


# Penetrating Disease, Narcotic Use, and Loop Ostomy Are Associated with Ostomy and IBD-related Complications After Ostomy Surgery in Crohn's Disease Patients

Ayal Hirsch<sup>1</sup>  · Andres J. Yarur<sup>1</sup> · Hou Dezheng<sup>2</sup> · Dylan Rodriguez<sup>1</sup> · Noa Krugliak Cleveland<sup>3</sup> · Tauseef Ali<sup>4</sup> · Roger D. Hurst<sup>5</sup> · Konstantin Umanskiy<sup>5</sup> · Neil Hyman<sup>5</sup> · Janice Colwell<sup>5</sup> · David T. Rubin<sup>1</sup>

Received: 6 May 2015 / Accepted: 30 July 2015 / Published online: 12 August 2015  
© 2015 The Society for Surgery of the Alimentary Tract

## Abstract

**Background** For medically refractory or obstructive Crohn's disease (CD), ostomy surgery remains an important therapeutic option. Outcomes and complications of this approach have not been well described in the era of biological therapies. Our study aims to characterize CD patients undergoing ostomy creation and assess outcome predictors.

**Methods** We performed a retrospective chart review of CD patients who underwent ostomy creation in our center from 2011 to 2014. Data collected include patient demographics, detailed disease- and surgery-related variables, and clinical outcomes after 26 weeks of follow-up.

**Results** Of the 112 patients, 54 % were female, the median age was 39 years (range 19–78), the median disease duration was 13 years (range 0–50), 54 % had ileo-colonic disease, 55 % had stricturing phenotype, and 59 % had perianal disease. Sixty-two percent received end ostomies, and 38 % received loop ostomies. The leading indications for surgery were stricturing, fistulizing, and perianal disease (35 %). Forty-three (38 %) patients had 76 major complications, including dehydration (22 cases), intra-abdominal infection (16), and obstruction (14). Increased major postoperative complications correlated with penetrating disease ( $p=0.02$ , odds ratio [OR]=5.52, 95 % confidence interval [CI]=1.25–24.42), the use of narcotics before surgery ( $p=0.04$ , OR=2.54, 95 % CI=1.02–6.34), and loop ostomies ( $p=0.004$ , OR=4.2, 95 % CI=1.57–11.23).

**Conclusions** Penetrating phenotype, the use of narcotics before surgery, and loop ostomies are associated with major complications in CD patients undergoing ostomy creation. These findings may influence risk management of CD patients needing ostomies.

**Keywords** Crohn's disease · Ostomy · Complications · Narcotics

✉ David T. Rubin  
drubin@uchicago.edu

<sup>1</sup> Inflammatory Bowel Disease Center, The University of Chicago Medicine, 5841 S. Maryland Ave., MC4076, Chicago 60637, IL, USA  
<sup>2</sup> Department of Public Health Sciences, The University of Chicago Medicine, Chicago, IL, USA  
<sup>3</sup> University of Illinois at Chicago, Chicago, IL, USA  
<sup>4</sup> University of Oklahoma Health Sciences Center, Oklahoma, OK, USA  
<sup>5</sup> Department of Surgery, The University of Chicago Medicine, Pritzker School of Medicine, Chicago, IL, USA

## Introduction

Crohn's disease (CD) is an immune-mediated disorder characterized by chronic inflammation of the gastrointestinal tract. Many patients with CD still require intestinal surgery despite the significant progress in medical management [1].

Ileostomy and colostomy creation are performed for medically refractory disease and CD-related complications (e.g., small bowel obstructions, fistula formation, or active severe perianal disease). The goals of ostomy creation may vary. In some patients, it is used as a temporizing measure for induction of remission through fecal diversion, with subsequent

restoration of bowel continuity. In others, the ostomy is a definitive treatment and therefore maintained indefinitely [2–4].

After surgery, CD patients often suffer from complications that may lead to hospital admissions, additional medical procedures, and overall decreased quality of life and increased costs [5–8]. Noninflammatory bowel disease (non-IBD) patients who undergo ostomy creation have a significant risk of complications with rates as high as 96 % during the 3 weeks after surgery; however, this has not been adequately studied in the IBD population [9, 10]. In addition, the associated risk factors following ostomy creation in CD patients have not been described previously.

The aims of this study are to characterize CD patients undergoing ostomy creation and to assess predictive variables for IBD and ostomy-related complications.

## Materials and Methods

### Study Design

We performed a retrospective chart review of all patients with a confirmed diagnosis of CD who underwent surgery for ostomy creation in our tertiary care academic center during a 45-month period (Feb. 2011 to July 2014). Patients were identified in an electronic data repository containing all IBD patients admitted for surgery. This study was approved by the University of Chicago Institutional Review Board.

### Inclusion Criteria

CD patients over 18 years old who underwent surgery for ostomy creation at the University of Chicago Hospital were included in our analyses. Major complications were defined as surgery- and CD-related conditions requiring hospitalization: hydro-electrolytic alterations (defined as abnormal electrolytes and dehydration requiring fluids infusion), partial or complete wound dehiscence, intestinal obstruction, intra-abdominal infection, ostomy stenosis, intestinal bleeding, para-stomal hernia, cutaneous complications, (e.g., ulcers, infections, or necrosis), ostomy stricture or retraction, ostomy necrosis, bad positioning, ostomy prolapse, and other IBD-related surgeries.

