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ORIGINAL SCIENTIFIC REPORT

The Effectiveness of Contralateral Drainage in Reducing Superficial Incisional Surgical Site Infection in Loop Ileostomy Closure: Prospective, Randomized Controlled Trial

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Abstract

Background Loop ileostomy reduces the rates of morbidity due to colorectal anastomotic dehiscence. For its part, ileostomy closure is associated with low mortality (0–4%) but substantial morbidity (11–37%). Incisional surgical site infection (SSI) is one of the most frequent complications (2–40%).

Methods A single-center, prospective, randomized controlled clinical trial of two study groups: control (conventional primary skin closure) and experimental (primary skin closure with a contralateral Penrose® drain).

Results Seventy patients undergoing loop ileostomy closure between April 2013 and June 2017 were included (35 per branch). Four were later removed from the study. Six of the remaining 66 patients (per protocol analysis) were diagnosed with incisional SSI (9.1%); there were no statistically significant differences between the two groups (control group: 9.7%; experimental group: 8.6%) or between the risk factors associated with incisional SSI. Rates of overall and relevant morbidity (Clavien $\geq$ III) were considerable (28.1% and 9.1%, respectively), and there were no statistically significant differences between the two groups. No patients died.

Conclusion Contralateral drainage does not significantly affect the results of primary ileostomy closure. The rate of incisional SSI was similar in the drainage and non-drainage groups, and the overall rate of 9.1% was in the low range of those reported in the literature. The absence of mortality (0%) and the non-negligible rates of overall and relevant morbidity (28.1% and 9.1%, respectively) in our series suggest that loop ileostomy is a safe procedure. However, the bowel reconstruction involves risks that must be borne in mind.

Clinical trial registration The study was registered and approved by the clinical research ethics committee of the study center (reference number 2012076). Clinical trial was registered in ClinicalTrial.gov (identification number NCT02574702 and reference: ILEOS-ISS_2013).

Abbreviations

LI	Loop ileostomy
AD	Anastomotic dehiscence
SSI	Surgical site infection
CDC	Center for Disease Control and Prevention
N	Sample size
ASA	American Society of Anesthesiologists anesthesia risk classification
AE	Adverse events
SD	Standard deviation
SS	Side-to-side

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Introduction

Loop ileostomy (LI) is recommended in patients undergoing low anterior rectal resection. It reduces rates of colorectal anastomotic dehiscence (AD), but does not rule it out altogether [1]. Patients with loop ileostomies are not free of morbidity: Complication rates of up to 43% have been reported, mainly emergency room readmissions, problems with the collection device, peristomal dermatitis, dehydration and kidney failure [2].

Ileostomy closure is associated with low mortality (0–4%) [3, 4] but with a non-negligible overall morbidity rate (11% to 37%) [3]. The most frequent complications are incisional surgical site infection (SSI), with a prevalence that ranges widely (2–40%) [5–9], and intestinal obstruction [3, 4]. Incisional SSI entails longer hospital stay, higher costs, more emergency room consultations and a greater likelihood of subsequent incisional hernia [3].

The main objective of this prospective, randomized controlled trial was to assess whether rates of incisional SSI after LI closure are reduced by inserting a Penrose® drain in the subcutaneous space during the primary skin closure. Secondary objectives were to identify possible risk factors associated with an incisional SSI and to determine the morbidity and mortality associated with the ileostomy closure.

Materials and methods

Study design

This is a single-center, prospective, randomized controlled clinical trial to assess the efficacy of the placement of a Penrose® drain contralateral to the primary LI closure for reducing incisional SSI. Two groups were studied: control (conventional primary skin closure) and experimental (primary skin closure with contralateral drainage).

The design was not altered during the 4 years of the study.

