Ostomy creation with fewer sutures using tissue adhesives (cyanoacrylates) in inflammatory bowel disease: a pilot study

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ABSTRACT

INTRODUCTION Fistula formation around the ostomy site is a stoma-related complication often requiring surgical intervention. This complication may be caused by sutures or may develop as a complication of inflammatory bowel disease. Before conducting a clinical trial, we set out to investigate the safety of ostomy creation with fewer sutures using tissue adhesives in this pilot study.

METHODS Patients with inflammatory bowel disease who required surgery with ostomy creation at the Hyogo College of Medicine between January 2014 and December 2015 were enrolled. Safety was assessed by evaluating the incidence of stoma-related complications. Ostomy was restricted to loop ileostomy and was created with two sutures and tissue adhesives.

RESULTS A total of 14 patients were enrolled. Mean body mass index was 18.9 ± 2.0 kg/m². There were no cases of ostomy retraction and no severe adverse events were observed.

CONCLUSIONS This pilot study demonstrates that ostomy creation using tissue adhesives is safe. Although retraction and adverse events were not observed, even in patients with inflammatory bowel disease who generally exhibit delayed wound healing, the body mass index was extremely low in this series. This study does not strongly recommend ostomy creation with tissue adhesives; further studies are needed to clarify the efficacy and safety of the procedure.

KEYWORDS

Inflammatory bowel disease – Ostomy – Tissue adhesives

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Introduction

Following ostomy creation for inflammatory bowel disease (IBD), reoperation due to long-term recurrence at the ostomy site is a relatively common complication. Complications around the ostomy site that typically require surgical treatment, despite conservative therapies, include stricture or fistula/abscess. Ostomy creation can itself cause short-term postoperative complications such as growth restriction, necrosis, outlet obstruction, prolapse or fistula/abscess.¹ The relationship between these early surgical complications and the recurrence of IBD remained unclear and several complications can develop simultaneously.

Early complications include subcutaneous fistula, mucocutaneous dehiscence or granulation, often developing as operative complications from the stitches around the ostomy site. Of these, subcutaneous fistulas often require surgical intervention, including recreation of the ostomy. We hypothesised that the use of tissue adhesives during ostomy creation would be safer and more effective than traditional stitches. We also predicted that ostomy creation using fewer stitches would prevent the development of

subcutaneous fistulas. In this pilot study, safety was set as the primary endpoint and the secondary endpoint was the prevention of ostomy-related complications.

Material and methods

Patients

The study took place between January 2014 and December 2015; 14 patients with IBD with a loop ileostomy were included. Based on the recommendations of our institutional review board, as an initial pilot study we created an ostomy using a rod and routinely inserted two stitches between the ostomy and subcutaneous tissue to prevent ostomy retraction soon after surgery. Only patients with a body mass index (BMI) less than 28 kg/m² were enrolled to decrease the risk of additional obesity-related complications. There were no restrictions on the number and doses of immunosuppressive therapies prior to surgery.

Exclusion criteria

Only patients who provided informed consent were included. Patients with a higher BMI (≥ 28 kg/m²) were

excluded, as were patients with end-ileostomy, end-colostomy or loop-colostomy. Patients with pan-peritonitis due to perforation, fulminant disease or toxic megacolon were also excluded, as this trial was designed as pilot study for evaluating treatment safety.

Ethical considerations

All study protocols were approved by the institutional review board of the Hyogo College of Medicine (no. 1574). Informed consent and approval for the use of patient data were obtained before surgery. The study protocols were registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR 000012334).

Surgical procedure for ostomy creation

Ostomy was performed using the method shown in Figures 1 and 2. First, an ostomy tunnel was created. A circular incision was made at the selected ostomy site using a scalpel. The subcutaneous tissue was bluntly separated above the anterior rectus fascia. The fascia was vertically incised to the width of two fingers and the rectus muscle was split bluntly. The posterior fascia was also incised in a similar manner. Second, the loop of the ileum was pulled out through the ostomy tunnel without fixed stitches to the fascia. For ostomy creation using tissue adhesives, according to suggestions from the review board for the safety in this initial pilot study, a total of two mucoserosal subcutaneous eversion sutures were placed (one each on the proximal and distal sides; Figure 2). These buried, non-removable subcutaneous sutures were placed using braided polyglactin 4-0

Figure 1 Schematic of the intestinal serosa-mucosubcutaneous buried suture used to maintain the height of the ostomy. To maintain the height of the ostomy on both the oral and anal side, eversion sutures were attached to the serosa during mucosubcutaneous suturing.

