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ORIGINAL ARTICLE

Quality of life following ileostomy takedown: single-centre, retrospective clinical trial—does closure time matter?

G. Didrikaite[1] · M. Klimovskij[1] · I. Civilka[1] · B. Buckus[1] · T. Aukstikalnis[1] · E. Sileika[1] · A. Dulskas[1,2]

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Abstract

Aim This study aimed to assess whether early closure of loop ileostomy reduces the rate of postoperative complications related to ileostomy closure and improves patients' quality of life, as measured by the Low Anterior Resection Syndrome (LARS) and Wexner questionnaires.

Methods All patients who underwent low anterior resection + ileostomy with subsequent reversal between January 2019 and May 2023 were included in the study. Patients were divided into two groups: early (< 3 months) and late closure (> 3 months). There were 46 (43%) patients in the early closure group and 61 (57%) in late closure. In this study, patients' demographics and complication rate (categorised by severity using the Clavien-Dindo scale) were assessed.

Results We assessed and contacted 180 patients. Of these, 107 (59%) completed the LARS and Wexner questionnaires. Of the 107 patients, 51 were male (47.7%) and 56 female (52.3%). The time to ileostomy closure ranged between 0.5 and 28 months, with a median of 5. In the early and late closure groups, postoperative complications were observed in 4.3% vs. 14.8% ($p = 0.08$) of patients and postoperative ileus occurred in 6.5% vs. 4.9% ($p = 0.72$) of patients respectively. Median LARS score was 25 vs. 20 ($p = 0.99$) and Wexner's 2.5 vs. 2 ($p = 0.82$), respectively. The previously discussed indicators (postoperative ileostomy complications, postoperative ileus rate, LARS and Wexner scores) were not statistically significantly different.

Conclusion In our small retrospective study, early ileostomy closure did not affect postoperative complications related to ileostomy closure and bowel dysfunction rates compared to late closure.

Trial registration This study was a secondary analysis of the prospective trial registered at ClinicalTrials.gov no. NCT03607370, 01.07.2017.

Keywords Quality of life · Low anterior resection syndrome · Rectal cancer · Oncology · Loop ileostomy

Introduction

In the field of oncology, how to preserve a better quality of life for individuals with severe illnesses or those who have undergone radical treatment is a common issue [1, 2]. Colorectal cancer is one of the most common malignant tumours worldwide, currently ranking third overall. It accounts for almost 10% of all new cancer cases and is the second leading cause of cancer-related death globally [3, 4].

Patients who undergo low anterior resection subsequently have a loop ileostomy formed. After these operations, patients often develop symptoms of low anterior resection syndrome (LARS), leading to a poorer quality of life [5]. The syndrome is characterized by a combination of symptoms such as incontinence or leakage of faeces, frequent or rapid defecation, loose stools, incomplete emptying and tenesmus. These symptoms can have a significant negative impact on the patient's daily functioning [6].

There is no precise timing regarding when to perform a reversal of loop ileostomy, but according to various published sources, closing a loop ileostomy within 3–6 months after the initial surgery is usually advised [7, 8]. Several factors can delay early ileostomy reversal. Some patients

✉ G. Didrikaite
didrikaite.gabriele@gmail.com

✉ M. Klimovskij
michail.klimovskij@nhs.net

1 Faculty of Medicine, Vilnius University, Vilnius, Lithuania

2 National Cancer Institute, Vilnius, Lithuania

require adjuvant chemotherapy, while others experience complications after rectal resection, which may interfere with treatment and extend the time to loop ileostomy reversal.

One systematic review has reported that earlier ileostomy removal improves low anterior resection syndrome [5], while other studies have found no association between lower LARS scores and early ileostomy closure [9–11]. In the studies discussed above, various scales (Memorial Sloan Kettering Cancer Centre Bowel Function Instrument, Fecal Incontinence Quality of Life scale, Hallbook questionnaire [5], European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 [11]) were used to measure quality of life after ileostomy closure, including the LARS scale.

This study aimed to assess whether early loop ileostomy closure reduces postoperative complications related to ileostomy closure and improves quality of life, as measured by the LARS and Wexner scores.

