*Original Article*

# Defunctioning Stoma in Locally Advanced Rectal Cancer Receiving Concurrent Chemoradiotherapy and Low Anterior Resection

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***Key Words***
Defunctioning stoma;
Rectal cancer;
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Radical proctectomy

***Purpose.*** Temporary defunctioning stoma reduces the rate of anastomotic leakage and reoperation in lower-third rectal cancer surgery. Preoperative radiotherapy or concurrent chemoradiotherapy raises the probability of performing sphincter-preserving surgery in locally advanced rectal cancer. The main purpose of this study is to clarify the role of defunctioning stoma in radical proctectomy in the subgroup of patients received concurrent chemoradiotherapy.

***Methods.*** From July 2010 to November 2012, we retrospectively analyzed 83 locally advanced rectal cancer patients receiving operation following concurrent chemoradiotherapy; seventy-five (90%) of them received subsequent radical proctectomies and bowel continuity was restored primarily by either colorectal anastomosis or coloanal anastomosis. Of them, defunctioning stomas were created in 43 (57%) cases.

***Results.*** More blood loss was found in patients received radical proctectomy with temporary stoma during operation ($p$ = 0.0281). However, the anastomotic leakage rate and re-operation rate were not significantly reduced by existence of defunctioning stoma. If we confined the anastomotic level to less than or equal to 4 cm from anal verge, defunctioning stoma reduced the anastomotic rate from 21.4% to 12.5% and reoperation rate from 14.3% to 3.1% in radical proctectomy.

***Conclusions.*** Although defunctioning stoma doesn't significantly decrease the anastomotic rate and reoperation rate in locally advanced rectal cancer patients receiving preoperative concurrent chemoradiotherapy, we can still find the trend of increasing importance when the anastomotic level is lower than or equal to 4 cm above the anal verge. For ultra-lower-third rectal cancer receiving concurrent chemoradiotherapy, anastomosis should still be protected by adding defunctioning stoma to radical proctectomy.

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Fecal diversion is widely used in managing various surgical situations that involve the colon and rectum including congenital disease, acute or chronic inflammation, and malignancy. Two common options for fecal diversion are transverse colostomy and ileostomy. They are often created temporarily for the purpose of protecting the distal anastomosis and are the so-called defunctioning stoma. Comparisons of these two kinds of defunctioning stoma can be found in some published trials, but none are conclusive about which of these is superior.[1,2] Since the role of defunctioning stoma in radical proctectomy is not well clarified in the subgroup of locally advanced rectal cancer patients receiving concurrent chemoradiotherapy (CCRT), we conducted a clinical study to determine the importance of defunctioning stoma in protecting distal anastomosis under this circumstance.

## Materials and Methods

### Patients

Data in our study were retrospectively retrieved from a single medical center. From July 2010 to November 2012, eighty-three patients with locally advanced rectal cancer (LARC, T3 or T4 or N+) with or without distant metastasis receiving neoadjuvant concurrent chemoradiotherapy (CCRT) were enrolled into this study. All patients received detailed studies, including laboratory data analyses, colonofiberoscopy, and imaging studies (i.e., abdominal computed tomography [CT], chest X-ray, etc.) before surgery. The median distance between lower margin of cancer and anal verge was 5.0 cm (Standard deviation [SD] = 2.3 cm). Radiation was delivered via 6- and 10-MV photons by use of a three-field technique (posterior and both laterals) in most patients as per the previous method.[3] Treatment was planned via computerized dosimetry, and a dose of 1.8 Gy per fraction was prescribed to cover the planning target volume. Radiotherapy was delivered 5 days per week, once per day, at 1.8 Gy/day. Pelvic radiotherapy consisted of 45 Gy in 25 fractions over a period of 5 weeks, which was followed by a boost dose of 5.4 Gy administered in three fractions to the primary tumor by two lateral fields. The clinical target volume contained the primary tumor, the mesorectum, the presacral space, and the lymph nodes, which included the perirectal, presacral, internal iliac, and/or external iliac nodes as indicated. The concurrent chemotherapy regimens used in our patients majorly included oral capecitabine (63.5%), FOLFOX4 (12.2%), and FOLFIRI plus bevacizumab (10.8%) for LARC with distant metastasis. Patients underwent surgery 6-8 weeks after completion of the CCRT. Total mesorectal excision technique was performed in all patients, and extended visceral resection was performed in clinical T4 patients. Anal sphincter-sparing surgery was performed when possible. Colorectal anastomosis (CRA) or coloanal anastomosis (CAA) was undertaken in 75 patients, while 7 patients receiving abdominoperineal resection and one receiving local excision were excluded (Fig. 1). The need to create temporary defunctioning stoma was at the discretion of the surgeon during the operative situation. Forty-three (57%) patients had defunctioning stoma at the same time of radical proctectomy, while 32 (43%) patients received low anterior resection (LAR) without defunctioning stoma. Among patients not having defunctioning stoma during the operation, three had subsequent transverse colostomy (T-colostomy) after radical proctectomy because of anastomotic leakage. Closure of each type of temporary stoma involved a peristomal incision and excision of both limbs with an end-to-end anastomosis. Seven of 8 ileostomies and twenty-five of 38 transverse colostomies were

