

Protection of low rectal anastomosis with a new tube ileostomy using a biofragmentable anastomosis ring

A retrospective study

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Abstract

A temporarily defunctioning stoma, while effective at reducing symptomatic anastomotic leakage after low anterior resection (LAR) of rectal cancer, and its subsequent closure, is associated with significant morbidity. Here, we devised a new tube ileostomy using a biofragmentable anastomosis ring (TIB) with no need for reversal.

This is a retrospective cohort study. From June 2011 to March 2015, TIBs were performed on 31 consecutive patients with mid- or low-rectal cancer who underwent elective laparoscopic LARs. From January 2008 to May 2011, 25 similarly diseased patients underwent elective laparoscopic LARs and conventional loop ileostomy (LI) and were included as controls. All of the anastomotic sites were within 6 cm of the anal verge. Demographic, clinical feature, and operative data were recorded.

The demographic features of both groups were similar. The TIB mean surgical duration was significantly lower than in the LI group (215 ± 28 vs 245 ± 54 min, $P=0.010$). Because of readmission for stoma closure, the total hospital stay of the LI group was longer than that of the TIB group (38.1 ± 26.5 vs 19.1 ± 7.9 days, respectively, $P=0.002$). Ileal content was completely diverted by TIB for 13.7 ± 2.1 (range, 10–19) days postoperatively. The drainage tube was removed on postoperative day 27.8 ± 6.9 (range, 20–44), and the mean continued duration of the discharge tract, before fistula healing, was 4.5 ± 1.9 (range, 2–10) days. Postoperative complications of the 2 modalities were not significant. In the TIB group, 1 rectovaginal fistula occurred 30 days postsurgery. In the LI group, 1 rectovaginal fistula occurred 3 months after stoma closure. Both complications were treated with transverse colostomy. No major TIB associated complications were observed in the present study.

TIB is a safe, feasible, effective, but time-limited diversion technique, which may reduce symptomatic anastomosis leakage after LAR for rectal cancer.

Abbreviations: BAR = biofragmentable anastomosis ring, CD = Clavien–Dindo classification, cN = clinical N stage, cT = clinical T stage, LAR = low anterior resection, LI = loop ileostomy, pTNM = pathological TNM stage, RVF = rectovaginal fistula, TIB = tube ileostomy using a biofragmentable anastomosis ring, TME = total mesorectal excision.

Keywords: anastomotic leakage, biofragmentable anastomosis ring, colorectal cancer, low anterior resection, rectal surgery complication

1. Introduction

Low anterior resection (LAR) with total mesorectal excision (TME) is regarded as the optimal surgical treatment for

potentially curable carcinomas of the mid- and lower-rectum.^[1,2] This operation requires an anastomosis close to the pelvic floor and has an increased risk of anastomotic leakage in approximately 10% of patients.^[3,4] Symptomatic anastomotic leakage can result in significant morbidity and mortality.^[5,6]

Several reports have suggested that proximal fecal diversion can dramatically reduce the incidence of symptomatic anastomotic leakage^[7,8] and the rate of leakage-related reinterventions.^[9,10] Currently, the proximal diversion of a distal rectal anastomosis can be achieved by using either a loop colostomy or a loop ileostomy (LI), although the latter is more common. Therefore, there are 2 main advantages of LI: reduction of symptomatic anastomotic leakage and treatment of anastomotic leakage to prevent reintervention.

Although the construction of a stoma is intended to protect against anastomosis, additional concerns with the potential to cause physical and psychological morbidity created by this operation must be considered.^[11] Stoma-related complications affect up to 30% of patients^[12]; they include symptoms such as leakage around the appliance, skin rash and excoriation, high output, hernia, retraction, and prolapse.^[13,14] Although, from the surgeon's point of view, stoma closure is a minor operation, its complications, including wound infection, anastomotic bleeding, and ileus, occur in 6.1% to 20% of patients.^[15–17] Moreover, it is well known that defunctioning stomas produce

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adverse physical and functioning effects.^[18] The use of a protective ileostomy in LAR, which is recommended based on randomized control trials, is similarly limited due to its related complications and need for reversal.

