Tech Coloproctol (2010) 14:19–23
DOI 10.1007/s10151-009-0550-y

ORIGINAL ARTICLE

Stapled ileostomy closure results in reduction of postoperative morbidity

Y. A. Shelygin · S. V. Chernyshov · E. G. Rybakov

Received: 21 June 2009 / Accepted: 21 October 2009 / Published online: 15 December 2009

Abstract
Background Loop ileostomy is widely employed as a defunctioning procedure for left-sided colonic anastomoses. Closure of the stoma carries a risk of morbidity and even mortality. The aim of this prospective trial was to evaluate the ability of stapled stoma closure to decrease the rates of perioperative morbidity.
Methods One hundred and nineteen patients (mean age 56.2 ± 5.4 years) underwent two-stage operations for rectal carcinoma with protective loop ileostomy between 2005 and 2008. All patients were randomly divided into two groups: 56 patients had conventional ileostomy takedown, while in the other 63, a functional end-to-end anastomosis was created using a linear stapler. Groups were comparable in terms of age, gender, body mass index, and other parameters.
Results Mean time of stoma closure using functional end-to-end anastomosis was 68 ± 7, when compared to 92 ± 11 min ($P = 0.01$) for conventional stoma closure. The overall morbidity rate after ileostomy closure using a stapler was 3.2%: one patient (1.6%) developed a wound infection and self-limited bleeding from the anastomotic line, while another patient (1.6%) had an ileal obstruction caused by adhesions and required additional intervention. Conventional ileostomy closure resulted in a 14.3% morbidity rate: six patients (10.7%) had prolonged ileus, 2 (3.6%) had small bowel obstruction, and 2 (3.6%) had wound infections ($P = 0.04$).
Conclusion Functional end-to-end anastomosis reduces operating time and morbidity compared to conventional ileostomy takedown.

Keywords Ileostomy · Closure · Morbidity

Introduction

Today, the temporary protection of ileoanal and coloanal/rectal anastomoses is often achieved by the creation of a loop ileostomy [1]. Although defunctioning of the colon does not provide true prophylaxis against anastomotic leakage, it is meant to mitigate potential complications after anastomosis formation. However, the possible morbidity/mortality associated with stoma formation and takedown is still a concern [2]. Common complications of stoma reversal range from wound infection, small bowel obstruction (SBO) or ileus to life-threatening leakage and peritonitis. Therefore, it is important to achieve the lowest possible rates of complications after stoma closure. The side-to-side stapler, or more precisely, the functional end-to-end anastomosis for ileostomy reversal, was introduced into practice in the 1980s [3] and has since gained popularity among surgeons. The advantages of the wider anastomosis achievable by stapler include decreased rates of ileus and SBO, as well as minimization of the so-called "human factor", i.e., the influence of a particular surgeon's skill and experience on the quality of the small bowel anastomosis [4, 5]. However, some controversy exists concerning the advantages of manually suturing anastomoses, e.g., cost effectiveness, reduction of operative time, postoperative hospital stay, and other parameters [6, 7].

This article was presented as a poster at the 12th Central European Congress of Coloproctology, May 6–7, 2008, Moscow, Russia.

Y. A. Shelygin · S. V. Chernyshov · E. G. Rybakov (✉)
Department of Rectal Cancer Surgery at the State Research Center of Coloproctology, Salyam Adyl st. 2, 123423 Moscow, Russia
e-mail: rybakov_e@yahoo.com; rybakov_e@mtu-net.ru

The results presented in this article are from a prospective, randomized trial designed to compare these two methods of stoma closure.

Materials and methods

The protocol of this prospective, randomized controlled trial was approved in January 2005 by the local ethics committee at the State Research Center of Coloproctology in Moscow, Russia. Operating time was chosen as the primary endpoint. Based on our previous experience and data from a previous meta-analysis [8], we expected application of the stapler technique to reduce operating time by at least 10–15 min. The secondary endpoint was the rate of complications, in particular SBO. Proponents of the stapled anastomosis [4, 7] reported a 2–7-fold decrease in the rate of SBO. Thus, we estimated that a total of 50 patients in each group would provide sufficient statistical power. Treatment assignment sequence was computer generated and randomization occurred in the operating room prior to incision. Patients and clinicians filling the study forms were blinded to treatment's allocation.

