Intracorporeal reinforcing sutures reduce anastomotic leakage in double-stapling anastomosis for laparoscopic rectal surgery

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Abstract

Introduction: *In rectal surgery, double-stapled anastomosis is one of the most common techniques. However, the crossing of the staple line is considered a weakness of this method and could lead to anastomotic leakage (AL), which is one of the major complications of rectal cancer surgery.*
Aim: *To investigate the usefulness of laparoscopic intracorporeal reinforcement suturing for preventing AL in laparoscopic rectal surgery.*
Material and methods: *A total of 153 patients with rectal cancer underwent laparoscopic rectal resection with anastomosis using the double-stapling technique between January 2015 and December 2018. Patient characteristics, surgical data, and outcomes were recorded and retrospectively analysed. Patients who received intracorporeal reinforcing sutures (n = 72) were compared with those who did not receive the reinforcing sutures (n = 81).*
Results: *AL was observed in 11 (7.2%) cases overall and in only 1 case in the group with intracorporeal reinforcing sutures. There were no associations between clinicopathological factors and the use of reinforcing sutures. Multivariate analysis revealed that a distance from the anal verge of less than 6.5 cm, diabetes mellitus, and the non-use of reinforcing sutures were independent risk factors for AL.*
Conclusions: *Laparoscopic intracorporeal reinforcing sutures reduced the incidence of AL. Therefore, laparoscopic reinforcing sutures for double-stapled anastomoses seem useful for the prevention of AL.*

Key words: *laparoscopic surgery, rectal cancer, double-stapling, reinforcing suture, anastomotic leakage.*

Introduction

Anastomotic leakage (AL) is a major complication of rectal cancer surgery and has also been implicated in postoperative morbidity and mortality. Furthermore, previous reports suggest that AL leads to increased local recurrence and a worse prognosis [1–3]. Risk factors for AL in laparoscopic rectal surgery have been reported, including distance from the anal verge to the tumour and tumour size [4–11]. Several methods have been introduced to reduce AL. For instance, patients with more than two risk factors require a diversionary stoma [10, 12]. Transanal decompression tubes have been used to prevent AL [13–15]. A vertical rectal incision avoids multiple stapler firings and leads to a decrease in AL [16], and sutures to reduce traction have also resulted in AL reduction [17].

In rectal anastomosis, double-stapled anastomosis is one of the most common techniques. However, the crossing of the staple line is considered a weakness of this anastomosis method. In this study, we investigated the usefulness of laparoscopic intracorporeal reinforcement sutures with a staple line for the prevention of AL.

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Aim

The purpose of this study was to investigate the usefulness of laparoscopic intracorporeal reinforcement suturing for preventing AL in laparoscopic rectal surgery.

Material and methods

Patients

Patient characteristics and surgical data were retrospectively analysed. A total of 153 consecutive patients who underwent laparoscopic rectal resection (double-stapled anastomosis) for primary rectal cancer at the Kobe City Medical Center General Hospital between January 2015 and December 2018 were included in the study. Each tumour was defined as being within 10 cm of the anal verge. The eligibility criterion was rectal cancer that was histologically diagnosed as adenocarcinoma. The exclusion criteria included laparoscopic Hartmann's surgery, stoma construction, emergency surgery, intersphincteric resection and transanal hand-sewn anastomosis, total pelvic resection, ileorectal anastomosis, and previous preoperative chemotherapy or radiation therapy. Patients were enrolled in groups that received (n = 72) or did not receive (n = 81) reinforcing sutures. This study was approved by the institutional review board of Kobe City Medical Center General Hospital (approval number: zn211107).

Surgical procedure

Since January 2017, intracorporeal reinforcing sutures have been routinely used at our institution. These rectal procedures were performed by skilled surgeons. No patients received reinforcing sutures between 2015 and 2016. The intracorporeal reinforcing suture technique is shown in Photo 1. Rectal division was performed using a linear stapler, and end-to-end anastomosis was performed using a circular stapler. Reinforcing sutures using 3-0 PDS (Ethicon Inc., New Jersey, USA) were placed intracorporeally. Two or more interrupted sutures were placed along the staple line. The procedure included at least two corners made by intersecting a circular staple line and a straight staple line. The distance from the anal verge was determined by colonoscopy. After anastomosis, an air leak test was performed for all patients. In patients with some risk factors, such as a positive air leak test or an incomplete doughnut of circular staples, a temporary diverting stoma was considered. No urgent patients underwent mechanical preparation. Cefmetazole was administered as antibiotic prophylaxis 30 min before the procedure and every 3 h during the surgical procedure.

