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ORIGINAL ARTICLE

When is the best time for temporary stoma closure in laparoscopic sphincter-saving surgery for rectal cancer? A study of 259 consecutive patients

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Abstract
Background There is no consensus regarding the best timing for temporary stoma closure after proctectomy for rectal cancer, especially if the patient requires adjuvant chemotherapy. This study aimed to assess whether the timing of stoma closure could influence postoperative morbidity.
Methods Patients with rectal cancer undergoing laparoscopic proctectomy with temporary stoma were included and divided into three groups according to the delay of stoma closure after proctectomy: ≤60 days (Group A), 61–90 days (Group B), and >90 days (Group C).
Results From 2008 to 2013, 259 patients (146 men, median age 61 years) were divided into Groups A ($n = 65$), B ($n = 115$), and C ($n = 79$). At the time of stoma closure, seven (11 %) patients received adjuvant chemotherapy in Group A versus 42 (37 %) in Group B ($p = 0.0002$) and 24 (30 %) in Group C ($p = 0.004$), and peristomal hernia was noted in four patients (6 %) in Group A versus 14 (12 %) in Group B and 21 (27 %) in Group C ($p < 0.0001$). Although overall postoperative morbidity was similar between groups, anastomotic leakage (at the stoma closure site) was noted in one patient in Group A versus zero in Group B versus four in Group C ($p = 0.03$). Median hospital stay was 5 days in Group A versus 6 in Group B versus 6 in Group C ($p = 0.004$).
Conclusions Our results suggested that timing of temporary stoma closure can influence postoperative morbidity. Best results were obtained if stoma closure was performed before 90 days, even during adjuvant chemotherapy. There is no benefit in delaying stoma closure after completion of adjuvant chemotherapy.

Keywords Temporary stoma · Stoma closure · Anastomotic leak · Rectal cancer

Introduction

Despite advances in the surgical management of rectal cancer, postoperative morbidity after subtotal mesorectal excision or total mesorectal excision (TME) remains an issue. Symptomatic anastomotic leakage is the most feared complication and is observed in up to 25 % of the patients [1, 2]. For this reason, routine use of a temporary defunctioning stoma is currently recommended. This recommendation is mainly based on the randomized study of Matthiessen et al. [2], where the rate of anastomotic leakage decreased from 28 % without a temporary stoma to only 10 % with a temporary stoma ($p < 0.001$). Furthermore, this benefit of the defunctioning stoma was confirmed by two recent meta-analyses [3, 4].

Because of the negative effect of a defunctioning stoma on the patient's quality of life, there is pressure from the patient to close this temporary stoma as soon as possible. We have also suggested in a randomized study [5] that early stoma closure around day 10 after TME is feasible, provided that the patient's postoperative course is completely uneventful. However, there is general agreement today, although without strong evidence, that the temporary stoma should be closed between 6 and 8 weeks after

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TME after imaging shows that the anastomosis is intact, without radiological leakage or stenosis.

However, there are two main reasons why temporary stoma closure is sometimes delayed. First reason is the occurrence of anastomotic leakage. In this case, the consensus is to wait until healing (or at least 6 months after TME in case of asymptomatic leakage if healing is not obtained) for closing the stoma. The second reason is the indication of adjuvant chemotherapy for 6 months, usually node-positive cancers. In this case, many surgeons delay stoma closure until after completion of the 6-month course of chemotherapy.

However, during this interval between TME and stoma closure, stoma-related complications occur frequently (21–70 %), such as dehydration (leading in rare cases to acute renal failure) or leakage around the stoma with skin burns, peristomal dermatitis, and parastomal ulceration. Furthermore, stoma necrosis, peristomal hernia, retraction, prolapse, and stenosis can sometimes be observed. All these complications can affect quality of life and cause psychological stress [6].

There is a consensus to avoid stoma closure before the beginning of adjuvant chemotherapy (so that <2 months pass between TME and beginning of chemotherapy) [7]. However, the choice between stoma closure at 6 months after the end of chemotherapy and stoma closure during chemotherapy (after two or three courses) remains difficult because data are sparse, especially concerning the possible impact of stoma closure timing on postoperative morbidity.

Thus, the aim of the present study was to assess the possible impact of stoma closure timing on postoperative results in a homogeneous group of patients undergoing laparoscopic sphincter-saving surgery for rectal cancer.

