



Transcecum catheterization ileostomy is safe and effective to prevent anastomotic leakage in post-laparoscopic rectal cancer surgery: a single-center retrospective study

Hao Sun^{1#}, Yongpeng He^{1#}, Xiaohua Li^{2#}, Zhixiong Chen¹, Maocai Tang¹, Jingkun Shang¹, Wang Huang¹, Shuaiqi Wang^{1^}

¹Chongqing Key Laboratory of Translational Research for Cancer Metastasis and Individualized Treatment, Chongqing University Cancer Hospital & Chongqing Cancer Institute, Chongqing, China; ²Department of Respiratory and Critical Care Medicine, Sixth People's Hospital of Chengdu, Chengdu, China

Contributions: (I) Conception and design: S Wang, H Sun; (II) Administrative support: H Sun; (III) Provision of study materials or patients: S Wang, Y He; (IV) Collection and assembly of data: S Wang, Y He; (V) Data analysis and interpretation: X Li; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Shuaiqi Wang. Deputy chief surgeon, Chongqing Key Laboratory of Translational Research for Cancer Metastasis and Individualized Treatment, Chongqing University Cancer Hospital & Chongqing Cancer Institute, 181 Hanyu Road, Shapingba District, Chongqing 400030, China. Email: 19830325@163.com.

Background: Preventive ileostomy (PI) is conventionally performed to prevent anastomotic leakage (AL) after laparoscopic total mesorectal excision (LTME) for low rectal cancer; however, secondary surgery is required to remove the ostomy tube. We designed a new type of ostomy, transcecum catheterization ileostomy (TCI) to prevent AL. Its principle is similar to PI, but no secondary operation is needed. We evaluated the safety and efficacy of TCI in AL prevention.

Methods: We analyzed the data of patients who underwent LTME with low anastomosis in Chongqing University Cancer Hospital from October 2015 to August 2021. Patients were divided into three groups according to their choice: those who underwent TCI (TCI group), those who underwent PI (PI group), and those who undergo none (C group). Intra-operation situation, postoperative efficacy and safety indicators were compared between three groups.

Results: Out of the total 534 patients included, 171 underwent TCI, 156 underwent PI, and 207 underwent none. No statistically difference was noted in baseline characteristics between three groups (all $P > 0.05$). Operation time was longer in TCI group and PI group than in C group ($P < 0.001$). No difference was noted in intraoperative blood loss or the number of lymph nodes dissected ($P = 0.685$ and $P = 0.153$). Moreover, no difference was noted in the serum levels of immune cells on postoperative day 1, 3, and 7 (all $P > 0.05$) or in the levels of serum C-reactive protein (CRP), procalcitonin (PCT), and interleukin 6 (IL-6; all $P > 0.05$). No difference was noted in postoperative incision, pulmonary infection rates and intestinal obstruction incidence ($P = 0.530$, $P = 0.971$, and $P = 0.938$). AL incidence and AL-related reoperation rates were lower in TCI or PI group ($P = 0.002$ and $P < 0.001$). The rate of anastomotic stricture was lower in TCI group than in the other two groups ($P < 0.001$).

Conclusions: TCI is effective to prevent AL when performed during LTME. But TCI cannot completely avoid AL. When AL occurs, TCI can reduce the degree of abdominal infection and the secondary surgical rate related AL. TCI presents an alternative option to PI, that does not require secondary operation. Therefore, TCI is safe and worthy of application.

[^] ORCID: 0000-0003-4072-6386.

Keywords: Transcecum catheterization ileostomy (TCI); low rectal cancer; laparoscopic total mesorectal excision (LTME); anastomotic leakage (AL)

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Introduction

Total mesorectal excision (TME) is a major treatment modality in patients with rectal cancer. Due to developments in surgical technology, surgical equipment, and preoperative neoadjuvant chemoradiotherapy, the rate of anus-preserving radical rectal cancer resection surgery has increased. However, the incidence of postoperative anastomotic leakage (AL) has also significantly increased (1). Presently, preventive loop ileostomy or loop colostomy is performed during surgery. The transfer of proximal intestinal content reduces the intraluminal intestinal pressure in the anastomosed segment. The anastomosed segment heals under conditions of low perfusion, low load, and low bacterial abundance (2). Preventive fistulas can reduce the incidence of AL, AL-related reoperation rate, and mortality (3,4). Although ileostomy and colostomy have advantages (4), both procedures increase the risk of complications such as fistula, prolapse, retraction, and bleeding. The difficulties in ostomy-related postoperative patient care affect the quality of life of patients. During follow-up, patients with ostomy tubes require another surgical procedure for ostomy tube removal, and this procedure is painful and costly. Based on the above considerations, we designed transcecum catheterization ileostomy (TCI) and optimized its procedure. We introduced it into LTME as an auxiliary procedure to work as ileostomy. Its principle to prevent AL is similar to that of ileostomy, which creates conditions for the healing of anastomotic intestines by effectively transferring the contents of ileum. The theoretical basis of the design is described in the following discussion. Compared with ileostomy, the main advantage of TCI is that it needs no surgical procedure for ostomy tube removal. TCI turbs can be removed from the patients in surgical dressing room without anesthesia.

We performed TCI during laparoscopic TME for low rectal cancer. We predicted TCI may be a choice procedure that can replace ileostomy. We aimed to investigate the efficacy, safety, and feasibility of TCI in preventing AL after low rectal cancer resection surgery. We present the following article in accordance with the STROBE reporting

checklist (available at <https://jgo.amegroups.com/article/view/10.21037/jgo-22-745/rc>).

