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Predictive factors for temporary defunctioning stoma permanence in the treatment of rectal adenocarcinoma✧

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ABSTRACT

Purpose: determine the predictive factors for non-closure of defunctioning stoma in the low anterior resection for the treatment of rectal adenocarcinoma.
Methods: a retrospective cohort study of patients undergoing low anterior resection with defunctioning stoma for a period of nine years was performed. We compared, using univariate and multivariate analysis, the group that closed the defunctioning stoma (Group A) with the group that did not (Group B).
Results: eighty-one patients were analyzed; mean age was 61 ± 11 years, with a predominance of women (55.6%). Middle rectal tumors (66.6%), pT3 (59.2%) and pN0 (71.6%) were the most frequent. Stapled anastomosis (65.4%), and loop colostomy (80.2%) were the procedures most frequently performed. Sixty-five patients (80.2%) underwent stoma closure. The mean time for closure was 8.7 ± 4.4 months. The independent risk factors for non-closure of defunctioning stoma were complications of the anastomosis (p = 0.008) and follow-up complications (p = 0.007).
Conclusion: complications with anastomosis and during the follow-up are factors that may justify a permanent stoma after low anterior resection for treatment of rectal adenocarcinoma.

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Fatores preditivos da permanência do estoma derivativo temporário no tratamento do adenocarcinoma de reto

Palavras-chave:
Câncer retal
Cirurgia
Complicações
Estoma cirúrgico
Anastomose cirúrgica

RESUMO

Objetivo: determinar quais os fatores preditivos de não fechamento do estoma desfuncionalizante na retossigmoidectomia anterior para tratamento do adenocarcinoma de reto.
Método: estudo de Coorte retrospectivo dos pacientes submetidos a retossigmoidectomia anterior e estoma derivativo em período de nove anos. Comparou-se o grupo que fechou o estoma derivativo (Grupo A) com o grupo que não fechou (Grupo B) através de análise uni e multivariada.
Resultados: foram estudados 81 pacientes, cuja média de idade foi de 61 ± 11 anos, com predomínio de mulheres (55,6%). Tumor de reto médio (66,6%), pT3 (59,2%) e pN0 (71,6%) foram os mais freqüentes. A anastomose mecânica foi a mais realizada (65,4%), assim como transversostomia em alça (80,2%). Sessenta e cinco pacientes (80,2%) fecharam o estoma. O tempo médio de fechamento foi 8,7 ± 4,4 meses. Os fatores de risco independentes de não fechamento do estoma foram complicações da anastomose (p = 0,008) e do seguimento (p = 0,007).
Conclusão: complicações da anastomose e do seguimento são fatores que podem justificar a permanência do estoma pós-retossigmoidectomia para tratamento do adenocarcinoma retal.
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Introduction

Historically, patients with middle and low rectal tumors were submitted to abdominoperineal resection and consequently to permanent colostomy. Nowadays, with the improvement of the surgical technique by total mesorectal excision, the use of staplers and neoadjuvant chemoradiotherapy, anterior rectal resection with low or ultra-low anastomosis became widely used and well accepted in terms of the oncological radicality. This has provided sphincter preservation,[1] while adding a new variable: the derivative or defunctioning stoma.

Low and ultralow anastomosis imply an increased risk of dehiscence.[2] Many authors, in the past, indicated a routine defunctioning stoma for any extra-peritoneal anastomosis: not to prevent dehiscence but to reduce the chance of systemic repercussions in case of dehiscence.[2-11]

However, currently, the selective indication for defunctioning stoma after low anterior resection predominates.[12] The decision regarding the need for the stoma should consider the following factors: male gender (narrow pelvis),[3,5] older age,[6] obesity,[2] malnutrition, comorbidities[13] or specifically cardiovascular disease,[6] clinical obstruction,[5] corticosteroid use,[13] preoperative radiotherapy[5,13,14] or transfusion,[2] anastomotic distance less than 5 cm from the anal verge,[3] infection[5] or pelvic contamination,[13] deficient blood supply,[2] technical failure (incomplete rings, positive anastomosis test)[1,3] or difficulty (bleeding)[1,13] and surgeon's inexperience.[5]

