Diverting ileostomy in low anterior resection: single center retrospective analysis

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ABSTRACT:
Introduction: Low anterior resection (LAR) is the standard procedure for distal rectal cancer allowing anal sphincter preservation. Anastomotic leakage remains one of the most dangerous complications following LAR and its management is difficult.

Aim: This study reviews our experience of LAR with and without protective ileostomy (PI).

Methods: One hundred ninety-nine patients undergoing LAR resection for low rectal cancer in this centre during the period 2015–2019 were divided retrospectively into two groups. Group A underwent rectal resection and coloanal/rectal anastomosis with diverting ileostomy and group B without ileostomy.

Results: Among our patients, 20 had a covering ileostomy (stoma group); 179 did not (control group). The stoma group comprised 14 men and 6 women ranging in age from 36 to 89 years (mean, 64.2 ± 10.5 years). Conventional v. minimally invasive surgery was 6/14. Anastomotic leakage occurred in 16/179 (8.93%) patients without a PI, and in 6/20 (30%) with a stoma (Tab. I.). Of the 16 patients experiencing an anastomotic leak, 3 (18.75%) from Group A and 5 (83.33%) from Group B were classified as Grade B leakage and were treated conservatively. As many as 13/16 (81.25%) in Group A and 1/6 (16.77%) in Group B were classified as Grade C leakage and required emergency surgery.

Conclusion: These results do not show a preventive effect on the occurrence of anastomotic leakage in low anterior resection, but may significantly reduce the need for further surgery due to septic complications in the early postoperative period. Selection of patients for protective ileostomy requires great care as its creation and closure are associated with severe complications.

KEYWORDS: anastomotic leakage, diverting ileostomy, low anterior resection

ABBREVIATIONS
AL – anastomotic leakage
EEA – end-to-end anastomosis
IMA – inferior mesenteric artery
LAR – low anterior resection
PI – protective ileostomy
QOL – quality of life
TA – Thoracoabdominal
TME – Total Mesorectal Excision
TNM – Tumor Nodule Metastases

INTRODUCTION
Low anterior resection (LAR) is the standard procedure for distal rectal cancer that allows anal sphincter preservation. Despite that anastomotic leakage remains one of the most threatening complications after LAR. Leakage is defined as a communication between the intra- and extraluminal compartments due to a defect in the integrity of the intestinal wall at the anastomotic area between the colon and the rectum [1]. In the last decade, this problem has been widely discussed. Postoperative anastomotic leakage (AL) is a major complication in rectal surgery that affects the quality of life (QOL), significantly increases morbidity, mortality and worsens the oncologic outcomes [2, 3]. Despite the evolution of surgical techniques and instruments, its rate remains high, at 3 to > 20%. Even experienced surgeons had difficulties to predict which patients would develop an anastomotic leak, and leaks may occur even when the anastomosis looks intact and the risk factors for leakage are not present. Multiple studies have demonstrated that low anastomoses carried a higher risk of complications.

There are many options that surgeons use to prevent leakage, such as mechanical bowel preparation, drains, intra-luminal devices. Some surgeons use protective stoma. They believe that the fecal diversion will give rest to anastomosis, and this will prevent the leakage. However, opponents of fecal diversion disagree with this and have reported that the “protective ostomy” has no influence on anastomotic leakage and reoperation rates. Furthermore, they believe that the complications that can be caused by the stoma itself should not be ignored [4, 5].

Although protective stomas are widely used in LAR for rectal cancer, it remains unclear whether such procedures are useful for the patients.

AIM
The aim of this study is to analyze the protective feature of the stoma, as well as to compare the complications in the groups with and without ostomy.
Study design

The study was designed as a single-center retrospective cohort study for the period of 2015–2019 years. Patients’ selection (with low rectal cancer) was performed at the Department of Surgery in University Hospital "Kaspela", Plovdiv, Bulgaria. They were distributed into two groups: with rectal resection and coloanal/rectal anastomosis with a diverting ileostomy (group A) or rectal resection and coloanal/rectal anastomosis without protective stoma (group B). Patients in both groups were with low anastomoses. The main criterion for diverting ileostomy was a high leakage score. To evaluate it we used PROCOLE (Prognostic Colorectal Leakage-Weight of the factors for the calculation of the prognostic index of anastomotic leak).

In accordance with the study protocol, all patients were assessed preoperatively and during their hospital stay for primary surgery. Those with diverting ileostomy were assessed additionally at the time of stoma reversal, 8–12 weeks after hospital discharge. The others, without stoma, underwent a follow-up visit 10 weeks after the initial rectal resection. The study protocol was approved by the local ethics committee and institutional review board.

