Randomized clinical trial

Stoma-related complications are more frequent after transverse colostomy than loop ileostomy: a prospective randomized clinical trial

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Background: The consequences of leakage from low colorectal or coloanal anastomoses are reduced by the use of a loop stoma to divert the faecal stream. Controversy continues as to whether loop ileostomy (LI) or loop transverse colostomy (LTC) is the optimal method of defunctioning such anastomoses.
Methods: Patients requiring defunctioning following anterior resection and total mesorectal excision were randomized to receive either LI or LTC. Comparison was made between the groups regarding the difficulty of stoma formation and closure, the recovery after stoma closure and stoma-related complications. The minimum follow-up after stoma closure was 6 months (median 36 months).
Results: Between October 1995 and August 1999, 70 patients were randomized (LTC 36, LI 34) of whom 63 underwent stoma closure (LTC 31, LI 32). There were no significant differences in the difficulty of formation or closure, or in the postoperative recovery between the groups. However, there were ten complications related directly to the stoma in the LTC group: faecal fistula (one patient), prolapse (two), parastomal hernia (two) and incisional hernia during follow-up (five). None of these complications occurred in the LI group.
Conclusion: In this randomized study, the frequency of herniation before or after colostomy closure supports the choice of LI as a method of defunctioning a low anastomosis. Both methods appear to provide satisfactory protection for the low anastomosis.

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Introduction

Anastomotic leakage is a dreaded early complication of any intestinal anastomosis; there is a particularly high incidence following low colorectal and coloanal anastomosis[1]. The main factor determining the risk of leakage is the height of the anastomosis; the risk is particularly high when the anastomosis is less than 6 cm from the anal verge[1,2]. It is now generally acknowledged that a proximal defunctioning stoma does not abolish the risk of leakage, but certainly mitigates the consequences[1–3]. Dehni and colleagues[3] reported that the clinical leak rate was 17 per cent in patients who had a low colorectal anastomosis without a defunctioning stoma compared with 6 per cent in a similar group with a temporary stoma.

Loop stomas are commonly used to temporarily defunction distal colorectal or coloanal anastomoses, but there are complications associated with the stoma. While controversy continues as to whether all low anastomoses should have a temporary stoma[3] or whether selective usage is optimal[4], all agree that a stoma is occasionally necessary, and sometimes essential to prevent or treat the life-threatening complication of colorectal anastomotic leakage. In addition to moderating the consequences of anastomotic leakage, a temporary stoma may reduce the risk of complete anastomotic failure[3]. This is particularly relevant for low anterior resection (LAR) of the rectum, for which anastomotic leakage has been reported to be in excess of 10 per cent without a covering stoma[3,5]; consequent pelvic infection may result in a poor functional outcome or in anastomotic take-down and a permanent stoma[3,5].

Either a loop ileostomy (LI) or a loop transverse colostomy (LTC) can be used to defunction a low anastomosis, although there is no consensus as to the optimal temporary defunctioning stoma. Of the three published randomized controlled trials comparing loop

stomas to defunction left-sided colonic anastomoses, one has favoured LTC[6] and two have recommended ileostomy[7,8].

This study was a prospective comparison of LTC and LI in a randomized controlled setting in a single institution in patients undergoing LAR and total mesorectal excision (TME).

Patients and methods

Only patients undergoing anterior resection and TME were considered for entry into this trial, which was approved by the research ethics committee. All patients had sites for LI and LTC marked before operation by a stoma therapist and informed consent was obtained. After the colorectal or coloanal anastomosis had been completed and a decision to create a defunctioning stoma made, the patient was assessed to confirm that either stoma was feasible. The patients were then randomized to receive either a LI or a LTC. The time taken to fashion the stoma, and the relative ease of this procedure was recorded using a personally designed linear scale.

After operation each patient was reviewed on a daily basis by the stoma therapist who prospectively assessed the daily stoma output. All complications related to the stoma before closure were recorded.