The anastomotic dehiscence may have early complications such as localized abscess, intestinal subocclusion or peritonitis, sometimes requiring surgical treatment (reoperation) or non-surgical interventions (drainage), which can lead to resolution or sepsis and death. Furthermore, late complications such as anastomotic stenosis, fistula, sinus and chronic rectal pain could make a derivative stoma become a permanent one.[1,2,5]

The closing of the stoma should be ideally accomplished in six to 12 weeks.[10] However, it is known that this time may be further extended and, in some cases, the stoma becomes permanent. Some authors report that the non-closure is related to the patient's condition (older age, comorbidities) or treatment (chemotherapy, anastomotic dehiscence).[13]

Given this, it should be considered which patients do not benefit from sphincter-preserving surgery but could be designated for a permanent colostomy, either by Hartmann's procedure or even abdominoperineal amputation. The importance of determining the factors that lead to a temporary defunctioning stoma to become permanent is, precisely, to tailor the best treatment for each patient and prevent failure.

Thus, the objective of this study is to determine the risk factors for non-closure of defunctioning stoma in low anterior resection for treatment of rectal adenocarcinoma, and to determine the predictive factors for closure delay (secondary outcome).

Method

This was a retrospective cohort study carried out through analysis of medical records of patients with the following inclusion criteria: elective surgery performed by the coloproctology team of Hospital Heliópolis in São Paulo, between January 2004 and December 2012, submitted to anterior rectal resection with total mesorectal excision and defunctioning stoma for the treatment of rectal adenocarcinoma, with a minimum follow-up of six months. Poorly documented records regarding histological features of the tumor, intraoperative evaluations, surgical and follow-up complications and uncertainty regarding the closure, in addition to the patients whose follow-up was not carried out by this service were excluded.

The data collected, related to patient was: gender, age (years), comorbidities, smoking status and alcohol consumption. Data collected related to the tumor was: location (low, middle, upper rectum and rectosigmoid junction), carcinoembryonic antigen (CEA) levels, histological differentiation (G0, G1, G2, G3), tumor penetration of the intestinal wall (pT0, pT1, pT2, pT3, pT4), lymph node involvement (pN0, pN1, pN2),

presence of metastasis, staging (0-II, III-IV), perineural, lymphatic and venous invasion. Data related to the treatment was: neoadjuvant chemotherapy and radiotherapy, type of anastomosis (manual and mechanical), stoma type (ileostomy and transversostomy), radicality of surgery (R0, R1, R2), distal margin (cm), adjuvant chemotherapy and radiotherapy. Data related to treatment complications or follow-up complications included anastomotic and stomal complications and those occurring during follow-up.

The rectal tumor was divided into low, middle and upper rectum, considering the measurement in centimeters from the anal verge to the distal end of the tumor through rigid rectosigmoidoscopy. The distal 5 cm were considered as low rectum, from 5 cm to 10 cm, as middle rectum and over 10 cm, upper rectum. The rectosigmoid junction tumor was identified as such when it was found during surgery, completely intraperitoneal at the level of the promontory.

The degree of histological differentiation was divided into well (Grade 1 - G1), moderate (G2) and poorly differentiated (G3), and G0 when the histological differentiation was undetermined due to absence of lesion in the surgical specimen after neoadjuvant therapy. Histological analysis of the surgical specimen was classified according to the sixth edition of the American Joint Committee on Cancer (AJCC),[15] being pT0 and stage 0 the absence of tumor in the surgical specimen after neoadjuvant treatment.

The neoadjuvant radiotherapy consisted in 4500 to 5040 cGy irradiation, whereas the neoadjuvant chemotherapy consisted of 5-fluorouracil and leucovorin (the first and last weeks, when combined with radiotheraphy) from six to eight weeks before surgery.

The classification of surgical radicality regarding tumor resection were R0 = no residual lesion, R1 = microscopic residual lesion and R2 = macroscopic residual lesion.[16]

All complications that occurred within 30 days after surgery were categorized as postoperative complications. Anastomotic complications were considered as late complications (stenosis, sinus, fistula, recurrence in the anastomotic line). For this purpose, all patients underwent endoscopic examination of the anastomosis and selected patients were also submitted to radiological evaluation to detect asymptomatic anastomotic complications.