Patient population

Patients aged 19–85 years with biopsy-proven and resectable rectal cancer, with or without neoadjuvant chemo/radiation therapy. The following data were gathered and collected: pre-operative (gender, age, body height and weight, body mass index, smoking habits, pre-operative chemo/radiation therapy, tumor location, cTNM, blood chemistry including serum albumin, ASA status), intraoperative data (anastomotic height, intraoperative blood loss, duration of surgery, intra-op adverse events), postoperative data during primary hospitalization (anastomotic leakage, treatment of leakage, postoperative complications and morbidity, pTNM stage, duration of hospital stay) and data from hospital stay for ileostomy closure (days until closure, duration of stay, complications).

All patients underwent preoperative mechanical bowel preparation and received antithrombotic prophylaxis. Prophylactic intravenous single-shot antibiotic was given 30–60 minutes before the anesthesia.

The patient is brought to the operating room and general anesthesia is administered with the placement of an endotracheal tube. A Foley catheter is steriley placed within the bladder. Then it is moved to the lithotomy position with the weight of the leg resting on the heel and appropriate support provided to alleviate pressure from both the low back and the lateral peroneal nerve of the lower leg. The arms are placed on arm boards bilaterally so as not to cause undue stretch on the brachial plexus.

Mini-invasive group

The technique of surgical resection was constant; all of the surgeries were accomplished or assisted by only two surgeons. In both groups, surgery started laparoscopically with Verres needle or Hasson technique, followed by routine abdominal exploration to
rule out distant metastasis. Complete mobilization of the left colonic flexure only if the sigmoid colon is short and could not reach the pubic tubercle, high ligation of the inferior mesenteric vein, and flush ligation of the inferior mesenteric artery at 2 cm distal from the aorta, preserving the hypogastric nerves, was performed in all cases. Tumors of the mid and low rectum were resected by TME to the pelvic floor.

**Open technique**

A midline vertical subumbilical incision was made. Once access to the abdomen was gained, the abdomen was explored for signs of metastatic disease of the peritoneal surfaces and the liver. The tumor was manually inspected within the pelvis to assess fixation and likelihood of invasion to surrounding structures. The abdominal self-retractor was used for adequate exposure. Mobilization of the colon begun laterally along the white line of Toldt. The ureter was identified at the bifurcation of the common iliac artery. After mobilization the length of the colon was grossly estimated and, subsequently, the need to mobilize the splenic flexure assessed. The inferior mesenteric artery (IMA) pedicle was isolated and doubly ligated. The IMV was also ligated. The bowel was subsequently transected at a level ensuring adequate blood supply to the remaining colon. TME was undertaken for adequate oncologic resection. After identifying the sympathetic nerves traveling over the pelvic brim, electrocautery was used to dissect the posterior avascular, alveolar plane between the fascia propria of the rectum and the parietal fascia of the pelvic floor structures, with the rectum being retracted anteriorly. This, when undertaken accurately, allows for sparing of the autonomic nerves as well as the surrounding pelvic structures and results in a smooth mesorectal specimen. Middle and distal rectal tumors require removal of the entire mesorectum. Multiple studies have shown that a 2-cm margin of the mucosa is likely more than adequate.

Mobilization of the rectum was performed and the level of transection was established. The mesorectum was divided with bipolar ligation. The rectal wall was transected using a stapling device, (TA) linear stapler or GIA, depending on the width of the pelvis. The length of the proximal colon was then evaluated for construction of a tension-free anastomosis. If more length was needed, a variety of maneuvers were employed. The size of the end-to-end anastomosis (EEA) stapler was decided by the caliber of the colon.

After completion of the anastomosis, anastomotic integrity was tested by air leakage test. Patient withdrawal from the study was warranted if a primary leak of the anastomosis was identified intraoperatively. Each patient with primary leak after air insufflation underwent anastomotic repair and fecal diversion. Drainage was placed in the pelvis at the end of the procedure.

In the postoperative period computed tomography scan and/or digital rectal examination or sigmoidoscopy were performed immediately in patients with clinical signs of anastomotic leakage and further management was planned. In diverted patients suffering from leakage and in those primarily not defunctioned undergoing fecal diversion owing to anastomotic leakage in their postoperative course, follow-up visits to investigate anastomotic integrity were performed and stoma closure was carried out after complete healing of the anastomoses. Stoma closure in an uneventful course was scheduled 8–12 weeks after the primary surgery.

