/mL), *n* (%)			0.430
≥ 5	57 (33.9)	45 (29.8)	
< 5	111 (66.1)	106 (70.2)	
Preoperative hemoglobin levels (g/L), *n* (%)			0.239
≥ 90	138 (82.1)	116 (76.8)	
< 90	30 (17.9)	35 (23.2)	
Preoperative serum albumin level (g/L), *n* (%)			0.301
≥ 35	139 (82.7)	118 (78.1)	
< 35	29 (17.3)	33 (21.9)	
Preoperative serum CRP level (mg/L), *n* (%)			0.375
≥ 10	28 (16.7)	28 (20.5)	
< 10	140 (83.3)	123 (79.5)	

BMI: Body mass index; ASA: American society of anesthesiologists; COPD: Chronic obstructive pulmonary disease; CEA: Carcinoma embryonic antigen; CPR: C-reactive protein.

mental group had considerably decreased severity of AL compared with that of the control group (P = 0.020). A total of 15 patients (60.0%) underwent reoperations (laparoscopy and terminal ileostomy) because of failure in conservative management. Meanwhile, the control group had evidently increased reoperation rate compared with that of the experimental group (P = 0.028). With regard to nonoperative treatment, no statistical difference was found between the two groups. Table 4 shows the univariate and

Table 2 Surgical outcomes and postoperative complications

Variables	Reinforcing sutures		*P* value
	Yes, *n* = 168	No, *n* = 151	
Left colic artery ligation, *n* (%)			0.637
Yes	79 (47.0)	75 (49.7)	
No	89 (53.0)	76 (50.3)	
Number of staple firings, *n* (%)			0.902
≥ 3	16 (9.5)	15 (9.9)	
< 3	152 (90.5)	136 (90.1)	
Operation time (min)	150.4 ± 25.1	146.6 ± 20.2	0.135
Intraoperative transfusion, *n* (%)	20 (11.9)	15 (9.9)	0.574
Intraoperative blood loss (mL)	60.5 ± 43.9	58.2 ± 46.3	0.652
Complications, *n* (%)			
Anastomotic leakage	8 (4.8)	17 (11.3)	0.031
Postoperative intestinal obstruction	25 (14.9)	17 (11.3)	0.339
Anastomosis stricture	12 (7.1)	17 (13.1)	0.202
Postoperative defecation dysfunction, 3 mo	31 (18.5)	25 (16.6)	0.657
Postoperative defecation dysfunction, 6 mo	23 (13.7)	21 (13.9)	0.955
Postoperative defecation dysfunction, 12 mo	12 (7.1)	9 (6.0)	0.671

Table 3 Anastomotic leakage related indices (*n* = 25)

	Reinforcing sutures		*P* value
	Yes, *n* = 8	No, *n* = 17	
AL classification			0.020
Grade A	3	2	
Grade B	3	2	
Grade C	2	13	
AL time (d)	5 (2–7)	4 (1–7)	0.715
Treatment			
Trans-anal lavage and drainage	2	1	0.231
Peritoneal lavage and drainage	1	1	1.000
Reoperation	2	13	0.028

AL: Anastomotic leakage.

multivariate analysis results in AL-related risk factors. The tumor site, tumor size, and reinforcing sutures were associated with AL upon univariate and multivariate regression. AL-related risk factors were stratified, then subgroup analyses on reinforcing sutures' efficacy were performed (Table 5). All patients were divided into two risk groups by combining AL-associated risk factors (low rectal cancer and tumor diameter of ≥ 4 cm). Patients without any risk factor were assigned to the low-risk group (n = 177), whereas those having one or two risk factors were assigned to the high-risk group (n = 142). In the high-risk group, the AL incidence considerably decreased in the experimental group compared with that in the control group (P = 0.038). Nonetheless, no statistically significant difference was found in the low-risk group between experimental group and control group.

