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Anastomotic leakage following rectal cancer laparoscopic surgery: can a transanal drainage tube be an alternative to diverting stoma?

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Abstract. – OBJECTIVE: Anastomosis leakage in laparoscopic surgery for rectal cancer is still a serious problem affecting the patient's treatment outcome. This study aimed to evaluate the role of a transanal drainage tube compared with a diverting stoma in reducing the rate of anastomosis leakage and limiting surgical complications.

PATIENTS AND METHODS: A retrospective study was conducted on 196 rectal cancer patients undergoing laparoscopic low anterior resection from July 2018 to October 2022 at 108 Central Military Hospital. The transanal drainage tube was placed in 133 patients (group A), and diverting stoma was performed in 63 patients (group B).

RESULTS: There was no difference between the two groups regarding age, sex, comorbidities, distance from the tumor to the anal verge, and preoperative stage. The amount of blood loss, the method of performing the anastomosis, and the distance from the anastomosis to the anal verge did not differ between the two groups. However, the surgical time was longer in the group with diverting stoma (138.3 ± 25.1 minutes *vs*. 127.6 ± 31 minutes, $p = 0.018$). The rate of anastomosis was not significantly different between groups A and B (8.3% in group A and 7.9% in group B, $p = 0.936$). The proportion of patients with anastomosis requiring reoperation in group A was higher than in group B. However, the difference was not statistically significant (8/11 patients in group A and 2/5 patients in group B, $p = 0.29$).

CONCLUSIONS: Placing a transanal drainage tube in laparoscopic surgery for rectal cancer to reduce the rate of anastomosis can be considered an alternative method for diverting stoma with complications related to the stoma.

Key Words:
Colorectal anastomotic leak, Laparoscopic low anterior resection, Diverting stoma, Anal drainage tube, Rectal cancer.

Introduction

Anastomotic leakage (AL) is a defect of the intestinal wall at the anastomosis site that leads to intra- and extra-luminal communication[1], and it represents a challenging problem in rectal surgery. Although there have been many improvements in surgical techniques and stapling devices, the rate of anastomosis leaks in rectal surgery is still high, up to 9.7% (0-36.3%) in some studies[2].

AL leads to infection, prolonged hospital stays, and quality of life issues. Furthermore, anastomotic complications delay adjuvant chemoradiotherapy, decreasing survival time and increasing the recurrence rate. A meta-analysis[3] of 78,434 colorectal cancer patients who underwent surgery found that anastomosis leak was associated with increased recurrence and decreased overall survival after surgery.

Ileostomy to reduce the incidence of anastomosis was proposed by Mikulicz in 1903. However, results from recent studies[4-6] raised questions about the efficiency of diverting stoma (DS) for protecting the rectal as well as concerns about complications related to the stoma. Placement of a decompressive transanal drainage tube (TDT) is also a method that some authors[7-9] have mentioned to reduce the rate of anastomosis leak in surgery for rectal cancer. Therefore, we performed a retrospective study comparing transanal drainage and diverting stoma to protect anastomosis following rectal cancer laparoscopic surgery.

Patients and Methods

Study Design and Participants

This retrospective cohort study was approved by the Scientific Committee in Biomedical Re-

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search, 108 Military Central Hospital (Ref.: 4468/QĐ-BV108, dated September 25, 2020). A total of 196 patients with rectal cancer (clinical stage I-III) underwent laparoscopic low anterior resection (LAR) between July 2018 and October 2022 at the Department of Coloproctology and Pelviperineology, 108 Central Military Hospital, Hanoi, Vietnam. Patients were divided into two groups: group A of 133 patients underwent laparoscopic LAR with TDT, and group B of 63 patients underwent laparoscopic LAR with DS (Figure 1). All patients had rectal cancer diagnosed by endoscopy and biopsy, with tumors located 15 cm from the anal verge. Chest-abdominal CT scans and pelvic MRI were performed to evaluate clinical staging according to the American Joint Committee on Cancer (AJCC) 7th edition (Figure 2). Long-course chemoradiotherapy (CRT) was indicated for patients with cT3-4 and/or N (+) rectal cancer. Patients receiving preoperative CRT underwent surgery 6-8 weeks after the completion of CRT.