Patients

The study was carried out at Parc Taulí University Hospital, Sabadell, Catalonia, Spain. The sample comprised patients seen at the coloproctology unit of the general and digestive surgery services for LI closure, who met the inclusion criteria and none of the exclusion criteria. Inclusion criteria: (a) LI after surgery for rectal cancer; (b) age over 18 years; (c) elective surgery; (d) provision of signed informed consent. Exclusion criteria: (a) end ileostomy; (b) LI due to surgery not for rectal cancer; (c) during ileostomy closure, performance of some other associated surgical procedure; (d) emergency surgery; (e) refusal to participate; (f) age under 18.

Surgery performed

All patients underwent the same surgical procedure, with the exception of skin closure and the insertion of the drain.

Bowel was reconstructed using a mechanical side-to-side anastomosis (SS), with GIA® of 70 cm (blue charge) and TA® of 90 cm (blue charge). Aponeurosis closure was performed with a PDS® 1 continuous loop suture.

Closure of skin and subcutaneous tissue differed according to group. Both the control group and the experimental group underwent conventional primary closure of the skin with metal staples, but in the experimental group, a medium-sized Penrose® drain was inserted in the subcutaneous space and drained through an incision contralateral to the main wound at a distance of some 4 cm; then, the skin was also primary closure with metal staples.

Preoperative care: Antibiotic prophylaxis, with 2 g of amoxicillin–clavulanic acid, was administered intravenously in a single dose. Patients allergic to penicillin were administered metronidazol (1 g/kg) and gentamicin (3–5 g/kg), also intravenously.

Postoperative care: Antithrombotic prophylaxis was administered to all patients (enoxaparin 20 mg or bemiparin 2500 units, both every 24 h subcutaneously) throughout the hospital stay. In all cases, the evolution of the surgical wound was monitored by an independent observer in order to rule out signs of incisional SSI during admission and until day 30 after surgery.

In the experimental group, the Penrose® drain was maintained immobile for the first 48 h; it was mobilized on day 3 and withdrawn on day 4.

Study variables

The main variable of the study was incisional SSI, defined according to the clinical practice guide of the Center for Disease Control and Prevention (CDC) (1999) [10, 11], in which the following three criteria have to be met:

a. The infection is detected within 30 days of surgery.
b. The infection involves only skin and subcutaneous tissue of the incision.
c. At least one of the following:

(1) Drainage of purulent exudate from the wound, with or without confirmation of positive culture; (2) positive culture of the wound exudate; (3) and at least one of the following signs or symptoms of infection: pain on palpation, localized swelling, redness or heat.

Incisional SSIs are divided into two types [10, 11]:

- Primary incisional SSI: an incisional SSI identified in the primary incision performed in a surgical procedure with one or more incisions.
- Secondary incisional SSI: an incisional SSI identified in the secondary incision performed in a surgical procedure with one or more incisions.

In our study, we focused on primary incisional SSI, since we were interested in detecting incisional SSI in the wound of the ileostomy closure.

Secondary variables

– Risk factors associated with incisional SSI: age, obesity, diabetes mellitus, smoking, radiotherapy, chemotherapy, immunosuppression, treatment with glucocorticoids, ASA and the existence of parastomal hernia [12] (classified by abdominal computed tomography) and duration of surgery.
– The presence of adverse events (AE) and preventable AE, as defined by the Clavien–Dindo classification [13], and 30-day mortality. AEs are defined as incidents that cause harm to the patient and are due to the care provided, not to the underlying disease [14]. Preventable AEs are defined as AEs caused by an error in management [15]. Morbidity is defined as relevant when the AE is classified as Clavien–Dindo score of III or higher [4, 16, 17].

Sample size

Sample size was calculated on the basis of an unpublished prospective observational study carried out at our center, in which incisional SSI after LI closure was evaluated in 67 patients (with or without insertion of a contralateral drain). The overall rate of incisional SSI was 22.4%: In 19 patients, a primary closure was performed (rate of SSI 31.6%), and in 23, the drainage was left in the subcutaneous tissue (rate of incisional SSI 17.4%). Based on the data, the expected difference between the two groups was set at 30%, with a β error of 0.20 (80% power) and a two-sided α error of 0.05%. The result was 64 patients (32 per branch). Assuming a 10% loss, we estimated a total sample size (N) of 70 patients (35 per branch).

