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ORIGINAL SCIENTIFIC REPORT

Is An Ostomy Rod Useful for Bridging the Retraction During the Creation of a Loop Ileostomy? A Randomized Control Trial

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Abstract

Background A loop ileostomy is generally created during restorative proctocolectomy (RPC) for treating ulcerative colitis (UC), and an ostomy rod is often used to prevent stoma retraction. However, its usefulness or harmfulness has not been proven. We performed a prospective randomized control study to investigate the non-inferiority of ostomy creation without a rod to prevent stoma retraction.

Methods Patients with UC who underwent RPC were enrolled and randomly divided into groups either with or without ostomy rod use. Incidences of stoma retraction and dermatitis were compared.

Results Of the 320 patients in the study groups, 308 qualified for the intention-to-treat (ITT) analysis, and 257 were included in the per-protocol (PP) analysis. Ostomy retraction was recognized in 6 patients, 3 with a rod and 3 without. The difference with rod use (95% confidence interval) was 0.1 (−2.9 to 3.1)% in the PP analysis and 0.0 (−2.2 to 2.2)% in the ITT analysis. There were no significant differences in stoma retraction regardless of whether an ostomy rod was used in either analysis. Dermatitis was more common in patients with rod use (84/154) than in those without (40/154) ($p < 0.01$).

Conclusions Although median body mass indices were extremely low (20 kg/m^2), an ostomy rod is not routinely needed as it may increase the risk of dermatitis. However, results in obese patients may differ from those shown here, which should be clarified via further studies.

Introduction

A loop ileostomy is generally created during elective surgery for low rectal cancer, restorative proctocolectomy for ulcerative colitis (UC) or familial adenomatous polyposis. In emergent surgery, it may be created in treating penetrating diseases with pan-peritonitis, including anastomotic dehiscence to divert the diseased intestine at the anal side. A diverting loop ileostomy decreases the rate of re-operation due to septic complications associated with anastomotic dehiscence [1]. However, there are significant complications associated with the creation of an ostomy, including necrosis, prolapse, retraction, peri-stomal hernia, fistula, dermatitis, ulceration and outlet obstruction [2]. At many institutions, an ostomy rod is traditionally placed to prevent stoma retraction. However, the efficacy of this for preventing retraction has not been clearly demonstrated in a prospective analysis with a large number of patients. Moreover, ostomy rods are known to be associated with the development of pressure ulcers and dermatitis caused by the hanging rod [3–5]. According to our observations, stoma retractions may occur 1 month or more after surgery due to body weight gain but are not likely to occur in the early post-operative days.

The study protocols have been registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR 00006658).

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However, poor wound healing may be expected in surgeries for UC as a result of malnutrition, anaemia, or corticosteroid use. In fact, the incidence of wound dehiscence has been shown to be more frequent in surgeries for UC than in surgeries for colorectal cancer [6]. In UC surgeries, restorative proctocolectomy has been the standard procedure [7]. Although a single-stage procedure without diversion can be performed, the majority of patients with UC still undergo a two-stage procedure with faecal diversion [8].

We investigated the incidence of stoma retraction in relation to ostomy rod use in UC surgery to clarifying the necessity of an ostomy rod in creating a loop ileostomy. The primary objective of this study was to determine whether ostomy rod use was useful in preventing stoma retraction when applied to diverting loop ileostomies in treating UC. The secondary objective was to clarify the incidence of dermatitis due to ostomy rod use as an adverse event.

Patients and methods

Patients

We carried out a prospective, randomized study between July 2011 and March 2016 at the Hyogo College of Medicine. Patients with UC who were 18 years of age or older and were scheduled to undergo elective or urgent 2-stage procedures were randomly divided into two groups, UC surgery performed either with or without the use of an ostomy rod, and were considered eligible for inclusion in the study. Enrolment was performed after consent had been obtained on the day of admission. Randomization via concealed group allocation was performed using opaque envelopes opened at the operating room by a certified surgical nurse. However, because surgeons were able to distinction between patients with or without an ostomy rod during and after the surgery, we could not describe this study as blinded. Demographic data for the patients and information on possible complicating factors, including age, sex, body mass index (BMI), disease duration and severity, active smoking, pre-operative treatment, serum albumin level before surgery, blood sugar level after surgery, intra-operative blood loss, duration of surgery and post-operative complications (e.g., incisional surgical site infection (SSI) and ostomy complications), were also collected.