Subsequently, the group that closed the defunctioning stoma (Group A) was compared to the group that did not (Group B), using the described variables. The statistical tests used were the chi-square and Fisher's exact test for qualitative variables and Levene's test for quantitative variables (age, CEA and margin). Statistical analysis was performed using SPSS (Statistical Package for Social Sciences) software, release 19.0. For variables with $p < 0.05$ in the univariate analysis, Cox regression (multivariate analysis) was performed and independent predictors for non-closure of the defunctioning stoma in the treatment of rectal carcinoma were identified.

For the secondary outcome, the same abovementioned predictive factors were analyzed, but patients who did not close the stoma were excluded and the delay in closing was analyzed. Stoma closure delay was defined as interval longer than six months. Patients who closed successfully within six months post-rectosigmoidectomy were compared with those that closed after six months. The statistical analysis was the same as described for the primary outcome, with 5% statistical significance.

Results

Eighty-eight patients underwent low anterior resection with defunctioning stoma for the treatment of rectal adenocarcinoma during nine years at the Coloproctology Service in a tertiary hospital. Seven of them were excluded due to a lack of well-documented information, especially regarding the follow-up and closure verification.

Eighty-one patients were studied, and the sample characteristics are shown in Tables 1 and 2. Sixty-five of the 81 patients (80.2%) closed the stoma until the end of the study. The mean time for closure was 8.7 months with a standard deviation of 4.4 months and a median of eight months.

The postoperative, anastomotic and follow-up complications are described in Table 3.

The significant variables in the univariate analysis related to the non-closure were: mechanical anastomosis, margin smaller than 2 cm, anastomotic complications and follow-up complications (Tables 4 and 5). At the multivariate analysis, anastomotic and follow-up complications were independent predictors for non-closure (Table 5).

Among the 65 patients who closed the stoma, only 23 of them (35.4%) closed it after six months. The variables that were related to closure delay in the univariate analysis were pT2-3 ($p = 0.001$), lymph node involvement (pN1-2, $p = 0.024$) and performance of adjuvant chemotherapy ($p = 0.032$).

However, none of these factors was significant in the multivariate analysis: pT2-3 ($p = 0.734$), pN1-2 ($p = 0.297$) and performance of adjuvant chemotherapy ($p = 0.732$).

Discussion

If on the one hand the abdominoperineal amputation of the rectum, created by Miles in 1908, requires a permanent stoma, on the other hand, the rectal anterior resection with low anastomosis and defunctioning stoma allows sphincter preservation. This operation, however, entails a potential risk of permanent stoma[4] and morbidity secondary to the stoma, and especially to its closure.[17] It is known that some factors may affect adversely stoma closure, leading to its delay or even its non-closure.

The rate of non-closure of the defunctioning stoma in our group was 19.8%, similar to that found by other authors who described a rate of 18% to 36%.[4,7,13,15,17-20]

The mean time of closure was 8.7 months. This number is above the mean value found in international literature, ranging from 4.1 to 5.9 months[4,7,13] and coincides with the mean time found in national studies, of 12 months.[20] Some authors report that 97% of patients closed their stomata within one year after the rectosigmoidectomy,[7] a much higher rate than ours of 67.9%.

Some authors have associated older age to non-closure of the stoma,[7,11] different from our findings in which age was not characterized as a predictive factor. Other factors related to the patient, such as obesity and smoking status, according to some authors, are predictive factors for defunctioning sto-

Table 1 – Clinical and tumor-related characteristics of the 81 patients submitted to low rectal anterior resection with defunctioning stoma at Hospital Heliópolis between 2004 and 2012. São Paulo, 2013.

Variable	Category	n[a] (%) / Measure
Gender	Male	36 (44.4)
	Female	45 (55.6)
Age (years)	Mean ± SD	61.05 ± 11.89
	Median	62
	Minimum (Min) - Maximum (Max)	28 – 84
Comorbidities		43 (53.0)
Smoking status		16 (19.7)
Alcohol consumption		6 (7.4)
Location	Lower rectum	6 (7.4)
	Middle rectum	54 (66.6)
	Upper rectum	18 (22.2)
	Rectosigmoid junction	3 (3.7)
CEA (ng/mL)	Mean ± SD	17.3 ± 54.2
	Median	3.4
	Min – Max	0.5 – 393.2
Histological differentiation [b]	G0	5 (6.2)
	G1	20 (24.7)
	G2	50 (61.7)
	G3	6 (7.4)
pT[c]	pT0	5 (6.2)
	pT1	7 (8.6)
	pT2	21 (25.9)
	pT3	48 (59.3)
pN[c]	pN0	58 (71.6)
	pN1	16 (19.7)
	pN2	7 (8.6)
Metastasis		1 (1.2)
Staging[c]	0	2 (2.5)
	I	19 (23.5)
	II	32 (39.5)
	III	27 (33.3)
	IV	1 (1.2)
Perineural invasion		7 (8.6)
Lymphatic invasion		24 (29.6)
Venous invasion		3 (3.7)