Materials and methods

Study design

This study was designed as a single-centre clinical trial. The study was conducted at the National Cancer Institute, located in Vilnius, Lithuania. Patients were recruited from January 2019 to May 2023 at this institution. A significant number of patients were enrolled in this study from another, not yet published, single-centre randomized clinical trial, also carried out at the National Cancer Institute: "Timing for Rectal Surgery After Chemoradiotherapy". We assessed and contacted 180 patients and 107 (59%) of them answered the LARS and Wexner questionnaires. All patients who completed the questionnaires had undergone ileostomy closure at least 1 year prior to the assessment. Participants selected for the clinical trial were excluded for various reasons. The most common cause was the inability to contact the patients ($n = 45$); other reasons included patient death ($n = 12$), refusal to talk about the subjects covered in the questionnaires ($n = 8$) and the ileostomy was left in indefinitely ($n = 8$). All eligible patients were divided into two groups according to the time of loop ileostomy closure: early (< 3 months) and late closure (> 3 months) groups (Fig. 1).

Participants

All patients in the study had to be ≥ 18 years of age and have undergone low anterior resection for cancer with formation of defunctioning loop ileostomy, which was later reversed. Patients who underwent additional resection of bowel, as well as patients who underwent urgent reversal of loop ileostomy for various reasons, were excluded from this study. The following demographic, clinical and operational variables were collected: sex, age, body mass index (BMI), neoadjuvant therapy, scope of the operation [total mesorectal excision (TME) or partial mesorectal excision (PME)], type of operation (laparoscopic or open surgery), height of anastomosis from the anal verge, stapler used to perform the anastomosis and adjuvant chemotherapy. Moreover, rates of relevant complications during the entire treatment period until ileostomy reversal were also collected (postoperative wound complication, postoperative intra-abdominal abscess, leakage of the anastomosis, coloanal fistula, haematoma). All complications were graded according to the Clavien-Dindo classification [12].

The study outcomes regarding the ideal timing of loop ileostomy closure were evaluated based on ileus and postoperative loop ileostomy complication (bleeding, surgical site infections, parastomal hernias) rates, which later were categorized according to the Clavien-Dindo classification. Patients' quality of life and bowel function were assessed using the LARS [13] and Wexner [14] scales.

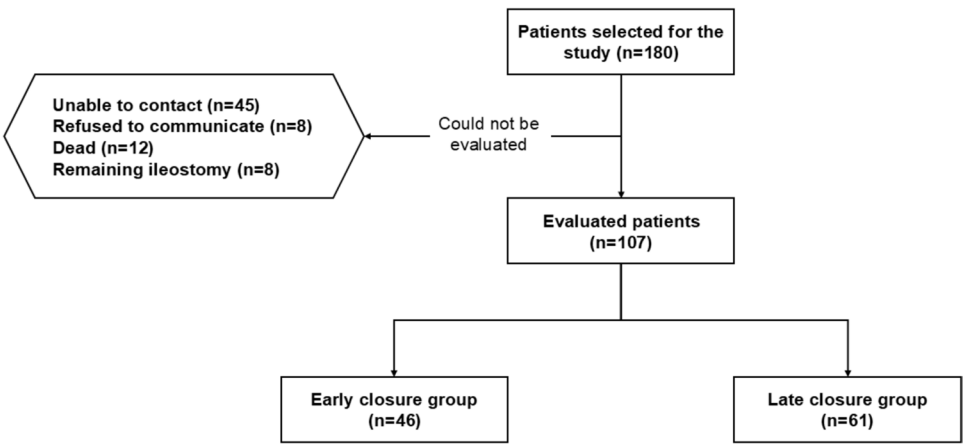

Fig. 1 Consort flow diagram of patient selection for the clinical trial

Data sources

Patients selected to participate in the study were asked to complete the LARS and Wexner questionnaires. Additionally, other relevant patient information was gathered from the National Cancer Institute database to ensure a comprehensive data analysis.

Statistical analysis

During the data analysis, a normality test was performed, which determined whether parametric or non-parametric tests would be used for the statistical analysis of the variables. The chi-squared test or Fisher's exact test was used to compare proportions, depending on the number of observed variants. Most of the clinical patient variables were evaluated as proportions and frequencies, parametric variables were evaluated as means with standard deviation (SD), and non-parametric variables were evaluated as medians with minimum and maximum values. Categorical data were analysed using Fisher's exact test and continuous data were analysed using the Wilcoxon rank-sum test. The results of the LARS and Wexner questionnaires were evaluated between groups using non-parametric tests; therefore, median values were compared. A p value of < 0.05 was considered statistically significant. Statistical analysis was carried out using R Commander statistical analysis software version 2.9-4.

Ethics and approvals

Patients provided written informed consent during the planned follow-up period prior to participating in the study. Verbal consent was also obtained during the phone call in which the LARS and Wexner questionnaires were administered. Given that the study involved access to sensitive patient information, approval was obtained from the Lithuanian Bioethics Committee to ensure that all ethical standards were met.