At our institution, disease activity in patients with UC is assessed primarily based on clinical features using the criteria of Truelove and Witts [9].

The criteria for diagnosing SSI were an infection occurring within 30 days post-operatively and at least one of following: (1) purulent discharge from the incision or from a drain placed through a puncture made into the organ/space; (2) the identification of pathogenic organisms isolated from cultures of fluid or tissue from the incision or organ/space; (3) an open wound with signs and symptoms of infection; or (4) an abscess or other evidence of infection found on examination of the incisional wound [10].

For pre-operative treatment of UC, the administration of biologics was considered as any infusion in the 12-week prior to surgery, and any administration of corticosteroids or immunosuppressants within 1 week prior to surgery were considered regardless of the dosage. Total prednisolone (PSL) doses were calculated based on previously administered steroid doses that were converted into PSL-equivalents received since the initial diagnosis.

The median values of continuous data were set as cut-off values when the analyses of risk factors for stoma retraction and dermatitis were performed. The median BMI value was extremely low in this series (19.7 kg/m^2). Accordingly, the cut-off value for BMI was set higher (25 kg/m^2) for the analyses.

Exclusion criteria

Patients who needed emergent surgery due to a fulminant disease were not included in this series because they were not suitable for pouch surgery as an initial surgery. For both analyses, those undergoing an end-ileostomy were not included. Exclusion criteria for the per-protocol (PP) analysis were the occurrence of any of the following: death, re-operation, early ostomy closure due to bowel obstruction at the ostomy site, separated double-barrel ileostomy or complicated para-stomal pyoderma gangrenosum (PPG) [11]. These patients were included and analysed in the intention-to-treat (ITT) analysis. Patients were evaluated according to both the ITT and PP analyses. Patients undergoing re-operation, including recreation of the ostomy at the same site or its relocation due to any surgical indications, were excluded from the PP analysis but were eligible for the ITT analysis. Patients whose ostomy rod was removed naturally or due to skin ulcerations within 7 days after surgery were eligible for the ITT analysis as part of the group with ostomy rod use.

Surgical techniques

The standard procedure for treating UC is a total proctocolectomy, ileal J-pouch anal anastomosis and diverting loop ileostomy. A diverting loop ileostomy was constructed after anastomosis, and 50–70 cm of the ileum at the oral ileal loop distant from the ileal pouch was delivered through a circular incision on the right lower abdominal wall without mesenteric torsion. A loop ileostomy was created as depicted in Fig. 1. In patients in whom

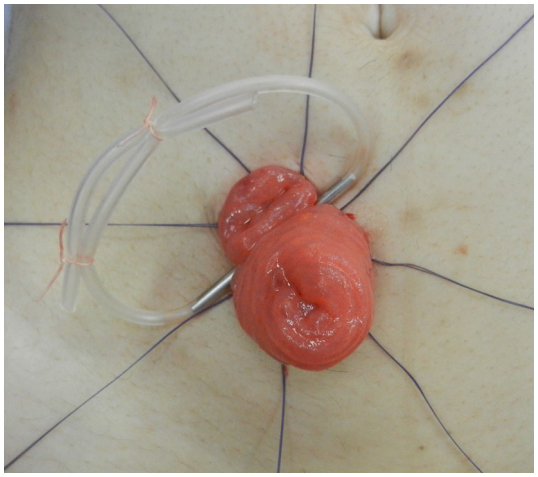

Fig. 1 Creation of the loop ileostomy with an ostomy rod. A 6-cm K-wire, which was placed inside an 8 Fr Nelaton's catheter tube, was inserted into the mesentery as an ostomy rod. The ileostomy was primarily opened and fixed to the subcutaneous layers with a total of eight eversion sutures

an ostomy rod was used, we placed a 6-cm K-wire placed inside an 8 Fr Nelaton's catheter tube closed with a stitch to create a ring, and no stitch was used to fix it to the skin. In all patients, regardless of ostomy rod use, the ileostomy was primarily opened and fixed to the subcutaneous layer with absorbable 4-0 sutures. Eversion to raise the lip height of the stoma by approximately 2 cm after suturing was performed to fix the ileostomy in place. In the loop ileostomy, 3 and 5 sutures were placed circumferentially on the anal and oral sides, respectively. No stitches were used to fix the ileostomy to the muscle, fascia, or peritoneum of the abdominal wall. The ostomy rod was removed 7–8 days after the surgery while performing ostomy care.