To overcome the disadvantages of traditional diverting ileostomy, we present a new tube ileostomy using a biofragmentable anastomosis ring (TIB), with no need for reversal. Because of the limited diversion time of our technique, it is not suitable for treating anastomotic leakage. Thus, the primary aim of the present study was to design a feasible and less-invasive diversion technique to reduce post-LAR symptomatic anastomotic leakage for rectal cancer, which is more mutually acceptable by both surgeons and their patients. This pilot study focused on the safety (any major TIB associated complications) and feasibility (no need for second surgery) of TIB. The clinical outcomes such as rate of symptomatic anastomotic leakage can only be assessed in a randomized controlled trial with larger samples, which is in progress.

2. Methods

2.1. Patients

This is a retrospective cohort study. From June 2011 to March 2015, 31 consecutive patients with mid- or low-rectal cancer who underwent elective LARs were included in this study at Shanghai Tongji Hospital. The inclusion criteria for the laparoscopy surgery included a localized mid- or low-rectal cancer, compliance with laparoscopy procedures, and sufficient heart and lung function to withstand pneumoperitoneum. The exclusion criteria included cancers infiltrating contiguous organs (T4b) and bowel obstruction. Preoperative studies were based on locoregional staging based on magnetic resonance imaging and contrast-enhanced computer tomography scans of the thorax and abdomen. Patients with locally advanced rectal carcinomas (T3N0 and all N+ patients) were suggested to receive neoadjuvant chemoradiation: 25 fractions of 45 Gy over 5 weeks with oral capecitabine 825 mg/m² twice daily. All patients treated with preoperative chemoradiation underwent operations 8 weeks after completing their neoadjuvant treatment. The patients with locally unresectable rectal cancer were excluded both before or during surgery. All patients were fully informed of the characteristics of TIB and its advantages and disadvantages over conventional LI. Written consent was obtained from all the participants or their family members before surgery. All of the procedures used in this study were approved by the Ethics Committee of Shanghai Tongji Hospital. To study the feasibility and effectiveness of the TIB procedure preliminarily, clinical data from patients who underwent conventional LI were used as the control. From January 2008 to May 2011, 25 eligible patients with mid- or low-rectal cancer who underwent elective LARs and conventional LI were included.

All of the patients underwent preoperative mechanical bowel preparation. All of the procedures were performed by the same surgical team. All of the anastomotic sites were within 6 cm or less of the anal verge.

2.2. Endpoints

This pilot study focused on the safety (any major TIB associated complications) and feasibility (no need for second surgery) of TIB. Therefore, the primary endpoint was total hospital stay and morbidity. Because there was no need for reversal, the total

hospital stay of TIB should theoretically be significantly decreased compared with that of LI.

2.3. Surgical procedure

All patients underwent laparoscopic LAR under general anesthesia. First, the left colon was mobilized from medial to lateral and high ligation of the inferior mesenteric artery at its origin, if necessary, followed by mobilization of the splenic flexure was performed. Then, mobilization of the rectum and the mesorectum all the way down to the pelvic floor followed by TME was achieved. The rectum was divided using an EndoGIA stapler at a point at least 1 cm distal to the mass such that a negative margin is accomplished, followed by end-to-end mechanical anastomosis. We routinely perform a rigid proctosigmoidoscopy and check the anastomotic line. The anastomosis was tested with air insufflation, with the pelvis filled with saline. The technical aspects of the LI are well known. The stomas were closed 3 to 6 months later.

2.4. TIB procedure

The TIB procedure was as follows:

