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NEPHROLOGY - ORIGINAL PAPER

Variations of the renal function parameters in rectal cancer patients with a defunctioning loop ileostomy

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Abstract

Purpose The objective of this study is to investigate the impact of the temporary loop ileostomy on renal function and also to assess the factors associated with the change in renal function observed between the index surgery (the moment of the radical surgical procedure) and the closure of the ileostomy (the moment of the secondary surgical act of suppression of the ileostomy).

Methods A total of 69 rectal cancer patients from a single referral surgical unit who had a loop ileostomy during low anterior resection of the rectum were included in this study. Serum creatinine levels were evaluated, and estimated glomerular filtration rate (eGFR) was calculated prior to index surgery and closure of the ileostomy.

Results During this time interval, there was a significant decrease in eGFR levels (mean difference -4.5 mL/min/1.73 m^2, 95% CI -7.8 to -1.3 mL/min/1.73 m^2), and also a significant increase in the serum creatinine values (mean difference 0.07, 95% CI 0.02–0.12 mg/dL). The eGFR decrease was more pronounced in diabetic patients, in those with a baseline Charlson Comorbidity Index score ≥ 1 or in those that received chemotherapy. In a multivariable regression analysis, the use of neoadjuvant chemotherapy was the only variable significantly associated with the change in eGFR levels between the two surgical interventions.

Conclusion Renal function impairment is an important event that the surgeon has to take into consideration when deciding upon opting for a loop ileostomy to temporarily defunction a colorectal anastomosis.

Keywords Rectal cancer · Loop ileostomy · Renal function

Abbreviations

CCI	Charlson Comorbidity Index
cT3/4	Clinical tumor staging—stage 3 or 4
cN+	Clinical lymph node staging—positive lymph nodes
DID	Difference in difference
eGFR	Estimated glomerular filtration rate
IQR	Inter-quartile range
SD	Standard deviation

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Introduction

Colorectal cancer is an important public health issue, that is responsible for an annual number of 746,000 and 614,000 new cases yearly in men and women, respectively, making it the third and second most common neoplasia, according to the 2012 Globocan study [1]. Approximately one-third of colorectal cancers are situated in the rectum [2].

The management of rectal cancer has seen important improvements in the last decades, with updates both in the matter of multidisciplinary treatment and regarding the surgical approach, thus not only improving the survival (71.9% 5-year overall survival) [3] in this pathological entity and lowering local recurrence rate, but also increasing the quality of life [4, 5]. As part of the modern therapeutic strategies, a temporary defunctioning ileostomy or colostomy may be used in order to temporarily deviate transit and decrease the complication rate following a possible anastomotic leak, thus reducing morbidity and shortening length of stay [6].

Given the fact that the colon receives approximately 1500 mL of fluid form the small bowel and absorbs approximately 1350 mL of water, 200 mmol of sodium, 150 mmol of chloride, and 60 mmol of bicarbonate over 24 h [7], ileostomies have the disadvantage of hydroelectrolytic and fluid depletion if not adequately compensated. Moreover, high output stomas with either an early, or late onset may require a complex treatment and will yield variable results, from complete resolution to high morbidity and even death [8].

This is an important problem to be discussed, because the impact of kidney disease on a patient with cancer not only increases morbidity, but also has the potential of modifying the adjuvant treatment plan (chemotherapy may be delayed or certain drugs may be contraindicated) [9].

This issue has previously been scarcely studied in the literature in two studies [10, 11] both showing an increased risk for renal impairment with ileostomy formation. However, there have been little analyzed data related to predisposing factors.

The objective of this study is to investigate the impact of the temporary loop ileostomy on renal function and also to assess the factors associated with the change in renal function observed between the index surgery (the moment of the radical surgical procedure) and the closure of the ileostomy (the moment of the secondary surgical act of suppression of the ileostomy).

Methods

Patients

In the study, we included patients treated for rectal cancer within the First Surgical Unit of the Iasi Regional Institute of Oncology over a period of 5 years, between May 2012 and April 2017. A total of 69 patients with radically treated rectal cancer which received a lateral Brooke defunctioning ileostomy were considered for this study, according to the flowchart depicted in Fig. 1.