Figure 2 Ostomy creation using tissue adhesives. A total of 2 mucosubcutaneous sutures were placed (one each on the proximal and distal sides) with using an ostomy rod. Cyanoacrylate tissue adhesives were then placed circumferentially.

absorbable suture (4-0 Vicryl®, Ethicon) attached to an atraumatic needle. To maintain the height of the ostomy, stitches were sutured to the serosa during the placement of the muco-subcutaneous sutures (Fig 1). An ostomy rod was routinely attached for five days post-surgery (Fig 2). Cyanoacrylate tissue adhesives (Dermabond®, Ethicon) were then placed and secured circumferentially. All surgical procedures were performed by a certified surgeon.

Definition of complications

Ostomy retraction was defined as a decrease in the height of the ostomy to a level below or equal to the level of the skin or a reduction in over half of the initial height immediately after ostomy creation. Incidence of mucocutaneous dehiscence, granulation or peristomal dermatitis due to adhesives was defined as requiring any treatment based on grade 3 of the Common Terminology Criteria for Adverse Events of the National Cancer Institute.² Complications above grade 2, including symptoms and indicated interventions, were defined as ostomy complications. Complications that required no treatment or change in ostomy care were not included. A wound ostomy care nurse was responsible for assigning the grade level of the complication.

Assessment of safety and efficacy

The primary end point was safety, which was defined as the absence of ostomy retraction based on comparisons between ostomy height immediately after creation and 30 days after surgery. The secondary end point was the incidence of ostomy-related complications, including mucocutaneous dehiscence, granulation and peristomal dermatitis, as evaluated 30 days after surgery during both hospitalisation and ostomy care at outpatient clinics.

Statistical analysis

Categorical variables were compared using chi-square or Fisher’s exact test. Continuous variables were reported as the means and standard deviations and were compared using paired t-tests. The level of statistical significance was set at $P < 0.05$. SPSS version 15.0 was used to perform all analyses.

Results

Patients

A total of 14 patients (5 men and 9 women) with IBD, including 4 patients with Crohn’s disease and 10 with ulcerative colitis were eligible for this study. At surgery, mean age was 38.3 ± 13.8 years (range 18–65 years) and mean BMI was 18.9 ± 2 (range 15.2–23.5 kg/m²). Preoperative tests and interventions are shown in Table 1.

Loop ileostomy was performed as the diversion in all patients. In patients with ulcerative colitis, the ostomy was created during total proctocolectomy with ileal pouch anal anastomosis. In patients with Crohn’s disease, the diverting ostomy was created during ileocolo or ileorectal anastomosis.

Safety

Stoma-related complications included five cases of dermatitis (35.7%). There were no cases of stoma retraction. A comparison of the ostomy height just after ostomy creation and 30 days after surgery is shown in Figure 3. Although the height decreased from 3.2 cm to 2.1 cm in one patient, on average there were no significant differences in ostomy height during the 30-day postoperative period. Two patients (14.3%) developed mucocutaneous dehiscence that required additional wound care. There were no cases of serious dermatitis resulting from the use of tissue adhesives.

Efficacy

Neither granulation nor fistula formation were observed during the study period (Table 2).

Discussion

Although the relationship between the recurrence of IBD and ostomy-related complications is not clear, Carlstedt *et al.*⁵ previously reported that the crude rate of repeat ileostomy was 34% and was significantly higher in patients with Crohn’s disease compared with patients with ulcerative colitis. The cumulative rate of surgical revision after 8 years was 75% in patients with Crohn’s disease and 44% in those with ulcerative colitis. Mucocutaneous fistulas after ostomy creation are often found following surgery for IBD. The development of fistulas soon after surgery is thought to arise as a complication of the surgical technique, specifically the deep insertion of stitches. However, although the correlation has yet to be clarified, early complications may not be exclusively linked to surgical technique, as sutures at the ostomy site have been suggested as a risk for recurrence at the ostomy site in IBD due to foreign body reactions. Therefore,

Table 1 Preoperative treatments and tests for 14 patients.

