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Side-to-End Versus End-to-End Colorectal Anastomosis Following Anterior Resection of Rectal and Recto-Sigmoid Cancers, A Randomized Clinical Trial

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ABSTRACT

Background: Recto-sigmoid and rectal tumors are now treated with anterior resection as the gold standard. However, anastomotic leakage and the temporary use of a covering stoma after resection provide a significant problem for colorectal surgeons. The technique of anastomosis is critical in preventing anastomotic leakage. Some surgeons believe that side-to-end anastomosis is superior to end-to-end anastomosis, whereas others do not.

Objective: The current study was aimed to compare the surgical outcome, particularly the incidence of anastomosis leakage, between two groups using various surgical techniques.

Patients and Methods: This is a prospective randomized clinical trial (RCT) that included 107 patients with recto-sigmoid and rectal malignancies. Between March 2018 and March 2022, patients were treated at Ain-Shams University Hospitals with elective laparoscopic anterior resection. Patients were divided into two groups using sealed envelope method. Following anterior resection, Group A had side-to-end anastomosis (SEA) using a double stapling technique, while Group B had end-to-end anastomosis (EEA) utilizing a trans-anal circular stapler.

Results: After anterior resection, Group A (35 men and 20 women) received side-to-end anastomosis, while Group B (31 men and 21 women) underwent end-to-end anastomosis. There were no statistically significant differences between the two groups as regard body mass index (BMI), smoking and tumor location. The end-to-end anastomosis group had a statistically significantly longer mean operative time than the side-to-end anastomosis group (251.71 vs. 227.15 minutes, respectively) (P value 0.001). There was no statistically significant difference in anastomotic leakage between the two groups, with a P value of 0.262 (2 instances, 3.6% in SEA Group vs. 5 cases, 9.6% in EEA Group).

Conclusion: It could be concluded that side to end colorectal anastomosis could be an alternative to end to end with shorter operative time.

Keywords: anastomotic leakage, anterior resection, side to end anastomosis.

INTRODUCTION

The standard operation for rectal and recto-sigmoid cancer is anterior resection [1,2]. Despite advancements in laparoscopic equipment and, more recently, robotic surgery, anastomotic leakage remains a serious difficulty and a terrifying consequence that occurs in the early postoperative period following resection [2]. The incidence of anastomotic leakage has been documented in the literature ranging from 2% to 15%, regardless of temporary usage of a covering stoma [3]. Anastomotic leaking is complicated. However, many of these characteristics are still debatable. An increase in anastomotic leakage rate has been associated to male sex, increased BMI, and medical comorbidities such as diabetes, hypertension, and chronic illnesses [4].

On the other hand, the technique of the anastomosis represents a crucial factor in avoiding anastomotic leakage. It has been reported that blood flow is better at the anti-mesenteric border than at the end of the colon [5]. Moreover, blood flow at the anastomotic site is associated with anastomotic leakage [6]. Therefore, side-to-end anastomosis could be associated with a better outcome than end-to-end anastomosis. Furthermore, the principle of side-to-end anastomosis is considered the standard technique in other gastrointestinal surgeries, such as esophago-jejunal anastomosis.

The aim of this study was to compare the surgical outcomes in terms of the incidence of anastomotic leakage between the side-to-end anastomosis group (SEA group) and the end-to-end anastomosis group (EEA group) following anterior resection for recto-sigmoid and rectal cancers.

PATIENTS AND METHODS

This prospective randomized clinical trial included a total of 112 patients with recto-sigmoid and rectal malignancies, treated at Ain-Shams University Hospitals with elective laparoscopic anterior resection. This study was conducted between March 2018 and March 2022.

A preoperative colonoscopy and histopathological evaluation revealed that the patients had sigmoid or rectal cancer. Pre-operative tri-phase pelvic-abdominal computed tomography (CT) and pelvic magnetic resonance imaging (MRI) revealed no distant metastases. Curative resection (R0), followed by colorectal continuity repair with or without a covering stoma.