Randomization

The 70 patients were randomly assigned to each group using sealed envelopes until their inclusion in the study, after providing signed informed consent.

Blinding

The design and application of the study did not permit the use of blinding techniques, since the use or nonuse of a drain cannot be concealed. However, the results were analyzed in a blind manner.

Statistical methods

Intention-to-treat analysis was performed in all randomized patients, and per protocol analysis in patients who met the inclusion criteria for each study group.

The variables were described, and the statistical analysis was performed using the SPSS® program, version 23. Quantitative variables are reported as means and standard deviation when the distribution was normal, and medians and interquartile ranges otherwise. Categorical variables are described in absolute numbers and percentages.

For the statistical analysis of the quantitative variables, with independent groups, the Student's T test (parametric test) was used, provided that its conditions for application were met; otherwise, the nonparametric Mann–Whitney U test was used. For the statistical analysis of the categorical variables, Pearson's Chi-square test was used.

The results of the statistical tests are presented with a 'p' value below 0.05 and a 95% confidence interval.

Results

Between April 2013 and June 2017, 79 patients with LI underwent bowel reconstruction surgery (Fig. 1). Six patients did not meet the inclusion criteria, and three refused to enter the study. In total, 70 patients were included, and 35 were randomized to each branch. In the control group, four patients were finally excluded from the study protocol (one in whom a drain was placed despite being in the control group, two who received an anastomosis other than the one established in the study protocol, and another who underwent a different surgical approach). In the experimental group (Penrose® drain group), there were no losses.

Table 1 shows the demographic data of the series (N = 70 patients). Male patients predominated, and the median age was 67 years (range 34–89). The majority were ASA II (45/70, 64.3%). Most received adjuvant chemotherapy (56/70, 80%), adjuvant radiotherapy (64/70, 91.4%) or both. Some patients received only radiotherapy due to their high morbidity. Twenty-five out of 70 presented parastomal hernia at the time of surgery (35.7%). The median time from the initial rectal surgery to reconstruction was 10 months (0–39 months), and the mean