Clinical data were retrieved retrospectively from medical records.

Inclusion criteria were as follows: patients with rectal cancer receiving curative treatment, with a restorative intervention (low/very low anterior resection of the rectum with total mesorectal excision) with a colorectal anastomosis, protected by a diverting ileostomy, with a closure of the diverting stoma, with documentation of both interventions, with documented values of the serum creatinine at both reference moments. Exclusion criteria consisted of the following: localization of the tumor at the level (or higher than) the rectosigmoid junction, patients that had only one of the interventions within the First Surgical Unit of the Iasi Regional Institute of Oncology, patients with incomplete biological records regarding serum creatinine.

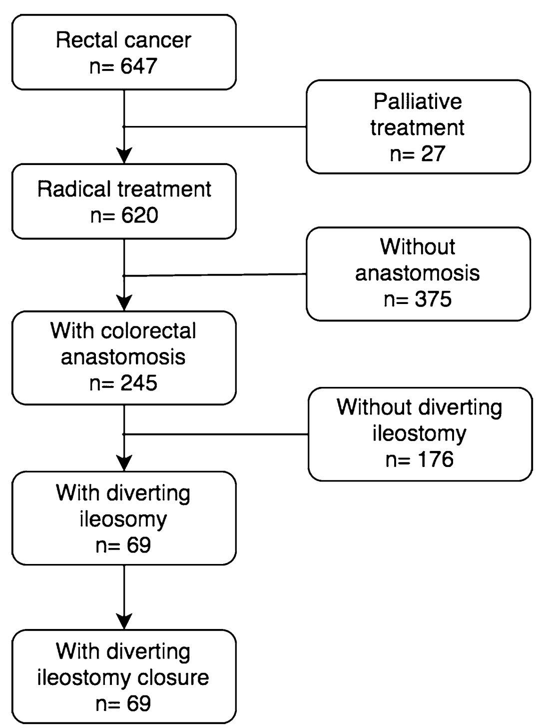

Fig. 1 Patient flow-chart

Medical records were reviewed to obtain the following information: age, gender, type, and localization of rectal neoplasia, tumor staging using the American Joint Committee on Cancer [12], existence of neoadjuvant treatment (radiotherapy or radiochemotherapy), time between neoadjuvant treatment and surgical sequence, type of surgery, type of anastomosis, use of diverting stoma and type of stoma, duration until the closure of the stoma.

Comorbidities were reviewed and hypertension, peripheral vascular disease, history of myocardial infarction in the last 12 months, congestive heart failure and diabetes mellitus were recorded. Charlson Comorbidity Index (CCI) was calculated (the existence of solid tumor was excluded from scoring) [13]. Serum creatinine levels were measured before the initial surgical intervention and before the closure of the ileostomy, within the Institute's integrated laboratory. The estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula [14].

Neoadjuvant treatment

Neoadjuvant treatment was indicated, in accordance to European Society of Medical Oncology and National Comprehensive Cancer Network guidelines for treatment in rectal cancer, in mid and low rectal cancers with imagistic criteria for positive circumferential resection margins (clinical tumor and lymph node grading—cT3/4 and cN+) [15, 16].

The patients that received neoadjuvant treatment underwent a long-course plan, with 50, 4 Gray in 28 fractions, during a 5-week and a half treatment program. Capecitabine was associated as chemotherapy to radiation treatment with the purpose of increasing susceptibility of tumor cells to radiation. There were no cases with standalone chemotherapy (i.e., without radiotherapy).

Postoperative care following index surgery

Postoperative patient management following index surgery was homogenous, with deep vein thrombosis prophylaxis using low molecular weight heparin in accordance with body weight, 3000 mL crystalloid intravenous perfusion in the first three postoperative days, followed by systematic decrease until the 5th postoperative day, when patients were encouraged to have an appropriate oral fluid intake. Pain management was also standardized, with opioids only used until the first postoperative day, followed by on-demand acetaminophen and metamizole. Ketoprofen was rarely used as an alternative to acetaminophen. Proton pump inhibitors were usually used.