Following anterior resection, the included subjects were divided into two equal groups using sealed envelope randomization method; **Group A (SEA Group):** consisted of 56 patients who underwent side-to-end colorectal anastomosis (SEA) with double stapling (linear and trans-anal circular staplers) and **Group B**

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(EEA Group): consisted of 56 patients who underwent end-to-end colorectal anastomosis (EEA group) using a trans-anal circular stapler following resection

Inclusion criteria:

Patients over the age of 18 of both sexes with and without neoadjuvant treatment were included in our study. Patients had rectal or rectosigmoid cancers with no distant metastasis, who underwent curative resection (R0) followed by colorectal anastomosis.

Exclusion criteria: We excluded patients presenting with obstructing, perforating, or non-resectable carcinomas. Patients with previous colonic or ano-rectal surgeries.

Surgical Technique:

All patients had laparoscopic anterior resections by the same surgical team at Ain Shams University Hospitals. A medial to lateral approach was done. Splenic flexure mobilization was performed to avoid tension on the anastomosis. After ligation of the inferior mesenteric vessels, total meso-rectal excision was done. After the dissection is complete, achieving 2 cm below the tumor, the rectum is stapled using an Endo-GIA stapler. At this point, the left iliac fossa wound widened with muscle splitting. The wound protector was applied and the descending colon was exteriorized. The proximal transaction point was identified and the colon was divided.

Group A (side to end anastomosis): The anvil of the circular stapler was inserted in the ante-mesenteric border of the descending colon 4 cm proximal to the transection point, then a linear stapler was applied at the end point of the colon. as shown in figure 1.

Group B (end to end anastomosis) A purse suture was applied over the anvil of the circular stapler at the transection point of the descending colon using prolene 2/0.

In both groups, the pneumoperitoneum was reestablished, the anvil was inserted in its trans-anal circular stapler under laparoscopic view to avoid twisting of the descending, and the anastomosis was carried out**.**