Between 2005 and 2008, 248 patients underwent two-stage surgery for rectal carcinoma with creation of a protective ileostomy or colostomy. Informed consent was given by 121 eligible patients with a defunctioning ileostomy, of whom 119 were then randomized. Patients were randomized into two groups: 56 patients had conventional ileostomy takedown, and 63 had a functional end-to-end anastomosis created by linear stapler. The only stratification criterion was obesity, i.e., body mass index (BMI) $\geq$ 30. Patient and surgical characteristics are listed in Table 1.

Table 1 Patient characteristics and description of surgical procedure

	Stapled $n = 63$	Hand-sewn $n = 56$
Gender		
Male (%)	33 (52.4)	29 (51.8)
Female (%)	30 (47.6)	27 (48.2)
Age (years), mean ± SD (range)	58 ± 5.4 (27–78)	56 ± 5.6 (26–80)
Type of rectal resection and anastomosis		
Straight coloanal anastomosis	3 (4.8)	2 (3.6)
Colonic pouch	18 (28.5)	15 (26.8)
Low anterior resection (LAR)	42 (66.7)	39 (69.6)
Median time of stoma existence before closure (days)	67 (49–413)	70 (52–182)
BMI at time of stoma closure		
Weight deficiency < 18.5 (%)	–	2 (3.6)
Normal 19–25 (%)	32 (50.8)	27 (48.2)
Overweight 26–30 (%)	24 (38.2)	21 (37.5)
Obese > 30 (%)	7 (11)	6(10.7)
Anesthesia type at time of stoma closure		
Spinal + sedation (%)	60 (95.2)	51 (89.2)
General anesthesia (%)	3 (4.8)	5 (10.8)
Timing of ileostomy takedown with respect to adjuvant chemotherapy		
No chemotherapy	28 (44.4)	20 (35.7)
Between 1st and 2nd cycle	15 (23.8)	23 (41.1)
After 6 cycles of chemotherapy	20 (31.8)	13 (23.2)
Complicated ileostomy		
Dermatitis	11 (17.5)	10 (17.9)
Parastomal herniation	3 (4.8)	5 (8.9)

At the time of the first operation, a loop ileostomy was formed in the right lower quadrant of the abdomen. The segment of ileum used for stoma creation was taken at 15–20 cm from the ileocecal junction. A 180° rotation of the ileum was performed to orient the efferent limb below the afferent limb, and a ~3-cm nipple was formed on the functioning limb to facilitate maturation of the ileostomy.

The median time to ileostomy closure did not differ significantly between groups. This time depended primarily on the need for a consolidating chemotherapy (usually capecitabine/oxaliplatin or capecitabine alone). If adjuvant treatment was necessary, stoma closure was performed between the 2nd and 3rd cycles or after definitive completion of chemotherapy.

All patients, including those who received adjuvant chemotherapy, were in suitable condition for surgery, without significant changes in blood work or signs of cancer progression. The integrity of the preexisting colonic anastomoses and pouches was documented before stoma closure using contrast enema and radiographic evaluation. No particular preparation of the ileum was undertaken before stoma closure; however, on the day before surgery, one or two water enemas were used to check for and clean out any impacted barium remaining in the defunctioned colon after contrast enema. Therapeutic antibiotics (cephalosporin + metronidazole or fluoroquinolone + metronidazole) were given at the time of operation and for 2–3 days thereafter.

Most of the operations were performed under a combination of spinal anesthesia and intravenous sedation (Table 1). All closures were performed by consultant surgeons or by senior registrars under direct supervision of the consultant.

Postoperative monitoring was continued for 30 days. Simple charts were given to all patients, on which they could mark time of first postoperative flatus, stool, and sensation of peristalsis if they were able to feel it. Bowel sounds were also checked by the registrar or consultant according to routine practice (three times per day, during

morning (7–8 a.m.), afternoon (4–5 p.m.) and evening (8–9 p.m.) ward rounds).

