Original Article

MEDICINE PALLIATIVE CARE

DOI: 10.47582/jompac.1254537

J Med Palliat Care 2023; 4(2): 163-167

Protective ileostomy in rectal cancer surgery-is it really temporary?

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Cite this article as: Ulusoy C, Duman MG, Güçlü Mete S, Nikolovski A. Protective ileostomy in rectal cancer surgery-is it really temporary?. J Med Palliat Care 2023; 4(2): 163-167.

ABSTRACT

Aim: This single-center retrospective study aimed to evaluate the rate of protective ileostomy closure in patients with rectosigmoid junction/rectal cancer and to investigate the factors that prevent ileostomy reversal.

Material and Method: Patients with rectal cancer treated with/without neoadjuvant chemoradiotherapy were included in this study. All were treated with anterior rectal resection and temporary protective ileostomy creation. Decision for ileostomy closure was brought upon predefined ileostomy closure protocol.

Results: Total number of 115 patients (17 with rectosigmoid junction and 98 with rectal cancer) were operated. Neoadjuvant chemoradiotherapy was conducted in 90 of them. Ileostomy closure rate was 73.9%. Mean time for stoma closure in patients with chemoradiotherapy conduction was 227.8 days, while in the rest, time was shorter (168.3 days), without statistical difference. Multivariate analysis revealed that endoscopic examination of the anastomosis during its creation was independent prognostic factor that affected ileostomy closure.

Conclusion: More than one quarter of the patients with protective ileostomy experienced non-closure of their stoma due to various events after index rectal cancer surgery. Endoscopic examination of the anastomosis during its creation presented as independent factor affecting ileostomy closure.

Keywords: Loop ileostomy, protective ileostomy, ileostomy reversal, ileostomy closure, rectal cancer

INTRODUCTION

Temporary enteric diversion with loop ileostomy in patients treated with sphincter-sparing rectal surgery for rectal cancer reduces the devastating septic consequences from eventual anastomotic leakage and the need for reoperation (1, 2). It also reduces significantly the postoperative mortality rates after the index surgery for rectal cancer (3). Protective ileostomy existence has certain negative impact on the quality of life and is associated with stoma-related morbidity (skin irritation, stoma-dressing leakage, dehydration, renal function alteration with subsequent chronic renal failure) (4-7). On contrary, the stoma closure caries risk with serious postoperative morbidity and mortality rates no matter the timing for closure (8-10). Significant number of the patients with "temporary" diverting ileostomy never experience their stoma closure due to various reasons (9). This study aimed to investigate the rate of non-closure for temporary ileostomy and the factors affecting this undesirable outcome.

MATERIAL AND METHOD

The study was carried out with the permission of İstanbul Prof. Dr. Cemil Taşcıoğlu City Hospital Clinical Researches Ethics Committee (Date 14.11.2022; Decision No: 322). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Patients and Index Surgery Protocol

Patients treated for rectal cancer with and without prior neoadjuvant chemoradiotherapy (CRT) were included in this retrospective single-center study in the period of 2017-2022. Inclusion criteria were set for patients with created protective "loop" ileostomy at index surgery for rectal cancer and the ones that were subsided to ileostomy closure in the same institution. Depending on the tumor localization, all patients were operated with anterior or low anterior rectal resection (open and laparoscopic). Splenic flexure was not routinely mobilized and the decision was made based on the length of the colon and localization of tumor. After

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Received: 21.02.2023 **Accepted:** 25.03.2023

colon resection, anastomosis creation with double stapled technique followed. Linear single use reloadable stapler was used for distal resection of the specimen. Circular stapler was employed for the anastomosis creation. All of the created anastomoses were tested with air-bubble test. In part of the cases, on surgeons' demand, rectoscopy with flexible rectosigmoidoscope was performed for the confirmation of the viability of bowel mucosa, patency of anastomosis and possible anastomotic hemorrhage presence. Creation of protective "loop" ileostomy followed (11).

Ileostomy Closure Protocol

Prior to ileostomy closure surgery, routine colonoscopy was performed by the surgeon. In cases of anastomotic stenosis, endoscopic balloon-dilatation was indicated. The ones with successful post dilatation outcome were subsided to ileostomy closure. Ileostomy reversal was done on ileostomy site with standard elliptical excision of the skin (12). In some patients, median laparotomy was forced due to heavy intestinal adhesions. The intestinal continuity was performed with side to side linear stapled anastomosis or with end to end hand-sewn technique.

Data Collection and Statistics

Patient and surgery data were collected (age, gender, conduction of neoadjuvant CRT, preoperative endoscopy findings, distance of anastomosis from the anal verge, postoperative complications and length of stay for the ileostomy closure admission period). Part of the patients were excluded from the study due to the COVID-19 pandemic obstacles and due to ileostomy reversal surgery performed in other centers. IBM SPSS, version 25 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Variable distribution normality was tested with Kolomogorov-Smirnof test. Chi-square test was used for two categorical and Student's T test for two numerical variables comparison. Multivariate logistic regression analysis were performed to test the relation between the variables in order to point on the factors affecting the non-closure of ileostomy. P value of less than 0.05 was considered significant.