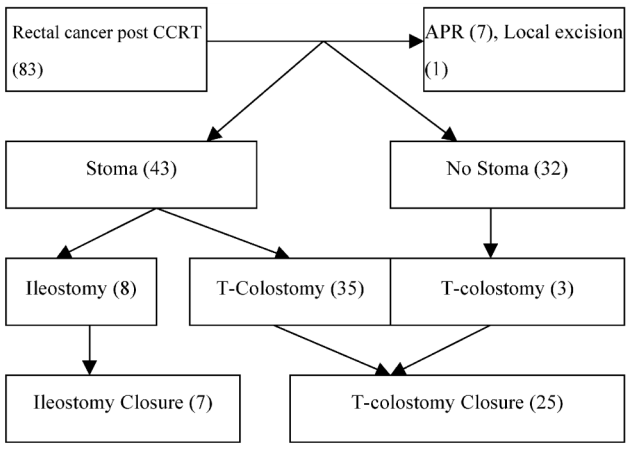


**Fig. 1.** Flow chart of data collected.

closed after distal anastomosis was secured and adjuvant chemotherapy (if necessary) completed. The median time from stoma creation to closing was 166 (range 58 to 326) days. All demographic data were recorded and clinical courses of perioperative period were compared.

### Statistical analysis

Continuous variables are presented as mean ± standard deviation, and dichotomous variables are presented as number and percentage values. All data were analyzed using the Statistical Package for the Social Sciences version 19.0 software (SPSS Inc., Chicago, IL, USA). A $p$ value less than 0.05 was considered as statistically significant. The clinicopathologic features between the two groups (stoma *vs.* non-stoma; leakage *vs.* non-leakage) were compared using chi-square test.

## Results

Among the 75 patients receiving neoadjuvant chemoradiation and subsequent radical proctectomy, age, gender, and body mass index (BMI) was similar in groups with and without defunctioning stoma (Table 1). The cancer histology and pathological TNM staging were also comparable in both groups. Synchronous distant metastasis was found in 5 (15.6%) and 7 (16.3%) patients respectively. Bevacizumab was preoperatively used in 6 of 7 (85.7%) and 3 of 5 (60%) metastatic diseases that received subsequent surgery with and without defunctioning stoma. Laparoscopic surgery was performed in 8 patients (25%) without defunctioning stoma and 7 patients (16.3%) with defunctioning stoma. However, for patients with their cancer having less distance from the anastomotic site to the anal verge, surgeons tended to perform coloanal anastomosis, used a hand-sewn technique, and favored creating a defunctioning stoma to protect the distal anastomosis. Patients with defunctioning stoma had slightly higher preoperative serum CEA (carcinoembryonic antigen) levels. Though the operating times were longer in patients receiving additional defunctioning stoma to radical proctectomy, it was not statistically significant (320 vs. 245 minutes, $p = 0.0585$), but more blood loss was encountered (452 *vs*. 280 ml, $p = 0.0281$) (Table 2). The stoma group had earlier flatus or stool passage, but the postoperative hospital stays were not different (11.1 and 10.8 days, $p = 0.87$). Interestingly, the anastomotic leakage rates were not largely affected by the existence of defunctioning stoma (16.7% without stoma vs. 11.9% with stoma, $p = 0.57$), and the reoperation rates were also not decreased remarkably (10% without stoma *vs*. 2.4% with stoma, $p = 0.16$). Time to leakage was 9 ± 2.8 days with and 9 ± 3.4 days without defunctioning stoma ($p = 1.0$). The total complication rate since the creation of stoma till the closure of the stoma was 30.4%. Electrolyte imbalance happened in 10 of 46 patients (21.7%) and was the leading cause of complications, followed by renal insufficiency (10.9%). The percentages of developing other stoma-related complications including hernia, stenosis, retraction, prolapse, necrosis and abscess were all very low.