Methods

Eligibility criteria

We screened patients with low rectal cancer who underwent laparoscopic TME with low anastomosis in Chongqing University Cancer Hospital from October 2015 to August 2021. The inclusion criteria were as follows: patients (I) with pathologically confirmed stage I–III low rectal cancer; (II) who underwent complete low anastomosis during laparoscopic TME; (III) with no serious major organ dysfunction, an American Society of Anesthesiologists (ASA) grade of ≤ 3 , and who were evaluated to be able to withstand surgery; (IV) who received preoperative neoadjuvant chemoradiotherapy (stage III), were in good physical condition, and needed to undergo surgery 8 weeks after chemoradiotherapy; (V) who could take compound polyethylene glycol electrolyte orally before surgery; and (VI) who were compliant and gave their informed consent. We excluded patients with the following criteria: (I) stage IV rectal cancer; (II) postoperative rectal cancer recurrence or a history of other tumors; (III) complete intestinal obstruction or perforation; (IV) immune system diseases; (V) serious chronic diseases; (VI) ASA grade of ≥ 4 ; and (VII) inability to undergo laparoscopic surgery for other reasons. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics committee of Chongqing University Cancer Hospital (No. 2017-Ethics Review-110). Individual consent for this retrospective analysis was waived. To choose TCI and PI for comparison mainly based on the following reasons: (I) TCI and PI are performed on distal ileum, their principles are similar and comparable; (II) Ileum walls can heal quickly after TCI or ostomy tube removal due to the good blood supply of ileum in most cases. We informed patients of the risk of AL due to low anastomosis in rectal cancer. The purpose and advantages of TCI and PI were introduced to the patients. We particularly emphasized that

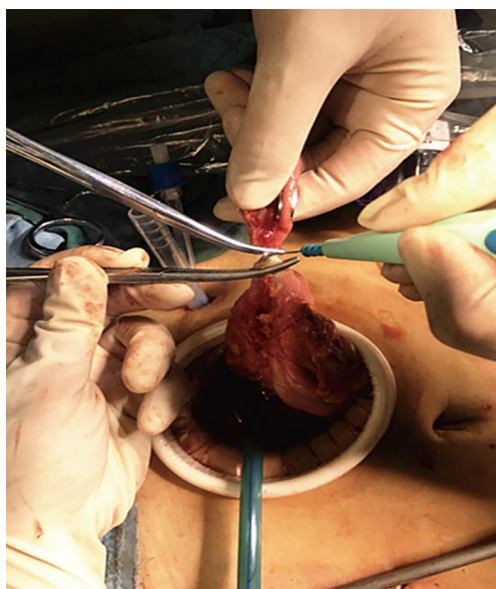


Figure 1 The appendiceal root was clamped and removed.

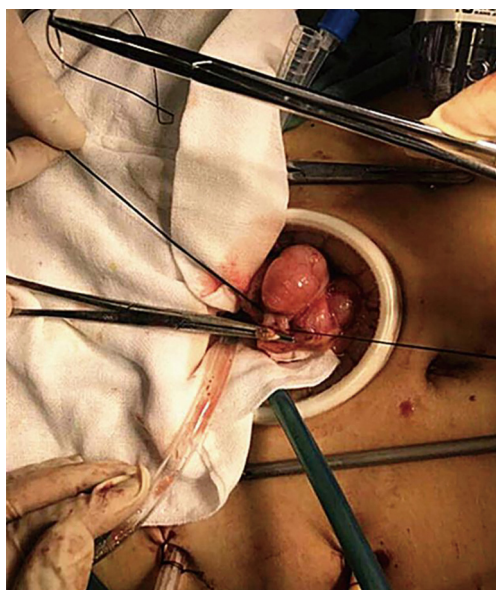


Figure 2 The appendiceal stump was sutured using a double-load package.

TCI was a new ostomy technique, and its effectiveness and safety need to be confirmed. According to the choices of patients, they were divided into a TCI group (those who underwent TCI), a preventive ileostomy (PI) group (those who underwent PI), and a control group (those with no preventive ostomy).

Therapeutic method

Surgical procedure

Laparoscopic TME was performed using the following procedure. First, during TME, full attention was paid to anastomotic blood supply preservation, and blood vessels were bared from the root of the inferior mesenteric artery where lymph node dissection starts. However, during blood vessel ligation, the left colic artery was retained as much as possible. Indocyanine green fluorescence was used to display the anastomotic blood supply. Second, the bowel was sufficiently freed to avoid bowel tension increase after anastomosis. If necessary, the splenic flexure of the colon was freed to allow the anastomotic tube to lie loosely in the pelvic floor.

Third, a right lower abdominal rectus abdominis incision was performed approximately 4–5 cm from the main operating hole (McBurney's point) of the master surgeon. The incision protective sleeve was placed. This incision was made in the TCI group to remove specimens and carry out TCI. The main operation hole of the master surgeon was used as the fistula orifice of the abdominal wall. An incision that is too close to the fistula orifice predisposes the patient to surgical site infection. However, an incision that is too far from the fistula orifice renders cecum and abdominal wall suturing difficult, which affects the adhesion between the cecum wall and the wall peritoneum. We considered and used 4–5 cm as an appropriate distance between the incision and the fistula orifice. Pneumoperitoneum was reconstructed with rubber glove cover after specimen resection, and low anastomosis was completed under laparoscopy. For the control group, we removed specimens via lower abdominal or left lower abdominal incisions because there was no fistula. Fourth, after low anastomosis was completely performed, patients in the TCI group underwent TCI. The cecum was properly dissociated to increase cecal activity. Tissue forceps were used to clamp the appendiceal root, and the appendix was removed (*Figure 1*). The ileocecal three-chamber single-cystic ileostomy tube (the invented patent applied by the research group; in the absence of such a device, a No. 26 hydrophilic urinary catheter was used) was introduced into the abdominal cavity via the main operating hole of the main surgeon. The appendiceal stump was sutured using a double-load package (*Figure 2*). The tip of the ileostomy tube was sent to the terminal ileum approximately 20 cm from the ileocecal through the ileocecal valve, and the double-load package was tightened (*Figures 3,4*). This procedure