Table 4 Univariate and multivariate regression on anastomotic leakage-related factors (*n* = 319)

Variables	Univariate regression			Multivariate regression		
	OR	95%CI	*P* value	OR	95%CI	*P* value
Male gender	1.189	0.523–2.705	0.680			
Age ≥ 60 (yr)	2.123	0.824–5.473	0.119			
BMI ≥ 25 (kg/m^2)	1.115	0.448–2.775	0.814			
Diabetic mellitus	2.604	1.060–6.394	0.037	1.662	0.588–4.669	0.338
Hypertension	1.039	0.374–2.888	0.941			
Heart disease	2.050	0.652–6.441	0.219			
COPD	1.739	0.372–8.124	0.482			
Low tumor location < 5 (cm)	2.954	1.289–6.769	0.010	2.856	1.133–7.198	0.026
Tumor diameter ≥ 4 (cm)	3.010	1.313–6.901	0.009	2.994	1.185–7.563	0.020
T3-T4	1.135	0.410–3.142	0.807			
Lymph node metastases	1.719	0.748–3.951	0.202			
Previous laparotomy	1.884	0.602–5.890	0.276			
Preoperative CEA ≥ 5 (ng/mL)	1.216	0.518-2.852	0.653			
Preoperative serum albumin level < 35 (g/L)	1.690	0.673–4.244	0.264			
Preoperative hemoglobin levels < 90 (g/L)	1.582	0.631–3.967	0.328			
Preoperative serum CRP level, ≥ 10 (mg/L)	2.242	0.918–5.476	0.076			
ASA score ≥ 3	1.244	0.499–3.102	0.639			
Ligation of left colic artery	2.435	1.019–5.819	0.045	2.195	0.869–5.546	0.096
Operation time ≥ 150 (min)	2.437	1.059–5.613	0.036	1.837	0.750–4.495	0.183
Number of staple firings ≥ 3	2.577	0.893–7.434	0.080			
Intraoperative transfusion	1.116	0.316–3.939	0.864			
Intraoperative blood loss ≥ 60 (mL)	1.223	0.537–2.787	0.632			
Reinforcing sutures	0.394	0.165–0.942	0.036	0.293	0.114–0.750	0.010
Postoperative intestinal obstruction	2.263	0.848–6.041	0.103			

OR: Odds ratio; CI: Confidence interval; BMI: Body mass index; COPD: Chronic obstructive pulmonary disease; CEA: Carcinoma embryonic antigen; CPR: C-reactive protein; ASA: American society of anesthesiologists.

DISCUSSION

AL is a main concern in a surgical procedure for rectal cancer. Among AL risk factors, the surgical procedure is most important, because it is the only controllable factor. The use of DST leads to the formation of at least two intersections of staple lines, creating ischemic corners that result in AL[23,24]. In the present study, after performing the DST procedure, we used a barbed suture to reinforce the intersection of the cutting lines and anterior anastomosis wall to eliminate vulnerable corners and prevent AL. The three main findings of our study are as follows. First, tumor diameter ≥ 4 cm, low rectal cancer, and reinforcing sutures are independent risk factors for AL. Second, reinforcing sutures reduce AL severity and decrease the reoperation rate. Finally, for patients with risk factors, reinforcing sutures can significantly lower AL incidence.

There are different approaches adopted for reducing the AL rate caused by the DST procedure or other risk factors. Asao *et al*[25] used a mattress suture to let the linear stapler line clump around the dummy shaft to eliminate dog ears and improve DST. However, the approach was technically restricted, which also required relatively upper anastomotic positions, making it difficult to popularize. Marecik *et al*[26] adopted a single-stapled, double-pursestring approach for colorectal anastomosis in 160 cases receiving LAR, resulting in a low AL rate. However, technical difficulties limited its

Table 5 Subgroup analysis of the effectiveness of reinforcing sutures

Reinforcing sutures	Anastomotic leakage		*P* value
	Yes	No	
Low-risk group			0.368
Yes	1	87	
No	4	85	
High-risk group			0.038
Yes	7	73	
No	13	49	