Seven patients who completed adjuvant chemotherapy did not have their transverse colostomy closed during the postoperative surveillance. One of them had spontaneous intracranial hemorrhage one month postoperatively, one developed liver metastasis 4 months after radical proctectomy, and another patient died from non-cancer cause before her stoma was closed. No perioperative mortality was recorded in our study. Of 25 patients with transverse colostomy and 7 patients with ileostomy closed, four developed postoperative ileus, 3 had surgical site infection (SSI), and anastomotic leakage developed in 2 patients. The total complication rate of stoma closure was 26.7%.

## Discussion

The role of defunctioning stoma in lower rectal cancer has been a controversial issue over the past decade. Gastinger *et al.* reviewed 2729 rectal cancer patients and found that although defunctioning stoma did not improve the overall anastomotic leakage rate in low anterior resection, the requirement of reoperation decreased.[1] A randomized multicenter trial

**Table 1.** Demographic data between stoma and non-stoma groups

| | No Stoma (N = 32) (43%) | Stoma (N = 43) (57%) | *p*-value |
|---|---|---|---|
| Age, years (SD) | 61.7 (10.9) | 63.8 (12.9) | 0.44 |
| Male (%) | 15 (46.9) | 28 (65.1) | 0.11 |
| BMI (SD) | 23.0 (3.0) | 23.7 (4.1) | 0.55 |
| Histology (%) | | | 0.84 |
| WD | 4 (13.3) | 7 (18.4) | |
| MD | 24 (80.0) | 29 (76.3) | |
| PD | 2 (6.7) | 2 (5.3) | |
| ypT (%) | | | 0.08 |
| T0 | 3 (9.4) | 8 (18.6) | |
| T1 | 1 (3.1) | 5 (11.6) | |
| T2 | 5 (15.6) | 13 (30.2) | |
| T3 | 22 (68.8) | 16 (37.2) | |
| T4 | 1 (3.1) | 1 (2.3) | |
| ypN (%) | | | 0.6 |
| N0 | 19 (59.4) | 30 (69.8) | |
| N1 | 7 (21.9) | 8 (18.6) | |
| N2 | 6 (18.8) | 5 (11.6) | |
| Metastatic disease (%) | 5 (15.6) | 7 (16.3) | 0.94 |
| Distance from anal verge, cm (SD) | 4.9 (2.6) | 3.4 (1.8) | 0.0088* |
| Surgery (%) | | | 0.35 |
| Open | 24 (75.0) | 36 (83.7) | |
| Laparoscopic | 8 (25.0) | 7 (16.3) | |
| Anastomotic method (%) | | | < 0.0001* |
| Hand sewn | 6 (18.8) | 32 (74.4) | |
| Double stapler | 26 (81.3) | 11 (25.6) | |
| Anastomosis by anatomy (%) | | | < 0.0001* |
| CAA | 3 (9.4) | 31 (72.1) | |
| CRA | 29 (90.6) | 12 (27.9) | |
| CEA, ng/mL (SD) | 4.64 (5.81) | 5.98 (9.82) | 0.5 |

BMI: body mass index.
WD: well differentiated; MD: moderately differentiated; PD: poorly differentiated.
CEA: carcinoembryonic antigen.
CAA: coloanal anastomosis; CRA: colorectal anastomosis.

**Table 2.** Operation situations and surgical complications between stoma and non-stoma groups

| | No Stoma (N = 32) (43%) | Stoma (N = 43) (57%) | *p*-value |
|---|---|---|---|
| Operating time, minutes (SD) | 245 (71) | 320 (151) | 0.0585 |
| Blood loss, ml (SD) | 280 (146) | 452 (293) | 0.0281* |
| Time to function, days (SD) | 3.3 (1.3) | 2.1 (1.3) | 0.0045* |
| Postoperative hospital stay, days (SD) | 11.1 (8.5) | 10.8 (5.0) | 0.87 |
| Perioperative mortality (%) | 0 | 0 | - |
| Anastomosis leakage (%) | 5 (16.7) | 5 (11.9) | 0.57 |
| Fistula (%) | 0 | 2 (4.8) | 0.14 |
| Reoperation (%) | 3 (10) | 1 (2.4) | 0.16 |

