



Fascial incision shapes and paracolostomy hernia: cruciate vs. reinforced longitudinal (the “Hepworth hitch”): longcross randomized controlled trial (GECO2 STUDY)

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Abstract

Purpose Primary objective was to compare the rates of parastomal hernia (PH) at 2 years after the creation of a terminal colostomy using two types of fascial incision: cross-shaped and reinforced longitudinal. Secondary objectives included the evaluation of postoperative complications, readmissions, reoperations for PH, and patients' quality of life.

Methods This was a multicenter superiority clinical trial conducted at 5 hospitals involving patients with rectal cancer and definitive colostomy. Patients were randomized into two groups: cross incision ($n=42$) or reinforced longitudinal incision ($n=52$), for the exteriorization of the colon in terminal colostomy. PH at 2 years was determined by physical examination, computed tomography (CT), and symptoms. Baseline data on risk factors for PH, postoperative complications, readmissions, reoperations for symptomatic PH, and quality of life were recorded.

Results A total of 95 patients were included: cross ($n=42$) and reinforced longitudinal ($n=52$). Demographic characteristics, risk factors for PH, and surgical factors were similar between the two groups. No significant differences were found in the clinical PH rate between the cruciate versus longitudinal incision groups (48.60% vs. 45.20%; $p=0.770$), radiological PH (54.30% vs. 53.70%; $p=0.956$), or symptomatic PH (14.30% vs. 19%; $p=0.579$). The comprehensive complication index (CCI), readmissions, and reoperation rates for symptomatic PH (8.6% vs. 7.1%; $p=0.816$) were similar in both groups. No significant differences were observed in the three health aspects evaluated using the EORTC QLQ-C30 scale.

Conclusion The reinforcement of a longitudinal fascial incision as an isolated surgical technique does not reduce the incidence of PH after a 2-year follow-up.

Keywords Fascial incision shapes · Paracolostomy hernia · Terminal colostomy

Introduction

Parastomal hernia (PH) is one of the most common complications following end colostomy formation and has been identified as the second most significant non-cancer-related issue in coloproctology [1]. The reported incidence varies widely, ranging from 11 to 78% at 2 years, depending on the definition used and the method of diagnosis (self-reported, clinical examination, or CT scan) [2–5]. Although many cases are asymptomatic, up to 25–30% of patients require at least one surgical repair, and one-third of them will require multiple surgeries due to recurrence [6]. A significant number of patients experience a reduced quality of life [7, 8], with problems ranging from leakage and skin irritation due

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to poor stoma appliance fit to life-threatening complications such as obstruction or perforation.

Several factors contribute to the development of PH, including age [9, 10], cancer [11], high BMI [10], waist circumference [12], chronically increased abdominal pressure, stoma placement site, and colostomy construction techniques [13].

Various technical modifications during colostomy formation have been explored in an effort to reduce the incidence of PH. These include the extra- or transperitoneal placement of the efferent colon, the location of the stoma opening (whether inside or outside the rectus fascia, lateral to the rectus muscle versus transrectus), the shape of the incision in the rectus fascia [14], the size of the aperture [10, 15], and the use of a prophylactic mesh during colostomy construction [16–19].

The traditional technique for externalizing the colon through the rectus muscle involves making a cruciate incision in the anterior rectus fascia. Alternatively, a circular incision has been used; however, a clinical trial showed no significant difference in PH development between the two incision shapes [14].

In 2018, Manook et al. [20] described a simple modification of the fascial opening in the anterior abdominal rectus, referred to as the “Hepworth hitch.” This modification involves creating a reinforced longitudinal incision at the superior and inferior ends of the fascia, with two interrupted sutures using heavy suture material. The authors reported a clinically detectable PH incidence of 8%. The rationale behind this technique is that reinforcing the longitudinal incision may serve as a “barrier,” preventing the dilation of the fascial opening.

Given the results reported by Manook et al. [20], which suggest that the Hepworth hitch may have a positive impact on PH prevention, we conducted a randomized, multicenter, exploratory study to determine whether the shape of the anterior rectus sheath incision (cruciate vs. reinforced longitudinal) during permanent end colostomy construction can reduce the rate of PH.

Methods

Study design

This was a randomized, multicenter, controlled, double-blind superiority clinical trial involving patients undergoing rectal cancer surgery and requiring an end colostomy without mesh. Participants were randomized to undergo one of two exteriorization techniques. The study protocol was approved by the regional ethics committees of the participating hospitals, in accordance with the Declaration of Helsinki. All patients provided written informed consent.

The study was registered at ClinicalTrials.gov (Identifier: NCT04397783) and adhered to the CONSORT 2010 guidelines for randomized controlled trials (RCTs).