The following data were collected from all patients: patient's characteristics [age, gender, body mass index (BMI), comorbidities, and American Society of Anesthesiologists (ASA) physical status classification], tumor characteristics (preoperative clinical stage, distance from tumor to the anal margin, neoadjuvant therapy), surgical characteristics (operative procedure, operative time, blood loss, numbers of staplers using to divide the distal rectum, technique to perform the anastomosis, distance from the anastomosis to the anal margin), and postoperative outcomes (AL – diagnosed and classified according to the International Study Group on Rectal Cancer – ISGRC[1], complications associated with a stoma).

Surgical Protocol

The patient underwent laparoscopic low anterior resection [total mesorectal excision (TME), intersphincteric resection (ISR), and transanal total mesorectal excision (taTME)]. The distal rectum was divided by tri-stapler technology (Endo GIA 45-60 mm, Medtronic, Dublin, Ireland). The anastomosis was performed by either a circular stapler (EEA™ Circular Stapler with Tri-Staple™ Technology, Medtronic, Dublin, Ireland) or hand-

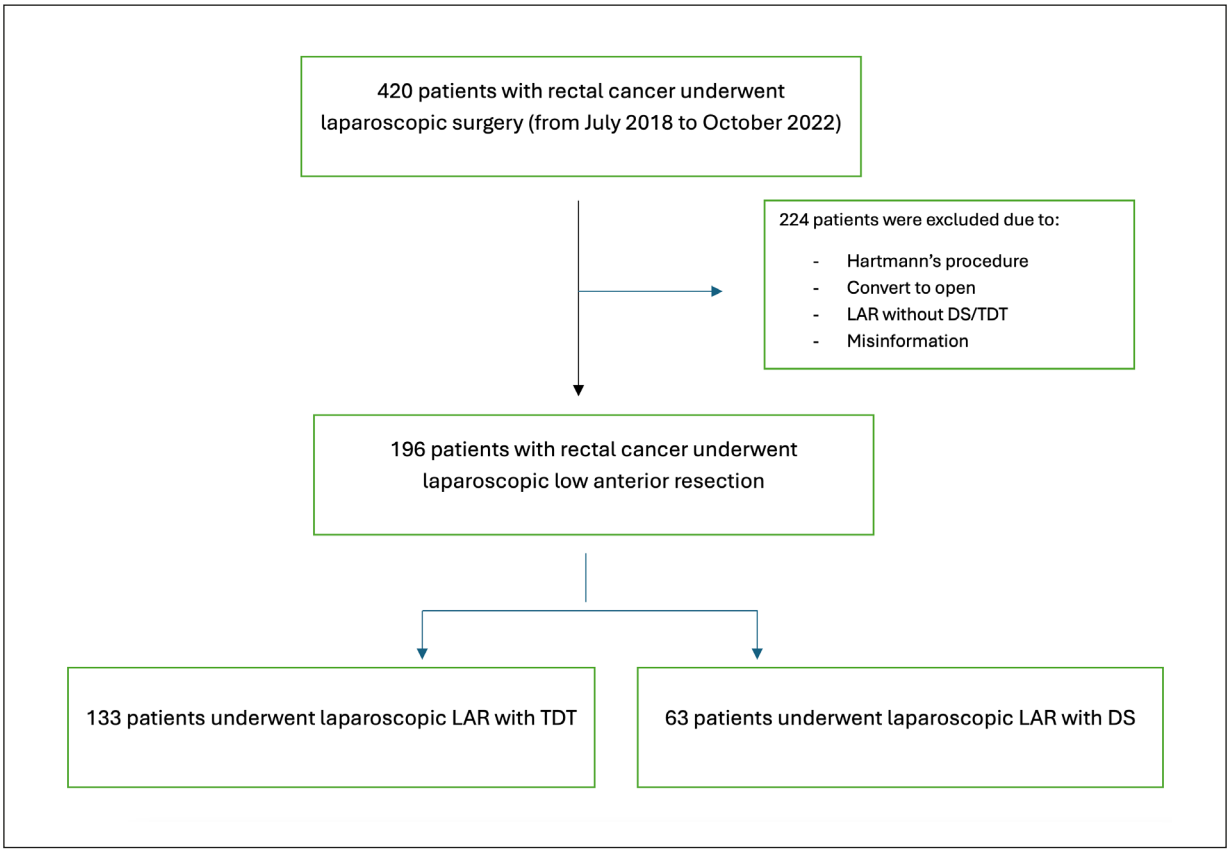

Figure 1. The flow diagram of the study. TDT: transanal drainage tube; DS: diverting stoma; LAR: low anterior resection.

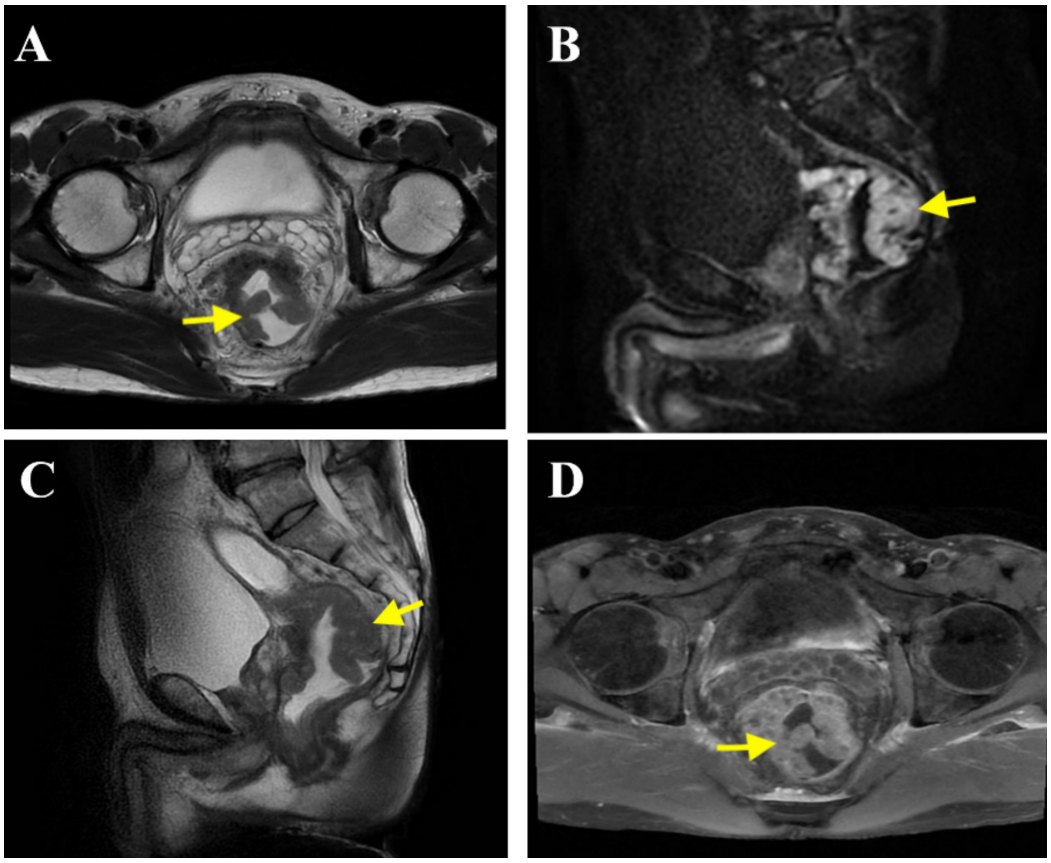

Figure 2. Rectal cancer (arrow) was assessed by MRI. **A**, Axial T2-weighted (T2W); (**B**) Sagittal diffusion-weighted imaging (DWI); (**C**) Sagittal T2W; (**D**) Axial T1W with contrast enhancement.

sewn using Vicryl 3.0 (VICRYL™. Suture Size. 3-0. Length. 75, Johnson & Johnson Medical, Machelen, Belgium) (Figure 3). The patients had a protective ileostomy or transanal drainage tube with a 71 D x 10 OD ~ Fr32 silicone tube (Drain tube with hole, Forte Grow Medical Co., Ltd, Thuan An City, Binh Duong Province, Vietnam) (Figure 4).