**Anastomotic leakage**

In 2010, the International Rectal Cancer Research Group gave the definition of postoperative anastomotic leakage after surgical treatment of rectal cancer and further graded it as follows:

- **Grade A** is defined as subclinical anastomotic leakage (also known as imaging anastomotic leakage) without clinical symptoms or a requirement for special treatment;
- **Grade B** is characterized by abdominal pain, fever, and purulent or fecal-like drainage from the anus, drainage tube, or vagina (rectovaginal fistula); an increased white blood cell count and C-reactive protein concentration; and anastomotic leakage requiring conservative treatment;
- **Grade C** is characterized by peritonitis, sepsis, and other clinical manifestations of Grade B anastomotic leakage.

<table>
<thead>
<tr>
<th>Complications</th>
<th>No</th>
<th>%</th>
<th>Sp</th>
<th>Yes</th>
<th>%</th>
<th>Sp</th>
<th>χ²</th>
<th>P</th>
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<tr>
<td><strong>Wound infection</strong></td>
<td>N</td>
<td>%</td>
<td>Sp</td>
<td>N</td>
<td>%</td>
<td>Sp</td>
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<tr>
<td>3</td>
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<td>22%</td>
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<td>1</td>
<td>14.29%</td>
<td>13%</td>
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<td><strong>Parastomal area maceration</strong></td>
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<td>0%</td>
<td>4</td>
<td>57.14%</td>
<td>19%</td>
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<td><strong>Dehydration</strong></td>
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<td>0.00%</td>
<td>0%</td>
<td>1</td>
<td>14.29%</td>
<td>13%</td>
<td></td>
<td></td>
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<tr>
<td><strong>Intestinal obstruction</strong></td>
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<td>20.00%</td>
<td>18%</td>
<td>0</td>
<td>0.00%</td>
<td>0%</td>
<td></td>
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<tr>
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<td>0.00%</td>
<td>0%</td>
<td>1</td>
<td>14.29%</td>
<td>13%</td>
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<tr>
<td><strong>Dysuria</strong></td>
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<td>20.00%</td>
<td>18%</td>
<td>0</td>
<td>0.00%</td>
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<tr>
<td><strong>Totally</strong></td>
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<td>100.00%</td>
<td></td>
<td>7</td>
<td>100.0%</td>
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<tr>
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<th>%</th>
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<td>3.5%</td>
<td>1.3%</td>
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<td><strong>conservative treatment</strong></td>
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<td>0.5%</td>
</tr>
<tr>
<td><strong>Intestinal obstruction surgery</strong></td>
<td>1</td>
<td>0.5%</td>
<td>0.5%</td>
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Tab. III. Complications after hospital discharge in patients with and without diverting ostomy.

Tab. IV. Complications after ileostomy reversal.
requiring a secondary surgery. By combining the above standards, patients who met any one of the following four criteria were determined to have anastomotic leakage in the present study: the drainage tube near the pelvic anastomosis drained the intestinal contents or had a fecal odor, outflow of contrast agent was observed by digestive tract radiography, gas accumulation and intestinal wall discontinuity were found around the anastomosis site by computed tomography examination, or the anastomotic opening was confirmed by anal palpation using a finger. These findings were combined with other clinical evidence of anastomotic leakage, such as fever, chills, positive blood culture, or high leukocyte count.

Statistical methods

Data are expressed as mean ± standard deviation and were analyzed with SPSS version 22.0 statistical software (IBM Corp., Armonk, NY, USA). Comparison between the groups was made with the Pearson Chi-squared test, Shapiro-Wilk test or Fisher exact test for qualitative variables. Differences were considered statistically significant at P < 0.05.

Results

In total, 199 patients were qualified for this study after inclusion and exclusion criteria. Among them, 20 underwent protective ileostomy (stoma group) and 179 did not (control group). The stoma group comprised 14 men and 6 women ranging in age from 36 to 89 years (mean, 64.2 ± 10.5 years). The conventional to mini-invasive surgery ratio is as follows: 6:14. The tumor stages were: stage I in 0 patients, stage II in 1, and stage III in 19. The histological classification was: highly differentiated adenocarcinoma in 7 patients, moderately differentiated adenocarcinoma in 4, poorly differentiated adenocarcinoma in 92, moderately differentiated adenocarcinoma in 48 patients, moderately differentiated adenocarcinoma in 24, and mucinous adenocarcinoma in 1.

