Advances in the application of prophylactic ostomy in radical resection of rectal cancer

Jingyao Chen^{1#}, Yubing Liu^{2#}, Chunhong Hong¹, Zichong Kuo¹, Hong Yu¹, Jianfeng Li¹, Mingzhe Li¹, Wenhui Wu¹, Jianlong Jiang¹

¹Digestive Diseases Center, the Seventh Affiliated Hospital, Sun Yat-sen University, Shenzhen, China; ²Department of General Surgery, Jieyang People's Hospital (Jieyang Affiliated Hospital, Sun Yat-sen University), Jieyang, China

Contributions: (I) Conception and design: J Jiang, J Chen, Y Liu; (II) Administrative support: M Li, W Wu; (III) Provision of study materials or patients: C Hong; (IV) Collection and assembly of data: H Yu, J Li; (V) Data analysis and interpretation: C Hong, Z Kuo; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

"These authors contributed equally to this work.

Correspondence to: Jianlong Jiang. Digestive Diseases Center, the Seventh Affiliated Hospital, Sun Yat-sen University, Shenzhen 518000, China. Email: jiangjlong@mail.sysu.edu.cn.

Abstract: Despite of technological improvements in surgical equipment, anastomotic leakage (AL) after anterior rectal resection is still the most important and common complication in laparoscopy and open surgery. According to reports, the clinically obvious leakage rate after laparoscopic anterior rectal resection is 3-19%. AL is associated with high morbidity and mortality, and usually requires re-operation with stoma creation. It significantly increases the length of hospital stay and rehabilitation costs. For a long time, there has been controversy about the role of protective stomas, and there are still controversies. Some authors recommend the routine use of temporary stomas to reduce the incidence and incidence of AL. On the contrary, other authors discourage the regular use of temporary stomas, and preferring selective use. For these authors, a protective stoma can only reduce the catastrophic clinical consequences of AL and decrease the burden of stoma-related complications. The conventional method of temporarily using the stoma reduces the advantages of the laparoscopic technique, so it is advisable to use it selectively. The difficulty in choosing to use temporary stoma is related to the necessity of effective anastomotic cracking risk stratification, which is not yet available today. In this article, we reviewed literatures regarding the indications of prophylactic ostomy, stoma-associated complications, timing of reversal, and surgical complications, aimed at providing useful summary of experience for early stoma closure, and thus reduce stoma-associated complications and ultimately improve the quality of life of patients.

Keywords: Rectal cancer; anastomosis leakage; prophylactic ostomy; stoma closure

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Introduction

With the development of anal sphincter-preserving technology in rectal cancer, resection of low and even ultra-low rectal cancer is becoming more and more common. Although perioperative management and surgical techniques have been greatly improved over the years, anastomotic leakage (AL) is still considered the most serious postoperative complication for rectal cancer surgery, with a rate of about 2–28% (1-4). In order to prevent AL, prophylactic stoma has emerged as a Band-Aid solution. It is reported that in some areas, about 57–70% of patients undergoing anterior resection of rectal cancer in some areas have undergone prophylactic ostomy (5,6). Although prophylactic ostomy can reduce the reoperation rate and related mortality rate of AL, it is controversial whether it

Risk level	Anastomotic position*
Low risk	>10 cm; or 5–10 cm with no more than two combined risk factors [#]
Moderate risk	5–10 cm or preoperative neoadjuvant radiotherapy and chemotherapy or emergency operation or three or more combined risk factors
High risk	<5 cm

 Table 1 Risk classification of AL after anterior rectal resection for rectal cancer (14)

*, The position of the anastomosis: the distance of the anastomosis from the anal margin. [#], Overall risk factors: older than 65 years old, male, BMI >25, ASA score 3 or 4, diabetes, blood transfusion, operation time more than 3 hours. AL, anastomotic leakage.

can reduce the incidence of AL (7). Moreover, the stomarelated complications caused by prophylactic ostomy, the rate of secondary operation, the complications of ostomy, the decreased quality of life post ostomy and the extra costs cannot be ignored (8-10). In addition, the timing of stoma closure is also controversial. While most of the literatures reported that it was done 2–6 months after operation. However, for a variety of reasons, most patients still have a stoma for more than 6 months. Thus, we had made a literature review and analysis based on the current research status and controversy of prophylactic ostomy in radical resection of rectal cancer.