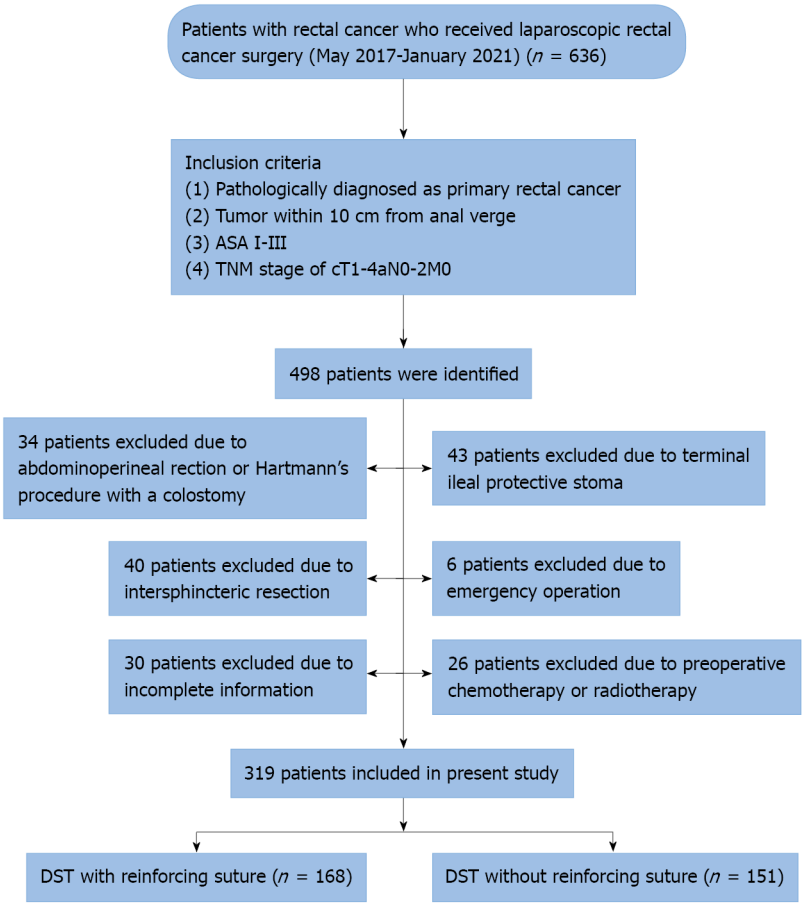

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Figure 3 Consort diagram of patient flow. DST: Double stapling technique; ASA: American Society of Anesthesiologists.

application in laparoscopic surgery. Baek *et al*[27] used transanal reinforcing sutures to improve DST and found that the procedure decreased the demand for diverting ileostomy. However, their sample size was relatively small, and no decrease was observed in the AL rate. Gadiot *et al*[28] compared 76 cases receiving anti-traction sutures with 77 non-suture cases, and found that AL occurrence remarkably decreased in the sutured group. In addition, several studies reported that trans-anal drainage tube could effectively decrease the incidence of AL after rectal surgery[29-32]. Among them, Xiao *et al*[29] retrospectively analyzed the clinical data of 398 patients undergoing LAR for rectal cancer and found that patients in transanal tube group were associated with lower AL and reoperation rates. According to their research, the potential benefits of transanal tube may be multifactorial, including promotion of gastrointestinal peristalsis, drainage, and reducing endoluminal pressure.

In this study, we evaluated whether a continuous suture using a barbed suture at the intersection of staple lines and anterior anastomosis wall was efficient in reducing the AL rate. We showed that AL incidence remarkably decreased in the reinforcing suture group than in the non-reinforcing suture group. In stratified risk factor analysis, though the low-risk group did not exhibit any distinct difference,

high-risk group showed significantly lower AL incidence in the reinforcing suture group than in the non-reinforcing suture group. Consequently, a reinforcing suture is considered an efficient approach to reduce AL for high-risk cases, and it is possibly not necessary for low-risk cases. Additionally, AL severity markedly decreased in the suture group compared with that in the non-suture group; the former had markedly decreased the demand for temporary diverting ileostomy. The possible reason for this is that anastomotic sutures may reinforce the anastomotic structure strength, while adding thickness to the staple line, distributing the tension of any individual staple across the length of the reinforcement strip and removing the risk of "dog ear" structures[33,34]. Moreover, a knotless barbed suture used in the present study makes it easier for a laparoscopic suture, as it requires no knot with the self-maintenance of tension in sutures running and does not require repetitive re-tightening of the sutures during stitching. This technique showed increased security and bursting pressure compared with those of the non-barbed monofilaments[35]. Several retrospective studies have verified its short- and long-term safety and efficacy in laparoscopic gastrointestinal operation[36-38]. As shown in the present study, reinforcing suture using barbed suture exhibited feasibility and safety as it does not prolong operation time, add to laparoscopic operation difficulty, or increase the complication rate, including defecation dysfunction and anastomosis stricture.

Based on our multivariate regression, tumor diameter ≥ 4 cm, and low rectal cancer are the other two factors that independently predict the risk of AL. Tumor size is related to AL, which is consistent with the results of previous studies[17,39]. The large tumor can make pelvic anastomosis and rectal transection difficult[40]. Furthermore, patients with a larger tumor or more advanced TNM stage always suffer from poorer systemic physical conditions, in some cases, the intestines can be oedematous, and pelvic adhesion may occur[39]. We also found that low tumor position influences the occurrence of AL. The lower tumor position is associated with an increased AL rate. Notably, the low tumor position can add technical difficulty in laparoscopic LAR, which can reduce the blood supply, and increase tension and local tissue trauma. Many studies have confirmed low tumor location as the AL-related independent risk factor[11,41].