All data were entered into a computerized database. Statistical analysis was performed by SPSS 10.0 for Windows™. The median or mean, depending on normality of distribution, and the standard deviation were chosen for descriptive statistics. Comparison between groups was performed by unpaired *t*-test. A two-tailed Fisher's exact test was used to compare dichotomous variables. A *P*-value less than 0.05 was considered to be significant.

In both groups, surgery began with local circumstomal access. The ileostomy-bearing segment of ileum was sharply dissected out through all layers of the abdominal wall. If inadvertent enterotomy or myotomy occurred, the gap was closed with interrupted seromuscular sutures of 3-0 Vicryl® (Ethicon, Int.).

A stapled, functional, end-to-end anastomosis was created using a linear stapler GIA™-80 (Auto Suture™, USA). After mobilization of the ileal segment which involved the stoma, an enterotomy was created at the base of the nipple valve allowing insertion of both branches of the stapler into the afferent and efferent limbs (Fig. 1a). Alternatively, resection of the ileostomy-bearing bowel segment was performed (Fig. 1b). The anastomotic line was checked for bleeding, and the reloaded stapler or any other available linear stapler, e.g., the TLH-60 (Johnson & Johnson, Inc.) was fired transversely to resect the ileostomy-bearing segment and close the anastomosis (Fig. 1c). In all cases, the distal staple line was oversewn and imbricated with a running suture using the Lembert technique, which added approximately 5 min to anastomosis creation. An additional Lembert stitch was used to reinforce the crotch site.

A hand-sewn end-to-end anastomosis was created using two-layered interrupted sutures of 3-0 Vicryl® (Ethicon, Int.). Excision of the ileostomy-bearing segment was performed in all cases.

In both groups, the postoperative wound was closed primarily in layers. An indwelling subcutaneous drain was used according to surgeon preference, usually in obese patients.

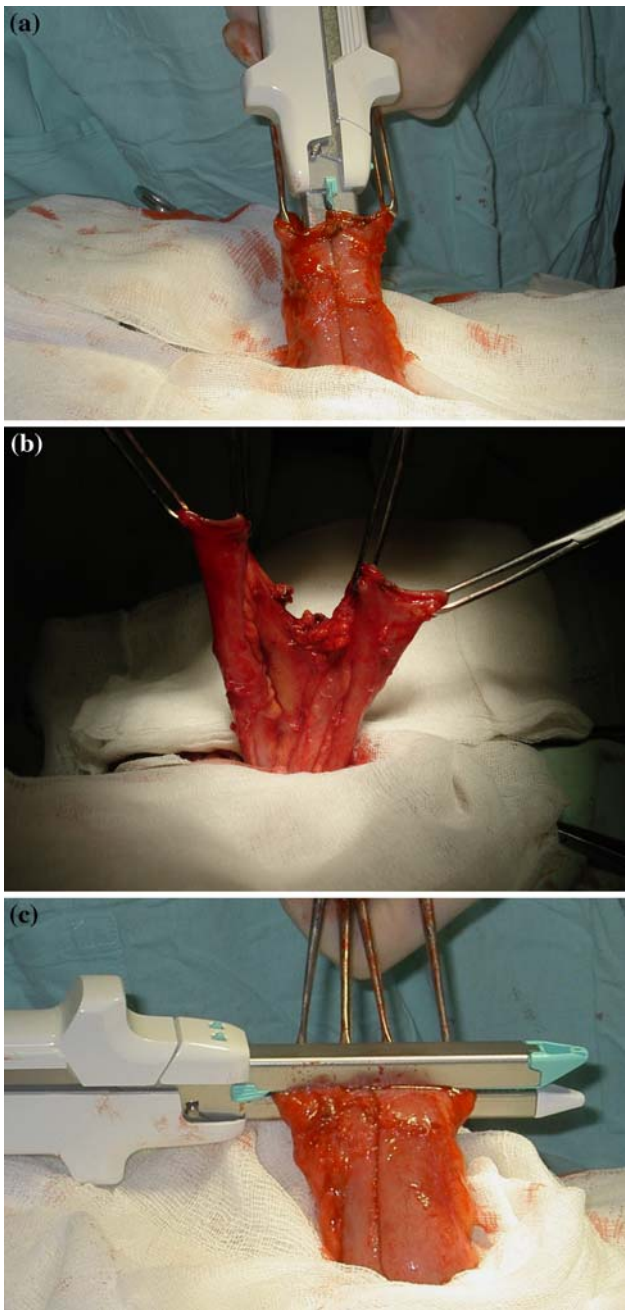

Fig. 1 Creation of functional end-to-end stapler anastomosis for ileostomy closure. **a** Both limbs of the ileum are mobilized, and the stoma-bearing segment is resected; **b** side-to-side stapler anastomosis; **c** the ileum is cross-stapled, and the anastomosis is complete