### Exclusion Criteria

We excluded patients with a diagnosis of ulcerative colitis or indeterminate colitis and patients undergoing surgeries other than for ostomy creation.

## Chart Review

Using electronic records, we extracted demographic data, including age at the time of surgery, age at diagnosis, gender, body mass index (BMI), and smoking status. We also collected disease-related clinical variables, including family history, personal history of intestinal resection, disease duration, presence of intra-abdominal abscess, disease location and behavior, perianal involvement, and albumin, measured within 30 days of surgery. Surgery-related data included the surgical indication, ostomy type (loop vs. end ostomy, ileostomy vs. colostomy), surgery type (open vs. laparoscopic), and perioperative therapies. Postoperative steroid treatment was defined as taking prednisone ( $\geq 10$  mg) at least 2 weeks following surgery.

## Outcomes

The primary outcome was the development of major complications related to the ostomy or CD that led to prolongation of the postoperative stay or readmission through 26 weeks of follow-up (predefined as outcomes by weeks 2, 4, and 26). We also extracted a physician global assessment (PGA) score by 2 weeks and 3 and 6 months following surgery.

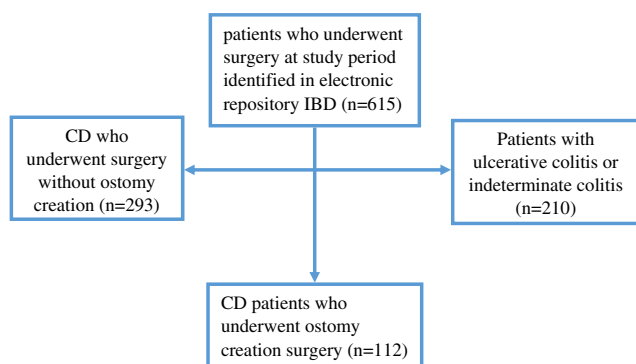
## Statistical Analysis

Descriptive statistics were calculated for each variable measured and are reported as means, medians, or proportions. Univariate analyses for differences in patients' characteristics and demographics were determined using unpaired *t* tests or Wilcoxon's rank-sum tests for means and Fisher's exact tests for categorical variables. Multivariate analyses were performed using logistic regression for predicting major complications. Kaplan-Meier estimate curves were plotted for complication-free survival. Cox regression, stratified by PGA scores and variables found to be statistically significant for predicting major complications, was used to estimate hazard ratios (HRs) for complication-free survival. A *p* value  $< 0.05$  was considered significant.

## Results

### Patient Demographics

A total of 112 CD patients had ostomy creation surgery by one of our four colorectal surgeons during the study period (Fig. 1). Of these, 61 (54 %) patients were females, the median age at the time of surgery was 39 years (range 19–78), and the median BMI was 22.75 kg/m<sup>2</sup> (range 14.5–53.4). Of 92 (82 %) nonsmokers, 63 were lifetime nonsmokers and 29



**Fig. 1** Patient selection for study

were former smokers. Seventy-five (67 %) patients had no family history of IBD (Table 1).

### Patients Characteristics

Among our patient cohort, median disease duration at the time of surgery was 13 years (range 0–50), with a predominant complicated phenotype of penetrating ( $n=62$ , 55 %) or stricturing ( $n=21$ , 19 %) disease. Six (5 %) patients had purely ileal disease (L1), 46 (41 %) had purely colonic disease (L2), and 60 (54 %) had ileo-colonic involvement (L3). Sixty-six (59 %) also had perianal disease (subtype p).

A minority of the patients presented with an intra-abdominal abscess ( $n=17$ , 15 %). The median albumin measured within 30 days preoperatively was 3.4 g/dL (range 2–4.7) (Table 1).

Before surgery, patients were frequently treated with steroids ( $n=90$ , 80 %), tumor necrosis factor (TNF) inhibitors ( $n=85$ , 76 %), 5-aminosalicylic acid (5-ASA) ( $n=80$ , 71 %), immunomodulators ( $n=66$ , 59 %), antibiotics ( $n=60$ , 53 %), and narcotics ( $n=47$ , 42 %). Only 12 (11 %) patients were treated with integrin inhibitors and 8 (7 %) with calcineurine inhibitors (Table 1).

Postoperatively, patients primarily received narcotics ( $n=83$ , 74 %) and antibiotics ( $n=41$ , 37 %), whereas a minority were treated with TNF inhibitors ( $n=18$ , 16 %), steroids ( $n=18$ , 16 %), immunomodulators ( $n=14$ , 12 %), integrin inhibitors ( $n=6$ , 5 %), and 5-ASA ( $n=5$ , 4 %) (Table 1).

### Surgery Characteristics

In this cohort, 106 (95 %) ileostomies and only 6 (5 %) colostomies were created. Of the ileostomies, 70 (62 %) were end ileostomies, and 42 (38 %) were loop ileostomies. The leading indications for ostomy surgery were penetrating and stricturing complications ( $n=39$ , 35 %), perianal disease ( $n=39$ , 35 %), and medically resistant distal luminal disease ( $n=28$ , 25 %). A minority of the patients had ostomy surgery for dysplasia ( $n=5$ , 4 %) or non-IBD-related indications ( $n=1$ , 1 %) (Table 1). Fifty-three (47 %) patients had laparoscopic surgery, and 59 (53 %) patients had open surgery techniques.