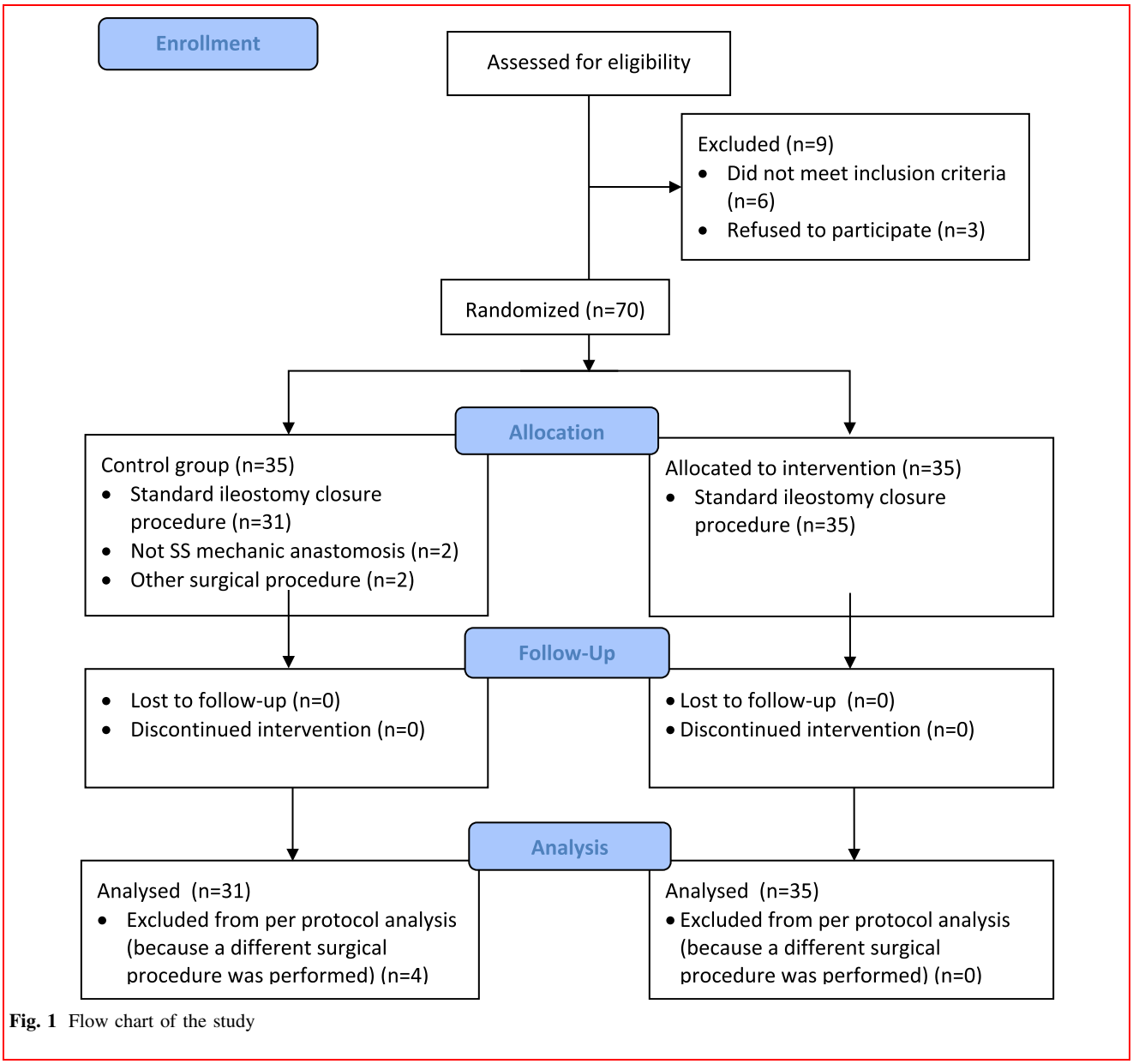

Fig. 1 Flow chart of the study

surgical time was 54.14 min (SD 17.62 min). The morbidity rate was 27.1%, and the mortality rate was zero.

Of the 66 patients included in the per protocol analysis (31 in the control group and 35 in the experimental group), six (9.1%) were diagnosed with incisional SSI. There were no statistically significant differences between the two randomized groups regarding the infection or according to the CDC diagnostic criteria (Table 2). In terms of risk factors for infection, there were no statistically significant differences between the six patients who presented incisional SSI and the 60 who did not (Table 3); nor there were significant differences between the two groups regarding ASA, the existence of parastomal hernia, age, body mass index, waiting time until the reconstruction of the transit and surgical time.

The six patients diagnosed with incisional SSI (6/66) presented no statistically significant differences for any of the above variables, regardless of group (Table 3). All the incisional SSIs were debrided without antibiotic treatment.

Most patients suffered Clavien grade I or II complications, with no statistically significant differences between the two groups ($p = 0.197$) (Table 4). Nor there were statistically significant differences between the groups in terms of clinically relevant morbidity (Clavien $\geq$ IIIa) ($p = 0.483$) (Table 4). Four patients (6.1% of the total sample, all in the experimental group) presented AD

Table 1 Demographic data of the sample

	N	%
Sex		
Male	48/70	68.6
Female	22/70	31.4
Diabetes mellitus	11/70	15.7
Smoking	6/70	8.6
Corticoid treatment	1/70	1.4
Adjuvant RT	56/70	80
Adjuvant QT	64/70	91.4
Immunodeficiency	0/70	0
ASA		
ASA I	3/70	4.3
ASA II	45/70	64.3
ASA III	22/70	31.4
ASA IV	0/70	0
Parastomal hernia		
No. Grade 0	37/70	52.9
No. Grade Ia	8/70	11.4
Yes. Grade Ib	12/70	17.1
Yes. Grade II	2/70	2.9
Yes. Grade III	11/70	15.7
Anastomosis		
Mechanical SS	68/70	97.1
Mechanical SE	1/70	1.4
Manual EE	1/70	1.4
Overall morbidity	19/70	27.1
Relevant morbidity (Cl–D $\geq$ III)	4/70	8.6
Mortality (Cl–D V)	0/70	0.0
	Mean $\pm$ SD[i]	
Age	65.7 $\pm$ 12.37	
BMI (kg/m^2)	27.67 $\pm$ 4.78	
Waiting time until reconstruction (months)	11.94 $\pm$ 7.36	
Surgical time	54.14 $\pm$ 17.62	

