



## **Diverting stoma after low anterior resection for rectal cancer could reduce postoperative complications: a propensity score matching study**

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**Abstract:** Objective: This study evaluates the protective diverting stoma (DS) after low anterior resection (LAR) for rectal cancer regarding its impact on short-term surgical outcomes. Methods: All patients with rectal carcinoma referred to south Egypt Cancer Institute for surgical management between July 2011, and July 2017, were involved in the study. Patients (203 patients) who underwent LAR for rectal cancer with or without diverting stoma were recruited from our prospectively maintained database. Propensity score matching was used to minimize bias between the group who had diverting stoma and the group who did not have one. Demographic, clinical, operative and short-term surgical outcomes were reviewed and analyzed. Results: Sixty-one patients were included in each group. No significant difference in the demographic and clinico-pathological data was found between the two groups. The operative parameters between the 2 groups showed no significant differences in surgical approach, intraoperative contaminations or the way of anastomosis. Post-operatively, the overall complications rate was 34.5 %. The stoma group had a statistically significant lower rate of complications compared to patients without stoma (21.3% vs. 38.7, P=0.023). Significant differences were noted in postoperative ileus (P=0.03), pneumonia (P=0.03), surgical site infection (P=0.05), reoperation (P=0.04), and length of hospital stay, (P=0.001). There were no significant statistical differences in incidence of thromboembolic disorders (P=0.52), anastomotic leaks (P=0.07) or hospital mortality (P=0.07). ICU admission rate was significantly less (P=0.05). Conclusion: The diverting stoma after LAR for rectal cancer significantly decreased postoperative complications and the need for reoperation suggesting its protective role after LAR.

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### **1. Introduction**

Intestinal anastomotic leaks may be associated with decreased local control and survival [1, 2] and it is one of the most fatal complications that may occur following low anterior resection (LAR) for rectal cancer [3]. Even experienced surgeons may find difficulties in predicting which patient will have an anastomotic leak since leaks may occur even when the anastomosis is technically sound and the risk factors for leakage seem to be absent. When leakage occurs, it may be associated with increased morbidity, mortality, duration of hospital stay, as well as impairment of the short- or long-term quality of life [4, 5]. The role of a temporary diverting stoma in patients undergoing low anterior resection remains controversial. Some authors believe that the risk of leakage is sufficiently low so that routine diversion is

unnecessary [6]. Others have suggested reconstructing a protective stoma in risky patients such as those who undergo total meso-rectal excision (TME) with neo-adjuvant treatment, obese patients and those with low anastomoses as well as technically demanding procedures [7-9]. The aim of this study was to evaluate the impact of protective diverting stoma after low anterior resection for rectal cancer on short-term surgical outcomes.

## 2. Material and Methods

This study includes 203 patients who were pathologically diagnosed with rectal cancer and undergone low anterior resection in the period from July 2011 to July 2017. Patients were eligible for this study if they had primary rectal cancer in which the lower edge of the tumor was within 10 cm from the anal verge. For inclusion in this study, patients had to fulfill the following requirements preoperatively: age greater than 20 years; rectal adenocarcinoma proven on preoperative pathologic examination; no multiple rectal lesions; and receipt of LAR with hand sewn or stapler anastomosis. Exclusion criteria were an emergency operation for bowel obstruction and a history of major colorectal surgery. Clinical staging was done using one or more of the following methods: digital rectal examination, proctoscopy, barium enema, CT, MRI, and colonoscopy examination. The patients were given sufficient information about the procedure and written informed consents were obtained. The study was approved by the ethical committee at south Egypt cancer institute. The following parameters have been obtained from our institutional prospectively maintained database: demographic and clinico-pathological characteristics, surgical outcomes and complications and short postoperative outcomes and complications. Surgeries were performed by expert surgeons in colorectal surgeries. The finally recruited 203 patients were divided into two groups (those with or those without protective stoma after LAR). To reduce the bias between the groups, analysis by propensity score matching was performed. Propensity scoring was done by a logistic regression model and 1:1 matching technique using the following parameters: sex, age, body mass index (BMI), American Society of Anesthesia (ASA), pathological tumor staging (pTNM), neo-adjuvant therapy, laparoscopic or open procedure, anastomotic type (hand sewn or stapled) as well as serum albumin level and tumor size. Finally 61 patients were included in each group. The two groups were compared for the following: postoperative complications including anastomotic leak, ICU admission, hospital readmission within 30 days, lengths of hospital stay, reoperation and 30 day hospital mortality.