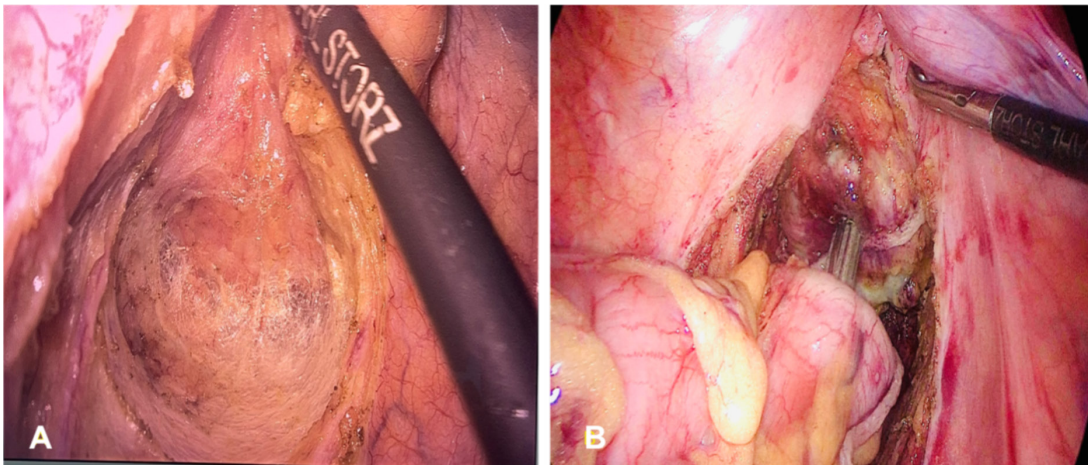

Figure 3. TME plane in the presacral space (**A**), anastomosis is created by EEA™ Circular Stapler with Tri-Staple™ Technology (**B**).

Figure 4. The silicone tube used to place transanal drainage.

Statistical Analysis

SPSS 23.0 statistical software (IBM Corp., Armonk, NY, USA) was adopted for statistical analysis. Measurement data were presented as mean ± standard deviation (± SD). Count data were presented as a proportion (percentage). All variables were compared using the χ^2 or Fisher's exact test for categorical data and the Wilcoxon Rank-Sum test for continuous and ordinal variables. A p-value < 0.05 was considered statistically significant.

Results

Patient Characteristics

There was no statistically significant difference between the two groups in terms of age, gender, BMI, and comorbidities (Table I). Distance for the tumor to the anal margin was similar between the two groups (8.9 ± 3.4 cm in group A and 7.7 ± 3.4 cm in group B, $p = 0.24$), the rate of preoperative chemoradiotherapy, as well as tumor invasion and lymph node status on MRI, did not differ between two groups.

Table I. Patients' characteristics.

	TDT (n = 133)	DS (n = 63)	p
Age ($\bar{x} \pm sd$)	61.9 ± 10.9	62.6 ± 11.4	0.722
Sex ratio (male/female)	93/40	40/23	0.368
BMI (kg/m^2) ($\bar{x} \pm sd$)	21.9 ± 3.5	22.5 ± 3.0	0.334
ASA (n, %)			0.651
I	95 (71.4)	43 (68.3)	
II	36 (27.1)	20 (31.7)	
III	2 (1.5)	0 (0.0)	
Comorbidities (n, %)	41 (30.8)	21 (33.3)	0.725
Treatment (n, %)			0.176
Preoperative CRT+ Surgery	91 (68.4)	49 (77.8)	
Surgery alone	42 (31.9)	14 (22.2)	
Distance from tumor to anal margin on MRI (cm) ($\bar{x} \pm SD$)	8.9 ± 3.4	7.7 ± 3.4	0.24
T stage on MRI (n)			0.722
cT1	4	0	
cT2	29	12	
cT3	84	43	
cT4a/b	10/6	4/4	
N stage on MRI (n, %)			0.891
cN0	31 (23.3)	15 (23.8)	
cN1	76 (57.2)	34 (54.0)	
cN2	26 (19.5)	14 (22.2)	

TDT: transanal drainage tube; DS: diverting stoma; BMI: body mass index; MRI: magnetic resonance imaging; ASA: American Society of Anesthesiologists; CRT: chemoradiotherapy.