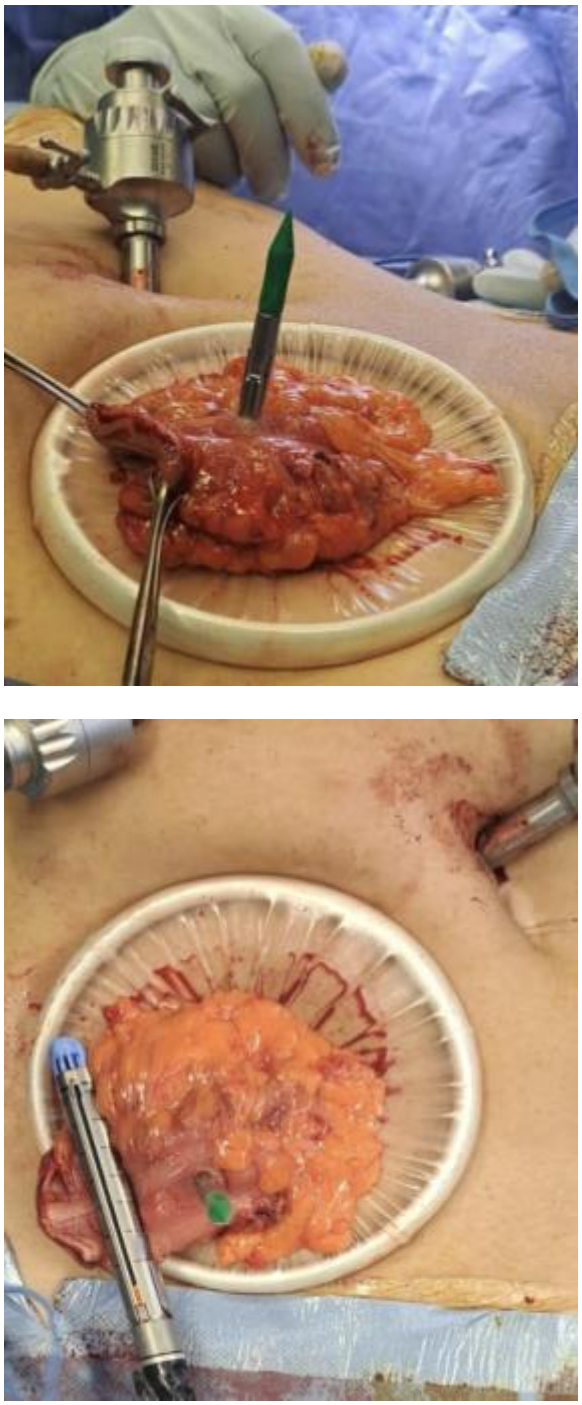

Figure (1): The anvil of circular stapler projected through the antimesenteric border of the colon.

Study outcomes and measurement

Primary outcome: to determine the incidence of anastomotic leakage in both groups.

Secondary outcomes include operative time (in minutes), intraoperative hemorrhage (in mL), vessel injury during surgery, hospital stay (in days), wound infection at any time point, and in-hospital mortality.

Definition of postoperative complications

According to The International Study Group of Rectal Cancer (ISREC), they depicted an anastomotic leak and assigned grades A, B, and C for a well-organized plan for dealing with an anastomotic leak after colorectal surgery [(7)].

Clinically, anastomotic leakage was described as (fever, abdominal pain, draining contents, and an increased inflammatory response) and radiologically by (i.e., a computed tomography scan and a contrast enema study). Peritonitis developed as a result of staple line leakage or the presence of a pelvi c abscess. Patients with Grade A anastomotic leakage did not require further intervention. Patients with Grade B anastomotic leaks require minimally invasive treatments such as ultrasound-guided aspiration or pigtail insertion. Grade C patients had anastomotic leakage that necessitated reoperation or relaparoscopy.

During the early postoperative period, patients were monitored for symptoms of anastomotic leakage, ileus, and surgical site infections graded as Grade II or higher using the Clavien-Dindo classification [(8)]. Hospital stay was defined as the time spent in the hospital from admission to discharge. Surgical site infection (SSI) was defined as any sign of infection (erythema, purulent discharge, discomfort) that necessitated antibiotic treatment and/or wound opening.

Postoperative follow up

All patients started oral fluids on the 4th postoperative day. Both groups were followed-up clinically for early signs of leakage. If any suspicious signs were detected, such as unexplained fever, tachycardia, or signs of peritonitis, abdominal and pelvic computed tomography with oral and intravenous contrast was scheduled. According to patient hemodynamics, laboratory investigations, and radiological findings, the plan of management was scheduled for either conservative care or surgical intervention.

Ethical Considerations

All patients signed a written, informed consent describing the procedure and possible postoperative complications. The study was approved by the Ethical Committee and Institutional Review Board, General Surgery Department, Ain Shams University. All surgeries were performed by the same surgical team.

Statistical analysis

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) Shapiro wilk's test was used to evaluate normal distribution of continuous data. Student t test was used to compare a Quantitative variable between two study groups. Chi square and Fisher's exact test were used to examine the relationship between Categorical variables. A P-value< 0.05 was considered statistically significant

RESULTS

This was a prospective RCT that included 112 individuals with recto-sigmoid and rectal malignancies. 56 individuals received side-to-end colorectal anastomosis (SEA) with double stapling after elective laparoscopic anterior resection (linear and trans-anal circular staplers). (Because one patient had an intra-operative low rectal tumor during resection with no safety margin below, a colo-anal anastomosis was created, making this group had 55 patients.)

Following resection, 56 patients received end-to-end colorectal anastomosis (EEA) with a trans-anal circular stapler (two patients accidently had intra-operative low rectal tumors during resection with no safety margin below. So, Colo-anal anastomosis was fashioned. Two other patients were lost during the follow up period, so this group had 52 patients).