1. For the TIB (Fig. 1), the cecum, ileocolic junction, and terminal ileum were laparoscopically freed from their peritoneal attachments along the avascular line of Toldt.
2. The ileocolic junction was pulled into the wound. The appendix was divided, thus leaving the stump unligated. A purse-string suture was placed around the stump.
3. A condom was connected with the biofragmentable anastomosis ring (BAR; Valtrac, United States Surgical, Princeton, NJ) via ligation, with the tip cut open. A 28-French chest tube was inserted into the condom 1 cm distal to the ring, and the condom was fixed around the tube with 2 other ligations (Fig. 2). The BAR consists of polyglycolic acid (87.5%) and barium sulfate (12.5%); consequently, it is biodegradable and radiologically detectable. This ring is available in 4 different outer diameters (25, 28, 31, and 34 mm) and 3 anastomotic gaps (1.5, 2.0, and 2.5 mm). The size of the BAR is selected according to the intestinal diameter and wall thickness. The size of 25/2.0 was commonly applied in the present procedure.
4. A window was created between the mesentery and ileum 5 cm from the ileocecal valve. Two purse-string sutures were then placed around the bowel at 5 mm intervals. Transverse enterotomy was then performed at the antimesenteric border between 2 purse-string sutures (Fig. 3).
5. The distal end of the tube was inserted into the ileum and then pulled out through the ileocecal valve and guided outside the stump of the appendix (Fig. 4). The first edge of the BAR was advanced into the distal lumen of the ileum, and the purse-string suture was tied down. The second edge of the bowel ring was advanced into the opposite lumen of the ileum, with its purse-string suture attached (Fig. 5). The second purse-string suture was tied down. Then, the BAR was closed until a click was heard.
6. The purse-string suture around the appendix stump was secured in place in such a manner as to secure the cecum around the tube. Lembert sutures were then placed to create a Witzel tunnel, and the tube was buried at approximately 3 cm.
7. The tube was then tacked to the anterior abdominal wall near the incision site, and the cecum was sutured to the abdominal wall with 4-quadrant sutures through the abdominal wall and

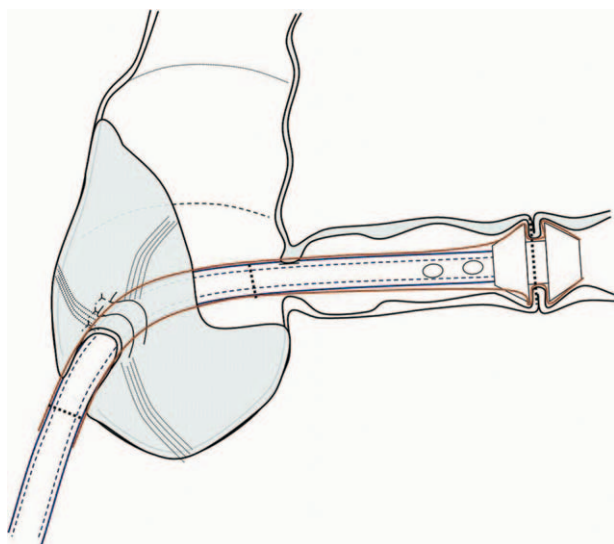


Figure 1. Diagrammatic representation of a new tube ileostomy using a bio-fragmentable anastomosis ring.

seromuscular bites on the cecum. The tube was secured onto the skin with a 3-0 silk suture. The tube was immediately attached to a gravity drainage bag and allowed to stay open.

2.5. Follow-up

On the first postoperative day, the discharge from the ileostomy began to flow (Fig. 6) and the patients were allowed to take liquids orally. Then, a semisolid diet and oral enteral nutrition were started. It was not necessary to irrigate the tube regularly because of the liquid nature of the discharge. Enterography through the ileostomy tube showed a complete diversion of the ileal content (Fig. 7). After the patient passed a stool through his/her anus, an abdominal X-ray was advised as an outpatient in the 3rd or 4th week to examine whether the ring had fragmented. The tube was removed easily after a BAR fragment was visible on the X-ray (Fig. 8). The wound was cleaned and dressed every day until it had fully healed.

The data regarding the following were recorded: gender, age, comorbidities, location of tumor, clinical T stage (cT), clinical N stage (cN), neoadjuvant chemoradiation, operation time, level of



Figure 2. A 28-French chest tube inserted into the condom 1 cm distal to the ring.