Materials and methods

Study population

All patients who underwent laparoscopic subtotal mesorectal excision or TME with sphincter-saving surgery (i.e., stapled colorectal or manual coloanal anastomosis with or without inter-sphincteric resection) for rectal adenocarcinoma were identified from our prospective single-center institutional review board-approved database. Patients were included if they had a temporary ileostomy, at the time of TME, closed not before 5 weeks after TME. Temporary ileostomy was systematically performed to defunction low colorectal anastomosis.

Data collection (Table 1) included: patient features [gender, age, body mass index (BMI)]; preoperative treatment (neoadjuvant radiochemotherapy); intraoperative features (type of anastomosis); pathological features (tumor location and staging according to TNM classification); and postoperative treatment (adjuvant chemotherapy).

Stoma closure

Stoma closure was routinely performed around 6–8 weeks after TME and if a computed tomography (CT) scan performed at around 5 weeks with contrast enema did not show any suspicion of anastomotic leakage. However, stoma closure was sometimes delayed, mainly because of radiological asymptomatic anastomotic leakage or indication for adjuvant chemotherapy. For these reasons, the patients were divided into three groups according to the timing of temporary stoma closure: ≤60 days (Group A), 61–90 days (Group B), and >90 days (Group C). In patients on adjuvant chemotherapy, stoma closure was performed from 2 to 3 weeks after the last administration of chemotherapy. Chemotherapy was given again approximately 10–15 days after uneventful stoma closure.

Closure of the ileostomy was performed under general anesthesia with a peristomal skin incision. After small bowel mobilization, a hand-sewn end-to-end anastomosis was fashioned using a single-layer interrupted serosubmucusal 5-0 PDS® (Ethicon Inc) suture. Fascia was closed using 1-0 Vicryl® (Ethicon Inc). The wound was partially closed with a purse string, as previously described [8].

Outcome measures

Postoperative stoma-related morbidity was defined as any related complication occurring during the hospital stay or within 30 days after stoma closure. We distinguished non-septic surgical complications (i.e., hemorrhage, hematoma, ileus or small bowel obstruction), septic surgical complications (i.e., peritonitis, anastomotic leakage at the site of stoma closure, intra-abdominal abscess, wound abscess), and medical complications (i.e., urinary/pulmonary infection, cardiac/neurologic problems). Complications were classified according to the Clavien–Dindo classification [9]. Major complications were defined as those requiring surgical, radiological or endoscopic intervention (Clavien–Dindo III) and life-threatening complications as those requiring intensive care management (Clavien–Dindo IV).

Statistical analysis

The quantitative data were reported as the median and range. Normally distributed quantitative data were analyzed with Student's t test, and otherwise, the Mann–Whitney test was used. The qualitative data were reported as the number of patients (percentage of patients) and were compared using Pearson's χ^2 test or Fisher's exact test, as

Table 1 Characteristics of 259 patients undergoing temporary stoma closure after laparoscopic or total mesorectal resection for rectal cancer

	Group A ≤60 days $n = 65$	Group B 61–90 days $n = 115$	Group C >90 days $n = 79$	p value
Gender				0.10
Male	36 (55)[a]	58 (50)	52 (66)	
Female	29 (45)	57 (50)	27 (34)	
Age	60 [25–78][b]	62 [29–85]	62 [34–89]	0.13
BMI	24 [16–33]	24 [16–42]	24 [16–34]	0.55
ASA grade				0.57
I	18 (28)	34 (29)	16 (20)	
II	41 (63)	72 (63)	53 (67)	
III	6 (9)	9 (8)	10 (13)	
IV	–	–	–	
Tumor location				0.55
Upper rectum	14 (21)	33 (29)	21 (27)	
Middle rectum	22 (34)	42 (36)	23 (29)	
Lower rectum	29 (45)	40 (35)	35 (44)	
Neoadjuvant radiochemotherapy	49 (75)	67 (58)	47 (59)	0.055
Surgical procedure				
Stapled colorectal anastomosis	38 (58)	73 (63)	46 (58)	0.70
Hand-sewn coloanal anastomosis	27 (42)	42 (37)	33 (42)	
Side to end	48 (74)	78 (68)	53 (67)	0.63
End to end	17 (26)	37 (32)	26 (33)	
pT stage				**0.003**
T3–T4	25 (38)	53 (46)	48 (61)	
T1–T2	20 (31)	38 (33)	21 (26.5)	
Tis	1 (2)	5 (4)	6 (7.5)	
T0	19 (29)	19 (17)	4 (5)	
pN stage				**<0.0001**
N+	10 (15)	45 (39)	45 (57)	
N0	55 (85)	70 (61)	34 (43)	
pM stage				0.54
M+	4 (6)	10 (9)	9 (11)	
M0	61 (94)	105 (91)	70 (89)	

