

Randomized clinical trial comparing loop ileostomy and loop transverse colostomy for faecal diversion following total mesorectal excision

W. L. Law, K. W. Chu and H. K. Choi

Department of Surgery, Queen Mary Hospital, University of Hong Kong Medical Centre, 102 Pokfulam Road, Hong Kong
Correspondence to: Dr K. W. Chu (e-mail: chukw@hkucc.hku.hk)

Background: The aim of this study was to compare loop ileostomy and loop transverse colostomy as the preferred mode of faecal diversion following low anterior resection with total mesorectal excision for rectal cancer.

Methods: Patients who required proximal diversion after low anterior resection with total mesorectal excision were randomized to have either a loop ileostomy or a loop transverse colostomy. Postoperative morbidity, stoma-related problems and morbidity following closure were compared.

Results: From April 1999 to November 2000, 42 patients had a loop ileostomy and 38 had a loop transverse colostomy constructed following low anterior resection. Postoperative intestinal obstruction and prolonged ileus occurred more commonly in patients with an ileostomy ($P = 0.037$). There was no difference in time to resumption of diet, length of hospital stay following stoma closure and incidence of stoma-related complications after discharge from hospital. A total of seven patients had intestinal obstruction from the time of stoma creation to stoma closure (six following ileostomy and one following colostomy; $P = 0.01$).

Conclusion: Intestinal obstruction and ileus are more common after loop ileostomy than loop colostomy. Loop transverse colostomy should be recommended as the preferred method of proximal faecal diversion.

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Introduction

Anastomotic leakage is a serious postoperative complication following colorectal surgery. The incidence is particularly high when an anastomosis involves the distal rectum or anal canal^{1,2}. Proximal faecal diversion reduces the incidence of clinical anastomotic leakage following low anterior resection with total mesorectal excision³. Although use of proximal faecal diversion to prevent leakage at rectal anastomoses remains controversial^{2,4}, most authors agree that a defunctioning stoma can reduce the risk of sepsis resulting from anastomotic leakage^{5,6}.

Proximal diversion of a distal rectal anastomosis can be achieved by either a loop colostomy or a loop ileostomy. It remains controversial whether a loop ileostomy or a loop transverse colostomy is a better form of faecal diversion. This randomized controlled trial compared loop ileostomy and loop transverse colostomy to determine the optimal mode of faecal diversion following low anterior resection with total mesorectal excision for rectal cancer.

Patients and methods

Patients who underwent low anterior resection for rectal cancer within 12 cm from the anal verge were eligible for inclusion in the study, which took place from April 1999 to November 2000. Informed consent was obtained from patients before the operation. The stoma therapist marked both the loop ileostomy site and the loop transverse colostomy site before surgery. During the study period all patients treated with total mesorectal excision with an anastomosis at or below 5 cm from the anal verge had a diverting stoma. Patients with proximal rectal cancer in whom the mesorectum was transected and a higher rectal anastomosis constructed (more than 5 cm from anal verge) did not have faecal diversion. The decision to create a diverting stoma and randomization of patients was made on completion of the colorectal or coloanal anastomosis.

In patients randomized to have a loop ileostomy, the loop of ileum destined for the ileostomy was brought out without tension through the abdominal wall at the premarked stoma

site. The distal limb of the loop was marked with a suture. A transverse incision was made involving the antimesenteric two-thirds of the ileum and a 1.5–2.0-cm spout constructed by everting the afferent limb. The loop was not rotated and the afferent limb constituted the superior aspect of the stoma.

In patients randomized to have a loop transverse colostomy, the stoma was created in the transverse colon to the right of the middle colic vessels. The mesentery adjacent to the bowel wall was incised for the passage of a Nelaton catheter, used to bring the transverse colon out through the premarked stoma site. The catheter was also used to support the colostomy in the early postoperative period and was removed 1 week after surgery. An incision was made along one of the taenia coli and the colostomy was matured with catgut sutures.

A contrast enema was performed before closure of the stoma to ensure the integrity of the anastomosis. Mechanical bowel preparation with polyethylene glycol solution was given to the patients the day before closure of the transverse colostomy. No bowel preparation was administered before closure of an ileostomy. Perioperative antibiotics were given at the time of induction of anaesthesia. A circumstomal incision was used for stoma closure. The loop of colon or ileum was freed by sharp dissection. Primary closure of the anterior colonic wall was performed for the loop transverse colostomies while resection and anastomosis was the procedure for closure of the loop ileostomies. The abdominal wall was closed with interrupted polydioxanone sutures and the skin was closed primarily.

Demographic data, details of the operation, postoperative complications and follow-up data formed part of the prospective database of patients with rectal cancer. Prolonged postoperative ileus was defined as the inability to tolerate diet 5 days after surgery in the absence of active bowel sounds with the need for nasogastric decompression. Data on stoma function and stoma-related morbidity were collected.