The control group comprised 89 men and 88 women ranging in age from 35 to 82 years (mean, 61.7 ± 10.3 years). Laparoscopic surgery was performed in 124 patients, and laparotomy in 55. The tumor stage was as follows: stage I in 5 patients, stage II in 31, stage III in 129, and stage IV in 12. The histological classification was highly differentiated adenocarcinoma in 48 patients, moderately differentiated adenocarcinoma in 92, poorly differentiated adenocarcinoma in 24, and mucinous adenocarcinoma in 15.

We compared the typical factors for anastomotic leakage: anastomotic height, sex, age, stage, neoadjuvant chemo/radiation therapy, hypoproteinemia, use of corticosteroids and NSAIDs, blood transfusions, diabetes, BMI, smoking habit, ASA score, operative methods, intraoperative blood loss, duration of surgery, air leakage test. In our study we found a correlation between anastomotic height (χ² = 12.52, P = 0.01), patients’ sex (χ² = 5.73, P = 0.02) and increased risk for anastomotic leakage. The other factors did not increase the risk: age (χ² = 0.85, P = 0.48), stage (χ² = 6.99, P = 0.22), neoadjuvant chemotherapy (χ² = 1.17; P = 0.23) or radiation therapy (χ² = 0.23, P = 0.63), hypoproteinemia (χ² = 0.02, P = 0.89), use of corticosteroids (χ² = 0.00, P = 0.99) and NSAIDs (χ² = 2.88; P = 0.09), blood transfusions (χ² = 3.47; P = 0.07), diabetes (χ² = 0.05; P = 0.78), BMI (χ² = 4.62, P = 0.13), smoking habit (χ² = 0.08, P = 0.78), ASA score (χ² = 3.80, P = 0.43), operative methods (χ² = 0.19, P = 0.59), intraoperative blood loss (χ² = 3.61, P = 0.16), duration of surgery (χ² = 1.17, P = 0.09).

Air leakage test in this research shows high predictive value for anastomotic complications (χ² = 8.12, P = 0.00).

We observed anastomotic leakage in 16/179 (8.93%) cases without PI, and in 6/20 (30%) with stoma (Tab. I.). It was interesting to compare the treatment strategies in both groups, and we found that 3/16 (18.75%) patients in the first group and 5/6 (83.33%) in the second one were classified as Grade B leakage and were treated conservatively, while 13/16 (81.25%) in the first and 1/6 (16.77%) in the second group were Grade C and required emergency surgery.

Complications that we noticed in the postoperative period are shown in Tab. II.

It was interesting to compare their rate in group A and B. For better evaluation we started with complications in the early post-op period.

It is easy to notice that the complication rate is much higher in stoma group patients – 23.46% vs. 55% (P = 0.01). We continued with two groups and focused on complications after hospital discharge (Tab. III.). And again, we obtained a similar result, P = 0.04 (Tab. IV.).

When we evaluated the mortality rate in both groups we found a significant difference again. Mortality due to small intestine anastomotic leakage after ileostomy reversal was found in 1 patient (5%) and because of septic complications of colorectal anastomosis leakage in 2 (1.11%), P = 0.04.

DISCUSSION

Diverting loop ileostomies have become a common procedure during low rectal anastomosis. Some authors think ostomy creation can reduce morbidity and avoid early resurgery if a leak occurs. But fecal diversion is also associated with complications in the early postoperative period, after hospital discharge, and the patients need another surgery for ostomy closure. This reversal procedure, as many published series have shown, can be associated with a high morbidity and mortality rate [6]. In a recent systematic review, high morbidity associated with ileostomy reversal raised concerns over the benefits of diverting stomas related to clinical outcomes and because of this a better selection of patients should be made.

According to Luglio et al., a > 5% risk of anastomotic leak in the primary operation requires a creation of a protective stoma. In our study, the anastomotic leakage rate was 11% but we did not prefer a routine stoma [7].

Complication rate after ileostomy take down and postoperative morbidity were high (35%). The most common complications in our study were postoperative ileus and wound infections. Complications were mostly minor, classified as Clavien-Dindo I-II, and 23% were considered major complications requiring reoperation or invasive interventions (Clavien-Dindo III). In a study by Mengual-Ballester et al. data were similar to ours, with complications up to 45.9%, ileus/obstruction being the most frequent one, followed by diarrhea and wound infection [8].
Early postoperative ileus is pointed out by surgeons as the most common complication that occurs in 1–15% after protective ileostomy reversal [9]. In most cases, conservative treatment is sufficient but in a numerous patients surgery is needed. The most common finding (in almost 90% of the cases) is the adhesions. We registered this complication in 7.14%, a result that is equivalent to that indicated by most authors.