A diverting loop ileostomy is generally closed approximately 90 days after the initial surgery as part of standard institutional protocol following the certified healing of the anastomotic site. However, patients suffering from bowel obstruction at the ostomy site as a result of outlet obstruction often required surgery for an early ostomy closure.

Criteria for endpoints

We set two endpoints for this study. Data on the prevalence of ostomy retraction as the primary objective measure of the efficacy of the procedure were collected. The retractions were distinct with regard to the timing of its onset. Early retraction was defined as occurring within 30 days after surgery. Late retraction was defined as occurring beyond 30 days after surgery. Both types of retraction were defined as any stoma that was less than 5 mm above the skin surface.

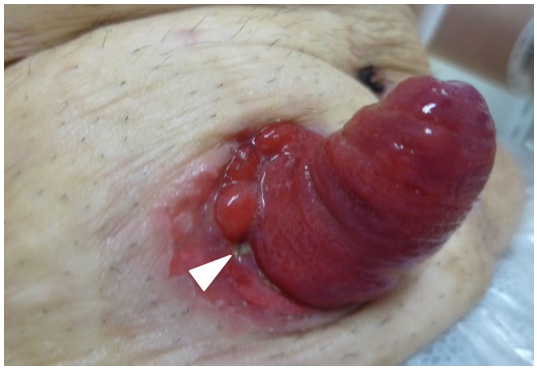

Fig. 2 Findings of dermatitis and ulceration soon after the removal of the ostomy rod. *Arrows* indicate pressure ulcers due to the ostomy rod

Data on the prevalence of dermatitis associated with ostomy rod use were collected as secondary endpoints. Dermatitis associated with ostomy rod use, defined as pressure ulcers or erosions extending to the dermal layer of the skin and mesentery close to the rod, was detected by a registered ostomy wound care nurse and a dermatologist during the insertion of rod (Fig. 2). They also diagnosed PPG at the ostomy site within 30 days after surgery.

Ethical considerations

All study protocols were approved by the institutional review board of Hyogo College of Medicine (No. 1574). Informed consent and approval for the use of patient data were obtained prior to surgery. The study protocols are registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR 00006658).

Statistical analysis

Prior to beginning this study, a sample size calculation was performed. In 2010, stoma retractions, including late- and early-onset retractions, occurred in 3/82 (3.7%) cases without the use of an ostomy rod. We hypothesized that ostomy rod use would not be useful for the prevention of ostomy retraction, and the treatment arm of the study was declared as a non-inferior test. To show that a 3% prevalence of retraction without ostomy rod use is not less than the prevalence with ostomy rod use based on a clinically meaningful difference of less than 10%, a sample size of 144 subjects was needed, with an alpha of 0.05 and a power of 80%. To allow for identifying these results, taking into account patient exclusion, a total sample size of 160 patients in each arm was chosen.

Continuous data are presented as medians and the range unless otherwise indicated. Comparative analyses of continuous variables were performed using Student's *t*-tests if