## Outcomes

### Major Complications

Overall, 43 (38 %) of the patients suffered a major stoma or IBD-related complication requiring prolongation of postoperative stay or readmission (Table 2).

The salient major complications were hydro-electrolytic abnormalities ( $n=22$ ), infections or abscesses ( $n=16$ ), and intestinal obstructions ( $n=14$ ). Other major but less frequent complications were cutaneous complications ( $n=4$ ), mucocutaneous dehiscence ( $n=3$ ), bleeding, stenosis, para-stomal hernia, bad positioning, and prolapse ( $n=1$  each).

Twelve patients had other IBD-related surgeries, including stoma revisions or bowel resections for peristomal pain, dysfunctioning stoma, active perianal disease, or luminal inflammation. These were more prevalent after the first month (Table 2).

### Physician Global Assessment

Higher PGA scores, at 2 weeks and 3 and 6 months following ostomy surgery, were associated with increased rates of major ostomy complications at 6 months ( $p=0.03$ ,  $p=0.005$ , and  $p=0.04$ , respectively) (Table 4). Kaplan-Meier survival curves for complication-free survival of patients following ostomy creation were plotted, stratified by PGA scores. Patients' PGA scores were categorized as a mild disease (scores 0–1) or advanced disease (scores 2–3). Patients with mild disease had improved complication-free survival compared with patients with advanced disease at 2 weeks ( $p=0.008$ , HR=2.55, 95 % confidence interval [CI]=1.28–5.09), 3 months ( $p=0.01$ , HR=2.38, 95 % CI=1.23–4.62), and 6 months ( $p=0.02$ , HR=2.43, 95 % CI=1.14–5.17) following surgery (Fig. 2).

### Ostomy Reversal

During the study period, 25 (22 %) patients underwent ostomy reversal. Patients who had loop ostomy creation were significantly more likely to have restoration of bowel continuity (18 of 42, 43 %) compared with patients with end ostomy (7 of 70, 10 %) ( $p=0.0001$ , odds ratio [OR]=6.75, 95 % CI=2.5–18.2). Fifteen (38 %) of the patients who had their ostomy created for stricturing or penetrating disease had ostomy reversal, compared with six (15 %) patients who had ostomy for perianal disease, four (14 %) patients who received ostomy for luminal disease, and none of the patients who had dysplasia or non-IBD-related indications; this association was also statistically significant ( $p=0.04$ ) (Table 3).

### Factors Associated with Major Complications

Clinical variables were tested using univariate analyses for associations with increased incidence of major complications.

**Table 1** Overall patient characteristics

Sex (M:F)	51:61	
Age (median)	39 (19–78)	
Age at diagnosis (median)	22 (3–64)	
Smoking status	Never	63 (56 %)
	Former	29 (26 %)
	Current	20 (18 %)
Disease duration (years)	13 (0–50)	
Family history of IBD	Negative	75 (67 %)
	Positive	26 (23 %)
	Unknown	11 (10 %)
BMI (kg/m <sup>2</sup> )	22.75 (14.5–53.4)	
Disease location <sup>a</sup>	Ileal	6 (5 %)
	Colonic	46 (41 %)
	Ileo-colonic	60 (54 %)
Disease behavior <sup>a</sup>	Non-penetrating, non-stricturing	29 (26 %)
	Stricturing	21 (19 %)
	Penetrating	61 (55 %)
Perianal disease <sup>a</sup>	66 (59 %)	
Prior intestinal resection	52 (46 %)	
Intra-abdominal abscess <sup>b</sup>	17 (15 %)	
Albumin (g/dL) <sup>c</sup>	3.4 (2–4.7)	
Treatment before surgery	Narcotics	47 (42 %)
	Antibiotics	60 (53 %)
	Steroids	90 (80 %)
	Mesalamine	80 (71 %)
	Immunomodulators	66 (59 %)
	Anti-TNF	Single 40 (36 %)
		Two 33 (29 %)
		Three 12 (11 %)
	Integrin inhibitors	12 (11 %)
	Calcineurin inhibitors	8 (7 %)
Treatment after surgery	Narcotics	83 (74 %)
	Antibiotics	41 (37 %)
	Steroids <sup>d</sup>	18 (16 %)
	Mesalamine	5 (4 %)
	Immunomodulators	14 (12 %)
	Anti-TNF	18 (16 %)
	Integrin inhibitors	6 (5 %)
Ostomy indication	Penetrating/stricturing disease	39 (35 %)
	Luminal disease	28 (25 %)
	Perianal disease	39 (35 %)
	Dysplasia	5 (4 %)
	Non-IBD	1 (1 %)
Ostomy type	Loop ileostomy	40 (36 %)
	Loop colostomy	2 (2 %)
	End ileostomy	66 (59 %)
	End colostomy	4 (3 %)