Definition of anastomotic leakage (AL):

Compromised intestinal wall integrity at the colorectal or coloanal anastomotic site, including the suture and staple lines of neo-rectal reservoirs that result in communication between the intra- and extra-

luminal compartments [3]. Clinical symptoms caused by AL were defined as the emission of gas, pus, or feces from the drain or wound or the vagina. Contrast enema radiography and CT were used to confirm any clinically suspicious symptoms, such as fever, peritonitis, or turbid drain discharge to be related to the anastomotic site or not. If imaging studies revealed the absence of anastomotic insufficiency, they were defined as pelvic abscess and not as AL.

### Statistical analysis:

Statistical package SPSS version 19 (SPSS, Chicago, IL, USA) was used to analyze data. Chi square test was used for categorical data and the Student's t-test used for continuous data. Data presented as numbers, percentage, and arithmetic mean (M) and standard deviation (SD). All P values refer to two-sided tests, and were considered statistically significant if P value  $\leq 0.05$ .

## 3. Results

Characteristics of the patients:

The clinical and pathological characteristics of LAR group with stoma and LAR group without stoma are presented in Table-1. After calculating the propensity scores to balance the covariates between the two groups, 61 patients were included in each group. The selected patients after propensity score matching did not show significant difference for the balanced parameters between the two study groups, Table-1.

Postoperative complication rate in stoma and non-stoma groups:

Post-operatively, the overall complications rate was 33.5 %. The stoma group had a statistically significant lower rate of complications compared to patients without stoma (21.3% vs. 38.7,  $P=0.023$ ). Patients in the stoma group had significantly decreased incidence of postoperative ileus ( $P=0.03$ ), pneumonia ( $P=0.03$ ), surgical site infection ( $P=0.05$ ), reoperation ( $P=0.04$ ), and length of hospital stay ( $P=0.001$ ). Anastomotic leakage has the tendency to be lower in stoma group compared to non-stoma group (6.6% vs. 16.2%,  $P=0.07$ ). There was no significant statistical difference in incidence of thromboembolic disorders ( $P=0.52$ ) however, hospital mortality has tendency to be lower in stoma group ( $P=0.07$ ). ICU admission rate was significantly less frequent in patients in stoma group in comparison to those in the non-stoma group ( $P=0.05$ ) (Table 2).

Table 1: Demographic and clinical parameters after propensity score matching:

Characteristics:	Stoma Group (61)	Non-Stoma Group (61)	P Value
Gender (M/F)	(29/31)	(32/29)	0.64
Age	49±14.3	51±15.6	0.22
BMI	29.1±5.3	29.8±6.4	0.81
DM	10(16.4%)	15 (24.6%)	0.26
COPD	8(13.1%)	6 (10%)	0.27
Smoking	15(24.6%)	17 (28.2%)	0.36
Normal albumin level	41(67.2%)	42 (69.0%)	0.46
Neo-adjuvant RTH	40(65.6%)	39 (64%)	0.046

Tumor stage:		0.31
A	21 (35.2%)	20 (33. %)
B	16 (26%)	16 (26.5%)
C	20 (33%)	22 (36.1%)
D	4 (5.8%)	3 (4.4%)

Table 2: Operative parameters and postoperative outcomes of the study groups:

Variables	Stoma Group (N=61)	Non-Stoma Group (N=61)	P value
Approach (lap/open)	11/50(18%/82.0%)	12/49 (19.7.5/80.3%)	0.1
Anastomosis (stapled/hand sewn)	20/41 (32.8%/67.2%)	19/42(31.2%/68.8%)	0.51
Intraoperative contamination	5(8.2%)	4(6.5%)	0.48
Post-operative Complications	13(21.3%)	23 (38%)	0.023
Ileus	2(3.3%)	10(17%)	<b>0.03</b>
Pneumonia	2 (3.3%)	7(12.0%)	<b>0.039</b>
Wound complications	5(8.2%)	10 (17%)	<b>0.05</b>
Anastomotic leakage	4(6.6%)	9(15%)	0.072
TED	1(1.6%)	2 (3.2%)	0.52
Reoperation	1(1.6%)	5(9%)	<b>0.04</b>
ICU Admission	2(3.2%)	7(11.3%)	<b>0.05</b>
30 days Readmission	3(4.9%)	8(12.7%)	0.07
LOS	10.7±4.4 days	15.2±9.1 days	<b>0.0001</b>
Hospital death	0	3(4.9%)	0.07

*TED*: Thromboembolic disorders, *LOS*: length of hospital stay

#### 4. Discussions

In the current study and after applying propensity score matching, we could show that postoperative incidence of complications were significantly less after stoma reconstruction and anastomotic leak tend to be less frequent.