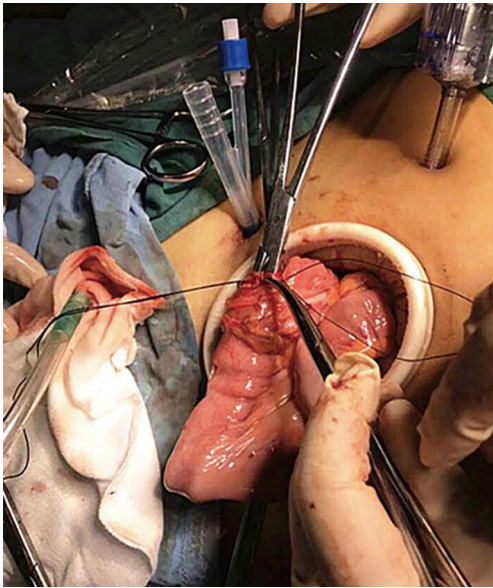


Figure 3 The TCI tube was sent to the terminal ileum through the ileocecal valve. TCI, transcecum catheterization ileostomy.

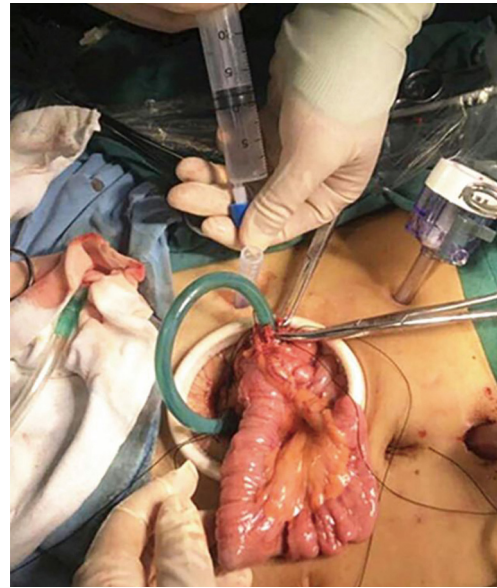


Figure 5 Saline was injected to fill the water sac such that the TCI tube fully filled the intestinal cavity. TCI, transcecum catheterization ileostomy.

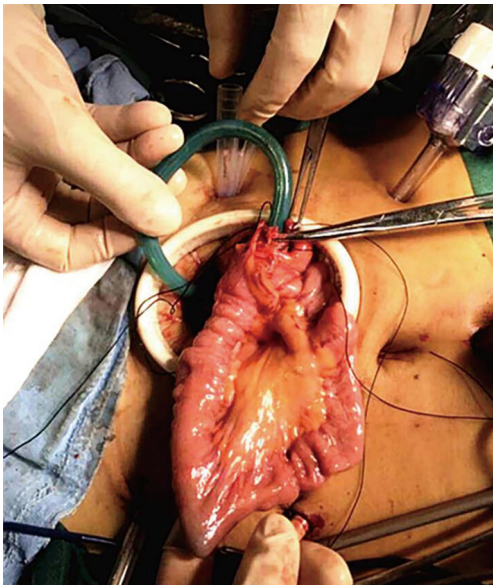


Figure 4 The double-load package was tightened.

was performed using small oval forceps lubricated by liquid paraffin; the forceps were passed through and used to gently expand the ileocecal valve to guide the tube tip through. The abovementioned procedure was performed to prevent blind tube insertion from causing intestinal mucosa and ileocecal valve injury. Based on

the size of the ileal cavity, 15–20 mL saline was injected to fill the water sac of the tube such that the tube fully filled the intestinal cavity (*Figure 5*). A loop was sutured with absorbable suture in the distal mesenteric avascular area of the water sac (diameter larger than the ileum and smaller than the water sac) to prevent the tube from sliding (*Figure 6*). The surgeon confirmed the absence of ischemia caused by excessive compression of the water sac or excessive tightening of the ring in the ileum. After completing the double-packed suture on the abdominal wall to bring the appendiceal opening close to the parietal peritoneum (*Figure 7*), which could effectively prevent postoperative intestinal content leakage, the abdominal cavity was washed repeatedly. Next, the presacral drainage tube was placed, the incision and the trocar holes were closed by suturing, the ostomy tube was fixed, and the fistula surgery was ended (*Figure 8*). Lastly, before the end of the surgery, the reliability of the anastomosis was evaluated as follows: (I) after the stapler was removed, the tissue of the anastomosis ring was confirmed to be intact; (II) intraoperative colonoscopy was used to confirm the absence of bleeding in the anastomotic mucosa, and the anastomotic nail was evenly distributed in the intestinal cavity of the anastomosis; (III) the absence of tension in the anastomosed intestine was confirmed by relaxation in the presacral; (IV) the absence of torsion in the mesentery was

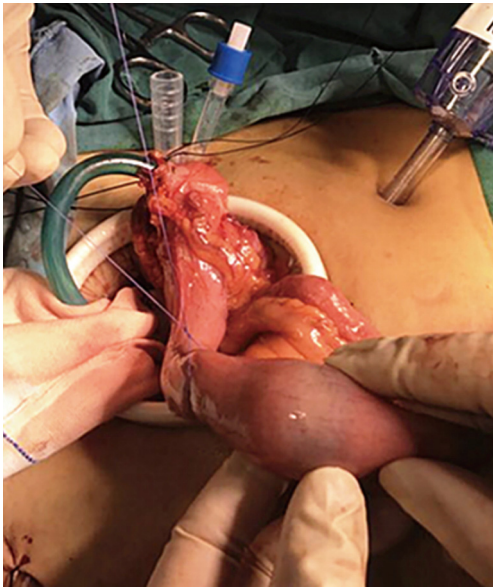


Figure 6 A loop was sutured in the distal mesenteric avascular area of the water sac to prevent the tube from sliding.



Figure 8 TCI tube was fixed. TCI, transcecum catheterization ileostomy.