BMI body mass index, *ASA* American Society of Anesthesiology

[a] Number of patients (percentage); [b] median [range]; $p < 0.05$ was considered as significant (in bold)

appropriate. The tests were always two-sided, and the level of statistical significance was set at $p < 0.05$. The analysis was performed using the GraphPad Prism software (La Jolla, California, USA).

Results

Patient characteristics

From 2008 to 2013, 259 patients with rectal cancer underwent laparoscopic subtotal mesorectal excision or TME for rectal adenocarcinoma with sphincter-saving surgery and temporary ileostomy, in our institution. Sixty-five patients underwent stoma closure before day 61 after proctectomy (Group A), 115 patients between day 61 and day 90 (Group B), and 79 patients after day 90 (Group C). Patient characteristics are detailed in Table 1.

There was no difference between the groups in gender, age, BMI, American Society of Anesthesiology (ASA) grade, tumor location, and surgical procedure.

Concerning pathologic examination of the specimen, significantly more patients from Groups A ($n = 19$, 29 %) and B ($n = 19$, 17 %) presented complete tumor response (ypT0) than those from Group C ($n = 4$, 5 %; $p = 0.0002$ vs. Group A and $p = 0.03$ vs. Group B, respectively).

Finally, 10 patients from Group A (15 %) had node involvement versus 45 (39 %) in Group B ($p = 0.0009$) and 45 (57 %) in Group C ($p < 0.0001$).

Operative results

Before stoma closure, as shown in Table 2, only one patient (1.5 %) in Group A and two (2 %) in Group B had a history of anastomotic leakage of the colorectal or coloanal anastomosis before stoma closure versus 44 (56 %) in Group C ($p < 0.0001$). No patient from Group A had stoma-related complications, whereas two cases of dehydration and two cases of acute renal failure occurred in Groups B (2 %) and C (2.5 %), respectively. One patient from Group B had stoma prolapse and one patient from Group C had peristomal evisceration, needing surgery.

Patients from Group A ($n = 7$, 11 %) were also less frequently on adjuvant chemotherapy than those from Groups B ($n = 42$, 37 %; $p = 0.0002$) and C ($n = 24$, 30 %; $p = 0.004$).

At the time of stoma closure, four patients (6 %) from Group A ($n = 4$, 6 %) and 14 (12 %) from Group B ($n = 14$, 12 %) had a peristomal hernia versus 21 (27 %) in Group C ($p = 0.001$ versus Group A and $p = 0.01$ versus Group B, respectively).

No significant difference between groups was noted regarding operative time, overall morbidity rate, and medical morbidity rates. However, significantly less patients from Group A ($n = 1$) and B ($n = 0$) had anastomotic leakage (at the site of stoma closure) than patients from Group C ($n = 4$; $p = 0.03$). Furthermore, there were significantly less patients with major morbidity (Clavien–Dindo III–IV) in Group B ($n = 0$) than in Group C ($n = 6$, $p = 0.004$).

Median length of hospital stay after stoma closure was significantly shorter in Group A (5 [4–15] days) than in Group C (6 [4–20] days, $p = 0.004$).