Results

No formal laparotomy was required in any case, and all ileostomies were closed via local, circumstomal access. A significant difference was observed in overall operating time (Table 2), which was shorter when a stapling technique was employed for closure (68 ± 7 vs. 92 ± 11 min ($P = 0.01$)).

A trend toward earlier fluid and solid food intake after functional end-to-end anastomosis was also identified; however, this did not reach statistical significance.

There was no perioperative mortality or rehospitalization in either group.

The overall morbidity rate was higher after suture anastomosis than after stapler anastomosis (14.2 vs. 2.4% ($P = 0.04$)). The main complication observed after suture anastomosis was prolonged ileus and small bowel obstruction. Nevertheless, no additional surgical intervention was necessary, as nasogastric decompression and

Table 2 Results: stapled versus hand-sewn ileostomy closure

	Stapled $n = 63$	Hand-sewn $n = 56$	P-value
Overall median operation time, minutes (range)	68 ± 7 (55–95)	92 ± 11 (60–105)	0.01
Median time to first liquids, days (range)[a]	0.5 (0–1)	0.5 (0–1)	NS
Median time to first solid food, days (range)	3 (2–6)	3 (2–7)	NS
Median time to first flatus, days (range)	2 (0–3)	3 (2–5)	NS
Median time to first stool, days (range)	3 (1–4)	4 (3–7)	NS
Overall morbidity rate *n*, %	2 (3.2)	8 (14.3)	0.04
Complications			
Wound infection	1 (1.6)	2 (3.6)	NS
Anastomotic bleeding	1 (1.6)	–	NS
Small bowel obstruction	1 (1.6)	2 (3.6)	NS
Prolonged ileus	–	6 (10.7)	0.009
Median hospital stay, days (range)	9 (8–16)	11 (8–20)	0.07

[a] All 8 patients in both groups operated on under general anesthesia were allowed oral fluid intake on POD2

conservative treatment were successful in all patients. The only case of small bowel obstruction (1.6%) in the stapler group was caused by adhesions and required midline laparotomy; adhesiolysis was followed by an uneventful postoperative period. Another anastomosis-related complication after stapler closure was bleeding from the staple line, which manifested first in bloody stool and next in a decrease in hemoglobin level from 15.0 to 13.5 g/dl. Nevertheless, bleeding was self-limited, and no reoperation was needed. No significant difference in incidence of wound infection was observed after use of stapler closure.

Discussion

Ever since protective ileostomy was introduced as an option for defunctioning the colon, numerous trials comparing closure, complications, cost effectiveness, and other parameters have been published [2, 4, 8–11]. The morbidity rate and severity of complications related to ileostomy formation vary from series to series, but it is widely agreed that the consequences of anastomotic failure are more devastating than those following ileostomy formation, existence, and closure [5]. Systematic reviews [12] have demonstrated overall morbidity rates of ileostomy takedown of 17.3%, with a mortality rate of 0.4% and conversion to formal laparotomy at the time of closure in 3.7% of patients. The most serious problems associated with stoma closure were SBO and leakage, because they can lead to reoperation, reestablishment of an ileostomy, mortality, and emotional and psychological trauma to the patient [11–13]. A better performance by stapled anastomoses with regard to SBO was identified in a prospective randomized trial by Hasegawa et al. [4], but could not be confirmed in a randomized trial from Hull et al. [7], or in other retrospective and prospective series [9–11]. A meta-analysis published by Leung et al. [8] also found no statistically significant differences between stapled and hand-sewn loop ileostomy closures, although it did report a trend favoring stapled closures with regard to lower small bowel obstruction rates and shorter operative time; this study also stressed the necessity of a prospective randomized trial. Our trial used the operating time required for temporary loop ileostomy closure as the primary endpoint and demonstrated shorter times in patients with a stapled anastomosis. In addition, significantly decreased rates of postoperative ileus were achieved when a stapled anastomosis was used. The single case of adhesion-related SBO that occurred in the stapled anastomosis group suggests that there is a greater reduction in intestinal obstruction rates in a stapled versus hand-sewn anastomosis because stapled anastomosis creation usually does not induce adhesion formation. On the other hand, the narrow edematous lumen of the hand-sewn end-to-end anastomosis is the leading cause of SBO [6]. Given these circumstances, the quickly accomplished, wide-mouthed end-to-end stapled anastomosis is an attractive alternative whose superiority has been demonstrated in our randomized trial.