In recent years, intraoperative ICG fluorescence angiography has been gaining recognition as an important intraoperative approach that provides real-time perfusion evaluation in anastomosis. Notably, ICG-based fluorescence angiography can decrease AL incidence by changing the surgical strategy[42,43]. In our study, patients with doubtful anastomotic blood perfusion, as well as other risk factors including insufficient circular stapling donut and positive results in air leakage tests, underwent a temporary diverting stoma. Therefore, these patients were excluded from this study. Moreover, the LCA was preserved in 52.2% of patients (165/319) in the present study, which was a relatively high rate of LCA preservation. It is controversial whether to conduct a high or low tie of the inferior mesenteric artery during laparoscopic rectal resections. Several studies[44,45] have reported that LCA preservation is associated with lower AL. This can be seen in the results of the univariate analysis in the present study, with *P* value of 0.045. Based on the above reasons, the incidence of AL was lower compared with that of other studies, with the overall and symptomatic AL rates of 7.5% (25/319) and 6.3% (20/319), respectively.

The present study had certain limitations. Firstly, the present study was a single-centered, retrospective, and non-randomized study. It is not possible to control all biases with this study design. Although the differences in the preoperative general clinical data of the patients were not significant between the two groups, there might still be residual or confounding variables. Second, there were chronological differences in operation between the two groups. Most patients in the suture group received treatment during the late period, when laparoscopic skills may have been better compared with the early period, and these may have influenced the incidence of complications. Hence, we should consider the impact of the learning curve. However, we believe that this limitation is slight because all procedures were performed by experienced surgeons and the incidence of AL in both groups did not differ from year to year. Third, patients in present study did not receive trans-anal drainage tube, which was also an effective method for preventing AL, as mentioned before. The combination of reinforcing sutures and trans-anal drainage tube may be more effective than the technique alone. However, we emphasize the efficacy and safety of reinforcing sutures for preventing AL in laparoscopic surgery for rectal cancer. Therefore, the combined effect of reinforcing sutures and trans-anal drainage tube remains unclear and deserves further investigation.

CONCLUSION

We demonstrated the safety and efficacy of barbed suture-based reinforcing sutures for patients with primary rectal cancer receiving laparoscopic LAR with a double-stapled anastomotic approach. This procedure can decrease AL incidence. However, large-scale prospective randomized controlled trials are required for evaluating the efficacy of reinforcing sutures for the prevention of AL.

ARTICLE HIGHLIGHTS

Research background

Anastomotic leakage (AL) is a severe complication in rectal cancer surgery. Various methods have been used to reduce the incidence of AL.

Research motivation

We hypothesized that staple-line reinforcement using barbed suture could reduce the incidence of AL in laparoscopic surgery for rectal cancer.

Research objectives

To evaluate the efficacy of staple-line reinforcement using barbed suture for preventing AL in laparoscopic surgery for rectal cancer.

Research methods

We compared the incidence of AL and other operative complications between two groups and analyzed patient-, tumor-, as well as surgery-related variables using univariate and multivariate logistic analyses.

Research results

AL incidence was significantly lower in the reinforcing suture group than in the control group (4.8% *vs* 11.3%, $P = 0.031$). The multivariate analyses demonstrated that the tumor site, tumor size and presence of staple-line reinforcement were independent risk factors for AL. In patients with risk factors, the AL incidence considerably decreased in the experimental group compared with that in the control group ($P = 0.038$). However, for patients without risk factor, no significant difference was found between experimental group and control group.

Research conclusions

Staple-line reinforcement can significantly lower AL incidence for patients with risk factors, while reducing AL severity and decreasing the reoperation rate. Besides, this technique does not increase the occurrence of postoperative complications.

Research perspectives

A large-scale prospective randomized controlled trial is needed for evaluating the efficacy of staple-line reinforcement for preventing AL.

FOOTNOTES

Author contributions: Ban B designed the research and wrote the manuscript; Shi J designed the research and supervised the manuscript; Shang A performed the research and contributed to the statistical analysis.

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Country/Territory of origin: China

ORCID number: Bo Ban 0000-0002-7404-2129; An Shang 0000-0001-7770-8523; Jian Shi 0000-0002-1239-4655.

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