Indications of prophylactic stoma

AL often causes serious consequences, including pelvic abscess, systemic infection, etc., which often requires emergency surgery, resulting in prolonged hospitalization, increased costs, increased complications and mortality, and can affect local recurrence and long-term survival of patients (11,12). At present, there is still a dispute over whether to routinely perform prophylactic stoma in radical resection of rectal cancer, but it is the consensus of most surgeons to carry out prophylactic stoma for patients with high risk factors of postoperative AL. The risk factors reported in multiple literatures for postoperative AL include (3-5,13):

- (I) Anastomotic factors: excessive anastomotic tension, poor blood circulation, low anastomotic location, incomplete anastomotic ring, positive intraoperative anastomotic air leakage test;
- (II) Tumor factors: preoperative radiotherapy and chemotherapy, low tumor location, local advanced stage of tumor;
- (III) Preoperative factors: intestinal obstruction or poor intestinal preparation;
- (IV) Systemic factors: male, diabetes, long-term use of hormones, hypoproteinemia, anemia, old age.

Some suggested that routinely grading the risk of postoperative AL according to the following criteria (*Table 1*), and also routinely perform prophylactic ostomy for the high-risk patients (14).

For moderate-risk patients, some surgeons have proposed a method of virtual ileostomy called ghost ileostomy (GI). The specific operation is as follows: a small incision was made in the non-vascularized area of the terminal ileum, which was then passed through with a thick rubber band (vessel loops commonly used), then pass the rubber band through the abdominal wall from the lower right abdomen, and then the material was fixed. If signs of AL were observed, then ileostomy could be carried out under local anesthesia in the ward. If the patient had an uneventful recovery after operation confirming under X-ray with water-soluble contrast enema (WCE), the rubber band could simply be removed on the 10th day post operation (15).

An Italian randomized controlled study divided patients with moderate risk of AL patients into a GI group and a blank control group. The results revealed that while there was no significant difference in the incidence of postoperative AL between the two groups, but the patients with AL in the GI group had minor symptoms and shorter hospital stay. All patients with AL had undergone ileostomy under local anesthesia on the third day post operation, and none of them underwent exploratory laparotomy (14). On another study, Mori retrospectively analyzed 20 cases (11.96%) of AL at 4–12 days post operation, of which 13 cases underwent ileostomy under local anesthesia, 5 cases received conservative treatment, 2 cases deteriorated rapidly and developed diffuse peritonitis, requiring abdominal lavage and ostomy (16).

Although prophylactic ostomy is technically simple and easy, its related complications could not be ignored and should be carefully treated. GI could be considered to avoid stoma-related complications when preoperative evaluation returned as moderate-risk, or when it was difficulty to judge whether ostomy is needed or not during the operation (17).

Ostomy-related complications

Complications related to stoma include local infection, skin irritation, prolapse of stoma, para-stoma hernia, stoma retraction, stoma stricture, renal dysfunction, water and electrolyte disorders, etc. The incidence rate was reported to be 19–74%, and increasing with the retention time of stoma (17,18). Studies have shown as the follow-up period lengthened from 10 days to 3 months post operation, stoma-related complications also increased from 5% to 30% (19). Ostomy-related complications can lead to rehospitalization, delayed adjuvant therapy, reduced quality of life and additional costs (20,21).