Five tertiary hospitals participated in the study. All surgical procedures were performed in accredited colorectal surgery units and were conducted or supervised by surgeons certified by the European Society of Coloproctology (ESCP).

Patients

Inclusion criteria: Patients with rectal cancer scheduled to undergo a permanent end colostomy following abdominoperineal resection, intersphincteric rectal resection, or a Hartmann procedure, aged 18 to 85 years, and undergoing surgery via laparotomy, laparoscopy, or robotic surgery.

Exclusion criteria: Patients scheduled for other types of stomas (e.g., temporary or non-end colostomies), those requiring emergency or palliative surgery, patients with a history of previous hernias or mesh implants (except for inguinal hernia), those undergoing surgery involving the extraction of the surgical specimen through the colostomy site, and patients whose colostomies were not previously marked by a nurse stomatherapist.

Procedure

Preoperative preparation, patient positioning, anesthetic management, and postoperative care followed local protocols, with the surgical approach determined at the surgeon's discretion. The descent of the splenic flexure was left to the surgeon's judgment, though this information was recorded in the case report form (CRF).

To standardize the surgical technique for colon exteriorization and colostomy formation, a demonstration video and an instructional booklet were created.

Using the previously marked site by a nurse stomatherapist, a circular disc of skin and a small amount of subcutaneous tissue, large enough to allow the stoma to sit comfortably, was excised. The colostomy was exteriorized through a transperitoneal and transrectus route within the rectus sheath. While exteriorization through the external oblique muscle was not an exclusion criterion, this information was also included in the CRF.

In the longitudinal incision group, a longitudinal incision of approximately 3 cm was made on the aponeurosis of the anterior rectus sheath, depending on the colon's diameter. Two interrupted Prolene 2/0 sutures (Ethicon, Johnson & Johnson) were placed at the superior and inferior edges of the incision for reinforcement.

In the cruciate incision group, a longitudinal incision approximately 3 cm in length was made on the aponeurosis of the anterior rectus or external oblique. Additionally, a

transversal incision of about 2 cm in length (1 cm on each side) was made.

When the stoma was located above the semilunar line, the posterior rectus sheath was incised in a manner similar to the anterior surface, but without reinforcement stitches for cases involving the longitudinal incision.

The lengths of the incisions in the aponeurosis, as well as the diameter of the colon and stoma, were recorded in the CRF.

The height of the stomal nipple was at least 1–2 cm and was not fixed either intraperitoneally or to the lateral edges of the fascial opening. Mucocutaneous suturing with interrupted absorbable sutures was used to secure the stoma to the skin.

Study outcome

The primary objective was to compare the PH rate at 2 years of follow-up, diagnosed through physical examination and CT scan. PH was defined as any clinically detectable bulge in the vicinity of the colostomy, identified by digital palpation within the stoma, with the patient in the supine position at rest and during the Valsalva maneuver. CT scans were performed following the protocol of each center and reviewed by radiologists who were blinded to the type of surgery, and the findings were classified according to the Moreno-Matias scale [21].

The secondary objectives were to analyze the rate of symptomatic and clinically relevant PH at 2 years post-surgery, the incidence of early complications related to the stoma and its construction one month post-surgery, the incidence of postoperative complications assessed according to the comprehensive complication index (CCI) scale [22], readmissions, need for interventions due to PH, and the quality of life analysis using the EORTC QLQ-C30 scale [23].

Data collection

Prospective data collection was conducted, and patients were followed up according to the study protocol using individual case report forms (CRFs). Demographic information, known risk factors for PH, co-morbidities, and surgical data were collected. Postoperative complications were recorded at one-month post-surgery, and at 12 and 24 months, data on readmissions, stoma complications, PH diagnosis via physical examination and CT scan, the presence of symptoms associated with PH, reinterventions for PH, and quality of life scores were also collected. All data were systematically recorded in the Redcap platform.

Sample size

The primary objective of the study was to assess whether there were statistically significant differences between the two colostomy techniques. Assuming a clinical incidence of parastomal hernia (PH) of 50% with the conventional cross-shaped incision and an expected incidence of 20% with the reinforced longitudinal incision, a type I error (α) of 0.05, and a power of 80% ($\beta=0.20$), the required sample size was calculated to be 84 patients (42 in each group). Accounting for an expected 10% loss to follow-up, the total sample size was adjusted to 94 patients (48 in each group).

Randomization and blinding

Randomization was performed using sealed envelopes with a 1:1 allocation ratio. The envelopes were prepared in bundles of twenty per hospital by the Hospital Universitario Donostia, without the involvement of the investigators. Neither the patient nor the surgeon assessing the patient postoperatively were informed of the treatment group to which the patient had been assigned.