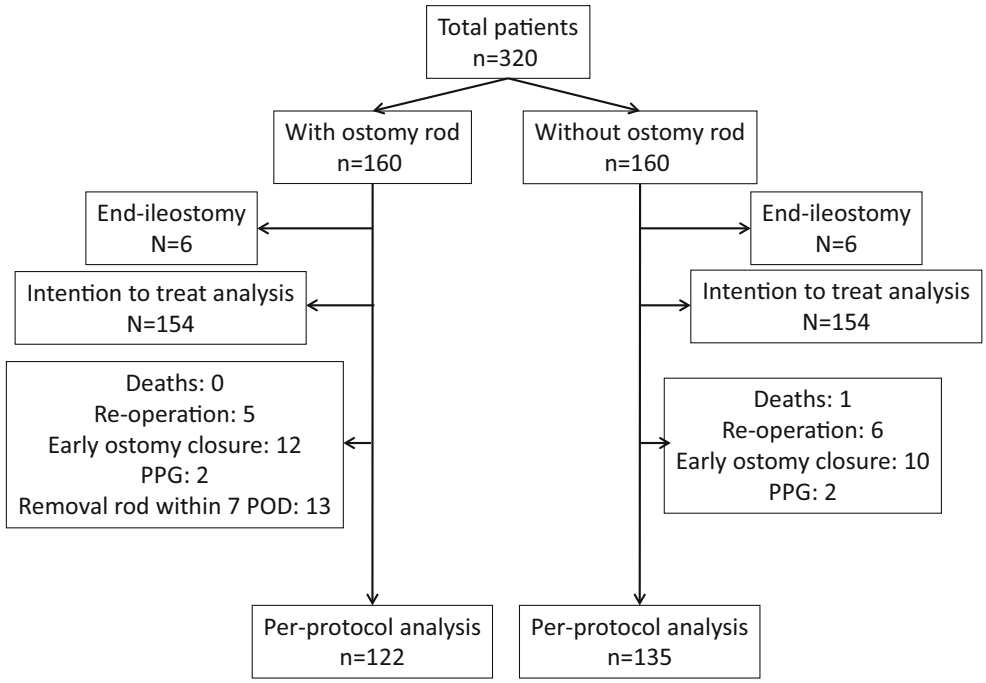

Fig. 3 Enrolment flow chart of the patient selection process. Patients were excluded from the per-protocol analysis for meeting more than one exclusion criterion but were still included in the intention-to-treat analysis. *PPG* para-stomal pyoderma gangrenosum, *POD* post-operative day

the variables were normally distributed; otherwise, the Mann–Whitney *U* test was employed. Categorical variables were compared using a Chi-square test or Fisher's exact test when necessary.

The median values of continuous data were set as cut-off values. Univariate analyses of the categorical data and each individual risk factor for both retraction and dermatitis were also conducted. All variables with p values less than 0.2 were subsequently entered into a stepwise logistic regression model. The level of significance was set at $p < 0.05$. SPSS version 15.0 (SPSS Inc., Tokyo, Japan) was used to perform all analyses.

Results

Of the 320 patients who were randomly assigned to the study groups, 308 qualified for the ITT analysis, and 257 were included in the PP analysis (Fig. 3). PPG developed in a total of 4 patients.

The demographic and peri-operative characteristics of patients were generally similar between the two groups (Table 1).

The occurrences of post-operative complications, including endpoints, are indicated in Table 2. Ostomy retraction was recognized in a total of 6 patients, including 2 early retractions and 4 late retractions. Their BMI values ranged from 16.9 to 21.8 kg/m^2. However, no patients had an ostomy retraction below skin level. Moreover, retraction onset was between 20 and 57 days after the operation, with onset occurring on days 20, 24, 32, 35, 54 and 57. No patients required additional intervention for ostomy retraction. There were no significant differences in either of the analyses regardless of whether an ostomy rod was used. The difference (95% CI) in the incidence of stoma retraction between the two groups was 0.1% (−2.9 to 3.1%) in the PP analysis and 0.0% (−2.2 to 2.2%) in the ITT analysis. Because the lower limit of the two-sided 95% CI was above −10%, outcomes in terms of the incidence of stoma retraction in patients without rod use were considered to be non-inferior to that in patients with rod use.

The incidence of incisional SSI was 36/308 (11.7%), and there was no significant difference in relation to the use of an ostomy rod.

Dermatitis around the ostomy site was found in 124/308 (40.3%) of the patients, and its occurrence was significant higher in both analyses for patients in whom an ostomy rod was used.

The results of a risk factor analysis for stoma retraction are shown in Table 3. No significant variables were identified in the univariate analysis, and the results showed that all factors had p values greater than 0.2.