Patients were not discharged until the daily ileostomy output was < 1000 mL. Ostomy teaching included dietary indications and education regarding high output. Loperamide was used to decrease output in the postoperative period and at discharge.

No major complications were reported in the postoperative period in the 69 cases that were studied. No reoperations were reported and no patient had major non-surgical-related complications in the early postoperative period. Four cases presented minor wound-related complications that were efficiently treated until the patients were discharged.

Stoma closure

Stoma closure was performed after radiologic or rectoscopic evaluation of the integrity of the anastomosis. Radiologic evaluation consisted of a barium enema, which has no mentioned effects on patient's renal function.

Statistical analysis

Data are expressed as mean ± standard deviation (SD), median with inter-quartile range (IQR) or as percent frequency, as appropriate. The distribution of the variables was assessed using the Shapiro–Wilk test. Pearson or point biserial correlation coefficient was used to determine correlations between paired variables. Multivariate regression analysis including all univariate associates ($p < 0.05$) was used to assess the predictors for change in eGFR or serum creatinine between the two surgical interventions. Continuous variables that were non-normally distributed in the cohort were log transformed to normality in order to comply with the conditions of validity of the regression models (normality and homogeneous variability of residuals). Time repeated measurements were analyzed using linear mixed models; group inferences, effect estimates, and 95% confidence intervals (CI) were taken from these models.

All analyses were performed using Stata SE software, version 12 (Stata Statistical Software: Release 12. College Station, TX: StataCorp LP.). A two-tailed $p < 0.05$ was considered to be significant.

Results

From a total of 245 patients with a restorative intervention, there were a total of 69 patients who had a defunctioning ileostomy. The mean age of the included patients was 62.8 years, 63.8% were male, and 23.2% had diabetes. The mean baseline eGFR and serum creatinine were 81.9 mL/min/1.73 m^2 and 0.9 mg/dL, respectively. Other clinical and demographical characteristics are presented in Table 1.

Table 1 Baseline characteristics of the patients

	Defunctioning ileostomy (*n* = 69)
Age (years)	62.8 ± 10.4
Male, *n* (%)	44 (63.8)
Diabetes, *n* (%)	16 (23.2)
Hypertension, *n* (%)	28 (40.5)
Chronic heart failure, *n* (%)	4 (5.7)
Coronary heart disease, *n* (%)	2 (2.8)
Peripheral vascular disease, *n* (%)	1 (1.4)
Charlson score ≥ 1, *n* (%)	18 (26.1)
Pathological staging, *n* (%)	
pCR	3 (4.3)
I	21 (30.4)
II	27 (39.1)
III	17 (24.6)
Neuroendocrine tumor	1 (1.4)
Neoadjuvant therapy, *n* (%)	
Radiotherapy and chemotherapy	43 (62.3)
Only radiotherapy	10 (14.4)
Duration of ileostomy (days)	61 (45–85)
Mechanical anastomosis, *n* (%)	65 (94.2)
Serum creatinine (mg/dL)	0.9 ± 0.2
eGFR (mL/min/1.73 m^2)	81.9 ± 15.1

Table 2 Glomerular filtration rate (eGFR) levels (mL/min/1.73 m^2) evolution during the follow-up across different subgroups

	Baseline	Ileostomy closure	p*	$p^{\dagger}$
Diabetes				
Yes	73.2 (63.4–83.1)	60.1 (50.2–69.9)	< 0.001	0.02
No	83.5 (79.4–87.5)	80.4 (76.4–84.5)		
$p^{\ddagger}$	0.06	< 0.001		
Hypertension				
Yes	76.4 (70.4–82.3)	71.1 (65.2–77.1)	0.005	0.73
No	85.8 (80.9–90.8)	81.8 (76.8–86.7)		
$p^{\ddagger}$	0.02	0.007		
Charlson score				
0	85.5 (80.1–90.8)	83.5 (78.2–88.9)	< 0.001	0.002
≥ 1	78.4 (72.9–83.8)	71.2 (65.8–76.6)		
$p^{\ddagger}$	0.07	0.008		
Chemotherapy				
Yes	81.4 (76.6–86.4)	73.3 (68.4–78.2)	0.03	0.002
No	82.9 (76.5–89.2)	84.4 (78.1–90.7)		
$p^{\ddagger}$	0.73	0.006		