Statistical analysis

The STATA 18.0 statistics software program was used. Continuous quantitative variables are expressed as mean and standard deviation or median and first-third quartile range, in cases where the data do not follow a normal distribution. Categorical variables are summarized through absolute frequency and relative frequency. Quantitative variables are analyzed using the Student *t* or Mann–Whitney *U* test; categorical variables were compared with Chi-square test or Fisher's exact test. All hypothesis tests are bilateral, with a significance level of 0.05.

Results

From July 2019 to May 2022, 98 patients were enrolled in the trial (Fig. 1). Three patients were excluded because an end colostomy was not ultimately performed. One patient in each group were lost to follow-up after being referred to non-participating hospitals and were missing from the follow-up. Sixteen patients died during the follow-up period, including 7 patients in the cruciate incision group and 9 patients in the longitudinal incision group (one patient died due to postoperative complications). Therefore, a total of 77 patients who completed a minimum follow-up of 24 months were analyzed: 35 in the cruciform incision group and 42 in the reinforced longitudinal incision group.

Table 1. presents the demographic, clinical, and surgical characteristics of the groups. No statistically significant

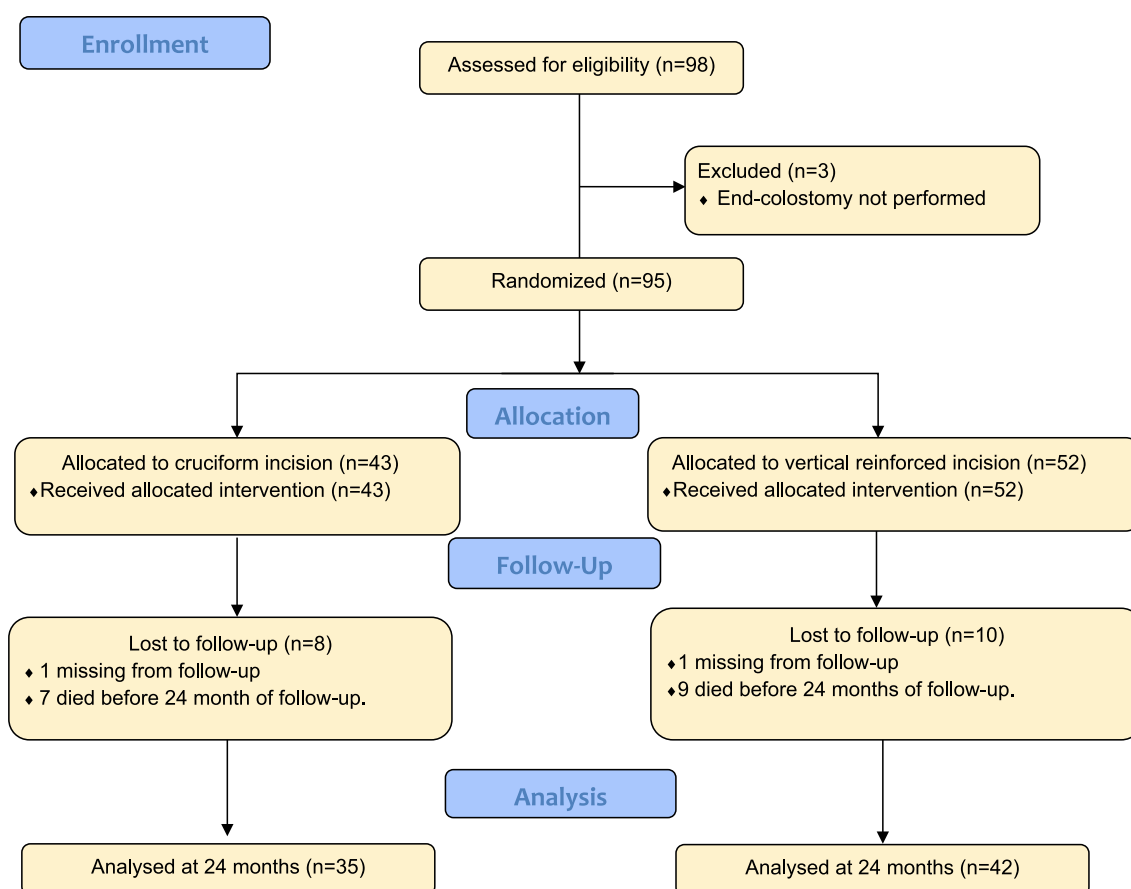


Fig. 1 CONSORT flow diagram

differences were observed between the two groups regarding demographic or surgical variables, or known risk factors associated with the development of PH.