Table II. Surgical characteristics.

	TDT (n = 133)	DS (n = 63)	p
Mean operative time (minute) ($\bar{x} \pm SD$)	127.6 ± 31.1	138.3 ± 25.1	0.018
Mean blood loss (ml) ($\bar{x} \pm SD$)	55.4 ± 33.5	55.6 ± 29.4	0.971
Distance from the anastomosis to the anal margin (cm) ($\bar{x} \pm SD$)	4.0 ± 1.7	3.7 ± 1.1	0.104
Technique to perform the anastomosis (n, %)			0.129
Circular stapler	99 (74.4)	53 (84.1)	
Hand-sewn	34 (25.6)	10 (15.9)	

TDT: transanal drainage tube; DS: diverting stoma.

Surgical Characteristics

The mean operative time in group B was longer than in group A (127.6 ± 31.1 minutes *vs.* 138.3 ± 25.1 minutes, $p = 0.018$), there was no difference between the volume mean blood loss (55.4 ± 33.5 ml in group A and 55.6 ± 29.4 ml in group B, $p = 0.971$) and the distance from the anastomosis to the anal margin (4.0 ± 1.7 cm for group A and 3.7 ± 1.1 cm, $p = 0.104$) (Table II).

Postoperative Outcome

There was no difference in the rate of anastomosis between the two groups (8.3% for group A and 7.9% for group B, $p = 0.936$) (Table III). Meanwhile, the incidence of complications related to stoma of group B was bowel obstruction (12.7%), wound infection (15.9%), dermatitis (15.9%), ileal prolapse (4.8%), ileostomy leakage (1.6%), fluid loss or electrolytes disturbance need re-admission (6.3%) (Table IV).

Discussion

Anastomotic leakage following surgery for rectal cancer is a challenging problem for surgeons

Table III. Anastomotic leakage.

	TDT (n = 133)	DS (n = 63)	p
Anastomotic leakage (n, %)	11 (8.3)	5 (7.9)	0.936
Intervention for AL			0.29
Conservative	3 (27.3)	3 (60.0)	
Reoperation	8 (72.7)	2 (40.0)	

TDT: transanal drainage tube; DS: diverting stoma; AL: anastomotic leakage.

Table IV. Surgical complications and complications associated with stoma.

Postoperative complications	TDT (n = 133)	DS (n = 63)	
		Unrelated with stoma	Related with stoma
Bowel obstruction (n, %)	3 (2.3)	1 (1.6)	8 (12.7)
Wound infection (n, %)	6 (4.5)	2 (3.2)	10 (15.9)
Anastomotic bleeding (n, %)	3 (2.3)	1 (1.6)	-
Urinary retention (n, %)	6 (4.5)	2 (3.2)	-
Bladder paralysis (n, %)	2 (1.5)	1 (1.6)	-
Abscess in abdomen (n, %)	2 (1.5)	1 (1.6)	-
Deep vein thrombosis (n, %)	1 (0.8)	0	-
Dermatitis (n, %)	-	-	10 (15.9)
Ileal prolapse (n, %)	-	-	3 (4.8)
Ileostomy leakage (n, %)	-	-	1 (1.6)
Fluid loss or electrolytes disturbance need re-admission (n, %)	-	-	4 (6.3)

TDT: transanal drainage tube; DS: diverting stoma.

and patients. AL leaves patients with many sequelae and affects the results of cancer treatment, such as increased recurrence rate, mortality, and interruption of adjuvant therapy after surgery. Research by Ha et al[3] showed that AL increased local recurrence [relative risk (RR) 1.90, 95% confidence interval (CI) 1.48-2.44, I^2 = 78%] and decreased overall survival time (RR 1.36, 95% CI 1.24-1.50, I^2 = 74%) as well as disease-free survival (RR 1.40, 95% CI 1.20-1.63, I^2 = 86%). There are many methods proposed to reduce the rate of AL in rectal surgery, such as the surgical approach, anastomosis technique, intraoperative assessment of the anastomosis, diverting stoma, and prophylactic decompressive transanal drainage tube. In our study, we found that the role of TDT is important in reducing the rate of AL. Recent studies[7,8,10,11] also support the role of TDT.