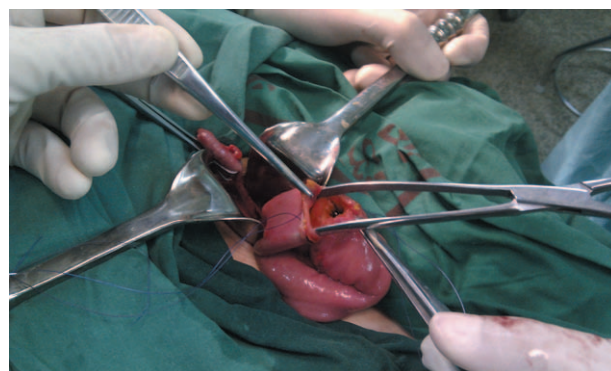


Figure 3. Transverse enterotomy at the antimesenteric border between 2 purse-string sutures.

anastomosis, pathological TNM (pTNM) stage, distal resection margin, time to first defecation through the anus postoperatively, and time to tube removal postoperatively, duration of the fistula at the TIB site to healing after the removal of the tube, postoperative complications, and total hospital stay. Complications were graded and reported using the Clavien–Dindo (CD) classification.^[19] Complications of grades I and II were defined as minor complications, and grades III and higher were defined as major complications. First defecation was defined as the first passage of a relative large volume of stool output, prior to the complete recovery of bowel movements over the following days. The total hospital stay in the LI group included the duration of the readmission for stoma closure. At our hospital, discharge from the department was performed when 3 conditions were fulfilled: normal body temperature for at least 24 h, normal leukocyte count, and no apparent surgical site infection. All of the patients were followed up for a minimum of 3 months.

2.6. Statistical analysis

The required sample size in each group was calculated using G*Power (Universitat Kiel, Kiel, Germany) software. Only the total hospital stay was used for power analysis because it was the only primary outcome measure that was predictable. For this purpose, the medical records of patients who had undergone LAR and conventional LI between January 2010 and May 2011 were reviewed. The total hospital stay for LI procedures was estimated

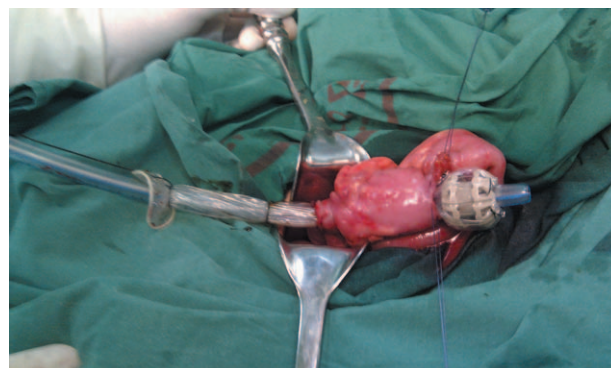


Figure 4. The distal end of tube inserted into the ileum and then pulled out through the ileocecal valve and guided outside the stump of the appendix.

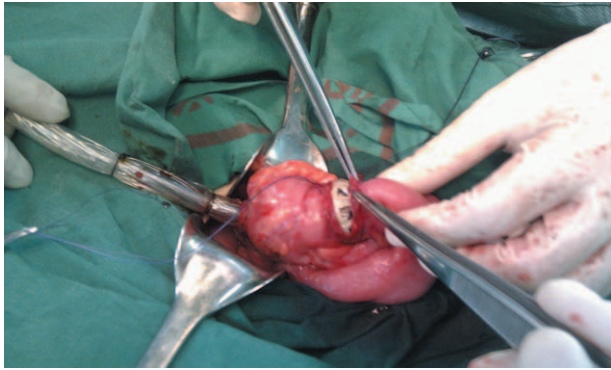


Figure 5. Advancement of the first edge of the bio-fragmentable anastomosis ring into the distal lumen of the ileum, and the purse-string suture was tied down. The second edge of the bowel ring advanced into the opposite lumen of the ileum, with its purse-string suture attached.

to be 36 ± 20 days. Among them, the mean hospital stay required to achieve LI closure was 12 days. Therefore, we assumed a 12-day decrease in total hospital stay for the TIB group, predicting a mean hospital stay for TIB of 24 days, with a clinically relevant difference of 10 days. A minimum sample size of 23 patients per group was estimated to obtain a power of 80% for detecting a difference at the 5% level.

The data were analyzed using SPSS (version 19.0; Chicago, IL). Continuous variables, such as age, hospital stay, and operative duration, were presented as the mean \pm SD, whereas categorical variables, such as gender and postoperative complications, were expressed as frequencies. Student *t* test was used to compare the means of the continuous variables, whereas categorical variables were compared using the Chi-squared test or Fisher exact test, as appropriate. *P* values ≤ 0.05 were considered significant.