The stomas were closed in standard fashion, under general anaesthetic and with standardized antibiotic and venous thrombosis prophylaxis. The time taken to close the stoma and the relative ease of closure were recorded. The time to passage of first flatus and first faeces, and the postoperative stay were assessed. All complications following closure were noted.

All patients have remained under outpatient follow-up of their rectal neoplasms. During this follow-up the stoma sites are examined for the presence of an incisional hernia.

Data are expressed as median (range) and were compared using analysis of variance or χ^2 test with Yates' correction.

Results

Between October 1995 and August 1999, 115 anterior resections for rectal neoplasm were performed. Of these 16 patients had mesorectal transection for upper-third tumours and did not have a defunctioning stoma. Of the remaining 99 patients, 20 were defunctioned with a soft anal stent, five did not enter the study and the remaining 74 were considered for randomization. Four could not be randomized to LTC at operation owing to previous colonic resection, so 70 patients were randomized as shown in *Table 1*.

Table 1 Demographics

	LI ($n=34$)	LTC ($n=36$)
Age (years)*	63 (40–85)	68 (32–90)
Sex ratio (M : F)	27 : 7	22 : 14
Tumour height (cm)*	7 (3–12)	6 (3–15)
Tumour stage		
Benign	1	1
Dukes' A	4	12
Dukes' B	9	6
Dukes' C	16	11
Metastases	4	6

*Values are median (range). LI, loop ileostomy; LTC, loop transverse colostomy

Table 2 Time and ease of operation

	LI	LTC
Formation of stoma		
Time (min)	15 (10–30)	16 (5–30)
Ease*	3 (1–7)	3 (1–9)
Interval to closure (days)	62 (17–120)	73 (28–141)
Closure of stoma		
Time (min)	48 (40–105)	48 (25–90)
Ease*	7 (2–10)	4 (3–9)

Values are median (range). *Ease was measured on a linear scale from 1 to 10. LI, loop ileostomy; LTC, loop transverse colostomy

The loop stoma was closed in 63 patients, with a follow-up after closure of 36 (6–48) months. Five patients died before the stoma was closed; there were three postoperative deaths following anterior resection (two from myocardial infarction and one from mesenteric ischaemia), one patient died from advanced metastatic disease and one died following a stroke. Two patients required conversion to an end-colostomy following clinical leakage from the coloanal anastomosis, resulting in major pelvic sepsis.

In the LI group there was one clinical and one radiological leak, and in the LTC group there was one clinical leak. The overall leakage rate was three of 67.

There were no significant differences in time taken to create or close the stomas, or in the difficulty of the procedure (*Table 2*). The postoperative recovery times following stoma closure were similar for both groups of patients (*Table 3*). At closure bowel resection was required in two patients who underwent LTC compared with six who had a LI.

There were no deaths attributable to a stoma or following stoma closure. The complications related to stomas and postoperative morbidity following stoma closure are shown

Table 3 Recovery from stoma closure

	LI	LTC
Time to first flatus (days)	2 (1–5)	2 (1–5)
Time to first defaecation (days)	3 (1–6)	4 (1–6)
Time to hospital discharge (days)	6 (4–13)	6 (4–9)

Values are median (range). LI, loop ileostomy; LTC, loop transverse colostomy

Table 4 Stoma- and stoma closure-related complications

	LI	LTC
Directly-related complications		
Stoma prolapse	0	2
Parastomal hernia	0	2
Faecal fistula	0	1
Incisional hernia	0	5
High-output stoma	1	0
Total	1	10
Other complications		
Wound infection	1	2
Small bowel obstruction	0	1
Deep venous thrombosis	1	1
Pulmonary embolus	1	0
Urinary retention	1	0
Total	4	4

LI, loop ileostomy; LTC, loop transverse colostomy

in *Table 4*. There were more complications in the LTC group than in the LI group ($\chi^2 = 4{\cdot}46$, 1 d.f., $P = 0{\cdot}05$). The difference was accounted for by direct colostomy-related complications in the LTC group (*Table 4*).