Results

All 107 patients were selected as the final sample. Their ages ranged between 42 and 92 (median 65) years. The time to ileostomy closure ranged between 0.5 and 28 months, with a median of 5. Patients were divided into two groups: early (< 3 months) and late closure (> 3 months).

Most demographic and clinical variables, such as BMI, age, sex and other surgery-related variables, were not statistically significantly different between the two groups. There was a significant difference between the groups depending on the cancer stage. More stage 3 or higher colorectal tumours were observed in the late closure group than in the early closure group ($p = 0.01$). There was also a significant difference between the evaluated groups in terms of adjuvant chemotherapy. In the late closure group, adjuvant therapy was significantly more common ($p < 0.01$) (Table 1).

Reasons for delayed reversal

A higher incidence of overall complications was observed in the late closure group throughout the entire treatment period leading up to ileostomy closure, 19.6% patients in the early closure group and 34.4% in the late closure group ($p = 0.03$). However, there was no statistically significant difference in the severity of these complications according to the Clavien-Dindo classification (Table 2).

Functional outcomes

Calculated p-values of LARS and Wexner median scores were 0.99 and 0.82, respectively. There were no significant differences in the results of the patient questionnaires between groups (Table 3, Fig. 2).

Postoperative outcomes

In the early and late closure groups, postoperative stoma complications were observed in 4.3% and 14.8% ($p = 0.08$) of patients and postoperative ileus in 6.5% and 4.9% ($p = 0.72$) of patients, respectively. In the early closure group one patient (2%) had a grade IIIb complication, in the late closure group three patients (5%) had grade IIIb complications, and one patient (1.5%) had a grade IVa complication. More severe complications were observed in the late closure group compared to the early closure group, but this was not statistically sufficiently different between the groups (Table 2).

Discussion

In our study, the rates of postoperative ileostomy-related complications did not differ significantly between the early and late closure groups. Similarly, no statistically significant differences were found in functional outcomes assessed by the LARS and Wexner scores. However, delayed closure was often linked to the administration of adjuvant chemotherapy and a higher rate of postoperative complications after rectal resection, suggesting a possible causal relationship between the treatment course and the timing of ileostomy reversal.

Impaired bowel function as assessed by the LARS score did not differ between the two groups, as in some similar articles [9–11]. Several of the studies reviewed had smaller samples compared to our study ($n = 107$ vs. $n = 82$ [9] vs. $n = 51$[11]). However, both studies were randomized, which

Table 1 Demographics of patients included in the study (early vs. late closure group)

	Early closure group ($n=46$)	Late closure group ($n=61$)	p value
Sex			0.98
Male	22 (47.8%)	29 (47.5%)	
Female	24 (52.2%)	32 (52.5%)	
Age, years (mean ± SD)	66.8 ± 11.5	63.8 ± 10.1	0.16
BMI, kg/m^2 (mean ± SD)	26.3 ± 4	26.1 ± 4	0.83
Tumour stage (rectal tumour) and neoadjuvant therapy			
Neoadjuvant therapy			
None	24 (52.2%)	21 (34.4%)	0.77
Chemotherapy	5 (10.9%)	6 (9.8%)	0.76
Radiotherapy	2 (4.3%)	2 (3.3%)	0.99
Chemotherapy and radiotherapy	15 (32.6%)	32 (52.5%)	**0.01**
Tumour stage			0.10
Stage 1	22 (51.2%)	16 (29.6%)	
Stage 2	12 (27.9%)	16 (29.6%)	
Stage 3	8 (18.6%)	21 (38.9%)	
Stage 4	1 (2.3%)	1 (1.9%)	
Tumour stage			**0.01**
≤ Stage 2	34 (79.1%)	29 (54.7%)	
≥ Stage 3	9 (20.9%)	24 (45.3%)	
Scope of the operation			0.74
Total mesorectal excision	43 (93.5%)	56 (91.8%)	
Partial mesorectal excision	3 (6.5%)	5 (8.2%)	
Operative approach			0.09
Open	25 (54.3%)	43 (70.5%)	
Laparoscopic	21 (45.7%)	18 (29.5%)	
Height of anastomosis from anal verge, cm (mean ± SD)	5.2 ± 2.1	5.3 ± 2.5	0.92
Apparatus used to perform the anastomosis			0.35
CEEA 25	1 (2.2%)	2 (3.3%)	
CEEA 29	22 (47.8%)	37 (60.7%)	
CEEA 31	23 (50%)	22 (36.1%)	
Adjuvant chemotherapy	9 (19.6%)	41 (67.2%)	**< 0.01**