The burden of ostomy:

- (I) Psychological burden: change in body image, odor, uncontrolled defecation, continued presence of ostomy may indicate disease recurrence and metastasis to the patient (7). These psychological and emotional changes can affect the compliance and integrity of subsequent adjuvant therapy (22).
- (II) Economic burden: a study compared the total cost of 5-year follow-up of patients with prophylactic ostomy and those without ostomy. Patients without ostomy saved an average of 5,741 Euros (23). It has also been reported that the early stoma closure (within 2 weeks) compared to the delayed group (average 4 months after operation) saved an average of NZ\$3,000 (24). There is still a lack of reports in China in this regard.
- (III) Quality of life: ostomy can lead to limited social activities, ostomy care difficulties, ostomy-related complications, re-hospitalization and other problems, such as low libido, body image issues (difficult to dress up, low self-esteem), and practical problems related to the stoma itself, such as finding a private place to clean the pouch, pouch leakage, etc. will have a negative impact on the overall quality of life (19). These problems can be recovered after stoma closure (21).

The time of stoma closure

The best time for stoma closure is after AL had healed and anastomotic complications had been excluded. The average time of postoperative AL was 12.7 days, with the average clinical AL at 7 days, and AL discovery on diagnostic imaging at 16 days, and 12% of delayed leakage occurred 30 days after operation (12). Delayed AL was more common in patients who underwent neoadjuvant therapy and with ultra-low anastomosis, and their clinical manifestations were often discrete and did not need emergency operation (25). Palmisano et al. retrospectively analyzed 70 patients who underwent prophylactic ostomy, and imaging leakage was found in 24.3% of the patients who underwent WCE imaging, WCE imaging was re-performed in 17 AL patients 2 months later, of which 7 cases had healed anastomosis, while the other 10 cases still had AL. One month later, 10 patients were reexamined for the third time with WCE imaging, and in 2 patients the AL disappeared, while in the other 8 patients there had no clinical symptoms. Nine patients received stoma closure immediately after the AL recovered, and 8 patients with persistent imaging leakage also received stoma closure. Six months later, there were no complications related to stoma closure.

According to previous understanding, stoma closure should be carried out 8-12 weeks after curative, and if adjuvant chemotherapy was needed, it should be done after the end of chemotherapy (26,27). The reasons were as follows: sufficient recovery time after operation, complete healing of anastomosis, regression of pelvic inflammation and reduction of abdominal adhesion (which could reduce the difficulty of surgery), and allowing a buffer period for the symptoms of low anterior resection syndrome (LARS). Perez and other studies had shown that stoma closure before 8.5 weeks after operation can lead to an increase in the incidence of postoperative complications (28). Yin et al. pointed out that the incidence of complications of early stoma closure was higher, and multivariate analysis showed that the time of closure ≤ 109 days was an independent risk factor for postoperative complications (29).

However, delaying the closure of stoma would increase the incidence of stoma-related complications, which would reduce the quality of life of patients, and would even affect the implementation of adjuvant chemotherapy, which would result in an increased risk of recurrence. Therefore, some researchers pointed out that the patients with an uneventful recovery could be closed in the early stages after operation (within 2 weeks) after WCE imaging and abdominal CT examination. The reasons were as follows: first of all, early closure could reduce stoma care time, reduce stoma-related complications and re-hospitalization, thereby reducing related costs, malabsorption from extended period of disuse. If both curative and stoma closure surgery could

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be performed in a single One instance of hospitalization, it would can both solve the rectal cancer operation and colostomy, avoid patients from leaving the hospital with colostomy, which would be conducive to the early psychological recovery of patients after operation. Secondly, a number of studies have shown that there was no significant difference in operation time and blood loss between early and delayed surgery, which indicated that there was no difference in the difficulty of operation between the two groups (30-32). Also, due to the usage of staplers for anastomosis, the use of stapler would not hinder the stoma closure surgery (19). Finally, the presence of stoma will affect the compliance of adjuvant therapy due to the fact that, some patients are required to pay it back prefer to have it closed before or immediately after treatment, and some patients even reportedly interrupted treatments due to it (32). Some studies have pointed out that the closure should not be delayed on the grounds that the entire chemotherapy process should be completed, and they recommended that the closure be completed between the second and third course of treatment (33). However, Thalheimer et al. believed that the closure of the stoma before the completion during the course of chemotherapy can lead to the postponement of the scheduled of chemotherapy and an increase in the incidence of complications of the surgery, so it was recommended that the closure be completed before beginning chemotherapy (34). Postoperative adjuvant therapy is generally recommended to be carried out before the 8th week post-op, so stoma closure could definitely be completed before the implementation of subsequent treatment.