**Table 1** (continued)

Surgery technique	Open	59 (53%)
	Laparoscopic	53 (47%)

<sup>a</sup> According to Montreal classification<sup>b</sup> Intra-abdominal abscess excluding perianal abscesses<sup>c</sup> Albumin level determined up to 30 days prior to ostomy surgery<sup>d</sup> Prednisone ( $\geq 10$  mg) at least 2 weeks following surgery

An increased rate of major complications was associated with the following variables: younger age at CD diagnosis (mean [M] $\pm$ standard error [SE]=22.05 $\pm$ 1.48 vs. 27.91 $\pm$ 1.59,  $p=0.01$ ), disease duration longer than 10 years ( $p=0.04$ , OR=2.58, 95 % CI=1.09–6.12), penetrating disease phenotype ( $p=0.02$ , OR=2.33, 95 % CI=1.05–5.17), loop ostomy creation ( $p=0.001$ , OR=4.25, 95 % CI=1.88–9.61), intake of narcotics 30 days prior to surgery ( $p=0.03$ , OR=2.57, 95 % CI=1.16–5.53), and antibiotic ( $p=0.04$ , OR=2.34, 95 % CI=1.06–5.17) and integrin inhibitor ( $p=0.003$ , OR=23.75, 95 % CI=1.3–433.6) therapy after surgery (Table 4).

In the multivariate analyses, the following variables remained significantly associated with major complications: the use of narcotics 30 days prior to surgery ( $p=0.04$ , OR=2.54, 95 % CI=1.02–6.34), loop ostomy creation ( $p=0.004$ , OR=4.2, 95 % CI=1.57–11.23), and penetrating phenotype ( $p=0.02$ , OR=5.52, 95 % CI=1.25–24.42).

Complication-free survival was plotted on a Kaplan-Meier estimate curve, and Cox regression was used to estimate HRs for variables associated with increases in major complications: the use of narcotics 30 days prior to surgery ( $p=0.02$ , HR=2.05, 95 % CI=1.12–3.74), loop ostomy creation ( $p=0.001$ , HR=2.86, 95 % CI=1.56–5.25), and penetrating phenotype ( $p=0.04$ , HR=1.94, 95 % CI=1.02–3.68) (Fig. 3).

No other variables were associated with increased major complications after ostomy surgery, including sex, age at surgery, smoking status, BMI, family history of IBD, disease location (ileal vs. colonic), perianal involvement, prior intestinal resection, preoperative intra-abdominal abscess, preoperative albumin level, indication for ostomy creation, surgical technique (open vs. laparoscopic), and treatment with steroids, 5-ASA, TNF inhibitors, immunomodulators, and calcineurine inhibitors pre- and post-surgery. Post-ostomy complications were also not associated with the use of antibiotics and integrin inhibitors prior to surgery and narcotic use following surgery (Table 4).

## Discussion

In this study, we characterize risk factors for postoperative complications related to ostomy creation in CD patients. We identified penetrating disease behavior, preoperative narcotic use, and the creation of a loop ostomy (vs. end ileostomy) as

**Table 2** Outcomes after ostomy creation surgery

Ostomy reversal	25 (22 %)				
Physician global assessment at 2 weeks	0		60 (54 %)		
	1		33 (30 %)		
	2		14 (13 %)		
	3		3 (3 %)		
Physician global assessment at 3 months	0		56 (55 %)		
	1		26 (25 %)		
	2		16 (16 %)		
	3		4 (4 %)		
Physician global assessment at 6 months	0		42 (58 %)		
	1		16 (22 %)		
	2		12 (17 %)		
	3		2 (3 %)		
Major complications		Week 2	Week 4	Week 26	Total
Hydro-electrolytic		10	6	6	22
Cutaneous		2	1	1	4
Mucocutaneous dehiscence		2	—	1	3
Collapse/retraction		—	—	—	—
Infection/abscess		6	5	5	16
Necrosis		—	—	—	—
Obstruction		8	2	4	14
Bleeding		1	—	—	1
Stenosis		—	—	1	1
Parastomal hernia		—	—	1	1
Bad position		—	—	1	1
Prolapse		—	—	1	1
Other		2	—	10	12
Total patients with complications		26 (23 %)	12 (11 %)	23 (20 %)	43 (38 %)
Total complications		31 (41 %)	14 (18 %)	31 (41 %)	76

independently related to major complications that result in prolongation of hospital length of stay or rehospitalization.