Table 2 presents the results of the PH rate at 24 months. As observed, based on clinical examination, a total of 36 patients (46.8%) developed PH, with 17 (48.6%) in the cruciform incision group and 19 (45.2%) in the reinforced longitudinal incision group ($p=0.770$); CT scans detected 41 (53.9%) PHs, with 19 (54.3%) and 22 (53.7%) in the cruciform incision and reinforced longitudinal incision groups, respectively ($p=0.956$). Results did not differ between the participating hospitals.

However, the rate of symptomatic PHs at 24 months was significantly lower, with 5 cases (14.3%) in the cruciform incision group and 8 cases (19%) in the reinforced longitudinal incision group ($p=0.579$). This low rate of symptomatic PHs aligns with the incidence of type II/III PHs according to Moreno-Matías, with 6 cases (17.3%) and 8 cases (19.5%), respectively ($p=0.902$).

The postoperative mortality rate in the series was 1% (1 patient in the longitudinal incision group). Table 3 shows the data on postoperative morbidity, readmissions, and stoma complications. Most complications and all reoperations

were associated with the index cancer operation performed at the same time as the stoma formation. The incidence of postoperative complications up to 30 days was recorded and assessed according to the CCI scale. No difference in the CCI scale was observed between both groups.

Stoma-related complications were rare: 2 patients in the reinforced longitudinal incision group had a colostomy obstruction, and 3 patients in the same group had a mucocutaneous dehiscence.

After 24 months of follow-up, 6 patients (7.8%) required reoperation due to symptomatic PH, with 3 cases (8.6%) in the cruciform incision group and 3 cases (7.1%) in the longitudinal incision group ($p=0.816$).

No differences were observed regarding quality of life in any of the 3 health concepts of the EORTC QLQ-C30 scale between the two groups.

Discussion

This clinical trial has not shown differences in the rate of PH at two years of follow-up based on the method of fascial incision—either cruciate or reinforced longitudinal—used for

Table 1. Baseline characteristics of the patients

	Cruciate Incision Group (n=43)	Longitudinal Rein- forced Group (n=52)	Total (n=95)	Adjusted P-value
Sex: - Female	11	18	29	0.341
- Male	32	34	66	
Age(Median, IQR)	73 (16)	74.5 (19)	73 (18)	0.603
BMI(Median, IQR)	26.67 (5.72)	26.74 (5.02)	26.72 (5.26)	0.6819
Abdominal circumference (Mean, SD)	100.01 (12.25)	101.207 (13.383)	100.640 (12.799)	0.403
Chronic Obstructive Pulmonary Disease	6	7	13	0.945
Respiratory failure	0	1	1	0.361
Chronic renal failure	4	3	7	0.512
Previous laparotomy	4	7	11	0.528
Antibiotic prophylaxis	43	52	95	1
Mechanical bowel preparation	43	52	95	1
Surgical Approach				
- Laparoscopy	30	29	59	0.097
- Laparotomy	4	2	6	
- Robot	9	21	30	
Conversion to open surgery	1	3	4	0.679
Type of procedure				
- Intersphincteric resection	11	16	27	0.599
- Abdominoperineal resection	26	30	56	
- Hartmann Procedure	3	5	8	
- Others	3	1	4	
Splenic flexure descent	1	4	5	0.244
Intraoperative blood transfusion	2	3	5	0.829
Surgical time (min) (Median, IQR)	300 (100)	275 (95)	280 (100)	0.507

Table 2 Results of PH at 24 months of follow-up

	Cruciate incision group, n = 43, missing = 8	Longitudinal reinforced group, n = 52, missing = 10	Adjusted p value
PH at 24 months by CT	19/35 (54.3%)	22/41 (53.7%)	0.956
PH at 24 months Moreno-Matias clas	7 (36.8%)	10 (45.4%)	0.90
Tipo IA	6 (31.6%)	4 (18.2%)	
Tipo IB	1 (5.3%)	1 (4.5%)	
Tipo II	5 (26.3%)	7 (31.8%)	
Tipo III			
PH at 24 months by CE	17/35 (48.6%)	19/42 (45.2%)	0.770
Symptomatic PH at 24 months	5/35 (14.3%)	8/42 (19%)	0.579
Reoperation due to PH	3/35 (8.6%)	3/42 (7.1%)	0.816

PH parastomal hernia, CE clinical evaluation

exteriorizing the colon in terminal colostomy. There were no differences in the incidence of postoperative complications, symptomatic PH, reoperations due to PH during follow-up, or quality of life between the two techniques.

