Usefulness of ileostomy defunctioning stoma after anterior resection of rectum on prevention of anastomotic leakage

A retrospective analysis

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Usefulness of ileostomy defunctioning stoma after anterior resection of rectum on prevention of anastomotic leakage. A retrospetice analysis

PURPOSES: *Anastomotic leakage is one of the major complications occurring after anterior resection of rectum. A defunctioning stoma is usually created routinely or on surgeons' discretion. The aim of this study was to investigate the usefulness of temporary ileostomy to prevent anastomotic leakage comparing the postoperative course of patients with and without defunctioning loop ileostomy.*
METHODS: *Patients that underwent anterior resection of rectum were recruited. 140 patients were enrolled and divided in two groups: patients without and with defunctioning loop ileostomy. Patients' characteristics and other useful data were recorded. A comparison between the two groups was made. The minimum follow-up was 11 months.*
RESULTS AND CONCLUSIONS: *18.6% of patients had a symptomatic anastomotic leakage. We observed more anastomotic leakages after medium-low resections of rectum with anastomosis than after resections with high anastomosis (15.7% vs 2.9%; p=0.03). There were no significant differences in overall and related mortality between patients without/with ileostomy. The presence of ileostomy was not protective towards anastomotic leakage either in the medium-low resections or in the high ones but it was towards its consequences such as clinical features.*
Nevertheless we found a statistically significative difference between recurrence rate of leakage in patients with and without ileostomy (p-Value=0.009).

KEY WORDS: Anterior resection of rectum, Ileostomy, Leakage

Introduction

Symptomatic anastomotic leakage after anterior resection of rectum is a common complication associated with strong risk of mortality, morbidity and permanent stoma [1-7]. The acute phase often requires emergency surgical procedures, certainly a prolongation of hospitalization or a readmission, obviously adding considerable financial costs [8,33].
Literature reports remarkably different rates of anastomotic leakage of colorectal anastomosis, ranging from 3% to 24% [9 10]; such differences can be explained by the varying definition of anastomotic leakage. The term "anastomotic leakage" is linked to peritonitis, pelvic abscesses or discharge of faeces from the pelvic drain. Any such condition may occur without time limit, even if they become less likely as time goes on [1].
Leakage can be ascertained by clinical symptoms and signs, endoscopic or radiological investigations or laparotomy.
Several studies have shown decreased clinical anastomotic leakage rates and reduced need for reintervention when a defunctioning loop ileostomy is created [11-15].

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Various studies analyzed the rate of anastomotic leakage and risk factors involved. We'd like to focus on the importance of faecal diversion through the creation of a loop ileostomy diverting on the preservation of primary anastomosis stoma after anterior resection of the rectum.

The aim of the study is to assess the usefulness of temporary ileostomy in preventing anastomotic leakage comparing the postoperative course of two groups of patients: a first group that underwent anterior resection of rectum and primary anastomosis without defunctioning loop ileostomy, and the second one that underwent anterior resection of rectum and primary anastomosis with a defunctioning loop ileostomy.

Material and Methods

We initially recruited 194 patients [median age 69, female 39.7%, male 60.3%] who underwent surgical treatment for anterior resection of rectum from January 2009 to June 2012 in the Department of General and Emergency Surgery of Policlinico Paolo Giaccone – Palermo University.

We performed a retrospective review of the data entered into the general surgery database and in the medical charts, including procedural and follow-up data.

Patients who underwent Hartmann's procedure or temporary colostomy (54 patients) were excluded from the study, which aimed to evaluate the usefulness of temporary ileostomy. To yield homogeneous the group, were selected all patients with double stapled anastomosis.

Totally 140 patients were enrolled in our study. We divided the patients in two groups: the first group (40 patients) underwent anterior resection of rectum and primary anastomosis without defunctioning loop ileostomy, and the second one (100 patients) underwent anterior resection of rectum and primary anastomosis with defunctioning loop ileostomy.

The following patient- and surgery-related variables were assessed: age, gender, diagnosis, level of anastomosis, creation of a defunctioning stoma, presence of a pelvic drain, testing of the anastomosis by air insufflation, temperature, i.v. intake, antibiotic treatment, mortality, anastomotic leakage, stool passing, hospital stay, restoration of bowel continuity.

Anastomotic leakage was diagnosed through clinical investigations, radiological or endoscopic signs or surgically during reintervention.

The median follow-up was 11 months (8-30 months).