Sample size calculation

The authors had shown previously that 15 per cent of patients who had a loop ileostomy for faecal diversion following rectal resection developed small bowel obstruction. It was assumed that obstruction was due mainly to the presence of a loop ileostomy which would not have occurred in case of a loop transverse colostomy. To reduce the obstruction rate by 15 per cent, it was estimated that a sample size of 36 patients in each group would be required to achieve a type I error of 0.05 with a power of 0.8. In calculation of the sample size, it was assumed that 10 per

cent of the patients would not undergo stoma closure. Therefore it was planned to recruit 80 patients.

Statistical analysis

Nominal variables were compared with the χ^2 test or Fisher's exact test as appropriate. Continuous variables were presented as means and compared with Student's *t* test. Non-parametric data were presented as median values and compared with the Mann–Whitney *U* test. $P < 0.05$ was considered statistically significant.

Results

Eighty patients, 31 women and 49 men, were randomly assigned to have a loop ileostomy (42) or a loop transverse colostomy (38). The mean age was 66.5 (range 38–87) years. There were no significant differences in demographic data, tumour characteristics or operative details between the two groups (*Table 1*).

There were two intraoperative complications, one splenic injury and one ureteric injury during concomitant total hysterectomy and bilateral oophorectomy. Non-stoma-related complications occurred in 13 patients in the ileostomy group and in eight patients in the transverse colostomy group ($P = 0.45$). Clinical anastomotic leakage occurred in four patients, two in each group. Laparotomy and peritoneal lavage was required in one patient while the other patients were managed without surgery. As regards stoma-related morbidity, three patients developed intestinal obstruction and four developed ileus in the ileostomy group while prolonged ileus occurred in only one patient in the colostomy group ($P = 0.037$). One patient required surgery; the obstruction was due to a kink in the ileum just proximal to the ileostomy site.

Recovery of bowel function and time to resumption of diet after the initial operation are shown in *Table 1*. Bowel function returned and a fluid diet was resumed more quickly in patients with a loop ileostomy. However, the time to resumption of solid diet and the length of hospital stay were no different.

Two patients in the ileostomy group died in the early postoperative period because of bowel ischaemia. Another patient developed gastrointestinal bleeding from a duodenal ulcer, resulting in hypotension and ischaemic injury to the colon. Emergency vagotomy and pyloroplasty with takedown of the anastomosis was performed. These three patients were excluded from the analysis of stoma-related complications after discharge from hospital.

Table 2 shows the stoma complications that occurred before closure. There were no differences in the number of complications between the two groups. The most common

Table 1 Comparison of patients with loop ileostomy and loop transverse colostomy

	Loop ileostomy (n = 42)	Loop transverse colostomy (n = 38)	P
Sex ratio (F : M)	16 : 26	15 : 23	0.89
Mean age (years)	65.2	67.8	0.28
Mean tumour level (cm)*	6.8	6.4	0.36
Mean level of anastomosis (cm)*	3.7	3.3	0.17
Anastomosis type			0.60
Double stapled	41	36	
Hand-sewn coloanal	1	2	
Additional organs resected	3	2	1.00
Mean blood loss (ml)	451	521	0.38
Mean duration of operation (min)	163	158	0.59
Laparoscopically assisted	3	3	1.00
Stage†			0.12
I	7	2	
II	21	14	
III	12	19	
IV	2	3	
Median time to stoma output (days)	3	4	0.001
Median time to fluid diet (days)	2	4	0.04
Median time to solid diet (days)	4	4	0.80
Median length of hospital stay (days)	9	9	0.74

*Above anal verge. †Stage according to American Joint Committee on Cancer

Table 2 Stoma-related complications during follow-up

	Loop ileostomy (n = 39)	Loop transverse colostomy (n = 38)
Prolapse	0	3
Retraction	0	0
Skin irritation	4	7
Parastomal hernia	1	0
High output	1	0
Incomplete diversion	0	1
Total	6	11*

*P = 0.16 versus loop colostomy (Fisher's exact test)

complications were minor skin problems, which occurred in 11 patients. No operations were needed to deal with the stoma complications.

One patient died from pneumonia before closure of the stoma. Three patients preferred not to have the stoma closed, two because of irresectable liver metastases. Stoma closure was therefore performed in 73 patients (35 ileostomies and 38 colostomies). The median time to closure was 183 days for patients with an ileostomy and 180 days for those with a loop colostomy ($P = 0.63$). The duration of operation, time to recovery of bowel function and time to resumption of diet are shown in *Table 3*. The duration of operation was shorter in the colostomy group. Patients in the ileostomy group had earlier return of bowel

function. However, there were no differences in the time to resume fluid and solid diet or length of hospital stay.

No death resulted from stoma closure. The morbidity of stoma closure is shown in *Table 3*. In the ileostomy group three patients had intestinal obstruction, one of whom required operative treatment. One patient in the loop transverse colostomy group developed intestinal obstruction following closure of the stoma which resolved with conservative treatment.

Overall, six of 35 patients who had an ileostomy that was ultimately closed developed intestinal obstruction. Obstruction occurred in one of the 38 patients who had a loop transverse colostomy ($P = 0.01$).

Discussion

Total mesorectal excision with sphincter-preserving surgery has become the treatment of choice for cancers of the middle and lower third of the rectum^{7,8}. However, the anastomotic leakage rate has been shown to be particularly high following distal colorectal or coloanal anastomosis^{2,9,10}. A few studies have shown lower anastomotic leakage rates in patients in whom there is proximal faecal diversion^{3,11}.