Diverting stoma was previously considered a valuable method in reducing the incidence of AL. However, recent studies[4-6] in the literature showing the effectiveness of DS for rectal AL are controversial as the rate of anastomosis is low in the group with DS, but there is weak evidence. DS reduces the severity of AL but leads to other complications. A randomized controlled study should be conducted before performing DS as a routine procedure[5]. Furthermore, in the study by Niu et al[6], which included 347 patients with rectal cancer, LAR was performed. 95 patients had DS (treatment group), and 252 patients did not have DS (control group). The study found that in the rate of AL, there was no difference between the two groups, with 6.32% for the treatment group and 8.73% for the control group ($p > 0.05$). The authors concluded that DS had no significant benefit in reducing the incidence of postoperative anastomosis in patients with rectal cancer.

Colorectal surgeons are also concerned about complications related to the stoma, which affect the quality of treatment for patients. The study of Nastro et al[12], which included 1,216 patients with DS, found 1,219 complications in 681 patients (56%), including 807 severe complications in 564 patients (46.4%). The stoma complications include parastomal hernia (14.1%), bleeding (12.8%), obstruction (9.5%), ischemia (8.2%), fistula (6.1%), retraction (5.9%), prolapse (5.4%), and stenosis (4.3%). Similarly, Mehboob et al[13] studied 84 patients undergoing ileostomy and showed that 61 patients (72.7%) had complications. The most common complication was skin excoriation (19.4%), followed by wound infection (13%), nonfunctioning stoma (11.9%), prolapse and stenosis (6%), retraction (4.7%), high-output fistula (3.5%), parastomal hernia and necrosis (2.3% each), and bleeding (1.1%)[13].

In this study, we encountered complications of ileostomy, including intestinal obstruction (12.7%), surgical site infection (15.9%), dermatitis (15.9%), ileal prolapse (4.8%), ileostomy fistula (1.6%), fluid loss or electrolytes disturbance required re-admission (n, %) (6.3%) (Table IV). DS's complications have greatly affected patients' psychology; they often complain of discomfort related to DS. In addition, they must undergo additional surgery to close the ileostomy, which dramatically affects the health and treatment costs of the patient.

One method that is considered to reduce the rate of AL in rectal cancer surgery was studied by many authors, which is the transanal drainage tube. This method is simple and easy to implement. After completing the anastomosis, we place the silicone drain through the anastomosis until the tube tip passes over 15 cm from the level of the anastomosis. Insertion of the tube must be supported from the intraabdominal instruments (colic traction axially) to avoid the tip of the tube rubbing against the colonic wall as well as the anastomosis. The TDT is removed about 4-5 days after surgery. In the TDT group, we did not encounter any complications related to the drainage tube, except for a small number of patients who felt some discomfort in the anus.

Our study compared rectal cancer patients undergoing laparoscopic LAR with DS and those with TDT. Between the two groups, there were similarities in patient characteristics (Table I), tumor characteristics (Table II), as well as the method of performing anastomosis, and the location of the anastomosis (Table III). The analysis showed that the AL of group A and group B was 8.3% (11/133) and 7.9% (5/63), respectively. The difference was not statistically significant, with $p > 0.05$. The results also showed that the rate of AL requiring reoperation of group A was 72.7% (8/11), higher than that of group B, which was 40% (2/5), but the difference was not statistically significant with $p > 0.05$.

TDT protects the anastomosis by reducing intraluminal pressure and minimizing the impact of bowel contents on it. It is considered an effective method to prevent AL in high-risk patients without exposing them to complications of DS[14]. In addition, our experience shows that TDT also helps to monitor and evaluate early

postoperative bleeding or leakage for timely management.