Data are presented as mean (95% CI). Analysis was conducted using a mixed model for repeated measures

*p value for time effect—trend over time in all arms

$^{\dagger}p$ value for treatment × time interaction—evaluates if changes in one group are different from the changes in the other group

$^{\ddagger}p$ value for comparison between groups at each moment

eGFR and serum creatinine change between the two interventions

The median number of days between the initial surgery and the ileostomy closure was 61 days. During this time interval, there was a significant decrease in eGFR levels (mean difference − 4.5 mL/min/1.73 m^2, 95% CI − 7.8 to − 1.3 mL/min/1.73 m^2), and also a significant increase in the serum creatinine values (mean difference 0.07, 95% CI 0.02–0.12 mg/dL).

As shown in Table 2, diabetic patients had lower eGFR values both at the initial and at the second intervention time. During this time, eGFR levels decreased in both diabetic and non-diabetic patients (Fig. 2a), with a more pronounced decrease in diabetic ones [difference in difference (DID) − 10.1 mL/min/1.73 m^2, 95% CI − 18.8 to − 1.4 mL/min/1.73 m^2]. There was also a decreased eGFR in hypertensive patients at both the assessment moments. Renal function significantly worsened only in hypertensive patients (mean difference between the two assessment moments − 5.2 mL/min/1.73 m^2, 95% CI − 10.2 to − 0.2 mL/min/1.73 m^2; Fig. 2b), but without reaching a statistical significance when compared with the change in eGFR in the normotensive patients (DID − 1.2 mL/min/1.73 m^2, 95% CI − 7.6 to 5.3 mL/min/1.73 m^2).

At the baseline moment, there was no difference in eGFR values between patients with a CCI of 0 versus a score ≥ 1 and in those that received chemotherapy versus those who did not (Table 2). However, at the second assessment moment, patients with a higher CCI and those who received chemotherapy had lower eGFR values. Between the two intervention moments, eGFR levels significantly decreased only in patients with a CCI ≥ 1 (mean difference − 12.5 mL/min/1.73 m^2, 95% CI − 18.3 to − 6.7 mL/min/1.73 m^2; Fig. 2c) or in those that received chemotherapy (mean difference − 8.2 mL/min/1.73 m^2, 95% CI − 11.9 to 4.4 mL/min/1.73 m^2; Fig. 2d); these differences remained significant also when compared with changes observed in patients with a CCI of 0 (DID − 10.8 mL/min/1.73 m^2, 95% CI − 17.5 to − 3.9 mL/min/1.73 m^2) or in those that did not receive chemotherapy (DID − 9.7 mL/min/1.73 m^2, 95% CI − 15.9 to − 3.6 mL/min/1.73 m^2).

Similar findings were also observed when we analyzed changes in serum creatinine, instead of eGFR, between the two intervention moments (Online Resource 1).