The latest meta-analysis with 570 cases (252 cases that underwent early closure vs. 318 cases that underwent delayed closure) showed that there was no significant difference in the overall incidence of complications between the two groups. Although the postoperative surgical wound infection rate was higher in the early closure group, the incidence of stoma-related complications and postoperative intestinal obstruction in the early group was much lower than that in the delayed closure group (32). The results of a randomized controlled study between early closure group (8 days post-op) and delayed closure group (2 months post-op) in France showed that there was no significant difference in the total incidence of complications (31% vs. 38%) and, mortality within 90 days, quality of life and anal function within 90 days after radical resection of rectal cancer between early (8 days after operation) and delayed closure (2 months after operation). There was no significant difference in the complication rate and reoperation rate of stoma closure surgery (30). The results of a Nordic randomized controlled study showed that the average number of postoperative complications in the early closure group (8-13 days after operation) was much lower than that in the delayed group (1.2 vs. 2.9). Not only there was no significant difference in the amount of blood loss and operation time between the two groups, while the early group had an earlier recovery of intestinal function was better than the delayed group in the recovery of intestinal function after operation (9). In another study, Lasithiotakis and other his cohorts randomly divided the patients with uneventful recovery and with no abnormalities in WCE imaging into early closure group (6 days after operation) and delayed group (6-8 weeks after operation). In the early group, the difficulty of abdominal wall suture and stoma reduction was evaluated by a visual analogue scale (0= difficulty, 100= easy), the operation time (was half of the time recorded in delayed group) and the cost of stoma care were significantly better than those in the delayed group (19). Li et al. conducted a case-control study of two groups according to surgical reduction time (within 3 months and after 3 months). There were no significant differences in intraoperative blood loss, operation time, hospital stay, postoperative complications (including incision surgical wound infection, intestinal obstruction, AL, abdominal abscess, reoperation, postoperative bleeding, blood transfusion, and re-hospitalization) between the two groups (31).

The timing of closure should depend on the specific conditions of the patients, including the regression of local inflammatory edema, anastomotic recovery, postoperative complications, and general condition and primary disease control, and should not be delayed on the grounds of adjuvant treatment. If the patients were asked about when they would prefer to have the stoma reduced, the sooner the stoma is closed, the better the patient will be (11). Thus, patients should be informed of the expected closure time prior to primary operation, rather than the recommended or required closure time, which could be scheduled for close surgery at the time of discharge (30,33). Adequate communication, proper propaganda, prior planning and mutual cooperation are all conducive to the implementation of early closure (24).

In summary, in carefully selected patients, early stoma closure is feasible, technically easier, with less operation time, shorter hospitalization stay, resulting in significant cost savings (17,19).

Reasons for stoma closure delay

A retrospective analysis of 4,879 patients in the UK showed that the rate of stoma closure at 18 months after operation was only 72.5% (8). The reasons for the delay were as follows (5,8,35):

- Postoperative adjuvant radiotherapy and chemotherapy;
- (II) The priority of surgical arrangement;
- (III) The occurrence of postoperative complications: after the occurrence of postoperative complications, patients and doctors were cautious about the reduction of stoma. Some patients even refused to accept it;
- (IV) Laparotomy, old age, poor basic condition, more complications;
- (V) Local recurrence or distant metastasis post operation;
- (VI) Economic difficulties.