Table (1): Comparison between the two study groups as regards demographic criteria and pre-operative data

		Group				P	Sig
		Group A		Group B			
		Mean	±SD	Mean	±SD		
Age (years)		59.44	5.49	59.75	5.42	0.76‡	NS
BMI (kg/m^2)		25.40	2.20	25.98	2.74	0.22‡	NS
Sex	Female	20	36.4%	21	40.4%	0.669*	NS
	Male	35	63.6%	31	59.6%		
Smoking	No	41	74.5%	35	67.3%	0.409*	NS
	Yes	14	25.5%	17	32.7%		
Tumor site	Low rectum	5	9.1%	6	11.5%	0.223*	NS
	Mid rectum	12	21.8%	5	9.6%		
	Recto- sigmoid	38	69.1%	41	78.8%		
P stage	1	20	36.4%	17	32.7%	0.231*	NS
	2	5	9.1%	12	23.1%		
	3	23	41.8%	16	30.8%		
	4	7	12.7%	7	13.5%		
Preoperative .chemo-radiation	No	50	90.9%	45	86.5%	0.474*	NS
	Yes	5	9.1%	7	13.5%		

student t test. Fisher's exact test. *Chi-Square Tests

After anterior resection, Group A (35 men and 20 women) underwent side-to-end anastomosis (SEA group), while Group B (31 men and 21 women) received end-to-end anastomosis (EEA group). Between the two groups, BMI and smoking were shown to be statistically insignificant. P\ stage was evaluated using the American Joint Committee on Cancer and Union for International Cancer Control's Eighth Edition tumor-node-metastasis staging criteria, and BMI (body mass index) was statistically negligible between both groups. There was no statistical significance between the two groups in terms of tumor location. In 38 of the SEA instances and 41 of the EEA cases, the tumor appeared to be in the recto-sigmoid region, which was statistically insignificant. In groups A and B, the tumor was in the lower rectum in five and six patients, respectively, and this was statistically insignificant. Furthermore, 12 cases received preoperative neoadjuvant chemotherapy and radiotherapy, 5 in group A and 7 in group B and this was statistically insignificant between both groups.

Table (2): Comparison between the two study groups as regards the intraoperative data

		Group				P	Sig
		Group A		Group B			
		Mean	±SD	Mean	±SD		
Time		227.15	36.34	251.71	19.20	**0.001**‡	**HS**
Complications	Bleeding	3	5.5%	2	3.8%	1.0**	NS
	Negative	52	94.5%	50	96.2%		
ligation of pedicle	Low	38	69.1%	44	84.6%	0.058*	NS
	High	17	30.9%	8	15.4%		
Operation	HAR	38	69.1%	41	78.8%	0.251*	NS
	LOW	17	30.9%	11	21.2%		
convert to open	No	52	94.5%	47	90.4%	0.481**	NS
	Yes	3	5.5%	5	9.6%		
Stoma	With	18	32.7%	10	19.2%	0.112*	NS
	Without	37	67.3%	42	80.8%		

‡Student t test. **Fisher exact test. *Chi-Square Tests.

The mean operative time differed statistically between the two groups (P value is 0.001). In Group B, the average operative time was 251.1 minutes, compared to 227.15 minutes in Group A.

In terms of vascular pedicle ligation, low ligation of the pedicle referred to ligation of the inferior mesenteric artery while sparing the left ascending colic branch, which was done in 38 cases in group A and 44 cases in group B. In the presence of a pathologically enlarged lymph node on the inferior mesenteric artery, high ligation of the pedicle implied ligation of the inferior mesenteric artery proper, which was done in 17 cases in group A and 8 cases in group B, and this was statistically insignificant between both groups. There is no statistical difference between the two groups in cases of high anterior resection (HAR): 38 cases in group A and 41 cases in group B. Furthermore, with no statistical significance, there were 17 cases of low anterior resection (LAR) in group A and 11 cases in group B. There was no statistically significant difference between the two groups when three in group A and five in group B were switched to the open method.