The results of an analysis of risk factors for dermatitis are shown in Table 4. A multivariate analysis identified significant risk factors for dermatitis, including age at surgery >42 years old (odds ratio: OR 1.81, $p = 0.03$),

Table 1 Patient's characteristics

	Patients in per-protocol analysis			Patients in intention-to-treat analysis		
	With ostomy rod $N = 122$	Without ostomy rod $N = 135$	p value	With ostomy rod $N = 154$	Without ostomy rod $N = 154$	p value
Age at surgery (years)	43.1 ± 14.3	41.1 ± 14.2	*0.28*	42.9 ± 15.2	41.9 ± 15.0	*0.54*
Gender (male/female)	72/50	93/42	*0.10*	91/63	106/48	*0.08*
BMI (kg/m^2)	19.7 ± 2.6	19.8 ± 3.2	*0.78*	19.5 ± 2.6	19.8 ± 3.1	*0.40*
Duration from onset of UC (months)	103.4 ± 99.7	111.3 ± 104.8	*0.54*	102.7 ± 99.2	110.5 ± 104.6	*0.50*
Surgical indication of cancer/ dysplasia	24 (19.7)	32 (23.7)	*0.43*	28 (18.2)	33 (21.4)	*0.47*
Disease activity						
Mild/moderate/severe/fulminant	26/61/35/0	20/72/43/0	*0.39*	29/81/44/0	22/86/46/0	*0.85*
Active smoker	3 (2.5)	3 (2.2)	*0.77*	3 (1.9)	3 (1.9)	*1.00*
Pre-operative serum albumin level (g/dL)	3.2 ± 0.8	3.3 ± 0.89	*0.49*	3.2 ± 0.8	3.3 ± 0.8	*0.29*
Pre-operative treatment						
Pre-operative PSL dose (mg/ kg/day)	0.35 ± 0.43	0.33 ± 0.42	*0.81*	230.3 ± 393.7	196.4 ± 233.0	*0.36*
Total given PSL dose (mg/kg)	246.4 ± 435.4	191.6 ± 227.7	*0.20*	0.34 ± 0.42	0.32 ± 0.42	*0.88*
Corticosteroid administration	75 (61.5)	83 (61.5)	*0.99*	99 (64.3)	97 (63.0)	*0.81*
Immunomodulator administration	70 (57.4)	75 (55.6)	*0.77*	91 (59.1)	84 (54.5)	*0.42*
Biologics administration	38 (31.1)	50 (37.0)	*0.32*	52 (33.8)	55 (35.7)	*0.72*
Urgent surgery	39 (32.0)	36 (26.7)	*0.35*	44 (28.6)	40 (26.0)	*0.61*
Duration of surgery (min)	230.5 ± 45.0	227.1 ± 43.0	*0.54*	227.2 ± 43.0	224.0 ± 43.9	*0.54*
Blood loss (mL)	283.9 ± 193.7	275.8 ± 216.8	*0.76*	275.2 ± 193.9	266.6 ± 213.6	*0.72*
Peri-operative transfusion	24 (19.7)	20 (14.8)	*0.30*	29 (18.8)	23 (14.9)	*0.36*
Post-operative blood sugar level (mg/dL)	141.9 ± 40.8	140.5 ± 44.7	*0.79*	140.3 ± 41.0	140.5 ± 45.0	*0.74*

Data are numbers with percentages in parentheses unless otherwise indicated. Continuous variables are indicated as mean ± SD

BMI body mass index, *UC* ulcerative colitis, *PSL* prednisolone

PSL administration (OR 1.77, $p = 0.04$) and ostomy rod use (OR 3.42, $p < 0.01$).

Discussion

Stoma retraction is thought to be caused by excessive bowel tension during the process of pulling the bowel beyond the abdominal wall. Previous studies have demonstrated that stoma retraction occur in 3 to 17% of ileostomies [12–15]. The main cause of stoma retraction is generally thought to be related to the effects of obesity. A previous small randomized control trial showed no advantage of ostomy rod use. Therefore, the routine use of ostomy rods was not recommended because it could make the care of the patient's ostomy more difficult, thereby increasing the risk of faecal soiling, leading to skin complications [16]. Similar to previous findings, dermatitis around the ostomy site was significantly increased in the patients with an ostomy rod in this series. In addition, ostomy rod use showed the highest OR for dermatitis in this analysis, higher than that of PSL use and increasing age.