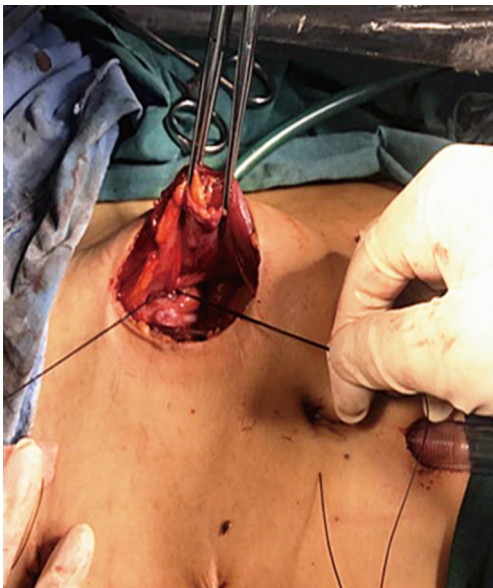


Figure 7 The double-packed was sutured on the abdominal wall to bring the appendiceal opening close to the parietal peritoneum.

confirmed; (V) indocyanine green fluorescence was used to confirm a good blood supply to the anastomosed intestine; (VI) a presacral drainage tube was placed, and the drainage was confirmed to be smooth without direct contact with the anastomosis (5). The abovementioned techniques were used to eliminate local risk factors of AL.

Postoperative nursing and fistula tube removal

During postoperative care, the fistula and drainage tubes were carefully observed to ensure that they were in place unobstructed. Furthermore, it was ensured that the small intestinal content was effectively diverted through the fistula tube to the fistula bag, and pelvic effusion was effectively drained by the presacral drainage tube. If the intestinal contents were sticky, the fistula tube was rinsed with sterile saline to restore patency or to avoid clogging the tube (*Figure 9*). A previous study has found that abdominal adhesions are formed and tend to stabilize within 7 and 14 days after surgery, respectively (6). Therefore, the fistula tube was removed 14 days after surgery when patient was in stable conditions with good incision healing and normal auxiliary examination indexes. The water in the water sac of the fistula tube was pumped out, and the tube was pulled out by removing the fixed sutures (*Figure 10*). The pores left by extubation were packed with Vaseline gauze, wrapped with sterile gauze, and disinfected regularly; these pores healed approximately 7–10 days later.

Data collection

Clinical data were collected from patients, hospitalized cases, and examination reports. We compared and analyzed baseline characteristics, Intraoperative situation, postoperative immune function, postoperative inflammatory factors,



Figure 9 The TCI tube was rinsed to restore patency or to avoid clogging the tube. TCI, transcecum catheterization ileostomy.

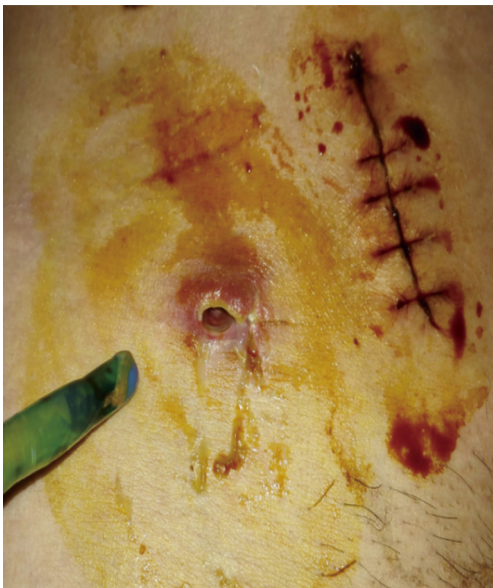


Figure 10 The water in the sac of the tube was pumped out, and the tube was pulled out by removing the fixed sutures.

postoperative recovery, and postoperative complications between patients in the TCI and control groups.

Statistical analysis

Data were analyzed using SPSS 19.0 (IBM Corp., Armonk,

NY, USA). Measurement data are presented as mean \pm standard deviation. The count data were compared using the analysis of variance and the χ^2 test. Between and within subjects, Post-hoc tests were conducted using LSD or Tukey test. A value of $P < 0.05$ was considered to be statistically significant.

Results

During the study period, 534 patients with low rectal cancer underwent laparoscopic TME in our center. One hundred and seventy-one patients underwent TCI (TCI group) during surgery, including 99 men and 72 women, with a mean age of 53.5 ± 10.05 years. TNM staging of the TCI group patients revealed 27, 66, and 78 patients in stages I, II, and III, respectively. Among these patients, 60 underwent preoperative neoadjuvant therapy.

A total of 156 patients underwent PI (PI group) during surgery, including 84 men and 72 women, with a mean age of 52.9 ± 9.8 years. TNM staging of the TCI group patients revealed 27, 60, and 69 patients in stages I, II, and III, respectively. Among these patients, 60 underwent preoperative neoadjuvant therapy. A total of 207 patients were classified as the control group, including 123 men and 84 women, with an average age of 53.7 ± 9.1 years. TNM staging of the patients in the control group revealed 36, 81, and 90 patients in stages I, II, and III, respectively. Among these patients, 69 received preoperative neoadjuvant therapy. The comparison of patient baseline characteristics between the three groups showed no significant differences in age, sex, body mass index, TNM stage, or ASA grade. There was no statistically significant between-group difference in the proportion of patients who received preoperative neoadjuvant therapy (all $P > 0.05$; *Table 1*). The comparison of intraoperative situation between the three groups is shown in *Table 2*. The operation time in the TCI group and the PI group was significantly longer than that in the control group (186.39 ± 62.04 vs. 180.23 ± 57.65 vs. 137.82 ± 44.45 , respectively; $P = 0.000$). There was no significant difference in intraoperative blood loss between the three groups (112.26 ± 30.12 vs. 109.45 ± 28.11 vs. 110.48 ± 30.51 ; $P = 0.685$). There was no significant difference in the number of lymph nodes dissected between the three groups (14.17 ± 2.66 vs. 13.97 ± 2.46 vs. 14.50 ± 2.75 ; $P = 0.153$).