As a result, some eventually patients even became "permanent ostomy" and about 19% of the patients did not reduce the ostomy during the follow-up period (5). The reasons were for not being able to pay it back (12): subjective factors include patients' fear for stoma closure surgery after the primary surgery, economic reasons and adaptation to lifestyle with ostomy because of the complications of the first operation. The objective causes were postoperative complications such as anastomotic stricture, local recurrence or distant metastasis of rectal cancer, short expected survival time, old age, poor general condition, and many complications (both the primary surgery first operation and the closure surgery has close operation face the same complications. However, the purpose of the primary surgery first operation is to improve the survival rate of patients, while the purpose of reduction surgery is to improve the quality of life) (36).

Therefore, for patients at risk of permanent ostomy, colostomy rather than ileostomy should be performed to improve the quality of life (35).

Complications of stoma closure

Although stoma closure is a simple surgery on the technical front, the operative complications could not be ignored (17). Routine examination: such as WCE imaging and abdominal CT, clinical examination (digital rectal examination, endoscope) should be done prior to surgery. The latest review (37) showed that the specificity, negative predictive value, sensitivity and positive predictive value of WCE imaging in diagnosing AL were 95.4%, 98.4%, 79.9% and 64.6%, respectively. Moreover, the diagnostic consistency between WCE imaging diagnosis of AL and clinical examination (anal finger examination, rectal endoscopy and rectal endoscopy) was 96.7%, the combination of the two would be more conducive to improve the negative predictive value. For patients with negative examination, the probability of secondary AL post reduction surgery was low. With the combination of CT and CE imaging, the diagnostic accuracy of AL would be greatly improved. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of AL detected by CT alone were 44%, 86%, 40%, 88% and 79%, respectively, when combined with CE imaging, the corresponding indicators increased to 82%, 100%, 100%, 89% and 92%. External leakage of contrast media shown through CT is the most accurate sign for the diagnosis of AL.

The incidence rate of surgery was 17.3-45.9%, mainly intestinal obstruction, surgical wound infection, peritonitis, abdominal abscess, AL, intestinal fistula, bleeding and so on (7,8,29). The incidence of intestinal obstruction is about 5.0–32.6%. Studies had shown that a sutureless anastomosis using a stapler could not only save surgery time when compared with manual anastomosis, but also reduce the incidence of postoperative intestinal obstruction (38,39). The incidence of surgical wound infection was 2–41%, and the incidence of surgical wound infection in the early stage reduction was higher than that of the patients whom underwent delayed stoma closure surgery (24,32). Stoma closure is a contaminated operation, and adequate intestinal preparation should be carried out prior to the surgery, preferably an anterograde approach. After disinfecting the abdominal surgical site, reduce the stoma and re-sterilize and redo surgical drapes the towel again; when separating the intestinal tube on the abdominal wall, surgeon should avoid damaging the intestinal walls to prevent contamination (40). Some studies had compared several skin suture methods, among which the incision infection rate using purse suture was the lowest, which is recommended for early reduction surgery (41). Recent studies had shown that purse suture can reduce the postoperative surgical wound infection rate to 0% (42,43) when compared with other sutures.

In a word, complete preoperative preparation, skillful methods during fine operation, reasonable selection of anastomosis methods and suitable skin suture method should be performed to avoid greater trauma to patients.

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Conclusions

For patients undergoing radical resection of rectal cancer, prophylactic ostomy should be carefully decided according to the risk of AL, and attention should be paid to the impact of stoma-related complications on patients' quality of life. For patients with moderate risk of AL, GI can be used as an option. The operation should not be postponed according to the end time of chemotherapy, but the specific date of closure should be informed to patient before discharged from hospital. Although technically unchallenging, stoma closure surgery should not be underestimated, and attention should be paid to prevent of surgical complications. For the patients with uneventful recovery with good general conditions, and no AL confirmed by WCE imaging combined with abdominal CT or endoscopy, stoma reduction can be performed at an early stage to reduce the occurrence of stoma-related complications.

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Footnote

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