Diagnosis of anastomotic leakage

AL was confirmed by computed tomography and/or retrograde colonography using a water-solu-

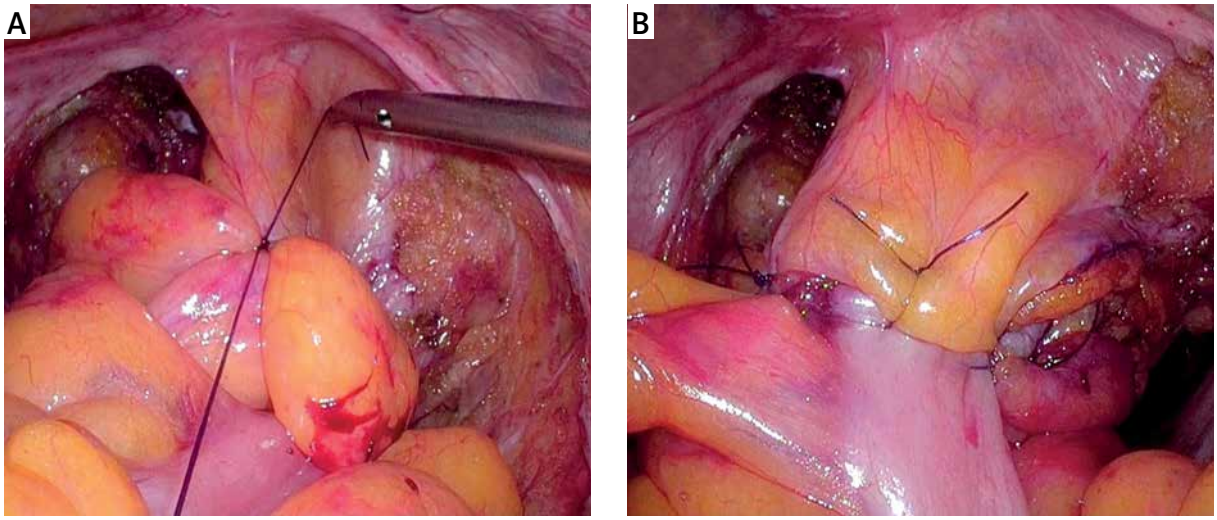

Photo 1. Anastomosis and reinforcing sutures. Reinforcing sutures are placed at the crossing point of the staple lines. **A** – Reinforcing sutures are placed at the crossing point of the staple lines. **B** – Two or more interrupted sutures are placed along the staple line.

ble medium. AL was confirmed within 7 days in all diagnosed patients in this study.

Evaluation of parameters

The risk factors for AL were evaluated using the following 21 factors: age, sex, body mass index (BMI), American Society of Anesthesiologists Physical Status (ASA-PS) score, history of abdominal surgery, presence of ischaemic cardiac disease, chronic obstructive pulmonary disease (COPD), diabetes mellitus, steroid use, tumour site from the anal verge, tumour size, depth of tumour invasion, lymph node metastases, distant metastases, operative time, intraoperative blood loss, ligation of the left colonic artery, preoperative haemoglobin level, preoperative serum albumin level, and presence of reinforcing sutures. The cut-off values for operative time and intraoperative blood loss, tumour site (distance from the anal verge), and tumour size were determined by mean values. The depth of tumour invasion, lymph node metastases, and distant metastases were classified by the TNM classification [18].

Statistical analysis

Statistical analysis were performed using JMP 10 (SAS Institute Japan, Tokyo, Japan). Univariate analyses were performed using the χ^2 test, Fisher exact test, or Mann-Whitney *U* test. All variables with a *p*-value less than 0.05 in the univariate analysis were included in the multivariate logistic regression analysis. Findings with a *p*-values less than 0.05 were considered statistically significant.

Results

The clinical characteristics of the 153 patients are shown in Table I. The mean age was 68.3 years (range: 39–88), 98.0% of the patients were classified into ASA-PS 1 or 2, and the mean body mass index (BMI) was 22.9 kg/m^2 (range: 16.4–33.7). Ten (6.5%) patients had ischaemic heart disease, 20 (13.1%) patients had diabetes mellitus, and 15 (9.8%) patients had COPD. The mean distance from the anal verge to the tumour was 6.5 cm (range: 2.0–10.0).