The level of serum CD3⁺ T cell%, CD4⁺ T cell%, CD8⁺ T cell%, CD4⁺/CD8⁺ and NK cell% levels in patients were normal in all groups (*Table 3*). The levels of CD3⁺ T cell%, CD4⁺ T cell% and CD4⁺/CD8⁺ in the three groups were

Table 1 Baseline characteristics of patients in the TCI, PI, and control groups

Baseline characteristics	TCI group (n=171)	PI group (n=156)	C group (n=207)	χ^2/F	P value
Age (years)	53.5±10.05	52.9±9.8	53.7±9.1	0.321	0.726
Gender				1.166	0.558
Male	99 (57.9)	84 (53.8)	123 (59.4)		
Female	72 (42.1)	72 (46.2)	84 (40.6)		
BMI (kg/m ²)	22.3±2.44	21.9±2.53	22.2±2.46	1.151	0.317
Clinical TNM stage				0.279	0.991
Stage I	27 (15.8)	27 (17.3)	36 (17.4)		
Stage II	66 (38.6)	60 (38.5)	81 (39.1)		
Stage III	78 (45.6)	69 (44.2)	90 (43.5)		
ASA score				2.527	0.640
1	36 (21.1)	33 (21.2)	48 (23.2)		
2	111 (64.9)	99 (63.5)	138 (66.7)		
3	24 (14.0)	24 (15.4)	21 (10.1)		
Preoperative neoadjuvant therapy	60 (35.1)	60 (38.5)	69 (33.3)	1.033	0.596

Count data (gender, clinical TNM stage, ASA score, preoperative neoadjuvant therapy) are presented as n (%); measurement data (age, BMI) are presented as mean values ± standard deviations. TCI, transcecum catheterization ileostomy; PI, preventive ileostomy; C, control; BMI, body mass index; ASA, American Society of Anesthesiologists.

Table 2 Intraoperative situation in the TCI, PI, and control groups

Intraoperative situation	TCI group (n=171)	PI group (n=156)	C group (n=207)	F	P value
Operation time (min)	186.39±62.04	180.23±57.65	137.82±44.45	44.972	0.000
Intraoperative blood loss (mL)	112.26±30.12	109.45±28.11	110.48±30.51	0.379	0.685
Lymph nodes dissected	14.17±2.66	13.97±2.46	14.50±2.75	1.881	0.153

Data of intraoperative situation are presented as mean values ± standard deviations. TCI, transcecum catheterization ileostomy; PI, preventive ileostomy; C, control.

significantly decreased on postoperative day 1. The levels of CD3⁺ T cell, CD4⁺ T cell% and CD4⁺/CD8⁺ in the three groups began rising on postoperative day 3, and thereafter increased on postoperative day 7, although the value remained lower than the normal value. NK cell% levels began to increase on postoperative day 1 and maintained higher than normal levels on postoperative day 3 and day 7. There was no significant difference in the preoperative or the postoperative day 1, 3, and 7 serum CD3⁺ T cell%, CD4⁺ T cell%, CD8⁺ T cell%, CD4⁺/CD8⁺ and NK cell% levels between the three groups (all P>0.05).

The preoperative serum C-reactive protein (CRP), procalcitonin (PCT), and interleukin 6 (IL-6) levels were

normal in patients in all groups (*Table 4*). The levels of CRP, PCT, and IL-6 in the three groups were significantly increased on postoperative day 1. CRP levels gradually decreased on postoperative days 3 and 7; however, the values remained higher than the normal value. PCT levels began rising on postoperative day 3, and thereafter decreased on postoperative day 7, although the value remained higher than the normal value. IL-6 levels decreased on postoperative day 3 and then decreased towards preoperative levels on postoperative day 7. There was no significant difference in the preoperative or the postoperative day 1, 3, and 7 serum CRP, PCT, and IL-6 levels between the three groups (all P>0.05).

Table 3 Perioperative immunity indicators in the TCI, PI, and control groups

Immunity indicators	TCI group (n=171)	PI group (n=156)	C group (n=207)	F	P value
CD3 ⁺ T cell%					
Baseline	70.47±7.57	68.89±7.05	69.95±7.29	1.969	0.140
1st day	39.93±2.82	40.76±2.82	40.27±4.17	2.433	0.089
3rd day	58.67±4.44	57.93±4.44	58.64±4.55	1.409	0.245
7th day	68.44±8.75	69.01±8.75	68.91±8.27	0.224	0.799
CD4 ⁺ T cell%					
Baseline	37.63±6.76	38.11±6.76	37.68±6.76	0.246	0.782
1st day	22.02±1.71	22.00±1.71	22.16±2.06	0.395	0.674
3rd day	26.40±2.16	26.51±2.16	26.34±1.99	0.281	0.755
7th day	30.39±3.00	30.46±3.00	30.42±3.02	0.023	0.977
CD8 ⁺ T cell%					
Baseline	27.80±3.16	28.33±3.16	27.80±3.20	1.468	0.231
1st day	27.43±9.04	26.99±9.04	27.47±9.03	0.148	0.863
3rd day	26.24±8.60	25.97±8.60	26.22±8.65	0.052	0.950
7th day	23.00±11.02	22.57±11.02	22.84±10.88	0.065	0.937
CD4 ⁺ /CD8 ⁺					
Baseline	0.86±0.52	0.87±0.52	0.85±0.52	0.067	0.935
1st day	0.76±0.36	0.79±0.35	0.76±0.36	0.390	0.677
3rd day	0.85±0.40	0.86±0.40	0.85±0.40	0.035	0.966
7th day	0.83±0.50	0.82±0.50	0.83±0.50	0.022	0.978
NK cell%					
Baseline	11.67±7.25	11.65±7.25	11.62±7.21	0.002	0.998
1st day	14.40±1.47	14.52±1.47	14.38±1.47	0.443	0.642
3rd day	15.16±1.77	15.22±1.77	15.13±1.69	0.120	0.887
7th day	15.34±1.99	15.42±1.99	15.35±1.88	0.084	0.920

Data of serum immune cell level are presented as mean values ± standard deviations. TCI, transcecum catheterization ileostomy; PI, preventive ileostomy; C, control; CD, cluster of differentiation; NK, natural killer.