The PH rate recorded in this study was approximately 50%, a figure that may be considered relatively high, though within the range reported in other clinical trials that include patients both with and without prophylactic mesh [14, 17–19]. In this study, no high-risk patients were

excluded, and both physical examination and CT imaging were used to identify all types of PH. Furthermore, as previously reported, the rate of symptomatic PH was low, around 15%, corresponding to type II/III in the Moreno-Matias classification. Similarly, the need for reoperation due to symptomatic PH was also low (7.5%) and was mainly associated with these types of PH. These findings align with the daily practical experience of stoma therapists outside clinical trials and studies, where patients do

Table 3 Postoperative complications at 30 days

	Cruciate incision group (<i>n</i> = 43)	Longitudinal reinforced group (<i>n</i> = 52)	Total (<i>n</i> = 95)	Adjusted <i>p</i> value
Overall postoperative morbidity	20	17	37	0.169
Comprehensive complication index (CCI) scale (median, IQR)	20.9 (17.5)	26.6 (27.5)	20.9 (19.150)	0.12
Length of stay (days) (median, IQR)	7.5 (7)	7 (5)	7 (6)	0.66
Reoperations	2	4	6	0.544
Colostomy obstruction	0	2	2	0.194
Mucocutaneous dehiscence	0	3	3	0.109
Peristomal infection	0	0	0	–
Colostomy prolapse	0	0	0	–
Mortality	0	1	1	0.361
Readmissions	5	2	7	0.148

not find minor PH particularly bothersome and would not seek medical consultation.

Another randomized clinical trial [14] compared cruciate fascial incision with a circular incision and likewise found no differences in PH rates between the two techniques, reporting a 12-month PH rate similar to that observed in the present study.

Reinforcement of a fascial incision by placing two sutures along the upper and lower edges of the opening was described by Manook et al. [20]. This is a simple maneuver intended to prevent tearing and enlargement of the external fascial defect, with the authors reporting an 8% rate of clinically detected PH in a series of 44 patients with terminal stomas. Notably, in their study, the distal colon was exteriorized via the retroperitoneal route, whereas in the present series, exteriorization was performed using a transperitoneal and transrectus approach. While the retroperitoneal route has been proposed to reduce PH rates by modifying the orientation of the colonic conduit [24] and altering the relationship between the internal and external orifices through the abdominal wall—similar to what occurs in the inguinal canal—it is unlikely that this maneuver alone accounts for such divergent results. As with the repair of an established PH, reinforcing only the external fascia—whether by placing an onlay mesh or using reinforcement sutures—appears to be insufficient for its prevention [14, 18, 19].

On the other hand, the postoperative complications recorded in the present study were due to the primary procedure, an abdominoperineal resection, rather than to the maneuvers involved in stoma formation.

This study has several limitations. We observed an 18% loss-to-follow-up rate, higher than initially estimated in the sample size calculation, mainly attributable to cancer-related mortality. This resulted in incomplete data regarding the primary endpoint. However, when performing

an intention-to-treat analysis, including all randomized patients in different simulations, no significant differences were found between the two groups.

Another limitation of the study was the lack of standardization in technique and patient positioning for CT scans across the participating centers. Although there was generally good clinical-radiological concordance in determining the presence of PH, CT identified more cases of PH than clinical examination and, in one instance, ruled out PH in patients with a clinical diagnosis of “bulging.”

Furthermore, this study used a quality-of-life questionnaire (EORTC QLQ-C30 scale), which is more related to cancer than to stoma functionality, limiting the validity of the analysis in this regard. Instead, the Stoma QoL questionnaire, validated in Spanish a few years earlier, should have been used.

The strengths of this study include its randomized, multicenter design for evaluating a standardized surgical maneuver through an instructional video, which enhances external validity. Moreover, the study includes only a homogeneous group of patients with a permanent end colostomy due to rectal cancer, treated with abdominoperineal resection or Hartmann’s procedure with curative intent using minimally invasive, robotic, or laparoscopic surgery, with a low conversion rate. The minimum follow-up period of 2 years is important to rule out the possibility that fascial reinforcement merely delays the onset of PH.

In conclusion, the use of a longitudinal incision reinforced at its ends does not reduce or delay the incidence of PH following the creation of a permanent end colostomy compared to a cruciate fascial incision.

Author contributions GE and JMEN wrote de main manuscript. MKC, GP, UDAO, TM, FJE,AT, JMGG, PP, EEB included patients to the trial. JMEN prepared Fig. 1. All authors reviewed the manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests GP is Editor on the Journal but was not involved in any way in the Editorial peer review process of this article.

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