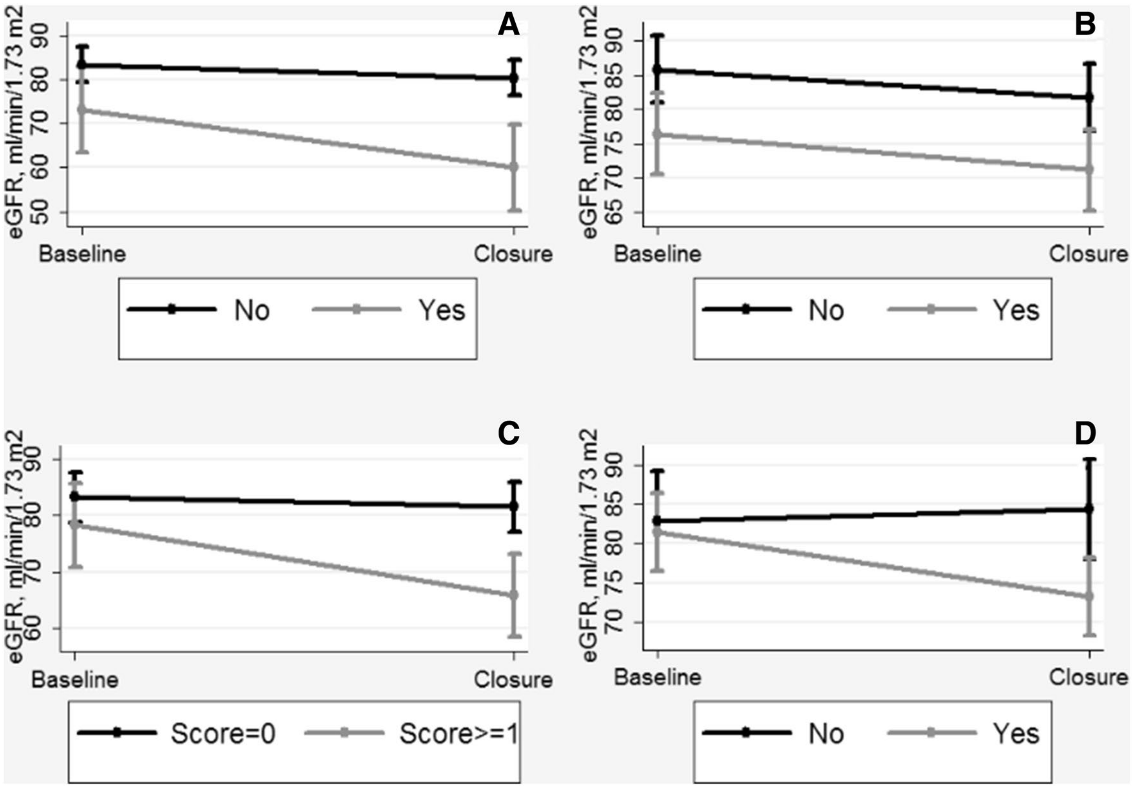

Fig. 2 eGFR change between the two interventions—a comparison between diabetic and non-diabetic (**a**), hypertensive and normotensive (**b**) patients, between patients with a Charlson score of 0 and ≥ 1 (**c**) and between patients that received and those that did not receive chemotherapy (**d**)

Table 3 Univariable associates of eGFR difference

Variables	Coefficient	*p*
Diabetes (yes = 1)	− 0.26	0.03
Chemotherapy (yes = 1)	− 0.35	0.003
Log Charlson score	− 0.31	0.01

eGFR estimated glomerular filtration rate

Table 4 Multivariable associates of eGFR difference

Variables	Coefficient	*p*
Diabetes (yes = 1)	− 4.12	0.44
Chemotherapy (yes = 1)	− 9.05	0.004
Log Charlson score	− 6.36	0.12

eGFR estimated glomerular filtration rate

Association of clinical, demographical, and therapeutical characteristics with changes in eGFR and serum creatinine levels

As shown in Table 3, diabetes, CCI, and the use of chemotherapy were negatively associated with the change in eGFR levels between the two intervention moments. In order to determine the independent predictors of eGFR changes, we performed a linear regression analysis, including all these variables that were associated with the eGFR changes in the univariable analysis. As shown in Table 4, only the use of chemotherapy remained significantly associated with eGFR changes.

Similar findings were also observed when analyzing changes in serum creatinine levels (Online Resource 2).

Discussions

This study shows for the first time that, in patients with rectal cancer that received a diverting ileostomy, the most important predictor for renal function decline observed between the two surgical interventions (creation and closure of the ileostomy) is the use of chemotherapy. We have also observed a more important decline in renal function in diabetic patients or in those with a CCI ≥ 1.