Time to first feeding and first flatus of patients in the TCI and PI groups was shorter than that of patients in the control group (TCI *vs.* C: $P=0.000$; PI *vs.* C: $P=0.000$, *Table 5*). Time to first postoperative bowel movement was significantly longer in the TCI and PI groups than in the control group ($P<0.001$). There was no significant between-group difference in the occurrence rate of postoperative incision infection ($P=0.530$). Similarly, there was no significant between-group difference in the incidence of intestinal obstruction or pulmonary infection ($P=0.938$ and $P=0.971$). Although AL occurred in all three groups, its

incidence was significantly lower in the TCI and PI groups than in the control group ($P=0.002$). Six patients in the TCI group and 6 patients in the PI group successfully underwent conservative treatment, instead of surgery, for AL. Of the 24 patients with AL in the control group, 21 underwent secondary surgery due to peritonitis. Therefore, the rate of secondary surgery related to AL was significantly lower in the TCI and PI groups than in the control group ($P<0.001$). Anastomotic stricture occurred in all three groups, but its incidence was significantly lower in the TCI group than in the PI group or the control group ($P<0.001$).

Table 4 Perioperative inflammatory cytokines in the TCI, PI, and control groups

Inflammatory cytokines	TCI group (n=171)	PI group (n=156)	C group (n=207)	F	P value
CRP (mg/L)					
Baseline	4.62±0.63	4.65±0.63	4.59±0.60	0.438	0.646
1st day	48.30±4.93	47.31±4.93	48.37±5.01	2.329	0.098
3rd day	35.99±5.21	36.12±5.21	35.80±4.98	0.184	0.832
7th day	20.50±6.23	21.02±6.23	20.47±6.22	0.421	0.657
PCT (ng/mL)					
Baseline	0.07±0.04	0.08±0.04	0.07±0.05	2.833	0.060
1st day	2.95±0.83	2.89±0.83	2.96±0.80	0.366	0.694
3rd day	2.98±0.74	3.02±0.74	2.97±0.72	0.231	0.794
7th day	2.44±0.81	2.43±0.81	2.44±0.83	0.008	0.992
IL-6 (ng/L)					
Baseline	15.36±2.28	15.47±2.28	15.38±2.27	0.111	0.895
1st day	50.48±5.34	51.01±5.34	50.42±5.46	0.623	0.537
3rd day	39.10±4.19	40.02±4.19	39.09±4.13	2.716	0.067
7th day	17.28±3.29	16.97±3.29	17.22±3.24	0.423	0.656

Data of inflammatory cytokines level are presented as mean values ± standard deviations. TCI, transcecum catheterization ileostomy; PI, preventive ileostomy; C, control; CRP, C-reactive protein; PCT, procalcitonin; IL-6, interleukin 6.

Table 5 Data of postoperative recovery conditions and main complications in the three groups

Recovery conditions	TCI group (n=171)	PI group (n=156)	C group (n=207)	χ^2/t	P value
Time to first feeding (d)	1.95±0.38	2.07±0.41	3.75±0.45	1,110.57	0.000
Time to first flatus (d)	3.08±0.45	3.17±0.42	3.57±0.57	53.629	0.000
Time to first bowel movement (d)	5.37±0.77	5.23±0.62	4.14±0.64	187.785	0.000
Main complications, n (%)					
Intestinal obstruction	3 (1.8)	3 (1.9)	3 (1.4)	0.128	0.938
Wound infection	12 (7.2)	9 (5.8)	9 (4.3)	1.268	0.530
Pulmonary infection	9 (5.3)	9 (5.8)	12 (5.8)	0.060	0.971
Anastomotic leakage	6 (3.5)	6 (3.8)	24 (14.5)	12.676	0.002
Secondary surgical rate	0 (0.00)	0 (0.00)	21 (87.5)	25.200	0.000
Anastomotic stricture rate	3 (1.8)	15 (9.6)	27 (13.0)	15.868	0.000

Data of recovery conditions are presented as mean values ± standard deviations; data of main complications are presented as n (%). TCI, transcecum catheterization ileostomy; PI, preventive ileostomy; C, control.

Discussion

With the rapid development of minimally invasive surgical technology and the need to preserve patient quality of life, the treatment concept of low rectal cancer has gradually changed

from the Miles operation, which involved simple radical cancer excision, to radical excision with anal preservation. Laparoscopic TME combined with low anastomosis has progressively become an important treatment choice for

patients with low rectal cancer (6). However, as low anal sphincter preservation surgery has become more common, postoperative AL occurrence has become an increasingly significant challenge. The incidence of postoperative AL increases with the distance between the anastomotic stoma and the anal margin (7). A previous study reported that the incidence of AL after anus-preserving surgery for low rectal cancer is approximately 10–20% (8). Once AL occurs, the probability of secondary surgery is high. Some patients are obliged to accept permanent ostomy, which affects their quality of life. Moreover, secondary surgery increases medical costs (9), hospital stay, postoperative mortality risk, and anastomotic recurrence (10).

The increased incidence of AL after sphincter-preserving surgery for low rectal cancer is caused by many factors, among which high anastomotic pressure is one of the most important (11). For example, the lack of preoperative bowel preparation increases the volume of intestinal contents and intestinal pressure. In addition, improper anastomotic operation might increase the risk of anastomotic tension, incomplete anastomosis, poor anastomotic stoma vascularization, and poor postoperative drainage, leading to local infection. Other causes of increased AL include poor nutritional status and hypoproteinemia (12). The treatment effect of chronic diseases is poor, such as poor glycemic control in diabetic patients and ineffective improvement of pulmonary function in COPD patients. To reduce the influence of other factors on our test results, we formulated inclusion and exclusion criteria with requirements for experimental group based on the abovementioned factors.