RESULTS

Total number of 115 patients with rectal/rectosigmoid junction cancer were operated during the study period and ended with the construction of temporary protective ileostomy. Mean age of the patients was 61. Majority were male patients (83), and the rest 32 were females. According to tumor localization, rectosigmoid junction cancer presented in 17 cases, while the rest 98 were rectal cancer cases subdivided due to tumors' distance from the anal verge (upper rectum, middle rectum and low rectum). Preoperative clinical magnetic resonance imaging (MRI) stage I was established in 4 patients, and in 5 patients with Stage IV. The rest of them (106) presented with Stage II/III. In 90 (78.3%) patents, long-course neoadjuvant chemoradiotherapy was conducted. No statistically significant difference was noted between the patients' gender according to tumor localization, preoperative tumor stage and the use of neoadjuvant CRT (**Table 1**).

Table 1. Demographics and tumor characteristics

Mean age, years	61
Female, no (%)	32 (27.8%)
Male, no (%)	83 (72.2%)
Cancer localization, no (%)	
Rectosigmoid junction	17 (14.8)
Upper rectum	36 (31.3)
Mid rectum	45 (39.1)
Low rectum	17 (14.8)
Preoperative cancer stage, no (%)	
Stage I	4 (3.5)
Stage II	19 (16.6)
Stage III	87 (75.6)
Stage IV	5 (4.3)
Use of neoadjuvant CRT according to cancer localization, no (%)	
Rectosigmoid junction	6 (6.7)
Upper rectum	30 (33.3)
Middle rectum	41 (45.6)
Low rectum	13 (14.4)
Use of neoadjuvant CRT according to stage, no (%)	
Stage II	12 (13.3)
Stage III	74 (82.2)
Stage IV	4 (4.5)

no=number; CRT=chemoradiotherapy

Complications after index surgery with protective ileostomy followed with overall complication rate of 17.4%. In 6 patients anastomotic dehiscence occurred with a rate of 5.2%. Eight patients developed anastomotic stenosis (6.9%). In 5 patients, postoperative mechanical obstruction due to adhesions developed. In one patient, twist of the created Ileostomy occurred, forcing re-laparotomy with re-creation of the stoma. One abdominal wall abscess was noted due to perforation of the terminal end of afferent ileostomy loop.

Ileostomy reversal was performed in 85 patients with ileostomy closure rate of 73.9%. In 70 of them, neoadjuvant CRT was conducted. In the group treated with upfront surgery (without neoadjuvant CRT), 15 patients experienced closure of their stoma. The difference between these two groups of patients presented without statistical difference. The group with CRT conduction had mean time of their stoma closure of 227.8 days (SE: 19.8), while the group with no neoadjuvant CRT use had shorter mean time of ileostomy reversal of 168.3 days (SE: 46.02). This difference was not statistically significant (**Table 2**).

Table 2. Neoadjuvant CRT use and timing of ileostomy closure

	Neoadjuvant CRT conducted	Neoadjuvant CRT not conducted	p value
Ileostomy			0.073[a]
closed	70	15	
non-closed	20	10	
Mean time of stoma closure (days)	227.8	168.3	0.186[b]
Total	90	25	

CRT= chemoradiotherapy; a Pearson Chi-Square Test; b Student's T Test

Before ileostomy closure, 10 patients died. In 7 patients, distant metastases developed in liver, brain and lungs. Local recurrence occurred in 5 patients. Prior to the decision for stoma closure, patients with anastomotic stenosis were treated with endoscopic balloon dilatation. In 4 of them, after satisfactory endoscopic stenosis treatment, ileostomy was closed. In the rest 4, the reversal procedure was contraindicated. In other 6 patients, endoscopy revealed partially disturbed anastomotic integrity as a consequence of subclinical dehiscence after the index surgery. In 2 of them, ileostomy closure followed. Two patients presented with anal sphincter insufficiency and were not suitable candidates for ileostomy reversal and one patient rejected ileostomy reversal procedure due to present comorbidities and increased operative risk (**Table 3**). Mean duration of hospital stay for the ileostomy reversal surgery was 6.5 days (range 3-28; SD±3.5).

Table 3. Complications and events after index surgery

Complication / event	no (%)
Anastomotic dehiscence	6 (5.2)
Postoperative intestinal mechanical obstruction	5 (4.3)
Ileostomy twisting	1 (0.8)
Ileostomy site abscess	1 (0.8)
Stenosis of colo-rectal anastomosis	8 (6.9)
Anal sphincter insufficiency	2 (1.7)
Local recurrence	5 (4.3)
Deceased	10 (8.7)
Metastases occurrence (liver/brain)	7 (6.1)

No=Number

Multivariate analysis on the factors that prevent stoma closure was performed by the use of Logistic Regression Model. Patients' gender, tumor localization and stage and conduction of neoadjuvant treatment did not affect the ileostomy closure. On contrary, the endoscopic examination of the anastomosis during its creation was the only independent prognostic factor that affected ileostomy closure (p=0.02; 95% CI 1.343-29.601) (**Table 4**).