The optimal mode of faecal diversion is debatable as it can be achieved by either a loop transverse colostomy or a loop ileostomy. Initially used for defunctioning the colon in patients with fulminant ulcerative colitis^{12,13}, loop ileos-

Table 3 Events after stoma closure

	Loop ileostomy (n = 35)	Loop transverse colostomy (n = 38)	P
Mean duration of operation (min)	61	51	0.008
Median time to first defaecation (days)	2	3	0.003
Median time to fluid diet (days)	2	2	0.49
Median time to solid diet (days)	3	3	0.69
Surgical complications			
Wound infection	1	2	
Enterocutaneous fistula	1	0	
Intestinal obstruction	3	1	
Total no. of patients	4*	3	0.70
Medical complications			
Pneumonia	0	1	0.49
Arrhythmia	0	1	
Median hospital stay (days)	5	6	0.64

*One patient had intestinal obstruction and wound infection

tomies have been used increasingly to provide proximal faecal diversion for distal colonic or rectal anastomoses¹⁴. Four randomized trials have compared loop colostomy and loop ileostomy^{15–18}. Three of these studies recommended loop ileostomy^{15,17,18} while one recommended loop transverse colostomy¹⁶. Three of the earlier studies included patients with various colorectal pathologies as well as anastomoses at different levels in the colon and rectum^{15–17}.

The recent study by Edwards *et al.*¹⁸, which is similar to the present study, included only patients who had total mesorectal excision for rectal cancer. They found more stoma-related complications following closure of a loop colostomy, although colostomy closure was technically easier. The most common complication was incisional hernia, which occurred during follow-up. In the present study, more emphasis was placed on early postoperative morbidity and stoma-related morbidity. Although loop ileostomies started to function earlier than loop transverse colostomies, this did not translate into earlier resumption of a solid diet or a shorter hospital stay. A higher incidence of postoperative ileus and intestinal obstruction was found in the ileostomy group after the initial operation. The results are similar to those of the randomized controlled trial by Gooszen *et al.*¹⁶, who reported more postoperative complications in patients with a loop ileostomy. The presence of a loop ileostomy in the infracolic compartment is more likely to create adhesion, twisting or herniation of the small bowel, leading to postoperative obstruction.

Stoma complications during follow-up were similar in the two study groups and were not serious compared with those reported in other studies¹⁶. The most common problems involved the peristomal skin and occurred at a similar rate in both groups. Prolapse of the stoma occurred

in three patients with a loop transverse colostomy. This incidence is similar to that reported by Edwards *et al.*¹⁸ and is much lower than the incidence reported by Gooszen and colleagues¹⁶. The fascial defect created for the colostomy was not large and was similar to that used for loop ileostomy. A flush colostomy was created without bringing the whole transverse colon out beyond skin level. This may account for the relatively low incidence of prolapse in the colostomy group.

The incidence of septic complications following closure of the stoma was similar in both groups. Intestinal obstruction occurred in three patients following closure of a loop ileostomy and resulted in one reoperation. This finding is similar to that in a previous review when loop ileostomy was the preferred defunctioning stoma¹⁹. Furthermore, the incidence of intestinal obstruction from the time of creation of the stoma to the postoperative period of closure was significantly higher in the ileostomy group.

Intestinal obstruction is a well recognized complication associated with ileostomy although its incidence following rectal cancer surgery is less well documented. Metcalf *et al.*²⁰ reported an incidence of intestinal obstruction of 6.4 and 14.8 per cent before and after closure of loop ileostomies respectively in patients with an ileoanal pouch anastomosis. The presence of a loop ileostomy may increase the chance of twisting the small bowel and the formation of adhesions adjacent to the stoma. Francois *et al.*²¹ reported that temporary ileostomy was responsible for two-thirds of the cases of postoperative obstruction in patients with restorative proctocolectomy.

Intestinal obstruction following loop ileostomy closure has also been well studied^{22–24}. Closure of a loop ileostomy is a more difficult operation than closure of a loop

colostomy¹⁸. In the present study, it took longer to close a loop ileostomy. Recent reports show that the method of closure has an important impact on subsequent intestinal obstruction^{22,25}. Hasegawa *et al.*²⁵ showed that stapled anastomosis during closure of an ileostomy was associated with a lower incidence of postoperative intestinal obstruction in a randomized controlled trial, while Phang *et al.*²² found that enterotomy suture was associated with the lowest incidence of postoperative intestinal obstruction. Further studies are required to confirm their findings.

In this randomized controlled trial, a higher incidence of postoperative ileus and intestinal obstruction was found in patients in whom a loop ileostomy was used for proximal faecal diversion. Loop ileostomy was found to be associated with a higher incidence of intestinal obstruction from the time of its creation to the postoperative period of closure. As other stoma-related complications were comparable in the two groups, a loop transverse colostomy appears to be the optimal form of faecal diversion for a distal rectal or anal anastomosis following total mesorectal excision.

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