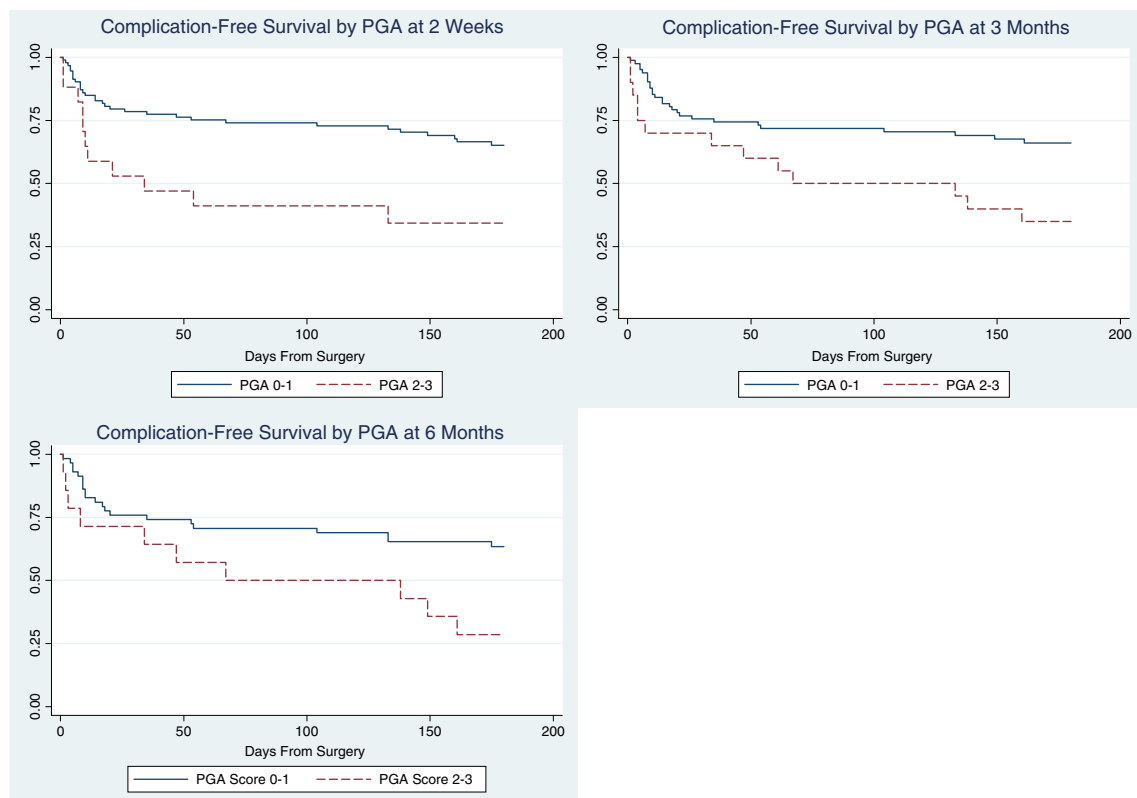
Ostomy creation is an effective option for medically resistant CD and other CD-related complications, either as a temporizing measure or definitive treatment [2–4]. Previous studies after ostomy creation in CD patients have focused on complications that require repeat surgery, such as peristomal abscesses, pyoderma gangrenosum, and disease recurrence [11–14]. Additional literature of ostomy-specific complications is limited to case reports or related to the psychosocial burden of living with a stoma [15–20]. We add to the literature with this retrospective analysis that uniquely evaluates the patient, disease, and surgery-related predictors of CD stoma-related complications.

In our study, patient age was not a predictor of complications; however, disease duration greater than 10 years was associated with a higher risk of major complications in the univariate analysis. This is most likely because patients who fail multiple medical therapies prior to requiring ostomy surgery have notably more comorbidities. Furthermore, on multivariate analysis, disease duration was no longer significant.

Our patient population was complex and sick, as would be expected in our tertiary center and among those who require ostomies. Interestingly, more patients had penetrating disease behavior (Montreal B3) than stricturing behavior (Montreal B2), likely because stricturing CD less often required ostomy as rescue or permanent management. As expected in a cohort of patients with refractory disease, a majority had failed to respond to multiple drugs prior to surgery, which underscores the refractoriness of this patient cohort to medical therapy and may also explain the low rate of eventual ostomy reversal (22 %). Importantly, our analysis did not identify complications associated with any IBD-related medications.

Of the 25 (22 %) patients who had ostomy reversal, most had loop ileostomies for stricturing or fistulizing small bowel disease rather than perianal disease. This is despite our frequent discussions about performing temporary fecal diversion to treat perianal disease. The inability to reverse stomas in this subpopulation is an important observation and contributes to more informed discussions with patients about the likelihood of salvaging a severely diseased rectum or perianal area.





**Fig. 2** Complication-free survival by PGA scores. Kaplan-Meier survival curves for complication-free survival of patients following ostomy creation, during study follow-up period of 180 days. Patients' physician global assessment (PGA) scores were extracted for 2 weeks and 3 and 6 months following ostomy creation surgery and stratified to mild disease (PGA scores 0–1) and advanced disease (PGA scores 2–3).

After ostomy creation surgery, 38 % of the patients experienced at least one major complication over a 6-month period. This is significantly higher than a previously reported rate of 16.9 % readmittance in non-IBD patients post ostomy creation [21]. Consistently throughout the study, the most common complications were hydro-electrolytic abnormalities (30 %),

infections and abscesses (22 %), and obstructions (19 %). Hydro-electrolytic abnormalities were also a leading complication in previous studies in non-IBD patients who had ostomy creation, accounting for 43 % of the indications for readmittance [21].

Previous studies in non-IBD populations identified risk factors for complications after stoma surgery, including age, BMI, comorbidities, diabetes, American Society of Anesthesia (ASA) anesthetic risk, ostomy height, lack of preoperative care by stoma nurse specialists, and emergency surgery [10, 22–26]. Only some of these variables were available to us because of the nature of a retrospective chart review study. By multivariate analyses in this study, increased risk for major complications was associated with stricturing phenotype, narcotics use before surgery, and loop ostomy creation.