Although cost was not an endpoint for our trial, we calculated possible savings and expenses in stapler versus hand-sewn closures. With regard to suture materials, the stapler anastomosis is far more expensive than the hand-sewn, with an estimated cost of 202€ (with a second cartridge for reloading) vs. 6€, respectively. On the other hand, according to Russian Ministry of Public Health estimates, the cost per diem of reconstructive surgery is approximately 158€. If we assume an average hospital stay in the stapler group is 2 days less than in the hand-sewn group, we can conclude that introduction of stapled ileostomy closure will lead to savings of roughly 100€ per patient.

Conclusion

Use of the stapling technique for ileostomy closure results in decreased operating time. A lower rate of morbidity (primarily due to ileus and SBO) is the main advantage of the procedure.

References

1. Kaiser AM, Israelit S, Klaristenfeld D et al (2008) Morbidity of ostomy takedown. J Gastrointest Surg 12:437–441
2. Riesener KP, Lehnen W, Höfer M, Kasperk R, Braun JC, Schumpelick V (1997) Morbidity of ileostomy and colostomy closure: impact of surgical technique and perioperative treatment. World J Surg 21:103–108
3. Kestenberg A, Becker JM (1985) Anew technique of loop ileostomy closure after endorectal ileoanal anastomosis. Surgery 98:109–111
4. Hasegawa H, Radley S, Morton DG, Keighley MR (2000) Stapled versus sutured closure of loop ileostomy: a randomized controlled trial. Ann Surg 231:202–204
5. Amin SN, Memon MA, Armitage NC, Scholefield JH (2001) Defunctioning loop ileostomy and stapled side-to-side closure has low morbidity. Ann R Coll Surg Engl 83:246–249
6. Bain IM, Patel R, Keighley MR (1996) Comparison of sutured and stapled closure of loop ileostomy after restorative proctocolectomy. Ann R Coll Surg Engl 78:555–556
7. Hull TL, Kobe I, Fazio VW (1996) Comparison of handsewn with stapled loop ileostomy closures. Dis Colon Rectum 39:1086–1089
8. Leung TT, MacLean AR, Buie WD, Dixon E (2008) Comparison of stapled versus handsewn loop ileostomy closure: a meta-analysis. J Gastrointest Surg 12:939–944
9. O'Toole GC, Hyland JM, Grant DC, Barry MK (1999) Defunctioning loop ileostomy: a prospective audit. J Am Coll Surg 188:6–9
10. Mann LJ, Stewart PJ, Goodwin RJ, Chapuis PH, Bokey EL (1991) Complications following closure of loop ileostomy. Aust N Z J Surg 61:493–496
11. Kraemer M, Seow-Choen F, Ho YH, Eu KW (2000) A comparison of sutured and stapled closure of diverting loop ileostomies. Tech Coloproctol 4:89–92
12. García-Botello SA, García-Armengol J, García-Granero E et al (2004) A prospective audit of the complications of loop ileostomy construction and takedown. Dig Surg 21:440–446
13. Chow A, Tilney HS, Paraskeva P, Jeyarajah S, Zacharakis E, Purkayastha S (2009) The morbidity surrounding reversal of defunctioning ileostomies: a systematic review of 48 studies including 6, 107 cases. Int J Colorectal Dis 24:711–723