Although stoma retraction has been suggested to be associated with obesity, steroid use, malnutrition and smoking [17–19], in regard to complicated dermatitis, ostomy rod use was not thought to be beneficial. However, ostomy rods are still often used in obese patients to prevent stoma retraction, even though their efficacy in preventing retraction has not been sufficiently demonstrated in these patients. Previous series have suggested that stoma retraction may be associated with a higher BMI [16, 18, 19]. However, BMI on its own has not been proven in any series to be a major factor in stoma retraction. In a recent report on emergent surgery and ileostomy from India, stoma retraction occurred in patients with a higher BMI, although the BMI of the patients was limited to values below 24.9 kg/m^2 [20]. In the present series, median

Table 2 Post-operative complications

	Patients in per-protocol analysis				Patients in intention-to-treat analysis			
	With ostomy rod $N = 122$	Without ostomy rod $N = 135$	Difference (95% CI)	p value	With ostomy rod $N = 154$	Without ostomy rod $N = 154$	Difference (95% CI)	p value
Stoma retraction	2 (1.6)	2 (1.5)	0.1 (−2.9 to 3.1)%	*0.92*	3 (1.9)	3 (1.9)	0.0 (−2.2 to 2.2)%	*1.00*
Peri-stoma dermatitis	66 (54.1)	38 (28.1)		*<0.01*	84 (54.5)	40 (26.0)		*<0.01*
Incisional SSI	14 (11.5)	15 (11.1)		*0.97*	17 (11.0)	19 (12.3)		*0.72*

Data are numbers with percentages in parentheses unless otherwise indicated

SSI surgical site infection, *CI* confidence interval

Table 3 Univariate analysis for risk factors associated with stoma retraction

Variables	OR (95% CI)	p value
Pre-operative variables		
Gender male	Not estimable	*1.00*
Age at surgery > 42 years	3.27 (0.34–31.9)	*0.31*
Duration from onset of UC (months)	0.21 (0.02–2.09)	*1.00*
Surgical indication = cancer/dysplasia	0.83 (0.09–8.17)	*0.88*
Disease activity = severe	Not estimable	*1.00*
BMI > 25 kg/m^2	1.24 (0.17–8.93)	*0.83*
Serum Alb level < 3.2 g/dL	1.20 (0.17–8.65)	*0.86*
Active smoking	Not estimable	*1.00*
Pre-operative treatments		
Total given PSL > 200 mg/kg	2.13 (0.22–20.75)	*0.52*
Pre-operative PSL > 0.33 mg/kg	1.66 (0.17–16.16)	*0.66*
PSL administration	1.64 (0.23–11.80)	*0.63*
IM administration	1.30 (0.18–9.38)	*0.80*
Biologics administration	Not estimable	*1.00*
Peri-operative variables		
Duration of surgery > 230 min	Not estimable	*1.00*
Intra-operative blood loss > 275 mL	0.59 (0.08–4.27)	*0.60*
Transfusion	0.20 (0.03–1.40)	*0.11*
Ostomy rod use	0.90 (0.13–6.51)	*0.92*
Post-operative BS level > 200 mg/dL	0.79 (0.11–5.73)	*0.82*
Urgent surgery	Not estimable	*1.00*
Incisional SSI	Not estimable	*1.00*

OR odds ratio, *CI* confidence interval, *UC* ulcerative colitis, *BMI* body mass index, *Alb* albumin, *PSL* prednisolone, *IM* immunosuppressant, *BS* blood sugar, *SSI* surgical site infection

BMI was also extremely low. Similar to previous reports, we cannot conclude that ostomy rods are not needed in all patients, including obese patients. However, in our study on UC, the safety of creating an ostomy without a rod was demonstrated in a series of patients with poor wound healing.