Table 2 Perioperative findings and postoperative morbidity in 259 patients undergoing temporary stoma closure after laparoscopic or total mesorectal resection for rectal cancer

	Group A ≤60 days $n = 65$	Group B 61–90 days $n = 115$	Group C >90 days $n = 79$	p value
Perioperative findings				
Anastomotic leakage	1 (1.5)[a]	2 (2)	44 (56)	**<0.0001**
Clinical	1 (1.5)	1 (1)	15 (19)	
Asymptomatic	–	1 (1)	29 (37)	
Delay to stoma closure (days)	51 [36–60][b]	73 [61–90]	134 [91–525]	**<0.0001**
Peristomal hernia[c]	4 (6)	14 (12)	21 (27)	**0.001**
Adjuvant chemotherapy ongoing	7 (11)	42 (37)	24 (30)	**0.001**
Operative time (min)[c]	70 [25–165]	70 [30–195]	75 [40–180]	0.33
Stoma closure-related morbidity	7 (11)	14 (12)	12 (15)	0.71
Surgical morbidity	3 (5)	9 (8)	14 (18)	**0.02**
Wound infection	1[♯]	3[♯]	1[♯]	0.77
Wound hematoma	–	2	2	0.46
Intraabdominal abscess	–	–	3[♯]	0.06
Anastomotic leakage[d]	1	–*	4*,[♯]	**0.03***
Ileus[e]	1	4[♯]	4[f,♯]	0.52
Medical morbidity	5 (8)	7 (6)	3 (4)	0.6
Electrolytic disorder	4[♯]	3	1	0.22
Urinary blockage	–	3	–	0.15
Urinary infection	–	1	1[♯]	–
Venous thromboembolism	–	–	1[♯]	–
Melena	1	–	–	–
Clavien–Dindo classification				**0.004***
I–II	6 (9)	14 (12)	6 (7.5)	
III–IV	1 (1.5)	–*	6 (7.5)*	
Length of stay (days)	5 [4–15]*	6 [3–20]	6 [4–20]*	**0.004***

[♯] Patients with several complications; * groups with statistically significant difference

[a] Number of patients (percentage); [b] median [range]; [c] at time of stoma closure; [d] at the stoma closure site; [e] defined by abdominal distension and pain, and vomiting in the postoperative period; [f] one case of ileus concerned strangled crural hernia; $p < 0.05$ was considered as significant (in bold)

After a median follow-up of 17 [0–66] months, no significant difference between groups was observed for: rehospitalization (3 % in Group A vs. 3 % in Group B vs. 8 % in Group C), bowel obstruction (0 % vs. 1 % vs. 1 %), late anastomotic leakage (1 % vs. 3 % vs. 1 %), or hernia at the stoma closure site (3 % vs. 11 % vs. 8 %).

Discussion

Our study suggested that waiting more than 6 months after TME for stoma closure, whatever the reason (i.e., adjuvant chemotherapy, radiological anastomotic leakage), is usually not justified. The longer the delay between TME and stoma closure, the higher the surgical morbidity rate and the longer the hospital stay after stoma closure. Furthermore, we observed that even with ongoing adjuvant chemotherapy, stoma closure is feasible without increased morbidity. Therefore, it is our opinion that except in the case of non-healed anastomosis, the stoma must be closed as soon as possible, and no later than 3 months after primary surgery, even if a 6-month course of adjuvant chemotherapy is indicated.

There is currently general agreement about the routine use of temporary stoma in patients undergoing TME and sphincter-saving surgery for rectal cancer. Randomized studies and meta-analysis [2–4, 10] demonstrated that a temporary stoma reduced not only the rate of anastomotic leakage, but also its consequences, including the need for emergency reoperation (8.6 vs. 25.4 %, $p < 0.001$) [2]. According to most surgeons, the stoma must be closed around 60–90 days after first operation after contrast enema has demonstrated that the colorectal or coloanal anastomosis is healed. This classic time interval would allow recovery after primary surgery, softening of intraabdominal adhesions, and resolution of inflammation and edema of the stoma border [11]. However, during this period between the two operations, the patient is at risk for specific complications of this temporary stoma. Whether it is loop ileostomy or colostomy, stoma-related complications are frequent (up to 71 %) and varied: inappropriate site, dehydration, acute renal failure, requirement for parenteral nutrition, infectious risks related to insertion of a central venous catheter, leakage around the stoma with skin burns and peristomal dermatitis, parastomal ulceration, stoma necrosis, peristomal hernia, retraction, prolapse, and stenosis [6]. A defunctioning stoma also affects quality of life due to odor (16 %), day and night leakage (35 %), or soiling (30 %) [12].