Table (3): Post -operative data in both groups

		Groups				P	Sig
		Group A		Group B			
		Mean	±SD	Mean	±SD		
Hospital Stay		7.87	1.84	8.29	1.98	0.30‡	NS
AL	No	53	96.4%	47	90.4%	**0.262***	**NS**
	Yes	2	3.6%	5	9.6%		
SSI	No	54	98.2%	48	92.3%	0.197**	NS
	Yes	1	1.8%	4	7.7%		
Ileus	No	52	94.5%	46	88.5%	0.311**	NS
	Yes	3	5.5%	6	11.5%		
Mortality	NO	55	100.0 %	52	100.0 %	N/A	N/A

‡Student t test. **Fisher exact test. *Chi-Square Tests
(AL , anastomotic leakage , SSI, surgical site infection)

There was no statistically significant difference in anastomotic leakage between the two groups, with a P value of 0.262 (2 instances, 3.6% in group A vs. 5 cases, 9.6% in group B). Without statistical significance, the mean hospital stay in the SEA group was 7.87 days compared to 8.29 days in the EEA group. Furthermore, there was no statistically significant difference in surgical site infection frequency between groups A and B. There was no statistically significant difference between the two groups in terms of postoperative ileus. Furthermore, Group A has 18 cases that necessitate an overlying stoma, but Group B only had 10 cases with no statistical significance. Finally, neither group reported any deaths.

DISCUSSION

Despite developments in laparoscopic setups and varied procedures, anastomotic leaking remains a significant concern for colorectal surgeons after resection. In this study, we compared the surgical outcomes of two different colorectal anastomosis methods after laparoscopic rectal cancer resection: group A (SEA) side-to-end anastomosis and group B (EEA) end-to-end anastomosis. There was no statistically significant difference in anastomotic leakage between the two groups. The anastomotic leakage rate was lower in the SEA group than in the EEA group (3.6% vs. 9.6%, with a P value of 0.262). In terms of postoperative complications, the SEA group outperformed the EEA group without statistical significance. The SEA is a more secure alternative to the EEA.

Anastomotic leakage is a significant predictor of the surgical outcome after resection of gastrointestinal cancers. According to the literature, the incidence of anastomotic leakage after rectal and rectosigmoid cancer surgeries ranged from 3.2% to 11.6% (10). Our study findings were consistent with those of **Brisinda *et al.* [9],** who compared the surgical outcome between the side-to-end anastomosis group in 40 patients and the end-to-end anastomosis group in 37 patients with T1 and T2 rectal carcinoma after laparoscopic resection. They came to the conclusion that side-to-end anastomosis minimizes the occurrence of anastomotic leakage. Anastomotic leak was statistically substantially lower in the side-to-end group than in the end-to-end group (5% vs. 29.2%, with a significant p value of 0.005). In addition, they claimed that an end-to-end anastomosis technique is a safe procedure in terms of postoperative complications.

Based on the idea that blood flow is better on the colon's antimesenteric border than at the distal end [10]. **Kato and colleagues [11]** included 162 rectal cancer patients in a randomized controlled comparative trial comparing side-to-end versus end-to-end anastomosis. They reported 4.8% anastomotic leakage in the side-to-end group versus 18.2% leakage in the end-to-end group, with a statistically significant p value of 0.02.

Previous studies have shown that anastomotic leaks can be induced by a number of characteristics, including male gender, tumor location (distal-located tumors in rectal malignancies are more prone to anastomotic leakage following resection than proximal ones), and BMI (obese and super obese patients are more liable for anastomotic leakage). However, the anastomosis technique (hand sewn or stapled, side to end or end to end) remains a point of contention [12–14]. Additionally, the main surgical technique-related causes of anastomotic leakage are a lack of blood flow to the anastomosis site and strain on the anastomosis [14]. In the current study, there was no statistically significant difference between the two groups in terms of age, gender, BMI, or tumor site. The majority of tumors were located in the recto-sigmoid region in 38 (69.1%) of the SEA cases and 41 (78.8%) of the EEA cases, with no statistical significance.