CEA, Carcinoembryonic antigen.
[a] n, number of patients.
[b] G0, indeterminate; G1, well-differentiated; G2; moderately differentiated; G3, little differentiated.
[c] TNM by AJCC sixth edition.

Table 2 – Treatment and complication characteristics of 81 patients submitted to low rectal anterior resection with defunctioning stoma at Hospital Heliópolis between 2004 and 2012. São Paulo, 2013.

Variable	Category	n[a] (%) / Measure
Neoadjuvant chemotherapy	Submitted	23 (28.3)
Neoadjuvant radiotherapy	Submitted	22 (27.1)
Anastomosis	Mechanical	53 (65.4)
	Manual	28 (34.5)
Defunctioning stoma (loop)	Transversostomy	65 (80.2)
	Ileostomy	16 (19.7)
Radicality	0	79 (97.5)
	2	2 (2.4)
Distal margin (cm)	Mean ± SD	2.3 ± 1.4
	Median	2.0
	Min – Max	0.2 – 7.0
Adjuvant chemotherapy	Submitted	55 (67.9)
Adjuvant radiotherapy	Submitted	28 (34.5)
Postoperative complication	Present	17 (20.9)
Anastomotic complication	Present	11 (13.5)
Stoma complication	Present	38 (46.9)
Follow-up complication	Present	10 (12.3)

[a] n, number of patients.

Table 3 – Complications in 81 patients submitted to low rectal anterior resection with defunctioning stoma at Hospital Heliópolis between 2004 and 2012, São Paulo, 2013.

Complications	Number of patients (%)
Postoperative	17 (20.9)
Anastomotic dehiscence	9 (52.9)
Surgical wound infection	6 (35.2)
Prolonged ileus	6 (35.2)
Reoperation	5 (29.4)
Decompensation of comorbidities	4 (23.5)
Anastomosis	11 (13.5)
Stenosis	6 (54.5)
Anastomosis recurrence	4 (36.3)
Fistula	2 (18.1)
Follow-up	10 (12.3)
Local recurrence	7 (70)
Metastasis	8 (80)
Another surgery	10 (100)
Comorbidity complication	2 (20)
Death	1 (10)

ma non-closure.[11] A possible explanation for those findings was the increase in the rate of clinical and postoperative complications in this group of patients. Their sample, however, did not include only patients with colorectal carcinoma.[11] The present study did not assess obesity, and only 19.7% of patients had a smoking status, thus they were not characterized as predictive factors.

Middle rectal tumors predominated (66.7%) in accordance with the literature data, where the defunctioning stoma is more frequently performed in tumors at that location.[7]

There are question regarding whether the defunctioning stoma should be avoided in patients with advanced disease, as authors have described that the probability of non-closure in stage IV patients is 30% compared to 3% at stages 0 to III.[13] Other authors have described extremely high rates (68.6%) of non-closure of defunctioning stoma in stage IV.[21] In the present study, we did not evaluate stage IV alone, as only one patient displayed this stage. Analysis of stages 0 (no residual lesion after neoadjuvant chemoradiotherapy) to II *versus* stages III and IV showed no differences between groups A and B, in constrast with a study that demonstrated that stage IV was a predictor of permanent stoma.[4]

The neoadjuvant radiotherapy is a risk factor for anastomotic dehiscence,[5,13,14] but it is not characterized as a risk factor

Table 4 – Univariate and multivariate analysis comparing clinical and tumor variables of patients submitted to anterior low rectal anterior resection that closed the defunctioning stoma (Group A) with those who did not close (Group B) at Hospital Heliópolis between 2004 and 2012. São Paulo, 2013.