TABLE I - *Patients' characteristics.*

	Without ileostomy (n=40)	**With ileostomy (n=100)**	**Total (n=140)**	***p-value***
Age (years) median (range)		68 (52-83)	70 (51-87)	n.s.
Gender				n.s.
Female	26/40 65%	24/100 24%	50/140 35.7%	
Male	14/40 35%	76/100 76%	90/140 64.3%	
Level of anastomosis				0.08 n.s
Medium-low	22/40 55%	72/100 72%	94/140 67.1%	
High	18/40 45%	28/100 28%	46/140 32.9%	
Diagnosis				0.68 n.s
Adenocarcinoma of rectum	38/40 95%	98/100 98%	136/140 97.1%	
Others	2/40 5%	2/100 2%	4/140 2.9%	
Anastomotic leakage	8/40 20%	18/100 18%	26/140 18.6%	0.97 n.s.
Body temperature				n.s.
Pyrexia (≥ 37.5°C)	8/40 20%	22/100 22%	30/140 21.4%	
Median	37.8° (37.5°-38.2°)	38.2° (37.5°-38.8°)		
i.v. fluid intake (>1000 ml/24h)	40/40 100%	100/100 100%	140/140 100%	n.s.
Pelvic drain	40/40 100%	100/100 100%	140/140 100%	n.s.
Stool passing	30/40 75%	80/100 80%	110/140 78.6%	0.67 n.s.
Antibiotic treatment (metronidazole 500 mg tid and ceftazidime 2 g tid)	40/40 100%	100/100 100%	140/140 100%	n.s.

Statistical Analysis

Categorical variables were analysed using the χ^2 *test or Fisher's exact test* when appropriate. Continuous normally distributed variables were analysed using the *t-Student test*. Statistical analyses were performed using PRIMIT for for Windows (v. 3.03). $p<0.05$ was considered statistically significant.

Results

18.6% of patients (26/140) had a symptomatic anastomotic leakage diagnosed during hospitalization or after hospitalization discharge; the leakage was confirmed by clinical, endoscopic or radiological features and/or surgical findings during intervention.

Patients' characteristics are shown in Table I. Details of anastomotic leakage are shown in Table II. Additional complications occurred are shown in Table III.

There were more anastomotic leakages after anterior rectum resection with medium-low resection and anastomosis than after resection with high anastomosis (15.7% *vs* 2.9%; p=0.03); this difference was statistically significative (Table II).

The median interval between primary resection and diagnosis of anastomotic leakage was 22.5 days. 69.2% of patients underwent reintervention whilst 30.8% was treated through conservative strategy (Table II).

Anastomotic leakage was differently treated on the basis of the general condition of each patient. Different approaches ranged from a watch and wait strategy to reintervention with the creation of a temporary or permanent stoma (ileo- or colostomy); during the reintervention we evaluated whether repairing the primary anastomosis or creating a new one.

The state of the anastomosis was tested through an air insufflation test both during first procedure and during the reintervention, where available.

There were no significant differences in overall mortality between patients without and with ileostomy (2.5% *vs* 4%; p=0.94) (Table IV).

Furthermore, five patients died within the hospital stay (Table IV), while the remaining were discharged after a median stay of 15.5 days. Death occurred after a median period of 16 days; patients with a fatal outcome spent significantly longer times in the intensive care unit (ICU) than patients who survived. Three of them had an anastomotic leakage that underwent on reoperation, while two hadn't (Table IV). Everyone of them had severe

Table II - *Details of anastomotic leakage.*

	Without ileostomy (n=8)	With ileostomy (n=18)	Total (n=26)	*p-value*
Time of leakage				0.002
Leakage during hospitalization	8/8	6/18	14/26 53.8%	
Leakage after hospitalization	0/8	12/18	12/26 46.2%	
Recurrence	4/8 50%	0/18 0%	4/26 15.4%	0.009
Operative strategy				0.03
Surgery reoperation	8/8	10/18	18/26 69.2%	
Watch and wait	0/8	8/18	8/26 30.8%	
Level of anastomosis				0.56 n.s (0.03)
Medium-low	6/8	16/18	22/26 84.6% (22/140 15.7%)	
High	2/8	2/18	4/26 15.4% (4/140 2.9%)	
Mortality	1/8 12.5%	2/18 11%	3/26 11.5%	1.00 n.s.