3. Results

The demographic features of both (TIB and LI) groups are shown in Table 1. Approximately 25% of patients (11 in 43) with locally advanced rectal cancer received chemoradiation before surgery. The 2 groups were comparable in age, gender, primary comorbidities, level of tumor, cT, and cN. The main comorbidities were hypertension and diabetes.

As shown in Table 2, the mean surgical duration of the TIB group, which was approximately 45 min longer than that of



Figure 6. The onset of flow of discharge from the ileostomy.



Figure 7. Enterography through the ileostomy tube showing a complete diversion of the ileal content. The contrast material delineated the ileum proximal to BAR (arrow) and did not enter the distal ileum or colon.

simple laparoscopic LAR (data not shown), was significantly shorter than that of the LI group (215 ± 28 vs 245 ± 54 min, $P = 0.010$). Posterior pelvic exenteration, cholecystectomy, resection of liver metastases, and resection of infiltrated ureter were performed in 4 TIB patients, where 2 LI patients underwent appendectomies and 1 underwent cholecystectomy. The mean distance from the anastomosis to the anal verge was 4.5 ± 2.0 cm in the TIB group and 4.6 ± 1.9 cm in the LI group ($P = 0.846$). There were no significant differences between the groups with respect to pTNM stage and distal resection margin. The time to



Figure 8. Abdominal X-ray showed the bio-fragmentable anastomosis ring fragment (arrows) on 20th postoperative day.

Table 1**Demographic features.**

	TIB (31 patients)	LI (25 patients)	P
Sex, male/female	20/11	18/7	0.551
Age, y	66.4±12.2	62.6±9.9	0.215
Comorbidity (patients)	12	12	0.485
Level of tumor, cm	6.8±2.2	7.1±2.0	0.781
cT stage (1/2/3/4)	2/4/16/9	3/4/13/5	0.795*
cN stage (0≥1)	21/10	17/8	0.984
Neoadjuvant chemoradiation (patients)	5	6	0.690*

cN=clinical N stage, cT=clinical T stage, LI=loop ileostomy, TIB=tube ileostomy using a biofragmentable anastomosis ring.

* Fisher exact test.

first anal defecation postoperatively was 13.7 ± 2.1 (range, 10–19) days, indicating BAR loosening. The drainage tube was removed on postoperative day 27.8 ± 6.9 (range, 20–44), after which the mean duration of continued tract discharge before the fistula eventually healed, was 4.5 ± 1.9 (range, 2–10) days.

The rates of postoperative complications of the 2 modalities did not significantly differ. In the TIB group, 2 patients developed CD grade I complications: the tube was blocked by semisolid ileal content in 2 cases; however, these occurrences were easily managed by irrigation with saline. Grade II complications occurred in 3 patients: 1 developed anastomotic bleeding requiring a blood transfusion and hemostatics, and 2 developed a peristomal infection requiring antibiotics. One patient experienced a grade III complication: 1 rectovaginal fistula (RVF) occurred on the 30th postoperative day and was treated with transverse colostomy. She was initially discharged from the hospital on the 10th postoperative day and had her first anal defecation on day 14. She was readmitted to remove the tube and receive adjuvant chemotherapy on the 30th day, revealing the presence of obvious symptoms of RVF. In the LI group, 2 patients experienced CD grade I complications: 2 developed dermatitis requiring antihistamines. Grade II complications occurred in 3 patients: 1 developed anastomotic bleeding requiring a blood transfusion and hemostatics, 1 developed a deep vein thrombosis and was started on anticoagulation therapy, and 1 developed a peristomal infection requiring antibiotics. Three patients developed a grade III complication: 1 RVF occurred 3 months

Table 2**Comparison of the clinical outcomes.**

	TIB (31 patients)	LI (25 patients)	P
Operation duration, min	215±28	245±54	0.010
Conversion (patients)	0	3	0.166*
Level of anastomosis, cm	4.5±2.0	4.6±1.9	0.836
Distal resection margin, cm	2.2±1.6	2.0±2.1	0.537
pTNM stage (patients)			0.846*
I	2	3	
II	15	10	
III	11	10	
IV	3	2	
Complication (patients)			0.380*
Clavien–Dindo ≤2	5	5	
Clavien–Dindo ≥3	1	3	
Total hospital stay, d	19.1±7.9	38.1±26.5†	0.002

LI=loop ileostomy, pTNM stage=pathological TNM stage, TIB=tube ileostomy using a biofragmentable anastomosis ring.