Although ostomy rods may have some advantages in obese patients, potential adverse events should be mentioned. The ostomy rod resulted in ulcerations not only on the skin around ostomy but also in the mesentery, as shown in Fig. 4. Ostomy rods may be harmful for obese patients but possibly not in relation to the prevention of retraction.

The limitations of this study are indicated below. First, as discussed above, the BMI values were extremely low in this series. Second, a relative small series at a single institution was analysed. Third, the incidence of stoma retraction was low in this series. Therefore, a multivariate analysis could be not performed on the occurrence of stoma retraction.

Table 4 Univariate and mutivarinate analyses for risk factors associated with peri-stoma dermatitis

Variables	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Pre-operative variables				
Gender male	0.96 (0.57–1.61)	*0.88*		
Age at surgery > 42 years	1.54 (0.93–2.54)	*0.09*	1.81 (1.05–3.11)	*0.03*
Duration from onset of UC > 104 (months)	0.91 (0.54–1.51)	*0.71*		
Surgical indication = cancer/dysplasia	1.24 (0.68–2.25)	*0.49*		
Disease activity = severe	1.33 (0.77–2.28)	*0.30*		
BMI > 25 kg/m^2	1.57 (0.47–5.25)	*0.46*		
Active smoking	0.73 (0.07–8.14)	*0.79*		
Serum Alb level < 3.2 g/dL	0.97 (0.59–1.60)	*0.91*		
Pre-operative treatments				
Total given PSL > 200 mg/kg	0.87 (0.52–1.45)	*0.59*		
Pre-operative PSL > 0.33 mg/kg	0.87 (0.52–1.47)	*0.60*		
PSL administration	1.68 (1.01–2.81)	*0.047*	1.77 (1.02–3.05)	*0.04*
IM administration	1.01 (0.61–1.66)	*0.98*		
Biologics administration	0.73 (0.45–1.18)	*0.21*		
Peri-operative variables				
Duration of surgery > 230 min	1.10 (0.66–1.83)	*0.72*		
Intra-operative blood loss > 275 mL	1.00 (0.60–1.67)	*1.00*		
Transfusion	1.96 (0.96–4.03)	*0.07*	2.50 (0.75–4.12)	*0.09*
Ostomy rod use	3.06 (1.82–5.14)	*<0.01*	3.42 (1.99–5.87)	*<0.01*
Post-operative BS level > 200 mg/dL	0.66 (0.28–1.58)	*0.35*		
Urgent surgery	1.14 (0.66–1.96)	*0.63*		
Incisional SSI	1.66 (0.77–3.61)	*0.20*	1.76 (0.75–4.12)	*0.19*

OR odds ratio, *CI* confidence interval, *UC* ulcerative colitis, *BMI* body mass index, *Alb* albumin, *PSL* prednisolone, *IM* immunosuppressant, *BS* blood sugar, *SSI* surgical site infection

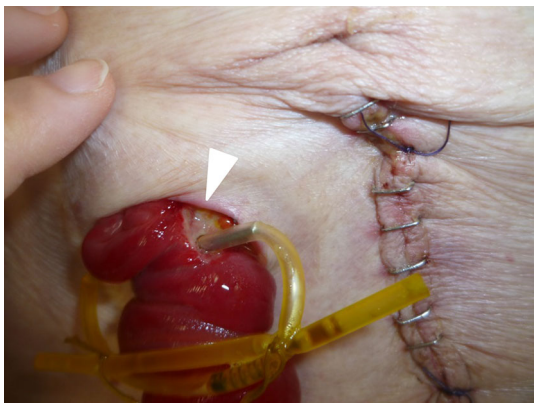

Fig. 4 Findings of ulceration in the mesentery caused by an ostomy rod. Ulceration development associated with a hanging ostomy rod

In conclusion, an ostomy rod does not need to be routinely used in loop ileostomies. It was found to be unnecessary for the prevention of ostomy retraction, even in UC patients whose wound healing may be poor due to malnutrition, steroid use, or the presence of immunosuppressive conditions, and its use may increase the risk of dermatitis. However, these results cannot be extrapolated to obese patients, and this should be clarified via further study.

Compliance with ethical standards

Conflict of interest Authors have nothing to disclose.

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