The temporary diverting ileostomy is used in diverticulitis, colorectal cancer, and inflammatory bowel disease surgery, being an option in order to prevent the morbidity after anastomotic leak in ileorectal, colorectal, or coloanal anastomoses [17]. Moreover, although retrospective studies argued the potential of a diverting stoma in preventing an anastomotic leak, several recent randomized controlled trials have demonstrated the benefit offered by fecal diversion in preventing this complication [6].

The morbidity of a loop ileostomy is significant and can go up to 43% of patients, with dehydration due to high output being one of the most common complications [18]. Important dehydration may appear as an early postoperative complication or as a chronic manifestation of continuous loss of high volumes of water and electrolytes—it is present in up to 20% of patients with ileostomy, according to Shabbir and Britton, Okamoto et al. [18, 19]. Data related to the renal impairment secondary to chronic loss of water through an ileostomy (even if temporary) are few in literature, with a previous study in 2011 with 107 patients [10] and a later one in 2014 on 308 patients in Sweden [11]. A mention of renal impairment after restorative surgery is also made in a recent American College of Surgeons National Surgery Quality Improvement Programme retrospective review; it is stated that patients with diversion had an increased rate of progressive renal insufficiency (2.1 vs. 0.8%), but with no impact on the risk of acute renal failure (1.3 vs. 0.7%) [20].

Neoplasia located higher than the rectosigmoid junction was excluded, thus excluding the possibility of tumor invasion of the kidney or ureters. Moreover, patients with surgery for inflammatory bowel disease were not included, so that the possible interference of the medication administered in these cases was excluded.

There were statistically significant variations both in eGFR and serum creatinine values depending on comorbidities. This shows that these aspects must be taken into consideration when deciding on performing an ileostomy, as well on the management of these patients. Taking into consideration that all patients were having surgery for rectal cancer and the majority had neoadjuvant treatment, we have demonstrated an important correlation between the use of chemotherapy and the worsening of renal function between the two recorded moments. Chemotherapy consisted of Capecitabine, which is metabolized to 5-fluorouracil, that has renal excretion, but has no enlisted nephrologic side effects. Thus, we can conclude that Capecitabine used in the neoadjuvant treatment has an additional prognostic risk that has to be taken into consideration.

The appropriate moment for ileostomy closure is 60–90 days, according to a study performed on 259 patients by Panis and co-workers. They have demonstrated that morbidity increases with delay to closure ($p=0.03$), as does anastomotic leak rate ($p=0.03$). They concluded that the best results are obtained when stomas were closed before 90 days [21]. The median of 61 days until stoma closure shows that the majority of patients had this intervention at an adequate time, according to literature. The few cases in which the recommended 90-day period until stoma closure was exceeded were not morbidity-related. However, this interval did not have a significant impact over renal function in these patients. This is an important finding, bearing in mind that the latency between the two surgical acts goes up to 1126 days.

This study is limited by the fact that cases were collected retrospectively, and thus no randomization was possible. Yet, randomization would be difficult, because certain decision factors arise intraoperatively, such as the aspect of the tissue in the anastomotic "partners"—the colon and rectum, technical difficulties in realizing the anastomosis and the anastomotic integrity test performed with methylene blue or air. Moreover, the study group is heterogenous in terms of neoadjuvant therapies used (i.e., standalone radiotherapy or chemoradiotherapy), as well as the time intervals between administration of neoadjuvant and radical treatment; these issues cannot be addressed, as they depend on each patient's general status and technical aspects of the neoadjuvant treatment. Certainly, other risk factors for renal function impairment may have been omitted due to lack of information from the patient records that were reviewed. In consequence, information on patient chronic medication, that might affect renal function, is lacking; however, the CCI with its included morbidities for which this medication would be administered may partially overcome this drawback.

Conclusion

We show for the first time that the use of chemotherapy might have an impact on renal function in patients with rectal cancer that receive a diverting ileostomy. In addition, our study indicates that increased attention should be also offered to diabetic patients or those with a higher comorbidity burden.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

Ethical approval This study was approved by the ethics boards of the Regional Institute of Oncology and the University of Medicine and Pharmacy "Grigore T Popa" Iasi. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Patients had given their written consent for clinical data to be used in scientific purposes.

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