Patients were classified into two groups based on whether they received reinforcing sutures. The associations between the clinicopathological factors and reinforcing sutures are summarised in Table I. Seventy-two patients received reinforcing sutures, and 81 patients did not receive reinforcing sutures. The operative time tended to be shorter in the group without reinforcing sutures than in the group with reinforcing sutures, but the difference was not significant.

The associations between clinicopathological factors, including reinforcing sutures, and AL, are summarised in Table II. Eleven (7.2%) of the 153 patients had AL. Five patients required stoma construction, and 6 of 11 recovered with conservative treatment. AL was observed in only 1 patient in the group that received reinforcing sutures. There was a significantly lower incidence of AL in patients with reinforcing issues than in patients without reinforcing sutures ($p < 0.01$). Three factors were significantly associated with AL in the univariate analysis: diabetes mellitus, tumour site, and the use of reinforced sutures. Multivariate analysis revealed that tumour site less than 6.5 cm from the anal verge, diabetes mellitus, and absence of reinforcing sutures were independent risk factors for AL (Table III).

A subgroup analysis was performed for lower rectal cancer (tumour site less than 6.5 cm from the anal verge). The results are shown in Table IV. There was no leakage in the patients with reinforcing sutures ($p = 0.005$).

Discussion

Recent studies have shown that laparoscopic rectal surgery is safe and feasible [19–21]. Moreover, several randomised trials have shown that laparoscopic colorectal resection is comparable to conventional open surgery in terms of oncologic safety, and it improves short-term perioperative outcomes [22–24].

Laparoscopic rectal surgery is technically more difficult than laparoscopic colorectal resection because of the difficulties associated with rectal resection and anastomosis in a narrow pelvic space. However, this technique cannot be performed for low rectal resection with open surgery due to blind areas, and hence the usefulness of laparoscopy can be demonstrated. Recently, in addition to the use of laparoscopy, the fascia space priority approach has been used to effectively demonstrate the outcomes of laparoscopic lateral lymph node dissection [25].

AL is a major problem in patients who undergo rectal cancer surgery. AL often requires reoperation

Table I. Patient characteristics and reinforcing suture

Characteristic		Number of patients $N = 153$	Reinforcing suture		*P*-value
			Yes $n = 72$	No $n = 81$	
Age [years]	Mean (range)	68.3 (36–88)	68.1	68.6	0.267
Gender	Male	83	38	45	0.730
	Female	70	34	36	
BMI	Mean (range)	22.9 (16.4–33.7)	22.9	23	0.415
ASA-PS score	1, 2	150	71	79	0.434
	3	3	1	2	
History of laparotomy	Absent	123	58	65	0.962
	Present	30	14	16	
Ischaemic cardiac disease	Absent	143	68	75	0.644
	Present	10	4	6	
COPD	Absent	138	64	74	0.608
	Present	15	8	7	
Diabetes mellitus	Absent	133	65	68	0.247
	Present	20	7	13	
Steroid use	Absent	146	70	76	0.316
	Present	7	2	5	
Tumour site (from anal verge) [cm]	Mean (range)	6.5 (2.0–10.0)	6.2	6.8	0.329
Tumour size (diameter) [cm]	Mean (range)	3.7 (0.5–9.0)	3.8.	3.5	0.052
Depth of tumour invasion	T1	20	6	14	0.296
	T2	33	14	19	
	T3	62	33	29	
	T4	38	19	19	
Lymph node metastases	N0	93	42	51	0.076
	N1	40	24	16	
	N2	20	6	14	
Distant metastases	M0	137	64	73	0.803
	M1	16	8	8	
Ligation of left colic artery	No	38	18	20	0.965
	Yes	115	54	61	
Operation time [min]	Mean (range)	294 (164–556)	301	285	0.503
Intra-operative blood loss [ml]	Mean (range)	7.8 (0–254)	5.6	9.7	0.284
Preoperative haemoglobin level [g/dl]	> 12	132	55	67	0.077
	≤ 12	31	17	14	
Preoperative serum albumin level [g/dl]	> 3.5	133	61	72	0.619
	≤ 3.5	20	11	9	

BMI – body mass index, ASA-PS – American Society of Anesthesiologists physical status, COPD – chronic obstructive pulmonary disease.