Preventive ostomy is a measure for reducing anastomotic pressure. Conventional mainstream techniques for reducing anastomotic pressure include ileostomy or colostomy. These techniques function by diverting intestinal contents to the ostomy bag, which reduces intestinal pressure in the anastomosed segment; thus, the anastomosed segment heals under conditions of low perfusion, low load, and low bacterial abundance. Most studies in China and abroad have shown that intraoperative prophylactic stoma creation can effectively reduce the incidence of postoperative AL (13,14). Although AL can occur in patients after preventive ostomy, the severity of related complications, mortality risk, and reoperation rate are significantly reduced in these patients (14).

Although the efficacy of preventive ostomy has been recognized, its shortcomings are obvious. Patients with preventive ostomy tubes require another procedure for fistula closure, which increases perioperative complication risk, pain, and cost. Prior to fistula closure, patient quality

of life is affected, as patients must care for the stoma and change the stoma bag when necessary. Some of these patients experience stoma bleeding, prolapse, contracture, parastomal hernia, and other stoma-related complications, resulting in a serious psychological burden.

TCI, a new surgical technique, can be used to avoid the abovementioned inconveniences and complications. This new type of ostomy has the following theoretical basis. First, appendectomy is a well-established operation (15). A previous study has confirmed that appendectomy has no obvious effect on adult physiological function (16). Second, through the opening of the appendix, the tube is placed at the end of the ileum. Based on the size of the ileal lumen, the amount of water injected into the water sac can be controlled. The water sac can fully fit within the intestinal cavity, and the intestinal contents in the distal intestinal cavity can be blocked and diverted to a great extent, leading to a good ileostomy effect. Third, it is difficult for the tube to slide and shift due to the fixation of an absorbable loop smaller than the water sac. Moreover, the ileocecal valve has a good contractility. Lastly, the possibility of appendicitis occurrence after colostomy is eliminated.

In this study, all surgeries were performed by senior gastrointestinal surgeons with experience in TCI and PI surgery. Therefore, there was no significant between-group difference in the amount of intraoperative blood loss or the number of lymph nodes dissected. This indicates that TCI will not affect the risk of bleeding or the outcome of radical surgery. The operation time of the patients in the TCI and PI groups was longer than that of the patients in the control group, as some surgical steps were added during TCI or PI. However, it was easy for the trained surgeons to maintain the operation time within 40 minutes. TCI time can be effectively shortened by freeing the mesocecum to increase cecal activity.

LTME is a traumatic procedure that affects immune function. The degree of trauma is related to changes in the levels of lymphocytes and their subsets. The peak of immunosuppression in cancer surgery occurs within 2 days after surgery. Postoperative immune status and tumor recurrence are somewhat correlated (17). Cluster of differentiation 3 (CD3⁺), CD4⁺, and CD8⁺ T cells are mature T cells in blood, helper T cells, and cytotoxic T cells, respectively. The ratio of CD4⁺ to CD8⁺ T cells can reflect body immune status, and its increase and decrease usually represents an increase and decrease in the immune function of the body (18). As one of the main effector cells of immunity, natural killer (NK) cells can recognize and

kill tumor cells that lack antigen presentation on the major histocompatibility complex (19).

NK cells do not only lyse tumor cells directly by secreting granzyme B and perforin but also secrete IFN- γ and other cytokines to promote an antitumor immune response. The higher the activity of NK cells in patients with stage IV colorectal cancer, the higher the remission rate and the longer the progression-free survival (20). We demonstrated that the preoperative levels of CD3⁺, CD43⁺, and CD83⁺; NK cell count; and CD4⁺/CD8⁺ T cell ratio of patients in the TCI and control groups were normal, although the values of these parameters were lower than the normal value on postoperative day 1. The levels of these parameters began to progressively normalize on the third postoperative day, and all the parameters were fully normalized in both groups by postoperative day 7. The levels of CD3⁺, CD4⁺, CD8⁺, and NK cells, as well as the CD4⁺/CD8⁺ ratio in the two groups on the first and third postoperative days, were significantly lower than those before surgery. This was probably related to immunosuppression caused by LTME. Due to the immune regulation that occurred in patients, there was no statistically significant difference in the abovementioned parameters on postoperative day 7 compared with those before surgery, indicating immune status recovery. There was no significant between-group difference in the abovementioned parameters before surgery and on the first, third, and seventh postoperative days, suggesting that the implementation of TCI does not increase the immunosuppressive effect in patients.

Compared with open surgery, laparoscopic surgery is less traumatic; however, a postoperative inflammatory reaction is still difficult to avoid. A variety of inflammatory factors in the sera of operated patients are related to the degree of surgical trauma (21). PCT is a glycoprotein with no hormonal activity that is released into the circulatory system in the acute stage of the inflammatory response due to bacterial infection or trauma. PCT is highly sensitive to postoperative and post-traumatic inflammatory reactions. Its serum levels are positively correlated with the severity of the inflammatory reaction (22); thus, PCT is one of the most commonly used inflammatory markers in the clinic. Serum CRP is a nonspecific acute-phase protein secreted by hepatocytes under the influence of IL-6. It can enhance the phagocytosis of damaged cells by activating the complement pathway, and it also plays an important role in innate immunity. IL-6 serum levels are closely related to the degree of the inflammatory reaction; hence, IL-6 can be used as an early indicator to predict infection

after abdominal surgery (23). IL-6 is an inflammatory factor with multiple functions. In the early stage of inflammation, monocytes and macrophages stimulated by toll-like receptors produce IL-6, which strongly induces the expression of a broad spectrum of acute-phase proteins and regulates B cell activity and humoral immunity. IL-6 plays a central role in acute inflammation, which is a host defense mechanism (24,25).