Table 4. Multivariate analysis on factors that affected ileostomy closure

	H.R.	S.E.	Wald	p value	95% C.I. for EXP(B)	
					Lower	Upper
Neoadjuvant CRT	1.838	0.557	1.197	0.274	0.617	5.474
Tumor localization	0.971	0.244	0.014	0.904	0.601	1.568
Tumor stage	1.536	0.412	1.082	0.298	0.684	3.445
Gender	0.753	0.507	0.315	0.575	0.279	2.031
Endoscopy	6.305	0.789	5.445	0.020	1.343	29.601
Constant	0.735	1.508	0.042	0.838		

H.R.=Hazard Ratio; S.E.=Standard Error; C.I.=Confidence Interval

DISCUSSION

Best way to avoid stoma-related complications including the ones after stoma reversal surgery is not to create one. Hence, the use of protective ileostomy is still widely present in patients operated for rectal cancer. Despite the proper training and meticulous operative technique, stoma-related morbidity is the reality (13).

In this study, majority of the patients in whom protective ileostomy was performed were with rectal cancer presentation. Still, patients with rectosigmoid cancer localization can be subsided for temporary fecal diversion and are not always excluded from this procedure. Possible reasons for ileostomy creation in these patients might depend on the tumor size, their preoperative status and intraoperative technical difficulties and anastomosis related issues.

When dealing with protective ileostomy closure, surgeon should keep in mind two key points: timing for stoma closure and risk factors that lead to complications after ileostomy reversal surgery. In the recent British multicenter, observational study CLOSE-IT, mean closure time of ileostomy following anterior rectal resection was around 9 months (14). In the study of Turner et al. (15) median duration with stoma was 237 days. Aktaş et al. (16) reported median interval between ileostomy creation and closure of 202 days. This study has median time for closure similar to the recent reports despite the delay for closure in part of the patients due to COVID-19 pandemic measures.

Patients in this series had average timing for closure of within the previous reports. As expected, the ones without adjuvant CRT conduction, the time for ileostomy closure was shorter. Still, this difference it this study showed no statistical difference. The optimal timing for temporary ileostomy closure is not defined. In the past decade accent was put on early ileostomy closure with certain advantages over the late closure. In the systematic review and meta-analysis of O'Sullivan et al. (10) six randomized controlled trials were analyzed. They showed no difference between early and late

ileostomy closure. Podda et al. (17) showed that early ileostomy closure presented with lower incidence of postoperative small bowel obstruction (P=0.02) and lower rate of stoma-related complications (P<0.00001). Identical advantages of early ileostomy closure regarding postoperative ileus/small bowel obstruction were drawn in the meta-analysis of Cheng et al. (18). They also confirmed shorter operative time duration for early stoma closure. Early closure (within 150 days) was associated with less complications (P<0.001) in the retrospective study of Werner (19). However, most of the recent meta-analyses advise patient selection for the early ileostomy closure strategy (18-20).

Unfortunately, not every patient will experience his protective ileostomy closure. Local recurrence, distant metastases development and patients' death were major factors for non-closure in this study. Disturbed anastomotic integrity and stenosis and the anal sphincter insufficiency were also obstacles that prevented ileostomy reversal procedure conduction in part of this series.

The reported rate of non-closure of the temporary protective ileostomy ranges between 15.1-41.3% (9,14, 19,21,22). In this study, the ileostomy non-closure rate (26.1%) was within the reported ranges.

Other reported factors that prevent stoma closure can be classified as patient related and other medical factors (cancer stage and localization, the use of neoadjuvant/ adjuvant therapy, anastomosis integrity) (21,22). According to Gustafsson, high level of patient education has higher chance of timely stoma-reversal. At the same time, advanced rectal cancer stage carries high risk for non-reversal (21). The multivariate analysis of the study of da-Fonseca points on the anastomotic fistula, presence of metastases and stoma closure during chemotherapy as factors that prevent stoma closure (22). Another risk factor for non-reversal of the temporary ileostomy is preoperative radiotherapy. Namely, in the study of Zhu et al. (1) patients without preoperative radiotherapy conduction had ileostomy closure rate of 100% contrary to the ones with radiotherapy conduction (P=0.004). The anastomotic stenosis and colon stiffness proximal to colorectal anastomosis caused by preoperative radiotherapy were pointed as risk factors for stoma permanence. The multivariate analysis in the present study pointed the anastomotic stenosis and intraoperative endoscopic examination of the created colo-rectal anastomosis as factors that affect ileostomy closure.

Limitations

This is retrospective single-center study with small number of patients.

CONCLUSION

This study showed that more than ¼ of patients with created protective ileostomy will never experience its closure. Even the ones with closed ileostomy suffer from certain postoperative complications, some of them requiring additional operative interventions. The performance of intraoperative endoscopy examination is independent factor affecting the protective ileostomy closure. Surgeon must think twice; primarily whether to create protective ileostomy, and at the second time, whether to close it. Temporary protective ileostomy is not always temporary.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of İstanbul Prof. Dr. Cemil Taşcıoğlu City Hospital Clinical Researches Ethics Committee (Date 14.11.2022; Decision No: 322).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the manuscript, and they have approved the final version.

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