Due to these possible problems observed with temporary stoma, patients push surgeons to close the stoma as soon as possible. Similarly, some surgeons have tried to reduce the delay between TME and stoma closure. A few authors have reported in retrospective studies an early stoma closure 2 weeks after primary surgery, with satisfactory results except as regards wound infection [5, 13–16]. Some years ago, we conducted a multicenter randomized study comparing early (around day 8) versus late stoma closure (around day 60) in 190 patients undergoing TME and sphincter-saving surgery for rectal cancer [5]. Our study showed the feasibility of early stoma closure in selected patients with an uneventful postoperative course and no leak on the CT-scan, with contrast enema on day 7. Overall, it was feasible in 190/253 patients (75 %). This limitation to early closure only in a subgroup of patients has been reported by other authors [13, 14, 17]. Furthermore, there can be logistic difficulties in organizing a second intervention during the same hospitalization. In the 190 patients, we observed a similar overall morbidity rate (31 vs. 38 %, $p = 0.254$), whereas small bowel obstruction (3 vs. 16 %, $p = 0.002$), medical complications (5 vs. 15 %, $p = 0.02$), and length of hospital stay (16 vs. 18 days, $p = 0.01$) were significantly reduced in case of early stoma closure. On the other hand, wound complications occurred more frequently after early closure (19 %) than after late closure (5 %, $p = 0.007$). Furthermore, controversial results have been also reported concerning the impact of delay for stoma closure on postoperative morbidity. Perez et al. [11] reported a significant correlation between the time interval between the primary procedure and ileostomy closure and the occurrence of postoperative morbidity. These authors suggested that the time interval should be longer than 8.5 weeks to lower the risk of postoperative complications. However, Cipe et al. [18] did not identify time to closure as a predictive factor of morbidity. Thus, and probably because of these controversial results, early stoma closure is not today routinely proposed after TME for rectal cancer.

Timing of early stoma closure can be also affected by two problems: first the occurrence of an anastomotic leakage, which can delay stoma closure up to 6 months after TME, and most importantly the indication for a 6-month course of adjuvant chemotherapy, mainly because of the presence of positive nodes in the resected specimen. In the latter case, many surgeons prefer to delay stoma closure until the end of adjuvant chemotherapy, for two reasons: first, any postoperative complication after stoma closure could delay chemotherapy and thus reduce disease-free survival; second, it is suggested by some authors that, if the stoma is closed during chemotherapy, postoperative morbidity could increase. However, there is no evidence that delaying stoma closure for 6 months is justified. First, it can expose the patient to all the complications observed in patients with a temporary stoma, at a probably higher rate than if stoma is closed earlier. For example, in our study, 2.5 % of the patients in Group C (>90 days)

developed acute renal failure and/or dehydration (vs. 0 % in Group A (≤60 days). Second, we observed that despite the lower rate of ongoing chemotherapy (30 %) in Group C (>90 days) than in Group B (61–90 days) (35 %), surgical morbidity including leakage at the site of stoma closure was significantly higher in the late group. Additionally, at the time of stoma closure, peristomal hernia was significantly more frequent in the late group (27 %) than in the other two groups (6 and 12 %, respectively), suggesting that the long-term risk of hernia development is probably higher in the late group. Finally, hospital stay was also significantly longer in the late group, probably because of the higher surgical morbidity observed in this group. Our results suggesting stoma closure during chemotherapy being safe and feasible are in accordance with a study reported by Tulchinsky et al. [19]. They observed no significant difference in postoperative complications, disease-free survival, and overall survival between patients whose stoma was reversed during adjuvant chemotherapy and those whose stoma was reversed after completion of chemotherapy.

This study is limited by its retrospective nature, with possible selection bias. However, we included consecutive patients undergoing stoma closure after subtotal mesorectal excision or TME. The highest incidence of anastomotic leakage of the colorectal or coloanal anastomosis in the last group was not an interpretation bias, given that the objective of this study concerned stoma closure-related morbidity.

Conclusions

Our results suggested that in patients undergoing sphincter-saving surgery for rectal cancer, closure of the temporary stoma is feasible and safe as soon as possible, around 60 and 90 days after TME. In the case of adjuvant chemotherapy, closure of the stoma is possible without increased morbidity between two courses of chemotherapy.

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent The authors declare that informed consent was obtained from all individual participants for whom identifying information is included in this article.

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