Penetrating disease was associated with an increased rate of major complications after ostomy creation; these patients exhibited more hydro-electrolytic abnormalities, infectious, and obstructive complications compared with patients with stricturing or non-penetrating, non-stricturing disease. The increased complication rate may be attributed to the advanced stage of patients with penetrating disease at the time of surgery.

**Table 3** Ostomy reversal-associated clinical variables

Outcomes: ostomy reversal ( <i>n</i> =25)		Ostomy reversal	No ostomy reversal	<i>p</i> value
Ostomy type	Loop ileostomy	16	24	0.0001
	Loop colostomy	2	0	
	End ileostomy	7	59	
	End colostomy	0	4	
Ostomy indication	Penetrating/stricturing disease	15	24	0.04
	Perianal disease	4	24	
	Luminal disease	6	33	
	Dysplasia	0	5	
	Non-IBD	0	1	

**Table 4** Comparison of clinical variables and risk factors for major complications

		No major complication ( <i>n</i> =69)	Major complications ( <i>n</i> =43)	<i>p</i> value
Sex (M:F)		30:39	21:22	0.70
Age at diagnosis (mean)		27.91	22.04	0.013
Age (mean)		42.22	39.65	0.34
Smoking status	Never	38	25	0.90
	Former	19	10	
	Current	12	8	
Disease duration (mean years)		13.79	17.56	0.11
Family history of IBD	Negative	52	23	0.06
	Positive	12	14	
	Unknown	5	6	
Disease location	Ileal	3	3	0.32
	Colonic	32	14	
	Ileo-colonic	34	26	
Disease behavior	Non-penetrating, non-stricturing	18	11	0.02
	Stricturing	18	3	
	Penetrating	32	29	
Perianal disease		40	26	1.00
Prior intestinal resection		31	21	0.70
Intra-abdominal abscess		10	7	0.79
Albumin (mean, g/dL)		3.44	3.36	0.64
BMI (mean, kg/m <sup>2</sup> )		23.14	23.86	0.51
Ostomy indication	Penetrating/stricturing disease	24	15	0.76
	Perianal disease	23	16	
	Luminal disease	19	9	
	Dysplasia	3	2	
	Non-IBD	0	1	
Ostomy type	Loop ileostomy	16	24	0.001
	Loop colostomy	1	1	
	End ileostomy	49	17	
	End colostomy	3	1	
Surgery technique	Open	39	20	0.36
	Laparoscopic	30	23	
Treatment before surgery	Narcotics	23 (33 %)	24 (56 %)	0.03
	Antibiotics	36 (52 %)	24 (56 %)	0.85
	Steroids	57 (83 %)	33 (77 %)	0.47
	Mesalamine	50 (72 %)	30 (70 %)	0.83
	Immunomodulators	44 (64 %)	22 (51 %)	0.24
	Anti-TNF	53 (77 %)	32 (74 %)	0.82
	Integrin inhibitors	8 (12 %)	4 (9 %)	0.77
	Calcineurin inhibitors	7 (10 %)	1 (2 %)	0.15
Treatment after surgery	Narcotics	47 (68 %)	36 (83 %)	0.08
	Antibiotics	20 (29 %)	21 (49 %)	0.04
	Steroids	13 (19 %)	5 (12 %)	0.43
	Mesalamine	3 (4 %)	2 (5 %)	1.0
	Immunomodulators	6 (9 %)	8 (19 %)	0.15
	Anti-TNF	11 (16 %)	7 (16 %)	1.0
	Integrin inhibitors	0	6 (16 %)	0.003
Ostomy reversal		13 (19 %)	12 (28 %)	0.35
Physician global assessment at 2 weeks	0	42	18	0.03
	1	20	13	

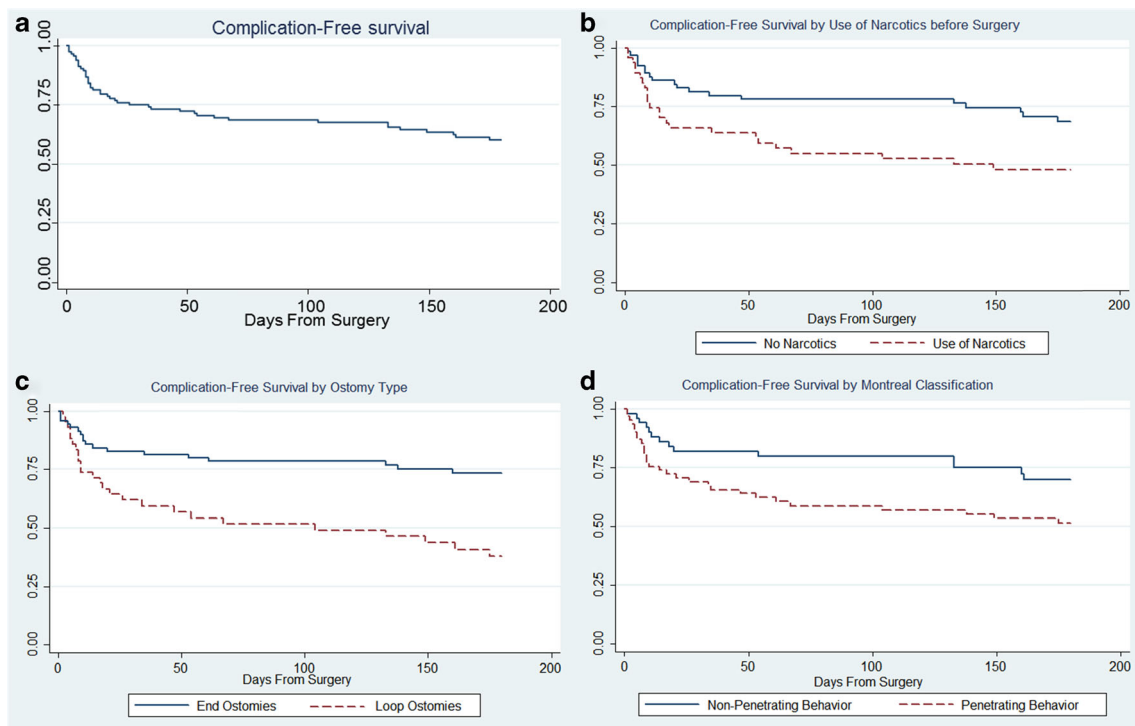
**Table 4** (continued)