Preoperative interventions	Results ^a
<i>Treatments:</i>	
Prednisolone	8 (57.1%)
Total dose (mg)	6978.6 ± 14040.8 (range 0–54,000)
Preoperative dose (mg/kg)	0.186 ± 0.188 (range 0–0.6)
Immunosuppressant (n)	9 (64.3%)
Biologicals (n)	10 (71.4%)
Total parenteral nutrition (n)	9 (64.3%)
<i>Blood tests:</i>	
Albumin level (g/dl)	3.2 ± 0.7 (range 2.3–4.5)
Haemoglobin level (g/dl)	10.9 ± 1.4 (range 8.7–13.2)

^a Continuous variables are indicated as mean ± standard deviation.

Figure 3 Changes in ostomy height within the 30-day post-surgery period. The median height was 2.4 ± 0.4 cm following the surgery and 2.3 ± 0.3 cm 30 days after surgery. There was no significant difference ($P = 0.38$).

before evaluating the link between IBD recurrence at the ostomy site or early postoperative development of mucocutaneous fistulas and stitches around the ostomy site, we first set out to achieve safe ostomy creation using tissue adhesives and less suturing.

Only one prior study has evaluated the safety of tissue adhesives in intestinal anastomoses in humans. Wang *et al.*⁴ evaluated the efficacy of tissue adhesives in patients with intra-abdominal sepsis who underwent primary

anastomosis and fibrin glue sealing. The authors concluded that sealing with adhesives protected the primary site of anastomosis in these patients, thus avoiding the need for stoma construction. However, the adhesives were only used to supplement the primary sutures. An additional seven studies have been performed using animal models.^{5–11} To our knowledge, no studies have evaluated ostomy creation using tissue adhesives. The present study thus features several IRB-mandated restrictions to ensure patient safety during ostomy creation, including using two sutures and an ostomy rod before tissue adhesives could be used alone.

In our previous cohort of patients with ulcerative colitis, the incidences of mucocutaneous fistula, wound dehiscence and granulation around the ostomy site were 11/378 (2.9%), 139/378 (36.8%) and 50/378 (13.2%), respectively, after restorative proctocolectomy with diverting loop ileostomy.¹² Compared with the results of this retrospective cohort study, in the present series we observed extremely low incidences of mucocutaneous fistula (0/14; 0%), wound dehiscence (2/14; 14.3%) and granulation (0/14; 0%) around the ostomy site.

Although the incidence of fistula is considered to be higher in IBD than in other diseases, we found no fistulas in this study, nor was there evidence of ostomy retraction. Despite the low incidence of complications, one concerning adverse effect reported by both the patients and the wound ostomy care nurse was the presence of 'sticky stools' that were difficult to remove from the tissue adhesives. Thus, the reduction in ostomy-related complications must be balanced with patient satisfaction and the potential impact of problems associated with ostomy wound care on quality of life should be further studied.

The limitations of this study include the small sample size, the fact that the tissue adhesives were not evaluated in the complete absence of sutures and the restriction of the study to patients with a low BMI. BMI is higher in patients with cancer than in those with IBD. Nevertheless, ostomy creation using tissue adhesives was safe, even in patients with IBD with poor nutritional status and corticosteroid administration, which induce delayed wound healing. At the very least, ostomy creation using tissue adhesives did not increase ostomy retraction in patients with IBD. Future prospective and randomised studies are planned to fully clarify

the safety profile, efficacy and any other advantages or disadvantages of using tissue adhesives, including cost and cosmetic considerations. The relationship between IBD recurrence and the use of traditional sutures in ostomy creation should be further evaluated and should include input from both patients and wound ostomy care nurses.

Conclusion

This pilot study suggests that ostomy creation with tissue adhesives is safe. However, both safety and efficacy should be assessed for several intestinal diseases using larger prospective studies.

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