Demographic data of the series (total number of 70 patients), shown in absolute numbers (*N*) and in percentages (%) for qualitative variables, and in means and standard deviations or medians and maxima and minima for quantitative variables

RT radiotherapy, *QT* chemotherapy, *ASA* American Society of Anesthesiologists score, *SS* side-to-side, *SE* side-to-end, *EE* end-to-end, *Cl–D* Clavien–Dindo, *BMI* body mass index, *SD* Standard deviation

causing an organ–cavity infection: Two of them (5.7% of the experimental group) required surgical treatment and the other two (5.7% of the experimental group) only antibiotic treatment and/or insertion of a percutaneous drain.

Most patients in the experimental group had the Penrose® subcutaneous drain removed on the fourth day (range 2–6 days). No differences in the postoperative stay were observed, and usually, the average length of stay is 4 days and the Penrose® drain removed on the fourth day. No patients required readmission within 30 days of discharge.

Discussion

The creation of a LI or colostomy is associated with lower symptomatic AD in low colorectal anastomoses [18]. Ideally, it should be reserved for those patients in which the risk of major or relevant complications (Clavien $\geq$ III) is greater than 5% [4].

Closure of the LI is associated with low (though not zero) mortality (0–4%) [3, 4] and non-negligible overall morbidity (11–37%) [3]. The overall morbidity in our series was 28.8% (19 out of 66 patients). Between groups, the overall morbidity was 6/31 (19.4%) in the control group and 13/35 (37.1%) in the Penrose group ($p = 0.197$), Table 2. As it is shown in Table 4, mainly the morbidity in the Penrose group is Clavien I and II, and most of them are medical complications. The relevant morbidity rate (Clavien $\geq$ III) was 9.1%, again with no significant differences between groups (Table 4).

In the literature, the most frequent complications after LI closure are incisional SSI and intestinal obstruction, both associated with low overall and relevant (Clavien $\geq$ III) morbidity rates of around 5% [4]. AD, the appearance of incisional hernias and, more rarely, the existence of enterocutaneous fistulas have also been reported [19]. As our study focused on the incidence of incisional SSI within 30 days of surgery, we do not provide data on intestinal obstruction in our series.

The rate of incisional SSI after ileostomy closure in our study was 9.1%, a figure in the lower range of those reported in the literature (2–40%) [5–9]. It is also far lower than the rate reported in the preliminary retrospective study (22.4%), probably due to the Hawthorne effect [20, 21].

In the past few years, various skin closure techniques have been described for reducing incisional SSI incidence [9]. These techniques include: delayed primary closure, which does not achieve a reduction in the rate of wound infection [5]; leaving the skin open at the stoma site, which reduces incisional SSI (from 36 to 5%) [22]; the application of antibiotic implants in the subcutaneous tissue, which does not reduce the incidence of incisional SSI with respect to primary closure (10%) [7]; and purse-string skin closure, which reduces the rate of incisional SSI from 12–40% to 0–6.6% [6, 8, 23–28].

