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Anastomotic Leakage Using Linear Stapling Device with Pre-attached Bioabsorbable Polyglycolic Acid Felt After Laparoscopic Anterior Resection

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Abstract. *Aim: Many studies have evaluated the risk factors for anastomotic leakage after laparoscopic anterior resection. In this study in order to increase the tightness of anastomoses and prevent bleeding from their staple lines, a linear stapler with pre-attached bioabsorbable polyglycolic acid (PGA) felt was used for rectal transection, and the short-term surgical outcomes were evaluated. Patients and Methods: A prospective registry of 62 patients with rectosigmoidal or rectal carcinoma who initially underwent laparoscopic anterior resection using PGA felt for rectal transection was reviewed. Results: The overall frequency of anastomotic leakage was 1.6% (1/62), and none of the patients developed postoperative staple line bleeding or other adverse events related to the use of PGA felt. Conclusion: The frequency of anastomotic leakage was relatively low, and therefore the use of a linear stapler with pre-attached bioabsorbable PGA felt might reduce the risk of adverse events related to anastomosis, especially anastomotic leakage.*

Controversy persists concerning the appropriateness of laparoscopic surgery for patients with rectal carcinoma due to uncertainty regarding its oncological outcomes compared with those of open surgery (1, 2). Although many studies have demonstrated that laparoscopic and open surgery for rectal carcinoma have similar short-term complications rates, the devices and techniques used for laparoscopic anterior resection (AR) differ from those used for open AR, which suggests that the risk factors for anastomotic leakage might also differ between laparoscopic AR and open AR (3-5).

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Anastomotic leakage is the most important complication after AR for rectal carcinoma and occurs at frequencies ranging from 1.0 to 23% (3-8). It contributes not only to postoperative morbidity and mortality, but also to local recurrence and poor functional outcomes (9). Several studies have evaluated the risk factors for anastomotic leakage in laparoscopic AR (10, 11). Recently, the use of a linear stapler with pre-attached bioabsorbable polyglycolic acid (PGA) felt in distal pancreatectomy and gastrointestinal surgery was reported to be safe and effective (12, 13). At our Institution, in order to increase the tightness of anastomoses and prevent bleeding from their staple lines, a linear stapler with PGA felt has been used to perform rectal transection. Herein, we present the short-term surgical outcomes of these procedures.

Patients and Methods

Between December 2014 and August 2017, we performed 62 continuous laparoscopic AR using PGA felt for rectal transection in patients with rectosigmoidal or rectal carcinoma. The laparoscopic resection techniques have been thoroughly described previously, and the patient's tumors were treated by tumor-specific or total mesorectal excision (14). The details of the staplers with pre-attached PGA felt (Endo GIA™ reinforced reload with Tri-Staple™, purple reload, 60-mm or 45-mm long; Medtronic, Minneapolis, USA) have been described previously (12, 13). In the rectal transection procedures, the first cartridge was either a 60-mm or 45-mm purple reinforced cartridge. If two or more cartridges were required for rectal transection, a stapler with or without PGA felt was used based on the surgeon's judgement. A stapler with an automatic anastomotic device (DST Series™ EEA™ Stapler, Medtronic, Minneapolis, USA) was used for the anastomosis.

Decisions about whether a protective ileostomy should be performed or whether a transanal decompression tube should be used were based on the surgeon's technical evaluation of the quality of the anastomosis. Tumor locations were defined according to the General Rules for Clinical and Pathological Studies on Cancer of the Colon, Rectum and Anus published by the Japanese Society for Cancer of the Colon and Rectum (15).

Table I. *Patient characteristics.*

No. of patients	62
Gender, male: female	44:18
Mean age (range), years	67 (34-85)
Mean body mass index (range), kg/m^2	23.6 (17.1-35.2)
ASA, I:II, n	26:36
Location, n	
Rectosigmoid	17
Upper rectum	34
Lower rectum	11
Pathological stage, n*	
I	20
II	20
III	18
IV	4

*According to the TNM Classification of Malignant Tumors (21).

