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 and/or retrograde colonography using a water-solu-
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 $\chi^2$ 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/m² (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 sutures 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 | Reinforcing suture | P-value |
|---------------------------------------------|--------------------|--------------------|---------|
| **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 | Leakage | P-value |
|-----------------------------------------|--------------------|---------|---------|
|                                         | N = 153            | Presence | Absent |
|                                         |                    | n = 11  | 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.
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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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