Our study compares simple skin closure (control) with skin closure plus placement of a Penrose® drain contralateral to the wound (experimental). The incidence of incisional SSI (9.1%) is in the low range of the values reported in the literature. No statistically significant or clinically relevant differences were found between the

Table 2 Incisional SSI

	Control group (n = 31)	Penrose group (n = 35)	p
Diagnosis of incisional SSI[a]	3/31 (9.7%)	3/35 (8.6%)	0.876
CDC diagnostic criteria of incisional SSI			
Exudate	2/31 (6.5%)	2/35 (5.7%)	0.900
Positive culture	0/31 (0.0%)	0/35 (0.0%)	–
Clinical signs of infection (pain on palpation, localized swelling, redness or heat)	3/31 (9.7%)	3/35 (8.6%)	0.876
Morbidity			
Overall	6/31 (19.4%)	13/35 (37.1%)	0.197
Relevant (Cl–D $\geq$ III)	2/31 (6.5%)	4/35 (11.4%)	0.483
Mortality (Cl–D V)	0/31 (0%)	0/35 (0%)	–

Absolute numbers and percentages of SSI and then broken down according to incisional SSI diagnostic criteria in patients included in the per protocol analysis (n = 66) and their statistical significance (p) with a 95% confidence interval

SSI surgical site infection, *Cl–D* Clavien–Dindo

Table 3 Risk factors for incisional SSI

	No incisional SSI (n = 60)	Incisional SSI (n = 6)	p	Control group (n = 3)	Penrose group (n = 3)	p
Qualitative variables: expressed in absolute numbers and frequencies						
DM	9/60 (15.0%)	1/6 (16.7%)	0.914	1/3 (33.3%)	0/3 (0.0%)	0.273
Corticoids	1/60 (1.7%)	0/6 (0.0%)	0.750	0/3 (0.0%)	0/3 (0.0%)	–
Active smoker	5/60 (8.3%)	1/6 (16.7%)	0.498	1/3 (33.3%)	0/3 (0.0%)	0.273
RT	48/60 (80.0%)	4/6 (66.7%)	0.446	3/3 (100.0%)	1/3 (33.3%)	0.083
QT	55/60 (91.7%)	5/6 (83.3%)	0.498	3/3 (100.0%)	2/3 (66.7%)	0.273
Immunodeficiency	0/60 (0.0%)	0/6 (0.0%)	–	0/3 (0.0%)	0/3 (0.0%)	–
ASA[c]						
I	3/60 (5.0%)	0/6 (0.0%)	0.746	0/3 (0.0%)	0/3 (0.0%)	1.00
II	38/60 (63.3%)	4/6 (66.7%)		2/3 (66.7%)	2/3 (66.7%)	
III	19/60 (31.7%)	2/6 (33.3%)		1/3 (33.3%)	1/3 (33.3%)	
Parastomal hernia						
No. 0	33/60 (55.0%)	1/6 (16.7%)	0.240	1/3 (33.3%)	1/3 (33.3%)	0.081
No. Ia	7/60 (11.7%)	1/6 (16.7%)		1/3 (33.3%)	1/3 (33.3%)	
Yes. Ib	11/60 (18.3%)	1/6 (16.7%)		0/3 (0.0%)	0/3 (0.0%)	
Yes. II	1/60 (1.7%)	1/6 (16.7%)		1/3 (33.3%)	1/3 (33.3%)	
Yes. III	8/60 (13.3%)	2/6 (33.3%)		0/3 (0.0%)	0/3 (0.0%)	
Quantitative variables: expressed as means $\pm$ SD (normal distribution)						
Age	65.332 $\pm$ 12.376	72.12 $\pm$ 14.770	0.208	66.00 $\pm$ 19.313	78.33 $\pm$ 7.638	0.362
BMI (kg/m^2)	27.135 $\pm$ 4.4419	28.856 $\pm$ 5.3494	0.377	32,139 $\pm$ 4.9142	25.574 $\pm$ 3.8808	0.144
Waiting time for reconstruction (months)	11.57 $\pm$ 7.228	12.50 $\pm$ 7.007	0.763	12.00 $\pm$ 5.000	13.00 $\pm$ 9.849	0.883
Surgical time (min)	53.75 $\pm$ 16.648	52.50 $\pm$ 16.047	0.861	45.00 $\pm$ 13.229	60.00 $\pm$ 17.321	0.299

The risk factors associated with incisional SSI, in absolute numbers and percentages for qualitative variables and as means and standard deviations for quantitative variables, stratified according to group