Table II. *Intraoperative and postoperative results of laparoscopic anterior resection using a linear stapling device with pre-attached bioabsorbable polyglycolic acid felt.*

Median operative time (range), min	253 (152-510)
Median blood loss (range), ml	10 (0-450)
Conversion, n	0
Lateral lymph node dissection, n	7
Temporary stoma at the first operation, n	38
Transanal decompression tube, n	26
Number of stapler cartridges fired for rectal transection, n	
1	32
2	28
3	2
Median liquid intake (range), days	1 (1-2)
Median solid intake (range), days	3 (1-10)
Median hospital stay (range), days	11 (8-59)
Mortality, n	0
Morbidity, n	
Ileus	3
Wound infection	2
Chylous ascites	2
Anastomotic leakage	1
Neurogenic bladder, urinary retention	1
Peptic ulcer hemorrhage	1
Ureter injury	1
Intra-abdominal bleeding	1

The short-term surgical outcomes of laparoscopic AR using PGA felt for rectal transection in patients with rectosigmoidal or rectal carcinoma was assessed.

Results

Intraoperative photographs of rectal transection using PGA felt and the subsequent anastomosis are shown in Figure 1, and patients' demographics are summarized in Table I. All of the operations in this series were completed laparoscopically.

The operative and postoperative results are shown in Table II. There were no cases of perioperative mortality. Twelve complications occurred in 11 patients, giving a morbidity rate of 17.7% (11/62). Anastomotic leakage occurred in one patient (1.6%). The postoperative course of the patient with anastomotic leakage was uneventful, and they were managed with conservative therapy. One patient required a re-operation because of a ureteral injury. Only one staple cartridge was used during the rectal transection in 32 patients (51.6%).

All of the patients in which a protective ileostomy was made underwent ileostomy closure, except for the patients that were operated on within 2 months.

Discussion

This is the first study to report that laparoscopic AR performed using a linear stapler with pre-attached PGA felt produced favorable outcomes. The incidence of anastomotic leakage in laparoscopic AR (1.6%) was lower than has been reported previously. The use of pre-attached PGA felt did not increase the frequency of adverse events. In fact, it might reduce the risk of adverse events related to anastomosis in laparoscopic AR, especially anastomotic leakage.

Clearly, a strict clinical study will be necessary to confirm whether the frequency of anastomotic leakage is reduced by the use of pre-attached PGA felt. However, in a previous prospective multicenter cooperative study (Lap RC) conducted in Japan, the frequency of anastomotic leakage in laparoscopicAR was found to be 8.3% (5, 14). It will be necessary to accumulate a considerable number of patients to perform a superiority trial examining whether the frequency of anastomotic leakage can be reduced by using pre-attached PGA felt. Compared with those in the Lap RC study, the subjects of the present study were characterized by higher frequencies of advanced clinical and pathological stages, old age, and high body mass index values, which were also found in randomized controlled trials carried out in Europe and the US (2, 16, 17). On the other hand, the proportion of patients in which protective stomas were indicated was high, and this should be taken into consideration. Despite these differences, the preliminary results described in this report suggest that the use of pre-attached PGA felt might reduce the frequency of anastomotic leakage.

With respect to laparoscopic AR, some reports have suggested that the risk of anastomotic leakage increases with the number of cartridges used for rectal transection (4, 18). On the other hand, few reports have indicated that the frequency of anastomotic leakage varies depending on the