* Fisher exact test.

† Total hospital stay in LI group includes that of the readmission for stoma closure.

poststomal closure and was treated with a transverse colostomy, 1 patient developed fascial dehiscence requiring suturing under local anesthesia, and 1 stoma prolapse occurred requiring intervention under general anesthesia. There was no perioperative mortality in this series.

Due to readmission for stoma closure, the length of the total hospital stay of the LI group was greater than that of the TIB group (38.1 ± 26.5 vs 19.1 ± 7.9 days, respectively, $P=0.002$). The median follow-up was 17 months (range 3–40) at which no bowel obstruction or anastomotic leakage at the BAR site was observed.

4. Discussion

A temporarily defunctioning stoma is effective at reducing symptomatic anastomotic leakage after an LAR, with TME, for rectal cancer.^[7,8] However, the presence of such a stoma and its subsequent closure are well associated with significant morbidity.^[11] Moreover, a series of prior studies showed that LAR with a temporary stoma negatively affected patients' quality of life, although this metric appeared to improve after the ileostomy's closure.^[14–16,18,20] Usually, the time between the formation and closure of the LI following LAR is approximately 12 weeks. It has been shown that adjuvant chemotherapy doubled stoma-related morbidity and delayed stoma closure greatly.^[21,22] Therefore, the stoma, a physical reminder of the cancer, affects patients' daily life for many months after the operation.

BAR is an absorbable intestinal anastomotic device that allows for serosal apposition under regulated circumstances, using interspersed pressure points that allow preservation of the blood supply, thus minimizing bowel necrosis and tissue damage. Once the bowel has healed, the BAR softens, fragments, and is passed imperceptibly in the stool after 2 to 3 weeks.^[23] Utilizing its fragmentable property, Valtrac has now been used in several studies to bypass and protect anastomotic sites.^[24] Chen et al^[25] designed an intracolonic bypass to consist of a BAR connected to a soft, thin vinyl tube in the colon, approximately 5 to 10 cm proximal to the anastomotic site. The distal end of the vinyl tube can be passed through the colonic anastomosis into the anus to allow bypassing of the fecal stream. In an animal model, this intracolonic bypass device has proven to be safe and reliable. Similar intracolonic bypasses have been widely used clinically by Ye et al,^[26] and have similarly proven to be safe, effective diversion techniques for protecting a low colorectal anastomosis. Stoma-related complications and readmissions for closure were avoided, and the procedure was associated with decreased total hospital stay and cost. Valtrac-secured intracolonic bypass, however, has several disadvantages. For this treatment, the patient is compelled to maintain a liquid diet to prevent the formation of hard stools. Moreover, frequent nursing care is required to irrigate the bypass. Apart from the discomfort imposed on the patient, proper stool collection from the condom protruding from the anus is also difficult.

Inspired by the studies mentioned above, we devised a new tube ileostomy using BAR to replace LI following LAR. Compared with routine LI, this tube ileostomy avoids the need for a secondary closure operation and for certain stoma-related complications, including dermatitis, retraction, and prolapse. The chances of tube blockage are less likely in this case, as the ileal contents are liquid. Therefore, irrigation of the tube is not necessary. Thus, the workload of the nursing staff is reduced, and the patient can be allowed a semisolid, rather than liquid diet. The anterior placement of the tube ileostomy does not affect the daily

activities of the patient, such as sitting or sleeping. Furthermore, the stool can be collected easily by connecting the tube to a drainage bag.