A meta-analysis[9] of two RCTs and five observational studies of 833 patients with TDT and 939 patients without TDT found that the TDT group had a lower incidence of AL, which was statistically significant (RR 0.44; 95% CI 0.29-0.66; $p < 0.0001$). There was no difference in the rate of anastomosis bleeding (RR 1.48; 95% CI 0.79-2.77; $p = 0.22$). Similarly, Carboni et al[8] studied 429 rectal cancer patients in which 275 (group A) had TDT and 154 patients (group B) did not have TDT and found the rate of AL was higher in group B ($p = 0.007$), complication grade C was higher than in group B ($p = 0.006$). The economic benefits assessment saved is about 4,000 euros per patient. In addition, other authors[9,11,15] also reported on the effectiveness of TDT in reducing the rate of AL, and it is also considered an option to replace DS in surgical treatment for rectal cancer.

In addition, our experience with TDT has found that drainage with an Fr32 silicone tube has several advantages: first, the large diameter tube helps to prevent tube obstruction due to blood clots and feces. Second, the tube wall is more potent and difficult to bend and flatten. Third, the silicone material does not cause tissue irritation like latex. Luo et al[9] compared the effectiveness of 3 different types of anal tubes, Fr32 silicone (81 cases), Fr24 silicone (54 cases), and Fr24 latex (47 cases), on a total of 182 rectal cancer patients who underwent laparoscopic LAR. The study demonstrated that although there was no significant difference in AL among the three different types of TDT, the AL in the group of patients using the Fr32 silicone tube was lower than the group of patients using the Fr24 latex and Fr24 silicone tube (1.23%, 5.56%, and 6.38%, respectively). In addition, the time of the first drainage and defecation with the 32Fr silicone tube after rectal cancer surgery was significantly earlier than with the Fr24 silicone tube and the Fr24 latex tube. The results show that the drainage efficiency of the Fr32 silicone tube is better than that of the Fr24 silicone tube and Fr24 latex tube. Some authors[16-18] also report that larger anal tubes are superior to smaller ones.

Limitations

One limitation of this study is that the number of patients is still small. This is a retrospective and non-randomized study, so there are no strict selection criteria, and the comparison's validity is not high. A large randomized clinical trial with a large number of patients is required for accurate results and recommendations for clinical practice.

Conclusions

Anastomosis leakage in surgery for rectal cancer is still challenging, and the choice of methods to protect the anastomosis is still debated. However, through our study, we found that the transanal drainage tube is a simple method with equivalent value to diverting stoma for reducing AL after laparoscopic LAR for rectal cancer, avoiding complications related to ileostomy.

Ethics Approval

This retrospective cohort study was approved by the Scientific Committee in Biomedical Research, 108 Military Central Hospital (Ref: 4468/QĐ-BV108, dated 25 Sep 2020) and was conducted according to the ethical standards of the 1964 Declaration of Helsinki and its later amendments.

Informed Consent

Informed consent was waived by the Scientific Committee in Biomedical Research, 108 Military Central Hospital, for the study's retrospective design. Moreover, the analysis used anonymous clinical data.

Availability of Data and Materials

The datasets generated and/or analyzed during the current study are not publicly available due to privacy concerns but are available from the corresponding author upon reasonable request.

Authors' Contributions

Ho Huu An, Trieu Trieu Duong, and Nguyen Minh Duc conceived the research idea for the study. Ho Huu An, Trieu Trieu Duong, and Nguyen Minh Duc led the study design. Ho Huu An and Nguyen Minh Duc contributed to data collection and extraction. Ho Huu An and Nguyen Minh Duc performed the statistical analysis. Ho Huu An and Nguyen Minh Duc drafted the manuscript first, and Ho Huu An and Nguyen Minh Duc revised the manuscript. Ho Huu An and Nguyen Minh Duc took the responsibility for manuscript revision and summary of information from the other authors. All authors contributed important intellectual content during manuscript revision, had full access to all the data in the study, and accepted responsibility for submitting it for publication.

Conflicts of Interest

There are no conflicts of interest to declare.

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