provided more reliable results compared to our retrospective study. Another article considered was a meta-analysis with a large sample of patients from different centres ($n=599$) [10], which allowed for a more reliable assessment of overall population patterns compared to smaller studies. There were also differences in the questionnaire design and the timing of ileostomy closure between groups. One paper used an additional questionnaire beyond the LARS for measuring patient's quality of life: the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 [11]. In our study, we decided to use the Wexner questionnaire as a supplementary measure of the patient bowel function. In these articles, patients were included in the early ileostomy closure group if their stoma was closed < 30 days after rectal resection compared to our early closure group, where closure was at < 3 months. We selected this sample based on a similar clinical trial previously conducted at the same centre. The study compared two ileostomy closure times: early (< 30 days) and standard (< 3 months). However, the study was stopped because of safety concerns as the early closure group had a higher complication rate and increased morbidity (27.9% vs. 7.9%; $p=0.024$) [15]. One meta-analysis found an association between the time of closure of the loop ileostomy and improved bowel function, with better results for earlier closure [5]. This meta-analysis has the advantage of a very large sample size, as the data were collected from a wide range of studies, covering a broader spectrum of patients. However, the main disadvantage is that this analysis does not directly compare groups. Instead, the median number of months to stoma closure was taken and the change in LARS scores was observed, but none of the studies analysed in this systematic review examined the direct difference between early and late closure to assess the change in LARS scores.

Table 2 Complications overall of patients included in the study (early vs. late closure group)

	Early closure group ($n=46$)	Late closure group ($n=61$)	p value
Complications (overall)	9 (19.6%)	21 (34.4%)	**0.03**
Postoperative wound complication	2 (4.3%)	4 (6.6%)	0.62
Postoperative intra-abdominal abscess	2 (4.3%)	6 (9.8%)	0.29
Leakage of the anastomosis	4 (8.7%)	6 (9.8%)	0.84
Coloanal fistula	2 (4.3%)	6 (9.8%)	0.29
Haematoma	1 (2.2%)	2 (3.3%)	0.73
Clavien-Dindo classification			0.22
1	2 (4.3%)	1 (1.6%)	
2	4 (8.7%)	7 (11.5%)	
3a	0 (0%)	4 (6.6%)	
3b	3 (6.5%)	8 (13.1%)	
4a	1 (2.2%)	0 (0%)	
4b	0 (0%)	0 (0%)	
5	0 (0%)	0 (0%)	
Postoperative outcomes			
Ileus	5 (10.9%)	5 (8.2%)	0.72
Complications of ileostomy	2 (4.3%)	9 (14.8%)	0.08
Clavien-Dindo classification			0.70
1	3 (6.5%)	3 (5%)	
2	0 (0%)	0 (0%)	
3a	0 (0%)	0 (0%)	
3b	1 (2%)	3 (5%)	
4a	0 (0%)	1 (1.5%)	
4b	0 (0%)	0 (0%)	
5	0 (0%)	0 (0%)	

Bold value indicates statistically significant p value ($p<0.05$)

Table 3 Low anterior resection syndrome and Wexner scores between early and late closure groups

	Closure groups	Min	Max	Median	p value
LARS score	Early closure	0	41	25	0.99
	Late closure	0	41	20	
Wexner score	Early closure	0	15	2.5	0.82
	Late closure	0	18	2	

Most articles describe an increase in postoperative complications in the late closure group [10, 16–20]. The main differences between our study and these were the sample size and the division of the treatment groups. The studies consisted of two systematic reviews [10, 19] and other studies [16–18] and the sample size ranged from 75 to 599 patients. Several of these studies defined delayed ileostomy closure as > 6 months [16, 17], while other studies selected a late closure group between > 15 days and 3 months [10, 18, 19]. However, in some cases the complication rate and its severity did not differ between groups, as was observed in our study, with one exception in this meta-analysis [21]: the routine closure group had a higher incidence of bowel obstruction.

We identified a possible link between later closure of the loop ileostomy and adjuvant chemotherapy, as in some other similar studies [5, 10, 16, 22]. When comparing the early versus late closure groups, adjuvant chemotherapy was used significantly more often in the latter group, 19.6% vs. 67.2%, respectively. This possibly indicates the reason for delay of closure of the loop ileostomy. In addition, more advanced stages of the disease were observed in the late closure group ($p=0.01$), which could have led to longer use of adjuvant chemotherapy (Table 1).