Table III - *Further complications.*

	Without ileostomy (n=40)	With ileostomy (n=100)	Total (n=140)
Obstruction	2/40	7/100	9/140
Wound site infection	0/40	2/100	2/140
Gastric ischemia	0/40	1/100	1/140
Rectum bleeding	0/40	2/100	2/140

TABLE IV - *Details on mortality.*

	Without ileostomy (n=40)	With ileostomy (n=100)	Total (n=140)	*p-value*
Overall mortality	1/40 2.5%	4/100 4%	5/140 3.6%	0.94
After watch and wait strategy	0/1	0/4	0/5	
After first surgical procedure	0/1	2/4	2/5	
After reintervention for anastomotic leakage	1/1	2/4	3/5	

TABLE V - *Hospital stay and time of diagnosis.*

	Without ileostomy (n=40)	With ileostomy (n=100)	*p-value*
Initial hospital stay, mean days (range)	14 (10-45)	17 (9-47)	0.98 n.s.
Hospital stay including readmission, mean days (range)	23 (10-70)	25 (9-60)	0.90 n.s.
Interval to diagnosis of leakage, mean days (range)	20 (5-45)	25 (10-65)	0.74 n.s.
Hospital stay during leakage, mean days (range)	60 (25-85)	43 (25-57)	0.95 n.s.

comorbidities such as Diabetes Mellitus 2, Ischemic-Hypertensive Cardiomyopathy, Ictus Cerebri History. Death occurred during ICU staying.
The overall mortality rate was 3.6%. Mortality rates broken down by groups were the following: patients without ileostomy 2.5%; patients with ileostomy 4%; p=0.94 (Table II).

Discussion

Aiming to validate the usefulness of loop ileostomy diverting stoma to prevent anastomotic leakage in patients undergoing anterior resection of rectum we selected 140 patients that were divided into two groups: the first group underwent anterior resection of rectum and primary anastomosis without defunctioning loop ileostomy (40 patients) while the second one underwent anterior resection of rectum and primary anastomosis with defunctioning loop ileostomy (100 patients). Patients in both groups had a comparable hospitalization course in terms of diagnostic tools employed, clinical management, antibiotic prophylaxis, type of anastomosis.
On the other hand we noticed marked differences during the postoperative course. We decided to readmit patients or to prolong hospitalization on the basis of clinical, laboratory or radiological signs of leakage (fever, peritoneal reaction, adynamic ileus, leukocytosis, increase of inflammation markers, free abdominal air, "anastomotic bubble", anastomotic abscess). CT scan demonstrated the leakage in up to 90% of patients; this rate is comparable with other data currently available in the literature [8,16,17].
26/140 patients (18.6%) developed an anastomotic leakage. 53.8% of the leakages occurred during hospitalization, while 46.2% occurred after hospital discharge. Patients were discharged after a median of ten days following the first procedure (Table II).
It's important to stress that 22/26 patients (84.6%) with anastomotic leakage underwent medium-low anterior resections with anastomosis at a median of 5 cm (range 2-7 cm) from the anal verge. A low anastomosis - as well as preoperative radiotherapy - is often considered a strong risk factor for anastomotic leakage; this data is confirmed by many currently available articles [1,9,18]. Our observation confirms a statistically significant difference in the rate of anastomotic leakage after medium-low resections and after high resections (Table II).
In our series, the presence of an ileostomy didn't show a protective effect on anastomotic leakage either in the medium-low resection group or in the high resection one (*p-value* not significant).
Concerning patients that developed an anastomotic leakage, 18% had an initial loop ileostomy defunctioning stoma, while 20% had not. The overall leakage rate was 18.6% which is similar to other published data [8,17,19] (Table I).
Moreover it is important to focus the attention upon the lack of standardized information on the management of anastomotic leakage after rectum resection. There are many possible treatments such as Hartmann's procedure, preservation of disrupted anastomosis with local oversewing, resection of leaked anastomosis with creation of a new anastomosis. Every scenario implies possible adverse events, such as impossibility to reverse the end colostomy, persistence of the septic focus with dramatic consequences, recurrence of the anastomotic leakage and

even death. Most studies differentiate between limited leakage with mild clinical manifestations and large leakages severely threatening the patient. In the first scenario a wait and see strategy is recommended, while in the second one a reintervention often proves life-saving [8,2022]. In our series 69.2% of patients underwent reintervention, while 30.8% was managed through a watch and wait strategy. The watch and wait group patients needed no further surgical operation (Table II).