enrolled 234 patients with rectal cancer receiving LAR and found that the symptomatic anastomotic rate (including peritonitis caused by leakage from any staple line, rectovaginal fistula, and pelvic abscess) was significantly reduced by defunctioning stoma from 28.0% to 10.3% and the urgent reoperation rate was also decreased from 15.4% to 8.6%.[4] The operating time and intraoperative blood loss was not influenced by adding stoma creation to radical resection, but the patients with defunctioning stoma experienced a longer hospital stay. The impact of stoma creation on hospital stay was also evident and consistent with a previous study, which concluded that the temporary stoma prolonged the hospital stay in laparoscopic colorectal resection.[5] On the contrary, Lee *et al.* found that sphincter-preserving operations including CRA with stapled and hand-sewn CAA without defunctioning stoma yielded low anastomotic leakage rates (4~7.1%) and could be easily treated by conservative management, especially in patients receiving CAA.[6] The management of anastomotic leakage was not always easy and remained challenging sometimes. The option of treating anastomotic leakage without defunctioning stoma includes use of empiric antibiotics, reanastomosis, and creation of stoma to divert stool stream. The outcome of reoperation is sometimes unsatisfactory.[7] Another issue that should be taken into consideration is the complications during stool diversion and the morbidity after stoma closure. The benefit of defunctioning stoma in protecting distal anastomosis should be balanced by the stoma-related adverse events and the risk evaluation of stoma closure.[8] Some studies have tried to clarify the importance of defunctioning stoma in low rectal cancer surgery, while some randomized control trials seemed to have concluded that defunctioning stoma in LAR not only reduced the necessity of unanticipated reoperation, but directly decreased the clinical anastomotic leakage rate.[4,9-13] However, leakage -related mortality was not influenced.[4,10,12,13]

Increasingly, more rectal cancer patients are receiving neoadjuvant therapy before radical resection, especially in locally advanced disease. Even in cases of total or near total obstruction, staged operation with temporary stoma in combination with preoperative therapy is widely implicated. This revolution has led to tumor down-sizing, down-staging, and increased the possibility of performing sphincter-preserving surgery.[14-16] The addition of chemotherapy to radiotherapy could even strengthen the tumoricidal effect and lead to better pathologic response, especially in LARC.[17,18] Five-year incidence of local recurrent rate has also been reduced after adding preoperative chemotherapy; however, the role defunctioning stoma plays in radical proctectomy is not definitely clarified in the subgroup of patients receiving neoadjuvant CCRT. Our present study demonstrated no statistic difference in anastomotic leakage rate no matter whether defunctioning stoma was created or not. The necessity of reoperation in the scenario of anastomotic leakage was only 2.4% in the stoma group, but still had no significant difference compared to the no stoma group. Indeed, bias existed in our study: the group with stoma had less cases of LARC but shorter distance between anastomotic site and anal verge; therefore, surgeons much preferred the hand-sewn CAA technique in the stoma group. Regarding the risk factors of anastomotic leakage in patients receiving neoadjuvant CCRT and subsequent LAR, age, gender, BMI, emergent operation, histology, methods of surgery and anastomosis did not influence the anastomotic leakage rate (Table 3). Likewise, locally advanced disease and distance between anastomotic sites from the anal verge showed no impact on leakage rate either. Contrary to a prior study, the existence of defunctioning stoma, no matter whether via colostomy or ileostomy, did not reduce the risk of anastomotic leakage in LAR after CCRT. If we confined the anastomotic level to less than or equal to 4 cm from the anal verge (45 patients), defunctioning stoma can reduce the anastomotic rate from 21.4% to 12.9% and reoperation rate from 14.3% to 3.2% (Fig. 2), which is not statistically marked ($p = 0.47$ and $p = 0.18$ respectively). No patients with metastatic disease developed anastomotic leakage, but this was possibly because of the small number of metastases in our study. Anastomotic leakage undoubtedly increased the length of postoperative hospital stay.

We followed the patients receiving LAR with defunctioning stoma. The total complication rate was

**Table 3.** Risk factors of anastomotic leakage in radical proctectomy

| | No-Leakage (N = 62) (86.1%) | Leakage (N = 10) (13.9%) | *p*-value |
|---|---|---|---|
| Age, years (SD) | 62.2 (12.5) | 67.5 (8.4) | 0.11 |
| Male (%) | 36 (58.1) | 6 (60.0) | 0.91 |
| BMI (SD) | 23.3 (3.5) | 23.5 (3.8) | 0.92 |
| Histology (%) | | | 0.61 |
| WD | 10 (18.2) | 1 (10.0) | |
| MD | 43 (78.2) | 8 (80.0) | |
| PD | 2 (3.6) | 1 (10.0) | |
| Distance from anal verge, cm (SD) | 4.0 (2.4) | 3.7 (1.9) | 0.67 |
| Surgery method (%) | | | 0.86 |
| Open | 51 (82.3) | 8 (80.0) | |
| Laparoscopic | 11 (17.7) | 2 (20.0) | |
| Anastomotic Method (%) | | | 0.92 |
| Hand-sewn | 32 (51.6) | 5 (50.0) | |
| Double stapler | 30 (48.4) | 5 (50.0) | |
| Anastomosis by anatomy (%) | | | 0.78 |
| CAA | 28 (45.2) | 5 (50.0) | |
| CRA | 34 (54.8) | 5 (50.0) | |
| Defunctioning Stoma (%) | 37 (59.7) | 5 (50.0) | 0.57 |
| Type of Stoma (%) | | | 0.95 |
| Colostomy | 30 (81.8) | 4 (80.0) | |
| Ileostomy | 7 (18.9) | 1 (20.0) | |
| Operating time, minutes (SD) | 292 (123) | 212 (68) | 0.0396* |