The time of ileostomy closure was significantly influenced not only by the use of requirement of adjuvant chemotherapy but also by postoperative rectal resection complications. The results showed that the overall incidence of these complications was statistically significant ($p=0.03$) and occurred more frequently in patients who underwent ileostomy closure later. However, when the severity was graded using the Clavien-Dindo classification, these complications did not reach the statistical significance threshold ($p=0.22$). These data suggest that the complications observed in the

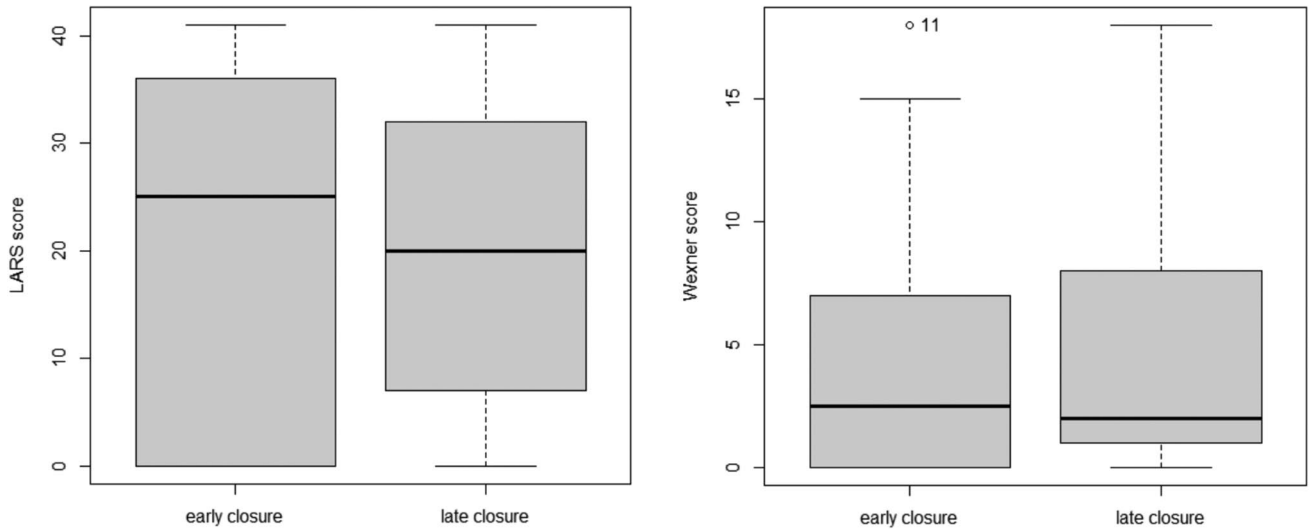

Fig. 2 Low anterior resection syndrome and Wexner scores between early and late closure groups

late closure group may have been an important factor influencing the decision to delay loop ileostomy closure. Therefore, comprehensive management of postoperative complications may be one of the key factors in avoiding prolonged ileostomy reversal, which in turn may affect patients' quality of life and recovery.

Our study has a few limitations. First, this was a single-centre, small, nonrandomized controlled trial not powered to find the statistically significant difference between the ileostomy closing times. Second, the patients were assessed at different times following the ileostomy closure, which might have affected the bowel function. However, all were assessed at least 1 year following the ileostomy takedown. Third, the major limitation is that the early group consisted of patients undergoing ileostomy takedown within 3 months. On the other hand, early takedown in most studies is considered within 2 weeks of the index surgery.

Conclusion

In our small study, early ileostomy closure had no effect on rates of postoperative ileostomy-related complications and bowel function (accessed by LARS and Wexner scores) compared to late closure.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10151-025-03196-2.

Authors contributions Gabriele Didrikaite: Data Curation (equal); Formal Analysis (lead); Investigation (lead); Methodology (lead); Visualization (lead); Writing—Original Draft Preparation (lead); Writing—Review & Editing (equal) Michail Klimovskij: Conceptualization (equal); Resources (equal); Supervision (equal); Validation (equal); Writing—Review & Editing (equal) Ignas Civilka: Data Curation (equal); Methodology (supporting); Writing—Review & Editing (equal) Bronius Buckus: Resources (equal); Writing—Review & Editing (equal) Tomas Aukstikalnis: Data Curation (equal); Resources (equal); Writing—Review & Editing (equal) Ernestas Sileika: Conceptualization (equal); Data Curation (equal); Resources (equal); Writing—Review & Editing (equal) Audrius Dulskas: Conceptualization (equal); Project Administration (lead); Resources (equal); Supervision (equal); Validation (equal); Writing—Original Draft Preparation (supporting); Writing—Review & Editing (equal).

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Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

Ethical approval Approval was obtained from Lithuanian Bioethics Committee. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to participate Informed consent was obtained from all individual participants included in the study.

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