The use of tube ileostomy for bowel decompression has proven to be effective. The various tube techniques that have been reported in the literature mostly involve the meconium ileus, bowel atresia, and typhoid ileal perforation in pediatric surgery.^[27–29] Although the luminal segment of tube ileostomy cases using BAR is different from previous techniques, all such uses of tube ileostomy share certain common methods regarding tube stabilization in the bowel and fixation to the abdominal wall. Still, internal hernia, the most serious complication of a tube ileostomy or LI, may be theoretically inevitable. Furthermore, to avoid the obstruction of the tube with ileal content, a large-bore chest tube may be used, making the Witzel tunnel unavailable. Entry site into the ileum is directly tacked to the anterior abdominal wall, increasing the chance of succus leakage into the abdomen, delaying the healing of the ileostomy after the removal of the tube. To overcome the disadvantages mentioned above, we improved the traditional tube ileostomy procedure by inventing the TIB. Briefly, we altered the entry site of the tube from the ileum to the stump of the appendix to avoid any internal hernia caused by tacking the ileum to the abdominal wall. Second, a Witzel tunnel was constructed to completely cover the entry site into the cecum and the tube for approximately 3 cm, based on the larger diameter of the cecum. The mean duration of the fistula at the TIB site before complete healing was 4.5 days for the TIB group, thus indicating that TIB is a safe procedure.

In the present study, the mean surgical duration of the TIB group was significantly shorter than that of the LI group. In our view, this finding may be attributed largely to the proficiency of the surgical team, indicating that the surgeon's learning curve is critical to the outcomes of patients undergoing laparoscopic LAR. Because of readmission for stoma closure, the mean length of the total hospital stay for the LI group doubled that of the TIB group, which confirmed the substantial advantage of TIB over LI.

The severity of anastomotic leakage was graded according to the impact on clinical management, with Grade A anastomotic leakage resulting in no change in patients management; Grade B leakage requiring active therapeutic (but manageable) intervention, without re-laparotomy; and Grade C anastomotic leakage requiring re-laparotomy.^[30] Two main aims of traditional protective ileostomy are to reduce symptomatic anastomotic leakage (Grades B and C anastomotic leakage) and to treat anastomotic leakage in order to prevent re-intervention thereafter. Due to the limited diversion time of our technique (approximately 2 weeks), anastomotic leakage treatment was not achievable. Therefore, the overall objective of the present study was to design a feasible and less-invasive diversion technique to reduce symptomatic anastomotic leakage after LAR. The previous study also showed that 60% of anastomotic leakages after LAR were diagnosed during the initial hospital stay, which occurred on median day 8 (range, 3–18 days). The remaining 40% of patients were initially discharged from the hospital and had their leakage diagnosed upon readmission during a second hospital stay on median day 24 (range, 13–172 days).^[7] Therefore, TIB may be an effective method for preventing the early onset of anastomotic leakage after LAR. In the present study, 1 patient with RVF in the TIB group was readmitted to remove the tube and receive adjuvant chemotherapy on the 30th day. After removal of the tube, the obvious RVF

symptoms were present. It has been reported that the RVF rate after LAR for rectal cancer was 3%,^[31] which is similar to that of this series. The RVF was diagnosed on median postoperative day 83. In 81.8% of the patients, the diagnosis of RVF was made after hospital discharge.^[31] Therefore, RVF is a typical late onset anastomotic leakage, which could not be prevented by TIB. To provide a longer protection time, the BAR anastomotic gap and fragment time must be adjusted to prolong the fecal diversion of TIB; this possibility is also under investigation by our team.

In this series, only approximately 25% of patients (11 in 43) with locally advanced rectal cancer received chemoradiation before surgery. High cost and low patient compliance account for the low neoadjuvant therapy rate for rectal cancer in China, but this has been improving with time. In the present study, the mean hospital stay was much longer than those previously reported in western countries,^[7] due to the requirement of Chinese surgeons to ensure that there were no complications or necessary treatment (if any) prior to discharge, thus reducing readmission rates. At the beginning of the study, we usually observed the patients more than 2 weeks after surgery. However, with the mounting success of the TIB procedure, more patients were discharged shortly after 1 week postsurgically.

To our knowledge, this is the first study to report the clinical application of new tube ileostomy using BAR. The TIB procedure is a safe, feasible, effective, but time-limited diverting technique for protecting an anastomosis after LAR. In contrast to LI, the use of TIB avoids stoma-related complications, thus requiring no readmission for closure. However, this is merely a pilot study showing preliminary TIB results. Further prospective, randomized, and controlled trials with larger samples are required to support the clinical application of TIB to reduce symptomatic anastomotic leakage in low rectal anastomosis and other high-risk colonic anastomosis.

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