One of the more common preventive measures of anastomotic leak (AL) is to create a diverting stoma (DS). However, the evidence of benefit for performing de-functioning stoma following LAR has been unclear. Various observational studies, systematic reviews and meta-analyses and other studies have reported a wide range of results. In a

recent clinical trial involving more than 1000 patients, the findings demonstrated that a DS could not significantly suppress anastomotic leakage incidence, instead, a DS was able to alleviate the consequences of anastomotic leakage by reducing the need for urgent abdominal reoperation [10-13]. Our study demonstrated a tendency for reduction in anastomotic leak rate and readmission rate in stoma group. Moreover, in this study ileus, pneumonia, wound complications as well as re-operation rates were significantly less frequent in patients with stoma diversion. Length of hospital stay shown to be significantly less after stoma formation in our study.

Therefore, our findings support the reconstruction of a temporary de-functioning stoma following LAR for low and mid rectal cancers.

The results of the present study are consistent with reported outcomes of several prior studies. These studies showed the higher leakage rates and reoperation rates for patients without stoma. Moreover, the odds of having symptomatic leakage following LAR was higher without stoma compared to those with diverting stoma. They also reported less incidence of urgent abdominal reoperation rate in patients with stoma compared to 25.4% in patients without stoma (8.6% vs. 25.4%) [7,14].

It's to be noted that measures of quality-of-life outcome were not included in our study. A temporary stoma could have a considerable impact on the physical and psychological status of the patient. This can be assessed using the 36-item Short-Form Health Survey (SF-36) [15]. A prospective longitudinal study was conducted in 22 patients with rectal cancer who underwent a LAR with loop ileostomy. The authors found significant reduction in European Organization for Research and Treatment of Cancer QLQ-CR38 and QLQ-C30 scores after the LAR procedure compared to baseline preoperative levels, indicating reductions in physical and role functioning. These scores markedly improved following ileostomy closure [16]. Moreover, many surgeons recorded that DS had no effect on leakage or reoperation, adding to this the probable complications that can occur during or after closure of DS [17-21]. Closing a protective DS indicates additional surgery, admission to a hospital, and a risk of complications and death [15, 22]. On the other hand, many surgeons think that they would harm their patients by preventing a protective DS because acceptable low rate of stoma-related complication could be achieved and an independent useful influence of DS has been demonstrated on anastomotic dehiscence [10-12-14].

Given the considerable quality-of-life implications, the decision to proceed with a stoma should be a highly individualized. The negative impact on role and function should be balanced with the reduction of postoperative complications specially reduction of the impact of anastomotic leak. Therefore a risk model of anastomotic leak following LAR may help in weighing up the risk of anastomotic leak with the reduction of quality of life and the rising risk of morbidity associated with a stoma [23].

Retrospective observational studies are susceptible to an inherent selection bias, in particularly favoring surgery without stoma. To minimize the effects of such bias, the present propensity score matched analysis pooled data from only prospectively maintained institutional data base that result in minimal heterogeneity detected in the

preoperative and operative data between the two groups.

The present study has several limitations. There has been a lack of reported long-term outcomes following stoma diversion or no diversion techniques for LAR therefore, the long-term morbidity associated with a diverting stoma is unclear. Some endpoints could not be pooled for analysis due to lack in the registered data, such as stoma retraction, obstruction, excoriation and prolapse. Our study also did not analyze quality-of life in the two groups. Certainly, the creation of a stoma regardless of its temporary or permanent status would reduce quality of life of patients in this population, particularly if stoma complications were to occur.

#### **Conclusion:**

The diverting stoma after LAR for rectal cancer significantly decreased postoperative short-term complications and the need for reoperation. So, DS can be useful for patients undergoing rectal surgery particularly after LAR for rectal cancer. Future randomized controlled trials are needed to address the long-term morbidity, mortality and quality of life issues related to DS in LAR for rectal cancer.

#### **Compliance with Ethical Standards:**

Conflicts of Interest: The authors declare that they have no conflicts of interests or financial ties to disclose.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the ethical committee at south Egypt cancer institute.

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