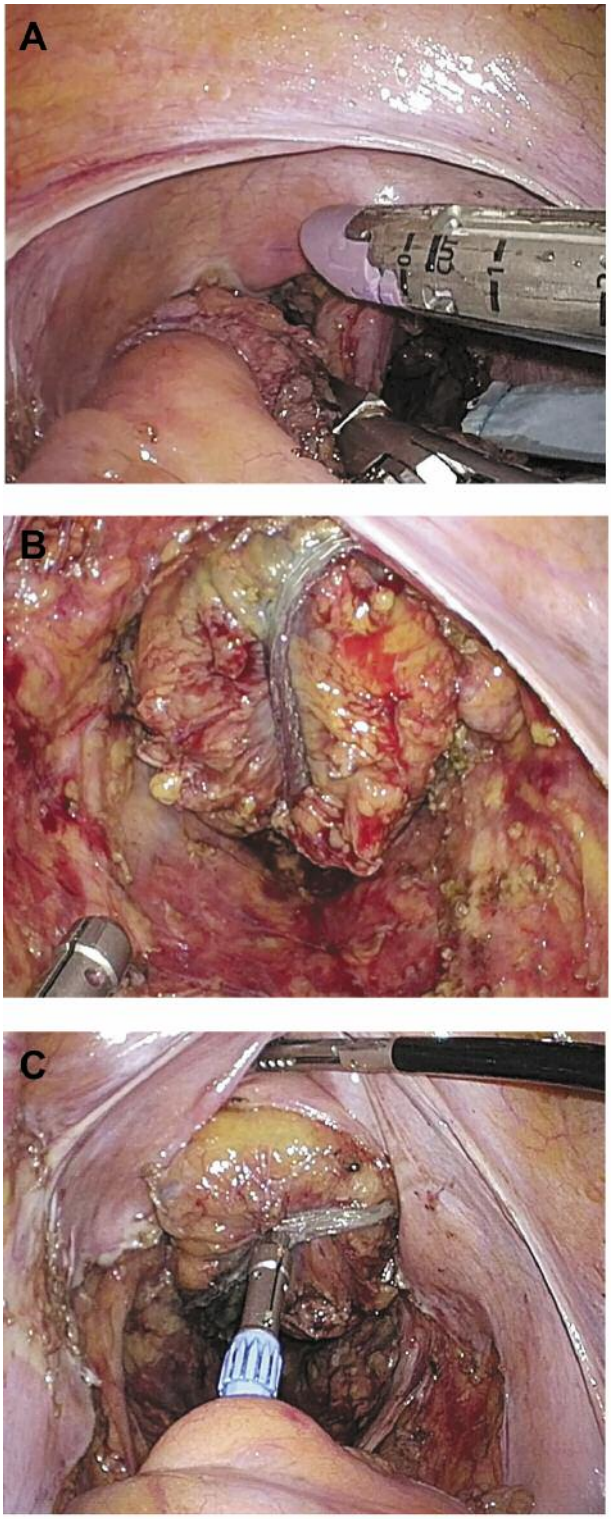

Figure 1. *Intraoperative photographs of rectal transection using polyglycolic acid (PGA) felt and the subsequent anastomosis. A: After isolation of the rectum, linear stapling device with pre-attached PGA felt was introduced. B: Staple line of the linear stapling device with pre-attached PGA felt. C: The puncturing cone was pushed through the linear staple line.*

device used for rectal transection/anastomosis. It is theoretically reasonable that the frequency of anastomotic leakage would be reduced by reinforcing a staple line created by a normal laparoscopic linear stapler with PGA felt to increase its pressure resistance, but further accumulation of patients is necessary to confirm this. The concept of reinforcing a linear staple line with material as a method for preventing leaks and bleeding has been reported in sleeve gastrectomy and lung surgery (19, 20). However, the material is usually prepared manually. In the Endo GIA™ reinforced reload with Tri-Staple™ device (Medtronic, Minneapolis, USA), which we used in this study, the material for reinforcement is pre-attached to the linear stapler, and we did not need to prepare the device, which made it much easier to use. On the other hand, in the double stapling technique, a circular stapler is used together with a linear stapler, and the pressure resistance of the resulting staple lines might be further increased by using a similar reinforcement material with a circular stapler. The development of such a device is anticipated.

This study is limited in that it only involved a single center, and the number of patients was small. Moreover, it was not a comparative study. A strict clinical trial is necessary to confirm that anastomotic leakage can be reduced by using pre-attached PGA felt, and we consider that the safety of pre-attached PGA felt is just beginning to be evaluated.

In conclusion, the use of a linear stapler with pre-attached bioabsorbable PGA felt might reduce the risk of adverse events related to anastomosis, especially anastomotic leakage. Based on the results of this study, it would be helpful to conduct a strict clinical trial examining whether the frequency of anastomotic leakage could be reduced by using this device, although it might be difficult to perform such a trial from the perspective of case accumulation.

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