This study showed normal preoperative levels of serum CRP, PCT, and IL-6 in patients in the TCI, PI, and control groups. The levels of the abovementioned parameters increased rapidly on postoperative day 1 and remained high until postoperative day 3. On postoperative day 7, the levels of serum CRP, PCT, and IL-6 in the 2 experimental groups decreased significantly, although these levels remained higher than preoperative levels. The serum levels of the 3 parameters on the first and third postoperative days were higher than preoperative levels, suggesting that the surgery triggered an inflammatory reaction. With appropriate treatment, the postoperative inflammatory response gradually subsided. There was no significant between-group difference in the levels of CRP, PCT, and IL-6 before surgery and on postoperative days 1, 3, and 7 (all $P < 0.05$). This suggests that intraoperative TCI neither significantly increases trauma nor aggravates the inflammatory response.

During the perioperative period, intestinal contents can be blocked by the TCI tube from entering the large intestine in patients who have undergone TCI or PI. Therefore, these patients were instructed to eat a liquid diet to avoid postoperative discomfort. Patients in the control group were instructed to eat after passage of flatus. Hence, the time to first feeding in the TCI and PI groups was significantly shorter than that in the control group ($P < 0.001$). Due to early feeding, the intestinal function of the patients in the TCI and PI groups recovered quickly, and hence time to first flatus was earlier than that of patients in the control group ($P < 0.001$). Time to first bowel movement in the TCI and PI groups was significantly delayed compared to that in the control group ($P < 0.001$). This suggests that it is difficult for intestinal contents to flow to the distal large intestine and anastomotic stoma due to TCI diversion as well as PI. Fecal excretion by patients in the TCI group resulted from residual contents in the distal colon.

In terms of perioperative complications, there was no significant between-group difference in the incidence of intestinal obstruction and postoperative pulmonary infection ($P = 0.938$ and $P = 0.971$), suggesting that TCI does not increase the risk of these 2 complications. There was no

difference in the incision infection rate in the three groups ($P=0.530$). This suggests that even opening the cecum wall in TCI does not significantly increase the risk of incisional infection as long as aseptic manipulation is emphasized. Emphatically, the fistula tube should be sent into the ileum through the appendix opening as quickly as possible to prevent repeated drainage and insertion. It is important to prevent from opening the appendix root repeatedly. It is also critical to protect the opening of the root by sterile gauze ring when catheter entering. To disinfect and wash the operation area and incision more than three times after TCI is able to reduce the risk of infection.

The incidence of AL was 3.51%, 3.80%, and 14.49% in the TCI, PI, and control groups, respectively, which was a significant between-group difference ($P=0.002$). This suggested that TCI could be as effective in preventing AL as PI. Six patients in the TCI and PI groups experienced AL, implying that any preventive ostomy, including TCI and PI, cannot completely avoid AL. Moreover, the patients who experienced AL had low-grade fever, and the pelvic drainage tube revealed a small amount of turbid fluid. The patients also intermittently experienced slight lower abdominal pain due to sufficient diversion. The infection that caused the abovementioned clinical presentation was limited and there were no signs of peritoneal irritation. After conservative treatment, the patients successfully recovered and were extubated; thus, the secondary operation rate was 0% in the TCI and PI group. In the control group, 24 patients had AL, 21 of whom (87.5%) had severe inflammatory reactions and required emergency ileostomy. The TCI and PI groups had a significantly lower incidence of AL-related reoperations compared to that in the control group ($P<0.001$). This suggests that TCI reduces the severity of abdominal infection after AL and thus reduces the likelihood of a second operation. The patients in the TCI group had their TCI tube removed 14–20 days after operation so that the anastomotic intestinal canal could be reperfused by intestinal content. This promotes the expansion and peristalsis of the intestinal canal. Therefore, the anastomotic stricture rate in the TCI group was lower than that in the PI group or the control group ($P<0.001$).

Concerning postoperative diet, patients should be instructed to eat strictly non-fibre food and drink large amounts of water to avoid viscous intestinal content from blocking the TCI tube. Care should be taken to maintain tube patency. If the drainage fluid from the TCI tube is significantly reduced while the patient has symptoms of abdominal distension, tube blockage should be considered

first. The tube should be quickly flushed with normal saline. After repeated flushing using a syringe, the drainage fluid should be light yellow (due to dilution with fecal fluid) and should flow smoothly, indicating that the tube was successfully flushed. After the removal of the TCI tube, the stomas of the aforementioned 26 patients (15.2%) did not heal within one week. Nonetheless, the stoma healed smoothly after debridement and closure by suturing under local anesthesia.

Conclusions

Our study showed that as a novel method of ostomy, TCI performed during laparoscopic TME for low rectal cancer can effectively reduce the incidence of AL after low anal sphincter preservation surgery. AL cannot be completely avoided after TCI; however, even if AL occurs, TCI can reduce the degree of abdominal infection and significantly reduce the secondary surgical rate related to AL. Furthermore, the implementation of TCI does not increase the incidence of perioperative inflammatory response, immunosuppression, and related complications. Thus, TCI is safe and feasible. After training and practice, senior gastrointestinal surgeons can skillfully perform TCI. Postoperative nursing is convenient for patients with TCI and their families. After removing the TCI tube, the stoma quickly heals. Early reperfusion and peristalsis in anastomotic intestinal canal reduces the risk of anastomotic stricture. TCI not only achieves a satisfactory diversion effect, but also avoids a secondary operation to close the fistula. As another option to replace ileostomy or colostomy, TCI is a preventive fistula operation method worthy of application.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics committee of Chongqing University Cancer Hospital (No. 2017-Ethics Review-110). Individual consent for this retrospective analysis was waived.

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