		No major complication (n=69)	Major complications (n=43)	p value
Physician global assessment at 3 months	2	4	10	0.005
	3	2	1	
	0	42	14	
	1	13	13	
	2	5	11	
Physician global assessment at 6 months	3	2	2	0.04
	0	29	13	
	1	8	8	
	2	4	8	
	3	0	2	

Patients receiving narcotics before surgery were also susceptible to major complications, primarily hydro-electrolytic and infectious complications. These findings are in line with the TREAT registry, which demonstrated higher rates of serious infections in IBD patients treated with narcotics; a smaller study reported higher pneumonia rates in IBD patients on narcotics [27, 28]. However, steroids and anti-TNF therapy, which have also been previously reported to be associated with adverse events in IBD patients, were not implicated in our study.

Loop ostomy, as opposed to end ostomy, creation was also associated with an increase in major complications, mainly

hydro-electrolytic abnormalities. This is likely due to the placement and anatomic requirement of such a loop, which short-circuits the bowel and results in reduced absorptive ability, leading to dehydration and electrolyte imbalance. This finding has already affected our postoperative management strategies by targeting such patients for additional support and education and closer follow-up. In addition, higher PGA scores, measured at 2 weeks and 3 and 6 months, were associated with decreased complication-free survival 6 months post ostomy creation (HR=2.55, HR=2.38, HR=2.43, respectively); thus, patients prone to developing major



**Fig. 3** Complication-free survival by clinical variables. Kaplan-Meier survival curves for complication-free survival of patients following ostomy creation, during study follow-up period of 180 days (a). Complication-free survival was compared for use of narcotics before

surgery ( $p=0.02$ , HR=2.05, 95 % CI=1.12–3.74) (b), ostomy type ( $p=0.001$ , HR=2.86, 95 % CI=1.56–5.25) (c), and penetrating disease phenotype ( $p=0.04$ , HR=1.94, 95 % CI=1.02–3.68) (d)



complications 6 months post ostomy creation may be identified clinically and monitored closely.

Despite these important findings, several limitations should be noted about our study. This was a retrospective chart review study; some patients may have been excluded by the initial search of the electronic data repository. Data may also be missing in charts, leading to incomplete data collection. Our study design focused on stoma and IBD-related postoperative complications and may have overlooked other medical or surgical postoperative complications prevalent in the study population. We defined major complication as those requiring prolongation of postoperative stay or readmission. We chose this definition over a validated surgical scale, such as the Clavien-Dindo scale, in order to deliver clinically meaningful information regarding ostomy and IBD-related postoperative complications in patients undergoing ostomy creation.

Statistical analyses of retrospective data can be used to generate hypotheses and test for correlations between clinical variables and outcomes. However, it cannot prove causality or elucidate the reasons for these findings. Future prospective studies are needed to test for causality and clarify the relationships between the hypothesized clinical risk factors and outcomes. Finally, this study focused on clinical “medical” risk factors and did not assess various “surgical” risk factors shown to be associated with post-ostomy complications in non-IBD patients, including comorbidities, diabetes, ASA anesthetic risk, emergency vs. different types of surgeries, and factors linked to surgical techniques (including ostomy height) [10, 22–26].

## Conclusion

For medically refractory disease or obstructive complications in CD, ostomy surgery remains an important therapeutic option. The leading indications for ostomy creation are stricturing or fistulizing disease, perianal involvement, and luminal medically refractory disease. Following ostomy creation, 54 % of our Crohn’s patients had at least one major complication, most frequently dehydration and electrolyte disorders, infections, and obstructions. Clinical variables associated with increased major complications were penetrating disease, the use of narcotics before surgery, and loop ostomy. These findings should be used to stratify patients for follow-up and management after surgery. Future studies of interventions to reduce these complications are needed.