Currently the management of anastomotic leakages depends on the surgeon's experience and on the evaluation of the patient's clinical conditions, with particular attention on risk factors favoring the leakage.

Two key facts are important to take into account. The first one is the high mortality rate associated with leakage: the mortality rate related to anastomotic leakage was 11.5%. We didn't observe a difference in mortality rates between groups with and without protective ileostomy (11% *vs* 12.5%; p=1.00); this data was comparable to other data series [8]. The cause of death was septic shock, in a background of severe comorbidities. The second important fact is the frequency of major complications associated to the confectioning of a loop ileostomy defunctioning stoma [11], solution often adopted in high risk patients to develop leakage [8].

Even if we don't consider the reduced quality of life connected with the necessity of the stoma creation [15], there is a variety of complications to take into account such as dehydration caused by high output, infections, hernia, obstruction, bleeding, leakage, skin problems [23-25], and the risk that temporary ileostomy becomes a permanent stoma [11,26,27]. Another important observation is that the reversal of a loop ileostomy requires another hospital stay, in turn associated with morbidities, most frequently obstructions [2,25,28-30].

Concluding, a diverting stoma reduces the rate of clinically relevant anastomotic leakages in low rectal resections [31]. The findings suggest that ileostomy allowed a lower percentage of reoperations to manage leak in the ileostomy group. Furthermore, a protective ileostomy is often used, whether routinely or at surgeons' own discretion.

Conclusions

The results of the study prove a protective effect of diverting stoma, consistent with other published data [32], not directly on leakage but on its consequences such as clinical features and recurrence, demonstrating the effectiveness of defunctioning stoma in presence of a leakage. Anastomotic leakages could be predicted analyzing risk factors such as emergency surgery, malnutrition, severe critical illness, use of steroids and height of anastomosis [32].

Several studies have shown decreased clinical anastomotic leakage rates and reduced need for reintervention when a defunctioning loop ileostomy is created [11-15,23,24]. This is doubtlessly an sound evidence: data published by some authors such as Wong N.Y. et al. support the hypothesis that a diverting stoma does not reduce postoperative anastomotic leakage rate, while reducing related adverse events such as fecal peritonitis or septicemia, according to our data. We might say with a certain degree of confidence that it could be useful to identify a population with high risk to develop anastomotic leakage who may benefit the most from the creation of a diverting stoma, thus modifying the present tendence to perform it routinely or on surgeons' evaluation.

Considering the evolution of leakages (mortality rate 12-42% [32] - 11.5% in our series - permanent stoma, local recurrence of leakage, poor functional results), a defunctioning stoma should be recommended to avoid anastomotic leakage and its consequences.

Last but not least, we might spontaneously consider that the length of hospital stay in every single condition (Table V) is absolutely comparable with other similar data published in the international literature [8]: these data prove show that higher the rates of complications relate to longer hospital stay.

Nevertheless, our data series shows a relevant feature associated to anastomosis leakages occurring in patients without ileostomy: we found a statistically significative value of the recurrence rate of leakage in this group of patients (rate 50%; *p-value*=0.009) that should be taken into account when considering the creation of an ileostomy.

Riassunto

Una delle principali e più temute complicanze della resezione anteriore di retto è stata ed è la deiscenza anastomotica. Solitamente, sia essa una scelta di principio od a discrezione del chirurgo operatore, viene confezionata una ileostomia laterale di sicurezza con lo scopo di prevenire tale circostanza. Scopo di tale studio è stato quello di investigare circa la utilità della stomia laterale di sicurezza quale strumento di prevenzione della deiscenza anastomotica, mettendo a paragone il decorso post-operatorio dei paziente con e senza stomia laterale. Le evidenze hanno portato alla conclusione che il confezionamento della stomia laterale di sicurezza è fattore di protezione non tanto dell'evento deiscenza anastomotica in senso stretto, quanto delle complicanze e della evoluzione clinica della stessa, vedasi ad esempio tasso di ricorrenza di deiscenza/quadro clinico in corso di deiscenza/tempi di degenza, pur rendendosi necessario sottolineare l'assenza di significatività statistica nel tasso di mortalità nei due gruppi in studio. Cosi detto appare dunque sinottico affermare che il confezionamento di ileostomia laterale di sicurezza in corso di resezione anteriore di retto non determina una diretta azione sull'evento "deiscenza anastomotica" né "morte", purtuttavia modifica certamente in positivo il decorso clinico ed evolutivo dell'evento "deiscenza anastomotica".

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