Variable	Category	Number of patients (%) Group A	Number of patients (%) Group B	Univariate p	Multivariate p
Gender	Male	27 (75)	9 (25)	0.401	—
	Female	38 (84.4)	7 (15.6)		
Age (years)	Mean ± SD	62.0 ± 10.5	60.8 ± 12.1		—
	Median	62.5	62	0.708	
	Min – Max	48-80	28-84		
Comorbidities	Present	32 (74.4)	11 (25.6)	0.263	—
	Absent	33 (86.8)	5 (13.2)		
Smoking	Present	11 (68.8)	5 (31.3)	0.290	—
	Absent	54 (83.1)	11 (16.9)		
Alcohol consumption	Present	5 (83.3)	1 (16.7)	0.844	—
	Absent	60 (80)	15 (20)		
Location	Lower rectum	3 (50)	3 (50)		—
	Middle rectum	44 (81.5)	10 (18.5)		
	Upper rectum	15 (83.3)	3 (16.7)	0.225	
	Rectosigmoid junction	3 (100)	0 (0)		
CEA (ng/mL)	Mean ± SD	16.7 ± 56.1	19.5 ± 48.5		
	Median	3.7	1.955	0.863	—
	Min – Max	0.5 – 393.2	0.8 – 184.3		
[a]Histological differentiation	G0	3 (60)	2 (40)		
	G1	19 (95)	1 (5)	0.200	—
	G2	38 (76)	12 (24)		
	G3	5 (83.3)	1 (16.7)		
[b]pT	pT0	4 (80)	1 (20)		
	pT1	6 (85.7)	1 (14.3)	0.694	—
	pT2	15 (71.4)	6 (28.6)		
	pT3	40 (83.3)	8 (16.7)		
[b]pN	pN0	49 (84.5)	9 (15.5)		
	pN1	11 (68.8)	5 (31.3)	0.311	—
	pN2	5 (71.4)	2 (28.6)		
Metastases	Present	1 (100)	0 (0)	0.618	—
	Absent	64 (80)	16 (20)		
[b] Staging	0-II	44 (83)	9 (17)	0.396	—
	III-IV	21 (75)	7 (25)		
Perineural invasion	Present	4 (57.1)	3 (42.9)	0.135	—
	Absent	61 (82.4)	13 (17.6)		
Lymphatic invasion	Present	17 (70.8)	7 (29.2)	0.222	—
	Absent	48 (84.2)	9 (15.8)		
Venous invasion	Present	2 (66.7)	1 (33.3)	0.488	—
	Absent	63 (80.2)	15 (19.8)		

CEA, carcinoembryonic antigen.

[a] G0, indeterminate; G1, well-differentiated; G2; moderately differentiated; G3, little differentiated.

[b] TNM by AJCC sixth edition.

for non-closure. Some authors have demonstrated an association in the univariate, but not in the multivariate analysis.[4,22,23]

Our sample shows some association of non-closure with mechanical anastomosis and distal margin smaller than 2 cm in the univariate analysis, but that was not confirmed as an independent factor. There have been no reports of other studies that correlated these variables.

As for the stoma topography, 80.2% were loop transversostomy. It is a preference of the service to perform a transversostomy rather than an ileostomy. There was no correlation of this variable with the rate of stoma closure. In contrast, other authors have described the colostomy as an independent variable for permanence of the stoma.[4] However, these authors do not consider the location of the temporary stoma, but the topography of the stoma at the end of treatment.[4] In brief, the recreation of the stoma is very common in patients who develop pelvic recurrence and this is preferred with the use of colostomy, which generates an interpretation bias of this variable.

Although common sense makes us believe that adjuvant chemotherapy and radiotherapy are factors that influence closure delay of the defunctioning stoma, these variables were not related to the delay in closure or the permanence of the stoma.

Among the early and late postoperative complications of low anterior resection with defunctioning stoma, the most common are those related to the anastomosis, such as dehiscence and stenosis.[4] These were independent risk factors for the permanence of the stoma.[4,7,8,13,19,22,23] Thus, the complications of the anastomosis itself are added to complications 30 days after the surgery. In our sample, anastomotic complications were an independent predictor of failure of closure of

Table 5 – Univariate and multivariate analyses comparing treatment and complication variables of patients submitted to low rectal anterior resection that closed the defunctioning stoma (Group A) with those who did not close it (Group B) in Hospital Heliopolis between 2004 and 2012, São Paulo, 2013.