BMI: body mass index.
WD: well differentiated; MD: moderately differentiated; PD: poorly differentiated.
CAA: coloanal anastomosis; CRA: colorectal anastomosis.

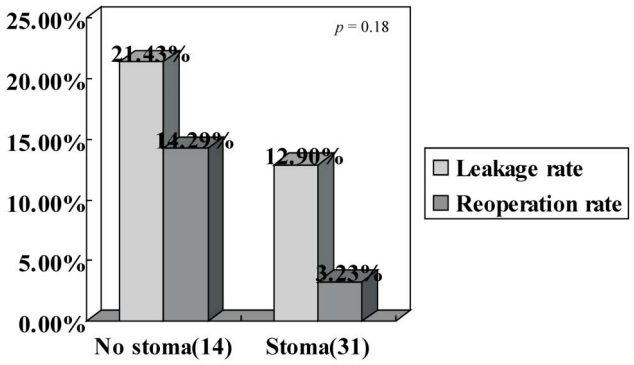


**Fig. 2.** Leakage rate and reoperation rate in the anastomotic level less than or equal to 4cm from the anal verge.

30.4% during stool diversion and electrolyte imbalance was the leading cause of this. Mostly, these complications could be managed promptly in the outpatient department and only 6.7% of patients were readmitted for stoma-related complications. There was no perioperative mortality of stoma creation and closure in our study. Postoperative ileus and surgical site infection were the main complications following stoma closure.

We are aware of the fact that our study is not prospective and therefore the surgeon-dependent decision of the anastomotic method and creating stoma is less evident. Further prospective studies with larger sample sizes need to be conducted to show the real value of defunctioning stoma in lower rectal cancer surgery receiving CCRT.

## Conclusions

Although defunctioning stoma group operations lengthen operating time and produces more intraoperative bleeding, it does not significantly decrease the anastomotic and reoperation rates in LARC patients receiving preoperative CCRT. We could still find its increasing importance when the anastomotic level was lower than or equal to 4 cm above the anal

verge. For ultra-lower-third rectal cancer, CRA or CAA in LAR should still be protected by defunctioning stoma.

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**原　著**

# 暫時性腸造口在局部廣泛性直腸癌患者接受術前化學放射協同治療後行低前位切除術中所扮演之角色

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**目的**　暫時性腸造口對低位直腸癌手術而言可以減少吻合處滲漏與再度手術之機率。術前放射性治療或同步化學放射治療則增加了局部廣泛性直腸癌施行括約肌保留手術之可能性。本篇文章在釐清暫時性腸造口在接受過化學放射協同治療後施行根治性直腸切除手術中所扮演的角色。

**方法**　從 2010 年 7 月至 2012 年 10 月，我們回朔分析 83 個曾接受術前同步化學放射治療之局部廣泛性直腸癌患者，75 人 (90%) 接受了根治性直腸切除手術，並且藉大腸直腸或大腸肛門吻合來重建腸道連續性。當中的 43 個 (57%) 個案同時施行了暫時性腸造口。

**結果**　根治性直腸切除手術合併暫時性腸造口的病人有較多的術中出血情形 ($p$ = 0.0281)。但吻合處滲漏與再度手術之機率並未因暫時性腸造口而有明顯減少。如果我們把吻合高度限制在距肛門口 4 公分或 4 公分以下，那暫時性腸造口可將低前位切除術吻合處滲漏機率從 21.4% 降到 12.5%，再度手術機率由 14.3% 降到 3.1%。

**結論**　雖然暫時性腸造口無法顯著地將曾接受術前化學放射協同治療之局部廣泛性直腸癌患者吻合處滲漏與再度手術之機率降低，但我們依舊可以發現，當吻合處高度在肛門口 4 公分或 4 公分以下，暫時性腸造口之重要性有提升之傾向。對於經術前化學放射協同治療後之超低位直腸癌，低前位切除術仍建議加作暫時性腸造口以保護吻合處。

**關鍵詞**　暫時性腸造口、直腸癌、同步化學放射治療、根治性直腸切除手術。