Ostomy wound infection is the second most common complication and depends on individual preferences of the surgeon to leave the skin open or primarily sutured. Most authors describe it in a range between 1.3–14.2% [10]. We usually closed the skin incision with single absorbable sutures 2/0. We observed suppuration in 14.28% of the cases, a result that is close to that cited by most researchers. We controlled the inflammation by opening the wound, applying drainage and daily dressings. After local improvement and the appearance of fresh granulations, a secondary suture was applied.

Anastomotic leakage rate after ileostomy take down ranges from 1–7% according to most studies. Numerous meta-analyses have tried to establish whether there is an increased risk of its occurrence. The following factors were compared: manual and mechanical anastomosis creation, operating time, comorbidity, obesity and others. However, no such relationship has been established [11]. Our data showed the development of this complication in 7.14% of the patients with ileostomy closure. In all cases, we used two layers of running sutures in side-to-side anastomosis.

Bleeding from the anastomotic line is one of the complications that can occur after ileostomy reversal, described in the range between 0–7%. It is usually mild and it presents with a single discharge of black stools. Rarely, it may be profuse with haemodynamic instability and significant decrease in blood counts, requiring blood transfusions, medications or invasive therapy. It is much more common when linear staplers are used [12]. We did not register such a complication as we had already noted, we prefer the manual two-layer anastomosis.

Stoma site hernia is rare. Its incidence ranges between 0–11.1% and is significantly less common in small intestinal stoma closure than in colonic one. The main factors for its occurrence are considered to be infectious complications of the wound, chronic lung diseases and severe co-morbidity [13]. We did not register such a hernia in our patients.

Morbidity associated with stoma reversal according to a number of surgeons is between 10.8–69%. In our series, it was 28.57%, a result that falls within the cited wide range, but significantly lower than that of most studies (about 54%) [14]. Unfortunately, we registered one case of AL of small intestinal anastomosis, with the development of peritonitis, septic complications and patient’s death.

The analysis of the data obtained by us is in line with the conclusions of most authors that protective ileostomy in low rectal resections and its subsequent recovery is not a simple procedure and it is associated with significant morbidity and mortality. When we focused on anastomotic leakage rate and recommendations for protective ileostomy we found serious controversies.

Matthiessen et al., observing 234 individuals operated on with LAR, from 21 surgical wards in Sweden and randomizing them into two groups (116 with protective stoma and 118 without protective stoma), found 3.4 times higher frequency of manifested AL in the second group. The reoperation rate was 8.6% compared to 25.4%, respectively [15]. Mrak K. et al. obtained similar results. They followed 166 patients with LAR and found a significant statistical difference in the occurrence of AL and the need for re-surgery in those two groups [16]. Poon et al. reported clinically manifested AL in 12.6% of patients with LAR without PI and in only 3.3% of cases in the other group [17]. Karanja et al., Carlsen et al., and Dehni et al., demonstrated a significant reduction in the clinically manifested leakage in patients with protective stoma [18]. Pakkastie et al. in their study did not find a statistically significant difference in this complication in the two groups [19].

At the opposite pole there are Shiomi A. et al. with their study covering 1000 patients operated on with LAR. They did not find any significant difference in AL between both groups. They noticed a slight decrease in the frequency of early postoperative revisions in stoma patients [20]. As we have already mentioned, based on our data, a significantly higher rate of re-surgery is seen in the absence of protective ostomy – 81.25% vs. 16.77% (P = 0.01). The same trend is registered and illustrated by a meta-analysis of Wen-long Gu et al.

Wexner et al. believe that the protective stoma does not affect the incidence of anastomotic leakage but it reduces the risk of developing diffuse peritonitis in patients with low anterior resection [21]. Gastinger et al., in a series of 2729 patients with low anastomosis diverted the passage in 881 of them. The result clearly shows that there is no difference in the frequency of AL in the groups "with" and "without" PI, i.e. 14.5% vs. 14.2%, respectively [22]. Park et al., in a study of 1609 cases, concluded that the deviation of the passage did not significantly reduce the risk of AL (OR = 0.649, P = 0.154) [23]. The same conclusions were reached by Akiyoshi et al. who followed 363 patients and registered AL in 4.8% of patients “with” protective stoma and in 3.3% of those “without it” (P = 0.4718) [24].

CONCLUSION

Based on our results, we did not establish a preventive effect of protective ileostomy on the occurrence of anastomotic leakage in low anterior resection, but we support the thesis that it significantly reduces the frequency of re-surgeries due to septic complications in the early postoperative period. However, we recommend careful refinement of patient candidates for diverting ileostomy due to potential morbidity and mortality that accompanies its creation and closure.