Variable	Category	Number of patients (%)		Univariate	Multivariate
		Group A	Group B	p	p
Neoadjuvant chemotherapy	Present	15 (65.2)	8 (34.8)	0.060	—
	Absent	50 (86.2)	8 (13.8)		
Neoadjuvant radiotherapy	Present	15 (68.2)	7 (31.8)	0.120	—
	Absent	50 (84.7)	9 (15.3)		
Anastomosis	Mechanical	39 (73.6)	14 (26.4)	0.044	0.115
	Manual	26 (92.9)	2 (7.1)		
Defunctioning stoma	Transversostomy	53 (81.5)	12 (18.5)	0.726	—
	Ileostomy	12 (75)	4 (25)		
Surgical radicality	0	0	16 (20.3)	0.477	—
	2	2	0 (0)		
Distal margin (cm)	Mean ± SD	2.5 ± 1.4	1.6 ± 1.3		
	Median	2	1.25	0.039	0.230
	Min – Max	0.6 – 7	0.2 – 5		
Adjuvant chemotherapy	Present	41 (74.5)	41 (74.5)	0.077	—
	Absent	24 (92.3)	24 (92.3)		
Adjuvant radiotherapy	Present	23 (82.1)	5 (17.9)	0.755	—
	Absent	42 (79.2)	11 (20.8)		
Postoperative complication	Present	11 (64.7)	6 (35.3)	0.090	—
	Absent	54 (84.4)	10 (15.6)		
Anastomosis complication	Present	4 (36.4)	7 (63.6)	7 (63.6)	0.008
	Absent	61 (87.1)	9 (12.9)	9 (12.9)	
Stoma complication	Present	30 (78.9)	8 (21.1)	0.788	—
	Absent	35 (81.4)	8 (18.6)		
Follow-up complication	Present	3 (30)	7 (70)	< 0.001	0.007
	Absent	62 (87.3)	9 (12.7)		

stoma, but not postoperative complications. Differently from our study, a similar study characterized postoperative complications as a predictive variable.[20]

We know that complications related to the stoma affect quality of life, especially when they are permanent. However, there is no correlation between these complications and lower rates of stoma closure. It is noteworthy the fact that if we consider that around 20% of stomata become permanent, these complications should be minimized by good defunctioning stoma construction (previous planning, transrectal, adequate size site, good blood supply).[7]

Regarding the follow-up, the appearance of metastasis and local recurrence can also slow down or prevent closure. Patients with disease progression can have their general status affected and often retain the use of chemotherapeutic agents, thus contributing to the non-closure of the stoma.[7]

Among all variables analyzed, follow-up complications (local recurrence, synchronous or metachronous tumors, disease progression, surgical indications and clinical complications) are the most obvious predictors of non-closure,[4,7,8,13] which corroborated our findings.

Local recurrence is considered the most important factor of stomal non-closure.[4,19,22,23] In a critical analysis, one can say that it is difficult to predict preoperatively if the patient will have a poor evolution, but measures such as adequate staging, radical surgery, effective chemotherapy, radiotherapy if necessary, careful monitoring of patients are the only ways to prevent follow-up complications.

An interesting study reports an overall five-year survival in patients submitted to low anterior rectal resection without derivation (81.1%), with temporary stoma (81.5%) and those who progressed to permanent stoma (45.5%).[4] This suggests that it is actually the disease progression that determines non-closure.

Considering the delay in closure, none of the variables was independently related to the closure after more than six months, which suggests that those patients whose stomata become permanent have specific characteristics, not just being the result of closure delay.

Finally, one should critically consider the limitations of this study: a retrospective design, small sample size, single center and selective decision of defunctioning stoma based on the surgeon's choice. However, it is undeniable the importance to highlight the findings that point to the need of the construction of a good anastomosis, even with the false safety inherent to the presence of defunctioning stoma, as well as the absence of benefit of this stoma in patients who will potentially progress in the disease.

Conclusion

The rectal adenocarcinoma surgery with defunctioning stoma has the potential to become permanent. Anastomotic and follow-up complications are predictors of failure.

Conflicts of interest

The authors declare no conflicts of interest.

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