Even though laparoscopically assisted total mesorectal excision (TME) is commonly utilized for radical rectal cancer resection, the optimal degree for IMA ligation is still debatable [15]. Previous studies have found that low ligation of the inferior mesenteric artery during TME may enhance blood flow to the anastomosis site [16-17]. Besides that, there was no link between the level of IMA ligation and the rate of lymph node harvest, tumor recurrence rate, metastasis, or mortality [18]. **You *et al.*** [18] reported that low IMA ligation is safe and associated with a minimal risk of anastomotic leak and stricture. In the current study, the inferior mesenteric artery was ligated low, sparing the ascending left colic artery in 38 patients in the SEA group (69.1%) and 44 patients in the EEA group (84.6%), with a negligible P value (0.058).

According to several studies, anastomosis stricture occurs in 8% of instances and is caused by anastomotic site ischemia or anastomotic leakage [19]. Despite the fact that the end-to-end group had a slightly greater frequency of anastomotic leakage than the side-to-end group, no cases of anastomosis stricture were found in either group during the postoperative follow-up period. **Back *et al.*** [20] additionally emphasize the significance of measuring mucosal blood flow in the remaining rectal stump with a laser Doppler flow metric study in order to decrease stricture induced by stump ischemia.

Smoking is a risk factor for anastomosis leakage because it reduces mucosal blood flow [21]. In the current investigation, 14 patients (25.5%) in group A were smokers, compared to 17 smokers (32.7%) in group B, with no statistically significant difference. The smoking index was one of the limitations of this study as it discriminates between current and ex-smokers. Moreover, it may be useful to determine the relationship between anastomotic leakage and smoking history.

For many years, the utility of a protective stoma has been a source of debate. It has been thought to minimize leakage and its catastrophic consequences [22]. On the other hand, previous publications have stated that the overall leakage and reoperation rates were similar in patients with and without a protective stoma [23]. In a meta-analysis of 11 publications on the role of the covering stoma in anastomotic leakage following rectal surgery, they concluded that creating a covering stoma in low anterior resection considerably lowered the incidence of anastomotic leaks and the number of reoperations associated with leakage [24]. In the present study, covering loop ileostomies were performed in mid and low rectal carcinoma patients as the blood flow to the rectal stump is impaired after resection. We performed covered stomas in 18 patients in the SEA group (32.7%) and 10 cases (19.2%) in the EEA group. The P value was statistically insignificant (0.112).

Regarding the operating time, the end-to-end anastomosis group had a statistically significantly longer mean operative time than the side-to-end anastomosis group (251.71 vs. 227.15 minutes, respectively) (P value 0.001). This may be due to the time consumed in the purse-string technique in the EEA group in comparison to the use of linear staplers in the SEA group. Finally, there was no statistical difference between the two groups in terms of hospital stay, surgical site infection, or postoperative ileus.

Hou *et al.* [25] investigated the functional results of patients with low anterior resection who had a side-to-end, colonic J-pouch, or end-to-end anastomosis. They stated that side-to-end colorectal anastomosis is superior to end-to-end anastomosis in terms of restoration of the bowl's function in the early postoperative period. In 2008, **Akira and his colleagues** [26] examined the functional outcomes of a side-to-end (SEA) anastomosis, a colonic J-pouch (CJP) reconstruction, and an end-to-end anastomosis (EEA) in 49 patients following low anterior resection by postoperative manometric studies. They concluded that the functional outcomes of the SEA anastomosis are equivalent to the CJP reconstruction and superior to the EEA anastomosis in the early postoperative period

In the present study, there were several limitations. First, the judgment on anastomosis tension and the need for covering a stoma were subjectively determined by the surgeon. Therefore, the use of Indocyanine Green Angiography (ICG) may be objectively beneficial for the determination of blood flow to the anastomosis surface. Second, assessments of the functional outcome using anal manometric studies and low anterior resection syndrome questionnaires were not obtained from both groups. To validate our findings, several multi-center, prospective, randomized studies on a large number of patients are required.

CONCLUSION

It could be concluded that side-to-end colorectal anastomosis could be an alternative to end-to-end with a shorter operative time, for patients undergoing anterior resection for recto-sigmoid and rectal cancers. More research with a larger sample size, assessment of functional outcomes for each modality of anastomosis, and longer follow-up to assess late consequences are required.

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