## References

1. Peyrin-Biroulet L, Loftus EV, Jr., Colombel JF, Sandborn WJ. The natural history of adult Crohn’s disease in population-based cohorts. *The American journal of gastroenterology* 2010;105:289–97.
2. McIlrath DC. Diverting ileostomy or colostomy in the management of Crohn’s disease of the colon. *Archives of surgery* 1971;103:308–10.
3. Zelas P, Jagelman DG. Loop ileostomy in the management of Crohn’s colitis in the debilitated patient. *Annals of surgery* 1980;191:164–8.
4. Coscia M, Gentilini L, Laureti S, et al. Risk of permanent stoma in extensive Crohn’s colitis: the impact of biological drugs. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2013;15:1115–22.
5. Ludwig KA, Milsom JW, Church JM, Fazio VW. Preliminary experience with laparoscopic intestinal surgery for Crohn’s disease. *American journal of surgery* 1996;171:52–5; discussion 5–6.
6. Regimbeau JM, Panis Y, Pocard M, et al. Long-term results of ileal pouch-anal anastomosis for colorectal Crohn’s disease. *Diseases of the colon and rectum* 2001;44:769–78.
7. Colombel JF, Loftus EV, Jr., Tremaine WJ, et al. Early postoperative complications are not increased in patients with Crohn’s disease treated perioperatively with infliximab or immunosuppressive therapy. *The American journal of gastroenterology* 2004;99:878–83.
8. Marchal L, D’Haens G, Van Assche G, et al. The risk of postoperative complications associated with infliximab therapy for Crohn’s disease: a controlled cohort study. *Alimentary pharmacology & therapeutics* 2004;19:749–54.
9. de Miguel Velasco M, Jimenez Escovar F, Parajo Calvo A. [Current status of the prevention and treatment of stoma complications. A narrative review]. *Cirugia espanola* 2014;92:149–56.
10. Porter JA, Salvati EP, Rubin RJ, Eisenstat TE. Complications of colostomies. *Diseases of the colon and rectum* 1989;32:299–303.
11. Takahashi K, Funayama Y, Fukushima K, et al. Stoma-related complications in inflammatory bowel disease. *Digestive surgery* 2008;25:16–20.
12. Uchino M, Ikeuchi H, Matsuoka H, et al. Clinical features and management of parastomal pyoderma gangrenosum in inflammatory bowel disease. *Digestion* 2012;85:295–301.
13. Hoentjen F, Colwell JC, Hanauer SB. Complications of peristomal recurrence of Crohn’s disease: a case report and a review of literature. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2012;39:297–301.
14. Leal-Valdivieso C, Marin I, Manosa M, et al. Should we monitor Crohn’s disease patients for postoperative recurrence after permanent ileostomy? *Inflammatory bowel diseases* 2012;18:E196.
15. Markham DW, Ruppert M, Noel R, Surawicz CM. A parastomal hernia causing small-bowel obstruction. *Journal of clinical gastroenterology* 1996;22:218–9.
16. Parascandolo ME. Multiple ostomy complications in a patient with Crohn’s disease: a case study. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2001;28:236–41; discussion 41–3.
17. Tsao SK, Baker M, Nightingale JM. High-output stoma after small-bowel resections for Crohn’s disease. *Nature clinical practice Gastroenterology & hepatology* 2005;2:604–8; quiz 9.
18. Kelly C. WOC nurse consult: peristomal complication. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2012;39:425–7.
19. Carlsson E, Bosaeus I, Nordgren S. What concerns subjects with inflammatory bowel disease and an ileostomy? *Scandinavian journal of gastroenterology* 2003;38:978–84.
20. Knowles SR, Wilson J, Wilkinson A, et al. Psychological well-being and quality of life in Crohn’s disease patients with an ostomy: a preliminary investigation. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2013;40:623–9.
21. Messaris E, Sehgal R, Deiling S, et al. Dehydration is the most common indication for readmission after diverting ileostomy creation. *Diseases of the colon and rectum* 2012;55:175–80.

22. Duchesne JC, Wang YZ, Weintraub SL, Boyle M, Hunt JP. Stoma complications: a multivariate analysis. *The American surgeon* 2002;68:961–6; discussion 6.
23. Bass EM, Del Pino A, Tan A, Pearl RK, Orsay CP, Abcarian H. Does preoperative stoma marking and education by the enterostomal therapist affect outcome? *Diseases of the colon and rectum* 1997;40:440–2.
24. Arumugam PJ, Bevan L, Macdonald L, et al. A prospective audit of stomas—analysis of risk factors and complications and their management. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2003;5:49–52.
25. Parmar KL, Zammit M, Smith A, et al. A prospective audit of early stoma complications in colorectal cancer treatment throughout the Greater Manchester and Cheshire colorectal cancer network. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2011;13:935–8.
26. Shabbir J, Britton DC. Stoma complications: a literature overview. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2010;12:958–64.
27. Lichtenstein GR, Feagan BG, Cohen RD, et al. Serious infections and mortality in association with therapies for Crohn's disease: TREAT registry. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association* 2006;4:621–30.
28. Long MD, Martin C, Sandler RS, Kappelman MD. Increased risk of pneumonia among patients with inflammatory bowel disease. *The American journal of gastroenterology* 2013;108:240–8.