The first three columns show the results obtained in the per protocol analysis (total number of patients: 66); non-incisional SSI group (60 patients) and incisional SSI group (six patients); statistical significance (p) with a 95% CI

The next three columns show the results of the six patients (3 control, 3 experimental) with incisional SSI according to group and per protocol analysis, and statistical significance (p) with a 95% CI

RT radiotherapy, *QT* chemotherapy, *ASA* American Society of Anesthesiologists score, *SD* standard deviation, *BMI* body mass index

Table 4 Overall and relevant morbidity according to Clavien–Dindo score

	Control group (n = 31)	Penrose group (n = 35)	p
Overall morbidity			
Clavien I	0 (0.0%)	4 (11.4%)	0.197
Clavien II	4 (12.9%)	5 (14.3%)	
Clavien IIIa	1 (3.2%)	1 (2.9%)	
Clavien IIIb	1 (3.2%)	2 (5.7%)	
Clavien IVa	0 (0.0%)	0 (0.0%)	
Clavien IVb	0 (0.0%)	1 (3.2%)	
Clavien V	0 (0.0%)	0 (0.0%)	
Relevant morbidity			
Non-relevant morbidity (Clavien < III)	29 (93.5%)	31 (88.6%)	0.483
Relevant morbidity (Clavien ≥ III)	2 (6.5%)	4 (11.4%)	

Overall morbidity in the 66 patients included in the per protocol analysis, in absolute numbers and percentages, according to group, and statistical significance (p) with a 95% CI

Relevant morbidity (≥ Clavien III) in the 66 patients included in the per protocol analysis, in absolute numbers and percentages, according to group, and its statistical significance (p) with a 95% CI

control and experimental groups: The rate of wound infection in the control group was 9.7% (3/31 patients) versus 8.6% (3/35) in the experimental group (p = 0.876) (Table 2). Nor statistically significant or clinically relevant differences were found between the groups with regard to risk factors for wound infection (Table 3).

Some authors report lower morbidity and mortality (intestinal obstruction and AD) with the simple closure of the stoma loop than with the intestinal resection of the ileostomy segment and the creation of an ileo-ileal anastomosis [4]. At our center, in most cases, the segment that formed the LI with a mechanical SS anastomosis was resected; four patients (6.1%) were presented AD, two of which required percutaneous drainage and antibiotic treatment and the other two required surgical reintervention. None of the patients that were diagnosed to have an AD were diagnosed at the same time of an incisional SSI. The SS anastomosis, used mostly for reconstruction, is ideal in these cases due to the relatively long time until surgery (since for the most part these patients receive adjuvant treatment) and the resulting disproportion between the two intestinal loops.

The delay between the creation of the LI until closure is another known factor. Danielsen et al. [2] reported early closure of a temporary stoma (8–13 days after its creation compared with standard closure after more than 12 weeks) to be a protective factor against complications in patients with satisfactory colorectal anastomosis, although it did not protect against wound infection. Even so, there is no specific predetermined time for intestinal reconstruction; it may be feasible within a month of the creation of the stoma or may be delayed in the case of adjuvant treatment [29]. In our study, we did not find statistically significant differences with regard to the rate of incisional SSI, nor a higher frequency of AD in relation to the time before bowel reconstruction. The median time for reconstruction is 10 months, due mainly to the need for postsurgical adjuvant treatment and also depending on operating theater availability.

The main limitation of the study is its single-center design. For this reason, the study duration was longer than expected.

Conclusions

There are no statistically significant or clinically relevant differences between primary ileostomy closure alone and primary closure with the application of a contralateral drain. Rates of incisional SSI were similar, in the low range of those described in the literature.

The absence of mortality (0%) and the rates of overall and relevant morbidity (28.1% and 9.1%, respectively) suggest that the creation of a LI is a safe procedure, but that reconstruction involves risks that must be borne in mind. Further studies are needed to guide decisions regarding the creation of a LI in selected cases.

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Compliance with ethical standards

Conflicts of interests The authors declare that they have no conflict of interest.

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