Discussion

Low colorectal and coloanal anastomoses have the highest risk of leakage of any intestinal anastomosis[1–3,5]. Patients undergoing LAR with TME were selected for this study as the leak rate is among the highest for elective colorectal or coloanal anastomoses[5]. Anastomotic leakage may be reduced by triple stapling[1] and the routine use of a stapled colon pouch[9].

Three previous trials have addressed the question of whether a LI or LTC is the optimal stoma for defunctioning a colonic or colorectal anastomosis. Williams and colleagues[7] reported 47 patients (LI 23, LTC 24) who underwent elective colorectal surgery. They found significant differences in favour of LI with regard to odour and appliance changes, and a higher wound infection rate associated with LTC closure. Khoury and colleagues[8] recruited 61 patients (LI 32, LTC 29) into their trial, of which 52 had closure of the stoma. They found no significant difference between the groups, except that LIs functioned earlier than LTCs. They recommended ileostomy as an alternative to LTC. The third study, that of Gooszen and colleagues[6], contained 76 patients (LI 37, LTC 39) and reported statistically better results with LTC as a temporary defunctioning stoma. However, this was a multicentre trial in five centres over a period of 6 years. Patients presenting as an emergency with left-sided colonic obstruction were included with those having elective surgery for any colorectal pathology, including sigmoid diverticular resection.

In the present series there was no significant difference in the ease of construction and the time taken to fashion LIs and LTCs although, as suggested by Khoury and colleagues[8], LIs appeared to be more difficult to construct in the markedly obese. In contrast to the findings of Williams and colleagues[7], there was no difference in complications related to management of the different stomas in the current study. This may be due to improvements in stoma appliances and accessories that have resulted in a reduction in seepage of liquid faeces from a flush LTC and in the odour associated with LTC (a major factor in previous series).

In this series consultants or senior trainees performed stoma closure. There were no significant differences in the time taken to close stomas, or in the ease of the procedures. However, LI closure did appear more difficult than LTC closure, perhaps because of the need to either reduce or resect the spout of the ileostomy (six LIs *versus* two LTCs). In addition, the fascial defect used to create LTCs is larger than that for LIs, improving access to the peritoneal cavity for stoma mobilization at the time of closure. It may be as a result of the relative bulk of a loop colostomy compared with a LI and the size of the fascial opening that two stomal prolapses and two parastomal hernias were observed in the LTC group.

The postoperative recovery from stomal closure was similar for LI and LTC. However, during follow-up five patients developed an incisional hernia at the site of the LTC. This cannot be explained by the difficulty of closure, as LTCs appeared somewhat easier to close than LIs. The higher bacterial concentration of LTC effluent may have resulted in greater contamination of the wounds at the time of closure, increasing the risk of deep wound dehiscence. Alternatively, the spout of an ileostomy may reduce leakage of faecal fluid during mobilization of the ileostomy. Whatever the mechanisms, the frequency of LTC complications both before and after closure resulted in a significantly greater number of revisional procedures in the LTC group than the LI group.

LI may be associated with a high incidence of adhesion-related small bowel obstruction following total colectomy and an ileoanal pouch procedure, but after distal colorectal resection this complication is seen less frequently[10]. There are concerns that with longer follow-up adhesion-related complications might become more evident, particularly after LI. To date, however, there has been only one patient (in the LTC group) with small bowel obstruction. Longer follow-up may also result in detection of further incisional hernias, seen more frequently in the LTC group.

This prospective randomized trial has shown a significantly greater number of major stoma-related complications associated with LTC. Both methods appeared to provide effective defunctioning of the high-risk anastomosis and the overall leak rate of 4 per cent (three of 67) is among the lowest reported in a series of patients with TME and low anastomoses. The high incidence of stoma-related complications supports the use of LI as the optimal defunctioning stoma for patients who require a stoma to defunction a low anastomosis following LAR and TME with adequate bowel preparation. A loop colostomy may provide better defunctioning in a poorly prepared bowel, or where leakage has occurred and defunctioning is required.

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