Table II. Clinicopathological factors and anastomotic leakage

Variable		Number of patients *N* = 153	Leakage		*P*-value
			Presence *n* = 11	Absent *n* = 142	
Age [years]	Mean (range)	68.3 (36–88)	62.9	68.8	0.616
Gender:	Male	83	7	76	0.516
	Female	70	4	66	
BMI	Mean (range)	22.9 (16.4–33.7)	22.7	23	0.250
ASA-PS score:	1, 2	150	10	140	0.181
	3	3	1	2	
History of laparotomy:	Absent	123	8	115	0.506
	Present	30	3	27	
Ischaemic cardiac disease:	Absent	143	10	133	0.722
	Present	10	1	9	
COPD:	Absent	138	10	128	0.934
	Present	15	1	14	
Diabetes mellitus:	Absent	133	7	126	0.017
	Present	20	4	16	
Steroid use:	Absent	146	11	135	0.451
	Present	7	0	7	
Tumour site (from anal verge) [cm]	Mean (range)	6.5 (2.0–10.0)	4.1	6.6	0.001
Tumour size (diameter) [cm]	Mean (range)	3.7 (0.5–9.0)	3.5	3.7	0.902
Depth of tumour invasion:	T1	20	1	19	0.658
	T2	33	4	29	
	T3	62	4	58	
	T4	38	2	36	
Lymph node metastases:	N0	93	4	89	0.177
	N1	40	4	36	
	N2	20	3	17	
Distant metastases:	M0	137	11	126	0.239
	M1	16	0	16	
Ligation of left colic artery:	No	38	3	35	0.846
	Yes	115	8	107	
Operation time [min]	Mean (range)	294 (164–556)	323	292	0.664
Intra-operative blood loss [ml]	Mean (range)	7.8 (0–254)	32.1	6.5	0.053
Preoperative haemoglobin level [g/dl]:	> 12	132	8	114	0.548
	≤ 12	31	3	28	
Preoperative serum albumin level [g/dl]:	> 3.5	135	10	125	0.775
	≤ 3.5	18	1	17	
Reinforcing suture:	Yes	72	1	71	0.008
	No	81	10	71	

BMI – body mass index, ASA-PS – American Society of Anesthesiologists physical status, COPD – chronic obstructive pulmonary disease.

Table III. Multivariate analyses according to the correlations of clinicopathological factors and anastomotic leakage

Variable		Multivariate analysis		*P*-value
		Odds ratio	95% CI	
Reinforcing suture:	Yes	0.122	0.006–0.701	0.015
	No			
Tumour site (from anal verge) [cm]	> 6.5	0.130	0.017–0.605	0.008
	≤ 6.5			
Diabetes mellitus:	Absent	0.153	0.029–0.763	0.023
	Present			

CI – confidence interval.

Table IV. Relationship with reinforcing sutures and anastomotic leakage in the patients with low rectal cancer

Reinforcing suture	Number of patients	Anastomotic leakage		*P*-value
		Present	Absent	
Yes	32	0	32	0.005
No	41	9	32	
		9	64	

and prolonged hospitalization and also results in high morbidity and mortality rates. The incidence of AL has been reported to be 3.6–21% [4–6, 26]. AL is associated with several risk factors, such as old age, male sex, smoking, diabetes, obesity, intraoperative bleeding, prolonged surgery, more than three rectal incisions, large tumours, and low-sited tumours.

The double-stapled anastomotic technique is widely used in rectal surgery because it allows the anastomosis to be performed at a low position in the pelvis and preserves the anal sphincter. In this technique, the stapled corner was weakened by crossing the two staple lines. To solve this problem, intracorporeal reinforcing sutures were placed in staple lines. We considered that reinforcing the circular staple anastomosis by suturing laparoscopically would reduce AL. In the present study, only 1 case of AL was observed in the patients with reinforced sutures. Therefore, reinforcing sutures may be useful in reducing AL in patients who are at high risk for leakage. In addition, it may be technically difficult to use reinforcing sutures in open rectal surgery. The magnified view of the laparoscope is suitable for reinforcing sutures in laparoscopic rectal surgery. However, technically, laparoscopic reinforcing sutures are occasionally difficult to achieve. If reinforcing sutures are not possible, a covering stoma may be necessary. Recently, circular staplers with three rows of staples of different heights or circular powered staplers have been introduced to make anastomosis safer [27, 28], and reinforcing sutures may be necessary only in some cases.

This study had some limitations. The surgeon's laparoscopic technique may have improved in the later years. The learning curve of the laparoscopic surgical technique may have been involved in the reduction of AL. In addition, this was not a randomised study. Thus, there might have been selection bias in selecting those to receive reinforcing sutures.

Conclusions

This study demonstrates that the use of intracorporeal reinforcing sutures may reduce AL. However, a randomised trial seems necessary to evaluate the effects of reinforcing sutures for preventing AL.

Conflict of interest

The authors declare no conflict of interest.

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